

**FINAL REGISTRATION REPORT**

**Part B**

**Section 9**

**Ecotoxicology**

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:

Acetamiprid, 250 g/L

Deltamethrin, 30 g/L

Central Zone

Zonal Rapporteur Member State: Poland

**CORE ASSESSMENT**

(authorization)

Applicant: Innvigo Sp. z o.o.

Submission date: July 2021

**MS Finalisation date: 24/10/2024**

CHR/I/ADEL 280 SC/ ADEL 280 SC, PYRIFOS ADE 280 SC.  
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## Version history

When	What
September 2021	Dossier sent for evaluation
December 2021	Updated by Applicant
February 2022	Updated by Applicant
November 2022	Updated by Applicant
July 2024	The applicant has modified the GAP
August 2024	zRMS finalised evaluation
October 2024	Final version prepared by zRMS after Commenting period

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## 9 Ecotoxicology (KCP 10)

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) INNVIGO 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 30<sup>th</sup>, 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, 1<sup>st</sup> 2019).

### **Review Comments:**

This document describes the acceptable use conditions required for registration of CHR/I/ADEL 280 SC, a SC formulation containing 250 g/L acetamiprid and 30 g/L deltamethrin for the use as an insecticide in winter oilseed rape, cereals and sugar beet.

This Part B document only reviews data and additional information that has not previously been considered within the EU review process.

Since this document is based on the information provided by the applicant, all review comments, additions and corrections have been made using commenting boxes or highlighted in grey.

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## 9.1 Critical GAP and overall conclusions

Table 9.1-1: Table of critical GAPs

1	2	3	4	5	6	7	8	9	15	11	12	13	14	15	16	17	18	19	20	21
Use -No. (e)	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F, Fn, G, Gp n or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days )	Remarks:  e.g. g safener/synergis t per ha (f)	Conclusion						
					Method / Kind	Timing / Growth stage of crop & season	Max. numbe r a) per use b) per crop/ season	Min. interval between applicatio ns (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/seaso n	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/seaso n	Water r L/ha  min / max			Birds	Mammals	Aquatic organisms	Bees	Non-target arthropods	Soil organisms	Non-target plants
Zonal uses (field or outdoor uses, certain types of protected crops)																				
1	PL	Winter Oilseed rape (BRSNW)	F	Aphids: <i>Brevicoryne brassicae</i> , <i>Myzus persicae</i> , <i>Athalia/Athali a rosae</i>	Spray, mediu m sprayer	Autum n BBCH 10-21	a)1 b)1	n/a	a) 0.08 - 0.16 L/ha b) 0.08 - 0.16 L/ha	a) (0.02 kg as/ha A + 0.0024 kg as/ha D) - (0.04 kg as/ha A+0.0048 kg as/ha D) b) (0.02 kg as/ha A + 0.0024 kg as/ha D) - (0.04 kg	200- 300	n/a		A	A	R	A	R	A	A

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1	2	3	4	5	6	7	8	9	15	11	12	13	14	15	16	17	18	19	20	21
Use -No. (e)	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F, Fn, G, Gn, Gp or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/synergis t per ha (f)	Conclusion						
					Method / Kind	Timing / Growth stage of crop & season	Max. numbe r a) per use b) per crop/ season	Min. interval between applicatio ns (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/seaso n	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/seaso n	Water L/ha min / max			Birds	Mammals	Aquatic organisms	Bees	Non-target arthropods	Soil organisms	Non-target plants
										a-s/ha A+0.0048 kg-a-s/ha D)										
2	PL	Winter Oilseed rape (BRSNW)	F	<i>Ceutorhynchus quadridens</i> , syn. <i>C. pallidactylus</i> , <i>Ceutorhynchus napi</i> , <i>Brassicogethes aeneus</i> syn. <i>Meligethes aeneus</i> , <i>Ceutorhynchus assimilis</i> , <i>Dasineura brassicae</i>	Spray, medium sprayer	Spring BBCH 30-70	a)1 b)1	n/a	a) 0.08 - 0.16 L/ha b) 0.08 - 0.16 L/ha	a) (0.02 kg as/ha A + 0.0024 kg as/ha D) - (0.04 kg as/ha A+0.0048 kg-a-s/ha D) b) (0.02 kg as/ha A + 0.0024 kg as/ha D) - (0.04 kg as/ha	200- 300	n/a		A	A	R	A	R	A	A



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1	2	3	4	5	6	7	8	9	15	11	12	13	14	15	16	17	18	19	20	21
Use -No. (e)	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F, Fn, G, Gn, Gp or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/synergis t per ha (f)	Conclusion						
					Method / Kind	Timing / Growth stage of crop & season	Max. numbe r a) per use b) per crop/ season	Min. interval between application s (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/seaso n	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/seaso n	Water L/ha min / max			Birds	Mammals	Aquatic organisms	Bees	Non-target arthropods	Soil organisms	Non-target plants
										A+0.0048 kg a.s/ha D)										
3	PL	Winter wheat (TRZAW)	F	<i>Sitobion avenae</i> , <i>Thrips</i> sp.	Spray, medium sprayer	Spring BBCH 37-75	a)1 b)1	n/a	a) 0.08 - 0.16 L/ha b) 0.08 - 0.16 L/ha	a) (0.02 kg as/ha A + 0.0024 kg as/ha D) - (0.04 kg as/ha A+0.0048 kg a.s/ha D) b) (0.02 kg as/ha A +	200- 300	n/a		A	A	R	A	R	A	A

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1	2	3	4	5	6	7	8	9	15	11	12	13	14	15	16	17	18	19	20	21
Use -No. (e)	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F, Fn, G, Gn, Gp or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/synergis t per ha (f)	Conclusion						
					Method / Kind	Timing / Growth stage of crop & season	Max. numbe r a) per use b) per crop/ season	Min. interval between applicatio ns (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/seaso n	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/seaso n	Water L/ha min / max			Birds	Mammals	Aquatic organisms	Bees	Non-target arthropods	Soil organisms	Non-target plants
										0.0024 kg as/ha D) – (0.04 kg as/ha A + 0.0048 kg as/ha D)										
4	PL	Winter triticale (TTLWI)	F	<i>Sitobion avenae</i> , <i>Thrips</i> sp.	Spray, medium sprayer	Spring BBCH 37-75	a)1 b)1	n/a	a) 0.08 - 0.16 L/ha b) 0.08 - 0.16 L/ha	a) (0.02 kg as/ha A + 0.0024 kg as/ha D) – (0.04 kg as/ha A + 0.0048 kg as/ha D) b) (0.02 kg as/ha A + 0.0024 kg as/ha D) – (0.04 kg	200- 300	n/a		A	A	R	A	R	A	A

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1	2	3	4	5	6	7	8	9	15	11	12	13	14	15	16	17	18	19	20	21
Use -No. (e)	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F, Fn, G, Gn, Gp or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/synergis t per ha (f)	Conclusion						
					Method / Kind	Timing / Growth stage of crop & season	Max. numbe r a) per use b) per crop/ season	Min. interval between applicatio ns (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/seaso n	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/seaso n	Water L/ha min / max			Birds	Mammals	Aquatic organisms	Bees	Non-target arthropods	Soil organisms	Non-target plants
										a-s/ha A+0.0048 kg-a-s/ha D)										
5	PL	Sugar beet (BEAVA)	F	<i>Aphis</i> sp.: <i>Aphis fabae</i> , <i>Pegomya</i> <i>hyoscyami</i>	Spray, medium sprayer	Spring BBCH 12-19	a)1 b)1	n/a	a) 0.08 - 0.16 L/ha b) 0.08 - 0.16 L/ha	a) (0.02 kg as/ha A + 0.0024 kg as/ha D) - (0.04 kg as/ha A+0.0048 kg-a-s/ha D) b) (0.02 kg as/ha A + 0.0024 kg as/ha D) - (0.04 kg as/ha	200- 300	n/a		A	A	R	A	R	A	A

[illegible]

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\* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

\* 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

### Explanation for column 15 – 21 “Conclusion”

A	Acceptable, Safe use
R	Further refinement and/or risk mitigation measures required
C	To be confirmed by cMS
N	No safe use

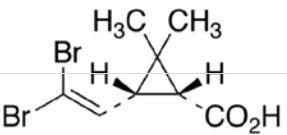
#### Remarks

##### table:

- (1) Numeration necessary to allow references
- (2) Use official codes/nomenclatures of EU
- (3) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
- (4) F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
- (5) Scientific names and EPPO-Codes of target pests/diseases/ weeds or when relevant the common names of the pest groups (*e.g.* biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named
- (6) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench  
Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
- (7) Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
- (8) The maximum number of application possible under practical conditions of use must be provided
- (9) Minimum interval (in days) between applications of the same product.
- (10) For specific uses other specifications might be possible, *e.g.*: g/m<sup>3</sup> in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products
- (11) The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
- (12) If water volume range depends on application equipments (*e.g.* ULVA or LVA) it should be mentioned under “application: method/kind”.
- (13) PHI - minimum pre-harvest interval
- (14) Remarks may include: Extent of use/economic importance/restrictions

### 9.1.1 Overall conclusions

Table 9.1 4 — Metabolites of deltamethrin

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Risk assessment required?
Br <sub>2</sub> CA	297.97		Soil: 23% Water and Sediment Total system: 43%	Yes

#### 9.1.1.1 Effects on birds (KCP 10.1.1), Effects on terrestrial vertebrates other than birds (KCP 10.1.2), Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

CHR/I/ADEL 280 SC pose no unacceptable risk to birds and mammals used according to the label.

#### 9.1.1.2 Effects on aquatic organisms (KCP 10.2)

CHR/I/ADEL 280 SC pose no unacceptable risk to aquatic organisms according to the label with appropriate buffer zone.

##### Review Comments:

Only for *Daphnia magna* was possible to performed mixture toxicity assessment, as for *Chironomus riparius* the acute endpoint for deltamethrin is not available. Based on toxic units, it is concluded that deltamethrin is driving the toxicity of the mixture ( $TU \geq 90\%$ ) for *Daphnia magna*.

Following mitigation measures are required:

- 20 meters vegetative buffer zone and 20 meters no-spray buffer zone for sugar beet and winter cereals in Poland,
- 20 meters vegetative buffer zone and 25 meters no-spray buffer zone for winter cereals in other Central Zone countries,
- Autumn: 20 meters vegetative buffer zone and 20 meters no-spray buffer zone and 50% nozzles reduction for winter oilseed rape (BBCH 10-21),
- Spring: 20 meters vegetative buffer zone and 20 meters no-spray buffer zone for winter oilseed rape (BBCH 30-70).

#### 9.1.1.3 Effects on bees (KCP 10.3.1)

CHR/I/ADEL 280 SC pose no unacceptable risk to bees according to the label

#### **Review Comments:**

The evaluation of the acute risk for bees was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002). The submitted risk assessment, based on laboratory studies, has been accepted. It can therefore be concluded that there will be negligible acute risk associated with the exposure of *Apis mellifera* to CHR/I/ADEL 280 SC.

The data requirements in accordance with Commission Regulation (EU) No 284/2013 for the chronic toxicity to adult honeybees and honeybee larvae are fulfilled.

The risk assessment based on the EFSA Guidance (2013) is not yet approved and certain parts are currently under revision.

Nevertheless, some CEU countries require evaluation according to EFSA 2013. This approach is still not harmonised, but it was discussed at the last meeting of the Central Zone in the field of ecotoxicology (Warsaw, 12.2023), where it was agreed to present an assessment in the Core in accordance with EFSA 2013.

The evaluation of the acute and chronic risk for bees was performed by zRMS in accordance with the recommendations of the “EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees)” (EFSA Journal 2013;11(7):3295; hereafter referred to as EFSA/2013/3295). Refinement of risk, where required, has been left to the national level.

#### **9.1.1.4 Effects on arthropods other than bees (KCP 10.3.2)**

~~CHR/I/ADEL 280 SC pose no unacceptable risk to NTA according to the label.~~

### **Review Comments:**

For the application rate of 0.16 L/ha, based on currently available data, it was not possible to demonstrate an acceptable in-field risk for non-target arthropods. Therefore, the Applicant modified the product's application pattern by including a lower application rate of 0.08 L/ha.

For application rate of 0.08 L/ha, the in-field risk for non-target arthropods is acceptable. For higher application rate an unacceptable risk is considered.

Based on the results of the conducted risk assessment it can be concluded that no off-field risk for non-target arthropods is expected from use of CHR/I/ADEL 280 SC. Following mitigation measures are required:

1. Application rate of 0.16 L/ha
  - 75 meters buffer zone
  - 40 meter buffer zone with 50% nozzles reduction
  - 20 meters buffer zone with 75% nozzles reduction
  - 10 meters buffer zone with 90% nozzles reduction
2. Application rate of 0.08 L/ha
  - 40 meters buffer zone
  - 20 meter buffer zone with 50% nozzles reduction
  - 10 meters buffer zone with 75% nozzles reduction
  - 5 meters buffer zone with 90% nozzles reduction

#### **9.1.1.5 Effects on non-target soil meso- and macrofauna (KCP 10.4), Effects on soil microbial activity (KCP 10.5)**

CHR/I/ADEL 280 SC pose no unacceptable risk to non-target soil meso- and macrofauna and microbial activity according to the label.

#### **9.1.1.6 Effects on non-target terrestrial plants (KCP 10.6)**

CHR/I/ADEL 280 SC pose no unacceptable risk to non-target terrestrial plants according to the label. Based on the predicted rates of CHR/I/ADEL 280 SC in off-field areas, the TER values describing the risk for non-target plants following exposure to CHR/I/ADEL 280 SC according to the GAP of the formulation CHR/I/ADEL 280 SC achieve the acceptability criteria  $TER \geq 5$ , with applying buffer zone of 1m mitigation measures.

#### **9.1.1.7 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)**

Not relevant

### **9.1.2 Grouping of intended uses for risk assessment**

The following table documents the grouping of the intended uses to support application of the risk envelope approach (according to SANCO/11244/2011).



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**Table 9.1-2: Critical use pattern of CHR/I/ADEL 280 SC grouped according to crop, application rate, number of applications, timing, etc.**

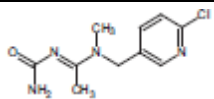
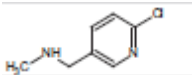
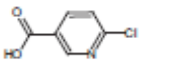
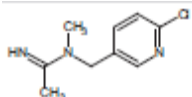
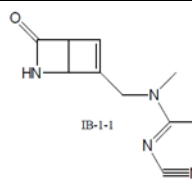
Grouping according to crop, application rate, number of applications, timing, etc.			
Group	Intended uses	relevant use parameters for grouping	relevant parameter or value for sorting
Winter oilseed rape	174.18 g prod/ha	crop, application rate, number of applications, timing criterion	crop, application rate, number of applications, timing criterion
Winter cereals	174.18 g prod/ha	crop, application rate, number of applications, timing criterion	crop, application rate, number of applications, timing criterion
Sugarbeet	174.18 g prod/ha	crop, application rate, number of applications, timing criterion	crop, application rate, number of applications, timing criterion

Grouping according to worst-case application				
Area	Group	Intended uses	Relevant use parameters for grouping	Relevant parameter or value for sorting
Birds	OSR, cereals, sugar beet	1 x 0.16 L product/ha	Crop group according to EFSA/2009/1438	The maximum application dose rate
Birds secondary poisoning		1 x 0.16 L product/ha	Worst-case PEC values	Worst-case PEC <sub>sw</sub> and PEC <sub>soil</sub>
Mammals	OSR, cereals, sugar beet	1 x 0.16L product/ha	Crop group according to EFSA/2009/1438	The maximum application dose rate
Mammals secondary poisoning		1 x 0.16L product/ha	Worst-case PEC values	Worst-case PEC <sub>sw</sub> and PEC <sub>soil</sub>
Aquatic organisms	OSR, cereals, sugar beet	1 x 0.16L product/ha	Worst-case PEC values	Worst-case PEC <sub>sw</sub>
Bees	Maximum single application rate	1 x 0,16 L product/ha	Maximum single application rate	The maximum application dose rate
Non-target arthropods	Field crops	1 x 0.08 and 0.16 L product/ha	Crop group according to ESCORT 2	The application dose rate of 0.08 L/ha and 0.16 L/ha
Soil macro- and mesofauna, soil microorganisms	Onion/cucurbits	1 x 16 L product/ha	Worst-case PEC values	Worst-case PEC values calculated for sugar beet
Non-target plants	Field crops	1 x 0.16 L product/ha	Maximum single application rate	The maximum application dose rate

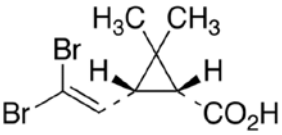
### 9.1.3 Consideration of metabolites

A list of metabolites found in environmental compartments is provided below. The need for conducting a metabolite-specific risk assessment in the context of the evaluation of CHR/I/ADEL 280 SC is indicated in the table.

**Table 9.1-3 Metabolites of acetamiprid**

Metabolite	Chemical structure	Molar mass	Maximum occurrence in compartments	Risk assessment required?
IM-1-2		240.69	Soil: > 10 % of a.s.	Yes
IM-1-4		156.61	Soil: > 10 % of a.s.	Yes
6-chloronicotinic acid (IC-0)		157.55	Soil: > 10 % of a.s.	Yes
IM-1-5		197.66	Soil: > 10 % of a.s.	Yes
IB-1-1		204.23	Water/Sediment: > 10 % of a.s.	Yes

**Table 9.1-4 Metabolites of deltamethrin**

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Risk assessment required?
Br <sub>2</sub> CA	297.97		Soil: 23% Water and Sediment Total system: 13%	Yes

## 9.2 Effects on birds (KCP 10.1.1)

### 9.2.1 Toxicity data

Avian toxicity studies have been carried out with acetamiprid, deltamethrin and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents. Effects on birds of CHR/I/ADEL 280 SC were not evaluated as part of the EU assessment of acetamiprid and deltamethrin.

