FINAL REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: SHA5500A

Product name(s): ASSET ~~(ZUXION)~~

Chemical active substance:

Acetamiprid, 200 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: April 2020;2021

MS Finalisation date: 10/2020; 07/2021

Version history

When	What
July 2020	Assessment by expert
May 2021	Updated by applicant / The product name was corrected (ASSET instead of Zuxion)
July 2021	Assessment after the update

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6 Mammalian Toxicology (KCP 7)

6.1 Summary

Table 6.1-1: Information on SHA5500A/ Acetamiprid 20% SG*

Product name and code	SHA5500A/ ASSET ~~ZUXION~~
Formulation type	Water soluble granules [Code: SG]
Active substance	Acetamiprid 200 g/kg
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 SHA5500A/ ASSET ~~ZUXION~~ 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 SHA5500A/ Acetamiprid 20% SG according to Regulation (EC) No 1272/2008

Hazard class(es), categories:	Acute Tox. 4, Repr.2
Hazard pictograms or Code(s) for hazard pictogram(s):	GHS07
Signal word:	Warning
Hazard statement(s):	H302,H361d
Precautionary statement(s):	P264, P270, P280, P301+P312, P **P308+P313**501
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

Table 6.1-3: Summary of risk assessment for operators, workers, bystanders and residents for SHA5500A/ ASSET ~~ZUXION~~

	Result	PPE / Risk mitigation measures
Operators	Acceptable	Work wear (arms, body and legs covered) M/L and A
Workers	Acceptable	Work wear (arms, body and legs covered) : Oilseed rape Work wear (arms, body and legs covered) + gloves - time period of 4 days after application : Pome fruits Work wear (arms, body and legs covered) + gloves : Pome fruits
Residents& Bystanders	Acceptable	None

No unacceptable risk for operator and workers was identified when the product is used as intended and

provided that the PPE stated in Table 6.1-3 are applied.

A summary of the critical uses and the overall conclusion regarding exposure for operators, workers and bystanders/residents 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, bystander or resident exposure based on [Exposure model]**	**Acceptability of exposure assessment**			
			Method / Kind **(incl. application technique *****)**	**Max. number (min. interval between applications)** **a) per use** **b) per crop/ season**	**Max. application rate kg as/ha** **a) a.s. 1** **b) a.s. 2**	**Water L/ha** **min / max**			**Operator**	**Worker**	**Bystander**	**Residents**
1	Oilseed rape (At pest presence before BBCH 69)	F	Foliar spray	a) 1 b) 1	a) 0.04 b) 0.04	200-600	28					
2	Pome fruits (At pest presence, Before BBCH 59 and from BBCH 69)	F	Foliar spray	a) 2 (14) b) 2 (14)	a) 0.05 b) 0.10	900-1000	14					
3	Pome fruits	F	Foliar spray	a) 2 (14) b) 2 (14)	a) 0.036 b) 0.072	900-1000	14					

* 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

	Acetamiprid
Common Name	Acetamiprid
CAS-No.	135410-20-7
Classification and proposed labelling	
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	Hazard classes (s), categories: Acute Tox. ~~4~~ 3, Repr.2/H361 Code(s) for hazard pictogram(s): GHS07 Signal word: Warming Hazard statement(s): ~~H302~~ H301, H361d

	Acetamiprid
Additional C&L proposal	-
Agreed EU endpoints	
AOEL systemic	0.025 mg/kg bw/d
Reference	SANTE/10502/2017 Rev 4, 13 December 2017;ECHA Committee for Risk Assessment RAC opinien 4 May 2020
Conditions to take into account/critical areas of concern with regard to toxicology	
Review Report/EFSA Conclusion for active substance	-

6.3 Toxicological Evaluation of Plant Protection Product

The assessment of all acute toxicological properties of Acetamiprid 20% SG are derived from the classification of the active compound and co-formulants. When considering the properties of all co-formulants and toxicity study Acetamiprid 20% SG is classified as "H302: Harmful by swallow".

Table 6.3-1: Additional toxicological information relevant for classification/labelling of ASSET ~~ZUXION~~

	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)	Acetamiprid (20 % (w/w))	H302, H361d	Reg. 1272/2008	H302, H361d
Toxicological properties of non-active substance(s) (relevant for classification of product)	-	-	-	-
Further toxicological information	-	-	-	-

* 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 ASSET ~~ZUXION~~ are presented in the following table.

Table 6.5-1: Dermal absorption rates for active substances in ASSET ~~ZUXION~~

	Acetamiprid	
	Value	**Reference**
Concentrate	0.83 %	New study reported in Appendix 2
Dilution	35 %	

6.5.1 Justification for proposed values - Acetamiprid

Proposed dermal absorption rates for Acetamiprid are based on dermal absorption studies on a formulation Acetamiprid 20 % SG. The study results are summarised in the following table. Full summaries of studies on the dermal absorption of Acetamiprid 20 % SG that have not previously been evaluated within an EU peer review process are described in detail in Appendix 2. The dermal absorption of ASSET ~~ZUXION~~ is summarised in Table 6.5-2.

Table 6.5-3: Default dermal absorption rates for Acetamiprid

	Value	**Justification for value**	**Acceptability of justification**
Concentrate	0.83 %	*In vitro* human skin	Acceptable
Dilution	35 %	*In vitro* human skin	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	SHA5500A/ ASSET ~~ZUXION~~
Formulation type	SC
Category	Insecticide
Active substance(s) (incl. content)	**Acetamiprid** 200 g/kg
AOEL systemic	0.025 mg/kg bw/d
Inhalation absorption	100 %
Oral absorption	100 %
Dermal absorption	Concentrate: 0.83 % Dilution: 35 %

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
No unacceptable risk for operator and workers was identified when the product is used as intended and provided that the PPE stated in Table 6.1-3 are applied.

A summary of the critical uses and the overall conclusion regarding exposure for operators, workers and bystanders/residents is presented in the following table.

Table 6.1-4. A list of all intended uses within the EU 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 ASSET ~~ZUXION~~ according to the critical use(s) is presented in Table 6.6-2. Outcome of the estimation is presented in Table 6.6-3. Detailed calculations are in Appendix 2.

