

# FINAL REGISTRATION REPORT

## Part B

### Section 6

#### Mammalian Toxicology

Detailed summary of the risk assessment

Product code: CHR/I/ADEL 280 SC

Product name(s): ADEL 280 SC; PYRIFOS ADE 280 SC

Chemical active substance(s):

Acetamiprid, 250 g/L

Deltamethrin, 30 g/L

Central Zone

Zonal Rapporteur Member State: Poland

#### CORE ASSESSMENT

(authorization)

Applicant: Innvigo Sp. z o.o.

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## Version history

When	What
September 2021	Dossier sent for evaluation
December 2021	Updated by Applicant
March 2022	zRMS finalised evaluation
October 2024	Final version prepared by zRMS after Commenting period
September 2025	zRMS update

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**zRMS comments:**

The text highlighted in grey was provided by the evaluator.

## **6 Mammalian Toxicology (KCP 7)**

Data matching studies for acetamiprid have been evaluated by RMS – Netherland and later by Po-land. As a result of the assessment all reports were accepted and considered as equivalent to protected studies. Therefore, to support the authorization of CHR/I/ADEL 280 SC (ADEL 280 SC/ PYRIFOS ADE 280 SC) INNVIKO is allowed to refer to EU approved reports

In the following document, data for active substance deltamethrin was described during its inclusion on Annex 1 process in 2009. Were reference to active substance data in the current risk assessment has been made, it was based on the data presented by Bayer (AgroEvo).

In November 30th, 2009r Decis 2.5 EC product has been authorized in Poland thus according to the art. 59 reg. 1107/2009, data protection for mentioned data expired 10 years from date of first authorization of product containing that active substance (in this case December, 1st 2019).

### **6.1 Summary**

**Table 6.1-1: Information on CHR/I/ADEL 280 SC \***

Product name and code	CHR/I/ADEL 280 SC
Formulation type	Suspension concentrate [SC]
Active substance(s) (incl. content)	Acetamiprid, 250 g/L Deltamethrin, 30 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 CHR/I/ADEL 280 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 CHR/I/ADEL 280 SC according to Regulation (EC) No 1272/2008**

Hazard class(es), categories:	Acute Tox. 4, H302 Repr. 2, H361d
Hazard pictograms or Code(s) for hazard pictogram(s):	GHS07, GHS08
Signal word:	Warning
Hazard statement(s):	H302 – Harmful if swallowed. H361d – Suspected of damaging the unborn child.
Precautionary statement(s):	<p><del>WARNING SECTION OF THE LABEL (first page)</del></p> <p>P264 - Wash hands thoroughly after handling.  P270 - Do not eat, drink or smoke when using this product.  P280 - Wear protective gloves, protective clothing, eye/face protection.  P301 + P312 – IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell.  P308 + P313 – IF exposed or concerned: Get medical advice/ attention.</p> <p><del>Other section of the label:</del>  P261: Avoid breathing spray.  P271: Use only outdoors.  P264: Wash hands thoroughly after handling.  P270: Do not eat, drink or smoke when using this product.  P362 + 364: Take off contaminated clothing and wash before reuse.  P501: Dispose of contents/container to...</p> <p><del>And P280 as follows:</del></p> <p><del>OPERATOR:</del></p> <p><del>„Stosować rękawice ochronne oraz odzież ochronną zabezpieczającą przed oddziaływaniem środków ochrony roślin oczu w trakcie przygotowywania cieczy użytkowej oraz rękawice ochronne i odzież roboczą w trakcie wykonywania zabiegu. W czasie oprysku należy zastosować techniki zmniejszające znoś preparatu.”</del></p> <p><del>„Wear protective gloves, protective clothing and face/eye protection during mixing and loading and protective gloves and workwear during application. During application, techniques reducing spray drift must be implemented.”</del></p> <p><del>WORKER:</del>  <del>“Stosować rękawice ochronne oraz odzież roboczą”.</del>  <del>“Wear protective gloves and work wear”</del></p> <p><del>Section “First Aid”</del></p> <p><del>P305+P351+P338</del>  <del>P310</del>  <del>P302 + P352</del>  <del>P332 + P313</del>  <del>P304+P340</del>  <del>P301+P312</del>  <del>P330</del></p>

	For polish version: see the label
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. May produce an allergic reaction. [EUH208]

Comments of zRMS:	Classification of CHR/I/ADEL 280 SC based on the calculation method with valid data available for each component of the mixture is accepted.
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**Table 6.1-3: Summary of risk assessment for operators, workers, bystanders and residents for CHR/I/ADEL 280 SC**

	Result	PPE / Risk mitigation measures
Operators	Acceptable	Gloves and workwear at mixing and loading and workwear during application. Drift reduction during application. Due to product classification: Protective gloves, protective clothing, eye/face protection at M&L.
Workers	Acceptable	Workwear Gloves during removing bolting sugar beets.
Bystanders	Acceptable	None
Residents	Acceptable	None

No unacceptable risk for operators, workers, bystanders and residents 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.

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

1 Use- No.*	2 Crops and situation (e.g. growth stage of crop)	3 F, Fn, Fpn G, Gn, Gpn or I **	4 Application		6 Application rate		8 PHI (d)	9 Remarks: (e.g. safener/synergist (L/ha))  critical gap for operator, worker, bystander or resident exposure based on [Exposure model]	10 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) Acetamiprid b) Deltamethrin	Water L/ha  min / max			Operator	Worker	Bystander	Residents
1, 2	Winter Oilseed rape (BRSNW) (Autumn and spring BBCH 10-5921, 30-70)	F	Spray, medium sprayer, LC TM	a) 1 b) 1	a) 0.04 0.02 b) 0.0048 0.0024	200-300	n/a		R	A	A	A
2, 3, 4	Winter cereals (wheat and triticale) (TRZAW), (TTLWI) (Spring BBCH 37-75 65-)	F	Spray, medium sprayer, LC TM	a) 1 b) 1	a) 0.04 0.02 b) 0.0048 0.0024	200-300	n/a 35		R	A	A	A

1	2	3	4	5	6	7	8	9	10
	75 (wheat), 49-75 (triticale))								
3 5	Sugar beet (BEAVA) (Spring BBCH 12-19)	F	Spray, medium sprayer, LC TM	a) 1 b)1	a) 0.04 0.02 b) 0.0048 0.0024	200-300	n/a		R A A A

\* 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

## Data gaps

Noticed data gaps are:

## 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)**

	Acetamiprid	Deltamethrin
Common Name	Acetamiprid	Deltamethrin
CAS-No.	135410-20-7	52918-63-5
<b>Classification and proposed labelling</b>		
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	Hazard class and category codes: According to RAC Opinion (04/05/2020) Repr. 2 Acute Tox. 3 Aquatic Acute 1 Aquatic Chronic 1  Hazard codes H361d H301 H400 H410  Pictogram, signal word codes: GHS06 GHS08 GHS09 Danger	Hazard class and category codes Acute tox. 3 Aquatic Acute 1 Aquatic Chronic 1  Hazard statement codes H301 H331 H400 H410  Pictograms, signal words codes: GHS09 GHS06 Danger  Specific Conc. Limits, M-factor M=1000000



	Acetamiprid	Deltamethrin
	<p>Specific Conc. Limits, M-factors and ATE:  M=10  M=10  Oral: ATE = 140 mg/kg bw</p> <p>Precautionary statement(s):  P264 – Wash hands thoroughly after handling.  P270 - Do not eat, drink or smoke when using this product.  P280 – Wear protective gloves/protective clothing/eye protection/face protection.  P301 + P310 – IF SWALLOWED: Immediately call a POISON CENTER/doctor.  P308 + P313 – IF exposed or concerned: Get medical advice/attention.  P391 – Collect spillage.</p>	<p>Precautionary statement(s):  P261 - Avoid breathing dust/fume/gas/mist/vapours/ spray  P264 – Wash hands thoroughly after handling.  P280 – Wear protective gloves/protective clothing/eye protection/face protection.  P301 + P310 – IF SWALLOWED: Immediately call a POISON CENTER/doctor.  P304 + P340 – IF INHALED: Remove person to fresh air and keep comfortable for breathing.  P403 + P233 – Store in a well-ventilated place. Keep container tightly closed.  P391 – Collect spillage.</p>
Additional C&L proposal		
<b>Agreed EU endpoints</b>		
AOEL systemic	0.025 mg/kg bw/day	0.0075 mg/kg bw/day
AAOEL	0.025 mg/kg bw	-
Reference	EFSA Journal 2016;14(11):4610 SANTE/10502/2017 Rev 4; 13 December 2017	Deltamethrin 6504/VI/99-final 17 October 2002
<b>Conditions to take into account/critical areas of concern with regard to toxicology</b>		
<p>Acetamiprid</p> <p>SANTE/10502/2017 Rev 4, 13 December 2017</p> <p>Deltamethrin 6504/VI/99-final 17 October 2002</p>	<p>On the basis of the proposed and supported uses (as listed in Appendix II), the following issues have been identified as requiring particular and short term attention from all Member States, in the framework of any authorisations to be granted, varied or withdrawn, as appropriate:  -the risk to operators.</p>	<p>On the basis of the proposed and supported uses, the following particular issues have been identified as requiring particular and short term attention from all Member States, in the framework of any authorisations to be granted, varied or withdrawn, as appropriate:  - Member States must pay particular attention to the operator safety and must ensure that the conditions of authorisation include appropriate protective measures.</p>

### 6.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for CHR/I/ADEL 280 SC is given in the following tables. Full summaries of studies on the product that have not been previously considered within an EU peer review process are described in detail in Appendix 2.

**Table 6.3-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for CHR/I/ADEL 280 SC**

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD <sub>50</sub> oral, rat (calculation method)	> 300 mg/kg bw	Yes	Acute Tox. 4, H302	M. Kolodziej, 2021
LD <sub>50</sub> dermal, rat (calculation method)	> 2 000 mg/kg bw	Yes	None	M. Kolodziej, 2021
LC <sub>50</sub> inhalation, rat (calculation method)	>20 mg/L air	Yes	None	M. Kolodziej, 2021
Skin irritation (calculation method)	Non-irritant	Yes	None	M. Kolodziej, 2021
Eye irritation, (calculation method)	Non-irritant	Yes	None	M. Kolodziej, 2021
Skin sensitisation, (calculation method)	Non-sensitising	Yes	None	M. Kolodziej, 2021
Supplementary studies for combinations of plant protection products	Suspected of damaging the unborn child.	Yes	Repr. 2, H361d	M. Kolodziej, 2021

**Table 6.3-2: Additional toxicological information relevant for classification/labelling of CHR/I/ADEL 280 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 (relevant for classification of product)	Acetamiprid (23.0 % (w/w))	Repr. 2, H361d (criteria > 10%) Acute Tox. 3, H301 (criteria, ATE> 300 mg/kg bw)	Reg. 1272/2008	Repr. 2, H361d Acute Tox. 4, H302
Toxicological properties of active substance (relevant for classification of product)	Deltamethrin (2.80% (w/w))	Acute Tox. 3, H301 (criteria, ATE> 300 mg/kg bw)	Reg. 1272/2008	Acute Tox. 4, H302
Toxicological properties of non-active substance(s) (relevant for classification of product)	NA	NA	NA	NA
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

Comments of zRMS:	Accepted. Detailed information available in Doc. B.10.
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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 CHR/I/ADEL 280 SC are presented in the following table.

