FINAL REGISTRATION REPORT

Part B

Section 9

Ecotoxicology

Detailed summary of the risk assessment

Product code: SHA 9700 A

Product name: RULER

Chemical active substance:

Fenazaquin, 200 g/L

Interzonal

Zonal Rapporteur Member State: POLAND

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: May 2019

MS Finalisation date: July 2020, February 2021; May 2021

Version history

When	What
July 2020	The evaluation of PPP Ruler by ZRMS-PL
February/May 2021	Final zRMS version of RR after Commenting period

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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: developmental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/ synergist per ha	**Conclusion**						
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Birds	Mammals	Aquatic organisms	Bees	Non-target arthropods	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 (only permanent glasshouse)	Spider mites	Foliar spray	Pest presence BBCH 70-79	a) 1 b) 1	NA	a) 1 b) 1	a) 0.2 b) 0.2	1000	7	-							
2	CEU/SEU/NEU	**Ornamentals**	G (only permanent glasshouse)	Spider mites	Foliar spray	Pes presence BBCH 35-64	a) 2 b) 2	7-10	a) 1 b) 2	a) 0.2 b) 0.4	1000	-	-							
3	CEU/SEU/NEU	**Tomato**	G (only permanent glasshouse)	Spider mites	Foliar spray	Pest presence BBCH 5189	a) 2 b) 2	7-10	a) 1 b) 2	a) 0.2 b) 0.4	1000	3	-							
4	CEU/SEU/NEU	**Strawberry**	G (only permanent glasshouse)	Spider mites	Foliar spray	Pest presence BBCH 15-91	a) 2 b) 2	7-10	a) 1 b) 2	a) 0.2 b) 0.4	1000	3	-							

* 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 glasshouse was considered in the Ecotoxicology risk assessment in the current dossier.

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

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

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 20% SC presents no unacceptable acute and long-term risk to mammals according to the intended uses.

ZRMS comments:

No risk assessment for mammals for Ruler (Fenazaquin 20% SC) 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 20% SC presents no unacceptable acute and long-term risk to birds according to the intended uses.

- Mammals

According to the Commission Regulation (EU) No 284/2013 of 1 March 2013, "*possible risks to vertebrate species other than birds shall be investigated **except when the test substance is included in plant protection products used, for example, in enclosed spaces** and wound-healing treatments where vertebrate species other than birds will experience neither direct nor secondary exposure*".
The detailed risk assessment is not required due to the negligible exposure. Moreover, the EFSA Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438 does not propose scenarios relevant to the indoor uses.
According to the GAP, the intended uses are control of spider mites in permanent greenhouses, therefore negligible exposure of birds is considered. Fenazaquin 20% SC presents no unacceptable acute and long-term risk to mammals according to the intended uses.

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 (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*

The risk assessment provided by the applicant with consideration PECsw calculated by GEM 3.3.2 model should be considered at National level. In Poland the GEMv3.3.2 PECsw calculations are not acceptable for using in the risk assessment for glasshouse uses. Due to the fact that the applicant did not provide the exposure assessment for other protected structures, the use was limited and accepted to only permanent glasshouses taking into account the PECsw calculations provided by zRMS in Section 8. Based on this assessment for the intended uses for permanent glasshouse, no specific risk mitigation measures are required for Poland.

However, final aquatic organisms risk mitigations measures for greenhouse uses should be considered at national level.

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.
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 nonrele-

vant when crossreading with the OECD Guidance to the environmental safety evaluation of microbial biocontrol agents (OECD Environment, Safety and Health Publications, Series on Pesticides, No 67, 2012, ENV/JM/MONO/2012(1))
According to the EFSA PPR Panel (EFSA Journal 2015;13(2): 3996), "*in some cases* ***off-field exposure is considered to be negligible and not further assessed, e.g. in the case of*** *rodenticides, substances used for wound protection or in the case of substances used in stored products or in* ***greenhouses***".
The in-field and off-field HQ values were not calculated for the product Fenazaquin 20% SC due to the negligible exposure following application according to the proposed use pattern .
However, integrated pest management (IPM) with the introduction of parasitoid/ predatory arthropods cannot be conducted during the production season.
Therefore, the roduct Ruler cannot be used in IPM program in glasshouse.

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).

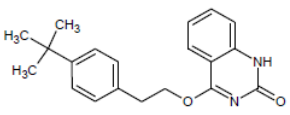
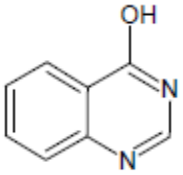
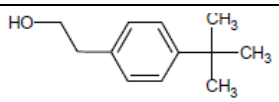
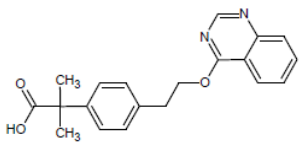
Table 9.1-2: Critical use pattern of Fenazaquin 20% SC grouped according to criterion

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 20% SC 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 microbial activity
4-(2-(4-(1,1-dimethylethanoic acid)phenyl)ethoxyl)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 20% SC were not evaluated as part of the EU assessment of Fenazaquin.