Table 6.6-2: Exposure models for intended uses

Critical use(s)	Oilseed rape (max. 0.2 kg product/ha) Pome fruits (max. 0.25 kg product/ha) Pome fruits (max. 0.18 kg product/ha)
	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 6.6-3: Estimated operator exposure (longer term exposure)

		Acetamiprid	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Tractor mounted boom spray application outdoors to low crops Application rate: 0.04 kg/ha			
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Without RPE/PPE	0.0041222	**16**
	Work wear (arms, body and legs covered) M/L and A	0.0029078	**12**
Tractor mounted boom spray application outdoors to high crops Application rate: 0.05 kg product/ha			
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Without RPE/PPE	0.0384759	154
	Work wear (arms, body and legs covered) M/L and A	0.0130069	**52**
Tractor mounted boom spray application outdoors to high crops Application rate: 0.036 kg product/ha			
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Without RPE/PPE	0.028077	112
	Work wear (arms, body and legs covered) M/L and A	0.0097623	**39**

***Oilseed rape use*:**
According to the AOEM model calculations it can be concluded that the risk for the operator using ASSET is acceptable with use of personal protective equipment.

***Pome fruits uses*:**
According to the AOEM model calculations is acceptable with the use working clothing (long

sleeved shirt and trousers) during mix/loading and application
Implication for labelling: P280 : Wear protective gloves

6.6.3 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 considering above mentioned personal protective equipment (PPE), a study to provide measurements of operator exposure was not necessary and was therefore not performed.

6.6.4 Worker exposure (KCP 7.2.3)

6.6.4.1 Estimation of worker exposure

Table 6.6-4 shows the exposure model(s) used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with ASSET ~~ZUXION~~ according to the critical use(s). Outcome of the estimation is presented in Table 6.6-5. Detailed calculations are in Appendix 2.

Table 6.6-4: Exposure models for intended uses

Critical use(s)	Oilseed rape (max. 1x 0.2 kg product/ha) Pome fruits (max. 2x 0.25 kg product/ha) Pome fruits (max. 2 x 0.18 kg 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)

		Acetamipryd	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Oilseed rape Inspection, irrigation / Outdoor Work rate: 2 hours/day, DT_{50}: 30 days DFR: 3 µg/cm²/kg a.s./ha Interval between treatments: 365 days			
Number of applications and application rate		1 x 0.04 kg a.s./ha	
Body weight: 60 kg	Potential TC: 12500 cm²/person/h	0.0175000	70
	Work wear (arms, body and legs covered) TC: 1400 cm²/person/h	0.0019600	**8**
Pome fruits Searching, reaching, picking / Outdoor Work rate: 8 hours/day, DT_{50}: 30 days DFR: 3 µg/cm²/kg a.s./ha			

Interval between treatments: 14 days			
Number of applications and application rate		2 x 0.05 kg a.s./ha	
Body weight: 60 kg	Potential TC: 22500 cm^2/person/h	0.2714725	1086
	Work wear (arms, body and legs covered) TC: 4500 cm^2/person/h	0.0542945	217
	Work wear (arms, body and legs covered) + gloves TC: 2250 cm2/person/h	0.0271472	109
Proposal re-entry of 4 days **Pome fruits** Searching, reaching, picking / Outdoor Work rate: 8 hours/day, DT_{50}: 30 days DFR: 2.73 µg/cm^2/kg a.s./ha Interval between treatments: 14 days			
Number of applications and application rate		2 x 0.05 kg a.s./ha	
Body weight: 60 kg	Potential TC: 22500 cm^2/person/h	0.2470399	988
	Work wear (arms, body and legs covered) TC: 4500 cm^2/person/h	0.0494080	198
	Work wear (arms, body and legs covered) + gloves TC: 2250 cm2/person/h	0.0247040	**99**
Pome fruits Searching, reaching, picking / Outdoor Work rate: 8 hours/day, DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha Interval between treatments: 14 days			
Number of applications and application rate		2 x 0.036 kg a.s./ha	
Body weight: 60 kg	Potential TC: 22500 cm^2/person/h	0.1954602	782
	Work wear (arms, body and legs covered) TC: 4500 cm^2/person/h	0.0390920	156
	Work wear (arms, body and legs covered) + gloves TC: 2250 cm2/person/h	0.0195460	78

It is concluded that no unacceptable risk is anticipated for the worker re-entering the treated Oilseed rape even without gloves.
It is concluded that there is no unacceptable risk anticipated for the worker wearing adequate work clothing and with personal protective equipment (gloves) for maintenance activities when for re-entering cotton treated pome fruits with ~~ZUXION~~ ASSET when a time period of 4days after application is respected.4 days is below PHI and therefore is acceptable.
Implication for labelling: P280: Wear protective gloves

Considering a dose reduction in Apple 0.036 kg a.s./ha, it is concluded that there is no unacceptable risk anticipated for the worker wearing adequate work clothing and with personal protective equipment (gloves).

Acceptable

6.6.5 Refinement of generic DFR value (KCP 7.2)

Not required.
If no DFR data for the specific compound are available, a conservative default value for the DFR may be taken as 3 µg/cm2 (30 mg a.s./m2).

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 pome fruits.

Body weight 60 kg.

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/cm^2)
DFR_0 Dislodgeable foliar residue just after application (µg/cm^2)
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/cm^2 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.

Pome fruits:
For pome fruits and almond, a number of 2 applications (n) and a 14 day interval (i) between applications is considered (worst case scenario) and MAF is 1.7 The following DFR value is calculated:
$DFR_0 = DFR_{def} \times 1.72 = 5.1$µg/cm^2 (where $DFR_{def} = 3$ µg/cm^2 per kg s.a/ha)

[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"

Therefore for 4 days of re-entry interval:
$DFR_T = DFR_0 \times e^{-k,t} = 5.2\ \mu g/cm^2 \times 0.923 = 4.71\ \mu g/cm^2$
Therefore for $DFR_T = DFR_{def\ ref} \times MAF = 4.71\ \mu g/cm^2$ the $DFR_{def\ ref} = 2.73\ \mu g/cm^2$ per kg s.a/ha

6.6.5.1 Measurement of worker exposure

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

6.6.6 Bystander and resident exposure (KCP 7.2.2)

6.6.6.1 Estimation of bystander and resident exposure

Table 6.6-6 shows the exposure model(s) used for estimation of bystander and resident exposure to Acetamiprid. Outcome of the estimation is presented in Table 6.6-7. Detailed calculations are in Appendix 2.

