

FINAL REGISTRATION REPORT

Part B

Section 9

Ecotoxicology

Detailed summary of the risk assessment

Product code: SHA 9700 B

Product name: RULER 10 EC

Chemical active substance:

Fenazaquin, 100 g/L

Interzonal

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: July 2019

MS Finalisation date: July 2020; March 2023

Version history

When	What
July 2020	Finalisation of the evaluation of the product by ZRMS-PL.
March 2023	Final Registration Report

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9 Ecotoxicology (KCP 10)

9.1 Critical GAP and overall conclusions

Table 9.1-1: Table of critical GAPs

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Use -No. *	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 saf- ener/ synergist per ha	Conclusion						
					Method / Kind	Timing / Growth stage of crop & season	Max. num- ber a) per use b) per crop/ season	Min. inter- val 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			Birds	Mammals	Aquatic organisms	Bees	Non-target arthro-	Soil organisms	Non-target plants
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 pres- ence BBCH 70- 79	a) 1 b) 1	NA	a) 2 b) 2	a) 0.2 b) 0.2	1000	7	-				R	R		
2	CEU/SEU/NEU	Ornamentals	G*	Spider mites	Foliar spray	Pes presence BBCH 35- 64	a) 2 b) 2	7-10	a) 2 b) 4	a) 0.2 b) 0.4	1000	-	-							
3	CEU/SEU/NEU	Tomato	G*	Spider mites	Foliar spray	Pest pres- ence BBCH 5189	a) 2 b) 2	7-10	a) 2 b) 4	a) 0.2 b) 0.4	1000	3	-							
4	CEU/SEU/NEU	Strawberry	G*	Spider mites	Foliar spray	Pest pres- ence BBCH 15- 91	a) 2 b) 2	7-10	a) 2 b) 4	a) 0.2 b) 0.4	1000	3	-							

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

** 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

*Only permanent covered crops was considered in the Ecotoxicology risk assessment

For the use in greenhouses and other indoor applications, it should be specified in which type of protected structure the representative use will be made (and whether the crop will remain within a permanent greenhouse throughout its entire life cycle). Since the intended application of the product in indoor applications is restricted to permanent greenhouses, these parts of dRR have been evaluated considering the permanent greenhouse scenario.

R the product Ruler cannot be used in IPM program in glasshouse., R For aquatic organisms risk mitigations measures for greenhouse uses should be considered at national level.

Explanation for column 15 – 21 “Conclusions”

A	Acceptable, Safe use
R	Further refinement and/or risk mitigation measures required
C	To be confirmed by cMS
N	No safe use

Remarks table:

- (1) Numeration necessary to allow references
- (2) Use official codes/nomenclatures of EU
- (3) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
- (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
- (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
- (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
- (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
- (8) The maximum number of application possible under practical conditions of use must be provided
- (9) Minimum interval (in days) between applications of the same product.
- (10) For specific uses other specifications might be possible, *e.g.*: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products
- (11) The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
- (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

9.1.1 Overall conclusions

zRMS comment:

The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. The changes are introduced directly as text in blue. Not agreed or not relevant information is struck through and shaded for transparency.

9.1.1.1 Effects on birds (KCP 10.1.1), Effects on terrestrial vertebrates other than birds (KCP 10.1.2), According to the GAP, the intended uses are control of spider mites in permanent greenhouses, therefore negligible exposure of birds is considered. Fenazaquin 10% EC presents no unacceptable acute and long-term risk to mammals according to the intended uses.

ZRMS comments:

No risk assessment for mammals for Ruler 10EC was conducted for the use on melon, ornamentals, tomato and strawberry in protected conditions. It can be assumed that no mammals would be exposed in these conditions.

9.1.1.2 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

- 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 10% EC 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 10% EC presents no unacceptable acute and long-term risk to mammals according to the intended uses.

9.1.1.3 Effects on aquatic organisms (KCP 10.2)

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 for permanent greenhouse only based on calculations of PEC_{sw} (acceptable for Poland) and toxicity endpoints -HC₅ of 0.96 µg a.s./Lvalue.

For the authorization of the plant protection product RULER the risk assessment for aquatic organism should be considered and completed, if relevant –the other PEC_{sw} calculations) at national level depend on their own requirements.

~~(risk for invertebrate as characterised by NOEC for *Daphnia magna* of 0.3 µg/L in connection with an assessment factor of 2).~~

~~For the intended uses on melon, no specific risk mitigation measures are required.~~

~~For the intended uses on tomato, the release to environment shall be reduced by 60%, for uses on strawberries reduction shall reach 90%, and for uses in ornamentals reduction shall be 95%.~~

~~The risk mitigation measures are not clearly listed in both EFSA GD, 2014 (EFSA Journal 2014;12(3):3615) and GEM 3.3.2 documentation. These may be, however:~~

- ~~— safe discharge of recirculation/ spent water and cultivation media, safe disposal of water used for filter cleaning~~
- ~~— closing the doors and windows and switching off the ventilation during the application~~
- ~~— use of activated carbon filters~~

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.

9.1.1.4 Effects on bees (KCP 10.3.1)

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.

SPe8 However, in case of bumble bees are pollinators the following phrase should be applied

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

9.1.1.5 Effects on arthropods other than bees (KCP 10.3.2)

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 nonrelevant when crossreading with the OECD Guidance to the environmental safety evaluation of microbial bio-control 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 10% EC 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.

9.1.1.6 Effects on non-target soil meso- and macrofauna (KCP 10.4), Effects on soil microbial activity (KCP 10.5)

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.

9.1.1.7 Effects on non-target terrestrial plants (KCP 10.6)

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 glasshouses where exposure is precluded*”.

9.1.1.8 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 rate.

9.1.1.9 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)

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.

9.1.2 Grouping of intended uses for risk assessment

The following table documents the grouping of the intended uses to support application of the risk envelope approach (according to SANCO/11244/2011).

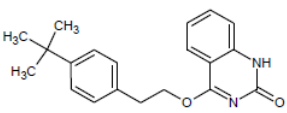
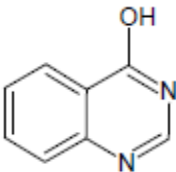
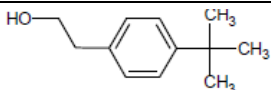
Table 9.1-2: Critical use pattern of Fenazaquin 10% EC grouped according to criterion

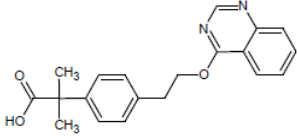
Grouping according to criterion			
Group	Intended uses	relevant use parameters for grouping	relevant parameter or value for sorting
All crops	Melon, ornamentals, tomato and strawberry	Application rate and application period	Worst-case application rate: 2 x 200 g a.s./ha
Fruiting vegetables	Melon and tomato	Application rate and application period	Same application rates: 2 x 200 g a.s./ha

9.1.3 Consideration of metabolites

A list of metabolites found in environmental compartments is provided below. The need for conducting a metabolite-specific risk assessment in the context of the evaluation of Fenazaquin 10% EC is indicated in the table.

Table 9.1-3 Metabolites of Fenazaquin

Metabolite	Chemical structure	Molar mass	Maximum occurrence in compartments	Risk assessment required?
2-oxy-fenazaquin 4-[2-(4-tertbutylphenyl)ethoxy]quinazolin-2(1H)-one		322.41 g/mol	Soil: 9.1% Sediment: 19.8% Water/sediment: 21.2%	Yes, aquatic organisms, earthworms and other non-target soil organisms and microbial activity
4-OHQ quinazolin-4-ol		146.15 g/mol	Soil: 36.6% Water/sediment: 79.3%	Yes, aquatic organisms, earthworms and other non-target soil organisms and microbial activity
TBPE 2-(4-tert-butylphenyl)ethanol		178.28 g/mol	Soil: 17.9% Water/sediment: 82.2%	Yes, aquatic organisms, earthworms and other non-target soil organisms and

Metabolite	Chemical structure	Molar mass	Maximum occurrence in compartments	Risk assessment required?
				microbial activity
4-(2-(4-(1,1-dimethylethanoic acid)phenyl)ethoxy)quinazoline 2-methyl-2-{4-[2-(quinazolin-4-yloxy)ethyl]phenyl}propanoic acid		336.39 g/mol	Soil: 2.1% Sediment: 10.3% Water/sediment: 11.5%	Yes, aquatic organisms

9.2 Effects on birds (KCP 10.1.1)

9.2.1 Toxicity data

Avian toxicity studies have been carried out with Fenazaquin. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on birds of Fenazaquin 10% EC were not evaluated as part of the EU assessment of Fenazaquin.

However, the provision of further data on the Fenazaquin 10% EC is not considered essential, because toxicity data to birds on active substance can be used.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process. Justifications are provided below.

Table 9.2-1: Endpoints and effect values relevant for the risk assessment for birds

Species	Substance	Exposure System	Results	Reference
Bobwhite quail	Fenazaquin	Oral 1 d Acute	LD ₅₀ = 1747 mg/kg bw	EFSA Journal 2013;11(4):3466
Mallard duck	Fenazaquin	Oral 1 d Acute	LD ₅₀ > 2000 mg/kg bw	EFSA Journal 2013;11(4):3466
Bobwhite quail	Fenazaquin	Dietary 8 d Short-term	LC ₅₀ > 1169 mg a.s./kg bw/d (5204 mg a.s./kg food)	EFSA Journal 2013;11(4):3466
Bobwhite quail	Fenazaquin	Dietary Reproductive toxicity	NOEL = 80.3 mg/kg bw/d	EFSA Journal 2013;11(4):3466

9.2.1.1 Justification for new endpoints

Not relevant as there is no deviation to the EU agreed endpoints.

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 sub-

*stance, 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.”*

9.2.2 Risk assessment for spray applications

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.

9.2.2.1 First-tier assessment (screening/generic focal species)

Not relevant due to the negligible exposure.