However, the provision of further data on the Fenazaquin 20% SC 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 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*."

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.

9.2.2.4 Effects of secondary poisoning

Not relevant due to the negligible exposure.

zRMS comments:

According to the "Guidance Document on Risk Assessment for Birds and Mammals under Council Directive 91/414/EEC (SANCO/4145/2000, issued September 25th, 2002), the bioaccumulation potential should be evaluated for substances with a log Pow of more than 3. As the log Pow of Fenazaquin is 5.71,

the food chain behaviour from earthworm to earthworm-eating birds and from fish to fish-eating birds as well as the potential for biomagnification in terrestrial food chains were assessed.

The risk assessment for effects on birds and mammals due to secondary poisoning is required since the log Pow of the active substance is higher than 3 and exposure to surface water and/or soil is anticipated. For other details, see EFSA Supporting publication 2015:EN-924 ("Outcome of the pesticides peer re-view meeting on general recurring issues in ecotoxicology", 2015).

A theoretical maximum daily dose of Fenazaquin for birds that feed exclusively on earthworms only and the resulting toxicity/exposure-ratio were estimated according to the model calculation proposed in SANCO/4145/2000 via the following steps:

With a Kow of 507000, a Koc of 26175 and 0.02 as default value for foc (factor for organic carbon content of soil), the bioconcentration factor of Fenazaquin for earthworms (BCF) was estimated according to the following equation:

BCF = (0.84 + 0.01 Kow) / foc * Koc = (0.84 + 0.01 * 507000) / 0.02 * 26175 = 9.68

Using the highest 3 weeks' time-weighted-average PECsoil of 0.345 mg ai/kg (a theoretical maximum residue in earthworms PECworm was estimated:

$PEC_{worm} = PEC_{soil} * BCF_{worm}$ = 0.345 mg ai/kg x 9.68= 0.852 mg ai/kg fresh worm

Based on a 100-g bird eating 113 g worms per day, daily doses were estimated by multiplying the PECworm with 1.1, equaling mg ai/kg bw/d

$PEC_{worm} = PEC_{soil} * BCF_{worm}$ = 0.852 mg ai/kg x1.1= 0.94 mg ai/kg fresh worm

The long-term NOEC of 80.3 mg/kg bw/d was derived from a reproduction study on Bobwhite quail

Accordingly, the toxicity/exposure ratio for bioaccumulation via the food chain from earthworm to earthworm-eating birds was estimated as follows:

TER = NOEC / daily dose = 80.3 mg/kg bw/d /0.94 mg/kg bw/d = 85.42

Thus the toxicity/exposure ratio was much higher than the relevant trigger value of 5.

Food chain from fish to fish-eating birds:

A theoretical maximum daily dose of Fenazaquin for birds that feed exclusively on fish and the resulting toxicity/exposure-ratio were estimated according to the model calculation proposed in SANCO/4145/2000 via the following steps:

The max PEC_{water} of 0.66 µg ai/L, calculated for exposure scenario for the application of 1 x 200 g Fenazaquin/ha to strawberry was applied representing the worst case. Using the highest peak bioconcentration factor for the wholefish BCF of 520 (please refer to DAR), a theoretical maximum residue in fish PECfish was estimated:

$PECfish = PEC_{water} * BCFfish$ = 0.66 µg ai/kg x 520 = 343 µg ai/kg = 0.343 mg ai/kg fresh fish

Based on a 1000 g bird eating 206 g per day, daily doses were estimated by multiplying the PECfish with 0.21, equaling 0.072 mg ai/kg bw/d.

The long-term NOEC of 80.3 mg/kg bw/d was derived from a reproduction study on Bobwhite quail

Accordingly, the toxicity/exposure ratio for bioaccumulation via the

food chain from fish to fish-eating birds was estimated as follows:

TER = NOEC / daily dose = 80.3 mg/kg bw/d / 0.072 mg/kg bw/d = 1115.3

Thus the toxicity/exposure ratio was much higher than the relevant trigger value of 5.

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 20% SC 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 20% SC (Ruler) 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 20% SC were not evaluated as part of the EU assessment of Fenazaquin.

However, the provision of further data on the formulation Fenazaquin 20% SC 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.

zRMS comments:

Food chain from earthworm to earthworm-eating mammals

A theoretical maximum daily dose of Fenazaquin for mammals that feed on earthworms only and the resulting toxicity/exposure-ratio were estimated according to the model calculation proposed in SANCO/4145/2000 via the following steps:

With a Kow of 507000, a Koc of 19136 and 0.02 as default value for foc (factor for organic carbon content of soil), the bioconcentration factor for earthworms (BCF) was estimated according to the following equation:

BCF = (0.84 + 0.01 Kow) / foc * Koc = (0.84 + 0.01 * 507000) / 0.02 * 26175 = 9.68

Using the highest 3 weeks time-weighted-average PECsoil grapes of 0.345 mg ai/kg, a theoretical maximum residue in earthworms PEC_{worm} was estimated:

PECworm = PECsoil * BCFworm = 0.345mg ai/kg x 9.68= 3.34 mg ai/kg fresh worm

Based on a 10-g mammal eating 14 g worms per day, daily doses were estimated by multiplying the PECworm with 1.4, equaling 4.67 mg ai/kg bw/d.

