

FINAL REGISTRATION REPORT

Part B

Section 3

Efficacy Data and Information

Concise summary

Product code: SHA 9700 B

Product name(s): Ruler 10 EC

Chemical active substance:

Fenazaquin 100 g/L

Interzonal

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España

Submission date: July 2019

MS Finalisation date: 08/09/2020 ; 03/2023

Version history

When	What
May 2020	Applicant updated document
September 2020	ZRMs evaluated version of dRR.
March 2023	ZRMs added missing information's to dRR according to comments from MRiRW

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3 Efficacy Data and Information (including Value Data) on the Plant Protection Product (KCP 6)

Transformation of the dRR (applicant version) into the RR (zRMS version)

The process chosen by the zRMS to transform the dRR into a RR should be explained. Options are to rewrite the document (with track change or not) or to use commenting boxes such as the following:

Comments of zRMS:	Comments of zRMS are in commenting boxes at the end of each chapter. The text of dRR was generally not changed or rewritten (small changes in the document are in grey). ZRMs added missing information's to dRR according to comments from MRiRW. Those changes are marked by yellow.
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3.1 Summary and conclusions of zRMS on Section 3: Efficacy (KCP 6)

Abstract

This document summarises the information related to the efficacy data of the plant protection product **Ruler 10 EC** containing the active substance fenazaquin, which was included into Annex I of Council Directive 91/414/EEC.

The SANCO review report for fenazaquin (SANCO/10324/2011 – final) is considered to provide the relevant review information or a reference to where such information can be found.

Ruler 10 EC is an Emulsifiable Concentrate (EC) containing 100 g/L fenazaquin for use in melon, strawberry, tomato and ornamentals.

This dossier demonstrates the broad efficacy spectrum of Ruler 10 EC against spider mites and demonstrates that the formulation is safe to the crop. To prove the insecticide efficacy and crop safety of Ruler 10 EC, trials were set up in melon, strawberry, tomato and ornamentals. The trials were conducted in 2017 and 2018 season in a range of European countries in the Mediterranean (i.e. Spain and Greece), North-east (i.e. Poland) and Maritime (i.e. Germany and France) EPPO zones

Studies from three climatic zones are used in this document to support the registration of Fenazaquin 10% EC. However, since 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. Studies in Melon were performed in open fields in the Mediterranean EPPO zone.

According to the GAP, the proposed application rate of Ruler 10 EC is 2.0-4.0 L per hectare (L/ha), with one or two applications per season, for the control of spider mites in melon, strawberry, tomato and ornamentals.

The data presented in this dossier fully support the label claim for fenazaquin for the control of of fenazaquin in melon, strawberry, tomato and ornamentals.

Ruler 10 EC gives good to excellent control of spider mites that we can find on melon, strawberry, tomato and ornamentals.

The claims of crop safety on these crops are supported with a total of 36 trials conducted in Spain, Greece, France, Poland and Germany in 2017 and 2018. In all trials, Ruler 10 EC proved to be crop safe in all trials did not affect the crop adversely when applied at a range of growth stages within and occasionally beyond the label recommended range, at the maximum proposed label recommended rates of 2.0 L/ha in melon, strawberry, tomato and ornamentals.

Overall, Ruler 10 EC is an effective, selective insecticide for spider mites control in melon, strawberry, tomato and ornamentals. Fenazaquin offers a solution for sustainable resistance strategies.

The Registration of Ruler 10 EC in the GAP claimed crops is endorsed.

Comments of zRMS:	Comments of zRMS: Overall summaries are not necessary here. It was provided at the end of each chapter of the dRR.
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Table 3.1-1: Acceptability of intended uses (and respective fall-back GAPs, if applicable)

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
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: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safen- er/synergist per ha (i)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. inter- val between applications (days)	kg or L prod- uct / 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		To be confirmed by cMS.
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			Acceptable
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		Acceptable
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	a) 0.2 b) 0.4	1000	3		Acceptable. Re- duced of number of application due to residue section

Column 15: zRMS conclusion.

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by cMS
N	Not acceptable / evaluation not possible
n.r.	Not relevant for section 3

3.2 Efficacy data (KCP 6)

Introduction

This document summarises the information related to the efficacy data of the plant protection product **Ruler 10 EC** containing the active substance fenazaquin, which was included into Annex I of Council Directive 91/414/EEC.

The SANCO review report for fenazaquin (SANCO/10324/2011 – final) is considered to provide the relevant review information or a reference to where such information can be found.

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on the active substance fenazaquin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 6/October/2007 shall be taken into account. Consideration of active substances for Annex 1 inclusion does not include an evaluation of efficacy. Therefore, there are no concerns to address arising from the inclusion directive of fenazaquin relating to efficacy.

These concerns have been addressed within the current submission.

The detailed assessment of the individual trial and study data is located in the following report:

Report:	KCP 6.0/001 Biological Assessment Dossier Fenazaquin 10% EC - Interzonal
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Description of the plant protection product

Ruler 10 EC is an Emulsifiable Concentrate (EC) containing 100 g/L fenazaquin for use in melon, strawberry, tomato and ornamentals.

To support the registration of Ruler 10 EC in the GAP claimed crops, trials have been set up in melon, strawberry, tomato and ornamentals. For trials conducted in Spain, Greece, Poland, France and Germany, the fenazaquin formulation prepared by Sharda Cropchem España – Fenazaquin 10% EC – was compared against reference fenazaquin formulations currently on the market in Europe (Magister Flow). Other reference products were included (bifenazate, tebufenpirad and abamectin). The trials were conducted in 2017 and 2018 season in a range of European countries in the Mediterranean (i.e. Spain and Greece), North-east (i.e. Poland) and Maritime (i.e. Germany and France) EPPO zones.

Studies from three climatic zones are used in this document to support the registration of Fenazaquin 10% EC. However, since 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. Studies in Melon were performed in open fields in the Mediterranean EPPO zone.

According to the GAP, the proposed application rate of Ruler 10 EC is 2.0-4.0 L per hectare (L/ha), with one or two applications per season, for the control of spider mites in melon, strawberry, tomato and ornamentals.

The data presented in this dossier fully support the label claim for fenazaquin for the control of fenazaquin in melon, strawberry, tomato and ornamentals.

Table 3.2-1: Simplified table of currently registered uses and requested uses for the product code.

Uses		Member State	Requested rate(s) (L/ha)	Comments / Other relevant details on GAPs
Crop(s)	Target(s)			
Melon	Spider mites	SEU, CEU, NEU	2.0	

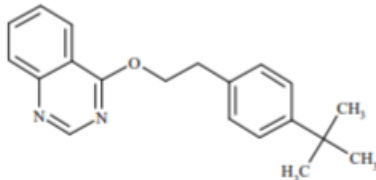
Uses		Member State	Requested rate(s) (L/ha)	Comments / Other relevant details on GAPs
Crop(s)	Target(s)			
Ornamentals	Spider mites	SEU, CEU, NEU	2.0	
Tomato	Spider mites	SEU, CEU, NEU	2.0	
Strawberry	Spider mites	SEU, CEU, NEU	2.0	

Further details are in the table “All intended uses” in Part B - Section 0.

Description of active substance fenazaquin

The activity of fenazaquin is well known, as it has been marketed since 1996 to control mites in many crops. Based on the knowledge about the active substance and the experiences with Fenazaquin 10% EC 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.

Table 3.2-2: Identity of fenazaquin

Common name	Fenazaquin
IUPAC name	4-[2-(4- <i>tert</i> -butylphenyl)ethoxy]quinazoline
CA name	4-[2-[4-(1,1-dimethylethyl)phenyl]ethoxy]quinazoline
CIPAC No	693
CAS Registry No.	120928-09-8
EEC No	Not allocated
Structural formula¹	
Empirical formula	C ₂₀ H ₂₂ N ₂ O
Molecular mass	306.409 g/mol

Mode of action

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.

¹ Source: Royal Society of Chemistry (RSC). Internet, Friday June 8th, 2018. URL: <http://www.chemspider.com/Chemical-Structure.55867.html>

Information on similar formulations and current approvals

Data presented in this dossier is generated using this formulation in comparison with reference products containing fenazaquin. Fenazaquin is currently registered under a variety of trade names and formulations throughout Europe and a selection of these are described in table below

Table 3.2-3: Current approvals of fenazaquin in the EU Central, Northern and Southern zone as well as connected EPPO zones where trials were conducted. Reference products used in trials are also included

Country	Product(s)	Active ingredient	Approval Number
Croatia	Demitan	Fenazaquin 200g/L	UP/I-320-20/94-01/7
France	Pride Ultra Magister	Fenazaquin 200g/L Fenazaquin 200g/L	9700552 9200313
Germany	Vermitec Floramite 240 SC	Abamectin 18/L Bifenazate 240 g/L	007030-00 006823-00
Italy	Pride Ultra Magister 200 SC	Fenazaquin 200g/L Fenazaquin 200g/L	008888 008891
Poland	Magus 200 SC Magister	Fenazaquin 200g/L Fenazaquin 100g/L	R-55/2016 R-470/2017b
Portugal	Magister Flow	Fenazaquin 195g/L	1271
Spain	Magister Comanche Plus	Fenazaquin 100g/L Tebufenpirad 200g/L	19254 19588
United Kingdom	Matador 200 SC	Fenazaquin 200g/L	17870

Description of the target pests

Throughout the reports that this dossier collects, we can appreciate various pests. Aphids like TETRUR (*Tetranychus urticae*).

All the listed weeds are present throughout or in parts of the Central, North and South zone and in relevant EPPO zones. These weed species compete with the crops for light, moisture and nutrients, reducing crop yields and may obstruct harvestability.

Table 3.2-4: Glossary of pests mentioned in the dossier.

EPPO code	Scientific name	Common name
Spider mites		
TETRUR	<i>Tetranychus urticae</i>	Red spider mite

Table 3.2-5: Major / minor status of intended uses (for all cMS and zRMS).