**Table 6.5-1: Dermal absorption rates for active substances in CHR/I/ADEL 280 SC**

	Acetamiprid		Deltamethrin	
	Value	Reference	Value	Reference
Concentrate	10 %	EFSA Journal 2017;15(6):4873	10 %	EFSA Journal 2017;15(6):4873
Dilution	50 %	EFSA Journal 2017;15(6):4873	50 %	EFSA Journal 2017;15(6):4873

### 6.5.1 Justification for proposed values – Acetamiprid

No data on dermal absorption for Acetamiprid in CHR/I/ADEL 280 SC is available. Justifications for default values according to Guidance on Dermal Absorption EFSA Journal 2017;15(6):4873) are presented in the following table.

**Table 6.5-2: Default dermal absorption rates for Acetamiprid**

	Value	Justification for value	Acceptability of justification
Concentrate	10 %	A default dermal absorption value of 10% may be applied for concentrated products that are water-based/dispersed or solid-formulated	Yes
Dilution	50 %	A default dermal absorption value of 50% may be applied for (in use) dilutions water-based/ dispersed or solid-formulated	Yes

## 6.5.2 Justification for proposed values - Deltamethrin

No data on dermal absorption for deltamethrin in CHR/I/ADEL 280 SC is available. Justifications for default values according to Guidance on Dermal Absorption EFSA Journal 2017;15(6):4873) are presented in the following table.

**Table 6.5-3: Default dermal absorption rates for deltamethrin**

	Value	Justification for value	Acceptability of justification
Concentrate	10 % 50 %	A default dermal absorption value of 10% may be applied for concentrated products that are water-based/dispersed or solid-formulated However, according to the SANTE/2018/10591 rev.1, 24 October 2018, a plant protection product is considered a dilution when the active substance is present in the plant protection product at a concentration lower than or equal to 50 g/L (or 50g/Kg or 5%). Therefore, for deltamethrin (30g/L in the formulation) it is considered as a dilution and a default dermal absorption value of 50% was applied.	Yes
Dilution	50 %	A default dermal absorption value of 50% may be applied for (in use) dilutions water-based/ dispersed or solid-formulated	Yes

## 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	CHR/I/ADEL 280 SC	
Formulation type	SC	
Category	Insecticide	
Container size(s), short description	Acetamiprid 250 g/L Deltamethrin 30 g/L	
Active substance(s) (incl. content)	Acetamiprid 250 g/L	Deltamethrin 30 g/L
AOEL systemic	0.025 mg/kg bw/day	0.0075 mg/kg bw/d
AAOEL	0.025 mg/kg bw	-
Inhalation absorption	100 %	100 %

Oral absorption	100 %	100 %
Dermal absorption	Concentrate: 10 % Dilution: 50 % (Default value according to Guidance on Dermal Absorption EFSA Journal 2017;15(6):4873)	Concentrate: 10 % 50 % Dilution: 50 % (Default value according to Guidance on Dermal Absorption EFSA Journal 2017;15(6):4873 and SANTE/2018/10591 rev.1, 24 October 2018)

### 6.6.1 Selection of critical use(s) and justification

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

### 6.6.2 Operator exposure (KCP 7.2.1)

#### 6.6.2.1 Estimation of operator exposure

Comments of zRMS:	<p>The operator exposure calculations for the proposed uses of CHR/I/ADEL 280 SC conducted by the Applicant using the EFSA calculator and presented in Table 6.6 3 are accepted. Evaluator completed the calculations adding the option “no PPE, only workwear”.</p> <p>The reference value of acutely toxic active substance (RVAAS) for Acetamiprid is determined, therefore the predicted acute operator exposure for Acetamiprid was calculated. The estimated acute operator exposure during application for winter oilseed rape, winter cereals and sugar beets via tractor mounted boom sprayer <b>with a drift reduction technology used</b> is within acceptable limit when operator uses <b>working wear and gloves at the mixing/loading step</b> (42.47% of the AAOEL for Acetamiprid). This exposure is further reduced when operator uses gloves also at the application step (12.51 of the AAOEL for Acetamiprid).</p> <p>The predicted longer term systemic operator exposure for application of the product via tractor mounted boom sprayer <b>with a drift reduction technology used in the case of Acetamiprid</b> is within acceptable limit when operator uses <b>working wear at the mixing/loading and application step</b> (60.84% of the AOEL for Acetamiprid and 41.17% of the AOEL for Deltamethrin). The exposure is further reduced when operator uses gloves at the both steps.</p> <p><b>Conclusions</b></p> <p>No unacceptable risk both acute and longer term for operators was identified when the <b>a drift reduction technology is used</b> during application of CHR/I/ADEL 280 SC and provided that the operator uses <b>working wear and gloves at the mixing/loading step</b>.</p> <p>However, taking into consideration the classification of the product and hygienic rules, the working wear and gloves are also recommended during application of the product.</p> <p>New exposure calculations were performed using the new EFSA calculator (2022, OPEX version 1.0.2) for accepted uses using lower application rates and default dermal absorption value of 50% (conc.) for deltamethrin. The calculation report is included in Appendix 3. The calculation results revealed that the use of CHR/I/ADEL 280 SC is safe for the operator in the scenarios Field crops and Low vegetables if gloves are used during the</p>
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	mixing/loading step.
	However, taking into consideration the classification of the product (Acute Tox. 4, H302 and Repr. 2, H361d) it is recommended to use protective gloves, protective clothing, eye/face protection at M&L.

A summary of the exposure models used for estimation of operator exposure to the active substances during application of CHR/I/ADEL 280 SC 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 3.

**Table 6.6-2: Exposure models for intended uses**

Critical use(s)	Winter oilseed rape, winter cereals, sugar beets (max. 0.16 L product/ha)
Model(s)	"EFSA Model" ver. 30.03.2015
Critical use(s)	Field crops (Winter Oilseed rape, Winter cereals), Low vegetables (Sugar beet) (max. 0.08 L product/ha)
Model(s)	"EFSA Model" 2022, OPEX ver. 1.0.2.

**Table 6.6-3: Estimated operator exposure**

		Acetamiprid				Deltamethrin***	
		Long-term		Acute		Long-term	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL	Total absorbed acute dose (mg/kg/day)	% of AAOEL	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to low crops Acetamiprid Application rate: 1 x 0.04 kg a.s./ha Vehicle mounted Drift Reduction Buffer strip 2-3 m Deltamethrin application rate: 1 x 0.0048 kg a.s./ha Vehicle-mounted Buffer strip 2-3 m							
EFSA model	no PPE*	0.0250224	100.09	0.207139	828.70	0.0054184	72.25
	no PPE – workwear*** during mixing/loading and application	0.0152104	60.84	0.0606317	242.53	0.0030880	41.17
	+ PPE, gloves and workwear at mixing/loading	0.0017056	6.82	0.0106187	42.47	0.0005737	7.65
	+ PPE, gloves and workwear at mixing/loading	0.0004924	1.97	0.0031287	12.51	0.0002785	3.71

	and during application						
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\* no PPE: Potential exposure Operator wearing T-shirt and shorts

\*\* no PPE: Operator wearing long sleeved shirt, long trousers ("permeable") but no gloves

\*\*\* No AAOEL is allocated and therefore only long term risk assessment was performed.

		Acetamiprid				Deltamethrin	
		Short-term		Acute		Short-term	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL	Total absorbed acute dose (mg/kg/day)	% of AAOEL	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Field crops/Low vegetables, Vehicle-mounted, Downward spraying Acetamiprid Application rate: 1 x 0.02 kg a.s./ha Deltamethrin application rate: 1 x 0.0024 kg a.s./ha Buffer strip 2-3 m							
EFSA model	no PPE		86.9		541		321
	Workwear	0.02	60.4		270		237
	Workwear + gloves at mixing/loading		6.6	0.02	91.2	0.0005	7.3

Winter oilseed rape crop was chosen as representative scenario for risk assessment since all input parameters for all crops are identical and risk assessment of operator to application on winter oilseed rape covers risk assessment for winter cereals and sugar beets.

### 6.6.3 Measurement of operator exposure

Since the operator exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) and acute acceptable operator exposure level (AAOEL for Acetamiprid) will not be exceeded under conditions of intended uses and considering above mentioned personal protective equipment (PPE) and a drift reduction technology, 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)

Comments of zRMS:	<p>The worker exposure calculations for the proposed uses of CHR/I/ADEL 280 SC conducted by the Applicant using the EFSA calculator and presented in Table 6.6 5 are accepted.</p> <p>The worker exposure is within acceptable limit assuming workers are wearing workwear (arms, body and legs covered). The obtained exposure values are below the AOEL values.</p> <p>New exposure calculations were performed using the new EFSA calculator (2022, OPEX version 1.0.2) for accepted uses using lower application rates and default dermal absorption value of 50% (conc.) for deltamethrin. The calculation report is included in Appendix 3. The calculation results confirmed that the use of CHR/I/ADEL 280 SC is safe for the</p>
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	workers in the scenarios Field crops (Inspection, irrigation) and Low vegetables (Inspection, irrigation and Removing bolting sugar beets) if workers are wearing workwear (arms, body and legs covered).
	Due to the calculation results for combined exposure: HQ=1 in the scenario Low vegetables (Removing bolting sugar beets) - workers should use gloves.

#### 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 CHR/I/ADEL 280 SC according to the critical use(s). Outcome of the estimation is presented in Table 6.6-5. Detailed calculations are in Appendix 3.

**Table 6.6-4: Exposure models for intended uses**

Critical use(s)	Winter oilseed rape, winter cereals, sugar beets (max. 0.16 L product/ha)
Model	"EFSA Model" ver. 30.03.2015

Critical use(s)	Field crops (Winter Oilseed rape, Winter cereals), Low vegetables (Sugar beet) (max. 0.08 L product/ha)
Model(s)	"EFSA Model" 2022, OPEX ver. 1.0.2

**Table 6.6-5: Estimated worker exposure**

		Acetamiprid		Deltamethrin	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Number of applications and application rate:		1 x 0.04 kg a.s./ha		1 x 0.0048 kg a.s./ha	
2 hours/day <sup>(1)</sup> ; TC: 12500 cm <sup>2</sup> /person/h (no PPE) TC: 1400 cm <sup>2</sup> /person/h (with no PPE—workwear) Body weight: 60 kg	no PPE <sup>(2)</sup>	0.0250000	100	0.0030000	40.00
	with no PPE <sup>(3)</sup> workwear	0.0028000	11.20	0.0003360	4.48

(1) e.g. 8 h/day for professional applications for harvesting, pruning, tying, thinning or weeding activities etc. or 2 h/day for professional applications for maintenance, inspection or irrigation activities etc.

