FINAL REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

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: June 2019

Update data: January 2020, July 2020

MS Finalisation date: 10/2020; 05/2021

Version history

When	What
January 2020	Updated by Applicant
July 2020	Updated by Applicant
October 2020	Assessment by the expert
May 2021	Final Version

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6 Mammalian Toxicology (KCP 7)

6.1 Summary

Table 6.1-1: Information on Fenazaquin 20% SC*

Product name and code	Fenazaquin 20% SC
Formulation type	Suspension Concentrate [Code: SC]
Active substance(s) (incl. content)	Fenazaquin; 200 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 20% SC 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 20% SC according to Regulation (EC) No 1272/2008

Hazard class(es), categories	Acute Tox. 4
Hazard pictograms or Code(s) for hazard pictogram(s)	GHS07
Signal word	Warning
Hazard statement(s)	H302
Precautionary statement(s)	P273, P280, P501
Additional labelling phrases	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]
	Contains 1,2-benzisothiazol-3(2H)-one (2634-33-5). May produce an allergic reaction. [EUH208]

Table 6.1-3: Summary of risk assessment for operators, workers, residents and bystanders for Fenazaquin 20% SC

	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	Not relevant	None

	Result	PPE / Risk mitigation measures
Bystanders		

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)	200	1000	7	-				
2	Ornamentals (BBCH 35-67)	G	Spraying, LCTM	2 (7)	200	1000	-	-				
3	Tomato (BBCH 51-89)	G	Spraying, LCTM	2 (7)	200	1000	3	-				
4	Strawberry (BBCH 15-91)	G	Spraying, LCTM	2 (7)	200	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	**Hazard classes, categories:** Acute tox. 3, Acute Tox. 4 **Codes for hazard pictograms:** GHS06, GHS09

	Fenazaquin
criteria in Reg. 1272/2008, as amended)	**Signal word:** Danger **Hazard statements:** H301, H332
Additional C&L proposal	Please insert proposal for additional C&L if no (sufficient) harmonised 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 20% SC was performed by calculation. When considering the properties of the active ingredient (20% w/w) Fenazaquin 20% SC is classified as a Acute Tox. 3 and Acute Tox. 4. When considering the properties of all co-formulants, Fenazaquin 20% SC is only classified toxicity in respect to acute oral .

Table 6.3-1: Additional toxicological information relevant for classification/labelling of Fenazaquin 20% SC

	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 (20% (w/w))	H301, H332	Reg. 1272/2008	H302
Toxicological properties of non-active substance(s) (relevant for classification of product)	co-formulant 1 (<1% w/w)	H302, H317	Reg. 1272/2008, MSDS	Not classified
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 20% SC are presented in the following table.

Table 6.5-1: Dermal absorption rates for active substances in Fenazaquin 20% SC

	Fenazaquin	
	Value	**Reference**
Concentrate	~~2%~~ 6.1%	~~EFSA Journal 2013;11(4):3166 (based on human study)~~ In vitro human skin
Dilution	~~14%~~ 12.1%	~~EFSA Journal 2013;11(4):3166 (based on human study)~~ In vitro human skin

6.5.1 Justification for proposed values – Fenazaquin

~~No data on dermal absorption for Fenazaquin in SHA 9700 A / RULER is available. Justifications for values according to EFSA Journal 2013;11(4):3166 are presented in the following table~~.

Proposed dermal absorption rates for Fenazaquin are based on dermal absorption studies on the comparable formulation Fenazaquin 20% SC. The study results are summarised in the following table. Full summaries of studies on the dermal absorption Fenazaquin 20% SC that have not previously been evaluated within an EU peer review process are described in detail in Appendix 2.

The dermal absorption of Fenazaquin is summarised in Table 6.5-2.