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However, the provision of further data on the CHR/I/ADEL 280 SC is not considered essential, because studies from Annex 1 inclusion can be used.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process. Justifications are provided below.

**Table 9.2-1: Endpoints and effect values relevant for the risk assessment for birds**

Species	Substance	Exposure System	Results	Reference
Anas platyrhynchos (mallard duck)	acetamiprid	Acute	LD <sub>50</sub> = 98 mg/kg bw	EFSA Journal 2016 14(11):4610
Colinus virginianus (bobwhite quail)	acetamiprid	Acute	LD <sub>50</sub> >100 mg/kg bw	EFSA Journal 2016 14(11):4610
Poephila guttata (zebra finch)	acetamiprid	Acute	LD <sub>50</sub> = 5.7 mg/kg bw	EFSA Journal 2016 14(11):4610
Geometric mean	acetamiprid	Acute	LD <sub>50</sub> = 38.2 mg/kg bw	EFSA Journal 2016 14(11):4610
	acetamiprid	Long-term	LD <sub>50</sub> /10 = 3.8 mg/kg bw	EFSA Journal 2016 14(11):4610
Anas platyrhynchos (mallard duck)	acetamiprid	Long-term	NOEL = 9.5 mg/kg bw/d	EFSA Journal 2016 14(11):4610
Colinus virginianus	Deltamethrin	Acute	LD <sub>50</sub> > 2250 mg/kg/bw	SANCO/6504/VI/99-final 17 October 2002
Colinus virginianus	Deltamethrin	Short-term dietary	LC <sub>50</sub> > 5620 mg/kg/bw	SANCO/6504/VI/99-final 17 October 2002
Colinus virginianus	Deltamethrin	Long-term	NOEC = 0.45 mg/kg/bw NOEC ≥ 450 mg a.s./kg diet NOED ≥ 53.6 mg a.s./kg bw/d	SANCO/6504/VI/99-final 17 October 2002

## 9.2.2 Risk assessment for spray applications

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).

### 9.2.2.1 First-tier assessment (screening/generic focal species)

The results of the acute and reproductive first-tier risk assessments are summarised in the following tables.

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**Table 9.2-2: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of CHR/I/ADEL 280 SC in winter oilseed rape**

Intended use		Winter oilseed rape			
Active substance/product		acetamirpid			
Application rate (g/ha)		1 x 40			
Acute toxicity (mg/kg bw)		38.2			
TER criterion		10			
Crop scenario Growth stage	Indicator/generic focal species	SV <sub>90</sub>	MAF <sub>90</sub>	DDD <sub>90</sub> (mg/kg bw/d)	TER <sub>a</sub>
Screening step	Small omnivorous bird	158.8	1.0	6.35	6.0
Oilseed rape BBCH 10 - 19	medium herbivorous/granivorous bird "pigeon" Non-grass herbs 100% crop shoots	55.6	-	- 2.22	17.2
Oilseed rape BBCH 10 - 19	Small insectivorous bird “wagtail” ground invertebrates without interception 100% soil dwelling invertebrates	10.9	-	- 0.44	87.6
Oilseed rape BBCH 10 - 29	Small omnivorous bird “lark” Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	24.0	-	- 0.96	39.8
Oilseed rape early (shoots) (BBCH 10-19)	Large herbivorous bird "goose" Non-grass herbs 100% crop shoots	39.0	-	- 1.56	24.5
Oilseed rape BBCH ≥ 40	medium herbivorous/granivorous bird "pigeon" Comby to be calculated 50 % crop leaves 50 % weed seeds	2.0	-	- 0.08	477.5
Oilseed rape BBCH ≥ 40	Small omnivorous bird “lark” Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	6.0	-	- 0.24	159.2
Oilseed rape BBCH 30 - 39	medium herbivorous/granivorous bird "pigeon" Comby to be calculated 50 % crop leaves 50 % weed seeds	2.4	-	- 0.096	397.9
Oilseed rape BBCH 30 - 39	Small omnivorous bird “lark” Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	7.2	-	- 0.29	132.6
Oilseed rape late – late (with seeds) (BBCH 30-99)	Small insectivorous bird "dunnock) ground invertebrates	7.4	-	- 0.30	129.1

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	with interception 100% soil dwelling invertebrates				
<b>Reprod. toxicity (mg/kg bw/d)</b>	3.8				
<b>TER criterion</b>	5				
<b>Crop scenario Growth stage</b>	<b>Indicator/generic focal species</b>	<b>SV<sub>m</sub></b>	<b>MAF<sub>m</sub> × TWA</b>	<b>DDD<sub>m</sub> (mg/kg bw/d)</b>	<b>TER<sub>it</sub></b>
Screening step	Small omnivorous bird	64.8	0.53	1.37	<b>2.8</b>
Oilseed rape BBCH 10 - 19	medium herbivorous/granivorous bird "pigeon" Non-grass herbs 100% crop shoots	22.7	- 0.53	- 0.53	7.9
Oilseed rape BBCH 10 - 19	Small insectivorous bird "wagtail" ground invertebrates without interception 100% soil dwelling invertebrates	5.9	- 0.53	- 0.125	30.4
Oilseed rape BBCH 10 - 29	Small omnivorous bird "lark" Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	10.9	- 0.53	- 0.231	16.4
Oilseed rape early (shoots) (BBCH 10-19)	Large herbivorous bird "goose" Non-grass herbs 100% crop shoots	15.9	- 0.53	- 0.337	11.3
Oilseed rape BBCH ≥ 40	medium herbivorous/granivorous bird "pigeon" Comby to be calculated 50 % crop leaves 50 % weed seeds	0.9	- 0.53	- 0.019	199.2
Oilseed rape BBCH ≥ 40	Small omnivorous bird "lark" Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	2.7	- 0.53	- 0.057	66.4
Oilseed rape BBCH 30 - 39	medium herbivorous/granivorous bird "pigeon" Comby to be calculated 50 % crop leaves 50 % weed seeds	1.1	- 0.53	- 0.023	163.0
Oilseed rape BBCH 30 - 39	Small omnivorous bird "lark" Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	3.3	- 0.53	- 0.070	54.3
Oilseed rape late – late (with seeds) (BBCH 30-99)	Small insectivorous bird "dunnock" ground invertebrates with interception 100% soil dwelling invertebrates	2.7	- 0.53	- 0.057	66.4

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

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**Table 9.2-3: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of CHR/I/ADEL 280 SC in winter cereals**

Intended use		Winter cereals				
Active substance/product		acetamirpid				
Application rate (g/ha)		1 x 40				
Acute toxicity (mg/kg bw)		38.2				
TER criterion		10				
Crop scenario Growth stage	Indicator/generic focal species	SV <sub>90</sub>	MAF <sub>90</sub>	DDD <sub>90</sub> (mg/kg bw/d)	TER <sub>a</sub>	
Screening step	Small omnivorous bird bird	158.8	1	6.35	6.0	
Cereals BBCH 30 - 39	Small omnivorous bird “lark” Combination (invertebrates with interception) 25% crop leaves 25% weed seeds 50% ground arthropods	12.0		0.48	79.6	
Cereals BBCH ≥ 40	Small omnivorous bird “lark” Combination (invertebrates with interception) 25% crop leaves 25% weed seeds 50% ground arthropods	7.2		0.29	132.6	
Cereals Late post-emergence (May-June) BBCH 71-89	Small insectivorus bird "passerine" Foliar insects 100% foliar insects	57.6		2.30	16.6	
Cereals Late season-Seed heads	Small granivorous/insectivorous bird “bunting” Grains/ear 100% cereal seeds	27.0		1.08	35.4	
Reprod. toxicity (mg/kg bw/d)		3.8				
TER criterion		5				
Crop scenario Growth stage	Indicator/generic focal species	SV <sub>m</sub>	MAF <sub>m</sub> × TWA	DDD <sub>m</sub> (mg/kg bw/d)	TER <sub>lt</sub>	
Screening step	Small omnivorous bird	64.8	0.53	1.37	2.8	
Cereals BBCH 30 - 39	Small omnivorous bird “lark” Combination (invertebrates with interception) 25% crop leaves 25% weed seeds 50% ground arthropods	5.4		0.114	33.2	
Cereals BBCH ≥ 40	Small omnivorous bird “lark” Combination (invertebrates with interception) 25% crop leaves 25% weed seeds 50% ground arthropods	3.3		0.070	54.3	
Cereals Late post-emergence (May-June) BBCH 71-89	Small insectivorus bird "passerine" Foliar insects 100% foliar insects	22.4		0.475	8.0	
Cereals Late season-Seed heads	Small granivorous/insectivorous bird “bunting” Grains/ear 100% cereal seeds	12.5		0.265	14.3	

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SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

**Table 9.2-4: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of CHR/I/ADEL 280 SC in sugarbeet**

Intended use		Sugarbeet			
Active substance/product		acetamirpid			
Application rate (g/ha)		1 x 40			
Acute toxicity (mg/kg bw)		38.2			
TER criterion		10			
Crop scenario Growth stage	Indicator/generic focal species	SV <sub>90</sub>	MAF <sub>90</sub>	DDD <sub>90</sub> (mg/kg bw/d)	TER <sub>a</sub>
Screening step	Small omnivorous bird	158.8	1	6.35	<b>6.0</b>
First Tier Risk Assessment		Short cut value		TER	
Sugar beet BBCH 10-19	Small insectivorous bird “wagtail” ground invertebrates without interception 100% soil dwelling invertebrates	10.9		0.436	87.6
Sugar beet early (spring) (BBCH 10-19)	Small omnivorous bird “lark” Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	24.0		0.96	39.8
Reprod. toxicity (mg/kg bw/d)		3.8			
TER criterion		5			
Crop scenario Growth stage	Indicator/generic focal species	SV <sub>m</sub>	MAF <sub>m</sub> × TWA	DDD <sub>m</sub> (mg/kg bw/d)	TER <sub>it</sub>
Screening step	Small omnivorous bird	64.8	0.53	1.47	<b>2.8</b>
First Tier Risk Assessment		Short cut value		DDD <sub>m</sub>	TER
Sugar beet BBCH 10-19	Small insectivorous bird “wagtail” ground invertebrates without interception 100% soil dwelling invertebrates	5.9		0.118	30.4
Sugar beet early (spring) (BBCH 10-19)	Small omnivorous bird “lark” Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	10.9		0.231	16.4

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

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**Table 9.2-5:** ~~First-tier~~ **Screening** assessment of the acute and long-term/reproductive risk for birds due to the use of CHR/I/ADEL 280 SC in winter oilseed rape



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Intended use		Winter oilseed rape				
Active substance/product		Deltamethrin				
Application rate (g/ha)		1 x 4.8				
Acute toxicity (mg/kg bw)		2250				
TER criterion		10				
Crop scenario Growth stage	Indicator/generic focal species	SV <sub>90</sub>	MAF <sub>90</sub>	DDD <sub>90</sub> (mg/kg bw/d)	TER <sub>a</sub>	
Screening step	Small omnivorous bird	158.8	1.0	0.76	2951.8	
Oilseed rape BBCH 10–19	medium herbivorous/granivorous bird "pigeon" Non grass herbs 100% crop shoots	55.6	-	-	8430.8	
Oilseed rape BBCH 10–19	Small insectivorous bird "wagtail" ground invertebrates without interception 100% soil dwelling invertebrates	10.9	-	-	43004.6	
Oilseed rape BBCH 10–29	Small omnivorous bird "lark" Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	24.0	-	-	19531.3	
Oilseed rape early (shoots) (BBCH 10–19)	Large herbivorous bird "goose" Non grass herbs 100% crop shoots	39.0	-	-	12019.2	
Oilseed rape BBCH ≥ 40	medium herbivorous/granivorous bird "pigeon" Comby to be calculated 50 % crop leaves 50 % weed seeds	2.0	■	■	534375.0	
Oilseed rape BBCH ≥ 40	Small omnivorous bird "lark" Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	6.0	■	■	78125.0	
Oilseed rape BBCH 30–39	medium herbivorous/granivorous bird "pigeon" Comby to be calculated 50 % crop leaves 50 % weed seeds	2.4	■	■	195312.5	
Oilseed rape BBCH 30–39	Small omnivorous bird "lark" Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	7.2	■	■	65104.2	
Oilseed rape late (with seeds) (BBCH 30–99)	Small insectivorous bird "duncock" ground invertebrates with interception 100% soil dwelling invertebrates	7.4	■	■	63344.6	
Reprod. toxicity (mg/kg bw/d)		0.45 53.6				

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TER criterion		5			
Crop scenario Growth stage	Indicator/generic focal species	SV <sub>m</sub>	MAF <sub>m</sub> × TWA	DDD <sub>m</sub> (mg/kg bw/d)	TER <sub>it</sub>
Screening step	Small omnivorous bird	64.8	0.53	0.165	<b>2.7</b> 324.85
Oilseed rape BBCH 10–19	medium herbivorous/granivorous bird "pigeon" Non-grass herbs 100% crop shoots	22.7	–	–	7.8
Oilseed rape BBCH 10–19	Small insectivorous bird "wagtail" ground invertebrates without interception 100% soil dwelling invertebrates	5.9	–	–	30.0
Oilseed rape BBCH 10–29	Small omnivorous bird "lark" Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	10.9	–	–	16.2
Oilseed rape early (shoots) (BBCH 10– 19)	Large herbivorous bird "goose" Non-grass herbs 100% crop shoots	15.9	–	–	11.1
Oilseed rape BBCH ≥ 40	medium herbivorous/granivorous bird "pigeon" Comby to be calculated 50 % crop leaves 50 % weed seeds	0.9	1	1	<b>196.5</b>
Oilseed rape BBCH ≥ 40	Small omnivorous bird "lark" Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	2.7	1	1	<b>65.5</b>
Oilseed rape BBCH 30–39	medium herbivorous/granivorous bird "pigeon" Comby to be calculated 50 % crop leaves 50 % weed seeds	1.1	1	1	<b>160.8</b>
Oilseed rape BBCH 30–39	Small omnivorous bird "lark" Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	3.3	1	1	<b>53.6</b>
Oilseed rape late late (with seeds) (BBCH 30–99)	Small insectivorous bird "damcock" ground invertebrates with interception 100% soil dwelling invertebrates	2.7	1	1	<b>65.5</b>

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

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**Table 9.2-6:** **First-tier Screening assessment of the acute and long-term/reproductive risk for birds due to the use of CHR/I/ADEL 280 SC in winter cereals**

Intended use		Winter cereals				
Active substance/product		deltamethrin				
Application rate (g/ha)		1 x 4.8				
Acute toxicity (mg/kg bw)		2250				
TER criterion		10				
Crop scenario Growth stage	Indicator/generic focal species	SV <sub>90</sub>	MAF <sub>90</sub>	DDD <sub>90</sub> (mg/kg bw/d)	TER <sub>a</sub>	
Screening step	Small omnivorous bird bird	158.8	1	0.76	2951.8	
Cereals BBCH 30–39	Small omnivorous bird “lark” Combination (invertebrates with interception) 25% crop leaves 25% weed seeds 50% ground arthropods	12.0			39062.5	
Cereals BBCH ≥ 40	Small omnivorous bird “lark” Combination (invertebrates with interception) 25% crop leaves 25% weed seeds 50% ground arthropods	7.2			65104.2	
Cereals Late post-emergence (May–June) BBCH 71–89	Small insectivorous bird “passerine” Foliar insects 100% foliar insects	57.6			8138.0	
Cereals Late season–Seed heads	Small granivorous/insectivorous bird “bunting” Grains/ear 100% cereal seeds	27.0			17361.1	
Reprod. toxicity (mg/kg bw/d)		0.45 53.6				
TER criterion		5				
Crop scenario Growth stage	Indicator/generic focal species	SV <sub>m</sub>	MAF <sub>m</sub> × TWA	DDD <sub>m</sub> (mg/kg bw/d)	TER <sub>lt</sub>	
Screening step	Small omnivorous bird	64.8	0.53	0.165	2.7 324.85	
Cereals BBCH 30–39	Small omnivorous bird “lark” Combination (invertebrates with interception) 25% crop leaves 25% weed seeds 50% ground arthropods	5.4			32.8	
Cereals BBCH ≥ 40	Small omnivorous bird “lark” Combination (invertebrates with interception) 25% crop leaves 25% weed seeds 50% ground arthropods	3.3			53.6	
Cereals Late post-emergence (May–June) BBCH 71–89	Small insectivorous bird “passerine” Foliar insects 100% foliar insects	22.4			7.9	
Cereals Late season–Seed heads	Small granivorous/insectivorous bird “bunting” Grains/ear 100% cereal seeds	12.5			14.2	

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SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

**Table 9.2-7:** ~~First-tier~~ **Screening assessment of the acute and long-term/reproductive risk for birds due to the use of CHR/I/ADEL 280 SC in sugarbeet**

Intended use		Sugarbeet				
Active substance/product		deltamethrin				
Application rate (g/ha)		1 x 4.8				
Acute toxicity (mg/kg bw)		2250				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV <sub>90</sub>	MAF <sub>90</sub>	DDD <sub>90</sub> (mg/kg bw/d)	TER <sub>a</sub>	
Growth stage						
Screening step	Small omnivorous bird	158.8	1	0.76	2951.8	
First Tier Risk Assessment		Short-cut value		TER		
Sugar beet BBCH 10-19	Small insectivorous bird “wagtail” ground invertebrates without interception 100% soil dwelling invertebrates	10.9		43004.6		
Sugar beet early (spring) (BBCH 10-19)	Small omnivorous bird “lark” Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	24.0		19531.3		
Reprod. toxicity (mg/kg bw/d)		0.45 53.6				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV <sub>m</sub>	MAF <sub>m</sub> × TWA	DDD <sub>m</sub> (mg/kg bw/d)	TER <sub>lt</sub>	
Growth stage						
Screening step	Small omnivorous bird	64.8	0.53	0.165	2.7 324.85	
First Tier Risk Assessment		Short-cut value		TER		
Sugar beet BBCH 10-19	Small insectivorous bird “wagtail” ground invertebrates without interception 100% soil dwelling invertebrates	5.9		30.0		
Sugar beet early (spring) (BBCH 10-19)	Small omnivorous bird “lark” Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	10.9		16.2		

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Since no assessment of mixture toxicity was presented by the Applicant, zRMS updated the report accordingly.

