FINAL REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: SHA 9700 B

Product name: RULER 10 EC

Chemical active substance:

Fenazaquin, 100 g/L

Interzonal

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: July 2019

MS Finalisation date: 11/2021 ; 03.2023

Version history

When	What
November 2021	Updated by Applicant
November 2021	Assessmnt after updated by Applicant
March 2023	Final Registration Report

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6 Mammalian Toxicology (KCP 7)

6.1 Summary

Table 6.1-1: Information on Fenazaquin 10% EC*

Product name and code	RULER 10 EC
Formulation type	Emulsifiable Concentrate [Code: EC]
Active substance(s) (incl. content)	Fenazaquin; 100 g/L
Function	insecticide
Product already evaluated as the 'representative formulation' during the approval of the active substance(s)	No
Product previously evaluated in another MS according to Uniform Principles	No

* Information on the detailed composition of Fenazaquin 10% EC can be found in the confidential dRR Part C.

Justified proposals for classification and labelling

According to the criteria given in Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008, the following classification and labelling with regard to toxicological data is proposed for the preparation:

Table 6.1-2: Justified proposals for classification and labelling for Fenazaquin 10% EC according to Regulation (EC) No 1272/2008

Hazard class(es), categories	Acute Tox. 4, Asp. Tox. 1;
Hazard pictograms or Code(s) for hazard pictogram(s)	GHS07, GHS08
Signal word	Danger
Hazard statement(s)	H302, H304
Precautionary statement(s)	P273, P280, P301+P310, P331, P501
Additional labelling phrases	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]
	Repeated exposure may cause skin dryness or cracking. [EUH066]

Table 6.1-3: Summary of risk assessment for operators, workers, residents and bystanders for Fenazaquin 10% EC

	Result	PPE / Risk mitigation measures
Operators	Acceptable	Work wear (arms, body and legs covered) M/L+ gloves M/L ~~and A +RPE (filtertype 2)~~
Workers	Acceptable	Toamto, melon, strawberry - Work wear (arms, body and legs covered) and gloves Ornamentals - Work wear (arms, body and legs covered) and gloves ~~– time period of 4 days after application~~
Residents and Bystanders	Not relevant	None

No unacceptable risk for operators and worker was identified when the product is used as intended and provided that the PPE/ risk mitigation measures stated in Table 6.1-3 are applied.
A summary of the critical uses and the overall conclusion regarding exposure for operators, workers and residents/bystanders is presented in the following table.

Table 6.1-4 Critical uses and overall conclusion of exposure assessment

1	2	3	4	5	6	7	8	9	10			
Use-No.*	**Crops and situation (e.g. growth stage of crop)**	**F, Fn, Fpn G, Gn, Gpn or I ****	**Application**		**Application rate**		**PHI (d)**	**Remarks: (e.g. safener/synergist (L/ha)) critical gap for operator, worker, resident or bystander exposure based on [Exposure model]**	**Acceptability of exposure assessment**			
			Method / Kind (incl. application technique ***	**Max. number (min. interval between applications)**	**Max. application rate kg as/ha Fenazaquin**	**Water L/ha min / max**			**Operator**	**Worker**	**Residents**	**Bystander**
1	Melon (BBCH 70-79)	G	Spraying, LCTM	1 (NA)	0.2	1000	7	-			-	-
2	Ornamentals (BBCH 35-67)	G	Spraying, LCTM	2 (7)	0.2	1000	-	-			-	-
3	Tomato (BBCH 51-89)	G	Spraying, LCTM	2 (7)	0.2	1000	3	-			-	-
4	Strawberry (BBCH 15-91)	G	Spraying, LCTM	2 (7)	0.2	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
*** e.g. LC: low crops, HC: high crop, TM: tractor-mounted, HH: hand-held

Explanation for column 10 "Acceptability of exposure assessment"

A	Exposure acceptable without PPE / risk mitigation measures
R	Further refinement and/or risk mitigation measures required
N	Exposure not acceptable/ Evaluation not possible

6.2 Toxicological Information on Active Substance(s)

Information regarding classification of the active substances and on EU endpoints and critical areas of concern identified during the EU review are given in Table 6.2-1.

Table 6.2-1: Information on active substance(s)

	Fenazaquin
Common Name	Fenazaquin
CAS-No.	120928-09-8
Classification and proposed labelling	
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	**Hazard classes, categories:** Acute tox. 3, Acute Tox. 4 **Codes for hazard pictograms:** GHS06 **Signal word:** Danger **Hazard statements:** H301, H332
Additional C&L proposal	Please insert proposal for additional C&L if no (sufficient) harmonised

	Fenazaquin
	classification is available
Agreed EU endpoints	
AOEL systemic	0.01 mg/kg bw/d
Reference	EFSA Journal 2013;11(4):3166
Conditions to take into account/critical areas of concern with regard to toxicology	
According to EFSA Journal 2013;11(4):3166 for Fenazaquin	None.

6.3 Toxicological Evaluation of Plant Protection Product

The classification of Fenazaquin 10% EC was performed by calculation. When considering the properties of the active ingredient (10% w/w) Fenazaquin 10% EC is classified as a Acute Tox. 3 and Acute Tox. 4. When considering the properties of all co-formulants, Fenazaquin 10% EC is classified as a acute tox with hazard statements H302, H304.

Table 6.3-1: Additional toxicological information relevant for classification/labelling of Fenazaquin 10% EC

	Substance (concentration in product, % w/w)	**Classification of the substance (acc. to the criteria in Reg. 1272/2008)**	**Reference**	**Classification of product (acc. to the criteria in Reg. 1272/2008)**
Toxicological properties of active substance(s) (relevant for classification of product)	Fenazaquin (10% (w/w))	H301, H332	Reg. 1272/2008	H302
Toxicological properties of non-active substance(s) (relevant for classification of product)	co-formulant 1 (>70% w/w)	H304	Reg. 1272/2008, MSDS	H304
Further toxicological information	No data – not required			

* Please use concentration range or concentration limit (e.g. 1-10% or > 1%) as provided in MSDS.
** Material safety data sheet by the applicant

6.4 Toxicological Evaluation of Groundwater Metabolites

All metabolite concentrations are predicted to stay below 0.1 µg/L – no groundwater assessment is required.

6.5 Dermal Absorption (KCP 7.3)

A summary of the dermal absorption rates for the active substances in Fenazaquin 10% EC are presented in the following table.