Table 6.6-6: Exposure models for intended uses

Critical use(s)	Oilseed rape (max. 1x 0.2 kg product/ha) Pome fruits (max. 2x 0.25 kg product/ha) Pome fruits (max. 2 x 0.18 kg 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 6.6-7: Estimated resident exposure (longer term exposure)

		Acetamipryd	
Model data		**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Oilseed rape			
Tractor mounted - application outdoors Buffer zone: 2-3(m) Drift reduction technology: no DT_{50}: 30 days DFR: 3 µg/cm²/kg a.s./ha Interval between treatments: 365 days			
Number of applications and application rate		1 x 0.04 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.0018814	7.53
	Vapour (75th perc.)	0.0010700	4.28
	Deposits (75th perc.)	0.0002363	0.95
	Re-entry (75th perc.)	0.0023625	9.45
	Sum (mean)	0.0041633	16.65
Resident adult Body weight: 60 kg	Drift (75th perc.)	0,0004500	1.80
	Vapour (75th perc.)	0.0002300	0.92
	Deposits (75th perc.)	0,0000954	0.38

		Acetamipryd	
Model data		**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
	Re-entry (75th perc.)	0.0013125	5.25
	Sum (mean)	0.0015601	**6.24**
Pome fruits Buffer zone: 5 (m) Drift reduction technology: no DT_{50}: 30 days DFR: 3 µg/cm²/kg a.s./ha Interval between treatments: 14 days			
Number of applications and application rate		2 x 0.05 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.0027021	10.81
	Vapour (75th perc.)	0.0010700	4.28
	Deposits (75th perc.)	0.0008329	3.33
	Re-entry (75th perc.)	0.0029531	11.81
	Sum (mean)	0.0058185	23.27
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.0014981	5.99
	Vapour (75th perc.)	0.0002300	0.92
	Deposits (75th perc.)	0.0003362	1.34
	Re-entry (75th perc.)	0.0016406	6.56
	Sum (mean)	0.0027665	**11.07**
Pome fruits Buffer zone: 5 (m) Drift reduction technology: no DT_{50}: 30 days DFR: 3 µg/cm²/kg a.s./ha Interval between treatments: 14 days			
Number of applications and application rate		2 x 0.036 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.0019455	7.78
	Vapour (75th perc.)	0.0010700	4.28
	Deposits (75th perc.)	0.0010337	4.13
	Re-entry (75th perc.)	0.0036649	14.66
	Sum (mean)	0.0060370	24.15
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.0010786	4.31
	Vapour (75th perc.)	0.0002300	0.92
	Deposits (75th perc.)	0.0004172	1.67
	Re-entry (75th perc.)	0.0020360	8.14
	Sum (mean)	0.0028675	11.47

For all crops, the calculated total systemic exposure for resident/bystander are below the AOEL for children and adults. Therefore, it is concluded that resident/bystander exposure to ~~ZUXION~~ ASSET is acceptable.

6.6.6.2 Measurement of bystander and/or resident exposure

Since the bystander and/or resident exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) for Acetamiprid will not be exceeded under conditions of intended uses and considering above mentioned risk mitigation measures, a study to provide measurements of bystander/resident exposure was not necessary and was therefore not performed.

6.6.7 Combined exposure

Not relevant. The product contains only one active substance.

Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Vertebrate study Y/N**	**Owner**
KCP 7.1.5	xxx, 2017	2017	Acetamiprid 20% SG:Acute Eye Irritation / Corrosion Study in Rabbit xxx, Report No.15366 GLP, Unpublished	Y	SHARDA Cropchem Ltd.
KCP 7.6.2	Brufau Donés, G	2018	In vitro percutaneous absorption of Acetamiprid, formulated as Acetamiprid 20 % SG, through human skin Triskelion B.V , Report No.21130/26 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

No additional study submitted.

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**
KCP XX	Author	YYYY	Title Company Report N Source	Y/N	Owner

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
			GLP/non GLP/GEP/non GEP Published/Unpublished		

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
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

Appendix 1 Detailed evaluation of the studies relied upon

A 1.1 Statement on bridging possibilities

Comments of zRMS:	N/A

A 1.2 Acute oral toxicity (KCP 7.1.1)

Comments of zRMS:	**The calculation methodology is acceptable** **According to the Regulation EC No. 1272/2008, using worse results from calculations, ZUXION should be classified for oral toxicity.** **Therefore the Signal Word "Warning" and Acute Tox.4/H302: Harmful by swallow"**

Acute toxicity studies for Acetamiprid 20% SG were **not** evaluated as part of the EU review of acetamiprid. Therefore, all relevant data are provided here and are considered adequate. Details of the co-formulants and their classification and the calculation methodology that was used to assess the acute oral toxicity of Acetamiprid 20% SG can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).
The acute oral toxicity of Acetamiprid 20% SG was calculated as follow:

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

$$ATE_{mix} = \frac{100\%}{\frac{20.20\%}{1000} + \frac{xx\%}{600} + \frac{xx\%}{2000} + \frac{xx\%}{2100} + \frac{xx\%}{2000}} = 1632\ \frac{mg}{kg}$$

Conclusion

The acute oral toxicity calculation for ~~ZUXION~~ ASSET ~~ZUXION~~ was estimated to be < 2000 mg/kg, ~~ZUXION~~ ASSET ~~ZUXION~~ therefore should be classified as harmful by swallow.

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

A 1.3 Acute percutaneous (dermal) toxicity (KCP 7.1.2)

Comments of zRMS:	**Acceptable** **According to the Regulation EC No. 1272/2008, Acetamiprid 20% SG is not classified. No signal word or hazard statement is required for this hazard.**

Acute toxicity studies for Acetamiprid 20% SG were **not** evaluated as part of the EU review of acetam-

iprid. Therefore, all relevant data are provided here and are considered adequate. Details of the co-formulants and their classification and the calculation methodology that was used to assess the acute oral toxicity of Acetamiprid 20% SG can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).
There is no co-formulant in the Acetamiprid 20% SG recipe classified as acute dermal toxicity.