Table 6.5-2: Default dermal absorption rates for Fenazaquin

	Value	**Justification for value**	**Acceptability of justification**
Concentrate	~~2%~~ 6.1%	~~EFSA Journal 2013;11(4):3166~~ *In vitro* human skin	Acceptable
Dilution	~~14%~~ 12.1%		Acceptable

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 20% SC
Formulation type	SC (Suspension concentrate)
Category	Insecticide
Active substance (incl. content)	**Fenazaquin** 200 g/L
AOEL systemic	0.01 mg/kg bw/d
Inhalation absorption	100%
Oral absorption	100%
Dermal absorption	Concentrate: ~~2%~~ 6.1% Dilution: ~~14%~~ 12.1%

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 Ta-

ble 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 20% SC 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~~ 5.0400	~~**967**~~ **840**
	Work wear (arms, body and legs covered) M/L+ gloves M/L and A +RPE (filtertype 2)	~~0.8400~~ 0.5040	~~**97**~~ **84**

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.**

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 6.6-4 shows the exposure model used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with Fenazaquin 20% SC according to the critical uses. Outcome of the estimation is presented in Table 6.6-5 (longer term exposure). Detailed calculations are in Appendix 3.

Table 6.6-4: 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 6.6-5: 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~~ 0.0294394	~~341~~ 294
	Work wear (arms, body and legs covered) TC: 2500 cm²/person/h	~~0.0146820~~ 0.0126894	~~147~~ 127
	Work wear (arms, body and legs covered) and gloves TC: 580 cm²/person/h	~~0.0034062~~ 0.0029439	~~**34**~~ **29**

Table 6.6-6: 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~~ 0.0294394	~~341~~ 294
	Work wear (arms, body and legs covered) TC: 3000 cm²/person/h	~~0.0176184~~ 0.0152273	~~176~~ 152
	Work wear (arms, body and legs covered) and gloves TC: 750 cm²/person/h	~~0.0044046~~ 0.0038068	~~**44**~~ **38**

Table 6.6-7: Estimated worker exposure (longer term exposure) – ornamentals (greenhouse)

		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~~ 0.0737274	~~849~~ 737
	Work wear (arms, body and legs covered) TC: 5000 cm²/person/h	~~0.0320306~~ 0.0280455	~~320~~ 280
	Work wear (arms, body and legs covered) and gloves TC: 1400 cm²/person/h	~~0.0108886~~ 0.0097727	~~109~~ **98**

It is concluded that no unacceptable risk is anticipated for the worker re-entering the treated tomato, melon and strawberry and ornamentalswith suitable protective clothing (work wear (arms, body and legs covered) and gloves./

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 glovesTC: 1400 cm²/person/h	0.0099213	**99**

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 4 days. Therefore we propose to calculate DFR value at 4 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):
Since the ornamentals use is intended for greenhouse, estimation of resident and bystander exposure after application of Fenazaquin 20% SC 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 20% SC on ornamentals is considered as negligible/acceptable.

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

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.

[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"

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 7.1.4-01	B. K. Indrani	2019	Fenazaquin 20% SC: *in vitro* skin irritation: reconstructed human epidermis test method Eurofins report No. G13250 GLP, Unpublished	N	SHARDA Cropchem Limited
KCP 7.1.4-02	Genesh Bhat	2018	Fenazaquin 20% SC: *in vitro* corrosion: reconstructed human epidermis (RHE) test method Eurofins report No. G13249 GLP, Unpublished	N	SHARDA Cropchem Limited
KCP 7.3	Ashwinkumar V Meru.	2020	In vitro percutaneous dermal absorption study of Fenazaquin 20% SC, through human skin, Eurofins, No. G18505 GLP, Unpublished	N	Sharda Cropchem Ltd

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

Comments of zRMS:	N/A

A 2.2 Acute ~~oral~~ toxicity (KCP 7.1.1)