(2) no PPE: Worker wearing long sleeved shirt, long trousers ("permeable") but no gloves

(3) with PPE: type of PPE / see 'Instructions for use' no PPE: Worker wearing work wear – arms, body and legs covered



		Acetamiprid		Deltamethrin	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Number of applications and application rate:		1 x 0.02 kg a.s./ha		1 x 0.0024 kg a.s./ha	
Field crops Inspection, irrigation 2 hours/day	no PPE	0.01	50	0.002	20
	Workwear	0.001	5.6	0.0002	2.2
Low vegetables Inspection, irrigation 2 hours/day	no PPE	0.01	50	0.002	20
	Workwear	0.001	5.6	0.0002	2.2
Low vegetables Removing bolting sugar beets 8 hours/day	no PPE	0.07	298	0.009	119
	Workwear	0.02	70.4	0.002	28.2

Winter oilseed rape crop was chosen as representative scenario for risk assessment since all input parameters for all crops are identical and risk assessment of worker to application on winter oilseed rape covers risk assessment for winter cereals and sugar beets.

#### 6.6.4.2 Refinement of generic DFR value (KCP 7.2)

Not required

#### 6.6.4.3 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.

#### 6.6.5 Bystander and resident exposure (KCP 7.2.2)

Comments of zRMS:	Evaluator recalculated the bystander and resident exposure for the worst scenario of 2-3 m buffer strip and without a drift reduction technology.
	<b>Bystander exposure:</b>
	The reference value of acutely toxic active substance (RVAAS) for Acetamiprid is determined, therefore the bystander exposure for Acetamiprid was calculated. The estimated bystander exposure to a child and adult resulted from spray drift, vapour, surface deposits and entry into treated crops for Acetamiprid for all intended uses is within acceptable limits.
	The reference value of acutely toxic active substance (RVAAS) for Deltamethrin is not determined, therefore it is assumed that bystander exposure is covered by the resident exposure assessed for Deltamethrin.
	<b>Resident exposure:</b>

	The exposure to a child and adult resident resulted from all pathways calculated for Acetamiprid and Deltamethrin are within acceptable limits. Therefore the use of CHR/I/ADEL 280 SC does not cause unacceptable health risk.
	New exposure calculations were performed using the new EFSA calculator (2022, OPEX version 1.0.2) for accepted uses using lower application rates and default dermal absorption value of 50% (conc.) for deltamethrin. The calculation report is included in Appendix 3. The calculation results confirmed that the use of CHR/I/ADEL 280 SC is safe for the bystander and residents.

### 6.6.5.1 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 and Deltamethrin. Outcome of the estimation is presented in Table 6.6-7. Detailed calculations are in Appendix 3.

**Table 6.6-6: Exposure models for intended uses**

Critical use(s)	Winter oilseed rape, winter cereals, sugar beets (max. 0.16 L product/ha)
Model	"EFSA Model" ver. 30.03.2015

Critical use(s)	Field crops (Winter Oilseed rape, Winter cereals), Low vegetables (Sugar beet) (max. 0.08 L product/ha)
Model(s)	"EFSA Model" 2022, OPEX ver. 1.0.2.

**Table 6.6-7: Estimated bystander exposure**

	Acetamiprid	
Model data	Total absorbed dose (mg/kg/day)	% of AAOEL
Tractor mounted boom spray application outdoors to low crops Acetamiprid Application rate: 1 x 0.04 kg a.s./ha Vehicle mounted Buffer strip 2-3 m		
Bystanders (adult) Drift rate: 0.57-1.21 (5-2-3 m) Body weight: 60 kg Spray drift	0.0003903 0.0016553	1.56 6.62
Bystanders (adult) Drift rate: 0.57-1.21 (5-2-3 m) Body weight: 60 kg Vapour	0.0002300	0.92
Bystanders (adult) Drift rate: 0.57-1.21	0.0000846 0.0004108	0.34 1.64

(5-2-3 m) Body weight: 60 kg Surface deposits		
Bystanders (adult) Drift rate: 0.57-1.21 (5-2-3 m) Body weight: 60 kg Entry into treated crops	0.0018750	7.5
Bystanders (children) Drift rate: 0.48-0.74 (5-2-3 m) Body weight: 10 kg Spray drift	0.00019763 0.0060904	7.91 24.36
Bystanders (children) Drift rate: 0.48-0.74 (5-2-3 m) Body weight: 10 kg Vapour	0.0010700	4.28
Bystanders (children) Drift rate: 0.48-0.74 (5-2-3 m) Body weight: 10 kg Surface deposits	0.0001995 0.0009690	0.8 3.88
Bystanders (children) Drift rate: 0.48-0.74 (5-2-3 m) Body weight: 10 kg Entry into treated crops	0.0033750	13.50

	Acetamiprid	
Model data	Total absorbed dose (mg/kg/day)	% of AAOEL
Field crops/Low vegetables, Vehicle-mounted, Downward spraying Acetamiprid Application rate: 1 x 0.02 kg a.s./ha Buffer strip 2-3 m		
Bystanders (adult) Body weight: 60 kg 95 <sup>th</sup> perc.	Drift 0.0008 Vapour 0.0003 Deposits 0.0005 Re-entry 0.0009	12.2 3.2 1.9 6.8
Bystanders (child) Body weight: 10 kg 95 <sup>th</sup> perc.	Drift 0.003 Vapour 0.0008 Deposits 0.0005 Re-entry 0.002	3.3 1.1 0.8 3.8

**Table 6.6-8: Estimated resident exposure**

	<b>Acetamiprid</b>		<b>Deltamethrin</b>	
<b>Model data</b>	<b>Total absorbed dose (mg/kg/day)</b>	<b>% of systemic AOEL</b>	<b>Total absorbed dose (mg/kg/day)</b>	<b>% of systemic AOEL</b>
Tractor mounted boom spray application outdoors to low crops Acetamiprid Application rate: 1 x 0.04 kg a.s./ha Vehicle mounted Buffer strip 2-3 m Deltamethrin application rate: 1 x 0.0048 kg a.s./ha Vehicle mounted Buffer strip 2-3 m				
Residents (adult) Drift rate: 0.12-0.22 (5-2-3 m) Body weight: 60 kg All pathways (mean)	0.0018309 0.0021304	7.32 8.52	0.0004348 0.0004580	5.80 6.14
Residents (children) Drift rate: 0.12-0.18 (5-2-3 m) Body weight: 10 kg All pathways (mean)	0.0043064 0.0054774	17.23 21.94	0.0015238 0.0015989	20.32 21.32

	<b>Acetamiprid</b>		<b>Deltamethrin</b>	
<b>Model data</b>	<b>Total absorbed dose (mg/kg/day)</b>	<b>% of systemic AOEL</b>	<b>Total absorbed dose (mg/kg/day)</b>	<b>% of systemic AOEL</b>
Field crops/Low vegetables, Vehicle-mounted, Downward spraying Acetamiprid Application rate: 1 x 0.02 kg a.s./ha Deltamethrin application rate: 1 x 0.0024 kg a.s./ha Buffer strip 2-3 m				
Residents (adult) Body weight: 60 kg All pathways (mean) 75 <sup>th</sup> perc.	0.001	4.9	0.0004	5.1
Residents (child) Body weight: 10 kg All pathways (mean) 75 <sup>th</sup> perc	0.003	12	0.001	14.2

Winter oilseed rape crop was chosen as representative scenario for risk assessment since all input parameters for all crops are identical and risk assessment of resident and bystander to application on winter oilseed rape covers risk assessment for winter cereals and sugar beets.

Additionally, no AAOEL for deltamethrin was allocated and therefore the risk assessment for bystander is covered by the risk assessment for resident.

### 6.6.5.2 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 and deltamethrin 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.

## 6.6.6 Combined exposure

The product is a mixture of two active substances.

### 6.6.6.1 Exposure Assessment of Acetamiprid and Deltamethrin in CHR/I/ADEL 280 SC

Comments of zRMS:	<p>The calculated Hazard Index is <math>&lt; 1</math>, therefore combined exposure to all active substances in CHR/I/ADEL 280 SC is not expected to present a risk for operator, workers and residents.</p> <p>The exposure assessment for residents also covers bystander exposure, therefore combined exposure is also not expected for bystanders.</p> <p>New exposure calculations were performed using the new EFSA calculator (2022, OPEX version 1.0.2) for accepted uses using lower application rates and default dermal absorption value of 50% (conc.) for deltamethrin. The calculation report is included in Appendix 3. The results of the combined exposure calculation confirmed that the use of CHR/I/ADEL 280 SC is safe for the operators, workers doing inspections, bystander and residents, however workers removing bolting sugar beets should use gloves.</p>
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Note: The combined toxicological effect of these active substances has not been investigated with regard to repeated dose toxicity.

At the first tier, combined exposure is calculated as the sum of the component exposures without regard to the mode of action or mechanism/target of toxicity. Initially, the individual Hazard Quotients (HQ) are calculated for all active substances in the PPP by assessing the exposure according to appropriate models and dividing the individual exposure levels by the respective systemic AOEL. This is equivalent to the predicted exposure as % of systemic AOEL from Table 6.6-3 converted to decimal. The Hazard Index (HI) is the sum of the individual HQs.

**Table 6.6-9: Acute risk assessment from combined exposure (longer term exposure)**

Application scenario	Active Ingredient	Estimated exposure / AOEL (HQ)
Operators — with PPE (gloves at mixing/loading step)	Acetamiprid	0.0682
	Deltamethrin	0.0765
	Cumulative risk Operators (HI)	0.1447
Operators — with ppePPE (gloves at mixing/loading and during application)	Acetamiprid	0.0197
	Deltamethrin	0.0374
	Cumulative risk Operators (HI)	0.0568

Application scenario	Active Ingredient	Estimated exposure / AOEL (HQ)
Workers— with ppe no PPE (work wear)	Acetamiprid	0.1120
	Deltamethrin	0.0448
	Cumulative risk Workers (HI)	0.1568
Resident – Adult	Acetamiprid	0.0732 0.0852
	Deltamethrin	0.0580 0.6107
	Cumulative risk Resident – Adult (HI)	0.1312 0.6959
Resident – Child	Acetamiprid	0.1723 0.2191
	Deltamethrin	0.2032 0.2132
	Cumulative risk Resident – Child (HI)	0.3755 0.4323

Application scenario	Combined exposure (Hazard index)
Operator Field crops/Low vegetables with PPE (gloves at mixing/loading step)	0.139
Worker Field crops/Low vegetables (Inspection, irrigation) Workwear	0.08
Worker Low vegetables (Removing bolting sugar beets) Workwear	1
Worker Low vegetables (Removing bolting sugar beets) Workwear + gloves	0.1
Resident – Adult Field crops/Low vegetables	0.1
Resident – Child Field crops/Low vegetables	0.3

The Hazard Index is < 1 for operators, workers doing inspections, resident and bystanders. Thus combined exposure to all active substances in CHR/I/ADEL 280 SC is not expected to present a risk for operators, workers doing inspections, bystanders and residents. For workers removing bolting sugar beets, HQ=1, therefore workers should wear gloves. No further refinement of the assessment is required.