Crop and/or situation	Crop status		Pests or group of pests controlled	Pest status	
	Major	Minor		Major	Minor
Melon	-	NEU/CEU/SEU	Spider mites	NEU/CEU/SEU	-
Strawberry	CEU	NEU/ SEU	Spider mites	NEU/CEU/SEU	-
Tomato	-	NEU/CEU/ SEU	Spider mites	NEU/CEU/SEU	-
Ornamentals	-	NEU/CEU/SEU	Spider mites	NEU/CEU/SEU	-

Compliance with the Uniform Principles

The trials for efficacy testing of Fenazaquin 10% EC were conducted in conducted in Spain, Greece, France, Poland and Germany, i.e. in the Mediterranean zone, the North-East and the Maritime zone as defined by EPPO Standard PP1/241(1).

Studies from three climatic zones are used in this document to support the registration of Fenazaquin 10% EC. However, since 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. Studies in Melon were performed in open fields in the Mediterranean EPPO zone.

Information on trials submitted (3.1 Efficacy data)

Trials in this dossier were carried out by contractor companies and Official Research institutes, all of which follow the EPPO guidelines and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP). The GEP-requirement and the Uniform Principles are therefore taken care of.

On the basis of the EPPO guideline 1/241(1) "Guidance on comparable climates", the trials included in this dossier have been grouped and summarized by EPPO zones. EPPO zones have been defined by taking into account differences between the agro-climatic sub-areas of the EPPO region.

In general, the trials were conducted according to the respective EPPO guidelines.

In support of the current application for registration of Fenazaquin 10% EC, 36 efficacy trials were conducted in the Mediterranean, North-east and Maritime EPPO zones.

Table 3.2-6: Presentation of efficacy trials (efficacy trials, preliminary trials...)

Use(s) *	Target(s)*	Country	Years	Type of trial**	Number of trials (number of valid trials)				GEP, non- GEP, offi- cial***	Comments (any other relevant infor- mation)
					EPPO zone					
					MAR	MED	S-E	N-E		
Melon	Spider mites	Spain	2017	MED + E + S	-	4	-	-	GEP	
		Greece	2017	MED + E + S	-	4	-	-	GEP	
					-		-	-	-	
Strawberry	Spider mites	Spain	2017	MED + E + S	-	6	-	-	GEP	
		France	2017	MED + E + S	-	1	-	-	GEP	
		Germany	2017	MED + E + S	1	-	-	-	GEP	
			-		-	-	-			
Tomato	Spider mites	Spain	2017	MED + E + S	-	4	-	-	GEP	
		Germany	2017	MED + E + S	3	-	-	-	GEP	
		Greece	2017	MED + E + S	-	1	-	-	GEP	
			-				-			
Ornamen- tals	Spider mites	Spain	2017	MED + E + S	-	6	-	-	GEP	
		Poland	2017	MED + E + S	-	-	-	5	GEP	
		Germany	2017	MED + E + S	1	-	-	-	GEP	
							-			
		Total, all crops			5	26	-	5		

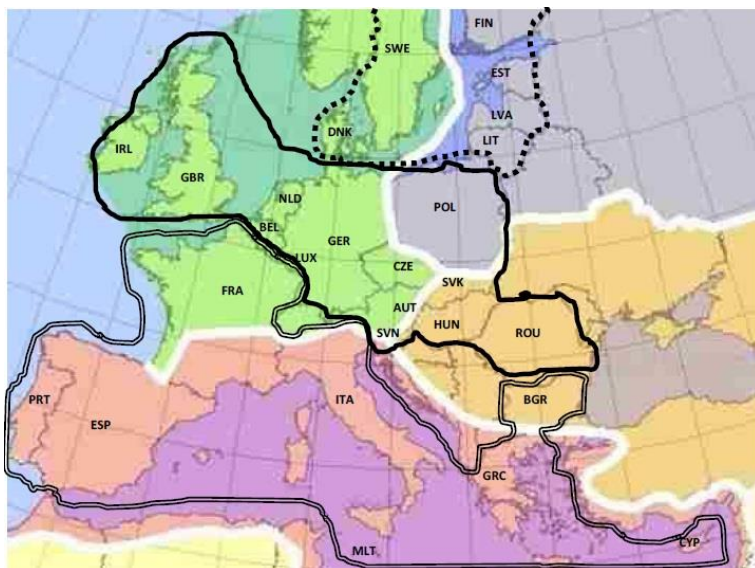
Climatic zones

Europe is divided into four climatic zones, according to EPPO standard PP 1/241 (1). Besides providing guidance in determining comparability of climatic conditions between geographical areas where efficacy evaluation trials are performed, the standard also supports the use of data generated in one country to support registration in another countryⁱ.

Spain, Greece and S-France are located in the Mediterranean EPPO zone; Poland is located in the North-east EPPO zone; Germany is located in the Maritime EPPO zone (Figure 3.2-1).

Studies from three climatic zones are used in this document to support the registration of Fenazaquin 10% EC. However, since 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. Studies in Melon were performed in open fields in the Mediterranean EPPO zone.

Figure 3.2-1: Representation of EPPO climatic zones (in colour: EPPO Standard PP1/241, Guidance on comparable climates) superimposed with the 3 European zones (EC Regulation 1107/2009) (Source: EPPO)



This Document is prepared to support the submission of Fenazaquin 10% EC throughout the Central, North and South Registration zone, therefore data from the Maritime, North-east and Mediterranean EPPO zone are included.

Agronomic conditions

Cultural conditions of the different crops and agronomy (e.g. cultivations used, application methods, cultivars, fertilizer regime, relative times of planting and harvest) do not differ significantly between these countries. In all the crops, the same fenazaquin containing pesticides are already registered and used in the countries where tested for the same uses.

(i) Pest physiology

The physiology of individual pests presented is common throughout Europe. Although trials were performed in different countries and EPPO zones, sites were selected to exert maximum control pressure and to exacerbate treatment differences. No difference in the level of control was apparent between the different countries or regions in which the trials were conducted. The level of control achieved from Fenazaquin 10% EC in the different countries was equivalent throughout the EU.

(ii) Agronomic practices

Agronomic practices in these crops are similar throughout the different zones as well as in the countries in the connected EPPO zones where trials were conducted. The levels of inorganic fertilizers and other crop inputs are similar between the countries.

(iii) Varieties

Although crop varieties tend to differ between countries, the crop safety of Fenazaquin 10% EC has been tested on a wide range of varieties in efficacy trials. The results from these trials show that there are no particularly sensitive varieties.

(iv) Trial methodology

Similar trial methodology was used in all countries. All trials were conducted to GEP by officially recognised testing organisations and in accordance with relevant EPPO standards.

(v) *Locations*

Trials were performed in the major crop growing areas in each respective country. These areas have been found to be particularly suitable for agricultural production of the respective crops due to their innate similarity in terms of soil type and climate.

(vi) *Soil*

It is not expected that an insecticide will be affected in any way by soil type and so this factor can be ignored for the purposes of this dossier.

On the basis that these factors do not influence the overall performance of Fenazaquin 10% EC, it is the applicant's contention that data from all countries is equally valid in demonstrating the products performance in the Central, Northern and Southern registration zone.

In efficacy trials conducted in melon, strawberry, tomato and ornamentals the performance of Fenazaquin 10% EC was compared against commercial standard of Fenazaquin currently on the market in Northern, Central and Southern Europe (Magister) and other reference standards (Floramite, Comanche Plus and Vermitec).

The reference products used in the efficacy trials are listed in Table 3.2-7.

Table 3.2-7: Presentation of reference standards used in trials (efficacy trials, preliminary trials...)

Trade name	Formulation	Composition	Rates [L/ha]	Indication	Country	N° of Trials
MAGISTER	EC	Fenazaquin	1.5 l/ha 2.0 l/ha		FR, ES, PL, GR	26
COMANCHE PLUS	WP	Tebufenpirad	0.75 l/ha 1.0 l/ha		ES	5
FLORAMITE	SC	Bifenazate	0.3 l/ha 0.4 l/ha		DE	4
VERMITEC	EC	Abamectin	0.75 l/ha 1.0 l/ha		DE	1

Comments of zRMS:	<p>This document was prepared by Applicant for registration the Ruler 10 EC (product code: SHA 9700 B) containing fenazaquin (100 g/L). The formulation of this product is an emulsifiable concentrate (EC). All necessary information's about tested plant protection products, active substances, studied pests, reference products, etc. are correctly presented in this drr by Applicant.</p> <p>The activity of fenazaquin is well known, as it has been marketed since 1996 to control mites in many crops. 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.</p> <p>In Poland only one plant protection product containing fenazaquin is already registered (Magus 200 SC). Magus 200 SC have different formulation (SC) than tested plant protection product – Ruler 10 EC and is registered only for control spider mites in ornamental plants. So, no insecticides against spider mites containing fenazaquin as active compound are registered in Poland for use in melon, strawberries and tomato.</p> <p>The product – Ruler 10 EC (product code: SHA 9700 B) containing fenazaquin by Sharda Cropchem España S.L. has not been previously evaluated in any country according to Uniform Principles. Poland is a ZRMs.</p>
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3.2.1 Preliminary tests (KCP 6.1)

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 10% EC 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.

Comments of zRMS:	Fenazaquin has been registered in a number of Member States for several years. The zRMS considers that preliminary data are not needed in this case.
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3.2.2 Minimum effective dose tests (KCP 6.2)

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 10% EC 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 10% EC is used.

Fenazaquin was tested at a range of dose rates, but to demonstrate minimum effective dose rate, the control obtained with Fenazaquin 10% EC applied at different dose rates was evaluated in 8 melon trials, 8 strawberry trials, 8 tomato trials and 12 ornamentals trials. In all trials, Fenazaquin 10% EC was applied at 1.0, 1.5 and 2.0 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.

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 France), North-east (i.e. Poland) and Maritime (Germany) EPPO zones. Studies from three climatic zones are used in this document to support the registration of Fenazaquin 10% EC. However, since 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. Studies in Melon were performed in open fields in the Mediterranean EPPO zone.

Summary and evaluation of Minimum Effective Dose trial results for 2.0 L/ha Fenazaquin 10% EC target rate against spider mites in strawberry crops

To prove and to support the requested dose rate of 2.0 L/ha Fenazaquin 10% EC applied post-emergence for the control of spider mites in strawberry crops, the assessment results of 8 efficacy trials with spider mites, performed in Spain, France and Germany in 2017 are reported.