ZRMS comments:

No risk assessment for birds was conducted for the use on melon, ornamentals, tomato and strawberry in protected conditions. It can be assumed that no birds would be exposed in these conditions.

Studies on the acute toxicity of Fenazaquin metabolites TBPE and 4-OHQ to mammals indicate that the metabolites were less toxic than the parent compound (please refer to Volume 3, B.6.8.1 of the DAR (May 2006) for TBPE and to Volume 3, B.6.8.1 of the Post Annex 1 Addendum to DAR (January 2012)). All metabolites of Fenazaquin which occurred in the environment also occurred in mammalian metabolism studies. Therefore, the mammalian toxicity studies with the parent also cover the toxicity of the metabolites (please refer to Volume 6, B.6.2 of the DAR (May 2006)). As no metabolites of toxicological concern were identified for mammals, it is unlikely that these metabolites could pose a risk for birds.

9.2.2.2 Higher-tier risk assessment

Not relevant due to the negligible exposure.

9.2.2.3 Drinking water exposure

When necessary, the assessment of the risk for birds due to uptake of contaminated drinking water is conducted for a small granivorous bird with a body weight of 15.3 g (*Carduelis cannabina*) and a drinking water uptake rate of 0.46 L/kg bw/d (*cf.* Appendix K of EFSA/2009/1438).

Leaf scenario

Not relevant due to the negligible exposure.

Puddle scenario

Not relevant due to the negligible exposure.

ZRMS comments:

No risk assessment for mammals from drinking water exposure was conducted for Ruler (Fenazaquin 10% SC) the use on melon, ornamentals, tomato and strawberry in protected conditions. It can be assumed that puddle scenario is not relevant due to the negligible exposure.

9.2.2.4 Effects of secondary poisoning

~~Not relevant due to the negligible exposure.~~

zRMS comment:

According to EFSA/2009/1438, the risk for vermivorous birds is assessed for a bird of 100 g body weight with a daily food consumption of 104.6 g. Bioaccumulation in earthworms is estimated based on measured/predicted concentrations in soil/porewater / is based on experimental data.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group strawberry also covers the risk for birds from all other intended uses in other groups (see 9.1.1).

Assessment of the risk for earthworm-eating birds due to exposure to fenazaquin via bioaccumulation in earthworms (secondary poisoning) for the intended use in protected crops/ strawberry

Parameter	Fenazaquin	comments
PEC _{soil} (twa = 21 d) (mg/kg soil)	0.42	The model conservative value representing PEC _{accu} following multiple application, 2 x 200 g as/ha to strawberries, BBCH 15-91, 7-10 days interval, 30% interception, under field conditions
log P _{ow} / P _{ow}	5.51/ 323593.66	
K _{oc}	26499	Mean
f _{oc}	0.02	Default
BCF _{worm}	7.33	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw}) = (0.84 + 0.12 \times P_{ow}) / f_{oc} \times K_{oc}$
PEC _{worm}	3.08	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	3.23	$DDD = PEC_{worm} \times 1.05$
NOEL (mg/kg bw/d)	80.3	
TER _{It}	24.85	

TER values shown in bold fall below the relevant trigger.

Risk assessment for fish-eating birds via secondary poisoning

According to EFSA/2009/1438, the risk for piscivorous birds is assessed for a bird of 1000 g body weight with a daily food consumption of 159 g. Bioaccumulation in fish is estimated based on predicted concentrations in surface water.

Assessment of the risk for fish-eating birds due to exposure to fenazaquin via bioaccumulation in fish (secondary poisoning) for the intended use in ornamental

Parameter	Fenazaquin	comments
PEC _{sw} max (mg/L)	0.000066	Max PEC _{sw} (1 application)
BCF _{fish}	699	From 28 d study with rainbow trout, value relevant for low concentration of fenazaquin
BMF	-	biomagnification factor (relevant for BCF ≥ 2000)
PEC _{fish}	0.046	PEC _{fish} = PEC _{water} × BCF _{fish}
Daily dietary dose (mg/kg bw/d)	0.007	DDD = PEC _{fish} × 0.159
NOEL (mg/kg bw/d)	80.3	
TER _{lt}	11471.4	

TER values shown in bold fall below the relevant trigger.

Moreover, due to the fact that the BCF is below 1000 (699 and 878) and the elimination of radioactivity during the 14 day depuration phase in the bioconcentration study is above 95 % (> 98 %), it can be concluded, that the potential of the active ingredient to bio concentrate is negligible and no food chain modelling is necessary” (Fenazaquin- Additional Report to Volume 3 Annex B.9- Ecotoxicology; January 2010).

9.2.2.5 Biomagnification in terrestrial food chains

Not relevant.

9.2.3 Risk assessment for baits, pellets, granules, pills or treated seed

Not relevant.

9.2.4 Overall conclusions

According to the GAP, the intended uses are control of spider mites in permanent greenhouses, therefore negligible exposure of birds is considered. Fenazaquin 10% EC presents no unacceptable acute and long-term risk to birds according to the intended uses.

ZRMS comments:

No risk assessment for birds was conducted for the use on melon, ornamentals, tomato and strawberry in protected conditions. It can be assumed that no birds would be exposed in these conditions.

According to the GAP, the intended uses are control of spider mites in permanent greenhouses, therefore negligible exposure of birds is considered. Fenazaquin 10% EC presents no unacceptable acute and long-term risk to birds according to the intended uses.

9.3 Effects on terrestrial vertebrates other than birds (KCP 10.1.2)

9.3.1 Toxicity data

Mammalian toxicity studies have been carried out with Fenazaquin. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on mammals of Fenazaquin 10% EC were not evaluated as part of the EU assessment of Fenazaquin.

However, the provision of further data on the formulation Fenazaquin 10% EC is not considered essential, because active substance data on toxicity to mammals can be used.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.3-1: Endpoints and effect values relevant for the risk assessment for mammals

Species	Substance	Exposure System	Results	Reference
Rat, male	Fenazaquin	Oral 1 d Acute	LD ₅₀ = 134 mg/kg bw	EFSA Journal 2013;11(4):3166
Rat	Fenazaquin	Dietary Reproductive toxicity Two-generation study	NOAEL = 25 mg/kg bw/d	EFSA Journal 2013;11(4):3166

9.3.1.1 Justification for new endpoints

Not relevant as there is no deviation to the EU agreed endpoints.

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***”.

9.3.2 Risk assessment for spray applications

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.

9.3.2.1 First-tier assessment (screening/generic focal species)

Not relevant due to the negligible exposure.

ZRMS comments:

No risk assessment for mammals was conducted for the use on melon, ornamentals, tomato and strawberry in protected conditions. It can be assumed that no mammals would be exposed in these conditions.

According to the GAP, the intended uses are control of spider mites in permanent greenhouses, therefore negligible exposure of mammals is considered. Fenazaquin 10% EC presents no unacceptable acute and long-term risk to mammals according to the intended uses.

9.3.2.2 Higher-tier risk assessment

Not relevant due to the negligible exposure.

9.3.2.3 Drinking water exposure

When necessary, the assessment of the risk for mammals due to uptake of contaminated drinking water is conducted for a small omnivorous mammal with a body weight of 21.7 g (*Apodemus sylvaticus*) and a drinking water uptake rate of 0.24 L/kg bw/d (cf. Appendix K of EFSA/2009/1438).

Puddle scenario

Not relevant due to the negligible exposure.

ZRMS comments:

No risk assessment for mammals from drinking water exposure was conducted for the use on melon, ornamentals, tomato and strawberry in protected conditions. It can be assumed that puddle scenario is not relevant due to the negligible exposure.

9.3.2.4 Effects of secondary poisoning

The log P_{ow} of Fenazaquin amounts to 5.51 and thus exceeds the trigger value of 3. A risk assessment for effects due to secondary poisoning is required.

Risk assessment for earthworm-eating mammals via secondary poisoning

~~Not relevant due to the negligible exposure.~~

Risk assessment for fish-eating mammals via secondary poisoning

~~Not relevant due to the negligible exposure.~~

zRMS comment:

According to EFSA/2009/1438, the risk for vermivorous mammals is assessed for a small mammal of 10 g body weight with a daily food consumption of 12.8 g. Bioaccumulation in earthworms is estimated based on measured/predicted concentrations in soil is based on experimental data.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group strawberry also covers the risk for mammals from all other intended uses in other groups (see 9.1.1).

Assessment of the risk for earthworm-eating mammals due to exposure to fenazaquin via bioaccumulation in earthworms (secondary poisoning) for the intended use in strawberry.

Parameter	fenazaquin	comments
PEC _{soil} (twa = 21 d) (mg/kg soil)	0.42	The model conservative value representing PEC _{accu} following multiple application, 2 x 200 g as/ha to strawberries, BBCH 15-91, 7-10 days interval, 30% interception, under field conditions
log P _{ow} / P _{ow}	5.51/ 323593.66	
K _{oc}	26499	Mean
f _{oc}	0.02	Default
BCF _{worm}	7.33	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw}) = (0.84 + 0.12 \times P_{ow}) / f_{oc} \times K_{oc}$
PEC _{worm}	3.07	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	3.92	$DDD = PEC_{worm} \times 1.28$
NOEL (mg/kg bw/d)	25.0	
TER _{It}	6.37	

TER values shown in bold fall below the relevant trigger.

Risk assessment for fish-eating mammals via secondary poisoning

According to EFSA/2009/1438, the risk for piscivorous mammals is assessed for a mammal of 3000 g body weight with a daily food consumption of 425 g. Bioaccumulation in fish is estimated based on predicted concentrations in surface water

Assessment of the risk for fish-eating mammals due to exposure to fenazaquin via bioaccumulation in fish (secondary poisoning) for the intended use in ornamentals

Parameter	Fenazaquin	comments
PEC _{sw} (twa = 21 d) (mg/L)	0.000066	PEC _{sw} max- 1 application
BCF _{fish}	699	From 28 d study with rainbow trout, value relevant for low concentration of fenazaquin
BMF	-	biomagnification factor (relevant for BCF ≥ 2000)
PEC _{fish}	0.046	$PEC_{fish} = PEC_{water} \times BCF_{fish}$
Daily dietary dose (mg/kg bw/d)	0.0065	$DDD = PEC_{fish} \times 0.142$
NOEL (mg/kg bw/d)	25.0	
TER _{It}	3846.1	

TER values shown in bold fall below the relevant trigger.