The classification of Fenazaquin 20% SC was performed by calculation. The assessment of all acute toxicological properties of Fenazaquin 20% SC 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	**19.39**	134 mg/kg	> 5000 mg/kg	> 1.5 mg/l [3)]	Not Irritating[1)]	Not Irritating[1)]	Not sensitising[1)]
Coformulant 1	**XXX**	22000 mg/ kg	> 2000 mg/kg[1)]	> 317.04mg/l	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)]	*Not classified	Not Irritating[1)]	Not Irritating[1)]	Not sensitising[1]
Coformulant 4	**XXX**	> 50000 mg/kg	> 3500 mg/kg	*Not classified	Not Irritating[1)]	Not Irritating[1)]	Not sensitising[1]
Coformulant 5	**XXX**	> 2000 mg/kg [1)]	> 2000 mg/kg[1)]	*Not classified	Not Irritating[1)]	Not Irritating[1)]	Not sensitising[1]
xxxxxxxxxxx	**XXX**	500 mg/kg[2)]	> 2000 mg/kg[1)]	*Not classified	Skin Irrit. H315	Eye Dam. H318	Skin Sens. 1 H317
Coformulant 6	**xxx**	> 5000 mg/kg	> 2000 mg/kg1)	21 mg/l	Not Irritating[1)]	Not Irritating[1)]	Not sensitising[1]
Coformulant 7	xxx	500 mg/kg[2)]	> 2000 mg/kg[1)]	*Not classified	Skin Corr. 1B H314	Not Irritating[1)]	Skin Sens. 1 H317
xxxxxxxxxxx	xxx	500 mg/kg[2)]	> 2000 mg/kg[1)]	*Not classified	Skin Irrit. H315	Eye Dam. H318	Skin Sens. 1 H317
xxxxxxxxxxx	xxx	Not classified[)]	Not classified	Not classified	Not classified	Not classified	Not classified
xxxxxxxxxxx	xxx	> 2000 mg/kg [1)]	> 2000 mg/kg[1)]	*Not classified	Skin Corr. 1B H314	Not Irritating[1)]	Not sensitising[1]
Coformulant 8	**xxx**	Not classified[)]	Not classified	Not classified	Not classified	Not classified	Not classified

* No Information / but in their MSDS are not classified acutely inhalation toxic

[1)] As co-formulant is not classified

[2)] According to the Regulation (EC) n°1272/2008, ATE = 500 mg/kg is used for the calculation for co-formulant classified as Acute Tox. 4; H302.

[3] According to the Regulation (EC) n°1272/2008, ATE = 1.5 mg/kg is used for the calculation for co-formulant classified as Acute Tox. 4; H332.

A 2.3 Acute oral toxicity (KCP 7.1.1)

Comments of zRMS:	**The calculation methodology is acceptable** **The acute oral toxicity classification for Fenazaquin 20% SC: was ATE-$_{mix}$:691 mg/kg** **The acute oral toxicity calculation for Fenazaquin 20% SC was estimated to be < 2000 mg/kg, Fenazaquin 20% SC According to the Regulation EC No. 1272/2008, using worse results from calculations, Fenazaquin 20% SC should be classified for oral toxicity.** **Therefore should be classified as Acute Tox.4/H302**

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

The acute oral toxicity classification for Fenazaquin 20% SC: was calculated:

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

$$ATE_{mix} = \frac{100\%}{\frac{19.39\%}{134} + \frac{\text{xxx}\%}{500} + \frac{\text{xxx}\%}{500}} = 691 \frac{mg}{kg}$$

Details of the co-formulants and their classification and the calculation methodology that was used to assess the acute oral toxicity of Fenazaquin 20% SC 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 20% SC was estimated to be < 2000 mg/kg, Fenazaquin 20% SC therefore should be classified as harmful by swallow.

According to the Regulation EC No. 1272/2008, using worse results from calculations, Fenazaquin 20% SC should be classified for oral toxicity. Therefore the Signal Word "**Warning**" and the Hazard Statement "**H302: Harmful by swallow**" are proposed.

A 2.4 Acute percutaneous (dermal) toxicity (KCP 7.1.2)

Comments of zRMS:	**The calculation methodology is acceptable** **According to the Regulation EC No. 1272/2008, Fenazaquin 20% SC is not classified.** **No signal word or hazard statement is required**

There is no co-formulant in the Fenazaquin 20% SC recipe classified as danger through dermal toxicity. The MSDS of the co-formulants do not specify a hazard in relation to this endpoint and online literature has not indicated any additional concerns. Fenazaquin 20% SC is considered of low concern via dermal.