To demonstrate the minimum effective dose of Fenazaquin 10% EC against spider mites, data is included from the assessments conducted in each trial following application.

3.2.2.1 Table 3.2-8: Minimum effective dose rate of Fenazaquin 10% SC against spider mites in strawberry.

Target: Spider mites	No. of trials	Untreated MITES		Mean % Control at a range of doses of fenazaquin Fenazaquin 10% EC					
				1.0 L/ha		1.5 L/ha		2.0 L/ha	
		Mean	Range	Mean	Range	Mean	Range	Mean	Range
3 days after treatment	8	12.0	0.6-24.7	69.5	34.9-91.7	84.0	44.5-100	87.6	57.9-100
7-8 days after treatment	8	22.6	0.4-56.3	86.1	73.1-100	92.9	85.0-98.3	95.9	90.2-100
14-16 days after treatment	2	13.5	0.1-26.8	85.7	75.0-96.3	86.6	75.0-98.2	86.9	75.0-98.8
Target: Spider mites	No. of	Untreated EGGS		1.0 L/ha		1.5 L/ha		2.0 L/ha	

	trials	Mean	Range	Mean	Range	Mean	Range	Mean	Range
3 days after treatment	4	11.4	7.9-14.4	76.4	21.8-96.9	88.2	79.4-92.4	91.1	75.0-98.4
7-8 days after treatment	4	16.0	5.0-37.2	88.1	74.0-93.2	92.3	88.1-96.3	98.9	98.2-100
16 days after treatment	1	38.4	38.4	94.3	94.3	97.8	97.8	99.0	99.0

Results from the two different parts assessed provided similar outcomes. The tested product applied at the recommended dose rate (2.0 L/ha) obtained a higher knockdown effect at 14-16 days after application than was observed in plots treated with lower than recommended dose rates. Furthermore, the control obtained with the recommended dose rate was more persistent and with less variability during the whole course of the trial than was observed with the less than recommended dose rates.

The data from the 8 trials proves the minimum effective dose rate of Fenazaquin 10% EC to control spider mites in strawberry is 2.0 L/ha (0.2 kg as/ha). Furthermore, the data demonstrated that if the application rate is reduced below this, a clear decrease in control as well as in persistence is observed.

Summary and evaluation of Minimum Effective Dose trial results for 2.0 L/ha Fenazaquin 10% EC target rate against spider mites in ornamentals crops

To prove and to support the requested dose rate of 2.0 L/ha Fenazaquin 10% EC applied post-emergence for the control of spider mites in ornamentals crops, the assessment results of 12 efficacy trials with spider mites, performed in Spain, Germany and Poland in 2017 are reported.

To demonstrate the minimum effective dose of Fenazaquin 10% EC against spider mites, data is included from the assessments conducted in each trial following application.

Table 3.2-9: Minimum effective dose of Fenazaquin 20% SC applied against spider mites in strawberry.

Target: Spider mites	No. of trials	Untreated MITES		Mean % Control at a range of doses of fenazaquin Fenazaquin 10% EC					
		Mean	Range	1.0 L/ha		1.5 L/ha		2.0 L/ha	
		Mean	Range	Mean	Range	Mean	Range	Mean	Range
All EPPO zone									
3 days after treatment	12	21.6	1.5-43.3	79.1	44.4-100	83.8	53.1-100	81.5	53.4-100
6-7 days after treatment	12	26.8	1.1-63.3	77.5	45.6-100	82.3	54.2-100	87.3	55.0-100
13-14 days after treatment	7	15.3	1.1-36.9	68.5	40.8-97.4	76.7	49.3-98.9	78.0	51.1-98.3
Target: Spider mites	No. of trials	Untreated EGGS		Mean % Control at a range of doses of fenazaquin Fenazaquin 10% EC					
		Mean	Range	1.0 L/ha		1.5 L/ha		2.0 L/ha	
		Mean	Range	Mean	Range	Mean	Range	Mean	Range
All EPPO zone									
3 days after treatment	7	33.2	5.8-76.0	85.7	64.9-99.6	93.0	77.9-99.6	87.4	56.2-99.3
7 days after treatment	7	34.9	7.1-76.0	78.4	48.3-99.6	91.3	83.0-95.1	95.6	91.3-98.1
14 days after treatment	3	11.9	8.0-14.7	84.0	66.8-94.2	93.3	86.3-96.9	98.9	97.5-99.6

Results from the two different parts assessed provided similar outcomes. The tested product applied at the recommended dose rate (2.0 L/ha) obtained a higher knockdown effect at 13-14 days in EGGS and at 6-7 days in MITES after application than was observed in plots treated with lower than recommended dose rates.

The data from the eleven trials proves the minimum effective dose rate of Fenazaquin 10% EC to control spider mites in ornamentals is 2.0 L/ha (0.2 kg as/ha). Furthermore, the data demonstrated that if the application rate is reduced below this, a clear decrease in control as well as in persistence is observed.

Summary and evaluation of Minimum Effective Dose trial results for 2.0 L/ha Fenazaquin 10% EC target rate against spider mites in tomato crops

To prove and to support the requested dose rate of 2.0 L/ha Fenazaquin 10% EC applied post-emergence for the control of spider mites in tomato crops, the assessment results of 8 efficacy trials with spider mites, performed in Greece, Spain and Germany zone in 2017 and 2018 are reported.

To demonstrate the minimum effective dose of Fenazaquin 10% EC against spider mites, data is included from the assessments conducted in each trial following application.

Table 3.2-10: Minimum effective dose of Fenazaquin 10% EC applied against spider mites in tomato.

Target: Spider mites	No. of trials	Untreated MITES		Mean % Control at a range of doses of fenazaquin Fenazaquin 10% EC					
		Mean	Range	1.0 L/ha		1.5 L/ha		2.0 L/ha	
				Mean	Range	Mean	Range	Mean	Range
All EPPO zone									
2-4 days after treatment	7	5.9	0.7-10.3	67.4	27.8-97.7	85.1	68.6-100	89.4	71.2-100
6-10 days after treatment	8	8.8	0.4-17.0	83.1	65.8-98.9	94.9	80.6-100	96.8	90.0-100
14 days after treatment	2	13.2	9.6-16.7	90.4	82.5-98.3	95.2	90.4-100	97.2	94.5-99.9
21-23 days after treatment	4	8.4	0.8-18.3	87.1	78.4-96.7	98.8	97.1-100	98.4	93.4-100
Target: Spider mites	No. of trials	Untreated EGGS		Mean % Control at a range of doses of fenazaquin Fenazaquin 10% EC					
		Mean	Range	1.0 L/ha		1.5 L/ha		2.0 L/ha	
				Mean	Range	Mean	Range	Mean	Range
All EPPO zone									
2 days after treatment	2	40.1	40.0-40.2	46.6	29.6-63.6	66.9	65.1-68.6	66.2	60.4-72.0
7-10 days after treatment	3	40.6	25.7-48.2	89.7	86.9-94.1	88.9	79.6-95.1	94.0	90.1-98.8
14 days after treatment	1	27.2	-	82.5	-	90.4	-	94.7	-
23 days after treatment	2	67.4	67.2-67.5	79.1	72.4-85.7	85.9	79.5-92.3	91.0	89.4-92.6

The tested product applied at the recommended dose rate (2.0 L/ha) obtained a higher knockdown effect after application than was observed in plots treated with lower than recommended dose rates. High dose rate works better than the other rates.

The data from the 8 trials proves the minimum effective dose rate of Fenazaquin 10% EC to control spider mites in ornamentals is 2.0 L/ha (0.2 kg as/ha). Furthermore, the data demonstrated that if the application rate is reduced below this, a clear decrease in control as well as in persistence is observed.

Summary and evaluation of Minimum Effective Dose trial results for 2.0 L/ha Fenazaquin 10% EC target rate against spider mites in melon crops

To prove and to support the requested dose rate of 2.0 L/ha Fenazaquin 10% EC applied post-emergence for the control of spider mites in melon crops, the assessment results of 8 efficacy trials with spider mites, performed in Spain and Greece in 2017 are reported.

To demonstrate the minimum effective dose of Fenazaquin 10% EC against spider mites, data is included from the assessments conducted in each trial following application.

Table 3.2-11: Minimum effective dose of Fenazaquin 10% EC applied against spider mites in melon.

	Mean % Control at a range of doses of fenazaquin Fenazaquin 10% EC
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Target: Spider mites	No. of trials	Untreated MITES		1.0 L/ha		1.5 L/ha		2.0 L/ha	
		Mean	Range	Mean	Range	Mean	Range	Mean	Range
All EPPO zone									
2-3 days after treatment	8	49.4	1.2-123.5	70.5	47.8-97.0	83.2	42.9-97.8	81.7	10.9-98.2
7 days after treatment	8	75.5	2.2-175.2	73.8	56.2-89.5	91.8	75.9-99.1	90.5	72.4-99.6
14 days after treatment	8	117.2	12.6-259.5	60.8	40.2-78.2	85.4	71.5-98.5	89.0	66.7-98.8
				Mean % Control at a range of doses of fenazaquin Fenazaquin 10% EC					
				1.0 L/ha		1.5 L/ha		2.0 L/ha	
Target: Spider mites	No. of trials	Untreated EGGS		Mean	Range	Mean	Range	Mean	Range
All EPPO zone									
2-3 days after treatment	8	74.6	9.0-192.3	66.8	38.6-93.6	74.8	63.3-92.6	81.2	64.7-95.0
7 days after treatment	8	108.2	15.1-234.0	78.6	62.6-91.7	90.6	86.2-94.4	90.5	82.3-95.5
14 days after treatment	8	163.4	76.1-281.5	63.8	46.9-86.7	75.9	43.1-94.1	80.6	46.4-94.9

Results from the two different parts assessed provided similar outcomes. The tested product applied at the recommended dose rate (2.0 L/ha) in the Mediterranean EPPO zone obtained the best knockdown at 7 days after the treatment assessing mites and eggs.