Moreover, due to the fact that the BCF is below 1000 (699 and 878) and the elimination of radioactivity during the 14 day depuration phase in the bioconcentration study is above 95 % (> 98 %), it can be concluded, that the potential of the active ingredient to bioconcentrate is negligible and no food chain modelling is necessary” (Fenazaquin - Additional Report to Volume 3 Annex B.9- Ecotoxicology; January 2010).

9.3.2.5 Biomagnification in terrestrial food chains

Not relevant.

9.3.3 Risk assessment for baits, pellets, granules, pills or treated seed

Not relevant.

9.3.4 Overall conclusions

According to the GAP, the intended uses are control of spider mites in permanent greenhouses, therefore negligible exposure of birds is considered. Fenazaquin 10% EC presents no unacceptable acute and long-term risk to mammals according to the intended uses.

ZRMS comments:

No risk assessment for mammals for Ruler 10EC was conducted for the use on melon, ornamentals, tomato and strawberry in protected conditions. It can be assumed that no mammals would be exposed in these conditions.

9.4 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

No data available. Not required.

9.5 Effects on aquatic organisms (KCP 10.2)

9.5.1 Toxicity data

Studies on the toxicity to aquatic organisms have been carried out with Fenazaquin and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents, as well as in Appendix 2 of this document (new studies).

Effects on aquatic organisms of Fenazaquin 10% EC were not evaluated as part of the EU assessment of Fenazaquin.

However, the provision of further data on the Fenazaquin 10% EC is not considered essential, because active substance data on toxicity to aquatic organisms can be used.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.5-1: Endpoints and effect values relevant for the risk assessment for aquatic organisms – Fenazaquin and relevant metabolites

Species	Substance	Exposure System	Results	Reference
Fish				
<i>Oncorhynchus mykiss</i>	Fenazaquin	96 h, f	LC ₅₀ = 0.0038 mg a.s./L	EFSA Journal 2013;11(4):3166
<i>Oncorhynchus mykiss</i>	Fenazaquin	96 h, s	Without sediment: LC ₅₀ = 0.0066 mg a.s./L With sediment: LC ₅₀ = 0.0119 mg a.s./L	
<i>Lepomis macrochirus</i>	Fenazaquin	96 h, f	LC ₅₀ = 0.0341 mg a.s./L	
<i>Rhodeus amarus</i>	Fenazaquin	96 h, ss	LC ₅₀ = 0.0363 mg a.s./L	
<i>Pimephales promelas</i>	Fenazaquin	96 h, ss	LC ₅₀ = 0.0042 mg a.s./L	
<i>Oryzias latiped</i>	Fenazaquin	96 h, ss	LC ₅₀ = 0.0136 mg a.s./L	
<i>Gasterosteus aculeatus</i>	Fenazaquin	96 h, ss	LC ₅₀ = 0.0082 mg a.s./L	
<i>Danio rerio</i>	Fenazaquin	96 h, ss	LC ₅₀ = 0.0080 mg a.s./L	
<i>Perca fluviatilis</i>	Fenazaquin	96 h, ss	LC₅₀ = 0.0032 mg a.s./L	
<i>Leucaspilus delineatus</i>	Fenazaquin	96 h, ss	LC ₅₀ = 0.0047 mg a.s./L	
<i>Poecilia reticulata</i>	Fenazaquin	96 h, ss	LC ₅₀ = 0.0590 mg a.s./L	
<i>Oncorhynchus mykiss</i>	4-(2-(4-(1,1-dimethyl ethanoic acid) phenyl) ethoxy) quinazoline	96 h, ss	LC₅₀ = 0.77 mg/L	
<i>Oncorhynchus mykiss</i>	TBPE	96 h, ss	LC₅₀ = 13.3 mg/L	
<i>Oncorhynchus mykiss</i>	4-OHQ	96 h, s	LC₅₀ = 91 mg/L	
<i>Oncorhynchus mykiss</i>	Fenazaquin	21 d, f	NOEC = 0.00096 mg a.s./L	
Invertebrates acute				
<i>Daphnia magna</i>	Fenazaquin	48 h, s	EC₅₀ = 0.0041 mg a.s./L	EFSA Journal 2013;11(4):3166
<i>Daphnia magna</i>	Fenazaquin	48 h, s	Withou sediment: EC ₅₀ = 0.0057 mg a.s./L With sediment: EC ₅₀ = 0.0127 mg a.s./L	
<i>Crassostrea virginica</i>	Fenazaquin	96 h, f	EC ₅₀ = 0.0054 mg a.s./L	
<i>Crangon crangon</i>	Fenazaquin	96 h, ss	EC ₅₀ = 0.015 mg a.s./L	
<i>Daphnia magna</i>	4-(2-(4-(1,1-dimethyl ethanoic acid) phenyl) ethoxy) quinazoline	48 h, s	EC₅₀ = 2.34 mg/L	
<i>Daphnia magna</i>	TBPE	48 h, ss	EC₅₀ = 3.86 mg/L	
<i>Daphnia magna</i>	4-OHQ	48 h, s	EC₅₀ > 100 mg/L	
<i>Daphnia magna</i>	Fenazaquin	21 d, ss	EC₅₀ = 0.0014 mg a.s./L	
<i>Chironomus riparius</i>	Fenazaquin	28 d, s	EC ₅₀ = 0.0025 mg a.s./L (equal to 18.8 µg a.s./kg sediment)	
<i>Chironomus riparius</i>	2-oxy-fenazaquin	96 h, ss	EC₅₀ > 3 mg/L	

Higher-tier studies (micro- or mesocosm studies)

A microcosm study has been submitted in the EFSA Journal 2013;11(4):3166 on invertebrate community during 8 weeks with a SC formulation containing 200 g/L of Fenazaquin. The NOEC of 0.3 µg/L has been derived from this study. The PRAPeR Expert Meeting 80, raised concerns regarding the recovery ability of slower than daphnia recovery macro-invertebrate species, therefore it was decided to use the NOEC value (0.3 µg/L with an assessment factor of 2 to remove uncertainties regarding recovery of macro(invertebrates and the use of indoor microcosm.

s: static; ss: semi-static; f: flow-through; nom: based on nominal concentrations; mm: based on mean measured concentrations; im: based on initial measured concentrations

Not relevant as there is no deviation to the EU agreed endpoints.

According to the Commission Regulation (EU) No 284/2013 of 1 March 2013, “possible effects on aquatic species (fish, aquatic invertebrates, algae and in the case of herbicides and plant growth regulators, aquatic macrophytes) **shall be investigated except where the possibility that aquatic species will be exposed can be ruled out**”.

9.5.2 Risk assessment

The evaluation of the risk for aquatic and sediment-dwelling organisms was performed in accordance with the recommendations of the “Guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters in the context of Regulation (EC) No 1107/2009”, as provided by the Commission Services (SANTE-2015-00080, 15 January 2015) with consideration of the provisions of the EFSA Guidance Document on clustering and ranking of emissions of active substances of plant protection products and transformation products of these active substances from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments. EFSA Journal 2014;12(3):3615.

According to the EFSA GD, 2014 (EFSA Journal 2014;12(3):3615), “for greenhouses, the relevant emission routes to surface water are drainage, condensation (and the following deposition onto surface water) and discharge of (recirculation) water. Emissions to air from greenhouses shortly after application can be reduced if doors and windows are closed and ventilation is limited for some time. For volatile substances, deposition on surface water via air can be assessed as soon as appropriate guidance is available. **Drift emission from greenhouses is negligible when openings are closed during application or when the application method is drip irrigation. In soil-less cultivation, the main driving factor with regard to emissions to surface water are filter cleaning and the necessity to discharge deteriorated nutrient solution; for soil-bound crops it is the amount of supplied water.**”

The relevant global maximum GEM (Greenhouse Emission Model) PEC_{sw} for risk assessments covering the proposed use pattern and the resulting PEC/RAC ratios are presented in the table below.

In the following table, the ratios between predicted environmental concentrations in surface water bodies (PEC_{sw}) and regulatory acceptable concentrations (RAC) for aquatic organisms are given per intended use for each GEM scenario and each organism group.