The long-term NOAEL of 25 mg/kg bw/d was derived from a multigeneration study on rats.

Accordingly, the toxicity/exposure ratio for bioaccumulation via the food chain from earthworm to earthworm-eating mammals was estimated as follows:

TER = NOAEL / daily dose = 25 mg/kg bw/d / 4.67 mg/kg bw/d = 5.35

Thus the toxicity/exposure ratio was higher than the relevant trigger value of 5.

Food chain from fish to fish-eating mammals

A theoretical maximum daily dose of Fenazaquin for mammals that feed exclusively on fish and the resulting toxictiy/exposure-ratio were estimated according to the model calculation proposed in SANCO/4145/2000 via the following steps:

The max PECwater of 0.66 µg ai/L, calculated by using exposure scenario for the application of 1 x 200 g Fenazaquin/ha to strawberry was applied representing the worst case. Using the highest peak bioconcentration factor for the whole fish BCF of 520 (please refer to DAR), a theoretical maximum residue in fish PECfish wasestimated:

PECfish = PECwater * BCFfish = 0.66 µg ai/kg x 520 = 343 µg ai/kg = 0.343 mg ai/kg fresh fish

Based on a 3000 g mammal eating 390 g per day, daily doses were estimated by multiplying the PECfish with 0.13, equalling 0.04459 mg ai/kg bw/d.

The long-term NOAEL of 25 mg/kg bw/d was derived from a multigeneration reproduction study on rats. Accordingly, the toxicity/exposure ratio for bioaccumulation via the food chain from fish to fish-eating mammals was estimated as follows:

TER = NOAEL / daily dose = 25 mg/kg bw/d / 0.04459 mg/kg bw/d = 560.66

Thus the toxicity/exposure ratio was much higher than the relevant trigger value of 5.

Biomagnification in terrestrial food chains

According to SANCO/4145/2000, the potential for biomagnification in terrestrial food chains should be assessed in a step-wise approach. If the bioaccumulation potential is indicated to be low both by toxicological and residual data, no further steps are required.

Based on the results of metabolism studies on several species (please refer to DAR), Fenazaquin and/or metabolites are not expected to accumulate in tissues. Accordingly, it can be assumed that the risk of Fenazaquin biomagnification along terrestrial food chains is low.

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. Ruler (Fenazaquin 20% SC) 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 Ruler (Fenazaquin 20% 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.

9.3.2.4 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.

ZRMS comments:

No risk assessment for mammals from secondary poising for earthworm-eating mammals was conducted to use on melon, ornamentals, tomato and strawberry in protected conditions. It can be assumed that is not relevant for earthworm-eating mammals via secondary poisoning due to the negligible exposure.

Risk assessment for fish-eating mammals via secondary poisoning

Not relevant due to the negligible exposure.

ZRMS comments:

No risk assessment for mammals was conducted for fish-eating mammls via secondary poising to use on melon, ornamentals, tomato and strawberry in protected conditions. It can be assumed that is not relevant for fish-eating mammals via secondary poisoning due to the negligible exposure.

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 20% SC presents no unacceptable acute and long-term risk to mammals according to the intended uses.

ZRMS comments:

No risk assessment for mammals for Ruler (Fenazaquin 20% SC) 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 20% SC were not evaluated as part of the EU assessment of Fenazaquin.