Table 6.5-1: Dermal absorption rates for active substances in Fenazaquin 10% EC

	Fenazaquin	
	Value	**Reference**
~~Concentrate~~	~~2%~~	~~EFSA Journal 2013;11(4):3166 (based on human study)~~
~~Dilution~~	~~14%~~	~~EFSA Journal 2013;11(4):3166 (based on human study)~~
	Fenazaquin	
	Value	**Reference**
Concentrate	1.4%	New study reported in Appendix 2 – Nabanita Sam, 2021
Dilution	8.7%	New study reported in Appendix 2 - Nabanita Sam, 2021

6.5.1 Justification for proposed values – Fenazaquin

~~No data on dermal absorption for Fenazaquin in Fenazaquin 10% EC is available. Justifications for values according to EFSA Journal 2013;11(4):3166 are presented in the following table~~.

~~**Table 6.5-2: Default dermal absorption rates for Fenazaquin**~~

	~~**Value**~~	~~**Justification for value**~~	~~**Acceptability of justification**~~
~~Concentrate~~	~~2%~~	~~EFSA Journal 2013;11(4):3166~~	~~text~~
~~Dilution~~	~~14%~~		~~text~~

Proposed dermal absorption rates for fenazaquin are based on dermal absorption studies on formulation Fenazaquin 10% EC. The study results are summarised in the following table. Full summaries of studies on the dermal absorption of Fenazaquin 10% EC that have not previously been evaluated within an EU peer review process are described in detail in Appendix 2.

Table 6.5-3: Summary of in vitro human dermal absorption

Test	**Concentrate**	**Spray dilution (dilution concentration)**	**Formulation in study**	**Acceptability of study**	**Justification provided on representativity of study formulation for current product**	**Acceptability of justification**	**Reference***
In vitro (human)	1.4 %	8.7 %	SHA 9700 B/ RULER 10EC	Yes	Yes (see Appendix A 2.10)	Justification accepted. Endpoint can be used for current product / Justification not accepted. Endpoint cannot be used for current product.	Nabanita Sam, 2021

* indicates that a study was reviewed at EU level

6.6 Exposure Assessment of Plant Protection Product (KCP 7.2)

Table 6.6-1: Product information and toxicological reference values used for exposure assessment

Product name and code	Fenazaquin 10% EC
Formulation type	EC (Emulsifiable Concentrate)
Category	Insecticide
Active substance (incl. content)	**Fenazaquin** 100 g/L
AOEL systemic	0.01 mg/kg bw/d
Inhalation absorption	100%
Oral absorption	20%
Dermal absorption	Concentrate: ~~2%~~ 1.4% Dilution: ~~14%~~ 8.7%

6.6.1 Selection of critical use(s) and justification

The critical GAPs used for the exposure assessment of the plant protection product are shown in Table 6.1-4. A list of all intended uses within the zone is given in Part B, Section 0.

6.6.2 Operator exposure (KCP 7.2.1)

6.6.2.1 Estimation of operator exposure

A summary of the exposure models used for estimation of operator exposure to the active substances during application of Fenazaquin 10% EC according to the critical uses is presented in Table 6.6-2. The outcome of the estimation is presented in Table 6.6-3 (longer term exposure). Detailed calculations are in Appendix 3.

Table 6.6-2: Exposure models for intended uses

Critical uses	Fruiting vegetables (melon, tomato) (max. 2 x 1 L product/ha) Low berries (strawberry) (max. 2 x 1 L product/ha) Ornamentals (max. 2 x 1 L product/ha)
Model	Dutch greenhouse model

Table 6.6-3: Estimated operator exposure (longer term exposure) – melon, ornamentals, tomato and strawberry (greenhouse)

		~~**Fenazaquin**~~	
~~**Model data**~~	~~**Level of PPE**~~	~~**Total absorbed dose (mg/kg/day)**~~	~~**% of systemic AOEL**~~
~~Manual Spraying in greenhouses~~			
~~Application rate~~		~~0.2 kg a.s./ha~~	

~~**Spray application** (Dutch Greenhouse model) Body weight: 60 kg~~	~~Without PPE~~	~~5.7000~~	~~**967**~~
	~~Work wear (arms, body and legs covered) M/L+ gloves M/L and A +RPE (filtertype 2)~~	~~0.8400~~	~~**97**~~

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

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

The Applicant has added the calculations using the own DA study. Please refer to point A 2.10 for details about dermal absorption values.

Table 6.6-4: Estimated operator exposure (longer term exposure) – melon, ornamentals, tomato and strawberry (greenhouse)

		Fenazaquin	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Manual Spraying in greenhouses			
Application rate		0.2 kg a.s./ha	
Spray application (Dutch Greenhouse model) Body weight: 60 kg	Without PPE	3.6800	**613**
	Work wear (arms, body and legs covered) M/L+ gloves M/L	0.5480	**91**

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

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

Conclusion is acceptable after reevaluation

6.6.2.2 Measurement of operator exposure

Since the operator exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses and consideration of the above mentioned personal protective equipment (PPE), a study to provide measurements of operator exposure was not necessary and was therefore not performed.

6.6.3 Worker exposure (KCP 7.2.3)

6.6.3.1 Estimation of worker exposure

Table 6.6-5 shows the exposure model used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with Fenazaquin 10% EC according to the critical uses. Outcome of the estimation is presented in Table 6.6-6 (longer term exposure). Detailed calculations are in Appendix 3.

Table 6.6-5: Exposure models for intended uses

Critical uses	Fruiting vegetables (melon, tomato) (max. 2 x 1 L product/ha) Low berries (strawberry) (max. 2 x 1 L product/ha) Ornamentals (max. 2 x 1 L product/ha)
Model	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874; calculator version: 30/03/2015

~~**Table 6.6-6: Estimated worker exposure (longer term exposure) melon and tomato (greenhouse)**~~

		Fenazaquin	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Reaching, picking /Indoor Work rate: 8 hours/day, DT_{50}: 30 days DFR: 0.85 µg/cm²/kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		2 x 0.2 kg a.s./ha	
Body weight: 60 kg	Potential TC: 5800 cm²/person/h	0.0340624	341
	Work wear (arms, body and legs covered) TC: 2500 cm²/person/h	0.0146820	147
	Work wear (arms, body and legs covered) and gloves TC: 580 cm²/person/h	0.0034062	**34**