Table 9.5-3: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Fenazaquin for each organism group based on GEM calculations for the use of Fenazaquin 10% EC in melon

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Aquatic insect	Algae	Microcosm
Test species		<i>Perca fluviatilis</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Chironomus riparius</i>	<i>S. capricornutum</i>	<i>Daphnia magna</i>
Endpoint (µg/L)		LC ₅₀ 3.2	NOEC 0.96	EC ₅₀ 4.1	NOEC 1.4	NOEC 2.5	E _r C ₅₀ /E _y C ₅₀ 208	NOEC 0.3
AF		100	10	100	10	10	10	2
RAC (µg/L)		0.032	0.096	0.041	0.14	0.25	20.8	0.15
GEM - Soilless	PEC _{gl-max} (µg/L)							
90 percentile peak concentration (µg/L)								
	0.022	0.69	0.23	0.54	0.16	0.09	0.00	0.15

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-4: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Fenazaquin for each organism group based on GEM calculations for the single/multiple use of Fenazaquin 10% EC in tomato

Group	Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Aquatic insect	Algae	Microcosm
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Test species		<i>Perca fluviatilis</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Chironomus riparus</i>	<i>S. capricornutum</i>	<i>Daphnia magna</i>
Endpoint (µg/L)		LC ₅₀ 3.2	NOEC 0.96	EC ₅₀ 4.1	NOEC 1.4	NOEC 2.5	E _r C ₅₀ /E _y C ₅₀ 208	NOEC 0.3
AF		100	10	100	10	10	10	2
RAC (µg/L)		0.032	0.096	0.041	0.14	0.25	20.8	0.15
GEM - Soiless	PEC _{gl-max} (µg/L)							
90 percentile peak concentration (µg/L)								
	0.075/ 0.081	2.34/ 2.53	0.78/ 0.84	1.83/ 1.98	0.54/ 0.58	0.3/ 0.324	<0.01/ <0.01	0.50/ 0.54
60% mitigation measures								
	0.03/ 0.032	0.94/ 1.00	-/-	0.73/ 0.78	-/-	-/-	-/-	-/-

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-5: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Fenazaquin for each organism group based on GEM calculations for the single/multiple use of Fenazaquin 10% EC in strawberry

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Aquatic insect	Algae	Microcosm
Test species		<i>Perca fluviatilis</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Chironomus riparus</i>	<i>S. capricornutum</i>	<i>Daphnia magna</i>
Endpoint (µg/L)		LC ₅₀ 3.2	NOEC 0.96	EC ₅₀ 4.1	NOEC 1.4	NOEC 2.5	E _r C ₅₀ /E _y C ₅₀ 208	NOEC 0.3
AF		100	10	100	10	10	10	2
RAC (µg/L)		0.032	0.096	0.041	0.14	0.25	20.8	0.15
GEM - Soiless	PEC _{gl-max} (µg/L)							
90 percentile peak concentration (µg/L)								
	0.157/ 0.263	4.91/ 8.22	1.64/ 2.74	3.83/ 6.41	1.12/ 1.88	0.63/ 1.05	0.01/ 0.01	1.05/ 1.75
90% mitigation measures								
	0.016/ 0.026	0.50/ 0.81	0.17/ 0.27	0.39/ 0.63	0.11/ 0.19	-/ 0.1	-/-	0.11/ 0.17

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-6: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Fenazaquin for each organism group based on GEM calculations for the single/multiple use of Fenazaquin 10% EC in ornamentals

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Aquatic insect	Algae	Microcosm
Test species		<i>Perca fluviatilis</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Chironomus riparus</i>	<i>S. capricornutum</i>	<i>Daphnia magna</i>
Endpoint (µg/L)		LC ₅₀ 3.2	NOEC 0.96	EC ₅₀ 4.1	NOEC 1.4	NOEC 2.5	E _r C ₅₀ /E _y C ₅₀ 208	NOEC 0.3
AF		100	10	100	10	10	10	2

RAC (µg/L)		0.032	0.096	0.041	0.14	0.25	20.8	0.15
GEM - Soiless	PEC gl-max (µg/L)							
90 percentile peak concentration (µg/L)								
	0.266/ 0.421	8.31/ 13.16	2.77/ 4.39	6.49/ 10.27	1.90/ 3.01	1.06/ 1.68	0.01/ 0.02	1.77/ 2.81
90% mitigation measures								
	0.026/ 0.042	0.81/ 1.31	0.27/ 0.44	0.63/ 1.02	0.19/ 0.30	0.1/ 0.17	-/ -	0.17/ 0.28
95% mitigation measures								
	-/ 0.021	-/ 0.66	-/ -	-/ 0.51	-/ -	-/ -	-/ -	-/ -

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Metabolites of Fenazaquin

Table 9.5-7: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for 2-oxy-fenazaquin for each organism group for the use of Fenazaquin 10% EC in melon, tomato, strawberry and ornamentals

Group		Inverteb. acute
Test species		<i>Chironomus riparius</i>
Endpoint (µg/L)		LC ₅₀
AF		3000
RAC (µg/L)		100
GEM - Soiless	PEC gl-max (µg/L)	30
<p>The PEC_{sw} for metabolite 2-oxy-fenazaquin has not been calculated since it is only produced in sediment. The GEM 3.3.2 allows the calculations of PEC_{sw}, but not PEC_{sed}. Nevertheless, the parent is more than three orders of magnitude more toxic than 2-oxy-fenazaquin, therefore it is justified to conclude that the risk assessment performed for parent molecule fenazaquin covers also the risk resulting from exposure of sediment dwellers to metabolite 2-oxy-fenazaquin.</p>		

Table 9.5-8: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for 4-OHQ for each organism group based on on GEM calculations for for the use of Fenazaquin 10% EC in melon

Group		Fish acute	Inverteb. acute
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>
Endpoint (µg/L)		LC ₅₀	EC ₅₀
AF		91000	> 100000
RAC (µg/L)		100	100
GEM - Soiless	PEC gl-max (µg/L)	910	>1000
90 percentile peak concentration (µg/L)			
	0,001	<0,001	<0,001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-9: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for 4-OHQ for each organism group based on GEM calculations for the single/multiple use of Fenazaquin 10% EC in tomato

Group		Fish acute	Inverteb. acute
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>
Endpoint (µg/L)		LC ₅₀ 91000	LC ₅₀ > 100000
AF		100	100
RAC (µg/L)		910	1000
GEM - Soiless	PEC _{gl-max} (µg/L)		
90 percentile peak concentration (µg/L)			
	<0.001/ 0.001	<0.001/ <0.001	<0.001/ <0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-10: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for 4-OHQ for each organism group based on GEM calculations for the single/multiple use of Fenazaquin 10% EC in strawberry

Group		Fish acute	Inverteb. acute
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>
Endpoint (µg/L)		LC ₅₀ 91000	LC ₅₀ > 100000
AF		100	100
RAC (µg/L)		910	1000
GEM - Soiless	PEC _{gl-max} (µg/L)		
90 percentile peak concentration (µg/L)			
	0.003/ 0.004	<0.001/ <0.001	<0.001/ <0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-11: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for 4-OHQ for each organism group based on GEM calculations for the single/multiple use of Fenazaquin 10% EC in ornamentals

Group		Fish acute	Inverteb. acute
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>
Endpoint (µg/L)		LC ₅₀ 91000	LC ₅₀ > 100000
AF		100	100
RAC (µg/L)		910	1000
GEM - Soiless	PEC _{gl-max} (µg/L)		
90 percentile peak concentration (µg/L)			
	0.002/ 0.004	<0.001/ <0.001	<0.001/ <0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-12: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for TBPE for each organism group based on GEM calculations for the use of Fenazaquin 10% EC in melon

Group		Fish acute	Inverteb. acute
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>
Endpoint (µg/L)		LC ₅₀ 13300	EC ₅₀ 3860
AF		100	100

RAC (µg/L)		133	38.6
GEM - Soiless	PEC_{gl-max} (µg/L)		
90 percentile peak concentration (µg/L)			
	<0.001	<0.001	<0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-13: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for TBPE for each organism group based on calculations calculations for the use of Fenazaquin 10% EC in tomato

Group		Fish acute	Inverteb. acute
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>
Endpoint (µg/L)		LC ₅₀ 13300	EC ₅₀ 3860
AF		100	100
RAC (µg/L)		133	38.6
GEM - Soiless	PEC _{gl-max} (µg/L)		
90 percentile peak concentration (µg/L)			
	<0.001/ <0.001	<0.001/ <0.001	<0.001/ <0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-14: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for TBPE for each organism group based on GEM calculations for the use of Fenazaquin 10% EC in strawberry

Group		Fish acute	Inverteb. acute
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>
Endpoint (µg/L)		LC ₅₀ 13300	EC ₅₀ 3860
AF		100	100
RAC (µg/L)		133	38.6
GEM - Soilless		PEC _{gl-max} (µg/L)	
90 percentile peak concentration (µg/L)			
	0.003/ 0.004	<0.001/ <0.001	<0.001/ <0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-15: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for TBPE for each organism group based on GEM calculations for the use of Fenazaquin 10% EC in ornamentals

Group		Fish acute	Inverteb. acute
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>
Endpoint (µg/L)		LC ₅₀ 13300	EC ₅₀ 3860
AF		100	100
RAC (µg/L)		133	38.6
GEM - Soiless		PEC _{gl-max} (µg/L)	
90 percentile peak concentration (µg/L)			
	0.003/ 0.005	<0.001/ <0.001	<0.001/ <0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-16: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for 4-(2-(4-(1,1-dimethylethanoic acid) phenyl) ethoxy) for each organism group for the use of Fenazaquin 10% EC in melon, tomato, strawberry and ornamentals

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>S. capricornutum</i>
Endpoint (µg/L)		LC ₅₀ 770	LC ₅₀ 2340	E _b C ₅₀ 8730
AF		100	100	10
RAC (µg/L)		7.7	23.4	873
GEM - Soilless	PEC _{gl-max} (µg/L)			

The PEC_{sw} for metabolite 4-(2-(4-(1,1-dimethylethanoic ac-id) phenyl) ethoxyl) quinazoline has not been calculated since it is only produced in sediment. The GEM 3.3.2 allows the calculations of PEC_{sw}, but not PEC_{sed}. Nevertheless, the parent is more than 2-3 orders of magnitude more toxic than 2-oxy-fenazaquin, therefore it is justified to conclude that the risk assessment performed for parent molecule fenazaquin covers also the risk resulting from exposure of aquatic organisms to metabolite 4-(2-(4-(1,1-dimethylethanoic ac-id) phenyl) ethoxyl) quinazoline.

ZRMS comments:

According to information given in Section 8, the calculations of PEC_{sw}/sed submitted by with model GEM v3.3.2 should be considered at national level. 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 by e-fate expert in Section 8. That calculations took 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 g x 0.001 (drift)] : 100 (m²) : 30000 (L).

Based on the new calculated PEC_{sw} and agreed toxicity endpoints (LoEP) the updated risk assessment was presented by ZRMS in the Tables below:

Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Fenazaquin for each organism group based on calculations for the use of Fenazaquin 10% EC in melon, tomato, strawberry and ornamentals.