The data from the 8 trials proves the minimum effective dose rate of Fenazaquin 10% EC to control spider mites in melon is 2.0 L/ha (2.0 kg as/ha). Furthermore, the data demonstrated that if the application rate is reduced below this, a clear decrease in control as well as in persistence is observed.

Summary of all uses claimed on the label

Fenazaquin 10% EC applied at 2.0 L/ha to control spider mites achieved moderate to excellent control of spider mites. Reducing the application rate of Fenazaquin 10% EC from the proposed dose rate (2.0 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 2.0 L/ha, it is recommended that Fenazaquin 10% EC is applied under optimal conditions, i.e. optimal weather conditions.

As will be demonstrated in the following section, this document clearly demonstrates that the efficacy and crop safety of Fenazaquin 10% EC is equivalent to that of the standard reference products (i.e. Magister Flow, Floramite, Comanche Plus and Vermitec) to which it was compared. The applicant therefore wishes to cite the original registrant's data on fenazaquin now out of protection in support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal Evaluator extrapolate from those data.

Comments of zRMS:	<p>In order to provide information to establish the minimum effective dose, some of the trials conducted to demonstrate efficacy should include at least two lower dose(s) than recommended dose. In the appropriate researches of efficacy were tested differ doses and to register was chosen the lowest effective, which is in accordance to EPPO 1/225 (2).</p> <p>During field tests Applicant used different doses (1,0 l/ha – 0,5N; 1,5 l/ha – 0,75 N and 2,0 l/ha – N) of insecticide – Ruler 10 EC (product code: SHA 9700 B) containing fenazaquin. So, in the appropriate researches of efficacy were tested differ doses and to register was chosen the lowest effective, which is in accordance to EPPO 1/225 (2).</p> <p>In total, Applicant submitted 36 trials carried out on: melon (8 trials), strawberry (8 trials), tomato (8 trials) and ornamentals (12 trials). Trials were carried out in MED (melon, strawberry, tomato, ornamentals), Maritime (strawberry, tomato, ornamentals) and N-E EPPO zone (ornamentals). Studies carried on ornamental, strawberries and tomatoes were performed in a glasshouse. So, they can be as-</p>
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	<p>essed together from different EPPO zones. Only studies carried out on melon were open fields. CMS should decide if open field trials from MED EPPO zone carried out on melon can be acceptable.</p> <p>Fenazaquin 10% EC applied at 2.0 l/ha to control spider mites achieved moderate to excellent control of spider mites. Reducing the application rate of Fenazaquin 10% EC from the proposed dose rate (2.0 L/ha) to 50% or 75% of that rate, resulted in lower levels of efficacy. So, for Fenazaquin 10% EC recommended dose is 2,0 l/ha.</p> <p>The submitted documentation can be observed as acceptable in the opinion of Evaluator for strawberries, tomato and ornamentals. Each CMS should decide if use on melon is acceptable on the basis on the open field trials from MED. For, Poland we cannot use open field trials for glasshouse use. Applicant should submit at least 2-3 trials carried out on melon in glasshouse (all EPPO zone s are acceptable). So, melon should be excluded from Polish GAP table and label project.</p> <p>Concerned Member States should consider the current authorization of a reference product (a.s. fenazaquin) in their own Member State when they setting a minimum effective dose.</p>
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3.2.3 Efficacy tests (KCP 6.2)

Data from 36 efficacy trials conducted in the Mediterranean (26, i.e. Spain (20), Greece (5) and France (1)), North-east (5, i.e. Poland (5)) and the Maritime EPPO zone (5, i.e. Germany (5)) have been included in this biological assessment dossier to support the label claims and recommendations on efficacy and selectivity in the EU Central, South and North Registration zone.

Studies from three climatic zones are used in this document to support the registration of Fenazaquin 10% EC. However, since 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. Studies in Melon were performed in open fields in the Mediterranean EPPO zone.

The 36 efficacy trials were conducted in melon (8), strawberry (8), tomato (8) and ornamentals (12). In the 36 trials, the level of control obtained by Fenazaquin 10% EC was assessed in spider mites presents in the trials. Data on each individual weed species is only included from trials in which a minimum of 4 plants per m² were seen at the timing of the assessment.

Table 3.2-9: Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/152 (4), PP 1/181 (4), PP 1/135(4)
	Specific guidelines	EPPO PP 1/239(2), PP 1/192(2), PP 1/168 (2), PP 1/37 (2)
Experimental design	Plot design	RACOB (36)
	Plot size	4-50 m ²
	Number of replications	4 (36)
Crop	Trials per crop	Melon (8) Strawberry (8) Tomato (8) Ornamentals (12)

	Varieties per crop	<u>Melon</u> : Magiar, Atomus, Kaman, 3261, Tito, Arava, Jador F1, Imperial F1 <u>Strawberry</u> : Amandine, Mar de Bois, Charlotte, Sonata, Clery, Fortuna (3) <u>Tomato</u> : Ninette, Retinto, Harzfeuer, Roma nao, Casa, Elpida, Eliseo, Volley <u>Ornamentals</u> : White victoria, Million, Mirabella, Starlight Scalet, Zembla White, Staviski white, Lady thumb, Rosa elschorn, Fairy, Velvet red (3)
	Sowing period	<u>Melon</u> : 11/5/17-3/6/17 <u>Strawberry</u> : 2/3/15-10/10/17 <u>Tomato</u> : 5/5/17-28/8/18 <u>Ornamentals</u> : 1/5/17-27/8/18
Application	Crop stage (BBCH)* at application	<u>Melon</u> : 61-85 <u>Strawberry</u> : 15-91 <u>Tomato</u> : 73-88 <u>Ornamentals</u> : 24-65
	Number of appl.	1 (8), 2 (28)
	Spray volumes	400-1567 L/ha
Assessment	Assessment types	- Visual estimation of pest presence per plot compared to 'untreated' ('untreated' = 0 % control); total control = 100 % control) or calculated, based on pest counts (MITES and EGGS) in a defined area, as compared to the untreated check. - Visual estimation of crop injury and crop stand reduction (thinning) compared to 'untreated' ('untreated' = 0% crop injury; 100% crop injury = total crop destruction). Where appropriate this overall score was substituted or supplemented by assessments of individual symptoms. - Emergence rate - Crop vigour
	Assessment dates	Efficacy: 2 to 23 DAT
Other relevant information	Soil type	Light to heavy soils
	Natural / artificial inoculation...	Natural
	Field / Greenhouse...	Greenhouse and Field

Use 001: Control of spider mites in strawberry

To demonstrate the effectiveness of the test product at the recommended dose rate against spider mites application in strawberry as compare it to the reference product included in the trials, results are presented from 2-16 days after application of the product.

Table 3.2-10: Strawberry – Spider mites control results by Fenazaquin 10% EC applied at 2.0 L/ha compared against control obtained with the fenazaquin reference product at equivalent rate in the efficacy tests (2-16 days of last app.; mean and variation in % control as compared to untreated check).

Days after last app.	No. of trials	MITES at assessment Mean	Efficacy obtained with		No. of trials where Fenazaquin 10% EC is >, < or =, compared to the fenazaquin reference product = : ± 5% control			Overall
			Fenazaquin 10% EC at:	National ref. prod. at				
			Mean					
			2.0 L/ha	1N	>	=	<	
All EPPO zones								
3	4	18.5 (15.4-24.7)	94.7 (89.2-100)	93.3 (79.8-99.5)		4		=
7-8	4	39.1 (24.4-56.3)	98.4 (95.7-100)	98.0 (95.4-100)		4		=
16	1	26.8	98.8	91.8		1		=
Days	No.	MITES at assess-	Efficacy obtained with		No. of trials where Fenazaquin 10%			

after last app.	of trials	ment Mean	Fenazaquin 10% EC at:	Floramite 240 SC at	EC is >, < or =, compared to the fenazaquin reference product = : ± 5% control			Overall
			Mean					
			2.0 L/ha	1N	>	=	<	
3	1	0.6	100	100		1		=
7	1	0.4	100	100		1		=
14	1	0.1	75.0	75.0		1		=
Days after last app.	No. of trials	MITES at assessment Mean	Efficacy obtained with		No. of trials where Fenazaquin 10% EC is >, < or =, compared to the fenazaquin reference product = : ± 5% control			Overall
			Fenazaquin 10% EC at:	Comanche Plus at				
			Mean					
			2.0 L/ha	1N	>	=	<	
3	3	7.3 (4.3-11.2)	73.9 (57.9-82.6)	81.6 (60.8-95.4)		3		=
7	3	8.0 (5.5-11.5)	91.3 (90.2-93.2)	94.8 (92.7-97.0)		3		=
Days after last app.	No. of trials	EGGS at assessment Mean	Efficacy obtained with		No. of trials where Fenazaquin 10% EC is >, < or =, compared to the fenazaquin reference product = : ± 5% control			Overall
			Fenazaquin 10% EC at:	National ref. prod. at				
			Mean					
			2.0 L/ha	1N	>	=	<	
3	4	11.4 (7.9-14.1)	91.1 (75.0-98.4)	89.9 (74.1-97.1)		4		=
7-8	4	16.0 (5.0-37.2)	98.9 (98.2-100)	97.0 (92.7-98.8)		4		=
16	1	38.4	99.0	87.1		1		=

When applied at 2.0 L/ha post-emergence, Fenazaquin 10% EC achieved excellent control of spider mites in strawberry. In all trials evaluated, the effect achieved with Fenazaquin 10% EC was similar to the effect obtained with the fenazaquin or other national reference product applied. Statistical evaluation supports this statement as no significant differences were observed between the tested products at any of the assessments carried out, where statistical evaluation of the assessment was reported.

Use 002: Control of spider mites in ornamentals

To demonstrate the effectiveness of the test product at the recommended dose rate against spider mites application in ornamentals as compare it to the reference product included in the trials, results are presented from 3-14 days after application of the product.

Table 3.2-11: Ornamentals – Spider mites results by Fenazaquin applied at 2.0 L/ha compared against control obtained with the fenazaquin reference product at equivalent rate in the efficacy tests (3-14 days of last app.; mean and variation in % control as compared to untreated check).