Table 6.6-7: Estimated worker exposure (longer term exposure) strawberries (field and greenhouse)

		Fenazaquin	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Reaching, picking /Indoor Work rate: 8 hours/day, DT_{50}: 30 days DFR: 0.85 µg/cm²/kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		2 x 0.2 kg a.s./ha	
Body weight: 60 kg	Potential TC: 5800 cm²/person/h	0.0340621	341
	Work wear (arms, body and legs covered) TC: 3000 cm²/person/h	0.0176184	176
	Work wear (arms, body and legs covered) and gloves TC: 750 cm²/person/h	0.0044046	**44**

Table 6.6-8: Estimated worker exposure (longer term exposure) – ornamentals (green-house)

		Fenazaquin	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Cutting, sorting, bundling, carrying/ Indoor Work rate: 8 hours/day, DT_{50}: 30 days DFR: 0.85 µg/cm²/kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		2 x 0.2 kg a.s./ha	
Body weight: 60 kg	Potential TC: 14000 cm²/person/h	0.0848856	849
	Work wear (arms, body and legs covered) TC: 5000 cm²/person/h	0.0320306	320
	Work wear (arms, body and legs covered) and gloves TC: 1400 cm²/person/h	0.0108886	109
Proposal of Re-entry period of 4 days Cutting, sorting, bundling, carrying/ Indoor Work rate: 8 hours/day, DT_{50}: 30 days DFR: 0.75 µg/cm²/kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		2 x 0.2 kg a.s./ha	
Body weight: 60 kg	Potential TC: 14000 cm²/person/h	0.0752128	752
	Work wear (arms, body and legs covered) TC: 5000 cm²/person/h	0.0285760	286
	Work wear (arms, body and legs covered) and gloves TC: 1400 cm²/person/h	0.0099213	**99**

The Applicant has added the calculations using the own DA study. Please refer to point A 2.10 for details about dermal absorption values.

Table 6.6-9: Estimated worker exposure (longer term exposure) – melon and tomato (green-house)

		Fenazaquin	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Reaching, picking /Indoor Work rate: 8 hours/day, DT_{50}: 30 days DFR: 0.85 µg/cm²/kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		2 x 0.2 kg a.s./ha	
Body weight: 60 kg	Potential TC: 5800 cm²/person/h	0.0211672	212
	Work wear (arms, body and legs covered) TC: 2500 cm²/person/h	0.0091238	91
	Work wear (arms, body and legs covered) and gloves TC: 580 cm²/person/h	0.0021167	**21**

Table 6.6-10: Estimated worker exposure (longer term exposure) – strawberries (field and greenhouse)

		Fenazaquin	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Reaching, picking /Indoor Work rate: 8 hours/day, DT_{50}: 30 days DFR: 0.85 µg/cm²/kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		2 x 0.2 kg a.s./ha	
Body weight: 60 kg	Potential TC: 5800 cm²/person/h	0.0211672	212
	Work wear (arms, body and legs covered) TC: 3000 cm²/person/h	0.0109485	109
	Work wear (arms, body and legs covered) and gloves TC: 750 cm²/person/h	0.0027371	**27**

Table 6.6-11: Estimated worker exposure (longer term exposure) – ornamentals (green-house)

		Fenazaquin	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Cutting, sorting, bundling, carrying/ Indoor Work rate: 8 hours/day, DT_{50}: 0.85 days DFR: 3 µg/cm²/kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		2 x 0.2 kg a.s./ha	
Body weight: 60 kg	Potential TC: 14000 cm²/person/h	0.0537599	538
	Work wear (arms, body and legs covered) TC: 5000 cm²/person/h	0.0209142	209
	Work wear (arms, body and legs covered) and gloves TC: 1400 cm²/person/h	0.0077760	**78**

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

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

6.6.3.2 Refinement of generic DFR value (KCP 7.2)

A proposal to refine the DFR was made in DAR Fenazaquin -Volume3, Annex B-7: Residue data.
Based on the conclusions concerning the Residue Section, the PHI are either 35 or 28 days depending on the crop, while the DFR varied from 0.36 µg/cm² (directly after application) and 0.19 µg/cm² (1 day post application) to 0.17 µg/cm² (7 days post application) based on a DFR study performed in apple seedlings (application rate 0.12 kg a.s/ha, 400L/h water volume) (DAR, Point B.7.10).

According to this model the dermal exposure can be estimated from the dislodgeable foliar residues which are adjusted 0.2 kg a.s/ha. Therefore, the DFR values of 0.17 µg/cm² obtained for 0.12 kg a.s/ha directly and 7 days post application, were adjusted to 0.85 µg/cm² , respectively.

For the refinement of the worker exposure, the value of DFR values was taken, i.e. 0.85 µg/cm²/kg a.s. applied.

~~**Refinement**~~

~~Proposal of Re-entry period~~

~~The Applicant propose to consider as refinement a re-entry period of 26 days. Therefore we propose to calculate DFR value at 26 days for ornamentals.~~

~~Body weight 60 kg.~~

~~For this calculation DT_{50} value of 30 days.~~

~~DFR_t is calculated according the following formula:~~

$$DFR_T = DFR_0 \times e^{-k,t}$$

~~Where:~~

~~DFR_T – Dislodgeable foliar residue at the time of re-entry (µg/cm²)~~

~~DFR_0 – Dislodgeable foliar residue just after application (µg/cm²)~~

~~k – Degradation constant (days $^{-1}$), calculated from the half life time:~~

~~$k = ln(2)/DT_{50}$,~~

~~DT_{50} – Foliar half-life time (days)~~

~~t – Re-entry interval (days)~~

~~– Dislodgeable foliar residue just after application is calculated as:~~

~~$DFR_0 = DFR_{def} \times MAF$~~

~~– Where:~~

~~DFR_{def} default value (If no DFR data for the specific compound are available, a conservative default value for the DFR may be taken as 3 µg/cm² per kg s.a/ha)~~

~~MAF_m (multiple application factor for mean residue data for *n* application) is:~~

~~$MAF = (1-e^{nki})/(1-e^{ki})$~~

~~where:~~

~~n is the number of applications~~
~~k is the rate constant for foliar dissipation $k = ln(2)/DT_{50}$,~~
~~i is the interval between applications (days)~~

~~DFR factor was calculated for every crop based on above formula and according to the EFSA Journal 2014;12(10):3874[1], corresponding to a half life $_{foliar}$ of 30 days.~~