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Aquatic insect	Algae	Microcosm
Test species		<i>Perca fluviatilis</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Chironomus riparus</i>	<i>S. capricornutum</i>	<i>Daphnia magna</i>
Endpoint (µg/L)		LC ₅₀ 3.2	NOEC 0.96	EC ₅₀ 4.1	NOEC 1.4	NOEC 2.5	E _r C ₅₀ /E _y C ₅₀ 208	NOEC 0.3
AF		100	10	100	10	10	10	2
RAC (µg/L)		0.032	0.096	0.041	0.14	0.25	20.8	0.15
	PEC _{gl-max}							

	(µg/L)							
	0.066	2.06	0.68	1.6	0.47	0.26	0.003	0.44

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Metabolites of Fenazaquin

Aquatic organisms: acceptability of risk (PEC/RAC < 1) for 2-oxy-fenazaquin for each organism group for the use of Fenazaquin 10% EC in melon, tomato, strawberry and ornamentals.

Group		Inverteb. acute
Test species		<i>Chironomus riparius</i>
Endpoint (µg/L)		LC ₅₀ 3000
AF		100
RAC (µg/L)		30
	PEC_{gl-max} (µg/L)	
	0.007	0.00023

Aquatic organisms: acceptability of risk (PEC/RAC < 1) for 4-OHQ for each organism group based on calculations for the use of Fenazaquin 10% EC in melon, tomato, strawberry and ornamentals.

Group		Fish acute	Inverteb. acute
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>
Endpoint (µg/L)		LC ₅₀ 91000	EC ₅₀ > 100000
AF		100	100
RAC (µg/L)		910	>1000
	PEC_{gl-max} (µg/L)		
	0.025	0.000027	0.000025

Aquatic organisms: acceptability of risk (PEC/RAC < 1) for TBPE for each organism group based on calculations for the use of Fenazaquin 10% EC in melon, tomato, strawberry and ornamentals.

Group		Fish acute	Inverteb. acute
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>
Endpoint (µg/L)		LC ₅₀ 13300	EC ₅₀ 3860
AF		100	100
RAC (µg/L)		133	38.6
	PEC_{gl-max} (µg/L)		
	0.038	0.00028	0.00098

Aquatic organisms: acceptability of risk (PEC/RAC < 1) for 4-(2-(4-(1,1-dimethylethanoic acid) phenyl) ethoxy) for each organism group for the use of Fenazaquin 10% EC in melon, tomato, strawberry and ornamentals.

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>S. capricornutum</i>
Endpoint (µg/L)		LC ₅₀ 770	LC ₅₀ 2340	E _b C ₅₀ 8730
AF		100	100	10

Group		Fish acute	Inverteb. acute	Algae
RAC (µg/L)		7.7	23.4	873
	PEC _{gl-max} (µg/L)			
	0.0084	0.0010	0.00035	0.0000096

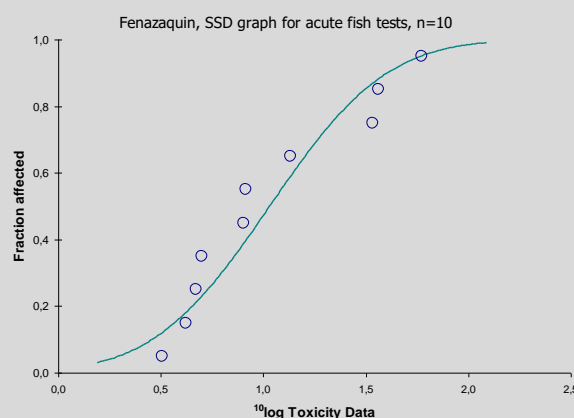
The TER_A values derived for the first tier risk assessment for Fenazaquin are below the trigger value of 1 for acute risk assessment for fish and aquatic invertebrates, indicating an unacceptable acute risk of Fenazaquin to fish and aquatic invertebrates following the use of Ruler 10 EC. Thus, a refined risk assessment was necessary.

Refined acute risk for fish:

A variety of single species acute toxicity studies was generated in the DAR to cover a wide range of taxonomic groups of fish as a basis for a sensitivity distribution and thus lower the uncertainty factor with regard to inter-species variability. Altogether 10 species of fish were tested belonging to 7 representative families like Percidae, Cyprinidae, Salmonidae, Gasterostidae, Adrianichthyidae, Centrarchidae and Poeciliidae.

Species Sensivity Distribution (SSD) was computed by ZRMS using the software ETX 2.0 by RIVM for the available acute toxicity studies to fish and presented below:

The species sensitivity distribution for fish is shown based on acute toxicity data (LC₅₀ / 96 h) for 10 species.



SSD of fish (toxicity data in µg a.s./L log transformed) exposed to Fenazaquin in acute toxicity tests

The median hazard concentration HC₅ calculated from data obtained in acute fish tests was calculated to be 1.862 µg/L using software ETX 2.0. According to AGD, 20013, the HC₅ of the different fish species tested can be used for the risk assessment maintaining the assessment factor of 9.

Acute refined RAC for fish based on and calculated HC₅ according to ETX 2.0 and PEC/RAC value.

Crop	Buffer zone [m]	HC ₅ [mg/L]	Initial PEC _{sw} [µg/L]*	AF	RAC	PEC/RAC	Trigger
All crops	1	1.862	0.066	9	0.20	0.33	<1

* calculated according to recommendations of CTGB (2013)

The PEC/RAC values based on a HC₅ for the species sensitivity distribution of acute toxicity tests on fish was calculated for the use of in protected conditions (permanent covered crops). The PEC/RAC values is below 1. Thus, the acute risk to fish is considered to be acceptable.

Overall, it can be concluded that Fenazaquin poses an acceptable acute risk to fish following application of at the proposed label rates for the permanent covered crops.

Refined acute risk for aquatic invertebrates

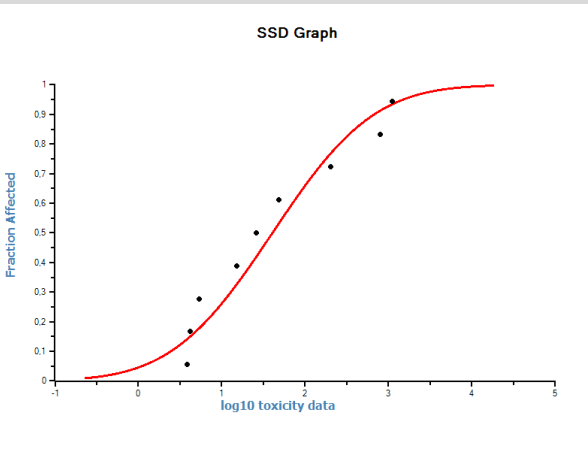
According to the AGD, 2013, the HC₅ of the different macroinvertebrates species (including *Asellus aquaticus*) tested can be used for the risk assessment maintaining the assessment factor of 3-6. The ranking of species is as presented in the table below:

Aquatic toxicity data for aquatic invertebrate species exposed to Fenazaquin

Rank	Species	LC ₅₀ [µg a.s./L]
1	<i>Asellus aquaticus</i>	3.86
2	<i>Gammarus pulex</i>	4.16
3	<i>Crassostrea virginica</i>	5.4
4	<i>Crangon crangon</i>	15
5	<i>Chironomus riparius</i>	26.0
6	<i>Notonecta maculate</i>	> 48.75
7	<i>Hydropsyche spec</i>	204
8	<i>Ephemera danica</i>	> 804
9	<i>Planorbarius corneus</i>	> 1101
HC₅:		0.96

The results of the HC₅ calculations are presented below:

Results of the HC5 calculations.

Parameter	E _T X estimation [µg a.s./L]	SSD curve
Mean of the SSD	1.61	
Standard deviation of the SSD	0.95	
Anderson-Darling test for normality	Accepted	
Kolmogorov-Smirnov test for normality	Accepted	
Cramer von Mises test for normality	Accepted	
HC ₅ lower confidence interval limit	0.05	
HC₅ median estimate	0.96	
HC ₅ upper confidence interval limit	4.6	

Acute refined RAC for aquatic invertebrates based on calculated HC₅ according to E_TX 2.0 and PEC/RAC value.

Crop	Endpoint [µg a.s./L]**	Initial PEC _{sw} [µg a.s./L]*	AF	RAC	PEC/RAC	Trigger value
All crops permanent covered crops.	0.96	0.066	6	0.16	0.41	<1

calculated according to recommendations of CTGB (2013)

** HC₅ from 9 aquatic invertebrate species

Using the HC₅ value of all 9 invertebrate species, the trigger values based on the PEC_{sw}/RAC value assuming a 0.1% emission of Fenazaquin from protected conditions for permanent covered crops being re-deposited on adjacent surface water bodies for the applications in protected conditions, is below the trigger value of 1. In addition, based on the microcosm study results with NOEC of 0.3 and AF of 2 (agreed at EU level) the risk is considered acceptable for aquatic invertebrates.

An acceptable acute risk for invertebrates can be concluded for only permanent covered crops.

However, for the authorization of the plant protection product RULER the risk assessment for aquatic organism for permanent greenhouse uses should be considered and completed, if relevant - the other PEC_{sw} calculations, at national level depend on their own requirements.

9.5.3 Overall conclusions

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—for permanent greenhouse only based on calculations of PEC_{sw} (acceptable for Poland) and toxicity endpoints - HC₅ of 0.96 µg a.s./L value.

For the authorization of the plant protection product RULER in other MSs, the risk assessment should be considered and completed, if relevant,- the other PEC_{sw} calculations, at national level depend on their own requirements.

~~(risk for invertebrate as characterised by NOEC for *Daphnia magna* of 0.3 µg/L in connection with an assessment factor of 2).~~

~~For the intended uses on melon, no specific risk mitigation measures are required.~~

~~For the intended uses on tomato, the release to environment shall be reduced by 60%, for uses on strawberries reduction shall reach 90%, and for uses in ornamentals reduction shall be 95%.~~

~~The risk mitigation measures are not clearly listed in both EFSA GD, 2014 (EFSA Journal 2014;12(3):3615) and GEM 3.3.2 documentation. These may be, however:~~

- ~~— safe discharge of recirculation/ spent water and cultivation media, safe disposal of water used for filter cleaning~~
- ~~— closing the doors and windows and switching off the ventilation during the application~~
- ~~— use of activated carbon filters~~

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.