According to the Regulation EC No. 1272/2008, Fenazaquin 20% SC is not classified. No signal word or hazard statement is required

A 2.5 Acute inhalation toxicity (KCP 7.1.3)

Comments of zRMS:	**The calculation methodology is acceptable** **Acute inhalation LC_{50} toxicity value is 7.74 mg/L** **According to the Regulation EC No. 1272/2008, Fenazaquin 20% SC is not classified.** **No signal word or hazard statement is required**

Acute inhalation toxicity classification for Fenazaquin 20% SC was calculated:

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

$$ATE_{mix} = \frac{100\%)}{\frac{19.39\%}{1.5}} = 7.74\ \frac{mg}{l}$$

Details of the co-formulants and their classification and the calculation methodology that was used to assess the dermal irritation of Fenazaquin 20% SC can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

Using the calculation method, it is therefore considered that Fenazaquin 20% SC has an acute inhalation LC_{50} toxicity value of > 5 mg/L, Fenazaquin 20% SC therefore does not require classification for this hazard.

Conclusion

According to the Regulation EC No. 1272/2008, Fenazaquin 20% SC is **not classified**. No signal word or hazard statement is required.

A 2.6 Skin irritation (KCP 7.1.4)

Comments of zRMS:	**The studies 1 and 2 are acceptable.** **Under the experimental conditions, Fenazaquin 20% SC is not a skin corrosive. N,** **No classification is required according to Regulation (EC) No. 1272/2008.**

A 2.6.1 Study 1

Reference	KCP 7.1.4-01
Report	Fenazaquin 20% SC: *in vitro* skin irritation: reconstructed human epidermis test method, B. K. Indrani, 2019, report G13250
Guideline	Yes, OECD guideline No. 439
Deviations	No
GLP	Yes
Acceptability	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test material (Lot/Batch No.)	Fenazaquin 20% SC (Batch No. SCL-22018)
Test system	EpiSkin (an *in vitro* reconstructed human epidermis (RHE) from normal human keratinocytes cultured on a collagen matrix)
Exposure	10 µL was added on the top of the epidermis units (3 replicates)
Vehicle/Dilution	None
Remarks	None

Results and discussions

Table A 1: Mean OD values of individual epidermis units

	Absorption (OD_{570nm})			
	R1	**R2**	**R3**	**Mean**
Negative control	0.7653	0.7693	0.7884	0.7743
Positive control	0.0957	0.0921	0.0889	0.0922
Test item	0.7780	0.7780	0.7848	0.7803

Table A 2: True OD values of individual epidermis units

	Absorption (OD_{570nm})				
	R1	**R2**	**R3**	**Mean**	**SD**
Negative control	0.7239	0.7279	0.7470	0.7329	0.01
Positive control	0.0543	0.0507	0.0475	0.0508	0.00
Test item	0.7366	0.7366	0.7434	0.7389	0.00

Blank OD value (mean of 6 replicate values): 0.0414

Table A 3: Individual tissue viability of epidermis units (relative)

	% individual viability				
	R1	**R2**	**R3**	**Mean**	**SD**
Positive control	7.41	6.92	6.48	6.94	0.46
Test item	100.50	100.50	101.43	100.81	0.54

Negative control mean: 0.7329

Conclusion

Under the experimental conditions, Fenazaquin 20% SC is not a skin irritant. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

A 2.6.2 Study 2

Reference	KCP 7.1.4-02
Report	Fenazaquin 20% SC: *in vitro* corrosion: reconstructed human epidermis (RHE) test method, study No. G13249
Guideline	Yes, OECD guideline No. 431
Deviations	Yes
GLP	Yes
Acceptability	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test material (Lot/Batch No.)	Fenazaquin 20% SC (Batch No. SCL-22018)
Test system	EpiSkin kit: *in vitro* human epidermis (RHE) from normal human keratinocytes cultured on a collagen matrix.
Exposure	50 µL applied topically
Vehicle/Dilution	None
Remarks	None