## Appendix 1 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 7.1.1 KCP 7.1.2 KCP 7.1.3 KCP 7.1.4 KCP 7.1.5 KCP 7.1.6	M. Kolodziej	2021	Toxicological classification of product CHR/I/ADEL 280 SC based on calculation method taking into consideration health hazards of constituent substances. PUH Chemirol Sp. z o.o. non GLP Unpublished	N	Chemirol

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner

The following tables are to be completed by MS

**List of data submitted by the applicant and not relied on**

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>

**List of data relied on not submitted by the applicant but necessary for evaluation**

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>



## Appendix 2 Detailed evaluation of the studies relied upon

### A 2.1 Statement on bridging possibilities

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

Comments of zRMS:	A prediction of acute oral toxicity of CHR/I/ADEL 280 SC based on calculation method as specified in the Regulation (EC) No 1272/2008 (CLP) is acceptable. Acute oral toxicity was determined taking into consideration valid data available for each component of the mixture. The calculated ATE <sub>mix</sub> is 514 mg/kg bw, therefore the formulation should be classified as Acute Tox. 4 with the statement H302.
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Reference:	KCP 7.1.1
Report	Toxicological classification of product CHR/I/ADEL 280 SC based on calculation method taking into consideration health hazards of constituent substances; M. Kolodziej; 2021
Guideline(s):	Regulation (EC) No. 1272/2008
Deviations:	-
GLP:	No
Acceptability:	Yes
Duplication (if vertebrate study)	No

According to point 7.1.1 of Part A of Annex to the Commission Regulation (EU) No 284/2013 as regards the data requirements for plant protection products:

” A test for acute oral toxicity shall be carried out, unless the applicant can justify an alternative approach under Regulation (EC) No 1272/2008. In the latter case, acute oral toxicity of all components shall be provided or reliably predicted with a validated method. Consideration shall be given to the possible effects of components on the toxic potential of the total mixture.”

The complete composition of the formulation with the classification of individual ingredients is available in part C.

Due to the fact, that all components of the formulation CHR/I/ADEL 280 SC are known, the acute oral toxicity test is not necessary.

### Materials and methods

We use the summation method using the formula:

$$ATE_{mix} = \frac{100}{\sum_{i=1}^n \frac{C_i}{ATE_i}}$$

Where:

- C<sub>i</sub> - concentration of ingredient i ( % w/w or % v/v)

- i – the individual ingredient from 1 to n
- n – the number of ingredients
- ATE<sub>i</sub> - Acute Toxicity Estimate of ingredient i.

We use the table:

Table 3.1.2

Conversion from experimentally obtained acute toxicity range values (or acute toxicity hazard categories) to acute toxicity point estimates for classification for the respective routes of exposure.

Exposure routes	Classification Category or experimentally obtained acute toxicity range estimate	Converted acute toxicity point estimate (see Note 1)
Oral (mg/kg bodyweight)	0 < Category 1 ≤ 5	0,5
	5 < Category 2 ≤ 50	5
	50 < Category 3 ≤ 300	100
	300 < Category 4 ≤ 2 000	500
Dermal (mg/kg bodyweight)	0 < Category 1 ≤ 50	5
	50 < Category 2 ≤ 200	50
	200 < Category 3 ≤ 1 000	300
	1 000 < Category 4 ≤ 2 000	1 100
Gases (ppmV)	0 < Category 1 ≤ 100	10
	100 < Category 2 ≤ 500	100
	500 < Category 3 ≤ 2 500	700
	2 500 < Category 4 ≤ 20 000	4 500
Vapours (mg/l)	0 < Category 1 ≤ 0,5	0,05
	0,5 < Category 2 ≤ 2,0	0,5
	2,0 < Category 3 ≤ 10,0	3
	10,0 < Category 4 ≤ 20,0	11
Dust/mist (mg/l)	0 < Category 1 ≤ 0,05	0,005
	0,05 < Category 2 ≤ 0,5	0,05
	0,5 < Category 3 ≤ 1,0	0,5
	1,0 < Category 4 ≤ 5,0	1,5

Note 1

These values are designed to be used in the calculation of the ATE for classification of a mixture based on its components and do not represent test results.

Five ingredients are classified in this class of hazard.

- 0.018% (Acute Tox. 4, H302, ATE = 500 mg/kg)
- 0.009% (Acute Tox. 4, H302, LD<sub>50</sub> < 333 mg/kg)
- 0.61% (Acute Tox. 4, H302, ATE = 500 mg/kg)
- 23.16% (Acute Tox. 3, H301, LD<sub>50</sub> = 140 mg/kg)
- 2.80% (Acute Tox. 3, H301, ATE = 100 mg/kg)

$$ATE_{mix} = \frac{100}{\sum_{i=1}^n ATE_i} = \frac{100}{\frac{0.018}{500} + \frac{0.009}{333} + \frac{0.61}{500} + \frac{23.16}{140} + \frac{2.80}{100}} = 514$$

## Results and discussions

According to the table 3.1.2, the result (514 mg/kg bw) is higher than generic concentration level (300 mg/kg b.w.) and below 2000 mg/kg bw.

## Conclusion

The formulation is classified as **Acute Tox. 4, H302**.

According to point 7.1.1 of part A of Annex Regulation No 284/2014, it is possible to waive from performing acute oral toxicity tests.

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

Comments of zRMS:	Justification is acceptable, although it was not included in the cited report. Taking into consideration valid data available for each component of the mixture, the formulation CHR/I/ADEL 280 SC should not be classified for acute dermal toxicity.
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#### A 2.3.1 Study 1

Reference:	KCP 7.1.2
Report	Toxicological classification of product CHR/I/ADEL 280 SC based on calculation method taking into consideration health hazards of constituent substances; M. Kolodziej; 2021
Guideline(s):	Regulation (EC) No. 1272/2008
Deviations:	-
GLP:	No
Acceptability:	Yes
Duplication (if vertebrate study)	No

According to point 7.1.2 of Part A of Annex to the Commission Regulation (EU) No 284/2013 as regards the data requirements for plant protection products:

”A test for dermal toxicity shall be carried out on a case by case basis, unless the applicant can justify an alternative approach under Regulation (EC) No 1272/2008. In the latter case, acute dermal toxicity of all components shall be provided or reliably predicted with a validated method. Consideration shall be given to the possible effects of components on the toxic potential of the total mixture. Findings of severe skin irritation or corrosion in the dermal study may be used instead of performing a specific irritation study.”

The complete composition of the formulation with the classification of individual ingredients is available in part C.

Due to the fact, that all components of the formulation CHR/I/ADEL 280 SC are known, the acute dermal toxicity test is not necessary.

### Conclusion

The active substances and the other co-formulants are not classified as acute, dermal toxic, it can be assumed that entire formulation is not classified in this class.

According to point 7.1.2 of part A of Annex Regulation No 284/2014, it is possible to waive from performing acute dermal toxicity tests.

### A 2.4 Acute inhalation toxicity (KCP 7.1.3)

Comments of zRMS:	Acceptable. Taking into consideration valid data available for each component of the mixture, the formulation CHR/I/ADEL 280 SC should not be classified for inhalation toxicity.
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#### A 2.4.1 Study 1

Reference:	KCP 7.1.3
Report	Toxicological classification of product CHR/I/ADEL 280 SC based on calculation method taking into consideration health hazards of constituent substances; M. Kolodziej; 2021
Guideline(s):	Regulation (EC) No. 1272/2008
Deviations:	-
GLP:	No
Acceptability:	Yes
Duplication (if vertebrate study)	No

According to point 7.1.3 of Part A of Annex to the Commission Regulation (EU) No 284/2013 as regards the data requirements for plant protection products:

“A study shall not be required if the applicant can justify an alternative approach under Regulation (EC) No 1272/2008, where applicable. For this purpose, acute inhalation toxicity of all components shall be provided or reliably predicted with a validated method. Consideration shall be given to the possible effects of components on the toxic potential of the total mixture.”

The complete composition of the formulation with the classification of individual ingredients is available in part C.

Due to the fact, that all components of the formulation CHR/I/ADEL 280 SC are known, the acute ~~oral~~ **inhalation** toxicity test is not necessary.

## Materials and methods

We use the summation method using the formula:

$$ATE_{mix} = \frac{100}{\sum_{i=1}^n \frac{C_i}{ATE_i}}$$

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
- $ATE_i$  - Acute Toxicity Estimate of ingredient i.

We use the table:

Table 3.1.2

Conversion from experimentally obtained acute toxicity range values (or acute toxicity hazard categories) to acute toxicity point estimates for classification for the respective routes of exposure.

Exposure routes	Classification Category or experimentally obtained acute toxicity range estimate	Converted acute toxicity point estimate (see Note 1)
Oral (mg/kg bodyweight)	0 < Category 1 ≤ 5	0,5
	5 < Category 2 ≤ 50	5
	50 < Category 3 ≤ 300	100
	300 < Category 4 ≤ 2 000	500
Dermal (mg/kg bodyweight)	0 < Category 1 ≤ 50	5
	50 < Category 2 ≤ 200	50
	200 < Category 3 ≤ 1 000	300
	1 000 < Category 4 ≤ 2 000	1 100
Gases (ppmV)	0 < Category 1 ≤ 100	10
	100 < Category 2 ≤ 500	100
	500 < Category 3 ≤ 2 500	700
	2 500 < Category 4 ≤ 20 000	4 500
Vapours (mg/l)	0 < Category 1 ≤ 0,5	0,05
	0,5 < Category 2 ≤ 2,0	0,5
	2,0 < Category 3 ≤ 10,0	3
	10,0 < Category 4 ≤ 20,0	11
Dust/mist (mg/l)	0 < Category 1 ≤ 0,05	0,005
	0,05 < Category 2 ≤ 0,5	0,05
	0,5 < Category 3 ≤ 1,0	0,5
	1,0 < Category 4 ≤ 5,0	1,5

Note 1

These values are designed to be used in the calculation of the ATE for classification of a mixture based on its components and do not represent test results.

Only one ingredient is classified in this hazard class.

- 2.80 % (Acute Tox. 3, H331)

LD<sub>50</sub> is not known. Therefore the estimated values were used to the calculation.

$$ATE_{mix} = \frac{100}{\sum_{i=1}^n \frac{C_i}{ATE_{mix}}} = \frac{100}{\frac{2.80}{3}} = 107$$

## Results and discussions

According to the table 3.1.2, the result (107 mg/L > 20.0 mg/L) is significantly higher than generic concentration level.