According to the Regulation EC No. 1272/2008, Acetamiprid 20% SG is **not classified**. No signal word or hazard statement is required for this hazard.

A 1.4 Acute inhalation toxicity (KCP 7.1.3)

Comments of zRMS:	**The calculation methodology is acceptable** **According to the Regulation EC No. 1272/2008, using worse results from calculations LC_{50} toxicity value is 18 mg/L , therefore ~~ZUXION~~ ASSET is unclassified for inhalation toxicity.**

Acute toxicity studies for Acetamiprid 20% SG were **not** evaluated as part of the EU review of acetamiprid. Therefore, all relevant data are provided here and are considered adequate. Details of the co-formulants and their classification and the calculation methodology that was used to assess the acute oral toxicity of Acetamiprid 20% SG can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

Acute inhalation toxicity classification for Acetamiprid 20% SG was calculated:

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

$$\boldsymbol{ATE_{mix} = \frac{100\% - (xx\% + xx\%)}{\frac{xx\%}{1.5}} = 18 \frac{mg}{l}}$$

sing the calculation method, it is therefore considered that ~~ZUXION~~ ASSET ~~ZUXION~~ has an acute inhalation LC_{50} toxicity value of > 5 mg/L, ASSET ~~ZUXION~~ therefore does not require classification for this hazard.

According to the Regulation (EC) No. 1272/2008, ~~ZUXION~~ ASSET ~~ZUXION~~ **is not classified**. No signal word or hazard statement is required.

A 1.5 Skin irritation (KCP 7.1.4)

Comments of zRMS:	**Acceptable** **According to the Regulation EC No. 1272/2008, Acetamiprid 20% SG is not classified. No signal word or hazard statement is required for this hazard.**

Acute toxicity studies for Acetamiprid 20% SG were **not** evaluated as part of the EU review of acetamiprid. Therefore, all relevant data are provided here and are considered adequate. Details of the co-formulants and their classification and the calculation methodology that was used to assess the acute oral

toxicity of Acetamiprid 20% SG can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

There is no co-formulant in the Acetamiprid 20% SG recipe classified as dermal irritants. 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.
According to the Regulation EC No. 1272/2008, ~~ZUXION~~ ASSET ~~ZUXION~~ is not classified. No signal word or hazard statement is required.

A 1.6 Eye irritation (KCP 7.1.5)

Comments of zRMS:	**The methodology is acceptable** **Under the experimental conditions, ~~ZUXION~~ ASSET is not an eye irritant. Thus, no classification is required according to Regulation (EC) No. 1272/2008.**

In the view of current regulation (EC Regulation 1272/2008, EC Regulation 1107/2009, EC Regulation 1907/2006), in vivo tests on animals should be avoided. Tests on animals within the meaning of Directive 86/609/EEC shall be undertaken only where no other alternatives, which provide adequate reliability and quality of data, are possible. In case of skin irritation, it is possible to classify the product based on validated in vitro tests or the additivity formula if all ingredients are of defined toxicological properties. In case of SHA5500A/ ASSET ~~ZUXION~~ the components are of known toxicological classification, thus, the additivity formula was implemented to assess skin irritation potency of the product.
Based on the composition and in accordance with the provisions of the Regulation EC 1272/2008, the formulation SHA5500A/ ASSET ~~ZUXION~~ requires classification in regards to eye irritation as Eye Irrit. 2 (H319).
However, since the results of eye irritation study on rabbits were available the applicant decided to compare the findings of in vivo testing with calculated result. According to acute eye irritation study (xxx, 2017) which was carried out in compliance with OECD Guideline No 405, SHA5500A ASSET ~~ZUXION~~ does not possess skin irritation potency.
In the opinion of applicant despite the lack of in vitro studies (multi-level approach), if the results of in vivo tests are contrary to the results obtained from calculation method, data generated from animal study should be considered superior.

A 1.6.1 Study 1

Reference:	KCP 7.1.5 – 01
Report	Acetamiprid 20% SG: Acute Eye Irritation / Corrosion Study in Rabbit. (OECD guideline No.405), xxx, 2017, R/ 15366
Guideline(s):	Yes (OECD 405)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test material (Lot/Batch No.)	Acetamiprid 20% SG (Lot/Batch No. SWEPL-10035)
Species	Rabbit, New Zealand White
No. of animals (group size)	3 females
Initial test using one animal	Yes
Exposure	0.1 mL (single instillation in conjunctival sac)
Irrigation (time point)	No
Vehicle/Dilution	Water
Post exposure observation period	14 days
Remarks	None

Results and discussions

Table A 1: Eye irritation of ASSET ~~ZUXION~~

Animal No.		Scores after treatment *				Mean scores (24-72 h)	Reversible (day)
		1 h	24 h	48 h	72 h		
1	Corneal opacity Iritis Redness conjunctivae Chemosis conjunctivae	0.00 0.00 0.00 0.00	0.00 0.00 0.00 0.00	0.00 0.00 0.00 0.00	0.00 0.00 0.00 0.00	0.00 0.00 0.00 0.00	-
2	Corneal opacity Iritis Redness conjunctivae Chemosis conjunctivae	0.00 0.00 1.00 0.00	0.00 0.00 1.00 .000	0.00 0.00 0.00 0.00	0.00 0.00 0.00 0.00	0.00 0.00 0.33 0.00	48h
3	Corneal opacity Iritis Redness conjunctivae Chemosis conjunctivae	0.00 0.00 1.00 0.00	0.00 0.00 1.00 0.00	0.00 0.00 0.00 0.00	0.00 0.00 0.00 0.00	0.00 0.00 0.33 0.00	48h

* scores in the range of 0 to 0 for cornea opacity, 0 for iritis, 0 to 1 for redness of conjunctivae and for chemosis.

Clinical signs:	No clinical signs of toxicity were observed.