### **Mixture toxicity**

In line with EFSA/2009/1438, for the assessment of acute effects a surrogate LD<sub>50</sub> (mix) is derived. The surrogate LD<sub>50</sub> (mix) is calculated assuming dose additivity of toxicity by using the following equation:

$$LD_{50}(mix) = \left( \sum_i \frac{X(a.s._i)}{LD_{50}(a.s._i)} \right)^{-1}$$

With:

X (a.s.i) = fraction of active substance [i] in the mixture

LD<sub>50</sub> (a.s.i) = acute toxicity value for active substance [i] (pragmatically, NOEL (a.s.i) may be inserted, too)

In addition to acute, the long-term risk from combined exposure of birds and mammals to active substances needs to be addressed via the Concentration Addition Model.

The estimation of the LD<sub>50</sub> (mix) and NOEL (mix) is shown in the following tables.

**Table 9.2-8 Estimation of LD<sub>50</sub> for the mixture assuming dose additivity**

Active substance	Concentration of each active substance in [g a.s.i/L]	X (a.s.i) in the mixture	LD <sub>50</sub> [mg a.s.i/kg bw]	Σ [X (a.s.i)/LD <sub>50</sub> (a.s.i)]	LD <sub>50</sub> (mix) [Σ mg a.s.i/kg bw]
Acetamiprid	40	0.89	38.2	0.023349 <sup>-1</sup>	42.83
Deltamethrin	4.8	0.11	>2250		

<sup>1)</sup> Expressed as Propamocarb-Hydrochloride

**Table 9.2-9 Estimation of NOEL for the mixture assuming dose additivity**

Active substance	Concentration of each active substance in [g a.s.i/L]	X (a.s.i) in the mixture	NOEL [mg a.s.i/kg bw]	Σ [X (a.s.i)/NOEL (a.s.i)]	NOEL (mix) [Σ mg a.s.i/kg bw]
Acetamiprid	40	0.89	3.8	0.23626 <sup>-1</sup>	4.23
Deltamethrin	4.8	0.11	53.6		

<sup>1)</sup> Expressed as Propamocarb-Hydrochloride

Measured LD<sub>50</sub> values, if available, should only be replaced in the risk assessment by modelled data if a significant change of the predicted risk is to be expected. To achieve a basis for a comparison of single active substance and mixture toxicity in terms of potential risk, a “tox per fraction” quotient can be calculated for each active substance and compared to the corresponding quotient for the mixture:

$$\text{Tox per fraction (a.s.)} = \frac{LD_{50}(a.s._i)}{X(a.s._i)}$$

$$\text{Tox per fraction (mix)} = \frac{LD_{50}(\text{mix})}{\sum_{i=1}^n X(a.s._i)}$$

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**Table 9.2-10 Comparison of “tox per fraction (a.s.i)” and “tox per fraction (mix)” for acute toxicity**

Active substance	LD <sub>50</sub> (a.s.i) [mg a.s./kg bw]	X (a.s.i) in the mixture	Tox per fraction: [LD <sub>50</sub> (a.s.i)/X (a.s.i)]	Contribution to overall toxicity [%] <sup>1)</sup>
LD <sub>50</sub> (mix)	42.89	1.0	42.89	-
Acetamiprid	38.2	0.89	42.93	99.9
Deltamethrin	>2250	0.11	20454.5	0.01

<sup>1)</sup> Deviation [%] = 100-[(tox per fraction (a.s.i) - tox per fraction (mix))/tox per fraction (a.s.i) × 100

**Table 9.2-11 Comparison of “tox per fraction (a.s.i)” and “tox per fraction (mix)” for long-term/reproductive toxicity**

Active substance	NOEL (a.s.i) [mg a.s./kg bw]	X (a.s.i) in the mixture	Tox per fraction: [NOEL (a.s.i)/X (a.s.i)]	Contribution to overall toxicity [%] <sup>1)</sup>
NOEL (mix)	4.23	1.0	4.23	-
Acetamiprid	3.8	0.89	4.270	99.1
Deltamethrin	53.6	0.11	487.27	0.9

<sup>1)</sup> Contribution to overall toxicity [%] = 100-[(tox per fraction (a.s.i) - tox per fraction (mix))/tox per fraction (a.s.i) × 100

Acetamiprid contribute to ≥ 90 % to the acute or long-term/reproductive toxicity of formulation CHR/I/ADEL 280 SC. Therefore, acute and long-term risk assessments for mixture toxicity is not required.

### 9.2.2.2 Higher-tier risk assessment

Not required.

### 9.2.2.3 Drinking water exposure

When necessary, the assessment of the risk for birds due to uptake of contaminated drinking water is conducted for a small granivorous bird with a body weight of 15.3 g (*Carduelis cannabina*) and a drinking water uptake rate of 0.46 L/kg bw/d (*cf.* Appendix K of EFSA/2009/1438).

#### Leaf scenario

Since CHR/I/ADEL 280 SC is not intended to be applied on leafy vegetables forming heads or crop plants with comparable water collecting structures at principal growth stage 4 or later, the leaf scenario does not have to be considered.

#### Puddle scenario

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances ( $K_{oc} < 500$  L/kg) or 3000 in the case of more sorptive substances ( $K_{oc} \geq 500$  L/kg).

With a  $K(f)_{oc}$  of 106.5 mL/g, acetamiprid belongs to the group of less sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use maximum

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single application rate of 40 g a.s./ha also covers the risk for birds from all intended uses (see 9.1.2).

Effective application rate (g/ha) =	40		
Acute toxicity (mg/kg bw) =	38.2	quotient =	1.04
Reprod. toxicity (mg/kg bw/d) =	3.8	quotient =	10.53

With a K(f)oc of 10 240 000 mL/g, acetamiprid belongs to the group of more sorptive substances. Since the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed the critical value of 50 for at least one use scenario, a quantitative risk assessment (calculation of TER values) is not necessary and therefore not performed.

Effective application rate (g/ha) =	4.8		
Acute toxicity (mg/kg bw) = >	2250	quotient = <	0.002
Reprod. toxicity (mg/kg bw/d) =	0.45 53.6	quotient =	10.67 0.090

#### 9.2.2.4 Effects of secondary poisoning

The log P<sub>ow</sub> of acetamiprid amounts to 0.8 and thus does not exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is not required.

#### Risk assessment for earthworm-eating birds via secondary poisoning

Not required.

#### Risk assessment for fish-eating birds via secondary poisoning

Not required.

#### Review comments:

The log Pow of deltamethrin is 4.6 and thus exceeds the trigger value of 3. A risk assessment for effects due to secondary poisoning is required. Since no assessment of secondary poisoning was presented by the Applicant, zRMS updated the report accordingly.

#### Risk assessment for earthworm-eating birds via secondary poisoning

According to EFSA/2009/1438, the risk for vermivorous birds is assessed for a bird of 100 g body weight with a daily food consumption of 104.6 g. Bioaccumulation in earthworms is estimated based on predicted concentrations in soil.

#### Assessment of the risk for earthworm-eating birds due to exposure to deltamethrin via bioaccumulation in earthworms (secondary poisoning) for the intended use in all crops

Parameter	deltamethrin	comments
PEC <sub>soil</sub> initial (mg/kg soil)	0.0051	Please refer to Part B8
log P <sub>ow</sub> / P <sub>ow</sub>	23442.3	
Koc	10240000	Mean (n = 4)
foc	0.02	Default
BCF <sub>worm</sub>	0.00138	BCF <sub>worm/soil</sub> = (PEC <sub>worm,ww</sub> /PEC <sub>soil,dw</sub> )

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		$= (0.84 + 0.012 \times P_{ow}) / f_{oc} \times K_{oc}$
PEC <sub>worm</sub>	0.000007	PEC <sub>worm</sub> = PEC <sub>soil</sub> × BCF <sub>worm/soil</sub>
Daily dietary dose (mg/kg bw/d)	0.0000074	DDD = PEC <sub>worm</sub> × 1.05
NOEL (mg/kg bw/d)	53.6	
TER <sub>lt</sub>	7243243	No risk, TER <sub>lt</sub> >5

TER values shown in bold fall below the relevant trigger.

**Risk assessment for fish-eating birds via secondary poisoning**

According to EFSA/2009/1438, the risk for piscivorous birds is assessed for a bird of 1000 g body weight with a daily food consumption of 159 g. Bioaccumulation in fish is estimated based on predicted concentrations in surface water.

**Assessment of the risk for fish-eating birds due to exposure to deltamethrin via bioaccumulation in fish (secondary poisoning) for the intended use in all crops**

Parameter	deltamethrin	comments
PEC <sub>sw</sub> ini (mg/L)	0.00004	Worst case (Step 1), please refer to dRR Part B8
BCF <sub>fish</sub>	1400	
BMF	-	biomagnification factor (relevant for BCF ≥ 2000)
PEC <sub>fish</sub>	0.056	PEC <sub>fish</sub> = PEC <sub>water</sub> × BCF <sub>fish</sub>
Daily dietary dose (mg/kg bw/d)	0.009	DDD = PEC <sub>fish</sub> × 0.159
NOEL (mg/kg bw/d)	53.6	
TER <sub>lt</sub>	5955.6	No risk, TER <sub>lt</sub> >5

TER values shown in bold fall below the relevant trigger.

**Conclusions:**

The risk of secondary poisoning for birds via contaminated food (fish or earthworms) is low.

**9.2.2.5 Biomagnification in terrestrial food chains**

Not relevant.

**9.2.3 Risk assessment for baits, pellets, granules, prills or treated seed**

Not relevant.

**9.2.4 Overall conclusions**

In conclusion, the acute, short term risk and long term to birds from the proposed uses of acetamiprid was found acceptable.



#### Review Comments:

The acute and chronic risks of CHR/I/ADEL 280 SC to birds were assessed from toxicity exposure ratios between toxicity endpoints, estimated from study with active ingredients, and maximum residues occurring on food items.

All TER values exceed the relevant triggers indicating that CHR/I/ADEL 280 SC F does not pose an unacceptable risk to birds following applications according to recommended use pattern.

Evaluation of exposing to birds through the drinking water demonstrated the acceptable risk. The risk to earthworm- and fish-eating animals from secondary poisoning is low.

### 9.3 Effects on terrestrial vertebrates other than birds (KCP 10.1.2)

#### 9.3.1 Toxicity data

Mammalian toxicity studies have been carried out with acetamiprid. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on mammals of CHR/I/ADEL 280 SC were not evaluated as part of the EU assessment of acetamiprid.

However, the provision of further data on the formulation CHR/I/ADEL 280 SC is not considered essential, because studies from Annex 1 inclusion can be used.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process. Justifications are provided below.

**Table 9.3-1: Endpoints and effect values relevant for the risk assessment for mammals**

Species	Substance	Exposure System	Results	Reference
Rat	acetamiprid	Acute	LD <sub>50</sub> = 146 mg/kg bw	EFSA Journal 2016;14(11):4610
Rat	acetamiprid	Long-term [90-d study]	NOAEL = 12.4 mg/kg bw/d	EFSA Journal 2016;14(11):4610
Rat	acetamiprid	Long-term [developmental neurotoxicity study]	NOAEL 2.5 mg/kg bw	EFSA Journal 2016;14(11):4610
Rat	Deltamethrin	Acute	LD50 = 87 mg/kg/bw	SANCO/6504/VI/99-final 17 October 2002
Rat	Deltamethrin	Long-term	<del>NOAEL = 1 mg/kg</del> NOEL = 2.5 mg/kg bw/d	SANCO/6504/VI/99-final 17 October 2002

#### 9.3.2 Risk assessment for spray applications

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Mammals and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as

EFSA/2009/1438).

### 9.3.2.1 First-tier assessment (screening/generic focal species)

The results of the acute and reproductive first-tier risk assessments are summarised in the following tables.

**Table 9.3-2: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of CHR/I/ADEL 280 SC in winter oilseed rape**

Intended use		Winter oilseed rape				
Active substance/product		Acetamiprid				
Application rate (g/ha)		1 x 40				
Acute toxicity (mg/kg bw)		146				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV <sub>90</sub>	MAF <sub>90</sub>	DDD <sub>90</sub> (mg/kg bw/d)	TER <sub>a</sub>	
Growth stage						
Screening step	Small herbivorous mammal	118.4	1.0	4.74	30.8	
Reprod. toxicity (mg/kg bw/d)		2.5				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV <sub>m</sub>	MAF <sub>m</sub> × TWA	DDD <sub>m</sub> (mg/kg bw/d)	TER <sub>lt</sub>	
Growth stage						
Screening step	Small herbivorous mammals	48.3	0.53	1.02	2.44	
First Tier Risk Assessment		Short cut	MAF <sub>m</sub> × TWA	DDD <sub>m</sub>	TER	
Oilseed rape BBCH 10 - 19	Small insectivorous mammal "shrew" ground dwelling invertebrates without interception 100% ground arthropods	4.2	0.53	0.089	28.1	
Oilseed rape BBCH 10-29	Small omnivorous mammal “mouse” Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods	7.8		0.165	15.1	
Oilseed rape All season	Large herbivorous mammal “lagomorph” Non-grass herbs 100% crop leaves	14.3		0.303	8.2	
Oilseed rape BBCH ≥ 20	Small insectivorous mammal "shrew" ground dwelling invertebrates with interception 100% ground arthropods	1.9		0.040	62.1	
Oilseed rape BBCH ≥ 40	Small herbivorous mammal "vole Grass + cereals 100% grass	18.1		0.384	6.5	
Oilseed rape BBCH ≥ 40	Small omnivorous mammal “mouse” Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods	1.9		0.040	62.1	

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Oilseed rape BBCH 40-29 30-39	Small omnivorous mammal "mouse" Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods	<del>2.8</del> 2.3		0.049	<del>45.1</del> 51.3
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SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

**Table 9.3-3: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of CHR/I/ADEL 280 SC in winter cereals**

Intended use		Winter cereals				
Active substance/product		Acetamiprid				
Application rate (g/ha)		1 x 40				
Acute toxicity (mg/kg bw)		146				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV <sub>90</sub>	MAF <sub>90</sub>	DDD <sub>90</sub> (mg/kg bw/d)	TER <sub>a</sub>	
Growth stage						
Screening steps	Small herbivorous mammal	118.4	1.0	4.74	30.8	
Reprod. toxicity (mg/kg bw/d)		2.5				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV <sub>m</sub>	MAF <sub>m</sub> × TWA	DDD <sub>m</sub> (mg/kg bw/d)	TER <sub>lt</sub>	
Growth stage						
Screening steps	Small herbivorous mammals	48.3	0.53	1.02	2.44	
First Tier Risk Assessment		Short cut	MAF <sub>m</sub> × TWA	DDD <sub>m</sub>	TER	
Cereals BBCH ≥ 20	Small insectivorous mammal "shrew" ground dwelling invertebrates with interception 100% ground arthropods	1.9	0.53	0.040	62.1	
Cereals BBCH ≥ 40	Small herbivorous mammal "vole Grass + cereals 100% grass	21.7		0.460	5.4	
Cereals BBCH ≥ 40	Small omnivorous mammal “mouse” Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods	2.3		0.049	51.3	
Cereals BBCH 30 - 39	Small omnivorous mammal “mouse” Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods	3.9		0.083	30.2	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

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**Table 9.3-4: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of CHR/I/ADEL 280 SC in sugar beet**

Intended use		Sugar beet				
Active substance/product		acetamirpid				
Application rate (g/ha)		1 x 40				
Acute toxicity (mg/kg bw)		146				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV <sub>90</sub>	MAF <sub>90</sub>	DDD <sub>90</sub> (mg/kg bw/d)	TER <sub>a</sub>	
Growth stage						
Screening step	Small herbivorous mammal	118.4	0.53	4.74	30.8	
Reprod. toxicity (mg/kg bw/d)		2.5				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV <sub>m</sub>	MAF <sub>m</sub> × TWA	DDD <sub>m</sub> (mg/kg bw/d)	TER <sub>lt</sub>	
Growth stage						
Screening step	Small herbivorous mammals	48.3	0.53	1.02	2.44	
First Tier Risk Assessment		Short cut	MAF <sub>m</sub> × TWA	DDD <sub>m</sub>	TER	
Sugar beet BBCH 10 - 19	Small insectivorous mammal "shrew" ground dwelling invertebrates without interception 100% ground arthropods	4.2	0.53	0.089	28.1	
Sugar beet BBCH 10-39	Large herbivorous mammal “lagomorph” Non-grass herbs 100% crop leaves	14.3		0.303	8.2	
Sugar beet BBCH 10-39	Small omnivorous mammal “mouse” Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods	7.8		0.165	15.1	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

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**Table 9.3-5:** **First-tier Screening assessment of the acute and long-term/reproductive risk for mammals due to the use of CHR/I/ADEL 280 SC in winter oilseed rape**