Results and discussions

Table A 4: Mean OD values of individual Epidermis Units

3-minutes exposure

	Absorption (OD_{570nm})	
	R1	**R2**
Negative control	0.8317	0.8385
Test item	0.8087	0.8048

60-minutes exposure

	Absorption (OD_{570nm})	
	R1	**R2**
Negative control	1.1254	1.0989
Test item	0.9611	0.9087

240-minutes exposure

	Absorption (OD_{570nm})	
	R1	R2
Negative control	1.3962	1.3900
Positive control	0.3226	0.3348
Test item	1.1341	1.0479

OD: optical density
R1, R2 : duplicate exposures

Table A 5: True OD values of individual Epidermis Units

3-minutes exposure

	Absorption (OD_{570nm})	
	R1	R2
Negative control	0.5412	0.5480
Test item	0.5182	0.5143

60-minutes exposure

	Absorption (OD_{570nm})	
	R1	R2
Negative control	0.8349	0.8084
Test item	0.6706	0.6182

240-minutes exposure

	Absorption (OD_{570nm})	
	R1	R2
Negative control	1.1057	1.0995
Positive control	0.0321	0.0443
Test item	0.8436	0.7574

OD: optical density
R1, R2 : duplicate exposures
Blank OD value (mean of 6 replicate values): 0.2905
True OD value = OD raw – OD blank

Table A 6: Individual tissue viability of Epidermis Units (relative)

3-minutes exposure

	% Individual viability			
	R1	R2	Mean viability	Variability
Test item	95.15	94.43	94.79	0.76

60-minutes exposure

	% Individual viability			
	R1	R2	Mean viability	Variability
Test item	81.61	75.24	78.43	7.81

240-minutes exposure

	% Individual viability			
	R1	R2	Mean viability	Variability
Positive control	2.91	4.01	3.46	-37.80
Test item	76.51	68.69	72.60	10.22

Negative control mean: 1.1026
R1, R2 : duplicate exposures

Conclusion

Under the experimental conditions, Fenazaquin 20% SC is not a skin corrosive. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

A 2.7 Eye irritation (KCP 7.1.5)

Comments of zRMS:	**The calculation methodology is acceptable** **According to the Regulation EC No. 1272/2008, Fenazaquin 20% SC is not classified.** **No signal word or hazard statement is required..**

The product contains < 1% of co-formulants considered as eye damage (classified as: Eye Dam. 1; H318). Under the GHS classification system this component is below the additive trigger value of the classification according to Regulation (EC) no. 1272/2008.
Details of the co-formulants and their classification and the calculation methodology that was used to assess the dermal irritation of Fenazaquin 20% SC can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

Conclusion

According to the Regulation EC No. 1272/2008, Fenazaquin 20% SC is not classified. No signal word or hazard statement is required.

A 2.8 Skin sensitisation (KCP 7.1.6)

Comments of zRMS:	**The calculation methodology is acceptable** **According to the Regulation EC No. 1272/2008, Fenazaquin 20% SC is not classified.** **No signal word or hazard statement is required.**

The product contains < 1% of co-formulants considered as skin sensitiser (classified as: Skin Sens. 1; H317). Under the GHS classification system this component is below the additive trigger value of the classification according to Regulation (EC) no. 1272/2008.

Details of the co-formulants and their classification and the calculation methodology that was used to assess the dermal irritation of Fenazaquin 20% SC can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

Conclusion

According to the Regulation EC No. 1272/2008, Fenazaquin 20% SC is **not classified**. No signal word or hazard statement is required.