~~Ornamentals:~~

~~For ornamentals, a number of 2 applications (n) and a 7 day interval (i) between applications is considered (worst case scenario) and MAF is 1.9. The following DFR value is calculated:~~

~~$DFR_0 = DFR_{def} \times 1.9 = 1.62$ µg/cm² (where $DFR_{def} = 0.85$ µg/cm² per kg s.a/ha)~~

~~Therefore for 4 days of re-entry interval:~~

~~$DFR_T = DFR_0 \times e^{-k,t} = 1.62$ µg/cm² $\times$ 0.883 = 1.43 µg/cm²~~

~~Therefore for $DFR_T = DFR_{def\,ref} \times MAF = 1.43$ µg/cm² the $DFR_{def\,ref} = 0.75$ µg/cm² per kg s.a/ha~~

6.6.3.3 Measurement of worker exposure

Since worker exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) was exceeded under conditions of intended uses / Since there are no representative data in available calculation models, a field study measuring the worker exposure needs to be provided.

6.6.4 Resident and bystander exposure (KCP 7.2.2)

6.6.4.1 Estimation of resident and bystander exposure

Melon, ornamentals, tomato and strawberry (greenhouse):

[1] Guidance of EFSA (EFSA Journal 2014;12(10):3874): "Guidance on the assessment of exposure of operators. workers. residents and bystanders in risk assessment for plant protection products"

Since the ornamentals use is intended for greenhouse, estimation of resident and bystander exposure after application of Fenazaquin 10% EC is not necessary taking into account that applications into confined areas will lead to an insignificant risk of expositions or residents and bystanders. Therefore, the use of Fenazaquin 10% EC on melon, ornamentals, tomato and strawberry is considered as negligible/acceptable.

The conclusion is acceptable

6.6.4.2 Measurement of resident and/or bystander exposure

Not relevant.

6.6.5 Combined exposure

Not relevant. The product contains only one active substance.

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

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

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 studies relied upon

A 2.1 Statement on bridging possibilitie

The classification of Fenazaquin 10% EC was performed by calculation. The assessment of all acute toxicological properties of Fenazaquin 10% EC are derived from the classification of the active compound and co-formulants as shown below. For obvious confidentiality reasons, the names and percentages of co-formulants are disclosed in Part C:

Formulant	% of formulation	Acute Oral Toxicity	Acute Dermal Toxicity	Acute Inhalation Toxicity	Dermal Irritation	Ocular Irritation	Sensitising potential
Fenazaquin Technicall	**10.89**	134 mg/kg	> 5000 mg/kg	> 1.9 mg/l	Not Irritating[1)]	Not Irritating[1)]	Not sensitising[1)]
Coformulant 1	**xxx**	> 2000 mg/kg[1)]	> 2000 mg/kg[1)]	*Not classified	Not Irritating[1)]	Not Irritating[1)]	Not sensitising[1)]
Coformulant 2	**xxx**	> 2000 mg/kg[1)]	> 2000 mg/kg[1)]	*Not classified	Not Irritating[1)]	Not Irritating[1)]	Not sensitising[1]
Coformulant 3	**xxx**	> 5000 mg/kg	> 2000 mg/kg[1)]	> 4688 mg/m^3 Not classified	Not Irritating[1)]	Not Irritating[1)]	Not sensitising[1]

* No Information / but in their MSDS are not classified acutely inhalation toxic
[1)] As co-formulant is not classified

According to Regulation (EC) No 1272/2008 classification of mixtures based on ingredients of the mixture is determined by calculation from the ATE values:

$$\frac{100}{ATE_{mix}} = \sum_{r} \frac{C_i}{ATE_i}$$

$$\frac{100 - (\sum C_{unknown} if > 10\%)}{ATE_{mix}} = \sum_{r} \frac{C_i}{ATE_i}$$

where:
C_i = concentration of ingredient i (% w/w or % v/v)
i = the individual ingredient from 1 to n
n = the number of ingredients

A 2.2 Acute oral toxicity (KCP 7.1.1)

Comments of zRMS:	**According to the Regulation EC No. 1272/2008, using worse results from calculations, Fenazaquin 10% EC should be classified for oral toxicity.** **Therefore the classification is "H302: Harmful by swallow".**

The acute oral toxicity classification for Fenazaquin 10% EC: was calculated:

$$ATE_{mix} = \frac{100}{\sum_r \frac{C_i}{ATE_i}}$$

$$ATE_{mix} = \frac{100\%}{\frac{10.89\%}{134}} = 1231 \frac{mg}{kg}$$

Details of the co-formulants and their classification and the calculation methodology that was used to assess the acute oral toxicity of Fenazaquin 10% EC can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

Conclusion
The acute oral toxicity calculation for Fenazaquin 10% EC was estimated to be 1231 mg/kg, Fenazaquin 10% EC therefore should be classified as harmful by swallow.

According to the Regulation EC No. 1272/2008, using worse results from calculations, Fenazaquin 10% EC should be classified for oral toxicity. Therefore the Signal Word "**Warning**" and the Hazard Statement "**H302: Harmful by swallow**" are proposed.

A 2.3 Acute percutaneous (dermal) toxicity (KCP 7.1.2)

Comments of zRMS:	**There is no co-formulant in the Fenazaquin 10% EC recipe classified as danger through dermal contact.** **Therefore according to the Regulation EC No. 1272/2008, Fenazaquin 10% EC is not classified.**

There is no co-formulant in the Fenazaquin 10% EC recipe classified as danger through dermal contact.

According to the Regulation EC No. 1272/2008, Fenazaquin 10% EC is **not classified**. No signal word or hazard statement is required for this hazard.

A 2.4 Acute inhalation toxicity (KCP 7.1.3)

Comments of zRMS:	**The acute inhalation toxicity of Fenazaquin 10% EC was estimated to be 17.5 mg/l.** **Therefore according to the Regulation EC No. 1272/2008, Fenazaquin 10% EC is not classified**

Acute inhalation toxicity classification for Fenazaquin 10% EC was calculated:

$$ATE_{mix} = \frac{100 - (\sum C_{unknown} if > 10\%)}{\sum_r \frac{C_i}{ATE_i}}$$

$$ATE_{mix} = \frac{100\%}{\frac{10.89\%}{1.9}} = 17.5\ \frac{mg}{l}$$

The acute inhalation toxicity of Fenazaquin 10% EC was estimated to be 17.5 mg/l. Under the GHS classification system this component does not trigger the value of the classification according to Regu-lation (EC) no. 1272/2008.