Days after last app.	No. of trials	MITES at assessment Mean	Efficacy obtained with		No. of trials where Fenazaquin 10% EC is >, < or =, compared to the fenazaquin reference product = : ± 5% control			Overall
			Fenazaquin 10% EC at:	National ref. prod. at				
			Mean					
			2.0 L/ha	1N	>	=	<	
All EPPO zones								
3	11	23.4 (1.5-43.3)	80.1 (53.4-100)	83.0 (59.0-100)		11		=
6-7	11	29.1 (1.1-63.3)	86.3 (55.0-100)	87.1 (54.4-100)		11		=
13-14	6	17.7 (2.4-36.9)	74.6 (51.1-98.3)	72.3 (50.4-93.0)		6		=
Days after last app.	No. of trials	MITES at assessment Mean	Efficacy obtained with		No. of trials where Fenazaquin 10% EC is >, < or =, compared to the fenazaquin reference product = : ± 5% control			Overall
			Fenazaquin 10% EC at:	Vermitec Pro ref. prod. at				
			Mean					
			2.0 L/ha	1N	>	=	<	
3	1	1.7	97.0	98.2		1		=
6	1	1.8	98.2	96.6		1		=
13	1	1.1	98.2	96.1		1		=
Days after last app.	No. of trials	EGGS at assessment Mean	Efficacy obtained with		No. of trials where Fenazaquin 10% EC is >, < or =, compared to the fenazaquin reference product = : ± 5% control			Overall
			Fenazaquin 10% EC at:	National ef. prod. at				
			Mean					

			2.0 L/ha	1N	>	=	<	
All EPPO zones								
3	7	33.2 (5.8-76.0)	87.4 (56.2-99.3)	90.2 (75.3-100)		7		=
7	7	34.9 (7.1-76.0)	95.6 (91.3-98.1)	92.8 (82.0-100)	2	5		=
14	3	11.9 (8.0-14.7)	98.9 (97.5-99.6)	89.6 (87.0-91.5)		3		=

When applied at 2.0 L/ha post-emergence, Fenazaquin 10% EC achieved excellent control of spider mites in ornamentals. In all trials evaluated, the effect achieved with Fenazaquin 10% EC was similar or better to the effect obtained with the fenazaquin or other national reference product applied. Statistical evaluation supports this statement as no significant differences were observed between the tested products at any of the assessments carried out, where statistical evaluation of the assessment was reported.

Use 003: Control of spider mites in tomato

To demonstrate the effectiveness of the test product at the recommended dose rate against spider mites application in tomato as compare it to the reference product included in the trials, results are presented from 2-23 days after application of the product.

Table 3.2-24: Tomato – spider mites control results by Fenazaquin 10% EC applied at 2.0 L/ha compared against control obtained with the fenazaquin reference product at equivalent rate in the efficacy tests (2-23 days of last app.; mean and variation in % control as compared to untreated check).

Days after last app.	No. of trials	MITES at assessment Mean	Efficacy obtained with		No. of trials where Fenazaquin 10% EC is >, < or =, compared to the fenazaquin reference product = : ± 5% control			Overall
			Fenazaquin 10% EC at:	Fenazaquin ref. prod. at				
			Mean					
			2.0 L/ha	1N	>	=	<	
All EPPO zones								
2	2	9.0 (7.6-10.3)	85.6 (71.2-100)	84.2 (83.8-84.6)		2		=
7-10	3	14.6 (11.4-17.0)	96.4 (90.0-100)	96.8 (95.6-99.1)		3		=
14	1	16.7	94.5	95.2		1		=
23	2	16.0 (13.6-18.3)	96.7 (93.4-100)	97.1 (97.1-97.1)		2		=
Days after last app.	No. of trials	MITES at assessment Mean	Efficacy obtained with		No. of trials where Fenazaquin 10% EC is >, < or =, compared to the fenazaquin reference product = : ± 5% control			Overall
			Fenazaquin 10% EC at:	Floramite 240 SC ref. prod. at				
			Mean					
			2.0 L/ha	1N	>	=	<	
3	3	1.5 (0.7-2.7)	93.1 (81.8-100)	80.5 (41.6-100)		3		=
6-7	3	2.9 (0.4-7.5)	99.7 (99.1-100)	98.1 (94.2-100)		3		=
14	1	9.6	99.9	81.7		1		=
21	2	0.9 (0.8-0.9)	100 (100-100)	100 (100-100)		2		=
Days after last app.	No. of trials	MITES at assessment Mean	Efficacy obtained with		No. of trials where Fenazaquin 10% EC is >, < or =, compared to the fenazaquin reference product = : ± 5% control			Overall
			Fenazaquin 10% EC at:	Comanche Plus ref. prod. at				
			Mean					
			1.0 L/ha	1N	>	=	<	
3-4	2	7.7 (7.5-7.9)	87.6 (84.9-90.3)	83.4 (79.2-87.6)		2		=
7-8	2	8.9 (8.7-9.1)	92.9 (91.0-94.8)	91.5 (89.0-94.0)		2		=
Days after last app.	No. of trials	EGGS at assessment Mean	Efficacy obtained with		No. of trials where Fenazaquin 10% EC is >, < or =, compared to the fenazaquin reference product = : ± 5% control			Overall
			Fenazaquin 10% EC at:	Fenazaquin ref. prod. at				
			Mean					
			1.0 L/ha	1N	>	=	<	
All EPPO zones								
2	2	40.1 (40.0-40.2)	66.2 (60.4-72.0)	81.8 (80.1-83.4)		2		=
7-10	3	40.6 (25.7-48.2)	94.0 (90.1-98.8)	96.6 (95.0-98.9)		3		=
14	1	27.2	94.7	94.5		1		=
23	2	67.4 (67.2-67.5)	91.0 (89.4-92.6)	90.6 (89.7-91.5)		2		=

When applied at 2.0 L/ha post-emergence, Fenazaquin 10% EC achieved excellent control of spider mites

in tomato. In all trials evaluated, the effect achieved with Fenazaquin 10% EC was similar to the effect obtained with the fenazaquin or other national reference product applied. Statistical evaluation supports this statement as no significant differences were observed between the tested products at any of the assessments carried out, where statistical evaluation of the assessment was reported.

Use 004: Control of spider mites in melon

To demonstrate the effectiveness of the test product at the recommended dose rate against spider mites application in melon as compare it to the reference product included in the trials, results are presented from 2-14 days after application of the product.

Table 3.2-25: Melon – Spider mites control results by Fenazaquin 10% EC applied at 2.0 L/ha compared against control obtained with the fenazaquin reference product at equivalent rate in the efficacy tests (2-14 days of last app.; mean and variation in % control as compared to untreated check).

Days after last app.	No. of trials	MITES at assessment Mean	Efficacy obtained with		No. of trials where Fenazaquin 10% EC is >, < or =, compared to the fenazaquin reference product = : ± 5% control			Overall
			Fenazaquin 10% EC at:	Fenazaquin ref. prod. at				
			Mean					
			2.0 L/ha	1N	>	=	<	
All EPPO zones								
2-3	8	49.4 (1.2-123.5)	81.7 (10.9-98.2)	88.5 (71.4-100)		8		=
7	8	75.5 (2.2-175.2)	90.5 (72.4-99.6)	89.5 (62.1-99.6)		8		=
14	8	117.2 (12.6-259.5)	89.0 (66.7-98.8)	81.3 (57.0-98.9)		8		=
Days after last app.	No. of trials	EGGS at assessment Mean	Efficacy obtained with		No. of trials where Fenazaquin 10% EC is >, < or =, compared to the fenazaquin reference product = : ± 5% control			Overall
			Fenazaquin 10% EC at:	Fenazaquin ref. prod. at				
			Mean					
			2.0 L/ha	1N	>	=	<	
All EPPO zones								
2-3	8	74.6 (9.0-192.3)	81.2 (64.7-95.0)	81.0 (63.0-92.2)		8		=
7	8	108.2 (15.1-234.0)	90.5 (82.3-95.5)	90.3 (81.8-95.5)		8		=
14	8	163.4 (76.1-281.5)	80.6 (46.4-94.9)	80.6 (47.8-92.1)		8		=

When applied at 2.0 L/ha post-emergence, Fenazaquin 10% EC achieved excellent control of spider mites in melon. In all trials evaluated, the effect achieved with Fenazaquin 10% EC was similar or better to the effect obtained with the fenazaquin or other national reference product applied. Statistical evaluation supports this statement as no significant differences were observed between the two tested products at any of the assessments carried out, where statistical evaluation of the assessment was reported.

Summary and conclusion

Based on the results of 36 field efficacy trials carried out in 2017 and 2018, the following can be concluded for the intended use to control spider mites with Fenazaquin 10% EC applied at the rate of 2.0 L/ha in melon, strawberry, tomato and ornamentals:

- Fenazaquin 10% EC applied at the proposed dose rate of 2.0 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 10% EC is comparable against all pest species.
- The trial results are considered valid for all intended EPPO zones countries.

Fenazaquin 10% EC applied is suitable for the control of spider mites in melon, strawberry, tomato and ornamentals.

Applicant would like to refer to the EPPO standard PP 1/226(3) where is indicated that full number of trials in different years is required “ particularly for plant protection products or active substances which

not have been on the market in the EPPO region in which authorization is sought". It is important to remark that the EPPO standard is referring to the region where registration is sought and not to a specific country, thus applicant considers that presence of standards has to be evaluated taking into account the registers in the whole Europe. The same EPPO PP 1/226(3) indicates that reduced number of trials can be presented "where there is a large amount of supporting evidence from use of the product, or of similar products with the same active substance on closely related pests or against the same pests on different crops". Fenazaquin formulations have been registered in whole Europe and in countries where trials were conducted for various years like Magus 200 SC (reg nr R55/2016) registered in Poland in 2016, Magister 10 (reg nr 19254) registered in Spain in 1993, Magister flow (reg nr 19255) registered in Spain in 1993, Magister (reg nr 9200313) registered in France in 1999, Magister 200 SC (reg nr 008891) registered in Italy in 1996, Magister 100 EC (reg nr 008892) registered in Italy in 1996, Matador 200 SC (reg nr 16875) registered in the United Kingdom in 2014 or Demitan (reg nr UP/I-320-20/94-01/7) registered in Croatia in 1999. According to this formulation has been widely proved in whole Europe where registration is sought, thus applicant considers that number of trials are enough to register formulation.