However, the provision of further data on the Fenazaquin 20% SC 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				
Oncorhynchus mykiss	Fenazaquin	96 h, f	LC_{50} = 0.0038 mg a.s./L	EFSA Journal 2013;11(4):3166
Oncorhynchus mykiss	Fenazaquin	96 h, s	Without sediment: LC_{50} = 0.0066 mg a.s./L With sediment: LC_{50} = 0.0119 mg a.s./L	
Lepomis macrochirus	Fenazaquin	96 h, f	LC_{50} = 0.0341 mg a.s./L	
Rhodeus amarus	Fenazaquin	96 h, ss	LC_{50} = 0.0363 mg a.s./L	
Pimephales promelas	Fenazaquin	96 h, ss	LC_{50} = 0.0042 mg a.s./L	
Oryzias latiped	Fenazaquin	96 h, ss	LC_{50} = 0.0136 mg a.s./L	
Gasterosteus aculeatus	Fenazaquin	96 h, ss	LC_{50} = 0.0082 mg a.s./L	
Danio rerio	Fenazaquin	96 h, ss	LC_{50} = 0.0080 mg a.s./L	
Perca fluviatilis	Fenazaquin	96 h, ss	**LC_{50} = 0.0032 mg a.s./L**	
Leucaspius delineatus	Fenazaquin	96 h, ss	LC_{50} = 0.0047 mg a.s./L	
Poecilia reticulate	Fenazaquin	96 h, ss	LC_{50} = 0.0590 mg a.s./L	
Oncorhynchus mykiss	4-(2-(4-(1,1-dimethyl ethanoic acid) phenyl) ethoxy) quinazoline	96 h, ss	**LC_{50} = 0.77 mg/L**	
Oncorhynchus mykiss	TBPE	96 h, ss	**LC_{50} = 13.3 mg/L**	
Oncorhynchus mykiss	4-OHQ	96 h, s	**LC_{50} = 91 mg/L**	
Oncorhynchus mykiss	Fenazaquin	21 d, f	**NOEC = 0.00096 mg a.s./L**	
Invertebrates acute				
Daphnia magna	Fenazaquin	48 h, s	**EC_{50} = 0.0041 mg a.s./L**	EFSA Journal 2013;11(4):3166
Daphnia magna	Fenazaquin	48 h, s	Withou sediment: EC_{50} = 0.0057 mg a.s./L With sediment: EC_{50} = 0.0127 mg a.s./L	
Crassostrea virginica	Fenazaquin	96 h, f	EC_{50} = 0.0054 mg a.s./L	
Crangon crangon	Fenazaquin	96 h, ss	EC_{50} = 0.015 mg a.s./L	
Daphnia magna	4-(2-(4-(1,1-dimethyl ethanoic acid) phenyl) ethoxy) quinazoline	48 h, s	**EC_{50} = 2.34 mg/L**	
Daphnia magna	TBPE	48 h, ss	**EC_{50} = 3.86 mg/L**	

Species	Substance	Exposure System	Results	Reference
Daphnia magna	4-OHQ	48 h, s	**EC_{50} > 100 mg/L**	
Daphnia magna	Fenazaquin	21 d, ss	**EC_{50} = 0.0014 mg a.s./L**	
Chironomus riparius	Fenazaquin	28 d, s	EC_{50} = 0.0025 mg a.s./L (equal to 18.8 µg a.s./kg sediment)	
Chironomus riparius	2-oxy-fenazaquin	96 h, ss	**EC_{50} > 3 mg/L**	
Algae				
S. capricornutum	Fenazaquin	72 h, s	**E_bC_{50} > 0.208 mg a.s./L**	EFSA Journal 2013;11(4):3166
S. capricornutum	4-(2-(4-(1,1-dimethyl ethanoic acid) phenyl) ethoxy) quinazoline	72 h	**E_bC_{50} = 8.73 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 assessmen 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

~~**Table 9.5-2: Endpoints and effect values relevant for the risk assessment for aquatic organisms - Fenazaquin 20% SC**~~

~~Species~~	~~Substance~~	~~Exposure System~~	~~Results~~	~~Reference~~
~~*Oncorhynchus mykiss*~~	~~Fenazaquin 20% SC~~	~~96 h, s~~	~~LC_{50} = xxx mg/L $_{nom}$~~	~~Author/Date/Study code~~
~~*Daphnia magna*~~	~~Fenazaquin 20% SC~~	~~48 h, s~~	~~EC_{50} = xxx mg/L $_{nom}$~~	~~Author/Date/Study code~~
~~*Pseudokirchneriella subcapitata*~~	~~Fenazaquin 20% SC~~	~~72 h, s~~	~~E_rC_{50} = xxx mg/L $_{nom}$~~	~~Author/Date/Study code~~
~~**Higher-tier studies (micro- or mesocosm studies)**~~				

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

9.5.1.1 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 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) PECsw 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 20% SC in melon

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Aquatic insect**	**Algae**	**Microcosm**
Test species		***Perca fluviatilis***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Chironomus riparus***	***S. capricornutum***	***Daphnia magna***
Endpoint (µg/L)		LC_{50} 3.2	NOEC 0.96	EC_{50} 4.1	NOEC 1.4	NOEC 2.5	E_rC_{50}/E_yC_{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 20% SC in tomato

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Aquatic insect**	**Algae**	**Microcosm**
Test species		***Perca fluviatilis***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Chironomus riparus***	***S. capricornutum***	***Daphnia magna***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	NOEC	E_rC_{50}/E_yC_{50}	NOEC

(µg/L)		3.2	0.96	4.1	1.4	2.5	208	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)								
	0.075/ 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 20% SC in strawberry

Group		**Fish acute**	**Fish pro-longed**	**Inverteb. acute**	**Inverteb. prolonged**	**Aquatic insect**	**Algae**	**Microcosm**
Test species		***Perca fluviatilis***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Chironomus riparus***	***S. capricornu-tum***	***Daphnia magna***
Endpoint (µg/L)		LC_{50} 3.2	NOEC 0.96	EC_{50} 4.1	NOEC 1.4	NOEC 2.5	E_rC_{50}/E_yC_{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)								
	0.157/ 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 20% SC in ornamentals