Conclusion

According to the Regulation EC No. 1272/2008, Fenazaquin 10% EC is **not classified**. No signal word or hazard statement is required.

A 2.5 Skin irritation (KCP 7.1.4)

Comments of zRMS:	**There is no co-formulant in the Fenazaquin 10% EC recipe classified as skin corrosion or irritant.** **Therefore according to the Regulation EC No. 1272/2008, Fenazaquin 10% EC is not classified**

There is no co-formulant in the Fenazaquin 10% EC recipe classified as skin corrosion or irritant.

According to the Regulation EC No. 1272/2008, Fenazaquin 10% EC is **not classified**. No signal word or hazard statement is required for this hazard.

A 2.6 Eye irritation (KCP 7.1.5)

Comments of zRMS:	**There is no co-formulant in the Fenazaquin 10% EC recipe classified as eye damage or irritation.** **Therefore according to the Regulation EC No. 1272/2008, Fenazaquin 10% EC is not classified.**

There is no co-formulant in the Fenazaquin 10% EC recipe classified as eye damage or irritation.

According to the Regulation EC No. 1272/2008, Fenazaquin 10% EC is **not classified**. No signal word or hazard statement is required for this hazard.

A 2.7 Skin sensitisation (KCP 7.1.6)

Comments of zRMS:	**There is no co-formulant in the Fenazaquin 10% EC recipe classified as skin sensitisation.** **Therefore according to the Regulation EC No. 1272/2008, Fenazaquin 10% EC is not classified**

There is no co-formulant in the Fenazaquin 10% EC recipe classified as skin sensitisation.

According to the Regulation EC No. 1272/2008, Fenazaquin 10% EC is **not classified**. No signal word or hazard statement is required for this hazard.

A 2.8 Supplementary studies for combinations of plant protection products (KCP 7.1.7)

A 2.9 Data on co-formulants (KCP 7.4)

A 2.9.1 Material safety data sheet for each co-formulant

Information regarding material safety data sheets of the co-formulants can be found in the confidential dossier of this submission (Registration Report - Part C).

A 2.9.2 Available toxicological data for each co-formulant

Available toxicological data for each co-formulant can be found in the confidential dossier of this submission (Registration Report - Part C).

A 2.10 Studies on dermal absorption (KCP 7.3)

~~A dermal absorption of 2% for the undiluted formulation and 14% for the spray dilution was considered based on a human study (Shaw, D., 2007)~~

Dermal absorption to Fenazaquin 10 % EC, **was not** evaluated as part of the EU review of Fenazaquin. Therefore, all relevant data and risk assessments are provided here and are considered adequate.

A 2.10.1 Study 1 – Fenazaquin 10 % EC in Fenazaquin 10 % EC

A 2.10.2 Comparative dermal absorption, in vitro using rat and human skin

Reference	KCP 7.6.2
Report	In vitro percutaneous dermal absorption study of Fenazaquin 100 g/L EC, through human skin, Nabanita Sam, 2021, G21266
Guideline(s)	OECD Guideline 428 “Skin Absortion: in vitro Method” April 2004
Deviations	Yes
GLP	Yes
Acceptability	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test material	Name (Lot/Batch No.)	^{14}C-Fenazaquin (TJIOS-NB80-162)
	Test preparation	radioformulation
	Specific activity	59.1 mCi/mmol
	Radiochemical purity	99.9 %
Product	Name (Lot/Batch No.)	Fenazaquin 10 g/L EC (SCL-52020)
	Company code	Fenazaquin

	Concentration a.s.	100 g.L-1
	Formulation type	Fenazaquin 10 g/L EC
Blank product	Name (Lot/Batch No.)	Fenazaquin 10% EC blank formulation (SCL-11265)
	Concentration a.s.	0 g/L

Test system		
Diffusion cell	Cell type	dynamic
	(if dynamic) Flow rate	1.8 mL/hr
	Exposed skin area	0.64 cm^2
Membrane	Skin type	isolated epidermis
	Skin thickness range	0.2-0.4 mm
	Skin donors age	38, 34, 35, 35 years
	Skin donors sex	female
	Location	abdomen
	Source	post-mortem
	Integrity test	yes
Receptor	Receptor medium	Phosphate buffered saline (PBS) + 0.01% sodium azide +6% polyoxybutylene-20-oleyl ether (PEG), pH *ca.* 7.3
	Solubility in receptor medium	Yes
Sample Time	Exposure time	8 h
	Observation time	16 h
Sampling	Sample intervals	At 0-1 h, 1-2 h, followed by 2-h intervals until 24 hours after application
Washing		At 8 h using water and a mild soap solution (3% Dove)
Final Procedure	Tape stripping	y
	TS1-2 analysed separately	y

Tested doses	Concentrate	Spray dilution
Target concentration	100 $g \cdot L^{-1}$	0.2 $g \cdot L^{-1}$
Area dose	1005.84 µg/cm^2	2.00 µg/cm^2
Specific activity	3.704 $MBq.mL^{-1}$	1.4698 $MBq.mL^{-1}$
No. of donors	4	4
No of cells used/valid cells*	8/8	8/8

Results and discussions - Fenazaquin

Dose group	High dose (Formulation concentrate)		Low dose (Spray dilution 1:500)	
Target concentration	100 $g \cdot L^{-1}$		0.2 $g \cdot L^{-1}$	
Mean actual applied dose	1005.84 µg/cm^2		2.00 µg/cm^2	
Number of replicates (n)	8		8	
	Mean	S.D.	Mean	S.D.
Dislodgeable dose				
Skin wash	97.51	1.57	87.33	1.76
Donor chamber wash	0.59	0.50	4.18	1.26
Dose associated to skin				
Tape strips: 1st sample, strips 1 + 2	0.45	0.12	1.94	0.20
Tape strips: 2nd sample; strips 3 - n	0.64	0.13	3.70	0.17
Skin preparation	0.32	0.08	3.89	0.22
Absorbed dose				

Receptor fluid	0.30	0.05	0.57	0.09
Receptor chamber wash	0.03	0.01	0.35	0.08
Total recovery[1]	99.84	1.88	101.96	0.77
Absorption essentially complete at end of study (>75% absorption within half the study duration) [%Absorption at $t_{0.5}$]	No [62.96%]		No [53.05%]	
If no: Absorption estimates = absorbed dose + skin preparation + tape strips sample 2)[2]	1.29	0.09	8.52	0.11
If yes: Absorption estimates = absorbed dose + skin preparation	N/A	N/A	N/A	N/A
Absorption estimate considering variability[3] (Absorption (mean value) + ks)	1.29 ± 0.84 × 0.09		8.52 ± 0.84 × 0.11	
Relevant absorption estimate	1.3656		8.6124	
Absorption estimates [4]	**1.4**		**8.7**	

[1] Values may not calculate exactly due to rounding of figures

[2] In accordance with the EFSA Guidance on Dermal Absorption (EFSA Journal 2017;15(6):4873) the radioactivity in the second tape-strip pool (3rd to nth tape strip) is considered potentially absorbable if less than 75% of the absorption occurred in the first half of the study (see Table 7.6.2-1) Finally, the skin preparation is also considered potentially absorbable.