## Conclusion

According to the table 3.1.2, the result (107 mg/L > 20.0 mg/L) is significantly higher than generic concentration level. Therefore the formulation is not classified in this class of hazard.

According to point 7.1.3 of part A of Annex Regulation No 284/2014, it is possible to waive from performing acute inhalation toxicity tests.

### A 2.5 Skin irritation (KCP 7.1.4)

Comments of zRMS:	Acceptable. Skin irritation potential was determined taking into consideration valid data available for each component of the formulation CHR/I/ADEL 280 SC. The sum of concentrations of the ingredients classified as corrosive and irritant to skin is lower than generic concentration level, therefore no classification is required for skin irritation.
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#### A 2.5.1 Study 1

Reference:	KCP 7.1.4
Report	Toxicological classification of product CHR/I/ADEL 280 SC based on calculation method taking into consideration health hazards of constituent substances; M. Kolodziej; 2021
Guideline(s):	Regulation (EC) No. 1272/2008
Deviations:	-
GLP:	No
Acceptability:	Yes
Duplication (if vertebrate study)	No

According to point 7.1.4 of Part A of Annex to the Commission Regulation (EU) No 284/2013 as regards the data requirements for plant protection products:

” The skin irritancy of the plant protection product shall be reported based on the tiered approach, unless the applicant can justify an alternative approach under Regulation (EC) No 1272/2008. In the latter case, skin irritation properties of all components shall be provided or reliably predicted with a validated method. Consideration shall be given to the possible effects of components on the irritant potential of the total mixture.”

The complete composition of the formulation with the classification of individual ingredients is available in part C.

Due to the fact, that all components of the formulation CHR/I/ADEL 280 SC are known, skin **corrosive irritation** test is not necessary.

### Materials and methods

For consideration of corrosive and irritant properties the following table applies:

Table 3.2.3

Generic concentration limits of ingredients classified for skin corrosive/irritant hazard (Category 1 or 2) that trigger classification of the mixture as corrosive/irritant to skin.

Sum of ingredients classified as:	Concentration triggering classification of a mixture as:	
	Skin Corrosive	Skin Irritant
	Category 1 (see note below)	Category 2
Skin Corrosive Categories 1A, 1B, 1C	$\geq 5 \%$	$\geq 1 \%$ but $< 5 \%$
Skin irritant Category 2		$\geq 10 \%$
$10 \times$ Skin Corrosive Category 1A, 1B, 1C) + Skin irritant Category 2		$\geq 10 \%$

#### Note

The sum of all ingredients of a mixture classified as Skin Corrosive Category 1A, 1B or 1C respectively, shall each be  $\geq 5 \%$  respectively in order to classify the mixture as either Skin Corrosive Category 1A, 1B or 1C. If the sum of the Skin Corrosive Category 1A ingredients is  $< 5 \%$  but the sum of Category 1A+1B ingredients is  $\geq 5 \%$ , the mixture shall be classified as Skin Corrosive Category 1B. Similarly, if the sum of Skin Corrosive Category 1A+1B ingredients is  $< 5 \%$  but the sum of Category 1A+1B+1C ingredients is  $\geq 5 \%$  the mixture shall be classified as Skin Corrosive Category 1C.

#### Corrosive:

Three ingredients are classified in this hazard class.

- 0.055% (Skin Corr. 1A, H314)
- 0.009% (Skin Corr. 1A, H314)
- 0.18% (Skin Corr. 1A, H314)

We use the summation method, consisting in adding up the percentages of all ingredients classified in the each class.

$$\sum C_{SkinCorr.} = 0.055\% + 0.009\% + 0.18\% = 0.244\%$$

**Irritant:**

Four ingredients are classified as corrosive/irritant to skin.

- 0.018% (Skin Irrit. 2, H315)
- 0.055% (Skin Corr. 1A, H314)
- 0.009% (Skin Corr. 1A, H314)
- 0.18% (Skin Corr. 1A, H314)

We use the summation method, consisting in adding up the percentages of all ingredients classified in the each class.

$$10 \times \sum C_{SkinCorr.} + \sum C_{SkinIrrit.} = 10 \times 0.244\% + 0.018\% = 2.46\%$$

**Results and discussions**

According to the table 3.2.3, the result (0.244%) is lower than generic concentration level (5%). Therefore the formulation is not classified as Skin Corr. 1A, H314.

Additionally, according to the table 3.2.3, the result (2.46%) is significantly lower than generic concentration level (10%). Therefore the formulation is not classified as Skin Irrit. 2, H315.

**Conclusion**

Additionally, according to the table 3.2.3, the result (2.46%) is significantly lower than generic concentration level (10%). Therefore the formulation is not classified as Skin Irrit. 2, H315.

According to point 7.1.4 of part A of Annex Regulation No 284/2014, it is possible to waive from performing skin irritation tests.

**A 2.6 Eye irritation (KCP 7.1.5)**

Comments of zRMS:	Acceptable. Eye irritation potential was determined taking into consideration valid data available for each component of the formulation CHR/I/ADEL 280 SC. The sum of concentrations of the ingredients classified as corrosive to eye and skin is lower than generic concentration level, therefore no classification is required for eye irritation.
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**A 2.6.1 Study 1**

Reference:	KCP 7.1.5
Report	Toxicological classification of product CHR/I/ADEL 280 SC based on calculation method taking into consideration health hazards of constituent substances; M. Kolodziej; 2021
Guideline(s):	Regulation (EC) No. 1272/2008
Deviations:	-
GLP:	No
Acceptability:	Yes



Duplication No  
 (if vertebrate study)

According to point 7.1.5 of Part A of Annex to the Commission Regulation (EU) No 284/2013 as regards the data requirements for plant protection products:

” Eye irritation tests shall be provided, unless it is likely that severe effects on the eyes may be produced or the applicant can justify an alternative approach under Regulation (EC) No 1272/2008. In the latter case, eye irritation properties of all components shall be provided or reliably predicted with a validated method. Consideration shall be given to the possible effects of components on the irritant potential of the total mixture.”

The complete composition of the formulation with the classification of individual ingredients is available in part C.

Due to the fact, that all components of the formulation CHR/I/ADEL 280 SC are known, eye irritation test is not necessary.

### Materials and methods

For consideration of corrosive and irritant properties the following table applies:

Table 3.3.3

Generic concentration limits of ingredients of a mixture classified as Skin corrosive Category 1 and/ or eye Category 1 or 2 for effects on the eye that trigger classification of the mixture for effects on the eye (Category 1 or 2).

Sum of ingredients classified as:	Concentration triggering classification of a mixture as:	
	Irreversible Eye Effects	Reversible Eye Effects
	Category 1	Category 2
Eye Effects Category 1 or Skin Corrosive Category 1A, 1B, 1C	$\geq 3 \%$	$\geq 1 \%$ but $< 3 \%$
Eye Effects Category 2		$\geq 10 \%$
$(10 \times \text{Eye Effects Category 1}) + \text{Eye effects Category 2}$		$\geq 10 \%$
Skin Corrosive Category 1A, 1B, 1C + Eye effects Category 1	$\geq 3 \%$	$\geq 1 \%$ but $< 3 \%$
$10 \times (\text{Skin Corrosive Category 1A, 1B, 1C} + \text{Eye Effects Category 1}) + \text{Eye Effects Category 2}$		$\geq 10 \%$

Five ingredients are classified as corrosive to eyes.

- 0.018% (Eye Dam. 1, H318)
- 0.055% (Skin Corr. 1A, H314)
- 0.009% (Eye Dam. 1, H318)
- 0.61% (Eye Dam. 1, H318)
- 0.18% (Skin Corr. 1A, H314)

$$\sum C_{\text{EyeDam.}} + C_{\text{SkinCorr.}} = 0.018\% + 0.055\% + 0.009\% + 0.61\% + 0.18\% = 0.87\%$$

### Conclusion

The sum of the concentration of components classified as corrosive to eyes and skin (0.87%) is lower than generic concentration level (1%). Therefore the whole formulation is not classified as corrosive and irritant to eyes.

According to point 7.1.5 of part A of Annex Regulation No 284/2014, it is possible to waive from performing eye ~~corrosion~~ irritation tests.

## A 2.7 Skin sensitisation (KCP 7.1.6)

Comments of zRMS:	Acceptable. Skin sensitisation potential was determined taking into consideration valid data available for each component of the formulation CHR/I/ADEL 280 SC. The concentration of the ingredient classified as skin sensitizer is lower than specific concentration limit, therefore no classification is required for skin sensitisation.
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### A 2.7.1 Study 1

Reference:	KCP 7.1.6
Report	Toxicological classification of product CHR/I/ADEL 280 SC based on calculation method taking into consideration health hazards of constituent substances; M. Kolodziej; 2021
Guideline(s):	Regulation (EC) No. 1272/2008
Deviations:	-
GLP:	No
Acceptability:	Yes
Duplication (if vertebrate study)	No

According to point 7.1.6 of Part A of Annex to the Commission Regulation (EU) No 284/2013 as regards the data requirements for plant protection products:

”The skin sensitisation test shall be carried out unless the active substances or co-formulants are known to have sensitising properties or the applicant can justify an alternative approach under Regulation (EC) No 1272/2008. In the latter case, skin sensitisation properties of all components shall be provided or reliably predicted with a validated method. Consideration shall be given to the possible effects of components on the sensitising potential of the total mixture.”

The complete composition of the formulation with the classification of individual ingredients is available in part C.

Due to the fact, that all components of the formulation CHR/I/ADEL 280 SC are known, the skin sensitisation test is not necessary.

### Materials and methods

We use the table:

Table 3.4.5

Generic concentration limits of ingredients of a mixture classified as either skin sensitizers or respiratory sensitizers that trigger classification of the mixture

Ingredient classified as:	Concentration triggering classification of a mixture as:	
	Skin Sensitizer	Respiratory Sensitizer

	All physical states	Solid/Liquid	Gas
Skin Sensitiser Category 1	$\geq 1,0 \%$	-	-
Skin Sensitiser Category 1A	$\geq 0,1 \%$	-	-
Skin Sensitiser Category 1B	$\geq 1,0 \%$		
Respiratory Sensitiser Category 1	-	$\geq 1,0 \%$	$\geq 0,2 \%$
Respiratory Sensitiser Category 1A	-	$\geq 0,1 \%$	$\geq 0,1 \%$
Respiratory Sensitiser Category 1B		$\geq 1,0 \%$	$\geq 0,2 \%$

Only one ingredient is classified in this hazard class.

- 0.018 % (Skin Sens. 1, H317)

The concentration of the ingredient is lower than a specific concentration level (0.05%). Therefore the formulation is not classified as Skin Sens. 1, H317.

## Conclusion

The concentration of the ingredient is lower than a specific concentration level (0.05%). Therefore the formulation is not classified as Skin Sens. 1, H317.