9.6 Effects on bees (KCP 10.3.1)

9.6.1 Toxicity data

Studies on the toxicity to bees have been carried out with Fenazaquin and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on bees of Fenazaquin 10% EC were not evaluated as part of the EU assessment of Fenazaquin.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.6-1: Endpoints and effect values relevant for the risk assessment for bees

Species	Substance	Exposure System	Results	Reference
<i>Apis mellifera</i>	Fenazaquin	Oral	LD ₅₀ = 4.29 µg/bee	EFSA Journal 2013;11(4):3166
<i>Apis mellifera</i>	Fenazaquin	Oral	LD ₅₀ = 7.35 µg/bee	
<i>Apis mellifera</i>	Fenazaquin	Contact	LD ₅₀ = 1.21 µg/bee	
<i>Apis mellifera</i>	Fenazaquin	Contact	LD ₅₀ = 8.18 µg/bee	
<i>Apis mellifera</i>	Fenazaquin 10% EC	Oral	LD ₅₀ > 100 µg/bee LD ₅₀ > 10.73 µg as/bee	Likith N.G., 2019, report No. G13464
<i>Apis mellifera</i>	Fenazaquin 10% EC	Contact	LD ₅₀ > 100 µg/bee LD ₅₀ > 10.73 µg as/bee	Likith N.G., 2019, report No. G13465
Higher-tier studies (tunnel test, field studies)				
The formulation containing 200 g/L Fenazaquin were applied at the application rates of 87 and 300 g a.s./ha. No adverse effects on bees were observed regarding flight activity, bee brood and mortality at 300 g a.s./ha, but some adverse effects were observed at the application rate of 87 g a.s./ha.				

9.6.1.1 Justification for new endpoints

Not relevant as there is no deviation to the EU agreed endpoints.

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*”.

9.6.2 Risk assessment

The evaluation of the risk for bees was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SAN-CO/10329/2002 rev.2 (final), October 17, 2002) and EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees) (EFSA Journal 2013;11(7):3295).

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.

Overall, the detailed risk assessment is not required due to the negligible exposure.

9.6.2.1 Hazard quotients for bees

~~Not relevant due to the negligible exposure.~~

ZRMS comments:

Acute oral and contact toxicity studies have been carried out with Fenazaquin and Ruler 10 EC.

In addition two semi-field studies are available for the representative formulation.

Full details of the toxicity studies can be found in the EU DAR. Further details regarding the tests with the formulation are provided in the relevant Chapter in this dRR.

The acute risk to honeybees from use of Ruler 10 EC was assessed using the single application rates and the LD₅₀ values to calculate hazard quotients.

Hazard quotients were calculated for oral exposure (Q_{HO}) and contact exposure (Q_{HC}) to Fenazaquin and Ruler 10 EC.

The acute and oral hazard quotients are summarised in Table below:

Hazard quotients for honey bees

Test substance	Use	Exposure route	LD ₅₀ [µg a.s./bee]	Maximum drift rate [g a.s./ha]	Hazard quotient (HQ)	HQ assessment trigger
Fenazaquin	Permanent covered crops	Oral	4.29	200	46.62	50
		Contact	1.21		165.28	50
Fenazaquin 10% EC		Contac and oral	10.73		18.63	50
Test substance		Exposure route	LD ₅₀ [µg a.s./bee]	0.1% drift rate [g a.s./ha]	Hazard quotient (HQ)	HQ assessment trigger
Fenazaquin		Oral	4.29	0.2*	0.04	50
		Contact	1.21		0.16	50
Fenazaquin 10% EC		Contact and Oral	10.73	0.2	0.02	50

* based on a spray drift percentage of 0.1 % for glasshouse applications (CtgB, 2013)

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.

In case of the risk assessment for bees for the a.s.- Fenazaquin (field uses) the HQcontact values was

above 50. In the same time the risk for formulation Ruler 10EC was considered acceptable as the HQoral, contact values was below 50.

During EU evaluation of the formulation containing 200 g/L Fenazaquin applied at the application rates of 87 and 300 g a.s./ha no adverse effects on bees were observed regarding flight activity, bee brood and mortality at 300 g a.s./ha, but some adverse effects were observed at the application rate of 87 g a.s./ha.

Taking into account the drift of 0.1.% for glasshouse the risk for the a.s. and for product Ruler 10EC is considered acceptable. 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.

However, in case of bumble bees are pollinators the following phrase should be applied:

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

9.6.2.2 Higher-tier risk assessment for bees (tunnel test, field studies)

Not relevant.

9.6.3 Effects on bumble bees

Not relevant.

9.6.4 Effects on solitary bees

Not relevant.

9.6.5 Overall conclusions

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.

However, in case of bumble bees are pollinators the following phrase should be applied:

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

9.7 Effects on arthropods other than bees (KCP 10.3.2)

9.7.1 Toxicity data

Studies on the toxicity to non-target arthropods have been carried out with Fenazaquin. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on non-target arthropods of Fenazaquin 10% EC were not evaluated as part of the EU assessment of Fenazaquin.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.7-1: Endpoints and effect values relevant for the risk assessment for non-target arthropods

Species	Substance	Exposure System	Results	Reference
<i>Aphidius rhopalosiphi</i> parasitoid	Fenazaquin	Lab. test	LR ₅₀ = 187.25 g a.s./ha No significant effects up to 75 g a.s./ha	EFSA Journal 2013;11(4):3166
<i>Typhlodromus pyri</i> Predatory mite	Fenazaquin	Lab. test	LR ₅₀ < 2 g a.s./ha	
<i>Coccinella septempunctata</i>	Fenazaquin	Lab. test	LR ₅₀ < 21.9 g a.s./ha 22.2% at 21.9 g a.s./ha	
<i>Typhlodromus pyri</i>	Fenazaquin	Extended lab. study	LR ₅₀ = 58.5 mg a.s./ha	
<i>Phytoseiulus persimilis</i> <i>Metaseiulus occidentalis</i> <i>Amblyseius californicus</i>	Fenazaquin	Extended lab. study	LR ₅₀ = 3 g a.s./ha LR ₅₀ = 3 g a.s./ha LR ₅₀ = 36 g a.s./ha	
<i>Coccinella septempunctata</i>	Fenazaquin	Extended lab. study	No significant effect at 150 g a.s./ha (14%)	
<i>Aphidius colemani</i> Aged residue	Fenazaquin	Extended lab. study	No significant effect (5%) at 252 g a.s./ha	
<i>Bembidion lampros</i> Aged residue	Fenazaquin	Extended lab. study	No significant effect (3%) at 252 g a.s./ha	
<i>Pardosa ssp.</i> Aged residue	Fenazaquin	Extended lab. study	No significant effect (13.5%) at 252 g a.s./ha	
<i>Typhlodromus pyri</i> Aged residue	Fenazaquin	Extended lab. study	25% effect at day 15 at 150 g a.s./ha	
Field or semi-field tests				
<p>- <i>Typhlodromus pyri</i> on apples: No significant effects after 14 days at 150 g a.s./ha (57% nymphs) No significant effects after 28 days at 225 g a.s./ha (59% adults)</p> <p>- <i>Typhlodromus pyri</i> on apples (1 trial): Significant effects after 90 days (55%) at 117-250 g a.s./ha Significant effects after 90 days (58 %) at 234-500 g a.s./ha</p> <p>- <i>Typhlodromus pyri</i> on apples (2 trial): No significant effects after 72 days (31%) at 117-250 g a.s./ha No significant effects after 72 days (48 %) at 234-500 g a.s./ha</p> <p>- <i>Typhlodromus pyri</i> on apples (3 trial): Significant effects after 63 days (22%) at 117-250 g a.s./ha Significant effects after 63 days (13 %) at 234-500 g a.s./ha</p> <p>- <i>Typhlodromus pyri</i> on apples (2 trial): No significant effects after 45 days (46%) at 117-250 g a.s./ha No significant effects after 45 days (39 %) at 234-500 g a.s./ha</p> <p>- <i>Typhlodromus pyri</i> on grapes: No significant effects after 35 days (11%) at 100 g a.s./ha</p> <p>- <i>Zetzellia mali</i> Predatory mites on grapes: No effect after 7 days of exposure at 100 g a.s./ha</p>				

9.7.1.1 Justification for new endpoints

Not relevant as there is no deviation to the EU agreed endpoints.

9.7.2 Risk assessment

The evaluation of the risk for non-target arthropods was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002), and in consideration of the recommendations of the guidance document ESCORT 2 and the EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2015. Scientific Opinion addressing the state of the science on risk assessment of plant protection products for non-target arthropods. EFSA Journal 2015;13(2):3996

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 windows) is not a point of concern in the available guidance documents on the safety of chemical pesticides, but may be considered as nonrelevant when crossreading with the OECD Guidance to the environmental safety evaluation of microbial bio-control 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*”.

ZRMS comments:

Non-target arthropods living in and around the crop can be exposed to residues from Ruler 10 EC *via* spray drift. As Ruler 10 EC is intended to be used in protected conditions only, direct contact is negligible and thus no in-field risk off non-target arthropods is expected.

However, the Ruler 10 EC cannot be used in IPM program.

9.7.2.1 Risk assessment for in-field exposure

Not relevant.

9.7.2.2 Risk assessment for off-field exposure

Not relevant due to the negligible exposure.

9.7.2.3 Additional higher-tier risk assessment

Not relevant.

9.7.2.4 Risk mitigation measures

Not relevant due to the negligible exposure.

9.7.3 Overall conclusions

The in-field and off-field HQ values were not calculated for the product Fenazaquin 10% EC 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 can not be conducted during the production season.