[3] In accordance with the EFSA Guidance on Dermal Absorption (2017), dermal absorption should be calculated as follows: Absorption (mean value) + ks, where s is the sample standard deviation. The multiplication factor required depends on the number of replicates and is given in Table 1 of EFSA Guidance.

[4] Relevant absorption estimate was rounded to the required number of significant figures.

N/A: not applicable

Conclusion/endpoint:

1.4 % of dose for undiluted Fenazaquin formulation (concentrate: 100 g/al) Fenazaquin)

8.7 % of dose for actual spray strength used in the field dilution (0.2 g/L Fenazaquin)

A 2.11 Other/Special Studies

Appendix 3 Exposure calculations

A 3.1 Operator exposure calculations (KCP 7.2.1.1)

A 3.1.1 Calculations for Fenazaquin

Table A 1: Dutch greenhouse model for the estimation of operator exposure – melon, ornamentals, tomato and strawberry (greenhouse)

OPERATOR EXPOSURE			**DUTCH GREENHOUSE MODEL**	
form			Application including mixing and loading	
a.s.	Fenazaquin			
Parameter		**Value**	**Unit**	**References, comments**
MANUAL SPRAYING in greenhouses				
AR	Application rate	0,2	kg a.s./ha	summary of intended uses
A	Area treated	1	ha/ day	Dutch model
Inhalation Exposure				without PPE
SV	Surrogate Exposure Value	1	mg a.s./ kg a.s.	For dusting see note* (Dutch model)
Inhalation Exposure (without PPE)		**0,2**	mg a.s./ day	IE = SV x AR x A
Inhalation Exposure (with PPE)				with PPE
	PPE-factor	10		Non-powered mask filtertype 2 (most conservative): 10; more advanced RPE: see note** (Dutch model)
Inhalation Exposure (with PPE)		**0,02**	mg a.s./ day	IE(PPE) = (1/PPE factor) x IE
Dermal Exposure				without PPE
SV	Surrogate Exposure Value	200	mg a.s./ kg a.s.	For dusting see note* (Dutch model)
Dermal Exposure		**40**	mg a.s./ day	DE = SV x AR x A
Dermal Exposure (with PPE)				with PPE
	PPE-factor	10		Gloves + coverall: 10 (Dutch model)
Dermal Exposure (with PPE)		**4**	mg a.s./ day	DE(PPE) = (1/PPE-factor) x DE
Internal exposure				
IA	Inhalation Absorption	100	%	
DA	Dermal Absorption	14	%	
	AOEL	0,6	mg a.s./ day	based on 60 kg bw
		Without PPE	**With PPE**	
	Internal exposure	[mg a.s. / day]	[mg a.s. / day]	
	Inhalation	0,2000	0,0200	IE(int) = IE x (IA/100)
	Dermal	5,6000	0,5600	DE(int) = DE x (DA/100)
	Total	**5,8000**	**0,5800**	**sum**
	% AOEL			
	Inhalation	33	3	%AOEL = 100 x IE(int) / AOEL
	Dermal	933	93	%AOEL = 100 x DE(int) / AOEL
	Total	**967**	**97**	**sum**

OPERATOR EXPOSURE			**DUTCH GREENHOUSE MODEL**	
form			Application including mixing and loading	
a.s.	Fenazaquin			
Parameter		**Value**	**Unit**	**References, comments**
MANUAL SPRAYING in greenhouses				
AR	Application rate	0,2	kg a.s./ha	summary of intended uses
A	Area treated	1	ha/ day	Dutch model
Inhalation Exposure				without PPE
SV	Surrogate Exposure Value	1	mg a.s./ kg a.s.	For dusting see note* (Dutch model)
Inhalation Exposure (without PPE)		**0,2**	mg a.s./ day	IE = SV x AR x A
Inhalation Exposure (with PPE)				with PPE
	PPE-factor	1		Non-powered mask filtertype 2 (most conservative): 10; more advanced RPE: see note** (Dutch model)
Inhalation Exposure (with PPE)		**0,2**	mg a.s./ day	IE(PPE) = (1/PPE factor) x IE
Dermal Exposure				without PPE
SV	Surrogate Exposure Value	200	mg a.s./ kg a.s.	For dusting see note* (Dutch model)
Dermal Exposure		**40**	mg a.s./ day	DE = SV x AR x A
Dermal Exposure (with PPE)				with PPE
	PPE-factor	10		Gloves + coverall: 10 (Dutch model)
Dermal Exposure (with PPE)		**4**	mg a.s./ day	DE(PPE) = (1/PPE-factor) x DE
Internal exposure				
IA	Inhalation Absorption	100	%	
DA	Dermal Absorption	8,7	%	
	AOEL	0,6	mg a.s./ day	based on 60 kg bw
		Without PPE	**With PPE**	
	Internal exposure	[mg a.s. / day]	[mg a.s. / day]	
	Inhalation	0,2000	0,2000	IE(int) = IE x (IA/100)
	Dermal	3,4800	0,3480	DE(int) = DE x (DA/100)
	Total	**3,6800**	**0,5480**	**sum**
	% AOEL			
	Inhalation	33	33	%AOEL = 100 x IE(int) / AOEL
	Dermal	580	58	%AOEL = 100 x DE(int) / AOEL
	Total	**613**	**91**	**sum**

A 3.2 Worker exposure calculations (KCP 7.2.3.1)

A 3.2.1 Calculations for Fenazaquin

Table A 2: Input parameters considered for the estimation of worker exposure – melon and tomato (greenhouse)