According to point 7.1.6 of part A of Annex Regulation No 284/2014, it is possible to waive from acute inhalation toxicity test.

## A 2.8 Supplementary studies for plant protection product (KCP 7.1.7)

Comments of zRMS:	Acceptable. Taking into consideration valid data available for each component of the mixture, the formulation CHR/I/ADEL 280 SC should be classified as Repr. 2, H361d.
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## Specific target organ toxicity

For consideration of specific target organ toxicity the following table applies:

Table 3.8.3

Generic concentration limits of ingredients of a mixture classified as a specific target organ toxicant that trigger classification of the mixture as Category 1 or 2.

Ingredient classified as:	Generic concentration limits triggering classification of the mixture as:	
	Category 1	Category 2
Category 1 Specific Target Organ Toxicant	Concentration $\geq 10 \%$	$1,0 \% \leq \text{concentration} < 10 \%$
Category 2 Specific Target Organ Toxicant		Concentration $\geq 10 \%$ [(Note 1)]

Note 1

If a Category 2 specific target organ toxicant is present in the mixture as an ingredient at a concentration  $\geq 1,0 \%$  a SDS shall be available for the mixture upon request.

We also took into account the point 3.8.3.4.5.: “Care shall be exercised when extrapolating toxicity of a mixture that contains Category 3 ingredient(s). A generic concentration limit of 20 % is appropriate; however, it shall be recognised that this concentration limit may be higher or lower depending on the Category 3 ingredient(s) and that some effects such as respiratory tract irritation may not occur below a certain concentration while other effects such as narcotic effects may occur below this 20 % value. Expert judgement shall be exercised.”

### **Specific target organ toxicity - repeated exposure**

#### **STOT RE 1, H372**

We consider only one ingredient at a concentration of 0.0055%. According to the point 3.8.3.4.5 CLP Regulation, the content of this ingredient is lower than a generic concentration level (1%). Therefore the formulation is not classified as STOT RE1 H372.

### **Carcinogenicity ( Carc. 1, H350)**

For consideration of carcinogenicity the following table applies:

Table 3.6.2

Generic concentration limits of ingredients of a mixture classified as carcinogen that trigger classification of the mixture

Ingredient classified as:	Generic concentration limits triggering classification of a mixture as:		
	Category 1 carcinogen		Category 2 carcinogen
	Category 1A	Category 1B	
Category 1A carcinogen	≥ 0,1 %	-	-
Category 1B carcinogen	-	≥ 0,1 %	
Category 2 carcinogen	-	-	≥ 1,0 % [Note 1]

Note

The concentration limits in the table above apply to solids and liquids (w/w units) as well as gases (v/v units).

Note 1

If a Category 2 carcinogen is present in the mixture as an ingredient at a concentration ≥ 0,1 % a SDS shall be available for the mixture upon request.

Only one ingredient (Carc. 1, H350) at the concentration of 0.0055% is relevant. The content of the ingredient classified in this hazard class is lower than generic concentration triggering classification (0.1%). Therefore according to table 3.6.2 the formulation is not classified as carcinogenic.

### **Reproductive toxicity**

Table 3.7.2

Generic concentration limits of ingredients of a mixture classified as reproduction toxicants or for effects on or via lactation that trigger classification of the mixture

Ingredient classified as:	Generic concentration limits triggering classification of a mixture as:			
	Category 1 reproductive toxicant		Category 2 reproductive toxicant	Additional category for effects on or via lactation
	Category 1A	Category 1B		
Category 1A reproductive toxicant	≥ 0,3 % [Note 1]	-	-	-

Category 1B reproductive toxicant	-	$\geq 0,3 \%$ [Note 1]	-	-
Category 2 reproductive toxicant	-	-	$\geq 3,0 \%$ [Note 1]	-
Additional category for effects on or via lactation	-	-	-	$\geq 0,3 \%$ [Note 1]

Note

The concentration limits in the table above apply to solids and liquids (w/w units) as well as gases (v/v units).

Note 1

If a Category 1 or Category 2 reproductive toxicant or a substance classified for effects on or via lactation is present in the mixture as an ingredient at a concentration  $\geq 0,1 \%$  a SDS shall be available for the mixture upon request.

Only one ingredient (Repr. 2, H361d) is relevant at the concentration of 23.16%. The content of the ingredient is higher than concentration triggering classification (3.0%), therefore according to table 3.6.2, the formulation is classified as **Repr. 2, H361d.**

## A 2.9 Data on co-formulants (KCP 7.4)

### A 2.9.1 Material safety data sheet for each co- formulant

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

### A 2.9.2 Available toxicological data for each co-formulant

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

## A 2.10 Studies on dermal absorption (KCP 7.3)

Comments of zRMS:	Acceptable. Default values (10% for concentrate and 50% for dilution for acetamiprid and 50% for concentrate and dilution for deltamethrin) was set according to the Guidance on Dermal Absorption (EFSA Journal 2017;15(6):4873 and SANTE/2018/10591 rev.1, 24 October 2018).
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For the dermal absorption of the active substances product the Applicant refers to Guidance on Dermal Absorption EFSA, EFSA Journal 2017;15(6):4873.

Based on an evaluation of agreed dermal absorption values for a range of concentrated pesticide formulations and their dilutions, the following default values are recommended (see opinion section 4.1.1.for details).

A default dermal absorption value of 10% may be applied for concentrated products that are water-based/dispersed or solid-formulated.

A default dermal absorption value of 50% may be applied for (in use) dilutions water-based/dispersed or solid-formulated.

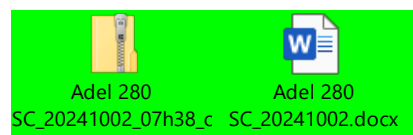
According to the SANTE/2018/10591 rev.1, 24 October 2018, a plant protection product is considered a dilution when the active substance is present in the plant protection product at a concentration lower

than or equal to 50 g/L (or 50g/Kg or 5%). Therefore, for deltamethrin (30g/L in the formulation) it is considered as a dilution and a default dermal absorption value of 50% was applied.

#### **A 2.11            Other/Special Studies**

Not required.

## Appendix 3 Exposure calculations



### A 3.1 Operator exposure calculations (KCP 7.2.1.1)

#### A 3.1.1 Calculations for Acetamiprid

**Table A 1: Estimation of operator exposure towards acetamiprid with PPE at mixing/loading and during application using EFSA Model ver. 30.03.3015**

Operator exposure for CHR/I/ADEL outdoor spray applications

Application rate of active substance	0.04 kg a.s./ha	I_AppRate
Assumed area treated	50 ha/day	d_AreaTreated
Amount of active substance applied	2 kg a.s./day	I_AmountAS
Dermal absorption of the product	10.00%	I_AbsorpProduct
Dermal absorption of in-use dilution	50.00%	I_AbsorInuse
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted-Drift Reduction	
Season	not relevant	

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	8281	30530	AOEM	
	Body	5807	88092	AOEM	
	Head	104	569	AOEM	
	Protected hands (gloves)	54	396	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	44	293	AOEM	
	Protected head (hood and face shield)	2	32	AOEM	
	Inhalation	5	29	AOEM	

Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes	Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered	Incl. in AOEM model	
	Head and respiratory PPE	None	1	1
	Water soluble bag	No	1	

Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	126	932	AOEM	
	Body	26	26	AOEM	
	Head	1	2	AOEM	
	Protected hands (gloves)	5	58	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	1	1	AOEM	
	Inhalation	1	2	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
		Gloves	Yes	Incl. in AOEM model	
		Clothing	Work wear - arms, body and legs covered	Incl. in AOEM model	
		Head and respiratory PPE	None	1	1
		Closed cab	No	vehicle mounted upward spraying only	

## 1. Total

	Without RPE/PPE	With RPE/PPE
Longer term		
Total systemic exposure from mixing, loading and application (mg a.s./day)	1.5013451	0.0295462
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0250224	0.0004924
% of RVNAS	100.09%	1.97%
Acute		
Total systemic exposure from mixing, loading and application (mg a.s./day)	12.4304336	0.1877229
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.2071739	0.0031287
% of RVAAS	828.70%	12.51%

Table A 2: Estimation of operator exposure towards acetamiprid with PPE at mixing/loading using EFSA Model ver. 30.03.2015

## Operator exposure for CHR/I/ADEL outdoor spray applications

Operator exposure for Chilly/ADEL outdoor spray applications

Application rate of active substance	0.04	kg a.s./ha	I_AppRate
Assumed area treated	50	ha/day	d_AreaTreated
Amount of active substance applied	2	kg a.s./day	I_AmountAS
Dermal absorption of the product	10.00%		I_AbsorpProduct
Dermal absorption of in-use dilution	50.00%		I_AbsorInuse
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		
Indoor or Outdoor application	Outdoor		
Application method	Downward spraying		
Application equipment	Vehicle-mounted-Drift Reduction		
Season	not relevant		

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	8281	30530	AOEM	
	Body	5807	88092	AOEM	
	Head	104	569	AOEM	
	Protected hands (gloves)	54	396	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	44	293	AOEM	
	Protected head (hood and face shield)	2	32	AOEM	
	Inhalation	5	29	AOEM	

Application	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	
	Exposure values	µg exposure/day applied		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	126	932	AOEM	
	Body	26	26	AOEM	
	Head	1	2	AOEM	
	Protected hands (gloves)	5	58	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	1	1	AOEM	
	Inhalation	1	2	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	



1. Total

	Without RPE/PPE	With RPE/PPE
Longer term		
Total systemic exposure from mixing, loading and application (mg a.s./day)	1.5013451	0.1023333
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0250224	0.0017056
% of RVNAS	100.09%	6.82%
Acute		
Total systemic exposure from mixing, loading and application (mg a.s./day)	12.4304336	0.6371199
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.2071739	0.0106187
% of RVAAS	828.70%	42.47%

Table A 3: Estimation of operator exposure towards acetamiprid without PPE using EFSA Model ver. 30.03.2015

Operator exposure for CHR/I/ADEL outdoor spray applications

Operator exposure for CMV/ABEC outdoor spray applications					
Application rate of active substance		0.04	kg a.s./ha	l_AppRate	
Assumed area treated		50	ha/day	d_AreaTreated	
Amount of active substance applied		2	kg a.s./day	l_AmountAS	
Dermal absorption of the product		10.00%		l_AbsorpProduct	
Dermal absorption of in-use dilution		50.00%		l_AbsorInuse	
Formulation type		Soluble concentrates, emulsifiable concentrate, etc.			
Indoor or Outdoor application		Outdoor			
Application method		Downward spraying			
Application equipment		Vehicle-mounted-Drift Reduction			
Season		not relevant			

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	8281	30530	AOEM	
	Body	5807	88092	AOEM	
	Head	104	569	AOEM	
	Protected hands (gloves)	54	396	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	44	293	AOEM	
	Protected head (hood and face shield)	2	32	AOEM	
	Inhalation	5	29	AOEM	

Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No		
	Clothing	Potential exposure	Incl. in AOEM model	
	Head and respiratory PPE	None	1	1
	Water soluble bag	No	1	

Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	126	932	AOEM	
	Body	26	26	AOEM	
	Head	1	2	AOEM	
	Protected hands (gloves)	5	58	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	1	1	AOEM	
	Inhalation	1	2	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total			
	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	1.5013451	1.5013451	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0250224	0.0250224	
% of RVNAS	100.09%	100.09%	
Acute			
Total systemic exposure from mixing, loading and application (mg a.s./day)	12.4304336	12.4304336	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.2071739	0.2071739	
% of RVAAS	828.70%	828.70%	

### A 3.1.2 Calculations for Deltamethrin

Table A 4: Estimation of operator exposure towards deltamethrin with PPE at mixing/loading and during application using EFSA Model ver. 30.03.3015

Operator exposure for CHR/I/ADEL outdoor spray applications					
Application rate of active substance	0.0048 kg a.s./ha	<i>i_AppRate</i>			
Assumed area treated	50 ha/day	<i>d_AreaTreated</i>			
Amount of active substance applied	0.24 kg a.s./day	<i>i_AmountAS</i>			
Dermal absorption of the product	10.00%	<i>i_AbsorpProduct</i>			
Dermal absorption of in-use dilution	50.00%	<i>i_AbsorInuse</i>			
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				
Indoor or Outdoor application	Outdoor				
Application method	Downward spraying				
Application equipment	Vehicle-mounted				
Season	not relevant				
Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	1619	5858	AOEM	
	Body	1308	47579	AOEM	
	Head	12	68	AOEM	
	Protected hands (gloves)	14	48	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	7	35	AOEM	
	Protected head (hood and face shield)	0	4	AOEM	
	Inhalation	2	28	AOEM	
Application	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	
	Exposure values	µg exposure/day applied		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	36	806	AOEM	
	Body	20	103	AOEM	
	Head	1	3	AOEM	
	Protected hands (gloves)	20	2822	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	1	1	AOEM	
	Inhalation	1	1	AOEM	
	Protective Equipment	Select. for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	0.3251030	0.0167085	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0054184	0.0002785	
% of RVNAS	72.25%	3.71%	
Acute			
Total systemic exposure from mixing, loading and application (mg a.s./day)	5.8351313	1.4572318	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0972522	0.0242872	
% of RVAAS	#DZIEL/0!	#DZIEL/0!	

Table A 5: Estimation of operator exposure towards deltamethrin with PPE at mixing/loading using EFSA Model ver. 30.03.3015

Operator exposure for CHR/I/ADEL outdoor spray applications

Operator exposure for emulsifiable concentrate outdoor spray applications					
Application rate of active substance		0.0048	kg a.s./ha	<i>i_AppRate</i>	
Assumed area treated		50	ha/day	<i>d_AreaTreated</i>	
Amount of active substance applied		0.24	kg a.s./day	<i>i_AmountAS</i>	
Dermal absorption of the product		10.00%		<i>i_AbsorpProduct</i>	
Dermal absorption of in-use dilution		50.00%		<i>i_AbsorInuse</i>	
Formulation type		Soluble concentrates, emulsifiable concentrate, etc.			
Indoor or Outdoor application		Outdoor			
Application method		Downward spraying			
Application equipment		Vehicle-mounted			
Season		not relevant			
Outdoor soluble concentrates, emulsifiable concentrate, etc. Downward spraying vehicle-mounted					
Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	1619	5858	AOEM	
	Body	1308	47579	AOEM	
	Head	12	68	AOEM	
	Protected hands (gloves)	14	48	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	7	35	AOEM	
	Protected head (hood and face shield)	0	4	AOEM	
Inhalation	2	28	AOEM		
Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor	
	Gloves	Yes	Incl. in AOEM model		
	Clothing	Work wear - arms, body and legs covered	Incl. in AOEM model		
	Head and respiratory PPE	None	1	1	
	Water soluble bag	No	1		
	Application	Exposure values	µg exposure/day applied		Reference
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
Hands		36	806	AOEM	
Body		20	103	AOEM	
Head		1	3	AOEM	
Protected hands (gloves)		20	2822	AOEM	
Protected body (workwear or protective garment and sturdy footwear)		1	1	AOEM	
Inhalation		1	1	AOEM	
Protective Equipment		Select for inclusion		Penetration factor	Inhalation Protection factor
Gloves		No			
Clothing		Potential exposure		Incl. in AOEM model	
Head and respiratory PPE		None		1	1
Closed cab		No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	0.3251030	0.0344245	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0054184	0.0005737	
% of RVNAS	72.25%	7.65%	
Acute			
Total systemic exposure from mixing, loading and application (mg a.s./day)	5.8351313	0.4997248	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0972522	0.0083287	
% of RVAAS	#DZIEL/0!	#DZIEL/0!	

Table A 6: Estimation of operator exposure towards deltamethrin without PPE using EFSA Model ver. 30.03.2015

Operator exposure for CHR/I/ADEL outdoor spray applications

Application rate of active substance 0.0048 kg a.s./ha <i>i_AppRate</i> Assumed area treated 50 ha/day <i>d_AreaTreated</i> Amount of active substance applied 0.24 kg a.s./day <i>i_AmountAS</i> Dermal absorption of the product 10.00% <i>i_AbsorpProduct</i> Dermal absorption of in-use dilution 50.00% <i>i_AbsorInuse</i> Formulation type Soluble concentrates, emulsifiable concentrate, etc. Indoor or Outdoor application Outdoor Application method Downward spraying Application equipment Vehicle-mounted Season not relevant					
Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	1619	5858	AOEM	
	Body	1308	47579	AOEM	
	Head	12	68	AOEM	
	Protected hands (gloves)	14	48	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	7	35	AOEM	
	Protected head (hood and face shield)	0	4	AOEM	
	Inhalation	2	28	AOEM	
Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor	
	Gloves	No			
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	
Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	36	806	AOEM	
	Body	20	103	AOEM	
	Head	1	3	AOEM	
	Protected hands (gloves)	20	2822	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	1	1	AOEM	
	Inhalation	1	1	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	0.3251030	0.3251030	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0054184	0.0054184	
% of RVNAS	72.25%	72.25%	
Acute			
Total systemic exposure from mixing, loading and application (mg a.s./day)	5.8351313	5.8351313	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0972522	0.0972522	
% of RVAAS	#DZIEL/0!	#DZIEL/0!	

### A 3.2 Worker exposure calculations (KCP 7.2.3.1)

#### A 3.2.1 Calculations for Acetamiprid

Worker exposure from residues on foliage for CHR/I/ADEL

Crop type	Oilseeds	
Indoor or outdoor	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted-Drift Reduction	
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	i_AppRate
Number of applications	1	i_AppNo
Interval between multiple applications	365 days	i_AppInt
Half-life of active substance	30 days	d_HalfLifeAS
Multiple application factor	1.0	d_MAF
Dermal absorption of the product	10.00%	i_AbsorpProduct
Dermal absorption of the in-use dilution	50.00%	i_Absorplnuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.12 µg a.s./cm²	d_DFR
Working hours	2 hr	d_WorkHr
Dermal transfer coefficient - Total potential exposure	12500 cm²/hr	d_DermTcUCV
Dermal transfer coefficient - arms, body and legs covered	1400 cm²/hr	d_DermTcCV1
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment cm²/hr	d_DermTcCV2
Inhalation transfer coefficient for automated applications	NA ha/hr*10 <sup>^</sup> (-3)	d_InhalTcAut
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 <sup>^</sup> (-3)	d_InhalTcCut
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 <sup>^</sup> (-3)	d_InhalTcSort

1. Total

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	1.5000000	0.1680000	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0250000	0.0028000		
% of RVNAS	100.00%	11.20%		

#### A 3.2.2 Calculations for Deltamethrin

Worker exposure from residues on foliage for CHR/I/ADEL				
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	0.0048	kg a.s./ha		i_AppRate
Number of applications	1			i_AppNo
Interval between multiple applications	365	days		i_AppInt
Half-life of active substance	7.7	days		d_HalfLifeAS
Multiple application factor	1.0			d_MAF
Dermal absorption of the product	10.00%			i_AbsorpProduct
Dermal absorption of the in-use dilution	50.00%			i_AbsorpInuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.0144	ug a.s./cm <sup>2</sup>		d_DFR
Working hours	2	hr		d_WorkHr
Dermal transfer coefficient - Total potential exposure	12500	cm <sup>2</sup> /hr		d_DermTcUCV
Dermal transfer coefficient - arms, body and legs covered	1400	cm <sup>2</sup> /hr		d_DermTcCV1
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment	cm <sup>2</sup> /hr		d_DermTcCV2
Inhalation transfer coefficient for automated applications	NA	ha/hr*10 <sup>^</sup> (-3)		d_InhalTcAut
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10 <sup>^</sup> (-3)		d_InhalTcCut
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10 <sup>^</sup> (-3)		d_InhalTcSort
<b>1. Total</b>				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	0.1800000	0.0201600	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0030000	0.0003360		
% of RVNAS	40.00%	4.48%		