Comments of zRMS:	<p>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.</p> <p>Applicant submitted in total 36 trials (28 – glasshouse and 8 – open field) showing the results in research into product efficacy carried out during one growing season in melon (8 trials), strawberries (8 trials), tomato (8 trials) and ornamentals (12 trials). Those efficacy trials were performed in MED (melon, strawberries, tomato, ornamentals), Maritime (strawberry, tomato, ornamentals) and N-E EPPO zone (ornamentals). The number of trials is sufficient and fulfil EPPO requirements for tomato, strawberries and ornamentals. Trials were carried out in a glasshouse, so all EPPO zones can be assessed together. For melon, Applicant presented open field trials performed in MED EPPO zone. In the opinion of Evaluator, those trials are acceptable only for MED 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. From Polish label, melon should be excluded due to not sufficient documentation. Melon is a minor crop, co in Poland it can be registered only according to 51 Article, without any valid trial.</p> <p>To demonstrate the effectiveness of the tested product at the recommended dose rate against spider mites application in studied crops is compare to the reference product included in the trials. Results are presented from 2-16 days (strawberries), 3-14 (ornamentals), 2-23 days (tomato) and after 2-14 days (melon) application of the product. In melon trials only one application of tested insecticide – Ruler 10 EC was used, and during trials carried out on ornamentals, strawberries and tomatoes – 2 applications were used. It was in accordance to proposed GAP table and label project.</p> <p><u>Submitted trials:</u></p> <ul style="list-style-type: none"> • melon – 8 trials from MED EPPO zone (4-ES, 4-GR). In all trials <i>Tetranychus urticae</i> as a pest was studied. • strawberry – 8 trials from Maritime (1 trial – DE) and MED (7 trials: ES-6, FR-1). In all trials <i>Tetranychus urticae</i> as a pest was studied. • tomato – 8 trials from Maritime (3-DE) and MED (5 trials: ES-4, GR-1). In all trials <i>Tetranychus urticae</i> as a pest was studied. • ornamentals – 12 trials from Maritime (1-DE), MED (ES-6) and N-E EP-
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	<p>PO zone (5 trials: PL). During glasshouses carried out in N-E EPPO zone following ornamental species were studied: <i>Chrysanthemum</i> - <i>Dendranthema indicum</i> (2 trials), <i>Fuchsia magellanica</i> (1 trial), <i>Rosa sp.</i> (2 trials). During glasshouses carried out in MED EPPO zone following ornamental species were studied: <i>Gypsophila paniculata</i> (3 trials), <i>Mandevilla sanderi</i> (3 trials). During glasshouses carried out in MAR EPPO zone following ornamental species was studied: <i>Callistephus chinensis</i> (1 trial). EPPO extrapolation table 1/257 IEET 75 indicates that tests on ornamental plants under greenhouse conditions should be conducted on <i>chrysanthemum</i> (indicator plant). In addition, it indicates that the appropriate bioindicators here are primarily the hop spider mite, and secondarily the mite species of the genera <i>Eotetranychus</i> and <i>Tetranychus</i>. In most trials <i>Tetranychus urticae</i> as a pest was studied, in one trial from MAR greenhouse – <i>Panonychus ulmi</i> was studied.</p> <p>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 rose-wood mite family, including the strawberry mite and <i>Polyphagotarsonemus latus</i>. 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 <i>Eotetranychus</i> and <i>Tetranychus</i>. In view of the above, the Applicant has also conducted tests on ornamental plants in an acceptable manner.</p> <p>According to Polish rules we can accepted following ornamental species: <i>Chrysanthemum</i> (2 trials), <i>Rosa sp.</i> (2 trials), <i>Gypsophila paniculata</i> (3 trials), <i>Mandevilla sanderi</i> (3 trials). Extrapolation results from <i>Chrysanthemum</i> is possible according to 2-3 selectivity/phytotoxicity trials submitted on other ornamental species. Unfortunately, the following species did not meet this requirement: a <i>Fuchsia magellanica</i> and <i>Callistephus chinensis</i>. CMS should accept ornamental plants according to EPPO 1/257 and their national guidelines.</p> <p>In the opinion of Evaluator, due to the fact that the Ruler 10 EC is intended to be used in greenhouses, it is not necessary to present research for Poland (N-E EPPO zone). It is enough that the Applicant in case of strawberries (1 trial-DE) and tomatoes (3 trials – DE) has presented research from neighbouring countries.</p> <p>When applied at 2.0 L/ha post-emergence, Fenazaquin 10% EC achieved excellent control of spider mites in tomato, strawberries, ornamentals and melon. In all trials evaluated, the effect achieved with Fenazaquin 10% EC was similar or better to the effect obtained with the fenazaquin or other national reference product applied. Only in a few trials' efficacy of tested Ruler 10 EC was slightly lower than standard reference product used.</p> <p>In our opinion spider mites can be accepted in GAP table. Spider mites are members of the <i>Acari</i> (mite) family <i>Tetranychidae</i>, which includes about 1,200 species. The applicant conducted research on only one mite family – <i>Tetranychidae</i>. (<i>Tetranychus sp.</i> – red spiders, <i>Tetranychus urticae</i> and <i>Panonychus ulmi</i> 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.</p>
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	<p>In Polish label we can accepted spider mites, however we proposed following entry: <i>Tetranychus urticae</i> (przędziorek chmielowiec) and other pests from the family of the <i>Tetranychidae</i> for ornamental plants and <i>Tetranychus urticae</i> (przędziorek chmielowiec) for strawberry. CMS should decide which entries on the label can be accepted. Ruler 10 EC was characterized by excellent control of those pests.</p> <p>Residue section accepted only one application on strawberry. However, in efficacy trials the efficacy of one and two application was studied. Both, were characterized by good efficiency (>80%). So, we accepted only one application per season on strawberries.</p> <p>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.</p> <p>It is recommended to authorize the product Ruler 10 EC in the extent of the authorization of the reference product (a.s. fenazaquin) at the equivalent dose rate.</p>
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3.3 Information on the occurrence or possible occurrence of the development of resistance (KCP 6.3)

3.3.1 Summary and Conclusions

Resistance to crop protection chemicals is a natural biological phenomenon that occurs in insects, weeds, fungi and molluscs. It usually becomes evident after the repeated use of a particular pesticide selects the naturally-occurring resistant strains within the wild population and allows them to multiply over several seasons until they become dominant in the population and pose a control problem.

The insect-resistant population develops because the sensitive population is suppressed and the rare insecticide-resistant individual is allowed to multiply and occupy the biological niche previously filled by the sensitive population. An increase in the frequency of such resistant strains may result in loss of control. As a general principle, resistance develops at different rates depending on the pathogen type, nature of the infestation and use pattern of the insecticide.

Reports of the appearance of resistant strains in laboratory studies do not necessarily imply that any loss of control is expected in the field. Likewise, the appearance of less-sensitive strains in the field does not always result in failure of insect control. When the frequency of resistant individuals is low and/or the level of resistance is moderate, insecticide applications in most cases will provide satisfactory control.

To avoid the misinterpretation of potential and/or possible resistance cases, the term resistance will be limited to situations where the conditions in both (a) and (b) below are met:

- (a) the development of resistance leads to failure of control under practical field conditions following application of an insecticide correctly and according to the label and
- (b) a demonstration that a loss of control is due to the presence of pathogenic strains with reduced insecticide sensitivity.

3.3.2 Mode of Action

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.

3.3.3 Mechanism(s) and evidence of resistance

Melon: spider mites

From resistance monitoring surveys conducted in Spain and Greece, no information of fenazaquin resistance in *Tetranychus urticae* and *Panonychus ulmi* has been reported.

Strawberry: spider mites

From resistance monitoring surveys conducted in Spain, Greece and Italy, no information of fenazaquin resistance in *Tetranychus urticae* and *Panonychus ulmi* has been reported.

Ornamentals: spider mites

From resistance monitoring surveys conducted in Spain, Greece, Poland and Germany, no information of fenazaquin resistance in *Tetranychus urticae* and *Panonychus ulmi* has been reported.

Tomato: spider mites

From resistance monitoring surveys conducted in Spain, Poland and Romania, no information of fenazaquin resistance in *Tetranychus urticae* and *Panonychus ulmi* has been reported.

3.3.4 Cross-resistance

Cross-resistance within actives in the quinazoline group as well as cross-resistance hasn't been reported. Until now no cross-resistance has been reported between other modes of action employed against spider mites.

3.3.5 Sensitivity data

Spider mites vary in their sensitivity towards insecticides both between and within populations, and this natural variation should be understood before shifts in sensitivity can be assessed. Fenazaquin has been tested and used worldwide for 9 years and it is therefore difficult to find unexposed insect pest populations. No true base line sensitivity data can therefore be established.

3.3.6 Use pattern

In the EU Central, Northern and Southern zone, Fenazaquin 10% EC is proposed for use spider mites, as listed in the GAP table in Appendix 2. The insecticide is applied once or twice times in the season at the recommended dose rates.

The application may be employed when the pest population in the crop has reached the threshold as recommended for the different crops in the different regions. Dependent on the crop and the pest to be controlled, this will deliver 0.2 kg/ha fenazaquin per application.

3.3.7 Resistance Risk Assessment of unrestricted use patterns

Agronomic practice

In terms of agronomic practice, the selection pressure on the intended targets for Sharda fenazaquin formulation is higher in some cropping systems compared to others. This can be due to the prevalence of

continuous cropping of e.g. cereal crops or short rotation intervals between successive crops where fenazaquin can be used. In contrast, other crops tend to be grown on a longer rotation cycle.

The plant protection product

For optimum insect control, Fenazaquin is applied at the rates recommended on the proposed label. These have been shown to be the minimum effective dose for the major targets (Section 6.1.2).

Unrestricted Use pattern

In the absence of any potential resistance risk and in the absence of any other restrictions on the GAP (residues, toxicology etc.) the unrestricted use pattern for fenazaquin would be season long usage with an unrestricted number of applications.