A 2.9 Supplementary studies for combinations of plant protection products (KCP 7.1.7)

A 2.10 Data on co-formulants (KCP 7.4)

A 2.10.1 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 2.10.2 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 2.11 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)~~

Comment:
In vitro percutaneous dermal absorption study of Fenazaquin 20% SC, through human skin is acceptable
Results:
6.1 % of dose for undiluted Fenazaquin20% (concentrate)
12.1% of dose for actual spray strength used in the field dilution

A 2.11.1 Fenazaquin

Comparative dermal absorption, in vitro using rat and human skin

Comments of zRMS:	

Reference	KCP 7.3
Report	In vitro percutaneous dermal absorption study of Fenazaquin 20% SC, through human skin, Ashwinkumar V Meru, 2020, G18505
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.)	14C-Fenazaquin (S020-480)
	Test preparation	radioformulation
	Specific activity	59.1 mCi/mmol
	Radiochemical purity	99.9 %
Product	Name (Lot/Batch No.)	Feanazaquin 20% SC (SCL-12840)
	Company code	Fenazaquinh
	Concentration a.s.	200 g/L
	Formulation type	SC
Blank product	Name (Lot/Batch No.)	Fenazaquin 20% SC blank (SCL-70318)
	Concentration a.s.	0 g/L

Test system		
Diffusion cell	Cell type	dynamic

	(if dynamic) Flow rate	1.0 mL.min-1
	Exposed skin area	0.64 cm2
Membrane	Skin type	isolated epidermis
	Skin thickness range	0.2– 0.4 mm
	Skin donors age	20, 53, 39, 32 years
	Skin donors sex	3 male + 1 female
	Location	breast and abdomen
	Source	Human: obtained from three donors directly after surgery
	Integrity test	yes
Receptor	Receptor medium	Phosphate buffered saline(PBS) + 0.01% sodium azaide+6% polyoxybutylene-20-oleyl ether(PEG)
	Solubility in receptor medium	n
Sample Time	Exposure time	8 h
Sampling	Sample intervals	24 h
Washing		At 8 h, using water and mild soap solution (3 % Dove))
Final Procedure	Tape stripping	y
	TS1-2 analysed separately	n
Remarks:		

Tested doses	Concentrate	Spray dilution
Target concentration [g.L/-1]	200.482	0.205
Area dose [µg/cm²]	2005± 0.085	2.05 ± 0.063
Specific activity [MBq/ml-1]	3.50	1.43
No. of donors	8	8

Results and discussions

Table A 7: In-vitro dermal penetration of Fenazaquin formulated as Fenazaquin 20% SC through human skin - Recovery data

Dose group	High dose (Formulation concentrate)		Low dose (Spray dilution 1:1000	
Target concentration [g/L-1]	200.45		0.20	
Mean actual applied dose [µg/cm²]	2005± 0.085		2.05 ± 0.063	
Number of replicates (n)	8		8	
	Recovery [%]		Recovery [%]	
	Mean	S.D.	Mean	S.D.
Dislodgeable dose				
e.g. Skin washing after 8 h	91.2281	6.1688	80.8898	5.4543
e.g. Skin washing after 24 h				
Donor chamber wash	2.6210	2.4693	3.7291	0.7923
Dose associated to skin				
Tape strips: 1st sample, strips 1 + 2	2.9415	2.0649	5.3933	1.1974
Tape strips: 2nd sample; strips 3 - n	1.8690	1.2876	4.0520	2.4042
Stripped skin	2.0124	1.7368	4.4767	1.4621
Absorbed dose	2.7335	1.7184	6.5870	1.5606
Receptor fluid	0.5798	0.2670	1.8269	0.3478
Receptor chamber wash	0.1413	0.0286	0.2835	0.0743
Total recovery[1]	101.3931	6.0042	100.6512	4.6346
Absorption essentially complete at end of study (>75% absorption within half the study duration) [%Absorption at $t_{0.5}$]	No		No	
If yes: Absorption = receptor fluid + receptor chamber	N/A	N/A	N/A	N/A

washes + skin sample (excluding all tape strips)				
If no: Absorption = receptor fluid + receptor chamber washes + skin sample (excluding tape strips 1 and 2) [2]	4.6025	1.7708	10.6390	2.3201
Absorption estimate normalised[3]	4.6025 ± 0.84 × 1.7708		10.6390 ± 0.84 × 2.3201	
Relevant absorption estimate	4.6025 ± 1.4874		10.6390 ± 1.9489	
Absorption estimates used for risk assessment[4]	**6.1**		**12.1**	

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

[2] In accordance with the EFSA Guidance on Dermal Absorption (EFSA Journal 2012;10(4):2665 and 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. 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.