Worker exposure from residues on foliage for			
Crop type	Fruiting vegetables		
Indoor or outdoor	Indoor		
Application method	Spray application		
Application equipment	0		
Worker's task	Reaching, picking		
Main body parts in contact with foliage	Hand and body		
Application rate of active substance	0,2	kg a.s./ha	*i_AppRate*
Number of applications	2		*i_AppNo*
Interval between multiple applications	7	days	*i_AppInt*
Half-life of active substance	30	days	*d_HalflifeAS*
Multiple application factor	1,9		*d_MAF*
Dermal absorption of the product	2,00%		*i_AbsorpProduct*
Dermal absorption of the in-use dilution	14,00%		*i_AbsorpInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,17	µg a.s./cm^2	*d_DFR*
Working hours	8	hr	*d_WorkHr*
Dermal transfer coefficient - Total potential exposure	5800	cm^2/hr	*d_DermTcUCV*
Dermal transfer coefficient - arms, body and legs covered	2500	cm^2/hr	*d_DermTcCV1*
Dermal transfer coefficient - hands, arms, body and legs covered	580	cm^2/hr	*d_DermTcCV2*
Inhalation transfer coefficient for automated applications	NA	ha/hr*10^(-3)	*d_InhalTcAut*
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10^(-3)	*d_InhalTcCut*
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10^(-3)	*d_InhalTcSort*

Worker exposure from residues on foliage for			
Crop type	Fruiting vegetables		
Indoor or outdoor	Indoor		
Application method	Spray application		
Application equipment	0		
Worker's task	Reaching, picking		
Main body parts in contact with foliage	Hand and body		
Application rate of active substance	0,2	kg a.s./ha	*i_AppRate*
Number of applications	2		*i_AppNo*
Interval between multiple applications	7	days	*i_AppInt*
Half-life of active substance	30	days	*d_HalflifeAS*
Multiple application factor	1,9		*d_MAF*
Dermal absorption of the product	1,40%		*i_AbsorpProduct*
Dermal absorption of the in-use dilution	8,70%		*i_AbsorpInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,17	µg a.s./cm^2	*d_DFR*
Working hours	8	hr	*d_WorkHr*
Dermal transfer coefficient - Total potential exposure	5800	cm^2/hr	*d_DermTcUCV*
Dermal transfer coefficient - arms, body and legs covered	2500	cm^2/hr	*d_DermTcCV1*
Dermal transfer coefficient - hands, arms, body and legs covered	580	cm^2/hr	*d_DermTcCV2*
Inhalation transfer coefficient for automated applications	NA	ha/hr*10^(-3)	*d_InhalTcAut*
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10^(-3)	*d_InhalTcCut*
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10^(-3)	*d_InhalTcSort*

Table A 3: Estimation of longer-term worker exposure towards Fenazaquin according to EFSA guidance – melon and tomato (greenhouse)

1. Total

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
~~Total systemic exposure (mg a.s./day)~~	~~2,0437288~~	~~0,8809176~~	~~0,2043729~~
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0340621	0,0146820	0,0034062
% of RVNAS	340,62%	146,82%	34,06%

1. Total

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	1,2700314	0,5474273	0,1270031	
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0211672	0,0091238	0,0021167	
% of RVNAS	211,67%	91,24%	21,17%	

Table A 4: Input parameters considered for the estimation of worker exposure - strawberry (greenhouse)

Worker exposure from residues on foliage for			
Crop type	Low berries and other small fruits		
Indoor or outdoor	Indoor		
Application method	Spray application		
Application equipment	0		
Worker's task	Reaching, picking		
Main body parts in contact with foliage	Hand and forearm		
Application rate of active substance	0,2	kg a.s./ha	*i_AppRate*
Number of applications	2		*i_AppNo*
Interval between multiple applications	7	days	*i_AppInt*
Half-life of active substance	30	days	*d_HalflifeAS*
Multiple application factor	1,9		*d_MAF*
Dermal absorption of the product	2,00%		*i_AbsorpProduct*
Dermal absorption of the in-use dilution	14,00%		*i_AbsorpInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,17	µg a.s./cm^2	*d_DFR*
Working hours	8	hr	*d_WorkHr*
Dermal transfer coefficient - Total potential exposure	5800	cm^2/hr	*d_DermTcUCV*
Dermal transfer coefficient - arms, body and legs covered	3000	cm^2/hr	*d_DermTcCV1*
Dermal transfer coefficient - hands, arms, body and legs covered	750	cm^2/hr	*d_DermTcCV2*
Inhalation transfer coefficient for automated applications	NA	ha/hr*10^(-3)	*d_InhalTcAut*
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10^(-3)	*d_InhalTcCut*
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10^(-3)	*d_InhalTcSort*

Worker exposure from residues on foliage for			
Crop type	Low berries and other small fruits		
Indoor or outdoor	Indoor		
Application method	Spray application		
Application equipment	0		
Worker's task	Reaching, picking		
Main body parts in contact with foliage	Hand and forearm		
Application rate of active substance	0,2	kg a.s./ha	*i_AppRate*
Number of applications	2		*i_AppNo*
Interval between multiple applications	7	days	*i_AppInt*
Half-life of active substance	30	days	*d_HalflifeAS*
Multiple application factor	1,9		*d_MAF*
Dermal absorption of the product	1,40%		*i_AbsorpProduct*
Dermal absorption of the in-use dilution	8,70%		*i_AbsorpInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,17	µg a.s./cm^2	*d_DFR*
Working hours	8	hr	*d_WorkHr*
Dermal transfer coefficient - Total potential exposure	5800	cm^2/hr	*d_DermTcUCV*
Dermal transfer coefficient - arms, body and legs covered	3000	cm^2/hr	*d_DermTcCV1*
Dermal transfer coefficient - hands, arms, body and legs covered	750	cm^2/hr	*d_DermTcCV2*
Inhalation transfer coefficient for automated applications	NA	ha/hr*10^(-3)	*d_InhalTcAut*
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10^(-3)	*d_InhalTcCut*
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10^(-3)	*d_InhalTcSort*

Table A 5: Estimation of longer-term worker exposure towards Fenazaquin according to EFSA guidance - strawberry (greenhouse)

1. Total			
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
~~Total systemic exposure (mg a.s./day)~~	~~2,0437288~~	~~1,0571011~~	~~0,2642753~~
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0340621	0,0176184	0,0044046
% of RVNAS	340,62%	176,18%	44,05%