Resistance risk assessment of unrestricted use pattern

Overall it is clear that the unrestricted use of fenazaquin presents an unacceptable resistance risk and therefore modifiers as part of a Management Strategy are proposed.

3.3.8 Acceptability of the resistance risk

Without any precautions the resistance risk is unacceptable. However; taking the right precautions and following Good Agricultural Practise, the risk is acceptable. Should resistant populations arise, control could be achieved through use of alternative products.

3.3.1 Management strategy for Fenazaquin 10% EC

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 10% EC 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

3.3.2 Implementation of the management strategy

Information on the management of resistance and the specific Resistance Management Strategy for Fenazaquin is disseminated by a number of routes including, but not exclusively:

- Product label has a clear statement regarding resistance risk and the management strategy
- Pack inserts- for general information or to address a particular issue in a specific geographical area were it to occur.
- Leaflets available at, and distributed by distributors/wholesalers/merchants
- Information released by national and local advisory services re. monitoring
- Training for distributors/wholesalers/merchants and farmer groups
- Links from company web sites to local Resistance working groups for information and advice

3.3.3 Monitoring, reporting and reaction to changes in performance

Monitoring of field performance

Where field performance is significantly less than expected and where no other explanation can be found for the reduced performance e.g. application errors, then samples may be taken for sensitivity testing. Where testing is carried out it will be conducted at laboratories experienced in carrying out such testing and using methods recommended by the authorities.

Analysis of performance-related complaints

Where no other reason for a failure in performance can be identified, samples may be taken for testing as described above

Where resistance is confirmed as the cause for loss of field performance this will be reported to the authorities on an annual basis or as required.

Containment plan

The above recommendations will be adjusted as needed depending on the success of the proposed strategy. In the event that practical field resistance should occur on any significant scale, Sharda's plan for containing the further development or spread of resistance includes a number of possible actions on a temporary or permanent basis, including but not exclusively:

- Recommendations to use only insecticides from alternative mode of action groups for the remainder of the growing season
- Recommendation to use only in a programme e.g. before or after an application of an insecticide from a different mode of action group.

Normally any action taken would be in consultation with the relevant authorities.

Comments of zRMS:	<p>The two-spotted spider mite, <i>Tetranychus urticae</i> Koch (<i>Acari: Tetranychidae</i>) 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.</p> <p>Resistance mechanisms to fenazaquin were surveyed in Iranian populations of the two-spotted spider mite, <i>Tetranychus urticae</i> Koch (Mahdavi Moghadam et al. 2012).</p> <p><i>Tetranychus urticae</i> 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.</p> <p>An EPPO conform analysis of the resistance risk was carried out. Evaluator accepted strategy against resistance developing.</p> <p>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.</p> <p>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 the risk of resistance development tend to vary between the Member States.</p>
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3.4 Adverse effects on treated crops (KCP 6.4)

Information on trials submitted (3.4: Adverse effects on treated crops)

Table 3.4-1: Presentation of selectivity trials

Use(s) *	Target(s)*	Country	Years	Type of trial**	Number of trials (number of valid trials)				GEP, non- GEP, official***	Comments (any other relevant information)
					EPPO zone					
					MAR	MED	S-E	N-E		
Melon	Spider mites	Spain	2017	MED + E + S	-	4	-	-	GEP	
		Greece	2017	MED + E + S	-	4	-	-	GEP	
						-		-	-	-
Strawberry	Spider mites	Spain	2017	MED + E + S	-	6	-	-	GEP	
		France	2017	MED + E + S	-	1	-	-	GEP	
		Germany	2017	MED + E + S	1	-	-	-	GEP	
				-		-	-	-		
Tomato	Spider mites	Spain	2017	MED + E + S	-	4	-	-	GEP	
		Germany	2017	MED + E + S	3	-	-	-	GEP	
		Greece	2017	MED + E + S	-	1	-	-	GEP	
				-				-		
Ornamentals	Spider mites	Spain	2017	MED + E + S	-	6	-	-	GEP	
		Poland	2017	MED + E + S	-	-	-	5	GEP	
		Germany	2017	MED + E + S	1	-	-	-	GEP	
								-		
		Total, all crops			5	26	-	5		

Table 3.4-2: Details on selectivity trial methodology

Guidelines	General guidelines	EPPO PP 1/152 (4), PP 1/181 (4), PP 1/135(4)
	Specific guidelines	EPPO PP 1/239(2), PP 1/192(2), PP 1/168 (2), PP 1/37 (2)
Experimental design	Plot design	RACOB (36)
	Plot size	4-50 m ²
	Number of replications	4 (36)
Crop	Trials per crop	Melon (8) Strawberry (8) Tomato (8) Ornamentals (12)
	Varieties per crop	<u>Melon</u> : Magiar, Atomus, Kaman, 3261, Tito, Arava, Jador F1, Imperial F1 <u>Strawberry</u> : Amandine, Mar de Bois, Charlotte, Sonata, Clery, Fortuna (3) <u>Tomato</u> : Ninette, Retinto, Harzfeuer, Roma nao, Casa, Elpida, Eliseo, Volley <u>Ornamentals</u> : White victoria, Million, Mirabella, Starlight Scalet, Zembla White, Staviski white, Lady thumb, Rosa elschorn, Fairy, Velvet red (3)
	Sowing period	<u>Melon</u> : 11/5/17-3/6/17 <u>Strawberry</u> : 2/3/15-10/10/17 <u>Tomato</u> : 5/5/17-28/8/18 <u>Ornamentals</u> : 1/5/17-27/8/18
Application	Crop stage (BBCH)* at application	<u>Melon</u> : 61-85 <u>Strawberry</u> : 15-91 <u>Tomato</u> : 73-88 <u>Ornamentals</u> : 24-65
	Number of appl.	1 (8), 2 (28)

	Spray volumes	400-1567 L/ha
Assessment	Assessment types	<ul style="list-style-type: none"> - Visual estimation of pest presence per plot compared to 'untreated' ('untreated' = 0 % control); total control = 100 % control) or calculated, based on pest counts (MITES and EGGS) in a defined area, as compared to the untreated check. - Visual estimation of crop injury and crop stand reduction (thinning) compared to 'untreated' ('untreated' = 0% crop injury; 100% crop injury = total crop destruction). Where appropriate this overall score was substituted or supplemented by assessments of individual symptoms. - Emergence rate - Crop vigour
	Assessment dates	Efficacy: 2 to 23 DAT
Other relevant information	Soil type	Light to heavy soils
	Natural / artificial inoculation...	Natural
	Field / Greenhouse...	Greenhouse and Field

In all trials, the performance of Fenazaquin 10% EC was measured against a commercial standard of fenazaquin currently on the market in Central, Northern and Southern Europe (Magister) and other reference standards (Floramite, Comanche Plus and Vermitec). The trials were carried out on melon, strawberry, tomato and ornamentals.

The reference products used in the trials are listed in Table 3.4-3.

Table 3.4-3: Presentation of reference standards used in trials (selectivity trials, transformation trials...)

Trade name	Formulation	Composition	Rates [L/ha]	Indication	Country	N° of Trials
MAGISTER	EC	Fenazaquin	1.5 l/ha 2.0 l/ha		FR, ES, PL, GR	26
COMANCHE PLUS	WP	Tebufenpirad	0.75 l/ha 1.0 l/ha		ES	5
FLORAMITE	SC	Bifenazate	0.3 l/ha 0.4 l/ha		DE	4
VERMITEC	EC	Abamectin	0.75 l/ha 1.0 l/ha		DE	1

3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

The crop safety of Fenazaquin 10% EC was assessed in melon, strawberry, tomato and ornamentals in 36 efficacy trials where Fenazaquin 10% EC was applied at 1.0 L/ha, 1.5 L/ha and 2.0 L/ha.

These trials were conducted in the Mediterranean (26, i.e. Spain (20), Greece (5) and France (1)), North-east (5, i.e. Poland (5)) and the Maritime EPPO zone (5, i.e. Germany (5)) in 2017 and 2018, to evaluate the crop safety of Fenazaquin 10% EC in melon, strawberry, tomato and ornamentals.

Studies from three climatic zones are used in this document to support the registration of Fenazaquin 10% EC. However, since 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. Studies in Melon were performed in open fields in the Mediterranean EPPO zone.

3.4.1.1 Summary and evaluation of trials

The crop safety of applying Fenazaquin 10% EC in melon, strawberry, tomato and ornamentals was evaluated in 36 efficacy trials.

3.4.1.1.1 Melon

Crop phytotoxicity was evaluated in efficacy trials where Fenazaquin 10% EC was applied, at growth stages ranging from BBCH 61 to BBCH 85, at the rate of 1.0, 1.5 and 2.0 L/ha in melon.

Phytotoxicity in melon trials

Eight efficacy trials were conducted in Greece and Spain to assess the crop safety of Fenazaquin 10% EC when applied as recommended in melon. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in none of the efficacy trials as well as no adverse effects were observed.

Country	Trial no.	Variety	GS at appl.
Efficacy trials, 1.0, 1.5 and 2.0 L/ha			
ES	17/SHA/358	Magiar	61
ES	17/SHA/359	Atomus	61
ES	17/SHA/360	Kaman	61
ES	17/SHA/361	3261	61
GR	S17-0142E-01	Tito	85
GR	S17-0142E-02	Arava	85
GR	S17-0142E-03	Jador F1	84
GR	S17-0142E-04	Imperial F1	76

3.4.1.1.2 Strawberry

Crop phytotoxicity was evaluated in efficacy trials where Fenazaquin 10% EC was applied, at growth stages ranging from BBCH 15 to BBCH 91, at the rate of 1.0, 1.5 and 2.0 L/ha in strawberry.

Phytotoxicity in strawberry trials

Eight efficacy trials were conducted in Germany, Spain and France to assess the crop safety of Fenazaquin 10% EC when applied as recommended in strawberry. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in none of the efficacy trials as well as no adverse effects were observed.