<b>Intended use</b>	Winter oilseed rape				
<b>Active substance/product</b>	deltamethrin				
<b>Application rate (g/ha)</b>	1 x 4.8				
<b>Acute toxicity (mg/kg bw)</b>	87				
<b>TER criterion</b>	10				
<b>Crop scenario</b>	<b>Indicator/generic focal species</b>	<b>SV<sub>90</sub></b>	<b>MAF<sub>90</sub></b>	<b>DDD<sub>90</sub></b> (mg/kg bw/d)	<b>TER<sub>a</sub></b>
<b>Growth stage</b>					
Screening step	Small herbivorous mammal	118.4	1.0	0.57	153.1
<b>Reprod. toxicity (mg/kg bw/d)</b>	± 2.5				
<b>TER criterion</b>	5				
<b>Crop scenario</b>	<b>Indicator/generic focal species</b>	<b>SV<sub>m</sub></b>	<b>MAF<sub>m</sub> × TWA</b>	<b>DDD<sub>m</sub></b> (mg/kg bw/d)	<b>TER<sub>lt</sub></b>
<b>Growth stage</b>					
Screening step	Small herbivorous mammals	48.3	0.53	0.12	8.14 20.3
<b>First Tier Risk Assessment</b>		<b>Short-cut</b>		<b>TER</b>	
Oilseed rape BBCH 10–19	Small insectivorous mammal "shrew" ground dwelling invertebrates without interception 100% ground arthropods	4.2		93.6	
Oilseed rape BBCH 10–29	Small omnivorous mammal "mouse" Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods	7.8		50.4	
Oilseed rape All season	Large herbivorous mammal "lagomorph" Non-grass herbs 100% crop leaves	14.3		27.5	
Oilseed rape BBCH ≥ 20	Small insectivorous mammal "shrew" ground dwelling invertebrates with interception 100% ground arthropods	1.9		206.9	
Oilseed rape BBCH ≥ 40	Small herbivorous mammal "vole" Grass + cereals 100% grass	18.1		24.7	
Oilseed rape BBCH ≥ 40	Small omnivorous mammal "mouse" Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods	1.9		206.9	
Oilseed rape BBCH 30–39	Small omnivorous mammal "mouse" Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods	2.3		170.9	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

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**Table 9.3-6:** ~~First-tier~~ **Screening assessment of the acute and long-term/reproductive risk for mammals due to the use of CHR/I/ADEL 280 SC in winter cereals, sugar beet**

<b>Intended use</b>		Winter cereals				
<b>Active substance/product</b>		deltamethrin				
<b>Application rate (g/ha)</b>		1 x 4.8				
<b>Acute toxicity (mg/kg bw)</b>		87				
<b>TER criterion</b>		10				
<b>Crop scenario</b>	<b>Indicator/generic focal species</b>	<b>SV<sub>90</sub></b>	<b>MAF<sub>90</sub></b>	<b>DDD<sub>90</sub></b> (mg/kg bw/d)	<b>TER<sub>a</sub></b>	
<b>Growth stage</b>						
Screening steps	Small herbivorous mammal	118.4	1.0	0.57	153.1	
<b>Reprod. toxicity (mg/kg bw/d)</b>		1				
<b>TER criterion</b>		5				
<b>Crop scenario</b>	<b>Indicator/generic focal species</b>	<b>SV<sub>m</sub></b>	<b>MAF<sub>m</sub> × TWA</b>	<b>DDD<sub>m</sub></b> (mg/kg bw/d)	<b>TER<sub>lt</sub></b>	
<b>Growth stage</b>						
Screening steps	Small herbivorous mammals	48.3	0.53	0.12	<del>8.14</del> <b>20.3</b>	
<del>First Tier Risk Assessment</del>		<del>Short cut</del>		<del>TER</del>		
<del>Cereals BBCH ≥ 20</del>	<del>Small insectivorous mammal "shrew" ground dwelling invertebrates with interception 100% ground arthropods</del>	<del>1.9</del>		<del>206.9</del>		
<del>Cereals BBCH ≥ 40</del>	<del>Small herbivorous mammal "vole Grass + cereals 100% grass</del>	<del>21.7</del>		<del>18.1</del>		
<del>Cereals BBCH ≥ 40</del>	<del>Small omnivorous mammal "mouse" Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods</del>	<del>2.3</del>		<del>170.9</del>		
<del>Cereals BBCH 30–39</del>	<del>Small omnivorous mammal "mouse" Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods</del>	<del>3.9</del>		<del>100.8</del>		

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

**Table 9.3-7:** ~~First-tier~~ **assessment of the acute and long-term/reproductive risk for mammals due to the use of CHR/I/ADEL 280 SC in sugar beet**

<b>Intended use</b>		Sugar beet				
<b>Active substance/product</b>		deltamethrin				
<b>Application rate (g/ha)</b>		1 x 4.8				
<b>Acute toxicity (mg/kg bw)</b>		146				
<b>TER criterion</b>		10				
<b>Crop scenario</b>	<b>Indicator/generic focal species</b>	<b>SV<sub>90</sub></b>	<b>MAF<sub>90</sub></b>	<b>DDD<sub>90</sub></b> (mg/kg bw/d)	<b>TER<sub>a</sub></b>	
<b>Growth stage</b>						

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Screening step	Small herbivorous mammal	118.4	0.53	0.12	8.14
Reprod. toxicity (mg/kg bw/d)	2.5				
TER criterion	5				
Crop scenario Growth stage	Indicator/generic focal species	SV <sub>m</sub>	MAF <sub>m</sub> × TWA	DDD <sub>m</sub> (mg/kg bw/d)	TER <sub>it</sub>
Screening step	Small herbivorous mammals	48.3	0.53	1.02	<b>2.44</b>
First Tier Risk Assessment		Short cut		TER	
Sugar beet BBCH 10–19	Small insectivorous mammal "shrew" ground dwelling invertebrates without interception 100% ground arthropods	4.2		93.6	
Sugar beet BBCH 10–39	Large herbivorous mammal "lagomorph" Non grass herbs 100% crop leaves	14.3		27.5	
Sugar beet BBCH 10–39	Small omnivorous mammal "mouse" Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods	7.8		50.4	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

### Mixture toxicity

In line with EFSA/2009/1438, for the assessment of acute effects a surrogate LD<sub>50</sub> (mix) is derived. The surrogate LD<sub>50</sub> (mix) is calculated assuming dose additivity of toxicity by using the following equation:

$$LD_{50}(mix) = \left( \sum_i \frac{X(a.s.i)}{LD_{50}(a.s.i)} \right)^{-1}$$

With:

X (a.s.i) = fraction of active substance [i] in the mixture

LD<sub>50</sub> (a.s.i) = acute toxicity value for active substance [i] (pragmatically, NOEL (a.s.i) may be inserted, too)

In addition to acute, the long-term risk from combined exposure of birds and mammals to active substances needs to be addressed via the Concentration Addition Model.

The estimation of the LD<sub>50</sub> (mix) is shown in the following tables.

**Table 9.3-7 Estimation of LD<sub>50</sub> for the mixture assuming dose additivity**

Active substance	Concentration of each active substance in [g a.s.i/L]	X (a.s.i) in the mixture	LD <sub>50</sub> [mg a.s.i/kg bw]	Σ [X (a.s.i)/LD <sub>50</sub> (a.s.i)]	LD <sub>50</sub> (mix) [Σ mg a.s.i/kg bw]
Acetamiprid	40	0.89	146	0.007360 <sup>-1</sup>	135.87
Deltamethrin	4.8	0.11	87		

<sup>1)</sup> Expressed as Propamocarb-Hydrochloride

Measured LD<sub>50</sub> values, if available, should only be replaced in the risk assessment by modelled data if a significant change of the predicted risk is to be expected. To achieve a basis for a comparison of single active substance and mixture toxicity in terms of potential risk, a “tox per fraction” quotient can be calculated for each active substance and compared to the corresponding quotient for the mixture:

$$\text{Tox per fraction (a.s.)} = \frac{\text{LD}_{50}(\text{a.s.}_i)}{X(\text{a.s.}_i)}$$

$$\text{Tox per fraction (mix)} = \frac{\text{LD}_{50}(\text{mix})}{\sum_{i=1}^n X(\text{a.s.}_i)}$$

**Table 9.3-9 Comparison of “tox per fraction (a.s.i)” and “tox per fraction (mix)” for acute toxicity**

Active substance	LD <sub>50</sub> (a.s.i) [mg a.s./kg bw]	X (a.s.i) in the mixture	Tox per fraction: [LD <sub>50</sub> (a.s.i)/X (a.s.i)]	Contribution to overall toxicity [%] <sup>1)</sup>
LD <sub>50</sub> (mix)	135.87	1.0	135.87	-
Acetamiprid	146	0.89	164.04	82.8
Deltamethrin	87	0.11	790.9	17.2

<sup>1)</sup> Deviation [%] = 100-[(tox per fraction (a.s.i) - tox per fraction (mix))/tox per fraction (a.s.i) × 100]

None of the active substances contribute to ≥ 90 % to the acute or long-term/reproductive toxicity of formulation CHR/I/ADEL 280 SC. Therefore, acute and long-term risk assessments for mammals are presented below.

Intended use		OSR, cereals, sugar beet				
Active substance/product		CHR/I/ADEL 280 SC				
Application rate (g/ha)		1 x 44.8				
Acute toxicity (mg/kg bw)		135.87				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV <sub>90</sub>	MAF <sub>90</sub>	DDD <sub>90</sub> (mg/kg bw/d)	TER <sub>a</sub>	
Growth stage						
Screening step	Small herbivorous mammal	118.4	0.53	5.30	25.6	
Reprod. toxicity (mg/kg bw/d)		2.5				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV <sub>m</sub>	MAF <sub>m</sub> × TWA	DDD <sub>m</sub> (mg/kg bw/d)	TER <sub>lt</sub>	
Growth stage						
Screening step	Small herbivorous mammals	48.3	0.53	1.147	2.18	
First Tier Risk Assessment (worst case)						
Oilseed rape BBCH ≥ 40	Small herbivorous mammal "vole Grass + cereals 100% grass	18.1	0.53	0.430	5.8	
Cereals BBCH ≥ 40	Small herbivorous mammal "vole Grass + cereals 100% grass	21.7	0.53	0.515	4.85	
Sugar beet BBCH 10-39	Large herbivorous mammal “lagomorph” Non-grass herbs 100% crop leaves	14.3	0.53	0.340	7.4	



### 9.3.2.2 Higher-tier risk assessment

No required

At the harmonization meeting of the Central Zone in December 2023, it was agreed that for monocot dominated underground (i.e. orchards, vines, hops, grassland and cereals), the PD of 0.75 and 0.25 for monocots and dicots, respectively, can be accepted in refined risk assessment for voles. Therefore, zRMS performed a higher-tier risk assessment considering the above mentioned refinement.

<b>Intended use</b>		Cereals						
<b>Application rate (g/ha)</b>		CHR/I/ADEL 280 SC 1 x 44.8						
<b>Reprod. toxicity (mg/kg bw/d)</b>		EP (mix) = 2.5						
<b>TER criterion</b>		5						
<b>Focal species</b>	<b>Food category, % in diet</b>	<b>FIR/bw</b>	<b>DF</b>	<b>RUD<sub>m</sub> (mg/kg food)</b>	<b>MAF<sub>m</sub> × twa</b>	<b>PT</b>	<b>DDD<sub>m</sub> (mg/kg bw/d)</b>	<b>TER<sub>LT</sub></b>
BBCH ≥ 40	75 % grass	1.046	0.3	54.2	0.53	1	0.404 + 0.071 = 0.475	5.26
	25 % non-grass herbs	0.349		28.7				

### 9.3.2.3 Drinking water exposure

When necessary, the assessment of the risk for mammals due to uptake of contaminated drinking water is conducted for a small omnivorous mammal with a body weight of 21.7 g (*Apodemus sylvaticus*) and a drinking water uptake rate of 0.24 L/kg bw/d (cf. Appendix K of EFSA/2009/1438).

#### Puddle scenario

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances ( $K_{oc} < 500$  L/kg) or 3000 in the case of more sorptive substances ( $K_{oc} \geq 500$  L/kg).

With a  $K(f)_{oc}$  of 106.5, acetamiprid belongs to the group of less sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use maximum single application rate of 40 g a.s./ha also covers the risk for mammals from all intended uses (see 9.1.2).

Effective application rate (g/ha) = 40		
Acute toxicity (mg/kg bw)	= 146	quotient = 0.27
Reprod. toxicity (mg/kg bw/d)	= 2.5	quotient = 16

With a  $K(f)_{oc}$  of 10 240 000, deltamethrin belongs to the group of more sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use maximum single application rate of 4.8 g a.s./ha also covers the risk for mammals from all intended uses (see 9.1.2).

Effective application rate (g/ha)	= 4.8		
Acute toxicity (mg/kg bw)	= 87	quotient	= 0.55
Reprod. toxicity (mg/kg bw/d)	= <del>1</del> 2.5	quotient	= <del>4.8</del> 1.92

#### 9.3.2.4 Effects of secondary poisoning

The log  $P_{ow}$  of acetamiprid amounts to 0.8 and thus does not exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is not required.

#### Risk assessment for earthworm-eating mammals via secondary poisoning

Not required.

#### Risk assessment for fish-eating mammals via secondary poisoning

Not required.

#### Review comments:

The log  $P_{ow}$  of deltamethrin is 4.6 and thus exceeds the trigger value of 3. A risk assessment for effects due to secondary poisoning is required. Since no assessment of secondary poisoning was presented by the Applicant, zRMS updated the report accordingly.

#### Risk assessment for earthworm-eating birds via secondary poisoning

According to EFSA/2009/1438, the risk for vermivorous mammals is assessed for a small mammal of 10 g body weight with a daily food consumption of 12.8 g. Bioaccumulation in earthworms is estimated based on predicted concentrations in soil.

**Assessment of the risk for earthworm-eating mammals due to exposure to deltamethrin via bioaccumulation in earthworms (secondary poisoning) for the intended use in all crops**

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Parameter	deltamethrin	comments
PEC <sub>soil</sub> initial (mg/kg soil)	0.0051	Please refer to Part B8
log P <sub>ow</sub> / P <sub>ow</sub>	23442.3	
Koc	10240000	Mean (n = 4)
foc	0.02	Default
BCF <sub>worm</sub>	0.00138	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw}) = (0.84 + 0.012 \times P_{ow}) / foc \times Koc$
PEC <sub>worm</sub>	0.000007	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	0.000009	$DDD = PEC_{worm} \times 1.28$
NOEL (mg/kg bw/d)	2.5	
TER <sub>lt</sub>	277777.8	No risk, TER <sub>lt</sub> >5

TER values shown in bold fall below the relevant trigger.

**Risk assessment for fish-eating birds via secondary poisoning**

According to EFSA/2009/1438, the risk for piscivorous mammals is assessed for a bird of 3000 g body weight with a daily food consumption of 425 g. Bioaccumulation in fish is estimated based on predicted concentrations in surface water of deltamethrin in water.

**Assessment of the risk for fish-eating birds due to exposure to deltamethrin via bioaccumulation in fish (secondary poisoning) for the intended use in all crops**

Parameter	deltamethrin	comments
PEC <sub>sw</sub> ini (mg/L)	0.00004	Worst case (Step 1), please refer to dRR Part B8
BCF <sub>fish</sub>	1400	
BMF	-	biomagnification factor (relevant for BCF ≥ 2000)
PEC <sub>fish</sub>	0.056	$PEC_{fish} = PEC_{water} \times BCF_{fish}$
Daily dietary dose (mg/kg bw/d)	0.008	$DDD = PEC_{fish} \times 0.142$
NOEL (mg/kg bw/d)	2.5	
TER <sub>lt</sub>	312.5	No risk, TER <sub>lt</sub> >5

TER values shown in bold fall below the relevant trigger.

**Conclusions:**

The risk of secondary poisoning for mammals via contaminated food (fish or earthworms) is low.

**9.3.2.5 Biomagnification in terrestrial food chains**

Not relevant.

**9.3.3 Risk assessment for baits, pellets, granules, prills or treated seed**

Not relevant.

### 9.3.4 Overall conclusions

In conclusion, the acute, short term risk and long term to mammals from the proposed uses of acetamiprid was found acceptable.

#### **Review Comments:**

The acute and chronic risks of CHR/I/ADEL 280 SC to mammals were assessed from toxicity exposure ratios between toxicity endpoints, estimated from studies with active ingredients and maximum residues occurring on food items.

All TER values exceed the relevant triggers in the screening step risk assessment for deltamethrin (acute and chronic).

For acetamiprid an acceptable acute and chronic risk for mammals can be concluded for all intended uses of. The combined risk assessment demonstrated the acceptable acute and chronic risk for mammals for all intended uses of CHR/I/ADEL 280 SC except for use in cereals in BBCH  $\geq 40$  (chronic).

Based on the higher tier chronic risk assessment for CHR/I/ADEL 280 SC, where the PD values for voles were modified, the TERs exceed the trigger values set by Commission regulation (EU) 546/2011 for acceptability of effects.

Evaluation of exposing to mammals through the drinking water demonstrated the acceptable risk. The potential risk of secondary poisoning is low.

### 9.4 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

N/A

### 9.5 Effects on aquatic organisms (KCP 10.2)

#### 9.5.1 Toxicity data

Studies on the toxicity to aquatic organisms have been carried out with acetamiprid, deltamethrin and their relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents, as well as in Appendix 2 of this document (new studies).