Conclusion

Under the experimental conditions, ASSET ~~ZUXION~~ is not an eye irritant. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

A 1.7 Skin sensitisation (KCP 7.1.6)

Comments of zRMS:	**Acceptable** **According to the Regulation EC No. 1272/2008, Acetamiprid 20% SG is not classified. No signal word or hazard statement is required for this hazard.**

Acute toxicity studies for Acetamiprid 20% SG were **not** evaluated as part of the EU review of acetam-

iprid. Therefore, all relevant data are provided here and are considered adequate. Details of the co-formulants and their classification and the calculation methodology that was used to assess the acute oral toxicity of Acetamiprid 20% SG can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).
There is no co-formulant in the Acetamiprid 20% SG recipe classified as skin sensitizer. Therefore no skin sensitization is expected during using this product.
According to the Regulation EC No. 1272/2008, Acetamiprid 20% SG is **not classified**. No signal word or hazard statement is required for this hazard.

A 1.8 Supplementary studies for combinations of plant protection products (KCP 7.1.7)

No supplementary studies are necessary.

A 1.9 Data on co-formulants (KCP 7.4)

A 1.9.1 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 1.9.2 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 1.10 Studies on dermal absorption (KCP 7.3)

Comments of zRMS:	**Study on dermal absorption is acceptable** **Undiluted Acetamiprid 20% SG (concentrate) 83 % of dose:** **Actual spray strength used in the field dilution 35 % of dose**

Reference	KCP 7.6.2
Report	In vitro percutaneous absorption of Acetamiprid, formulated as Acetamiprid 20 % SG, through human skin, Triskelion B.V, Brufau Donés,G, 2018 Report No.21130/26
Guideline(s)	OECD Guideline 428 “Skin Absortion: in vitro Method” April 2004
Deviations	Yes
GLP	Yes
Acceptability	Yes
Duplication	No

stratum corneum	0.072	0.061	0.069	0.076	0.103	0.140	0.113	0.072	0.088	0.028
Potentially absorbed	0.56	0.50	0.73	0.85	1.30	1.01	0.91	0.45	**0.79**	**0.29**
Skin wash	100.8	99.1	99.8	99.5	99.8	100.6	100.5	99.2	99.9	0.6
Donor compartment	0.07	0.30	0.29	0.09	0.03	0.02	0.32	0.10	0.15	0.13
Total recovery	101.4	100.0	100.9	100.5	101.1	101.6	101.8	99.8	**100.9**	**0.8**

Materials and methods

Test material	Name (Lot/Batch No.)	Acetamiprid, [pyridyl-2,6-14C] CC-701)
	Test preparation	radioformulation
	Specific activity	9.948 MBq·mg-1
	Radiochemical purity	100 %
Product	Name (Lot/Batch No.)	Acetamiprid 20 % SG (SCL-68293)
	Concentration a.s.	20.4 %
	Formulation type	SG
Blank product	Name (Lot/Batch No.)	Acetamiprid 20 % SG (SCL-77542)
	Concentration a.s.	0 g/L
Test system		
Diffusion cell	Cell type	dynamic
	(if dynamic) Flow rate	1.8 mL.h-1
	Exposed skin area	0.64 cm2
Membrane	Skin type	isolated epidermis
	Skin thickness range	0.2-0.4 mm
	Skin donors age	61, 47, 46, 48 years
	Skin donors sex	-
	Location	breast and abdomen
	Source	Human abdominal and breast skin
	Integrity test	yes
Receptor	Receptor medium	Scintillation liquid (Ultima Gold™)
	Solubility in receptor medium	n
Sample Time	Exposure time	8 h
Sampling	Sample intervals	24 h
Washing		At 8 h, using cottons swabs, a mild soap solution (3% Dove) and water
Final Procedure	Tape stripping	y
	TS1-2 analysed separately	n

Tested doses	Concentrate	Spray dilution 1
Target concentration [g·kg-1, g.L-1]	204	0.052
Area dose [µg/cm²]	1083 ± 76	0.50 ± 0.01
Specific activity [MBq·g-1,MBq.mL-1]	4.83	0.51
No. of donors	8	8

Results and discussions

Dose group		High dose (Formulation concentrate)		Low dose (Spray dilution 1:4000)	
Target concentration	[kg-1, g L-1]	200		0.05	
Mean actual applied dose	[µg/cm²]	1083 ± 76		0.50 ± 0.01	
Number of replicates (n)		8		8	
		Recovery [%]		Recovery [%]	
		Mean	S.D.	Mean	S.D.
Dislodgeable dose					
Donor chamber wash		99.2	0.2	67.1	6.8
Dose associated to skin					
Tape strips: 1st sample, strips 1 + 2		0.019	0.013	0.34	0.20
Tape strips: 2nd sample; strips 3 - n		0.023	0.011	0.75	0.46

Stripped skin	0.16	0.22	3.53	4.03
Absorbed dose	0.67	0.19	29.0	7.0
Receptor fluid	0.49	0.09	25.3	8.6
Receptor chamber wash	0.0024	0.0013	0.18	0.20
Total recovery[1]	88.8	7.3	97.7	0.6
Absorption essentially complete at end of study (>75% absorption within half the study duration) [%Absorption at $t_{0.5}$]	Yes [0.67 ± 0.19]		No [29.8 ± 6.6]	
If yes: Absorption = receptor fluid + receptor chamber washes + skin sample (excluding all tape strips)	0.67	0.19	N/A	N/A
If no: Absorption = receptor fluid + receptor chamber washes + skin sample (excluding tape strips 1 and 2) [2]	N/A	N/A	29.8	6.6
Absorption estimate normalised[3]	0.67 ± 0.84 × 0.19		29.8 ± 0.84 × 6.6	
Relevant absorption estimate	0.67 ± 0.16		29.8 ± 5.54	
Absorption estimates used for risk assessment[4]	**0.83**		**35**	

[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: 0.83 % of dose for undiluted Acetamiprid 20% SG (concentrate)

35 % of dose for actual spray strength used in the field dilution

A 1.11 Other/Special Studies

Not relevant.