Group		**Fish acute**	**Fish pro-longed**	**Inverteb. acute**	**Inverteb. prolonged**	**Aquatic insect**	**Algae**	**Microcosm**
Test species		***Perca fluviatilis***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Chironomus riparus***	***S. capricornu-tum***	***Daphnia magna***
Endpoint (µg/L)		LC_{50} 3.2	NOEC 0.96	EC_{50} 4.1	NOEC 1.4	NOEC 2.5	E_rC_{50}/E_yC_{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)								
	0.266/ 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 20% SC in melon, tomato, strawberry and ornamentals

Group		**Inverteb. acute**
Test species		***Chironomus riparius***
Endpoint		LC_{50}
(µg/L)		3000
AF		100
RAC (µg/L)		30
GEM - Soilless	**PEC $_{gl-max}$ (µg/L)**	
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.		

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 20% SC in melon

Group		**Fish acute**	**Inverteb. acute**
Test species		***Oncorhynchus mykiss***	***Daphnia magna***
Endpoint (µg/L)		LC_{50} 91000	EC_{50} > 100000
AF		100	100
RAC (µg/L)		910	>1000
GEM - Soilless	**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 9.5-9: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for 4-OHQ for each organism group based on on GEM calculations for the single/multiple use of Fenazaquin 20% SC in tomato

Group		**Fish acute**	**Inverteb. acute**
Test species		***Oncorhynchus mykiss***	***Daphnia magna***
Endpoint (µg/L)		LC_{50} 91000	LC_{50} > 100000
AF		100	100
RAC (µg/L)		910	1000
GEM - Soilless	**PEC $_{gl\text{-}max}$ (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 20% SC in strawberry

Group		**Fish acute**	**Inverteb. acute**
Test species		***Oncorhynchus mykiss***	***Daphnia magna***
Endpoint (µg/L)		LC_{50} 91000	LC_{50} > 100000
AF		100	100
RAC (µg/L)		910	1000
GEM - Soilless	**PEC $_{gl\text{-}max}$ (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 20% SC in ornamentals

Group		**Fish acute**	**Inverteb. acute**
Test species		***Oncorhynchus mykiss***	***Daphnia magna***
Endpoint (µg/L)		LC_{50} 91000	LC_{50} > 100000
AF		100	100
RAC (µg/L)		910	1000
GEM - Soilless	**PEC $_{gl\text{-}max}$ (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 20% SC in melon

Group		**Fish acute**	**Inverteb. acute**
Test species		***Oncorhynchus mykiss***	***Daphnia magna***
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)			
	<0.001	<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 20% SC in tomato

Group		**Fish acute**	**Inverteb. acute**
Test species		***Oncorhynchus mykiss***	***Daphnia magna***
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)			
	<0.001/ <0.001	<0.001/ <0.001	<0.001/ <0.001 GEM

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 20% SC in strawberry

Group		**Fish acute**	**Inverteb. acute**
Test species		***Oncorhynchus mykiss***	***Daphnia magna***
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 GEM

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 20% SC in ornamentals

Group		**Fish acute**	**Inverteb. acute**
Test species		***Oncorhynchus mykiss***	***Daphnia magna***
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/ 0.005	<0.001/ <0.001	<0.001/ <0.001 GEM

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 20% SC in melon, tomato, strawberry and ornamentals

Group		Fish acute	Inverteb. acute	Algae
Test species		*Oncorhynchus mykiss*	*Daphnia magna*	*S. capricornutum*
Endpoint (µg/L)		LC_{50} 770	LC_{50} 2340	E_bC_{50} 8730
AF		100	100	10
RAC (µg/L)		7.7	23.4	873
GEM - Soilless	PEC $_{gl\text{-}max}$ (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 PECsw/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 (m^2)] : 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		***Perca fluviatilis***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Chironomus riparus***	***S. capricornu-tum***	***Daphnia magna***
Endpoint (µg/L)		LC_{50} 3.2	NOEC 0.96	EC_{50} 4.1	NOEC 1.4	NOEC 2.5	E_rC_{50}/E_yC_{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 $_{gl\text{-}max}$ (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		***Chironomus riparius***
Endpoint		LC_{50}
(µg/L)		3000
AF		100
RAC (µg/L)		30
	PEC $_{gl\text{-}max}$ (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		***Oncorhynchus mykiss***	***Daphnia magna***
Endpoint (µg/L)		LC_{50} 91000	EC_{50} > 100000
AF		100	100
RAC (µg/L)		910	>1000
	PEC $_{gl\text{-}max}$ (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		**Oncorhynchus mykiss**	**Daphnia magna**
Endpoint (µg/L)		**LC_{50} 13300**	**EC50 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		***Oncorhynchus mykiss***	***Daphnia magna***	***S. capricornutum***
Endpoint		**LC_{50}**	**LC_{50}**	**E_bC_{50}**
(µg/L)		**770**	**2340**	**8730**
AF		**100**	**100**	**10**
RAC (µg/L)		**7.7**	**23.4**	**873**
	PEC $_{gl\text{-}max}$ (µg/L)			
	0.0084	0.0010	0.00035	0.0000096