Country	Trial no.	Variety	GS at appl.
Efficacy trials, 1.0, 1.5 and 2.0 L/ha			
ES	17/SHA/372	Amandine	83
ES	17/SHA/373	Mar de Bois	83
ES	17/SHA/374	Charlotte	83
DE	FRS072/17-V2	Sonata	91
FR	S17-00669-02	Clery	15
ES	SHA17OP2II028-01	Fortuna	89
ES	SHA17OP2II028-02	Fortuna	89
ES	SHA17OP2II028-03	Fortuna	89

3.4.1.1.3 Ornamentals

Crop phytotoxicity was evaluated in efficacy trials where Fenazaquin 10% EC was applied, at growth stages ranging from BBCH 24 to BBCH 65, at the rate of 1.0, 1.5 and 2.0 L/ha in ornamentals.

Phytotoxicity in ornamentals trials

Twelve trials were conducted in Spain, Germany and Poland to assess the crop safety of Fenazaquin 10% EC when applied as recommended in ornamentals. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in none of the efficacy trials as well as no adverse effects were observed.

Country	Trial no.	Crop	Variety	GS at appl.
Efficacy trials, 1.0, 1.5 and 2.0 L/ha				
ES	17/SHA/362	Baby's breath	White Victoria	62
ES	17/SHA/363	Baby's breath	Million	62
ES	17/SHA/364	Baby's breath	Mirabella	62
DE	FRS070/17-V3	China aster	Starlight Scalet	65
PL	SGS/2017/048050062/PL01	Chrysanthemum	Zembla white	24-25
PL	SGS/2017/048050062/PL02	Chrysanthemum	Staviski white	55
PL	SGS/2017/048050062/PL04	Hardy fuchsia	Lady Thumb	62-65
PL	SGS/2017/048050062/PL05	Rosa sp.	Rosa elmschorn	51-49
PL	SGS/2017/048050062/PL06	Rosa sp.	Fairy	24-25
ES	SHA17OP2II024-01	Mandevilla sanderi	Velvet red	61
ES	SHA17OP2II024-02	Mandevilla sanderi	Velvet red	63-64
ES	SHA17OP2II024-03	Mandevilla sanderi	Velvet red	63

3.4.1.1.4 Tomato

Crop phytotoxicity was evaluated in efficacy trials where Fenazaquin 10% EC was applied, at growth stages ranging from BBCH 73 to BBCH 88, at the rate of 1.0, 1.5 and 2.0 L/ha in tomato.

Phytotoxicity in tomato trials

Eight efficacy trials were conducted in Spain, Germany and Greece to assess the crop safety of Fenazaquin 10% EC when applied as recommended in tomato. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in none of the efficacy trials as well as no adverse effects were observed.

Country	Trial no.	Variety	GS at appl.
Efficacy trials, 1.0, 1.5 and 2.0 L/ha			
ES	17/SHA/370	Ninette	83-85
ES	17/SHA/371	Retinto	85
DE	FRS071/17-V1	Harzfeuer	73-83
DE	FRS071/17-V2	Roma nano	75-76
DE	FRS071/17-V3	Casa	75-76
GR	S17-0144E	Elpida	85-88
ES	SHA17OP2II027-02	Eliseo	87-88
ES	SHA17OP2II027-03	Volley	84-85

3.4.1.2 Overall conclusion

The claims of crop safety on these crops are supported with a total of 36 trials conducted in Spain, Greece, France, Poland and Germany in 2017 and 2018. In all trials, Fenazaquin 10% EC proved to be crop safe in all trials did not affect the crop adversely when applied at a range of growth stages within and occasionally beyond the label recommended range, at the maximum proposed label recommended rates of 2.0 L/ha in melon, strawberry, ornamentals and tomato.

Table 3.4-4: Phytotoxicity of product, in all crops

Number of trials with...		Trials (36 trials)				
		Test product			Standard	
		1.0 L/ha	1.5 L/ha	2.0 L/ha	1N	2N
Maximum of phytotoxicity recorded during the trials	0% to 5%	36	36	36	36	36
	>5% to 10%	0	0	0	0	0
	>10% to 15%	0	0	0	0	0
	>15 %	0	0	0	0	0
Level of symptoms at the last assessments	0% to 5%	36	36	36	36	36
	>5% to 10%	0	0	0	0	0
	>10% to 15%	0	0	0	0	0
	>15 %	0	0	0	0	0

Comments of zRMS:	<p>The applicant's conclusion on crop safety can be agreed. No phytotoxic effects were observed in efficacy trials.</p> <p>In conclusion, the test product Ruler 10 EC is regarded safe for the treated plants when applied at the intended dose rate and used according to the label recommendations.</p>
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3.4.2 Effect on the yield of treated plants or plant product (KCP 6.4.2)

No studies of yield of the crops had been recorded.

Comments of zRMS:	<p>The applicant's conclusion on crop safety can be agreed. The control of insects feeding from leaves, seeds and other plant parts is expected to positively impact the harvested mass of treated crops. So, no negative influence of the product Ruler 10 EC on the yield of treated plants or plant product is to be expected when applied at the proposed label rate of 2,0 l/ha – spider mites in melon, strawberries, tomato and ornamental plants.</p>
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3.4.3 Effects on the quality of plants or plant products (KCP 6.4.3)

No studies of quality of the crops had been recorded.

Comments of zRMS:	<p>No assessments of yield quality data are available. The control of insects feeding from leaves, seeds and other plant parts is expected to positively impact the quality of plants and plant products. The zRMS considers that the adverse effects on the quality of plants or plant products are low when Ruler 10 EC is applied at the proposed label rate and used according to the label recommendations.</p>
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3.4.4 Effects on transformation processes (KCP 6.4.4)

There are no indications that the use of fenazaquin will have influence on possible transformation processes. It is therefore expected that Fenazaquin 10% EC, when applied in accordance with good agricultural practices will not cause any unacceptable adverse effects on transformation processes.

Furthermore, the residue data (see Part B Section 4 Annex Point CP 8.3) clearly demonstrate that, at the proposed application rates, no fenazaquin nor its metabolites above the LOQ (= limit of quantification) are found in any of the tested crops. In case of undetectable residues, no special studies are required according to the EPPO guideline PP 1/243(1).

Finally, it should be noted that fenazaquin has been used for a long time as an insecticide in the GAP claimed crops. Since the market introduction no effects on transformation processes have been recorded for any of these products, nor do fenazaquin containing products have any label restrictions concerning their use on crops destined for processing.

Comments of zRMS:	The applicant demonstrated that residues are undetectable (Part B Section 7). It is not expected that Ruler 10 EC at the proposed label rate 2,0 l/ha will have adverse effects on transformation processes.
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3.4.5 Impact on treated plants or plant products to be used for propagation (KCP 6.4.5)

Special tests to investigate this purpose are not required.

The product complies with the Uniform Principles.

Comments of zRMS:	Applicant's statement can be agreed. A detailed evaluation of the adverse effect on parts of plants used for propagating purposes can be waived.
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3.5 Observations on other undesirable or unintended side-effects (KCP 6.5)

3.5.1 Impact on succeeding crops (KCP 6.5.1)

Effects on succeeding crops are not to be expected, since the active fenazaquin is degraded within the timeframe of a normal cropping season. Furthermore, fenazaquin lothrin is not phytotoxic.

No label restrictions on succeeding crops following application of Fenazaquin 10% EC are proposed, in accordance with current labelling of existing fenazaquin containing products.

Comments of zRMS:	No assessment following the EPPO Standard PP 1/207 'Effects on succeeding crops' was carried out. This assessment can be waived, since fenazaquin has no herbicidal activity. Applicant's statement can be agreed. Ruler 10 EC did not cause any symptoms of phytotoxicity. It is not probable that this product would cause damage to succeeding crops at the recommended rate.
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3.5.2 Impact on other plants including adjacent crops (KCP 6.5.2)

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 10% EC.

Comments of zRMS:	No assessment following the EPPO Standard PP 1/256 'Effects on adjacent crops' was carried out. This assessment can be waived, since fenazaquin has no herbicidal activity. Applicant's statement can be agreed. There should not be any negative effect on adjacent crops when Ruler 10 EC is used as recommended.
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3.5.3 Effects on beneficial and other non-target organisms (KCP 6.5.3)

Specific assessments of beneficial and non-crop organisms were taken in the efficacy trials and in these, no adverse effects were noted when visual observations were made within these field trial sites.

The impact of Fenazaquin against non-target organisms is summarized in the document Part B, Section 6 (Ecotoxicological studies). Detailed studies on the potential adverse effects to beneficial organisms are submitted in Part B Section 6 Annex Point CP 10.5 and CP 10.6.

Compatibility with current management practices including IPM

This is not an EC data requirement/ not required by Directive 91/414/EEC.

Comments of zRMS:	In efficacy trials no adverse effect on beneficial and other non-target organisms were seen. Reference should be made to Section 9 (Ecotoxicology). Applicant's statement can be agreed. Moreover, for details concerning adverse effects on beneficial and other non-target organisms see Part B9 of the dossier (eco-toxicological data).
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3.6 Other/special studies

No other studies were conducted

3.7 List of test facilities including the corresponding certificates

The following table gives information about the testing facilities where trials mentioned in this document were conducted. All facilities are certified, and the trials were conducted according to GEP guidelines.

Table 3.7-1: List of test facilities

			Trial type	
			Efficacy trials	Selectivity trials
Testing facility	Zone	Country		
Melon				
Agriscience	MED	GR	4	0
DAYE	MED	ES	4	0
Total, Melon			8	0
Strawberry				
Eurofins	MED	FR	1	0

DAYE	MED	ES	3	0
Field Research Support	MAR	DE	1	0
SICOP	MED	ES	3	0
Total, Strawberry			8	0
Ornamentals				
DAYE	MED	ES	3	0
Field Research Suport	MAR	DE	1	0
SGS	NE	PL	5	0
SICOP	MED	ES	3	0
Total, Ornamentals			12	0
Tomato				
DAYE	MED	ES	2	0
Field Research Suport	MAR	DE	3	0
Agriscience	MED	GR	1	0
SICOP	MED	ES	2	0
Total, Tomato			8	0

Appendix 1 Lists of data considered in support of the evaluation

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	Owner
KCP 6.0-001	Anonymous	2019	Biological Assessment Dossier: Fenazaquin 10% EC – EU Interzonal Sharda Cropchem España -, - Unpublished	N	Sharda