Appendix 2 Exposure calculations

A 2.1 Operator exposure calculations (KCP 7.2.1.1)

A 2.1.1 Calculations for Acetamiprid

Table A 2: Input parameters considered for the estimation of operator exposure

Substance	Acetamiprid 20% SG	Formulation = Wettable granules, soluble granules	Application rate-0,04 kg a.s. /ha	Spray dilution = 0,0444444444444444 g a.s./l	Vapour pressure = low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Oilseeds / Outdoor / Downward spraying / Vehicle-mounted			Buffer = 2-3	Number applications = 1, Application interval = 365 days
Percentage Absoprtion	Dermal for product = 0,83	Dermal for in use diluation = 35	Oral = 100	Inhalation = 100	
RVNAS	0,025 mg/kg bw/day		RVAAS	0,025 mg/kg bw/day	
DFR	3 µg a.s./cm2 per kg a.s./ha		DT50	30 days	

Operator Model		Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day		0,0041	% of RVNAS	16,49%
	Acute systemic exposure mg/kg bw/day		0,0360	% of RVAAS	144,13%
Mixing and Loading		Gloves = No	Clothing = Work wear - arms, body and legs covered	RPE = None	Soluble bags = No
Application		Gloves = No	Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No

Table A 3: Estimation of longer operator exposure towards Acetamiprid according to EFSA guidance

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	**0,2473317**	**0,1744699**	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	**0,0041222**	**0,0029078**	
% of RVNAS	**16,49%**	**11,63%**	

Table A 4: Input parameters considered for the estimation of operator exposure

Substance	Acetamiprid 20% SG	Formulation = Wettable granules, soluble granules	Application rate-0,05 kg a.s. /ha	Spray dilution = 0,0555555555555556 g a.s./l	Vapour pressure = low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Pome fruit / Outdoor / Upward spraying / Vehicle-mounted			Buffer = 2-3	Number applications = 1, Application interval = 365 days
Percentage Absoprtion	Dermal for product = 0,83	Dermal for in use diluation = 35	Oral = 100	Inhalation = 100	
RVNAS	0,025 mg/kg bw/day		RVAAS	0,025 mg/kg bw/day	
DFR	3 µg a.s./cm2 per kg a.s./ha		DT50	30 days	

Operator Model		Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day		0,0385	% of RVNAS	153,90%
	Acute systemic exposure mg/kg bw/day		0,1962	% of RVAAS	784,62%
Mixing and Loading		Gloves = No	Clothing = Work wear - arms, body and legs covered	RPE = None	Soluble bags = No
Application		Gloves = No	Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No

Table A 5: Estimation of longer operator exposure towards Acetamiprid according to EFSA guidance

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	**2,3085548**	**0,7804114**	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	**0,0384759**	**0,0130069**	
% of RVNAS	**153,90%**	**52,03%**	

Table A 6: Input parameters considered for the estimation of operator exposure

Substance	Acetamiprid 20% SG	Formulation = Wettable granules, soluble granules	Application rate-0,036 kg a.s. /ha	Spray dilution = 0,04 g a.s./l	Vapour pressure = low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Pome fruit / Outdoor / Upward spraying / Vehicle-mounted			Buffer = 5	Number applications = 2, Application interval = 14 days
Percentage Absoprtion	Dermal for product = 0,83	Dermal for in use diluation = 35	Oral = 100	Inhalation = 100	
RVNAS	0,025 mg/kg bw/day		RVAAS	0,025 mg/kg bw/day	
DFR	3 µg a.s./cm2 per kg a.s./ha		DT50	30 days	
Operator Model		Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day		0,0281	% of RVNAS	112,43%
	Acute systemic exposure mg/kg bw/day		0,1428	% of RVAAS	571,04%
Mixing and Loading		Gloves = No	Clothing = Work wear - arms, body and legs covered	RPE = None	Soluble bags = No
Application		Gloves = No	Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No

Table A 7: Estimation of longer operator exposure towards Acetamiprid according to EFSA guidance

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	**1,6864631**	**0,5857373**	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	**0,0281077**	**0,0097623**	
% of RVNAS	**112,43%**	**39,05%**	

A 2.2 Worker exposure calculations (KCP 7.2.3.1)

A 2.2.1 Calculations for Acetamiprid

Table A 8: Input parameters considered for the estimation of worker exposure for Oilseed rape

Worker exposure from residues on foliage for Acetamiprid 20% SG		
Crop type	Oilseeds	
Indoor or outdoor	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Worker's task	Inspection, irrigation	
Main body parts in contact with foliage	Hand and body	
Application rate of active substance	0,04	kg a.s./ha
Number of applications	1	
Interval between multiple applications	365	days
Half-life of active substance	30	days
Multiple application factor	1,0	
Dermal absorption of the product	0,83%	
Dermal absorption of the in-use dilution	35,00%	
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,12	µg a.s./cm^2
Working hours	2	hr
Dermal transfer coefficient - Total potential exposure	12500	cm^2/hr
Dermal transfer coefficient - arms, body and legs covered	1400	cm^2/hr
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment	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 9: Estimation of worker exposure towards Acetamiprid according to EFSA guidance for Oilseed rape

1. Total			
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	1,0500000	0,1176000	no TC available for this assessment
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0175000	0,0019600	
% of RVNAS	70,00%	7,84%	

Table A 10: Input parameters considered for the estimation of worker exposure for Pome fruits

Worker exposure from residues on foliage for Acetamiprid 20% SG		
Crop type	Pome fruit	
Indoor or outdoor	Outdoor	
Application method	Upward spraying	
Application equipment	Vehicle-mounted	
Worker's task	Searching, reaching, picking	
Main body parts in contact with foliage	Hand and body	
Application rate of active substance	0,05	kg a.s./ha
Number of applications	2	
Interval between multiple applications	14	days
Half-life of active substance	30	days
Multiple application factor	1,7	
Dermal absorption of the product	0,83%	
Dermal absorption of the in-use dilution	35,00%	
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,15	µg a.s./cm^2
Working hours	8	hr
Dermal transfer coefficient - Total potential exposure	22500	cm^2/hr
Dermal transfer coefficient - arms, body and legs covered	4500	cm^2/hr
Dermal transfer coefficient - hands, arms, body and legs covered	2250	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 11: Estimation of worker exposure towards Acetamiprid according to EFSA guidance for