### A 3.3 Bystander and resident exposure calculations (KCP 7.2.2.1)

#### A 3.3.1 Calculations for Acetamiprid

**Table A 7: Estimation of bystander exposure towards Acetamiprid**

Bystander exposure for CHR/I/ADEL				
Croptype	Oilseeds			
Application method	Downward spraying			
Application equipment	Vehicle-mounted-Drift Reduction			<i>i_AppEquip</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.			
Application rate of the product	0.04	kg a.s./ha		<i>i_AppRate</i>
Buffer strip	5	m		<i>i_Buffer</i>
Concentration of active substance (in-use dilution for liquid applications)	0.2	g a.s./l		<i>d_ConcAS</i>
Dermal absorption of product	10.00%			<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	50.00%			<i>i_AbsorpInuse</i>
Oral absorption	100.00%			<i>i_AbsorpOralInuse</i>
Dislodgeable foliar residue ( <i>i_AppRate</i> * <i>i_DFR</i> )	0.12	µg a.s./cm <sup>2</sup>		<i>d_DFR</i>
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5 *10 <sup>-3</sup> Pa			<i>i_Volat</i>
Concentration in air	0.001	mg/m <sup>3</sup>		<i>d_AirCon</i>
Bystander dermal spray drift exposure - adult	0.57	ml spray dilution/person		
Bystander dermal spray drift exposure - child	0.48	ml spray dilution/person		
Bystander inhal. spray drift exposure - adult	0.00048	ml spray dilution/person		
Bystander inhal. spray drift exposure - child	0.00083	ml spray dilution/person		
Exposure duration	2	hours		<i>d_ByExpDur</i>
Exposure duration entry into treated crops	0.25	hours		<i>d_ExpDurTreatCrop</i>
Light clothing adjustment factor	18.0%			<i>d_ClothAF</i>
Breathing rate adult	0.23	m <sup>3</sup> /kg bw/day		<i>d_BreathRAAd</i>
Breathing rate child (1-3 year old)	1.07	m <sup>3</sup> /kg bw/day		<i>d_BreathRCh</i>
Drift percentage on surface (90th percentile)	3.50%			
Turf transferable residues percentage	5.00%			<i>d_Turf</i>
Transfer coeff. of surface deposits-adult	14500	cm <sup>2</sup> /hour		<i>d_ByTCAd</i>
Transfer coeff. of surface deposits-child (1-3 year old)	5200	cm <sup>2</sup> /hour		<i>d_ByTCCh</i>
Saliva extraction percentage	50.00%			<i>d_SalExt</i>
Surface area of hands mouthed	20	cm <sup>2</sup>		<i>d_AreaHM</i>
Frequency of hand to mouth activity	20	events/hour		<i>d_ByFreqHM</i>
Ingestion rate for mouthing of grass per day	25	cm <sup>2</sup>		<i>d_MouthGrass</i>
Dislodgeable residues percentage transferability for object to mouth	20.00%			<i>d_DRP</i>
Transfer coefficient for entry into treated crops - adult	7500	cm <sup>2</sup> /h		<i>d_TcEntryAd</i>
Transfer coefficient for entry into treated crops - child	2250	cm <sup>2</sup> /h		<i>d_TcEntryCh</i>
<b>1. Total</b>				
<b>1.1 1-3 year old child</b>				
	Spray drift	Vapour	Surface deposits	Entry into treated crops
Total systemic exposure (mg a.s./day)	0.0197630	0.0107000	0.0019950	0.0337500
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0019763	0.0010700	0.0001995	0.0033750
% of RVAAS	7.91%	4.28%	0.80%	13.50%
<b>1.2 Adult</b>				
	Spray drift	Vapour	Surface deposits	Entry into treated crops
Total systemic exposure (mg a.s./day)	0.0234180	0.0138000	0.0050750	0.1125000
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0003903	0.0002300	0.0000846	0.0018750
% of RVAAS	1.56%	0.92%	0.34%	7.50%

**Table A 8: Estimation of resident exposure towards Acetamiprid**

Resident exposure for CHR/VADEL					
Crop type	Oilseeds				
Application method	Downward spraying				
Application equipment	Vehicle-mounted-Drift Reduction				<i>i_AppEquip</i>
Formulation type	Soluble concentrates, emulsifiable concentrates, etc.				<i>i_FormVal</i>
Buffer strip	5 m				<i>i_Buffer</i>
Application rate of the product	0.04 kg a.s./ha				<i>i_AppRate</i>
Concentration of active substance (in-use dilution for liquid applications)	0.2 g a.s./l				<i>d_ConcAS</i>
Dermal absorption of product	10.00%				<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	50.00%				<i>i_AbsorpInuse</i>
Oral absorption	100.00%				<i>i_AbsorpOralInuse</i>
Dislodgeable foliar residue ( <i>i_AppRate</i> *, <i>DFR</i> )	0.12 µg a.s./cm <sup>2</sup>				<i>d_DFR</i>
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10 <sup>-3</sup> Pa				<i>i_Volat</i>
Concentration in air	0.001 mg/m <sup>3</sup>				<i>d_AirCon</i>
Resident dermal spray drift exposure 75th percentile - adult	0.23798 ml spray dilution/person				
Resident dermal spray drift exposure 75th percentile - child	0.2175 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - adult	0.00009 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - child	0.00017 ml spray dilution/person				
Resident dermal spray drift exposure mean - adult	0.12278 ml spray dilution/person				
Resident dermal spray drift exposure mean - child	0.12 ml spray dilution/person				
Resident inhal. spray drift exposure mean - adult	0.00008 ml spray dilution/person				
Resident inhal. spray drift exposure mean - child	0.00014 ml spray dilution/person				
Exposure duration dermal	2 hours				<i>d_ExpDur</i>
Exposure duration inhalation	24 hours				<i>d_ExpDurInhal</i>
Exposure duration entry into treated crops	0.25 hours				<i>d_ExpDurTreatCrop</i>
Light clothing adjustment factor	18.0%				<i>d_ClothAF</i>
Breathing rate adult	0.23 m <sup>3</sup> /day/kg				<i>d_BreatHRAd</i>
Breathing rate child (1-3 year old)	1.07 m <sup>3</sup> /day/kg				<i>d_BreatHRCh</i>
Drift percentage on surface (75th percentile)	2.30%				
Drift percentage on surface (mean)	1.80%				
Turf transferable residues percentage	5.00%				<i>d_Turf</i>
Transfer coeff. of surface deposits-adult	7300 cm <sup>2</sup> /hour				<i>d_ReTCAd</i>
Transfer coeff. of surface deposits-child (1-3 year old)	2800 cm <sup>2</sup> /hour				<i>d_ReTCCh</i>
Saliva excretion percentage	50.00%				<i>d_SalExt</i>
Surface area of hands mouthed	20 cm <sup>2</sup>				<i>d_AreaHM</i>
Frequency of hand to mouth activity	9.5 events/hour				<i>d_RefreqHM</i>
Ingestion rate for mouthing of grass per day	25 cm <sup>2</sup>				<i>d_MouthGrass</i>
Dislodgeable residues percentage transferability for object to mouth	20.00%				<i>d_DRP</i>
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500 cm <sup>2</sup> /h				<i>d_TcEntryAd</i>
Transfer coefficient for entry into treated crops (75th percentile) - child	2250 cm <sup>2</sup> /h				<i>d_TcEntryCh</i>
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm <sup>2</sup> /h				<i>d_TcEntryAd</i>
Transfer coefficient for entry into treated crops (mean) - child	1794 cm <sup>2</sup> /h				<i>d_TcEntryCh</i>
1. Total					
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)	0.0089345	0.0107000	0.0006647	0.0337500	0.0430642
Total systemic exposure per kg body weight (mg/kg)	0.0008935	0.0010700	0.0000665	0.0033750	0.0043064
% of RVNAS	3.57%	4.28%	0.27%	13.50%	17.23%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0097662	0.0138000	0.0016790	0.1125000	0.1098560
Total systemic exposure per kg body weight (mg/kg)	0.0001628	0.0002300	0.0000280	0.0018750	0.0018309
% of RVNAS	0.65%	0.92%	0.11%	7.50%	7.32%

### A 3.3.2 Calculations for Deltamethrin



**Table A 9: Estimation of resident exposure towards deltamethrin**

Resident exposure for CHR/I/ADEL					
Crop type	Oilseeds				
Application method	Downward spraying				
Application equipment	Vehicle-mounted				
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				
Buffer strip	5 m				
Application rate of the product	0.0048 kg a.s./ha				
Concentration of active substance (in-use dilution for liquid applications)	0.024 g a.s./l				
Dermal absorption of product	10.00%				
Dermal absorption of in-use dilution	50.00%				
Oral absorption	100.00%				
Dislodgeable foliar residue (i_AppRate <sup>4</sup> , DFR)	0.0144 µg a.s./cm <sup>2</sup>				
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10 <sup>-3</sup> Pa				
Concentration in air	0.001 mg/m <sup>3</sup>				
Resident dermal spray drift exposure 75th percentile - adult	0.23798 ml spray dilution/person				
Resident dermal spray drift exposure 75th percentile - child	0.2175 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - adult	0.00009 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - child	0.00017 ml spray dilution/person				
Resident dermal spray drift exposure mean - adult	0.12278 ml spray dilution/person				
Resident dermal spray drift exposure mean - child	0.12 ml spray dilution/person				
Resident inhal. spray drift exposure mean - adult	0.00008 ml spray dilution/person				
Resident inhal. spray drift exposure mean - child	0.00014 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 <sup>3</sup> /day/kg				
Breathing rate child (1-3 year old)	1.07 m <sup>3</sup> /day/kg				
Drift percentage on surface (75th percentile)	2.30%				
Drift percentage on surface (mean)	1.80%				
Turf transferable residues percentage	5.00%				
Transfer coeff. of surface deposits-adult	7300 cm <sup>2</sup> /hour				
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm <sup>2</sup> /hour				
Saliva excretion percentage	50.00%				
Surface area of hands mouthed	20 cm <sup>2</sup>				
Frequency of hand to mouth activity	9.5 events/hour				
Ingestion rate for mouthing of grass per day	25 cm <sup>2</sup>				
Dislodgeable residues percentage transferability for object to mouth	20.00%				
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500 cm <sup>2</sup> /h				
Transfer coefficient for entry into treated crops (75th percentile) - child	2250 cm <sup>2</sup> /h				
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm <sup>2</sup> /h				
Transfer coefficient for entry into treated crops (mean) - child	1794 cm <sup>2</sup> /h				
1. Total					
1.1 1-3 year old child					
Spray drift (75th percentile)		Vapour (75th percentile)		Entry into treated crops (75th percentile)	
Total systemic exposure (mg a.s./day)		0.0021443		0.0040500	
Total systemic exposure per kg body weight (mg/kg)		0.0002144		0.0004050	
% of RVNAS		2.86%		5.40%	
1.2 Adult					
Spray drift		Vapour		Entry into treated crops	
Total systemic exposure (mg a.s./day)		0.0138000		0.0135000	
Total systemic exposure per kg body weight (mg/kg)		0.0002300		0.0002250	
% of RVNAS		3.07%		3.00%	

### A 3.4 Combined exposure calculations for acetamiprid and deltamethrin

At the first tier, combined exposure is calculated as the sum of the component exposures without regard to the mode of action or mechanism/target of toxicity. Initially, the individual Hazard Quotients (HQ) are calculated for all active substances in the PPP by assessing the exposure according to appropriate models and dividing the individual exposure levels by the respective systemic AOEL. This is equivalent to the predicted exposure as % of systemic AOEL from Table 6.6 3 converted to decimal. The Hazard Index (HI) is the sum of the individual HQs.

**Table 6.6-10: Acute risk assessment from combined exposure**

Application scenario	Active Ingredient	Estimated exposure / AOEL (HQ)
Operators with ppe	Acetamiprid	0.0197
	Deltamethrin	0.0371
	Cumulative risk Operators (HI)	0.0568
Workers with ppe	Acetamiprid	0.1120
	Deltamethrin	0.0448
	Cumulative risk Workers (HI)	0.1568
Resident Adult	Acetamiprid	0.0732
	Deltamethrin	0.0580
	Cumulative risk Resident Adult (HI)	0.1312
Resident Child	Acetamiprid	0.1723
	Deltamethrin	0.2032
	Cumulative risk Resident Child (HI)	0.3755

The Hazard Index is < 1. Thus combined exposure to all active substances in CHR/I/ADEL 280 SC is not expected to present a risk for operators, workers, bystanders and residents. No further refinement of the assessment is required.

#### 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)

Not required.