1. Total				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	1,2700314	0,6569128	0,1642282	
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0211672	0,0109485	0,0027371	
% of RVNAS	211,67%	109,49%	27,37%	

Table A 6: Input parameters considered for the estimation of worker exposure – ornamentals (greenhouse)

Worker exposure from residues on foliage for			
Crop type	Ornamentals		
Indoor or outdoor	Indoor		
Application method	Spray application		
Application equipment	0		
Worker's task	Cutting, sorting, bundling, carrying		
Main body parts in contact with foliage	Hand and body		
Application rate of active substance	0,2	kg a.s./ha	*i_AppRate*
Number of applications	2		*i_AppNo*
Interval between multiple applications	7	days	*i_AppInt*
Half-life of active substance	30	days	*d_HalflifeAS*
Multiple application factor	1,9		*d_MAF*
Dermal absorption of the product	2,00%		*i_AbsorpProduct*
Dermal absorption of the in-use dilution	14,00%		*i_AbsorpInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,17	µg a.s./cm^2	*d_DFR*
Working hours	8	hr	*d_WorkHr*
Dermal transfer coefficient - Total potential exposure	14000	cm^2/hr	*d_DermTcUCV*
Dermal transfer coefficient - arms, body and legs covered	5000	cm^2/hr	*d_DermTcCV1*
Dermal transfer coefficient - hands, arms, body and legs covered	1400	cm^2/hr	*d_DermTcCV2*
Inhalation transfer coefficient for automated applications	NA	ha/hr*10^(-3)	*d_InhalTcAut*
Inhalation transfer coefficient for cutting ornamentals	0,1	ha/hr*10^(-3)	*d_InhalTcCut*
Inhalation transfer coefficient for sorting / bundling ornamentals	0,01	ha/hr*10^(-3)	*d_InhalTcSort*

Worker exposure from residues on foliage for			
Crop type	Ornamentals		
Indoor or outdoor	Indoor		
Application method	Spray application		
Application equipment	0		
Worker's task	Cutting, sorting, bundling, carrying		
Main body parts in contact with foliage	Hand and body		
Application rate of active substance	0,2	kg a.s./ha	*i_AppRate*
Number of applications	2		*i_AppNo*
Interval between multiple applications	7	days	*i_AppInt*
Half-life of active substance	30	days	*d_HalflifeAS*
Multiple application factor	1,9		*d_MAF*
Dermal absorption of the product	1,40%		*i_AbsorpProduct*
Dermal absorption of the in-use dilution	8,70%		*i_AbsorpInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,17	µg a.s./cm^2	*d_DFR*
Working hours	8	hr	*d_WorkHr*
Dermal transfer coefficient - Total potential exposure	14000	cm^2/hr	*d_DermTcUCV*
Dermal transfer coefficient - arms, body and legs covered	5000	cm^2/hr	*d_DermTcCV1*
Dermal transfer coefficient - hands, arms, body and legs covered	1400	cm^2/hr	*d_DermTcCV2*
Inhalation transfer coefficient for automated applications	NA	ha/hr*10^(-3)	*d_InhalTcAut*
Inhalation transfer coefficient for cutting ornamentals	0,1	ha/hr*10^(-3)	*d_InhalTcCut*
Inhalation transfer coefficient for sorting / bundling ornamentals	0,01	ha/hr*10^(-3)	*d_InhalTcSort*

Table A 7: Estimation of longer-term worker exposure towards Fenazaquin according to EFSA guidance – ornamentals (greenhouse)

1. Total

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
~~Total systemic exposure (mg a.s./day)~~	~~5,0931384~~	~~1,9218351~~	~~0,6533138~~
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0848856	0,0320306	0,0108886
% of RVNAS	848,86%	320,31%	108,89%

1. Total

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	3,2255931	1,2548547	0,4665593	Calculation is based on inhalation exposure of task with the higher value
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0537599	0,0209142	0,0077760	
% of RVNAS	537,60%	209,14%	77,76%	

~~Table A 8: Input parameters considered for the estimation of worker exposure – ornamentals (greenhouse) for re-entry 4 days~~

Worker exposure from residues on foliage for			
Crop type	Ornamentals		
Indoor or outdoor	Indoor		
Application method	Spray application		
Application equipment	0		
Worker's task	Cutting, sorting, bundling, carrying		
Main body parts in contact with foliage	Hand and body		
Application rate of active substance	0,2	kg a.s./ha	*i_AppRate*
Number of applications	2		*i_AppNo*
Interval between multiple applications	7	days	*i_AppInt*
Half-life of active substance	30	days	*d_HalflifeAS*
Multiple application factor	1,9		*d_MAF*
Dermal absorption of the product	2,00%		*i_AbsorpProduct*
Dermal absorption of the in-use dilution	14,00%		*i_AbsorpInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,15	µg a.s./cm^2	*d_DFR*
Working hours	8	hr	*d_WorkHr*
Dermal transfer coefficient - Total potential exposure	14000	cm^2/hr	*d_DermTcUCV*
Dermal transfer coefficient - arms, body and legs covered	5000	cm^2/hr	*d_DermTcCV1*
Dermal transfer coefficient - hands, arms, body and legs covered	1400	cm^2/hr	*d_DermTcCV2*
Inhalation transfer coefficient for automated applications	NA	ha/hr*10^(-3)	*d_InhalTcAut*
Inhalation transfer coefficient for cutting ornamentals	0,1	ha/hr*10^(-3)	*d_InhalTcCut*
Inhalation transfer coefficient for sorting / bundling ornamentals	0,01	ha/hr*10^(-3)	*d_InhalTcSort*

~~Table A 9: Estimation of longer-term worker exposure towards Fenazaquin according to EFSA guidance – ornamentals (greenhouse) for re-entry 4 days~~

1. Total			
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
~~Total systemic exposure (mg a.s./day)~~	~~4,5127692~~	~~1,7145604~~	~~0,5952769~~
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0752128	0,0285760	0,0099213
% of RVNAS	752,13%	285,76%	99,21%

A 3.3 Resident and bystander exposure calculations (KCP 7.2.2.1)

Not relevant.

Appendix 4 Detailed evaluation of exposure and/or DFR studies relied upon (KCP 7.2, KCP 7.2.1.1, KCP 7.2.2.1, KCP 7.2.3.1)