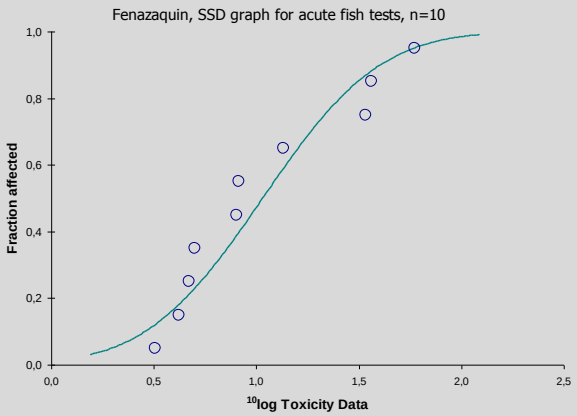
The TER_A values derived for the first tier risk assessment for Fenazaquin are below the trigger value of 1

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 .
Thus, a refined risk assessment was needed.

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, Adrianichtydae, Centrarchidae and Poecilidae.
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 (LC_{50} / 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 HC_5 calculated from data obtained in acute fish tests was calculated to be 1.862 µg/L using software *E_TX* 2.0. According to AGD, 20013, the HC_5 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 HC_5 according to *E_TX* 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 HC_5 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 exceed the trigger value of 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

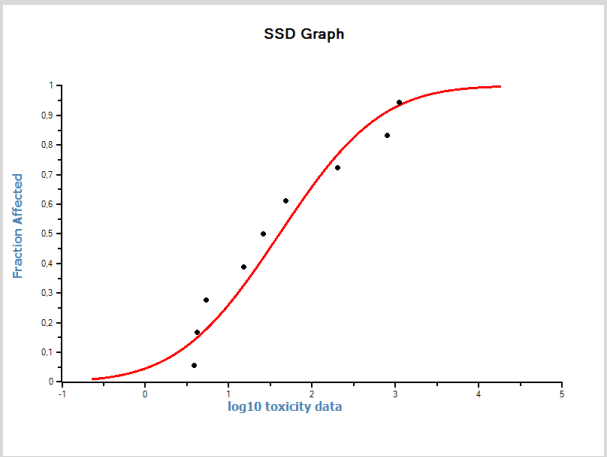
According to theAGD, 2013, the HC_5 of the different macroinvertebrates species (including *Asellus aquaticus*) tested can be used for the risk assessment maintaining the assessment factor of 3-6. The ranking of species is as presented in the table below:

Aquatic toxicity data for aquatic invertebrate species exposed to Fenazaquin

Rank	Species	LC_{50} [µg a.s./L]
1	*Asellus aquaticus*	3.86
2	*Gammarus pulex*	4.16
3	*Crassostrea virginica*	5.4
4	*Crangon crangon*	15
5	*Chironomus riparius*	26.0
6	*Notonecta maculate*	> 48.75
7	*Hydropsyche spec*	204
8	*Ephemera danica*	> 804
9	*Planorbarius corneus*	> 1101
HC_5:		**0.96**

The results of the HC_5 calculations are presented below:

Results of the HC5 calculations.

Parameter	E_TX 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	
HC_5 median estimate	**0.96**	
HC_5 upper confidence interval limit	4.6	

Acute refined RAC for aquatic invertebrates based on calculated HC_5 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)
** HC_5 from 9 aquatic invertebrate species

Using the HC_5 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 in below 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 permanent covered crops from exposure of Ruler.

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. (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.

ZRMS comments:

The risk assessment provided by the applicant with consideration PEC_{sw} calculated by GEM 3.3.2 model should be considered at National level. In Poland the GEMv3.3.2 PEC_{sw} calculations are not acceptable for using in the risk assessment for glasshouse uses. Due to the fact that the applicant did not provide the exposure assessment for other protected structures, the use was limited and accepted to only permanent glasshouses taking into account the PEC_{sw} calculations provided by zRMS in Section 8.
Based on this assessment for the intended uses for permanent glasshouse, no specific risk mitigation measures are required for Poland. However, final aquatic organisms risk mitigations measures for greenhouse uses should be considered at national level.

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 20% SC 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
Apis mellifera	Fenazaquin	Oral	**LD_{50} = 4.29 µg/bee**	EFSA Journal 2013;11(4):3166
Apis mellifera	Fenazaquin	Oral	LD_{50} = 7.35 µg/bee	

Species	Substance	Exposure System	Results	Reference
Apis mellifera	Fenazaquin	Contact	**LD_{50} = 1.21 µg/bee**	
Apis mellifera	Fenazaquin	Contact	LD_{50} = 8.18 µg/bee	
Apis mellifera	Fenazaquin 20% SC	Oral	LD_{50} > 100 µg/bee	Likith N.G., 2019, report No. G13474
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 (SANCO/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.