1. Total			
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	16,2883471	3,2576694	1,6288347
Total systemic exposure per kg body weight (mg/kg bw/day)	0,2714725	0,0542945	0,0271472
% of RVNAS	1085,89%	217,18%	108,59%

Table A 12: Input parameters considered for the estimation of worker exposure for re-entry period of 4 days

Worker exposure from residues on foliage for Acetamiprid 20% SG		
Crop type	Pome fruit	
Indoor or outdoor	Outdoor	
Application method	Upward spraying	
Application equipment	Vehicle-mounted	
Worker's task	Searching, reaching, picking	
Main body parts in contact with foliage	Hand and body	
Application rate of active substance	0,05	kg a.s./ha
Number of applications	2	
Interval between multiple applications	14	days
Half-life of active substance	30	days
Multiple application factor	1,7	
Dermal absorption of the product	0,83%	
Dermal absorption of the in-use dilution	35,00%	
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,1365	µg a.s./cm^2
Working hours	8	hr
Dermal transfer coefficient - Total potential exposure	22500	cm^2/hr
Dermal transfer coefficient - arms, body and legs covered	4500	cm^2/hr
Dermal transfer coefficient - hands, arms, body and legs covered	2250	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 13: Estimation of worker exposure towards Acetamiprid according to EFSA guidance for re-entry period of 4 days

1. Total			
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	14,8223959	2,9644792	1,4822396
Total systemic exposure per kg body weight (mg/kg bw/day)	0,2470399	0,0494080	0,0247040
% of RVNAS	988,16%	197,63%	98,82%

Table A 14: Input parameters considered for the estimation of worker exposure for Pome fruits

Crop type	Pome fruit	
Indoor or outdoor	Outdoor	
Application method	Upward spraying	
Application equipment	Vehicle-mounted	
Worker's task	Searching, reaching, picking	
Main body parts in contact with foliage	Hand and body	
Application rate of active substance	0,036	kg a.s./ha
Number of applications	2	
Interval between multiple applications	14	days
Half-life of active substance	30	days
Multiple application factor	1,7	
Dermal absorption of the product	0,83%	
Dermal absorption of the in-use dilution	35,00%	
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,108	µg a.s./cm^2
Working hours	8	hr
Dermal transfer coefficient - Total potential exposure	22500	cm^2/hr
Dermal transfer coefficient - arms, body and legs covered	4500	cm^2/hr
Dermal transfer coefficient - hands, arms, body and legs covered	2250	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 15: Estimation of worker exposure towards Acetamiprid according to EFSA guidance for

1. Total			
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	11,7276099	2,3455220	1,1727610
Total systemic exposure per kg body weight (mg/kg bw/day)	0,1954602	0,0390920	0,0195460
% of RVNAS	781,84%	156,37%	78,18%

A 2.3 Bystander and resident exposure calculations (KCP 7.2.2.1)

A 2.3.1 Calculations for Acetamiprid

Table A 16: Input parameters considered for the estimation of longer term resident exposure

Resident exposure for Acetamiprid 20% SG		
Croptype	Oilseeds	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Formulation type	Wettable granules, soluble granules	
Buffer strip	2-3	m
Application rate of the product	0,04	kg a.s./ha
Concentration of active substance (in-use dilution for liquid applications)	0,2	g a.s./l
Dermal absorption of product	0,83%	
Dermal absorption of in-use dilution	35,00%	
Oral absorption	100,00%	
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,12	µg a.s./cm^2
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa
Concentration in air	0,001	mg/m^3
Resident dermal spray drift exposure 75th percentile - adult	0,47	ml spray dilution/person
Resident dermal spray drift exposure 75th percentile - child	0,327	ml spray dilution/person
Resident inhal. spray drift exposure 75th percentile - adult	0,00010	ml spray dilution/person
Resident inhal. spray drift exposure 75th percentile - child	0,00022	ml spray dilution/person
Resident dermal spray drift exposure mean - adult	0,22318	ml spray dilution/person
Resident dermal spray drift exposure mean - child	0,18	ml spray dilution/person
Resident inhal. spray drift exposure mean - adult	0,00009	ml spray dilution/person
Resident inhal. spray drift exposure mean - child	0,00017	ml spray dilution/person
Exposure duration dermal	2	hours
Exposure duration inhalation	24	hours
Exposure duration entry into treated crops	0,25	hours
Light clothing adjustment factor	18,0%	
Breathing rate adult	0,23	m^3/day/kg
Breathing rate child (1-3 year old)	1,07	m^3/day/kg
Drift percentage on surface (75th percentile)	5,60%	
Drift percentage on surface (mean)	4,10%	
Turf transferable residues percentage	5,00%	
Transfer coeff. of surface deposits-adult	7300	cm^2/hour
Transfer coeff. of surface deposits-child (1-3 year old)	2600	cm^2/hour
Saliva extraction percentage	50,00%	
Surface area of hands mouthed	20	cm^2
Frequency of hand to mouth activity	9,5	events/hour
Ingestion rate for mouthing of grass per day	25	cm^2
Dislodgeable residues percentage transferability for object to mouth	20,00%	
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500	cm^2/h
Transfer coefficient for entry into treated crops (75th percentile) - child	2250	cm^2/h
Transfer coefficient for entry into treated crops (mean) - adult	5980	cm^2/h
Transfer coefficient for entry into treated crops (mean) - child	1794	cm^2/h

Table A 17: Estimation of longer term resident exposure towards Acetamiprid according to EFSA guidance

1.1 1-3 year old child

	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0188138	0,0107000	0,0040733	0,0407209	0,0565163
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0018814	0,0010700	0,0004073	0,0040721	0,0056516
% of RVNAS	7,53%	4,28%	1,63%	16,29%	22,61%

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0269980	0,0138000	0,0098647	0,1357362	0,1420779
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0004500	0,0002300	0,0001644	0,0022623	0,0023680
% of RVNAS	1,80%	0,92%	0,66%	9,05%	9,47%

Table A 18: Input parameters considered for the estimation of longer term resident exposure