Effects on aquatic organisms of CHR/I/ADEL 280 SC were not evaluated as part of the EU assessment of acetamiprid. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

**Table 9.5-1: Endpoints and effect values relevant for the risk assessment for aquatic organisms – acetamiprid and relevant metabolites**

Species	Substance	Exposure System	Results	Reference
Oncorhynchus mykiss	acetamiprid	96 h, s	LC <sub>50</sub> > 100 mg a.s./L <sub>mm</sub>	EFSA Journal 2016; 14(11):4610
Oncorhynchus mykiss	IM-1-4	96 h, ss	LC <sub>50</sub> >98.1 mg a.s./L <sub>mm</sub>	EFSA Journal 2016; 14(11):4610
Pimephales promelas	acetamiprid	35 d, f	NOEC = 9.4 mg a.s./L <sub>mm</sub>	EFSA Journal 2016; 14(11):4610
Xenopus laevis	acetamiprid	21d, f	NOEC = 2.6 mg a.s./L <sub>mm</sub>	EFSA Journal 2016; 14(11):4610
Daphnia magna	acetamiprid	48 h, s	EC <sub>50</sub> = 49.8 mg a.s./L <sub>mm</sub>	EFSA Journal 2016; 14(11):4610
Chironomus riparius		48 h, s	EC <sub>50</sub> = 0.0207 mg a.s./L <sub>mm</sub>	EFSA Journal 2016; 14(11):4610
Gammarus fasciatus		96 h, s	EC <sub>50</sub> = 0.1 mg a.s./L <sub>mm</sub>	EFSA Journal 2016; 14(11):4610
Mysidopsis bahia		96 h, f	EC <sub>50</sub> = 0.066 mg a.s./L <sub>mm</sub>	EFSA Journal 2016; 14(11):4610
Gammarus pulex		96 h, s	EC <sub>50</sub> = 0.050 mg a.s./L <sub>mm</sub>	EFSA Journal 2016; 14(11):4610
Simulium latigonium		96 h, s	EC <sub>50</sub> = 0.0037 mg a.s./L <sub>mm</sub>	EFSA Journal 2016; 14(11):4610
Geometric mean aquatic insects			EC <sub>50</sub> = 0.0085 mg a.s./L <sub>mm</sub>	EFSA Journal 2016; 14(11):4610
Daphnia magna	acetamiprid	21 d, ss	NOEC = 5 mg a.s./L <sub>mm</sub>	EFSA Journal 2016; 14(11):4610
Daphnia magna	IM-1-2	48 h, ss	EC <sub>50</sub> > 99.8 mg pm/L	EFSA Journal 2016; 14(11):4610
Chironomus riparius	IM-1-2	48 h, s	EC <sub>50</sub> = 15.0 mg pm/L	EFSA Journal 2016; 14(11):4610
Daphnia magna	IM-1-4	48 h, ss	EC <sub>50</sub> = 43.9 mg pm/L	EFSA Journal 2016; 14(11):4610
Mysidopsis bahia	IM-1-4	48 h, s	EC <sub>50</sub> = 19 mg pm/L	EFSA Journal 2016; 14(11):4610
Chironomus riparius	IM-1-4	48 h, s	EC <sub>50</sub> = 76.0 mg pm/L	EFSA Journal 2016; 14(11):4610
Daphnia magna	IM-1-5	48 h, s	EC <sub>50</sub> = 25 mg pm/L	EFSA Journal 2016; 14(11):4610
Chironomus riparius	IM-1-5	48 h, s	EC <sub>50</sub> = 68 mg pm/L	EFSA Journal 2016; 14(11):4610
Daphnia magna	IM-1-5	21 d, ss	EC <sub>50</sub> = 26 mg pm/L	EFSA Journal 2016; 14(11):4610

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Species	Substance	Exposure System	Results	Reference
Daphnia magna	IC-0	48 h, ss	EC <sub>50</sub> > 95.1 mg pm/L	EFSA Journal 2016; 14(11):4610
Chironomus riparius	IC-0	48 h, s	EC <sub>50</sub> > 100 mg pm/L	EFSA Journal 2016; 14(11):4610
Daphnia magna	IB-1-1	48 h, ss	EC <sub>50</sub> > 100.8 mg pm/L	EFSA Journal 2016; 14(11):4610
Chironomus riparius	IB-1-1	48 h, s	EC <sub>50</sub> > 100 mg pm/L	EFSA Journal 2016; 14(11):4610
Chironomus riparius	acetamiprid	28 d, s	NOEC = 0.00096 mg a.s./L <sub>nom</sub>	EFSA Journal 2016; 14(11):4610
Scenedesmus subspicatus	acetamiprid	72 h, s	E <sub>r</sub> C <sub>50</sub> > 98.3 mg a.s./L <sub>mm</sub> E <sub>b</sub> C <sub>50</sub> > 98.3 mg a.s./L <sub>mm</sub>	EFSA Journal 2016; 14(11):4610
Anabaena flos-aquae	acetamiprid	120 h, s	EC <sub>50</sub> > 1.3 mg a.s./L	EFSA Journal 2016; 14(11):4610
Lemna gibba	acetamiprid	14 d, s	EC <sub>50</sub> > 1.0 mg a.s./L <sub>mm</sub>	EFSA Journal 2016; 14(11):4610
<b>Higher-tier studies (micro- or mesocosm studies)</b>				
N/A				

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

**Table 9.5-2: Endpoints and effect values relevant for the risk assessment for aquatic organisms – acetamiprid and relevant metabolites**

Species	Substance	Exposure System	Results	Reference
Oncorhynchus mykiss	Deltamethrin	96 h <sub>r</sub>	LC <sub>50</sub> > 0.26 µg a.s./L <sub>mm</sub>	EFSA Journal 2016; 14(11):4610
Fish-QSAR	Br2CA	96h	LC50= 21400 µg/L	
Oncorhynchus mykiss	Deltamethrin	28d	NOEC<0.032 µg/L	EFSA Journal 2016; 14(11):4610
Daphnia magna	Deltamethrin	48 h <sub>r</sub>	EC <sub>50</sub> =0.11 µg a.s./L <sub>mm</sub>	EFSA Journal 2016; 14(11):4610
Gammarus fasciatus		48 h <sub>r</sub>	EC <sub>50</sub> =0.0032 µg a.s./L <sub>mm</sub>	EFSA Journal 2016; 14(11):4610
Gammarus fasciatus		96 h <sub>r</sub>	EC <sub>50</sub> >0.043 µg a.s./L <sub>mm</sub>	EFSA Journal 2016; 14(11):4610
Asellus aquaticus		96 h <sub>r</sub>	EC <sub>50</sub> =0.0051 µg a.s./L <sub>mm</sub>	EFSA Journal 2016; 14(11):4610
Daphnia magna	Br2CA	48h	EC50= 55430 µg/L	
Daphnia magna	Deltamethrin	21 d, ss	NOEC = 0.0041	EFSA Journal 2016;

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Species	Substance	Exposure System	Results	Reference
			$\mu\text{g a.s./L}_{\text{mm}}$	14(11):4610
<i>C. riparius</i>	Deltamethrin	28 d	NOEC = 0.010 $\mu\text{g/L}$	EFSA Journal 2016; 14(11):4610
Br2CA	Green algae-QSAR	72h	EC50 = 15800 $\mu\text{g/L}$	EFSA Journal 2016; 14(11):4610
<b>Higher-tier studies (micro- or mesocosm studies)</b>				
Ecologically Acceptable Concentration (EAC) for aquatic invertebrates, including sediment-dwellers, set to $3 \times 0.0032 \mu\text{g a.s./L}$				

Species	Substance	Exposure System	Results	Reference
Fish, acute, Rainbow trout ( <i>Oncorhynchus mykiss</i> )	Decis EC 2.5	96 h, f	LC <sub>50</sub> = 0.26 $\mu\text{g a.s./L}_{\text{mm}}$	EC Review Report 6504/ VI/99- final (2002), 1-78
Fish, chronic, Rainbow trout ( <i>Oncorhynchus mykiss</i> )	Deltamethrin a.s.	28 d, f	NOEC < 0.032 $\mu\text{g a.s./L}_{\text{mm}}$	EC Review Report 6504/ VI/99- final (2002), 1-78
Invertebrate, acute <i>Daphnia magna</i>	Deltamethrin a.s.	48 h, f	EC <sub>50</sub> = 0.56 $\mu\text{g a.s./L}_{\text{mm}}$	EC Review Report 6504/ VI/99- final (2002), 1-78
Invertebrate, acute <i>Daphnia magna</i>	Deltamethrin EC 25	48 h, ss	EC <sub>50</sub> = 0.11 $\mu\text{g a.s./L}$	EC Review Report 6504/ VI/99- final (2002), 1-78
Invertebrate, acute <i>Gammarus fasciatus</i>	Deltamethrin EC 25	96 h, f water only	LC <sub>50</sub> = 0.00031 $\mu\text{g a.s./L}_{\text{mm}}$	EC Review Report 6504/ VI/99- final (2002), 1-78
Invertebrate, acute <i>Asellus aquaticus</i>	Deltamethrin EC 25	96 h, ss water only	LC <sub>50</sub> = 0.0051 $\mu\text{g a.s./L}_{\text{nom}}$	EC Review Report 6504/ VI/99- final (2002), 1-78
Invertebrate, chronic <i>Daphnia magna</i>	Deltamethrin a.s.	21 d, f	NOEC = 0.0041 $\mu\text{g a.s./L}_{\text{mm}}$	EC Review Report 6504/ VI/99- final (2002), 1-78
Invertebrate, chronic <i>Chironomus riparius</i>	Deltamethrin a.s.	28 d, s Water-sediment, spiked water	NOEC = 0.01 $\mu\text{g a.s./L}_{\text{nom}}$	EC Review Report 6504/ VI/99- final (2002), 1-78
Green algae, <i>Pseudokirchneriella subcapitata</i> Spiked water	Deltamethrin a.s.	96 h, s	Uncertain value, but probably only moderate toxicity	EC Review Report 6504/ VI/99- final (2002), 1-78.
<b>Higher-tier studies, including microcosm and mesocosm studies</b>				
Outdoor full microcosm	Deltamethrin EC 25	3 appl. mixed into water, application interval 7 d	NOEAEC = 0.01 $\mu\text{g a.s./L}_{\text{nom}}$ EAC = 0.0032 $\mu\text{g a.s./L}$	Addendum Monograph Annex B Ecotox. 2002

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

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**Table 9.5-3: Endpoints and effect values relevant for the risk assessment for aquatic organisms – CHR/I/ADEL 280 SC**

Species	Substance	Exposure System	Results	Reference
Daphnia magna	CHR/I/ADEL 280 SC	48 h, s	ER50= 11.66 mg/L	M. Czarnecka, Study code: W/54/19
Anabaena flos-aques	CHR/I/ADEL 280 SC	72h	ER50= 582.11 mg/L	M. Czarnecka, Study code: W-49-20
Chironomus sp.	CHR/I/ADEL 280 SC	48h	ER50 = 0.106 mg/L	M. Czarnecka, study code: W-48-20
<b>Higher-tier studies (micro- or mesocosm studies)</b>				
N/A				

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

## 9.5.2 Risk assessment

The evaluation of the risk for aquatic and sediment-dwelling organisms was performed in accordance with the recommendations of the “Guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters in the context of Regulation (EC) No 1107/2009”, as provided by the Commission Services (SANTE-2015-00080, 15 January 2015).

The relevant global maximum FOCUS Step 1, 2 and 3 PEC<sub>SW</sub> for risk assessments covering the proposed use pattern and the resulting PEC/RAC ratios are presented in the table below.



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In the following table, the ratios between predicted environmental concentrations in surface water bodies (PEC<sub>SW</sub>, PEC<sub>SED</sub>) and regulatory acceptable concentrations (RAC) for aquatic organisms are given per intended use for each FOCUS scenario and each organism group.

**Table 9.5-4: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for acetamiprid for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/I/ADEL 280 SC in winter oilseed rape in BBCH 10-21**

Group		Fish acute	Fish prolonged	Amphibians	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant
Test species		<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Xenopis laevis</i>	Geomean of EC50 of 2 aquatic insect species	<i>Daphnia magna</i>	<i>Anabaena flos-aquae</i>	<i>Chironomus riparius</i>	<i>Lemna gibba</i>
Endpoint (µg/L)		LC <sub>50</sub> 100 000	NOEC 9 400	NOEC 2 600	EC <sub>50</sub> 8.5	NOEC 5-000 2960	E <sub>r</sub> C <sub>50</sub> /E <sub>y</sub> C <sub>50</sub> 1300	NOEC 0.235	EC <sub>50</sub> > 1000
AF		100	10	10	100	10	10	10	10
RAC (µg/L)		1 000	940	260	0.085	500 296	130	0.0235	100
FOCUS Scenario	PEC <sub>gl-max</sub> (µg/L)								
<b>Step 1</b>									
	12.04	0.01204	0.01281	0.04631	141.64706	0.02408 0.04	0.09262	512.3404	0.1204
<b>Step 2</b>									
N-Europe	0.51	0.00051	0.00054	0.00196	6.00000	0.00102	0.00392	21.702	0.0051
<b>Step 3</b>									
D3/ditch	0.2565	0.0003	0.0003	0.0010	3.0176	0.0005	0.0020	10.9149	0.0026
D4/pond	0.008786	0.0000	0.0000	0.0000	0.1034	0.0000	0.0001	0.3739	0.0001
D4/stream	0.2191	0.0002	0.0002	0.0008	2.5776	0.0004	0.0017	9.3234	0.0022
D5/pond	0.008787	0.0000	0.0000	0.0000	0.1034	0.0000	0.0001	0.3739	0.0001

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Group		Fish acute	Fish prolonged	Amphibians	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant
D5/stream	0.2364	0.0002	0.0003	0.0009	2.7812	0.0005	0.0018	10.0596	0.0024
R1/pond	0.008780	0.0000	0.0000	0.0000	0.1033	0.0000	0.0001	0.3736	0.0001
R1/stream	0.1675	0.0002	0.0002	0.0006	1.9706	0.0003	0.0013	7.1277	0.0017
R3/stream	0.2294	0.0002	0.0002	0.0009	2.6988	0.0005	0.0018	9.7617	0.0023
<b>Step 4 – 10 meters vegetative buffer zone and 15 meters no spray buffer zone with 75% nozzels reduction</b>									
D3/ditch	0.006320	0.0000	0.0000	0.0000	0.0744	0.0000	0.0000	0.2689	0.0001
D4/stream	0.007345	0.0000	0.0000	0.0000	0.0864	0.0000	0.0001	0.3126	0.0001
D5/stream	0.007934	0.0000	0.0000	0.0000	0.0933	0.0000	0.0001	0.3376	0.0001
R1/stream	0.005615	0.0000	0.0000	0.0000	0.0661	0.0000	0.0000	0.2389	0.0001
R3/stream	0.007690	0.0000	0.0000	0.0000	0.0905	0.0000	0.0001	0.3272	0.0001
<b>Step 4 – 20 meters vegetative buffer zone and 20 meters no spray buffer zone with 50% nozzels reduction</b>									
D3/ditch	0.01929	0.0000	0.0000	0.0001	0.2269	0.0000	0.0001	0.8209	0.0002
D4/stream	0.02204	0.0000	0.0000	0.0001	0.2593	0.0000	0.0002	0.9379	0.0002
D5/stream	0.02377	0.0000	0.0000	0.0001	0.2796	0.0000	0.0002	1.0115	0.0002
R1/stream	0.01685	0.0000	0.0000	0.0001	0.1982	0.0000	0.0001	0.7170	0.0002
R3/stream	0.02307	0.0000	0.0000	0.0001	0.2714	0.0000	0.0002	0.9817	0.0002

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; *PEC/RAC ratios above the relevant trigger of 1 are shown in bold*

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**Table 9.5-5: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for acetamiprid for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/I/ADEL 280 SC in winter oilseed rape in BBCH 30-70**

Group		Fish acute	Fish prolonged	Amphibians	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant
Test species		<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Xenopis laevis</i>	Geomean of EC50 of 2 aquatic insect species	<i>Daphnia magna</i>	<i>Anabaena flos-aquae</i>	<i>Chironomus riparius</i>	<i>Lemnagibba</i>
Endpoint (µg/L)		LC <sub>50</sub> 100 000	NOEC 9 400	NOEC 2 600	EC <sub>50</sub> 8.5	NOEC 5-000 2960	E <sub>r</sub> C <sub>50</sub> /E <sub>y</sub> C <sub>50</sub> 1300	NOEC 0.235	EC <sub>50</sub> > 1000
AF		100	10	10	100	10	10	10	10
RAC (µg/L)		1 000	940	260	0.085	500 296	130	0.0235	100
FOCUS Scenario	PEC <sub>gl-max</sub> (µg/L)								
<b>Step 1</b>									
	12.04	0.01204	0.01281	0.04631	141.64706	0.02408 0.04	0.09262	512.3404	0.1204
<b>Step 2</b>									
N-Europe	0.41	0.00041	0.00044	0.00158	4.82353	0.00082	0.00345	17.4468	0.0041
<b>Step 3</b>									
D3/ditch	0.2529	0.00025	0.00027	0.00097	2.97529	0.00051	0.00195	10.7617	0.0025
D4/pond	0.008781	0.00001	0.00001	0.00003	0.10331	0.00002	0.00007	0.3737	0.0001
D4/stream	0.2007	0.0002007	0.00021	0.000772	2.361176	0.00040	0.001544	8.5404	0.0020
D5/pond	0.008780	0.0000088	0.00001	0.000034	0.103294	0.00002	0.000068	0.3736	0.0001
D5/stream	0.2018	0.0002018	0.00021	0.000776	2.374118	0.00040	0.001552	8.5872	0.0020
R1/pond	0.008780	0.0000088	0.00001	0.000034	0.103294	0.00002	0.000068	0.3736	0.0001