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 (Fenazaquin 20% SC) was assessed using the single application rates and the LD_{50} values to calculate hazard quotients.

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

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 20 % SC		Oral	20		10	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 20% SC		Oral	20	0.2*	0.01	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, contactt 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 (Fenazaquin 20% SC) is considered acceptable. Since the product Ruler (Fenazaquin 20% SC) is to be used only in glasshouse and the intended uses do not require presence of pollinating insects, the risk assessment is low due to the negligible exposure.

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

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

9.6.2.1 Hazard quotients for bees

Not relevant due to the negligible exposure.

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.
In case when bumble bees are used as 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 20% SC 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
Aphidius rhopalosiphi 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
Typhlodromus pyri Predatory mite	Fenazaquin	Lab. test	LR_{50} < 2 g a.s./ha	
Coccinella septempunctata	Fenazaquin	Lab. test	LR_{50} < 21.9 g a.s./ha 22.2% at 21.9 g a.s./ha	
Typhlodromus pyri	Fenazaquin	Extended lab. study	LR_{50} = 58.5 mg a.s./ha	

Species	Substance	Exposure System	Results	Reference
Phytoseiulus persimilis *Metaseiulus occidentalis* *Amblyseius californicus*	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	
Coccinella septempunctata	Fenazaquin	Extended lab. study	No significant effect at 150 g a.s./ha (14%)	
Aphidius colemani Aged residue	Fenazaquin	Extended lab. study	No significant effect (5%) at 252 g a.s./ha	
Bembidion lampros Aged residue	Fenazaquin	Extended lab. study	No significant effect (3%) at 252 g a.s./ha	
Pardosa ssp. Aged residue	Fenazaquin	Extended lab. study	No significant effect (13.5%) at 252 g a.s./ha	
Typhlodromus pyri Aged residue	Fenazaquin	Extended lab. study	25% effect at day 15 at 150 g a.s./ha	
Field or semi-field tests				
- *Typhlodromus pyri* 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) - *Typhlodromus pyri* 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 - *Typhlodromus pyri* 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 - *Typhlodromus pyri* 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 - *Typhlodromus pyri* 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 - *Typhlodromus pyri* on grapes: No significant effects after 35 days (11%) at 100 g a.s./ha - *Zetzellia mali* Predatory mites on grapes: No effect after 7 days of exposure at 100 g a.s./ha				

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 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 biocontrol agents (OECD Environment, Safety and Health Publications, Series on Pesticides, No 67, 2012, ENV/JM/MONO/2012(1))
According to the EFSA PPR Panel (EFSA Journal 2015;13(2): 3996), "*in some cases* ***off-field exposure is considered to be negligible and not further assessed, e.g. in the case of*** *rodenticides, substances used for wound protection or in the case of substances used in stored products or in* ***greenhouses***".

ZRMS comments:

Non-target arthropods living in and around the crop can be exposed to residues from Ruler *via* spray drift.

As Ruler is intended to be used in protected conditions only, direct contact is negligible and thus no in-field risk of non-target arthropods is expected.

However, the Ruler (Fenazaquin 20% SC) 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 20% SC due to the negligible exposure following application according to the proposed use pattern .
However, integrated pest management (IPM) with the introduction of parasitoid/ predatory arthropods cannot be conducted during the production season.

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 20% SC 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
Eisenia fetida	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
Folsomia candida	Fenazaquin	Mixed into substrate 14 d, acute	LC_{50} > 1000 mg/kg dw $LC_{50,corr}$ > 500 mg/kg dw*	
Eisenia fetida	2-oxy-fenazaquin	Mixed into substrate 14 d, acute	LC_{50} > 1000 mg/kg dw $LC_{50,corr}$ > 500 mg/kg dw*	
Eisenia fetida	4-OHQ	Mixed into substrate 14 d, acute	LC_{50} > 1000 mg/kg dw $LC_{50,corr}$ > 500 mg/kg dw*	
Eisenia fetida	TBPE	Mixed into substrate 14 d, acute	LC_{50} = 265 mg/kg dw $LC_{50,corr}$ =132.5 mg/kg dw*	
Folsomia candida	2-oxy-fenazaquin	Mixed into substrate 14 d, acute	LC_{50} > 1000 mg/kg dw $LC_{50,corr}$ > 500 mg/kg dw*	
Folsomia candida	4-OHQ	Mixed into substrate 14 d, acute	LC_{50} > 1000 mg/kg dw $LC_{50,corr}$ > 500 mg/kg dw*	
Folsomia candida	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, melon, tomato, strawberry and ornamentals are cultivated in protected conditions.

For permanent covered crops, risk assessment is not considered necessary for soil organisms for Ruler (Fenazaquin 20% SC).

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 20% SC 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 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, melon, tomato, strawberry and ornamentals are cultivated in protected conditions.