9.8 Effects on non-target soil meso- and macrofauna (KCP 10.4)

9.8.1 Toxicity data

Studies on the toxicity to earthworms and other non-target soil organisms (meso- and macrofauna) have been carried out with Fenazaquin and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on earthworms and other non-target soil organisms (meso- and macrofauna) of Fenazaquin 10% EC were not evaluated as part of the EU assessment of Fenazaquin.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.8-1: Endpoints and effect values relevant for the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna)

Species	Substance	Exposure System	Results	Reference
<i>Eisenia fetida</i>	Fenazaquin	Mixed into substrate 14 d, acute	LC ₅₀ = 26.5 mg/kg dw LC _{50,corr} = 13.25 mg/kg dw*	EFSA Journal 2013;11(4):3166
<i>Folsomia candida</i>	Fenazaquin	Mixed into substrate 14 d, acute	LC ₅₀ > 1000 mg/kg dw LC _{50,corr} > 500 mg/kg dw*	
<i>Eisenia fetida</i>	2-oxy-fenazaquin	Mixed into substrate 14 d, acute	LC ₅₀ > 1000 mg/kg dw LC _{50,corr} > 500 mg/kg dw*	
<i>Eisenia fetida</i>	4-OHQ	Mixed into substrate 14 d, acute	LC ₅₀ > 1000 mg/kg dw LC _{50,corr} > 500 mg/kg dw*	
<i>Eisenia fetida</i>	TBPE	Mixed into substrate 14 d, acute	LC ₅₀ = 265 mg/kg dw LC _{50,corr} = 132.5 mg/kg dw*	
<i>Folsomia candida</i>	2-oxy-fenazaquin	Mixed into substrate 14 d, acute	LC ₅₀ > 1000 mg/kg dw LC _{50,corr} > 500 mg/kg dw*	
<i>Folsomia candida</i>	4-OHQ	Mixed into substrate 14 d, acute	LC ₅₀ > 1000 mg/kg dw LC _{50,corr} > 500	

Species	Substance	Exposure System	Results	Reference
			mg/kg dw*	
<i>Folsomia candida</i>	TBPE	Mixed into substrate 14 d, acute	LC ₅₀ = 169 mg/kg dw LC _{50,corr} = 84.5 mg/kg dw*	
Field studies				
No study is available and not required.				
Litter bag test				
-				

* Corrected value derived by dividing the endpoint by a factor of 2 in accordance with the EPPO earthworm scheme 2002.

9.8.1.1 Justification for new endpoints

Not relevant as there is no deviation to the EU agreed endpoints.

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*”.

9.8.2 Risk assessment

The evaluation of the risk for earthworms and other non-target soil organisms (meso- and macrofauna) was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002) with consideration of the EFSA Guidance Document on clustering and ranking of emissions of active substances of plant protection products and transformation products of these active substances from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments. EFSA Journal 2014;12(3):3615.

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.

ZRMS comments:

According to GAP, for Ruler 10EC melon, tomato, strawberry and ornamentals are cultivated in protected conditions.

For permanent covered crops, risk assessment is not considered necessary for soil organisms.

9.8.2.1 First-tier risk assessment

Not relevant due to the negligible exposure.

9.8.2.2 Higher-tier risk assessment

Not relevant.

9.8.3 Overall conclusions

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 rate.

9.9 Effects on soil microbial activity (KCP 10.5)

9.9.1 Toxicity data

Studies on effects soil microorganisms have been carried out with Fenazaquin and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on soil microorganisms of Fenazaquin 10% EC were not evaluated as part of the EU assessment of Fenazaquin.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.9-1: Endpoints and effect values relevant for the risk assessment for soil microorganisms

Endpoint	Substance	Exposure System	Results	Reference
N-mineralisation	Fenazaquin	28 d, aerobic	< 25% effect at concentrations up to 0.75 kg a.s./ha	EFSA Journal 2013;11(4):3166
C-mineralisation	Fenazaquin	28 d, aerobic	< 25% effect at concentrations up to 0.75 kg a.s./ha	
N-mineralisation	2-oxy-fenazaquin	28 d, aerobic	< 25% effect up to at least 0.21 kg test item/ha	
C-mineralisation	2-oxy-fenazaquin	28 d, aerobic	< 25% effect up to at least 0.21 kg test item/ha	
N-mineralisation	4-OHQ	28 d, aerobic	< 25% effect up to at least 0.11 kg test item/ha	
C-mineralisation	4-OHQ	28 d, aerobic	< 25% effect up to at least 0.11 kg test	

Endpoint	Substance	Exposure System	Results	Reference
			item/ha	
N-mineralisation	TBPE	28 d, aerobic	< 25% effect up to at least 0.18 kg test item/ha	
C-mineralisation	TBPE	28 d, aerobic	< 25% effect up to at least 0.18 kg test item/ha	

9.9.1.1 Justification for new endpoints

Not relevant as there is no deviation to the EU agreed endpoints.

According to the Commission Regulation (EU) No 284/2013 of 1 March 2013, “*the effects of plant protection products on soil microbial function shall be investigated if the toxicity of the plant protection product cannot be predicted on the basis of data for the active substance, unless the applicant shows that no exposure occurs*”.

9.9.2 Risk assessment

The evaluation of the risk for soil microorganisms was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002) with consideration of the EFSA Guidance Document on clustering and ranking of emissions of active substances of plant protection products and transformation products of these active substances from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments. EFSA Journal 2014;12(3):3615.

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.

ZRMS comments:

According to GAP, for Ruler 10EC melon, tomato, strawberry and ornamentals are cultivated in protected conditions. For permanent covered crops, risk assessment is not considered necessary for soil microorganisms.

9.9.3 Overall conclusions

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 rate.

9.10 Effects on non-target terrestrial plants (KCP 10.6)

9.10.1 Toxicity data

Studies on the toxicity to non-target terrestrial plants have been carried out with Fenazaquin. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on non-target terrestrial plants of Fenazaquin 10% EC were not evaluated as part of the EU assessment of Fenazaquin.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.10-1: Endpoints and effect values relevant for the risk assessment for non-target terrestrial plants

Species	Substance	Exposure System	Results	Reference
<i>Brassica oleracea</i> <i>Zea mays</i> <i>Gossypium hirsutum</i> <i>Cucumis sativus</i> <i>Raphanus sativus</i>	Fenazaquin	Seedling emergence	ER ₅₀ > 897 g a.s./ha	EFSA journal 2013;11(4):3166
<i>Oryza sativa</i> <i>Sorghum bicolor</i> <i>Glycine max</i> <i>Helianthus annuus</i> <i>Triticum aestivum</i>	Fenazaquin	Vegetative vigor	ER ₅₀ > 897 g a.s./ha	

m: monocotyledonous; d: dicotyledonous

9.10.1.1 Justification for new endpoints

Not relevant as there is no deviation to the EU agreed endpoints.

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 glasshouses where exposure is precluded”.

ZRMS comments:

According to GAP, Ruler 10 EC are cultivated in in melon, tomato, strawberry and ornamentals protected conditions

For permanent covered crops, risk assessment is not considered necessary for non-target plants.

It can be concluded that the application of Ruler 10EC does not have unacceptable effects on non-target terrestrial plants when applied at the maximum application rate in protected conditions.

9.10.2 Risk assessment

9.10.2.1 Tier-1 risk assessment (based screening data)

Not relevant.

9.10.2.2 Tier-2 risk assessment (based on dose-response data)

Not relevant due to the negligible exposure.

9.10.2.3 Higher-tier risk assessment

Not relevant.

9.10.2.4 Risk mitigation measures

No risk mitigation needed.

9.10.3 Overall conclusions

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 rate.

9.11 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)

Effects on biological methods for sewage treatments:

Respiration inhibition test: No effects up at least 100 mg a.s./L.

9.12 Monitoring data (KCP 10.8)

Not relevant.

9.13 Classification and Labelling

	Fenazaquin 10% EC
Common Name	RULER 10 EC
Classification and proposed labelling	
With regard to ecotoxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	Hazard classes (s), categories: Aquatic Chronic 2 Code(s) for hazard pictogram(s): GHS09 Signal word: - Hazard statement(s): H411 Precautionary statement: P273, P391, P501

Appendix 1 Lists of data considered in support of the evaluation

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	Owner
KCP 10.3.1.1.1	Likith N.G	2019	Fenazaquin 100 g/L SC: acute oral toxicity test in honey bees Eurofins report No. G13464 GLP, unpublished	N	SHARDA Cropchem Limited
KCP 10.3.1.1.2	Likith N.G	2019	Fenazaquin 100 g/L SC: acute contact toxicity test in honey bees Eurofins report No. G13465 GLP, unpublished	N	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	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	Owner

List of data relied on 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	Owner

Appendix 2 Detailed evaluation of the new studies

A 2.1 KCP 10.1 Effects on birds and other terrestrial vertebrates

A 2.1.1 KCP 10.1.1 Effects on birds

A 2.1.1.1 KCP 10.1.1.1 Acute oral toxicity

A 2.1.1.2 KCP 10.1.1.2 Higher tier data on birds

A 2.1.2 KCP 10.1.2 Effects on terrestrial vertebrates other than birds

A 2.1.2.1 KCP 10.1.2.1 Acute oral toxicity to mammals

A 2.1.2.2 KCP 10.1.2.2 Higher tier data on mammals

A 2.1.3 KCP 10.1.3 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians)

A 2.2 KCP 10.2 Effects on aquatic organisms

A 2.2.1 KCP 10.2.1 Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes

A 2.2.2 KCP 10.2.2 Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms

A 2.2.3 KCP 10.2.3 Further testing on aquatic organisms

A 2.3 KCP 10.3 Effects on arthropods

A 2.3.1 KCP 10.3.1 Effects on bees

A 2.3.1.1 KCP 10.3.1.1 Acute toxicity to bees

A 2.3.1.1.1 KCP 10.3.1.1.1 Acute oral toxicity to bees

Comments of zRMS:	The study is considered valid. All validity criteria were met. Agreed endpoints: LD₅₀/48h > 100 µg test item/honeybee (>10.73 µg a.i./bee).
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Reference:	KCP 10.3.1.1.1
Report	Fenazaquin 10% EC: acute oral toxicity test in honeybees, Likith NG, 2019, report No. G13464
Guideline(s):	Yes, OECD guideline No. 213 (1998)
Deviations:	None reported
GLP:	Yes
Acceptability:	Yes/No/Supplementary
Duplication (if vertebrate study)	No

The acute oral toxicity of Fenazaquin 100 g/L EC was studied on the honeybee *Apis mellifera* L. Active adult foraging worker bees were exposed to Fenazaquin 100 g/L at the concentrations of 6.25, 12.5, 25.0, 50 and 100 µg/bee along with sucrose (50% w/v sucrose in Milli-Q water) and three concentrations of the toxic standard Dimethoate at 0.075, 0.15 and 0.30 µg/bee. There were no mortalities and behavioral changes in control group observed for 4, 24 and 48h post treatment.