Resident exposure for Acetamiprid 20% SG		
Croptype	Pome fruit	
Application method	Upward spraying	
Application equipment	Vehicle-mounted	
Formulation type	Wettable granules, soluble granules	
Buffer strip	5	m
Application rate of the product	0,05	kg a.s./ha
Concentration of active substance (in-use dilution for liquid applications)	0,055555556	g a.s./l
Dermal absorption of product	0,83%	
Dermal absorption of in-use dilution	35,00%	
Oral absorption	100,00%	
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,15	µg a.s./cm^2
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa
Concentration in air	0,001	mg/m^3
Resident dermal spray drift exposure 75th percentile - adult	5,63	ml spray dilution/person
Resident dermal spray drift exposure 75th percentile - child	1,689	ml spray dilution/person
Resident inhal. spray drift exposure 75th percentile - adult	0,00210	ml spray dilution/person
Resident inhal. spray drift exposure 75th percentile - child	0,00164	ml spray dilution/person
Resident dermal spray drift exposure mean - adult	3,68	ml spray dilution/person
Resident dermal spray drift exposure mean - child	1,11	ml spray dilution/person
Resident inhal. spray drift exposure mean - adult	0,00170	ml spray dilution/person
Resident inhal. spray drift exposure mean - child	0,00133	ml spray dilution/person
Exposure duration dermal	2	hours
Exposure duration inhalation	24	hours
Exposure duration entry into treated crops	0,25	hours
Light clothing adjustment factor	18,0%	
Breathing rate adult	0,23	m^3/day/kg
Breathing rate child (1-3 year old)	1,07	m^3/day/kg
Drift percentage on surface (75th percentile)	15,79%	
Drift percentage on surface (mean)	11,69%	
Turf transferable residues percentage	5,00%	
Transfer coeff. of surface deposits-adult	7300	cm^2/hour
Transfer coeff. of surface deposits-child (1-3 year old)	2600	cm^2/hour
Saliva extraction percentage	50,00%	
Surface area of hands mouthed	20	cm^2
Frequency of hand to mouth activity	9,5	events/hour
Ingestion rate for mouthing of grass per day	25	cm^2
Dislodgeable residues percentage transferability for object to mouth	20,00%	
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500	cm^2/h
Transfer coefficient for entry into treated crops (75th percentile) - child	2250	cm^2/h
Transfer coefficient for entry into treated crops (mean) - adult	5980	cm^2/h
Transfer coefficient for entry into treated crops (mean) - child	1794	cm^2/h

Table A 19: Estimation of longer term resident exposure towards Acetamiprid according to EFSA guidance

1.1 1-3 year old child

	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0270215	0,0107000	0,0143565	0,0509011	0,0796861
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0027021	0,0010700	0,0014357	0,0050901	0,0079686
% of RVNAS	10,81%	4,28%	5,74%	20,36%	31,87%

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0898839	0,0138000	0,0347687	0,1696703	0,2335945
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0014981	0,0002300	0,0005795	0,0028278	0,0038932
% of RVNAS	5,99%	0,92%	2,32%	11,31%	15,57%

Table A 20: Input parameters considered for the estimation of longer term resident exposure

Resident exposure for Acetamiprid 20% SG		
Croptype	Pome fruit	
Application method	Upward spraying	
Application equipment	Vehicle-mounted	
Formulation type	Wettable granules, soluble granules	
Buffer strip	5	m
Application rate of the product	0,036	kg a.s./ha
Concentration of active substance (in-use dilution for liquid applications)	0,04	g a.s./l
Dermal absorption of product	0,83%	
Dermal absorption of in-use dilution	35,00%	
Oral absorption	100,00%	
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,108	µg a.s./cm^2
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa
Concentration in air	0,001	mg/m^3
Resident dermal spray drift exposure 75th percentile - adult	5,63	ml spray dilution/person
Resident dermal spray drift exposure 75th percentile - child	1,689	ml spray dilution/person
Resident inhal. spray drift exposure 75th percentile - adult	0,00210	ml spray dilution/person
Resident inhal. spray drift exposure 75th percentile - child	0,00164	ml spray dilution/person
Resident dermal spray drift exposure mean - adult	3,68	ml spray dilution/person
Resident dermal spray drift exposure mean - child	1,11	ml spray dilution/person
Resident inhal. spray drift exposure mean - adult	0,00170	ml spray dilution/person
Resident inhal. spray drift exposure mean - child	0,00133	ml spray dilution/person
Exposure duration dermal	2	hours
Exposure duration inhalation	24	hours
Exposure duration entry into treated crops	0,25	hours
Light clothing adjustment factor	18,0%	
Breathing rate adult	0,23	m^3/day/kg
Breathing rate child (1-3 year old)	1,07	m^3/day/kg
Drift percentage on surface (75th percentile)	15,79%	
Drift percentage on surface (mean)	11,69%	
Turf transferable residues percentage	5,00%	
Transfer coeff. of surface deposits-adult	7300	cm^2/hour
Transfer coeff. of surface deposits-child (1-3 year old)	2600	cm^2/hour
Saliva extraction percentage	50,00%	
Surface area of hands mouthed	20	cm^2
Frequency of hand to mouth activity	9,5	events/hour
Ingestion rate for mouthing of grass per day	25	cm^2
Dislodgeable residues percentage transferability for object to mouth	20,00%	
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500	cm^2/h
Transfer coefficient for entry into treated crops (75th percentile) - child	2250	cm^2/h
Transfer coefficient for entry into treated crops (mean) - adult	5980	cm^2/h
Transfer coefficient for entry into treated crops (mean) - child	1794	cm^2/h

Table A 21: Estimation of longer term resident exposure towards Acetamiprid according to EFSA guidance

1.1 1-3 year old child					
	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0194555	0,0107000	0,0103367	0,0366488	0,0603700
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0019455	0,0010700	0,0010337	0,0036649	0,0060370
% of RVNAS	7,78%	4,28%	4,13%	14,66%	24,15%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0647164	0,0138000	0,0250335	0,1221626	0,1720520
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0010786	0,0002300	0,0004172	0,0020360	0,0028675
% of RVNAS	4,31%	0,92%	1,67%	8,14%	11,47%

Appendix 3 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)

Not relevant.