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Group		Fish acute	Fish prolonged	Amphibians	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant
R1/stream	0.1666	0.0001666	0.00018	0.000641	1.960000	0.00033	0.001282	7.0894	0.0017
R3/stream	0.2616	0.0002616	0.00028	0.001006	3.077647	0.00052	0.002012	11.1319	0.0026
<b>Step 4 – 20 meters vegetative buffer zone and 20 meters no spray buffer zone</b>									
D3/ditch	0.01902	0.00002	0.00002	0.00007	0.22376	0.00004	0.00015	0.8094	0.0002
D4/pond	0.003592	0.00006	0.00006	0.00004	0.04226	0.00004	0.00003	0.1529	0.0000
D4/stream	0.02019	0.0000202	0.00002	0.000078	0.237529	0.00004	0.000155	0.8591	0.0002
D5/pond	0.003591	0.0000036	0.00006	0.000014	0.042247	0.00004	0.000028	0.1528	0.0000
D5/stream	0.02029	0.0000203	0.00002	0.000078	0.238706	0.00004	0.000156	0.8634	0.0002
R1/pond	0.003591	0.0000036	0.00006	0.000014	0.042247	0.00004	0.000028	0.1528	0.0000
R1/stream	0.01675	0.0000168	0.00002	0.000064	0.197059	0.00003	0.000129	0.7128	0.0002
R3/stream	0.02355	0.0000236	0.00003	0.000091	0.277059	0.00005	0.000184	1.0000	0.0002

**Table 9.5-6: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for acetamiprid for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/I/ADEL 280 SC in winter cereals**

Group		Fish acute	Fish prolonged	Amphibians	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant
Test species		<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Xenopis laevis</i>	Geomean of EC50 of 2 aquatic insect species	<i>Daphnia magna</i>	<i>Anabaena flos-aquae</i>	<i>Chironomus riparius</i>	<i>Lemnagibba</i>
Endpoint (µg/L)		LC <sub>50</sub> 100 000	NOEC 9 400	NOEC 2 600	EC <sub>50</sub> 8.5	NOEC 5 000 2960	E <sub>r</sub> C <sub>50</sub> /E <sub>y</sub> C <sub>50</sub> 1300	NOEC 0.235	EC <sub>50</sub> > 1000
AF		100	10	10	100	10	10	10	10

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Group		Fish acute	Fish prolonged	Amphibians	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant
RAC (µg/L)		1 000	940	260	0.085	500 296	130	0.0235	100
FOCUS Scenario	PEC <sub>gl-max</sub> (µg/L)								

**Step 1**

	12.04	0.01204	0.01281	0.04631	141.64706	0.02408 0.04	0.09262	512.3404	0.1204
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**Step 2**

N-Europe	0.58	0.00134	0.00143	0.00515	15.76471	0.00268	0.01031	57.0213	0.0134
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**Step 3**

D3/ditch	0.2537	0.0003	0.0003	0.0010	2.9847	0.0005	0.0020	10.7957	0.0025
D4/pond	0.008780	0.0000	0.0000	0.0000	0.1033	0.0000	0.0001	0.3736	0.0001
D4/stream	0.1934	0.0002	0.0002	0.0007	2.2753	0.0004	0.0015	8.2298	0.0019
D5/pond	0.008780	0.0000	0.0000	0.0000	0.1033	0.0000	0.0001	0.3736	0.0001
D5/stream	0.2022	0.0002	0.0002	0.0008	2.3788	0.0004	0.0016	8.6043	0.0020
D6/ditch	0.2506	0.0003	0.0003	0.0010	2.9482	0.0005	0.0019	10.6638	0.0025
R1/pond	0.008780	0.0000	0.0000	0.0000	0.1033	0.0000	0.0001	0.3736	0.0001
R1/stream	0.1668	0.0002	0.0002	0.0006	1.9624	0.0003	0.0013	7.0979	0.0017
R3/stream	0.2344	0.0002	0.0002	0.0009	2.7576	0.0005	0.0018	9.9745	0.0023
R4/stream	0.1676	0.0002	0.0002	0.0006	1.9718	0.0003	0.0013	7.1319	0.0017

**Step 4 – 20 meters vegetative buffer zone and 20 meters no spray buffer zone**

D3/ditch	0.01908	0.0000	0.0000	0.0001	0.2245	0.0000	0.0001	0.8119	0.0002
D4/stream	0.01945	0.0000	0.0000	0.0001	0.2288	0.0000	0.0001	0.8277	0.0002
D5/stream	0.02033	0.0000	0.0000	0.0001	0.2392	0.0000	0.0002	0.8651	0.0002
D6/ditch	0.01888	0.0000	0.0000	0.0001	0.2221	0.0000	0.0001	0.8034	0.0002

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Group		Fish acute	Fish prolonged	Amphibians	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant
R1/stream	0.01787	0.0000	0.0000	0.0001	0.2102	0.0000	0.0001	0.7604	0.0002
R3/stream	0.02357	0.0000	0.0000	0.0001	0.2773	0.0000	0.0002	1.0030	0.0002
R4/stream	0.01685	0.0000	0.0000	0.0001	0.1982	0.0000	0.0001	0.7170	0.0002
<b>Step 4 – 20 meters vegetative buffer zone and 25 meters no spray buffer zone</b>									
D3/ditch	0.01546	0.0000	0.0000	0.0001	0.1819	0.0000	0.0001	0.6579	0.0002
D4/stream	0.01579	0.0000	0.0000	0.0001	0.1858	0.0000	0.0001	0.6719	0.0002
D5/stream	0.01650	0.0000	0.0000	0.0001	0.1941	0.0000	0.0001	0.7021	0.0002
D6/ditch	0.01530	0.0000	0.0000	0.0001	0.1800	0.0000	0.0001	0.6511	0.0002
R1/stream	0.01675	0.0000	0.0000	0.0001	0.1971	0.0000	0.0001	0.7128	0.0002
R3/stream	0.01913	0.0000	0.0000	0.0001	0.2251	0.0000	0.0001	0.8140	0.0002
R4/stream	0.01368	0.0000	0.0000	0.0001	0.1609	0.0000	0.0001	0.5821	0.0001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; *PEC/RAC ratios above the relevant trigger of 1 are shown in bold*

CHR/I/ADEL 280 SC/ ADEL 280 SC, PYRIFOS ADE 280 SC.  
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**Table 9.5-7: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for acetamiprid for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/I/ADEL 280 SC in sugarbeets**

Group		Fish acute	Fish prolonged	Amphibians	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant
Test species		<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Xenopis laevis</i>	Geomean of EC50 of 2 aquatic insect species	<i>Daphnia magna</i>	<i>Anabaena flos-aquae</i>	<i>Chironomus riparius</i>	<i>Lemnagibba</i>
Endpoint (µg/L)		LC <sub>50</sub> 100 000	NOEC 9 400	NOEC 2 600	EC <sub>50</sub> 8.5	NOEC 5-000 2960	E <sub>r</sub> C <sub>50</sub> /E <sub>y</sub> C <sub>50</sub> 1300	NOEC 0.235	EC <sub>50</sub> > 1000
AF		100	10	10	100	10	10	10	10
RAC (µg/L)		1 000	940	260	0.085	500 296	130	0.0235	100
FOCUS Scenario	PEC <sub>gl-max</sub> (µg/L)								
<b>Step 1</b>									
	12.04	0.01204	0.01281	0.04631	141.6471	0.02408 0.04	0.09262	512.3404	0.1204
<b>Step 2</b>									
N-Europe	0.58	0.00092	0.00098	0.00354	10.82353	0.00184	0.00708	39.1489	0.0092
<b>Step 3</b>									
D3/ditch	0.2100	0.0002	0.0002	0.0008	2.4706	0.0004	0.0016	8.9362	0.0021
D4/pond	0.008481	0.0000	0.0000	0.0000	0.0998	0.0000	0.0001	0.3609	0.0001
D4/stream	0.1712	0.0002	0.0002	0.0007	2.0141	0.0003	0.0013	7.2851	0.0017
R1/pond	0.008480	0.0000	0.0000	0.0000	0.0998	0.0000	0.0001	0.3609	0.0001

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Group		Fish acute	Fish prolonged	Amphibians	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant
R1/stream	0.1450	0.0001	0.0002	0.0006	1.7059	0.0003	0.0011	6.1702	0.0015
R3/stream	0.2048	0.0002	0.0002	0.0008	2.4094	0.0004	0.0016	8.7149	0.0020
<b>Step 4 – 20 meters vegetative buffer zone and 20 meters no spray buffer zone</b>									
D3/ditch	0.01909	0.0000	0.0000	0.0001	0.2246	0.0000	0.0001	0.8123	0.0002
D4/stream	0.01982	0.0000	0.0000	0.0001	0.2332	0.0000	0.0002	0.8434	0.0002
R1/stream	0.01679	0.0000	0.0000	0.0001	0.1975	0.0000	0.0001	0.7145	0.0002
R3/stream	0.02371	0.0000	0.0000	0.0001	0.2789	0.0000	0.0002	1.0089	0.0002
<b>Step 4 – 20 meters vegetative buffer zone and 25 meters no spray buffer zone</b>									
R3/stream	0.01924	0.0000	0.0000	0.0001	0.2264	0.0000	0.0001	0.8187	0.0002

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold



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**Table 9.5-8: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for IM-1-2 for each organism group based on FOCUS Steps 1, 2 calculations for the use of CHR/I/ADEL 280 SC**

Group		Aquatic invertebrates
Test species		<i>Chironomus riparius</i>
Endpoint		EC <sub>50</sub>
(µg/L)		15000
AF		10
RAC (µg/L)		1 500
FOCUS Scenario	PEC <sub>gl-max</sub> (µg/L)	
Winter oilseed rape		
Step 1	9.25	0.0062
Step 2 N-Europe	0.26	0.0002
Winter cereals		
Step 1	9.25	0.0062
Step 2 N-Europe	0.32	0.0002
Sugarbeets		
Step 1	9.25	0.0062
Step 2 N-Europe	0.32	0.0002

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

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**Table 9.5-9: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for IM-1-4 for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/I/ADEL 280 SC**

Group		Aquatic invertebrates
Test species		<i>Mysidopsis bahia</i>
Endpoint		EC <sub>50</sub>
(µg/L)		19000
AF		10
RAC (µg/L)		1 900
FOCUS Scenario	PEC <sub>gl-max</sub> (µg/L)	
Winter oilseed rape		
Step 1	11.93	0.0063
Step 2 N-Europe	0.86	0.0005
Winter cereals		
Step 1	11.93	0.0063
Step 2 N-Europe	1.08	0.0006
Sugarbeet		
Step 1	11.93	0.0063
Step 2 N-Europe	1.08	0.0006

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**Table 9.5-10: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for IC-0 for each organism group based on FOCUS Steps 1, 2 calculations for the use of CHR/I/ADEL 280 SC**

Group		Aquatic invertebrates
Test species		<i>Daphnia magna</i>
Endpoint (µg/L)		EC <sub>50</sub> 95 100
AF		10
RAC (µg/L)		9 510
FOCUS Scenario	PEC <sub>gl-max</sub> (µg/L)	
Winter oilseed rape		
Step 1	3.39	0.0004
Step 2 N-Europe	0.15	0.00002
Winter cereals		
Step 1	3.39	0.0004
Step 2 N-Europe	0.18	0.00002
Sugarbeet		
Step 1	3.39	0.0004
Step 2 N-Europe	0.18	0.0002

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**Table 9.5-11: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for IM-1-5 for each organism group based on FOCUS Steps 1, 2 calculations for the use of CHR/I/ADEL 280 SC**

Group		Aquatic invertebrates
Test species		<i>Daphnia magna</i>
Endpoint		EC <sub>50</sub>
(µg/L)		25 000
AF		10
RAC (µg/L)		2 500
FOCUS Scenario	PEC <sub>gl-max</sub> (µg/L)	
Winter oilseed rape		
Step 1	1.65	0.0007
Step 2 N-Europe	0.2	0.00008
Winter cereals		
Step 1	1.65	0.0007
Step 2 N-Europe	0.26	0.0001
Sugarbeet		
Step 1	1.65	0.0007
Step 2 N-Europe	0.26	0.0001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

CHR/I/ADEL 280 SC/ ADEL 280 SC, PYRIFOS ADE 280 SC.  
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**Table 9.5-12: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for IB-1-1 for each organism group based on FOCUS Steps 1, 2 calculations for the use of CHR/I/ADEL 280 SC**

Group		Aquatic invertebrates
Test species		<i>Daphnia magna</i>
Endpoint (µg/L)		EC <sub>50</sub> >100 000
AF		10
RAC (µg/L)		10 000
FOCUS Scenario	PEC <sub>gl-max</sub> (µg/L)	
Winter oilseed rape		
Step 1	4.40	0.0004
Step 2 N-Europe	0.19	0.00002
Winter cereals		
Step 1	4.40	0.0004
Step 2 N-Europe	0.22	0.00002
Sugarbeet		
Step 1	4.40	0.0004
Step 2 N-Europe	0.22	0.00002

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

CHR/I/ADEL 280 SC/ ADEL 280 SC, PYRIFOS ADE 280 SC.

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**Table 9.5-13: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for deltamethrin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/I/ADEL 280 SC in winter oilseed rape in BBCH 10-21**

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Sed. dwell. prolonged
Test species		<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Chironomus riparius</i>
Endpoint (µg/L)		LC <sub>50</sub> 0.26	NOEC 0.032	EC <sub>50</sub> 0.11	NOEC 0.0041	NOEC 0.010
AF		100	10	100	10	10
RAC (µg/L)		0.0026	0.0032	0.0011	0.00041	0.001
FOCUS Scenario	PEC <sub>gl-max</sub> (µg/L)					
<b>Step 1</b>						
	0.04	15.38462	12.50000	36.36364	97.56098	40.00000
<b>Step 2</b>						
N-Europe	0.04	15.38462	12.50000	36.36364	97.56098	40.00000
<b>Step 3</b>						
D3/ditch	0.02848	10.954	8.900	25.891	69.463	28.480
D4/pond	0.001005	0.387	0.314	0.914	2.451	1.005
D4/stream	0.02453	9.435	7.666	22.300	59.829	24.530
D5/pond	0.001005	0.387	0.314	0.914	2.451	1.005
D5/stream	0.02648	10.185	8.275	24.073	64.585	26.480
R1/pond	0.001004	0.386	0.314	0.913	2.449	1.004
R1/stream	0.01872	7.200	5.850	17.018	45.659	18.720
R3/stream	0.02623	10.088	8.197	23.845	63.976	26.230

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Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Sed. dwell. prolonged
Step 4 – 20 meters vegetative buffer zone and 20 meters no spray buffer zone						
D3/ditch	0.002128	0.818	0.665	1.935	5.190	2.128
D4/stream	0.002354	0.905	0.736	2.140	5.741	2.354
D5/stream	0.002541	0.977	0.794	2.310	6.198	2.541
R1/stream	0.001796	0.691	0.561	1.633	4.380	1.796
R3/stream	0.002517	0.968	0.787	2.288	6.139	2.517

CHR/I/ADEL 280 SC/ ADEL 280 SC, PYRIFOS ADE 280 SC.

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Taking into account the existence of higher tier study on aquatic described in SANCO/6504/VI/99-final 17 October 2002, the risk refinement was conducted on the basis of results of mesocosm study. The final refinement was based on EAC (Ecological acceptable concentration) of 0.0032 µg a.s./L with assessment factor 1.

**Table 9.5-14: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for deltamethrin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/I/ADEL 280 SC in winter oilseed rape in 10-21**

Group		Fish prolonged
Test species		<i>Mesocosm</i>
Endpoint		NOEC
(µg/L)		0.0032
AF		1
RAC (µg/L)		0.0032
FOCUS Scenario	PEC <sub>gl-max</sub> (µg/L)	
<b>Step 1</b>		
	0.04	12.50000
<b>Step 2</b>		
N-Europe	0.04	12.50000
<b>Step 3</b>		
D3/ditch	0.2565	8.900
D4/pond	0.008786	0.314
D4/stream	0.2191	7.666
D5/pond	0.008787	0.314
D5/stream	0.2364	8.275
R1/pond	0.008780	0.314
R1/stream	0.1675	5.850



**Table 9.5-15: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for deltamethrin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/I/ADEL 280 SC in winter oilseed rape in BBCH 30-70**

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Sed. dwell. prolonged
Test species		<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Chironomus riparius</i>
Endpoint (µg/L)		LC <sub>50</sub>	NOEC	EC <sub>50</sub>	NOEC	NOEC
AF		0.26	0.032	0.11	0.0041	0.010
RAC (µg/L)		100	10	100	10	10
		0.0026	0.0032	0.0011	0.00041	0.001
FOCUS Scenario	PEC <sub>gl-max</sub> (µg/L)					
Step 1						
	0.04	15.38462	12.50000	36.36364	97.56098	40.00000
Step 2						

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Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Sed. dwell. prolonged
N-Europe	0.04	15.38462	12.50000	36.36364	97.56098	40.00000
<b>Step 3</b>						
D3/ditch	0.02829	10.88077	8.84063	25.71818	69.00000	28.29000
D4/pond	0.001004	0.38615	0.31375	0.91273	2.44878	1.00400
D4/stream	0.02246	8.6384615	7.01875	20.418182	54.780488	22.46000
D5/pond	0.001004	0.3861538	0.31375	0.912727	2.448780	1.00400
D5/stream	0.02258	8.6846154	7.05625	20.527273	55.073171	22.58000
R1/pond	0.001004	0.3861538	0.31375	0.912727	2.448780	1.00400
R1/stream	0.01862	7.1615385	5.81875	16.927273	45.414634	18.62000
R3/stream	0.02622	10.0846154	8.19375	23.836364	63.951220	26.22000
<b>Step 4 – 20 meters vegetative buffer zone and 20 meters no spray buffer zone</b>						
D3/ditch	0.002113	0.81269	0.66031	1.92091	5.15366	2.11300
D4/pond	0.000362	0.13923	0.11313	0.32909	0.88293	0.36200
D4/stream	0.002155	0.8288462	0.67344	1.959091	5.256098	2.15500
D5/pond	0.000362	0.1392308	0.11313	0.329091	0.882927	0.36200
D5/stream	0.002166	0.8330769	0.67688	1.969091	5.282927	2.16600
R1/pond	0.000362	0.1392308	0.11313	0.329091	0.882927	0.36200
R1/stream	0.001785	0.6865385	0.55781	1.622727	4.353659	1.78500
R3/stream	0.002516	0.9676923	0.78625	2.287273	6.136585	2.51600

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Taking into account the existence of higher tier study on aquatic described in SANCO/6504/VI/99-final 17 October 2002, the risk refinement was conducted on the basis of results of mesocosm study. The final refinement was based on EAC (Ecological acceptable concentration) of 0.0032 µg a.s./L with assessment factor 1.