For permanent covered crops, risk assessment for Ruler (Fenazaquin 20% SC) is not considered necessary for soil micro-organisms.

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 20% SC 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
Brassica oleracea *Zea mays* *Gossypium hirsutum* *Cucumis sativus*	Fenazaquin	Seedling emergence	ER_{50} > 897 g a.s./ha	EFSA journal 2013;11(4):3166

Species	Substance	Exposure System	Results	Reference
Raphanus sativus *Oryza sativa* *Sorghum bicolor* *Glycine max* *Helianthus anuus* *Triticum aestivum*	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, melon, tomato, strawberry and ornamentals are cultivated in 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 (Fenazaquin 20% SC) 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 is classified as Aquatic Acute and Chronic Category 1 (M = 100).
FENAZAQUIN 20% SC contains for aquatic acute 100 × 19.39 > 25% and for aquatic chronic 100 × 19.39 > 25% [(M × Acute 1) ≥ 25 or (M × Chronic 1) ≥ 25] of these substances, therefore the hazard statements H400 and H410 with pictogram GHS09 and signal word “Warning” is proposed.

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 200 g/L SC: acute oral toxicity test in honey bees Eurofins report No. G13474 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

A 2.3.1.1.2 Study 1

Comments of zRMS:	The study is considered acceptable. All validity criteria were met. **Agreed endpoints:** The LD_{50} voral alue of the test item, Fenazaquin 200 g/L SC at 24 and 48 h is > 100 µg/bee.

Reference:	KCP 10.3.1.1.1
Report	Fenazaquin 200 g/L SC: acute oral toxicity test in honey bees, Likith N.G., 2019, report No. G13474
Guideline:	Yes, OECD guidelines No. 213
Deviations:	No
GLP:	Yes
Acceptability:	Yes/No/Supplementary
Duplication (if vertebrate study)	No

Materials and methods

Test item concentration:

Volume of stock (mL)	Volume of control (mL)	Test item concentration (µg a.s./µL)	Test concentration considering 20 µL exposure volume (µg a.i./bee)	Group No.
0.625	9.375	0.3125	6.25	G2
1.25	8.75	0.625	12.5	G3
2.5	7.5	1.25	25.0	G4
5	5	2.5	50.0	G5
Stock	NA	5.0	100.0	G6

Outline of the method

Adult worker honeybees were fed with a range of test concentrations of the test item dispersed in 50% w/v sucrose in Milli-Q water via glass feeding tubes placed in each age in order to study the effects of the test item on bees. The bee mortality and behavioural changes were observed at 4, 24 and 48 h. The results were compared with the control.

Results and discussions

There was no mortality and behavioural changes in honey bees in the control group as well as in any of the test item concentration of 6.25, 12.5, 25.0, 50.0 and 100.0 µg/bee during 4, 24 and 48 h post treatment.

The percent mortalities for the toxic standard, Dimethoate technical at 4h post treatment was 0.00, 20.00 and 26.67% at tested concentrations of 0.075, 0.15 and 0.30 µg a.s./bee, respectively.

The per cent mortalities for the toxic standard, Dimethoate technical at 24h post treatment were 13.33, 50.00 and 73.33% at the tested concentrations of 0.075, 0.15 and 0.30 µg a.s./bee, respectively.

The percent mortalities for the toxic standard, Dimethoate technical at 48h post treatment were 20.00, 60.00 and 80.00% at the tested concentrations of 0.075, 0.15 and 0.30 µg a.i./been respectively.

The LD_{50} value of the test item, Fenazaquin 200 g/L SC at 24 and 48 h is > 100 µg/bee.

The percent mortalities for the toxic standard, Dimethoate technical at 48 h post treatment were 20.0, 60.0 and 80.0 % at the tested concentrations of 0.075, 0.15 and 0.30 µg a.i./bee, respectively.

The LD_{50} value of the test item, Fenazaquin 200 g/L SC at 24 and 48 h is > 100 µg/bee.
The LD_{50} value of toxic standard, Dimethoate at 24h was 0.17 µg a.i./bee with fiducial limits at 95 per cent ranging from 0.12 to 0.214 µg a.i./bee.
The LD_{50} value of toxic standard, Dimethoate at 48h was 0.14 µg a.i./bee with fiducial limits at 95 per cent ranging from 0.109 to 0.175 µg a.i./bee.
The amount of diet consumed by the bees in different experimental groups, from the initial volume of 200 µL per group of 10 bees, was estimated. While the mean volume of diet consumed in the control group was 193.98 µL and the consumption of diet in the treatment group ranged from 192.99 to 195.06 µL. The mean volume of diet consumed in the toxic standard group at 0.075, 0.15 and 0.30 µg a.i./bee were 192.64, 191.55 and 188.10 µL, respectively.

Conclusion

The LD_{50} value of the test item, Fenazaquin 200 g/L SC at 48 h is > 100 µg/bee.

A 2.3.1.1.3 KCP 10.3.1.1.2 Acute contact toxicity to bees

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