The per cent mortalities for the toxic standard, Dimethoate at 4 h post treatment were 0.0, 26.67 and 26.67% at the tested concentrations of 0.075, 0.15 and µg/bee, respectively.

The per cent mortalities for the toxic standard, Dimethoate at 24 h post treatment were 13.3, 50.0 and 56.67% at the tested concentrations of 0.075, 0.15 and µg/bee, respectively.

The per cent mortalities for the toxic standard, Dimethoate at 48 h post treatment were 20.0, 56.6 and 66.67% at the tested concentrations of 0.075, 0.15 and µg/bee, respectively.

The LD₅₀ value of the test item, Fenazaquin 100 g/L EC at 24 and 48 h is >100 µg/bee.

The LD₅₀ value of the toxic reference, Dimethoate at 24 h was 0.21 µg as/bee with fiducia limits at 95 per cent ranging from 0.148 to 0.302 µg as/bee.

The LD₅₀ value of the toxic reference, Dimethoate at 48 h was 0.16 µg as/bee with fiducia limits at 95 per cent ranging from 0.12 to 0.224 µg as/bee.

Materials and methods

Test item:	Fenzaquin 10% EC content: 10% (w/v) of fenazaquin (CAS no.: 120928-09-8) batch number: SCL-92593 production date: 29.08.2017 expiry date: 28.08.2019
Biological test system:	the honeybee, <i>Apis mellifera</i> L. strain: not specified source: an apiary of the Laboratory of Ecotoxicology, Eurofins Advinus Limited, Bengaluru 560 058, India age: not specified
Test design:	- test item: exposure time: 48 hours number of doses: 5 doses and a control number of replicates: 3 replicates

number of bees: 10 bees/replicate
- reference item:
exposure time: 24 hours
number of doses: 3 doses
number of replicates: 3 replicates
number of bees: 10 bees/replicate
Test item doses: 6.25, 12.5, 25.0, 50 and 100 µg test item/bee, and a control (0.0 µg/bee) Refer-
ence item doses: 0.075, 0.15, and 0.3 µg a.i./bee
Test conditions: temperature: 23- 26°C
relative air humidity: 64- 67%
place: a laboratory room
light: not specified
Endpoints: - honeybee mortality after 48 hours of exposure (LD₅₀)
- the 24/48h LD₅₀ of the reference item (dimethoate)
Statistical method: regression analysis using the probit method

Results:

Results:

Table: Summary of the bees mortality and test endpoints

Dose		Number of tested bees	Mortality after 48 h		LD ₅₀ after 48h	
[µg/bee] ^a	[µg a.i./bee] ^b		[No.]	[%]	[µg/bee] ^a	[µg a.i./bee] ^b
0.0 (control)		30	0	0	>100.0	>10.73
6.25	0.67	30	0	0		
12.5	1.34	30	0	0		
25.0	2.68	30	0	0		
50.0	5.37	30	0	0		
100.0	10.73	30	0	0		

^a: µg test item/bee

^b: µg active ingredient/bee, based on d= 0.9317 g/mL (study G13902)

Conclusions

The median lethal doses (LD₅₀/24h and LD₅₀/48h) are higher than the maximum used dose, i.e. 100 µg test item/honeybee (>10.73 µg a.i./bee).

A 2.3.1.1.2 KCP 10.3.1.1.2 Acute contact toxicity to bees

Comments of zRMS:	The study is considered valid. All validity criteria were met. Agreed endpoints: LD₅₀/48h > 100 µg test item/honeybee (>10.73 µg a.i./bee).
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Reference: KCP 10.3.1.1.2
Report Fenazaquin 10% EC: acute contact toxicity test in honeybees, Likith NG, 2019, report No. G13465
Guideline(s): Yes, OECD guideline No. 214 (1998)
Deviations: None reported

GLP: Yes
Acceptability: Yes/No/Supplementary
Duplication No
(if vertebrate study)

The acute oral toxicity of Fenazaquin 100 g/l EC was studied on the honeybee *Apis mellifera* L. Active adult foraging worker bees were exposed to Fenazaquin 100 g/L at the concentrations of 6.25, 12.5, 25.0, 50 and 100 µg/bee along with controls (Milli-Q water) and three concentrations of the toxic standard Dimethoate at 0.075, 0.15 and 0.30 µg/bee.

There were no mortalities and behavioral changes in control group observed for 4, 24 and 48h post treatment.

The per cent mortalities for the toxic standard, Dimethoate at 4 h post treatment were 0.0, 16.67 and 23.3% at the tested concentrations of 0.075, 0.15 and µg/bee, respectively.

The per cent mortalities for the toxic standard, Dimethoate at 24 h post treatment were 16.67, 53.3 and 76.67% at the tested concentrations of 0.075, 0.15 and µg/bee, respectively.

The per cent mortalities for the toxic standard, Dimethoate at 48 h post treatment were 16.67, 63.3 and 83.3% at the tested concentrations of 0.075, 0.15 and µg/bee, respectively.

The LD₅₀ value of the test item, Fenazaquin 100 g/L EC at 24 and 48 h is >100 µg/bee.

The LD₅₀ value of the toxic reference, Dimethoate at 24 h was 0.16 µg as/bee with fiducial limits at 95 per cent ranging from 0.129 to 0.201 µg as/bee.

The LD₅₀ value of the toxic reference, Dimethoate at 48 h was 0.14 µg as/bee with fiducial limits at 95 per cent ranging from 0.112 to 0.169 µg as/bee.

Materials and methods

Test item: Fenazaquin 10% EC
content: 10% (w/v) of fenazaquin (CAS no.: 120928-09-8)
batch number: SCL-92593
production date: 29.08.2017 expiry date: 28.08.2019

Biological test system: the honeybee, *Apis mellifera* L. strain: not specified
source: an apiary of the Laboratory of Ecotoxicology, Eurofins Advinus Limited, Bengaluru 560 058, India
age: not specified

Test design: - test item:
exposure time: 48 hours
number of doses: 5 doses and a control
number of replicates: 3 replicates
number of bees: 10 bees/replicate
- reference item:
exposure time: 24 hours
number of doses: 3 doses
number of replicates: 3 replicates
number of bees: 10 bees/replicate

Test item doses: 6.25, 12.5, 25.0, 50 and 100 µg test item/bee, and a control (0.0 µg/bee) Refer-
ence item doses: 0.075, 0.15, and 0.3 µg a.i./bee

Test conditions: temperature: 23- 25°C
relative air humidity: 64- 65%
place: a laboratory room
light: not specified

Endpoints: - honeybee mortality after 48 hours of exposure (LD₅₀)
- the 24/48h LD₅₀ of the reference item (dimethoate)

Statistical method: regression analysis using the probit method

Results:

Results:

Table: Summary of the bees mortality and test endpoints

Dose		Number of tested bees	Mortality after 48 h		LD ₅₀ after 48h	
[µg/bee] ^a	[µg a.i./bee] ^b		[No.]	[%]	[µg/bee] ^a	[µg a.i./bee] ^b
0.0 (control)		30	0	0	>100.0	>10.73
6.25	0.67	30	0	0		
12.5	1.34	30	0	0		
25.0	2.68	30	0	0		
50.0	5.37	30	0	0		
100.0	10.73	30	0	0		

^a: µg test item/bee

^b: µg active ingredient/bee, based on d= 0.9317 g/mL (study G13902)

Conclusions

The median lethal doses (LD₅₀/24h and LD₅₀/48h) are higher than the maximum used dose, i.e. 100 µg test item/honeybee (>10.73 µg a.i./bee).

A 2.3.1.2	KCP 10.3.1.2.	Chronic toxicity to bees
A 2.3.1.3	KCP 10.3.1.3	Effects on honey bee development and other honey bee life stages
A 2.3.1.4	KCP 10.3.1.4	Sub-lethal effects
A 2.3.1.5	KCP 10.3.1.5	Cage and tunnel tests
A 2.3.1.6	KCP 10.3.1.6	Field tests with honeybees
A 2.4	KCP 10.4	Effects on non-target soil meso- and macrofauna
A 2.4.1	KCP 10.4.1	Earthworms
A 2.4.1.1	KCP 10.4.1.1	Earthworms - sub-lethal effects
A 2.4.1.2	KCP 10.4.1.2	Earthworms - field studies
A 2.4.2	KCP 10.4.2	Effects on non-target soil meso- and macrofauna (other than earthworms)

A 2.4.2.1	KCP 10.4.2.1	Species level testing
A 2.4.2.2	KCP 10.4.2.2	Higher tier testing
A 2.5	KCP 10.5	Effects on soil nitrogen transformation
A 2.6	KCP 10.6	Effects on terrestrial non-target higher plants
A 2.6.1	KCP 10.6.1	Summary of screening data
A 2.6.2	KCP 10.6.2	Testing on non-target plants
A 2.6.3	KCP 10.6.3	Extended laboratory studies on non-target plants
A 2.7	KCP 10.7	Effects on other terrestrial organisms (flora and fauna)
A 2.8	KCP 10.8	Monitoring data