**Table 9.5-16: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for deltamethrin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/I/ADEL 280 SC in winter oilseed rape in BBCH 30-70**

<b>Group</b>		<b>Fish prolonged</b>
<b>Test species</b>		<i>Mesocosm</i>
<b>Endpoint</b>		NOEC
<b>(µg/L)</b>		0.0032
<b>AF</b>		1
<b>RAC (µg/L)</b>		0.0032
<b>FOCUS Scenario</b>	<b>PEC<sub>gl-max</sub> (µg/L)</b>	
<b>Step 1</b>		
	0.04	12.50000
<b>Step 2</b>		
N-Europe	0.04	12.50000
<b>Step 3</b>		
D3/ditch	0.02829	8.84063
D4/pond	0.001004	0.31375
D4/stream	0.02246	7.01875
D5/pond	0.001004	0.31375
D5/stream	0.02258	7.05625
R1/pond	0.001004	0.31375
R1/stream	0.01862	5.81875

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Group		Fish prolonged
R3/stream	0.02622	8.19375
Step 4 – 20 meters vegetative buffer zone and 20 meters no spray buffer zone		
D3/ditch	0.002113	0.66031
D4/pond	0.000362	0.11313
D4/stream	0.002155	0.67344
D5/pond	0.000362	0.11313
D5/stream	0.002166	0.67688
R1/pond	0.000362	0.11313
R1/stream	0.001785	0.55781
R3/stream	0.002516	0.78625

**Table 9.5-17:** Aquatic organisms: acceptability of risk (PEC/RAC < 1) for deltamethrin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/I/ADEL 280 SC in winter cereals

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Sed. dwell. prolonged
Test species		<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Chironomus riparius</i>
Endpoint (µg/L)		LC <sub>50</sub> 0.26	NOEC 0.032	EC <sub>50</sub> 0.11	NOEC 0.0041	NOEC 0.010
AF		100	10	100	10	10
RAC (µg/L)		0.0026	0.0032	0.0011	0.00041	0.001
FOCUS Scenario	PEC gl- max (µg/L)					

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Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Sed. dwell. prolonged
<b>Step 1</b>						
	0.04	15.38462	12.50000	36.36364	97.56098	40.00000
<b>Step 2</b>						
N-Europe	0.04	15.38462	12.50000	36.36364	97.56098	40.00000
<b>Step 3</b>						
D3/ditch	0.02839	10.919	8.872	25.809	69.244	28.390
D4/pond	0.001004	0.386	0.314	0.913	2.449	1.004
D4/stream	0.02164	8.323	6.763	19.673	52.780	21.640
D5/pond	0.001004	0.386	0.314	0.913	2.449	1.004
D5/stream	0.02262	8.700	7.069	20.564	55.171	22.620
D6/ditch	0.02803	10.781	8.759	25.482	68.366	28.030
R1/pond	0.001004	0.386	0.314	0.913	2.449	1.004
R1/stream	0.01858	7.146	5.806	16.891	45.317	18.580
R3/stream	0.02641	10.1577	8.2531	24.0091	64.4146	26.4100
R4/stream	0.01873	7.2038	5.8531	17.0273	45.6829	18.7300
<b>Step 4 – 10 meters vegetative buffer zone and 15 meters no spray buffer zone</b>						
D3/ditch	0.002732	1.051	0.854	2.484	6.663	2.732
D4/stream	0.002861	1.100	0.894	2.601	6.978	2.861
D5/stream	0.002992	1.151	0.935	2.720	7.298	2.992
D6/dith	0.002697	1.037	0.843	2.452	6.578	2.697
R1/stream	0.002456	0.945	0.768	2.233	5.990	2.456
R3/stream	0.003493	1.343	1.092	3.175	8.520	3.493

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Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Sed. dwell. prolonged
R4/stream	0.002697	1.037	0.843	2.452	6.578	2.697
Step 4 – 20 meters vegetative buffer zone and 20 meters no spray buffer zone						
R3/stream	0.002534	0.975	0.792	2.304	6.180	2.534

CHR/I/ADEL 280 SC/ ADEL 280 SC, PYRIFOS ADE 280 SC.

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Taking into account the existence of higher tier study on aquatic described in SANCO/6504/VI/99-final 17 October 2002, the risk refinement was conducted on the basis of results of mesocosm study. The final refinement was based on EAC (Ecological acceptable concentration) of 0.0032 µg a.s./L with assessment factor 1.

**Table 9.5-18: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for deltamethrin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/I/ADEL 280 SC in winter cereals**

Group		Fish prolonged
Test species		<i>Mesocosm</i>
Endpoint		NOEC
(µg/L)		0.0032
AF		1
RAC (µg/L)		0.0032
FOCUS Scenario	PEC <sub>gl-max</sub> (µg/L)	
<b>Step 1</b>		
	0.04	12.50000
<b>Step 2</b>		
N-Europe	0.04	12.50000
<b>Step 3</b>		
D3/ditch	0.01609	8.872
D4/pond	0.000743	0.314
D4/stream	0.01257	6.763
D5/pond	0.000743	0.314
D5/stream	0.01309	7.069
D6/ditch	0.01591	8.759
R1/pond	0.000743	0.314

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Group		Fish prolonged
R1/stream	0.01094	5.806
R3/stream	0.01507	8.2531
R4/stream	0.01102	5.8531
Step 4 – 10 meters vegetative buffer zone and 15 meters no spray buffer zone		
D3/ditch	0.002732	0.854
D4/stream	0.002861	0.894
D5/stream	0.002992	0.935
D6/ditch	0.002697	0.843
R1/stream	0.002456	0.768
R3/stream	0.003493	1.092
R4/stream	0.002697	0.843
Step 4 – 20 meters vegetative buffer zone and 20 meters no spray buffer zone		
R3/stream	0.002534	0.792

**Table 9.5-19:** Aquatic organisms: acceptability of risk (PEC/RAC < 1) for deltamethrin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/I/ADEL 280 SC in sugar beet

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Sed. dwell. prolonged
Test species		<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Chironomus riparius</i>
Endpoint (µg/L)		LC <sub>50</sub> 0.26	NOEC 0.032	EC <sub>50</sub> 0.11	NOEC 0.0041	NOEC 0.010



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Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Sed. dwell. prolonged
AF		100	10	100	10	10
RAC (µg/L)		0.0026	0.0032	0.0011	0.00041	0.001
FOCUS Scenario	PEC <sub>gl-max</sub> (µg/L)					
<b>Step 1</b>						
	0.04	15.38462	12.50000	36.36364	97.56098	40.00000
<b>Step 2</b>						
N-Europe	0.04	15.38462	12.50000	36.36364	97.56098	40.00000
<b>Step 3</b>						
D3/ditch	0.02374	9.131	7.419	21.582	57.902	23.740
D4/pond	0.000912	0.351	0.285	0.829	2.224	0.912
D4/stream	0.01908	7.338	5.963	17.345	46.537	19.080
R1/pond	0.000912	0.351	0.285	0.829	2.224	0.912
R1/stream	0.01614	6.208	5.044	14.673	39.366	16.140
R3/stream	0.02284	8.785	7.138	20.764	55.707	22.840
<b>Step 4 – 10 meters vegetative buffer zone and 15 meters no spray buffer zone</b>						
D3/ditch	0.002732	1.051	0.854	2.484	6.663	2.732
D4/stream	0.002916	1.122	0.911	2.651	7.112	2.916
R1/stream	0.002467	0.949	0.771	2.243	6.017	2.467
R3/stream	0.003493	1.343	1.092	3.175	8.520	3.493
<b>Step 4 – 20 meters vegetative buffer zone and 20 meters no spray buffer zone</b>						
R3/stream	0.002534	0.975	0.792	2.304	6.180	2.534

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Taking into account the existence of higher tier study on aquatic described in SANCO/6504/VI/99-final 17 October 2002, the risk refinement was conducted on the basis of results of mesocosm study. The final refinement was based on EAC (Ecological acceptable concentration) of 0.0032 µg a.s./L with assessment factor 1.

**Table 9.5-20: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for deltamethrin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/I/ADEL 280 SC in sugar beet**

Group		Fish prolonged
Test species		<i>MEsocosm</i>
Endpoint (µg/L)		NOEC 0.0032
AF		1
RAC (µg/L)		0.0032
FOCUS Scenario	PEC <sub>gl-max</sub> (µg/L)	
<b>Step 1</b>		
	0.04	12.50000
<b>Step 2</b>		
N-Europe	0.04	12.50000
<b>Step 3</b>		
D3/ditch	0.01368	7.419
D4/pond	0.000680	0.285
D4/stream	0.01121	5.963
R1/pond	0.000680	0.285
R1/stream	0.009625	5.044
R3/stream	0.01321	7.138
Step 4 – 10 meters vegetative buffer zone and 15 meters no spray buffer zone		
D3/ditch	0.002732	0.854
D4/stream	0.002916	0.911
R1/stream	0.002467	0.771
R3/stream	0.003493	1.092
Step 4 – 20 meters vegetative buffer zone and 20 meters no spray buffer zone		
R3/stream	0.002534	0.792

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**Table 9.5-21:** Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Br2CA for each organism group based on FOCUS Steps 1, 2 calculations for the use of CHR/I/ADEL 280 SC

Group		Fish	Aquatic invertebrates	Algae
Test species		QSAR	<i>Daphnia magna</i>	<i>Green algae</i> QSAR
Endpoint (µg/L)		EC <sub>50</sub> 21 400	EC <sub>50</sub> 55 430	EC <sub>50</sub> 15 800
AF		100	100	100
RAC (µg/L)		214	554.3	158
FOCUS Scenario	PEC gl-max (µg/L)			
Winter oilseed rape				
Step 1	0.33	0.002	0.001	0.002
Step 2 N-Europe	0.02	0.000	0.000	0.000
Winter cereals				
Step 1	0.33	0.002	0.001	0.002
Step 2 N-Europe	0.03	0.000	0.000	0.000
Sugarbeet				
Step 1	0.33	0.002	0.001	0.002
Step 2 N-Europe	0.03	0.000	0.000	0.000

**Table 9.5-22:** Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CHR/I/ADEL 280 SC

Group		Inverteb. acute	Algae	Sed. dwell. prolonged
Test species		<i>Daphnia magna</i>	<i>Anabaena flos-aquae</i>	<i>Chironomus riparius</i>
Endpoint (µg/L)		EC <sub>50</sub> 11 660	ErC50 582 110	NOEC 106
AF		100	10	10
RAC (µg/L)		116.6	58 211	10.6
Buffer zone	PEC gl-max (µg/L)			
Winter oilseed rape				

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Group		Inverteb. acute	Algae	Sed. dwell. prolonged
1m	1.190	0.01	2.04E-05	0.11
Winter cereals				
1m	1.190	0.01	2.04E-05	0.11
Sugarbeet				
1m	0.9252	0.008	1.59E-05	0.087

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

### Decision scheme for mixture toxicity risk assessment for CHR/I/ADEL 280 SC

**Step 1. Are measured toxicity data (EC<sub>x</sub>) available for the given endpoint (typically chronic data available only for a.s.)?**

**Only for the a.s. (EC<sub>x,a.s.</sub>): Go to 7**

**For both formulation (EC<sub>x,PPP</sub>) and a.s. (EC<sub>x,a.s.</sub>): Go to 2**

Answer: Measured toxicity data for the formulation and the a.s. are available for daphnia. As these are the most sensitive aquatic organisms, it is justified to conduct the mixture toxicity risk assessment only for this organism groups → Go to 2

Measured toxicity data only for the a.s. are available for fish.. → Go to 7

**STEP 7. Is there evidence that synergistic interactions between mixture components might occur (e.g. based on toxicological knowledge from literature or from counter-checking measured and calculated mixture toxicity in other species) which cannot be ruled out for the given species with sufficient certainty).**

Yes (mixture toxicity calculation not feasible): Measured mixture toxicity data required for RA (if becoming available):	<u>Go to 2</u>	
No (mixture toxicity calculation feasible):	<u>Go to 8</u>	

Answer: Yes. → Go to step 2.

**STEP 2. Check the plausibility of the measured formulation toxicity (EC<sub>x,PPP</sub>) against the calculated mixture toxicity EC<sub>x,mix</sub>-CA (assuming CA, Equation 13) for exactly the mixture composition of the a.s. in the formulation (EC<sub>x,PPP</sub>) by means of the model deviation ratio (MDR = EC<sub>x,mix</sub>-CA/EC<sub>x,PPP</sub>).**

**If MDR = 0.2–5 (CA approximately holds for the mixture)**

**If MDR > 5 (mixture more toxic than CA)**

**If MDR < 0.2 (mixture less toxic than CA)**

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Equation 13:

$$EC_{X_{mix-CA}} = \left( \sum_{i=1}^n \frac{p_i}{EC_{X_i}} \right)^{-1}$$

Equation 15:

$$MDR = \frac{EC_{X_{mix-CA}} \text{ (calculated mixture toxicity)}}{EC_{X_{PPP}} \text{ (measured mixture toxicity)}}$$

**Calculation of the acute mixture toxicity of the formulation**

**Table 1. Composition of CHR/I/ADEL 280 SC**

Name/code of the product	CHR/I/ADEL 280 SC		
Name of the active substance A	Acetamiprid		
Name of the active substance B	Deltamethrin		
Density [g product/cm <sup>3</sup> ]	1.0886		
	Nominal [g a.s./kg or L product]	Fraction considering density [%]	p <sub>i mix</sub> = Fraction of active substance i in the mixture with $\sum p_{i mix} = 100$ [%]
Concentrations of the active substance Acetamiprid in the product	250	23.0%	89.3%
Concentrations of the active substance Deltamethrin in the product	30	2.8%	10.7%

Endpoint/Test species	Toxicity of the product [mg product/L]	Toxicity of the product (a.s. based) (EC <sub>x PPP</sub> ) [mg a.s./L]	Toxicity of the a.s. Acetamiprid (EC <sub>x A</sub> ) [mg a.s./L]	Toxicity of the a.s. Deltamethrin (EC <sub>x B</sub> ) [mg a.s./L]	Triggers (from EFSA Journal 2013;11(7):3290)
LC50 fish	-	0.000	9.4	0.00026	0.01
EC50 daphnia	11.66	2.999	0.0085 49.8	0.0000032 0.00056	0.01
ErC50 algae	582.11	149.725	1.3	-	0.1

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ErC50 higher plant	-	0.000	+	-	0.1
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**Table 3. Calculation of toxicity exposure in CHR/I/ADEL 280 SC**

Toxicity per fraction of the Acetamiprid (1/TU <sub>A</sub> ) [mg a.s./L]	Toxicity per fraction of the Deltamethrin (1/TU <sub>B</sub> ) [mg a.s./L]	Calculated mixture toxicity (a.s. in product) (EC <sub>x mix-CA</sub> = 1/Σ (TU <sub>i</sub> )) [mg a.s./L]	Model deviation ratio (MDR = EC <sub>x mix-CA</sub> /EC <sub>x PPP</sub> )	EC <sub>x mix-CA</sub> (a.s. in product)/EC <sub>x mix-CA</sub> (a.s. in PEC <sub>mix</sub> ) (at lower exposure tier)
10.528	0.002426667	0.002	-	0.389
0.00952 55.776	2.98667E-05 0.0052267	0.000 0.005	0.000 0.002	0.391 0.031
1.456	-	-	-	-
1.12	-	-	-	-

Answer: MDRs only for daphnia could calculate and its value is below triggers value <0.2. Go to step 9.

**Step 9. Carefully recheck the apparent antagonism as observed in the measured mixture toxicity data (EC<sub>x</sub> PPP) regarding potential impacts of the default assumption of CA and/or heterogeneous input data used for the CA calculation. Does the apparent antagonism remain and no toxicologically plausible explanation is available (e.g. special feature of the formulation type)?**

Yes (measured mixture toxicity not plausible):	Go to 8	
No (measured mixture toxicity plausible):	Go to 3	
No:	Go to step 3	

Answer: No. → Go to step 3

**Step 3. Check whether the mixture composition in the formulation study giving the measured mixture toxicity (ECx PPP) in terms of the relative proportions of the individual a.s. is similar to the mixture composition at the PECmix. As a direct comparison on the basis of the relative proportions of the a.s. at the ECx PPP with the relative proportion at the PECmix is not informative as such, the comparison is done based on calculated mixture toxicity (assuming CA) for both mixture compositions. Therefore, calculate ECx mix-CA (see Equation 13) for the mixture composition of the a.s. at the PECmix and compare with the estimate calculated for the formulation (as already done in step 2 above).**

**Table 4. Results of compare ECmix-CA(a.s. in PPP) to ECmix-CA (a.s. in PECmix)**

Endpoint/Test species	ECx mix-CA (a.s. in product)/ECx mix-CA (a.s. in PECmix)	Triggers	
		0.8-1.2	<0.8 or >1.2
<del>LC50 fish</del>	<del>0.389</del>		<del>Go to 5</del>
EC50 daphnia	<del>0.391</del> 0.031		Go to 5
ErC50 algae	-	-	-
ErC50 higher plant	-	-	-
ErC50 myriophyllum	-	-	-

Equation 13: 
$$ECx_{mix-CA} = \left( \sum_{i=1}^n \frac{p_i}{ECx_i} \right)^{-1}$$

where:

- n: number of mixture components
- i: index from 1...n mixture components
- p<sub>i</sub>: the i<sup>th</sup> component as a relative fraction of the mixture composition (note:  $\sum p_i$  must be 1)
- ECx<sub>i</sub>: concentration of component i provoking x % effect (pragmatically, NOEC<sub>i</sub> may be inserted, too).