According to the Table 1 of EFSA Guidance for n = 8 the Multiplication factor (k) is 0.84.

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

N/A: not applicable

Conclusion/endpoint: 6.1 % of dose for undiluted Fenazaquin20% (concentrate)

12.1% of dose for actual spray strength used in the field dilution

A 2.12 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 8: 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	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	12,1	%	
	AOEL	0,6	mg a.s./ day	based on 70 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	4,8400	0,4840	DE(int) = DE x (DA/100)
	Total	**5,0400**	**0,5040**	**sum**
	% AOEL			
	Inhalation	33	3	%AOEL = 100 x IE(int) / AOEL
	Dermal	807	81	%AOEL = 100 x DE(int) / AOEL
	Total	**840**	**84**	**sum**

A 3.2 Worker exposure calculations (KCP 7.2.3.1)

A 3.2.1 Calculations for Fenazaquin

Table A 9: 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*

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
Number of applications	2	
Interval between multiple applications	7	days
Half-life of active substance	30	days
Multiple application factor	1,9	
Dermal absorption of the product	6,10%	
Dermal absorption of the in-use dilution	12,10%	
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,17	µg a.s./cm^2
Working hours	8	hr
Dermal transfer coefficient - Total potential exposure	5800	cm^2/hr
Dermal transfer coefficient - arms, body and legs covered	2500	cm^2/hr
Dermal transfer coefficient - hands, arms, body and legs covered	580	cm^2/hr
Inhalation transfer coefficient for automated applications	NA	ha/hr*10^(-3)
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10^(-3)
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10^(-3)

Table A 10: 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%

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	1,7663656	0,7613645	0,1766366
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0294394	0,0126894	0,0029439
% of RVNAS	294,39%	126,89%	29,44%

Table A 11: 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*

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
Number of applications	2	
Interval between multiple applications	7	days
Half-life of active substance	30	days
Multiple application factor	1,9	
Dermal absorption of the product	6,10%	
Dermal absorption of the in-use dilution	12,10%	
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,17	µg a.s./cm^2
Working hours	8	hr
Dermal transfer coefficient - Total potential exposure	5800	cm^2/hr
Dermal transfer coefficient - arms, body and legs covered	3000	cm^2/hr
Dermal transfer coefficient - hands, arms, body and legs covered	750	cm^2/hr
Inhalation transfer coefficient for automated applications	NA	ha/hr*10^(-3)
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10^(-3)
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10^(-3)

Table A 12: 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%

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	1,7663656	0,9136374	0,2284093
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0294394	0,0152273	0,0038068
% of RVNAS	294,39%	152,27%	38,07%

Table A 13: 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*

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
Number of applications	2	
Interval between multiple applications	7	days
Half-life of active substance	30	days
Multiple application factor	1,9	
Dermal absorption of the product	6,10%	
Dermal absorption of the in-use dilution	12,10%	
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,17	µg a.s./cm^2
Working hours	8	hr
Dermal transfer coefficient - Total potential exposure	14000	cm^2/hr
Dermal transfer coefficient - arms, body and legs covered	5000	cm^2/hr
Dermal transfer coefficient - hands, arms, body and legs covered	1400	cm^2/hr
Inhalation transfer coefficient for automated applications	NA	ha/hr*10^(-3)
Inhalation transfer coefficient for cutting ornamentals	0,1	ha/hr*10^(-3)
Inhalation transfer coefficient for sorting / bundling ornamentals	0,01	ha/hr*10^(-3)

Table A 14: 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%

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	4,4236410	1,6827289	0,5863641
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0737274	0,0280455	0,0097727
% of RVNAS	737,27%	280,45%	97,73%

~~Table A 15: 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 16: 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)