Answer: Calculated factors for fish and daphnia gives results outside 0.8-1.2 Therefore, go to step 5.

**STEP 5. Check whether one mixture component clearly drives the toxicity if considering the measured mixture toxicity (ECx PPP), that is, does the largest part of the sum of toxic units (Equation 14) calculated for the formulation ( $\geq 90$  %) comes from a single a.s. (TUi)?**

**Table 6. Results of toxicity driver's calculation**

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Endpoint/Test species	Calculated mixture toxicity (a.s. in product) (EC <sub>x mix-CA</sub> ) [mg a.s./L]	Acetamiprid		Delthamterin		Triggers	
		Toxicity per fraction (1/TU <sub>i</sub> ) [mg a.s./L]	Deviation from mixture toxicity = $1 - EC_{x \text{ mix-CA}} \times (1/EC_{x \text{ mix-CA}} - TU_i)$ [%]	Toxicity per fraction (1/TU <sub>i</sub> ) [mg a.s./L]	Deviation from mixture toxicity = $1 - EC_{x \text{ mix-CA}} \times (1/EC_{x \text{ mix-CA}} - TU_i)$ [%]	>=90% for one a.s.	>=90% for no a.s.
LC50 fish	0.002	10.528	0.0%	0.002	99.98%	Yes	-
EC50 daphnia	0.000 0.005	0.010 55.776	0.3 0.0%	0.000 0.005	99.69 100%	Yes	-
ErC50 algae	-	1.456	-	-	-	-	-
ErC50 higher plant	-	1.120	-	-	-	-	-
ErC50 myriophyllum	-	-	-	-	-	-	-

Equation 14:

$$\sum_{i=1}^n TU_i = \sum_{i=1}^n \frac{c_i}{EC_{X_i}}$$

Answer: Toxicity drivers were found for ~~fish and~~ daphnias. Therefore, got to Step 6

**STEP 6. Conduct a RA based on single-substance toxicity data (ECx a.s.) for the identified ‘driver‘ of mixture toxicity, with the exposure-toxicity ratio (ETRa.s.) being defined as the PECa.s. divided by the measured ECx a.s. and compare the outcome with the acceptability criterion (trigger value) decisive for the specific endpoint/exposure scenario combination.**

Answer: Mixture toxicity covered by active substance assessment.

### 9.5.3 Overall conclusions

The risk for the entry routes run-off and drainage is also not acceptable without buffer zones for the intended use of CHR/I/ADEL 280 SC . Therefore, using buffer zone of :

- e) 20 meters vegetative buffer zone and 20 meters no-spray buffer zone for sugar beet and winter cereals in Poland,
- f) 20 meters vegetative buffer zone and 25 meters no-spray buffer zone for winter cereals in other Central Zone countries,
- g) ~~Autumn:~~ 20 meters vegetative buffer zone and 20 meters no-spray buffer zone and 50% nozzles reduction for winter oilseed rape (BBCH 10-21)
- h) Spring: 20 meters vegetative buffer zone and 20 meters no-spray buffer zone for winter oilseed rape (BBCH 30-70)

the use CHR/I/ADEL 280 SC according to the label will not pose risk to aquatic organisms (ratio PEC/RAC is below 1).



**Review Comments:**

The relevant predicted environmental concentrations in water (PEC<sub>sw</sub>) for risk assessments covering the proposed use pattern are taken from Part B Section 8 (Environmental Fate). The initial risk assessment was based on the worst case PEC<sub>sw</sub> values and the results of laboratory toxicity testing. The PEC<sub>sw</sub> Step 1-2 (for active substances and their metabolites) and Step 3-4 (for active substances) were used.

Only for *Daphnia magna* was possible to performed mixture toxicity assessment, as for *Chironomus riparius* the acute endpoint for deltamethrin is not available. Based on toxic units, it is concluded that deltamethrin is driving the toxicity of the mixture (TU ≥ 90%) for *Daphnia magna*.

CHR/I/ADEL 280 SC applications close to surface water pose acceptable risk to aquatic organisms with appropriate risk mitigation measures.

## 9.6 Effects on bees (KCP 10.3.1)

### 9.6.1 Toxicity data

Studies on the toxicity to bees have been carried out with acetamiprid. Full details of these studies are provided in the respective EU DAR and related documents as well as in Appendix 2 of this document (new studies).

Effects on bees of CHR/I/ADEL 280 SC were not evaluated as part of the EU assessment of acetamiprid and deltamethrin. New data submitted with this application are listed in Table 9.6-1 and summarised in Appendix 2.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

**Table 9.6-1: Endpoints and effect values relevant for the risk assessment for bees**

Species	Substance	Exposure System	Results	Reference
<i>Apis mellifera</i>	acetamiprid	Chronic	10d LC <sub>50</sub> = 11.7 µg a.s./bee	EFSA Journal 2016;14(11):4610
<i>Apis mellifera</i>	acetamiprid	Bee brood development	LD <sub>50</sub> = 1.3 µg/bee	EFSA Journal 2016;14(11):4610
<i>Apis melifera</i>	Deltamethrin	Acute oral	LD50= 0.079 µg a.s./bee	SANCO/6504/VI/99-final 17 October 2002
<i>Apis melifera</i>	Deltamethrin	Acute contact	LD50= 0.0015 µg a.s./bee	SANCO/6504/VI/99-final 17 October 2002
<i>Apis mellifera</i>	CHR/I/ADEL 280 SC	Contact	LD <sub>50</sub> = 7.96 µg prod/bee	M. Grzesica, Study code: B-12-20
<i>Apis mellifera</i>	CHR/I/ADEL 280 SC	Oral	LD <sub>50</sub> > 10.8 µg prod/bee	M. Grzesica, Study code: B-11-20
<i>Apis mellifera</i>	CHR/I/ADEL 280 SC	Larval	EC50= 34.53 mg [prod].kg diet ED50 = 5.32 µg	T. Anslaoani, Study code: S21-05568

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Species	Substance	Exposure System	Results	Reference
			prod/larva 22-d NOEC = 12.99 mg prod/kg diet 22-d NOED = 2.00 µg prod/larve	
Apis mellifera	CHR/I/ADEL 280 SC	Chronic	LC50 = 260.46 mg prod/kg feeding solution  LDD50= 4.50 µg prod/bee/day	T. Anslaoani, Study code: S21-05567
<b>Higher-tier studies (tunnel test, field studies)</b>				

## 9.6.2 Risk assessment

The evaluation of the risk for bees was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002).

~~Risk assessment have been provided for worst case situation (pome fruit, 1 x 60 g/ha), which covered a risk envelopment for all uses of data gap.~~

### 9.6.2.1 Hazard quotients for bees

To achieve a concise risk assessment, the risk envelope approach is applied.

The assessment for the use group pome fruits also covers the risk assessment from all other intended uses.

**Table 9.6-2: First-tier assessment of the risk for bees due to the use of CHR/I/ADEL 280 SC**

Intended use		Winter oilssed rape/winter cereals/sugar beet	
Product		CHR/I/ADEL 280 SC	
Application rate (g/ha)		1 x 174.18	
Test design	LD <sub>50</sub> (lab.) (µg/bee)	Single application rate (g/ha)	Q <sub>HO</sub> , Q <sub>HC</sub> criterion: Q <sub>H</sub> ≤ 50
Oral toxicity	10.8	174.18	16.13
Contact toxicity	7.96		21.88
Intended use		Winter oilssed rape/winter cereals/sugar beet	
Product		deltamethrin	
Application rate (g/ha)		1 x 4.8	
Test design	LD <sub>50</sub> (lab.) (µg/bee)	Single application rate (g/ha)	Q <sub>HO</sub> , Q <sub>HC</sub> criterion: Q <sub>H</sub> ≤ 50
Oral toxicity	0.079	4.8	60.8
Contact toxicity	0.0015		3 200

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Q<sub>HO</sub>, Q<sub>HC</sub>: Hazard quotients for oral and contact exposure. Q<sub>H</sub> values shown in **bold** breach the relevant trigger.

### Review Comments:

At the harmonization meeting of the central zone in December 2023, it was agreed to present the chronic and larvae RA based on EFSA (2013) in the Core. The zRMS therefore completed the risk assessment for bees accordingly.

### Screening assessment

**Table 9.6-7: Screening assessment - acute risk for adult honeybees from contact exposure**

Crop	Single application rate (g prod./ha)	Species (life stage)	LD <sub>50</sub> (µg prod/bee)	HQ <sub>contact</sub>	Trigger value
OSR, cereals, sugar beet	174.18 (DW)	Honeybee (adult)	7.96	21.88	42

HQ: Hazard quotient. HQ values shown in **bold** breach the relevant trigger, indicating potential concern. SUW: sideward/upward spray; DW: downward spray.

The above screening risk assessment demonstrates an acceptable risk for honeybees from acute contact exposure from all proposed uses of CHR/I/ADEL 280 SC.

**Table 9.6-8: Screening assessment - acute risk for adult honeybees from oral exposure**

Crop	Single application rate (g prod./ha)	Species (life stage)	LD <sub>50</sub> (µg prod/bee)	SV	ETR <sub>oral</sub>	Trigger value
OSR, cereals, sugar beet	174.18 (DW)	Honeybee (adult)	>10.8	7.6	< 0.12	0.2

SV: Shortcut value; ETR: Exposure toxicity ratio. ETR values shown in **bold** are greater than the relevant trigger, indicating potential concern. SUW: sideward/upward spray; DW: downward spray.

The above screening risk assessment demonstrates an acceptable risk for honeybees from acute oral exposure from all proposed uses of CHR/I/ADEL 280 SC.

**Table 9.6-9: Screening assessment - chronic risk for adult honeybees and honeybee larvae from oral exposure**

Crop	Single application rate (g prod./ha)	Species (life stage)	Endpoint	SV	ETR <sub>oral</sub>	Trigger value
OSR, cereals, sugar beet	174.18 (DW)	Honeybee (adult)	LDD <sub>50</sub> = 4.5 µg prod./bee/day	7.6	<b>0.294</b>	0.03
		Honeybee (larvae)	NOED = 2.0 µg prod./larvae	4.4	<b>0.38</b>	0.2

SV: Shortcut value; ETR: Exposure toxicity ratio. ETR values shown in **bold** are greater than the relevant trigger, indicating potential concern. SUW: sideward/upward spray; DW: downward spray.

In the above screening risk assessment, an acceptable risk could not be demonstrated for adult and honeybee larvae for any of the proposed uses of CHR/I/ADEL 280 SC. Therefore, a first-tier risk assessment is provided.

### First-tier assessment

A first-tier assessment of the chronic risk for adult honeybees and honeybee larvae is required for all proposed uses.

In the following tables, crop categories have been assigned according to the EFSA Bee Tool (V3).

**Table 9.6-10: Foraging on the treated crop - chronic risk for adult honeybees and honeybee larvae from oral exposure**

Species (life stage)	Endpoint	BBCH	Ef	SV	TWA	ETR <sub>oral</sub>	Trigger value
OSR 1 x 0.17418 kg prod./ha; BBCH 10-21 and 30-70							
Honeybee (adult)	LDD <sub>50</sub> = 4.5 µg prod./bee/day	10-29 30-39 40 – 69	1	5.8	0.72	<b>0.162</b>	0.03
		≥70	1	0	0.72	0.000	
Honeybee (larvae)	NOED = 2.0 µg prod./larvae	10-29 30-39 40 – 69	1	4.4	0.85	<b>0.33</b>	0.2
		≥70	1	0	0.85	0.00	
Cereals 1 x 0.17418 kg prod./ha; BBCH 37-75							
Honeybee (adult)	LDD <sub>50</sub> = 4.5 µg prod./bee/day	30 - 39 40 – 69	1	0.92	0.72	0.026	0.03
		≥ 70	1	0	0.72	0.000	0.03
Honeybee (larvae)	NOED = 2.0 µg prod./larvae	10 - 19 20 – 39 40 – 69	1	0.15	0.85	0.01	0.2
		≥ 70	1	0	0.85	0.00	0.2
Sugar beet 1 x 0.17418 kg prod./ha; BBCH 12-19							
Honeybee (adult)	LDD <sub>50</sub> = 4.5 µg prod./bee/day	10 - 39	1	5.8	0.72	<b>0.162</b>	0.03
Honeybee (larvae)	NOED = 2.0 µg prod./larvae	10-39	1	4.4	0.85	<b>0.33</b>	0.2

SV: Shortcut value; Ef: exposure factor; TWA: time weighted average; ETR: Exposure toxicity ratio. ETR values shown in **bold** are greater than the relevant trigger, indicating a potential concern. SUW: sideward/upward spray; DW: downward spray.

The first-tier risk assessment for the “treated crop” exposure scenario demonstrates an acceptable risk for adult honeybees and honeybee larvae for use in cereals. The ETR<sub>oral</sub> values exceeded the trigger values of at BBCH stages < 70 in OSR and sugar beet.

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**Table 9.6-11: Foraging on the adjacent crop - chronic risk for adult honeybees and honeybee larvae from oral exposure**

Species (life stage)	Endpoint	BBCH	Ef	SV	TWA	ETR <sub>oral</sub>	Trigger value
<b>OSR 1 x 0.17418 kg prod./ha; BBCH 10-21 and 30-70</b>							
Honeybee (adult)	LDD <sub>50</sub> = 4.5 µg prod./bee/day	10 - 19 20 – 39 40 – 69 ≥ 70	0.0033	5.8	0.72	0.001	0.03
Honeybee (larvae)	NOED = 2.0 µg prod./larvae	10 - 19 20 – 39 40 – 69 ≥ 70	0.0033	4.4	0.85	0.00	0.2
<b>Cereals 1 x 0.17418 kg prod./ha; BBCH 37-75</b>							
Honeybee (adult)	LDD <sub>50</sub> = 4.5 µg prod./bee/day	30-39 40-69 ≥ 70	0.0033	5.8	0.72	0.001	0.03
Honeybee (larvae)	NOED = 2.0 µg prod./larvae	30-39 40-69 ≥ 70	0.0033	4.4	0.85	0.00	0.2
<b>Sugar beet 1 x 0.17418 kg prod./ha; BBCH 12-19</b>							
Honeybee (adult)	LDD <sub>50</sub> = 4.5 µg prod./bee/day	10 – 39	0.0033	5.8	0.72	0.001	0.03
Honeybee (larvae)	NOED = 2.0 µg prod./larvae	10-39	0.0033	4.4	0.85	0.00	0.2

SV: Shortcut value; Ef: exposure factor; TWA: time weighted average; ETR: Exposure toxicity ratio. ETR values shown in **bold** are greater than the relevant trigger, indicating a potential concern. SUW: sideward/upward spray; DW: downward spray.

The first-tier risk assessment for the “adjacent crop” exposure scenario demonstrates an acceptable chronic risk for adult honeybees and honeybee larvae for all proposed uses of CHR/I/ADEL 280 SC, at all relevant BBCH stages.

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**Table 9.6-11: Foraging on weeds in the treated field - chronic risk for adult honeybees and honeybee larvae from oral exposure**

Species (life stage)	Endpoint	BBCH	Ef	SV	TWA	ETR <sub>oral</sub>	Trigger value
OSR 1 x 0.17418 kg prod./ha; BBCH 10-21 and 30-70							
Honeybee (adult)	LDD <sub>50</sub> = 4.5 µg prod./bee/day	10-29	1	2.9	0.72	<b>0.081</b>	0.03
		20-39	0.3	2.9	0.72	0.024	
		40 – 69 ≥ 70	0.25	2.9	0.72	0.02	
Honeybee (larvae)	NOED = 2.0 µg prod./larvae	10-29	1	2.2	0.85	0.16	0.2
		20-39	0.3	2.2	0.85	0.05	
		40 – 69 ≥ 70	0.25	2.2	0.85	0.04	
Cereals 1 x 0.17418 kg prod./ha; BBCH 37-75							
Honeybee (adult)	LDD <sub>50</sub> = 4.5 µg prod./bee/day	30-39	0.5	2.9	0.72	<b>0.040</b>	0.03
		40 – 69 ≥ 70	0.3	2.9	0.72	0.024	
Honeybee (larvae)	NOED = 2.0 µg prod./larvae	30-39	0.5	2.2	0.85	0.08	0.2
		40 – 69 ≥ 70	0.3	2.2	0.85	0.05	
Sugar beet 1 x 0.17418 kg prod./ha; BBCH 12-19							
Honeybee (adult)	LDD <sub>50</sub> = 4.5 µg prod./bee/day	10 – 39	1	2.9	0.72	<b>0.081</b>	0.03
Honeybee (larvae)	NOED = 2.0 µg prod./larvae	10-39	1	2.2	0.85	0.16	0.2

SV: Shortcut value; Ef: exposure factor; TWA: time weighted average; ETR: Exposure toxicity ratio. ETR values shown in **bold** are greater than the relevant trigger, indicating a potential concern. SUW: sideward/upward spray; DW: downward spray.

The first-tier risk assessment for the “weeds in the treated field” exposure scenario demonstrates an acceptable risk for honeybee larvae for all proposed uses of CHR/I/ADEL 280 SC, at all relevant BBCH stages.

The ETR<sub>oral</sub> values were greater than the trigger value of 0.03 for adult honeybees for proposed uses in OSR BBCH 10-29, cereals BBCH 30-39 and sugar beet BBCH 10-39.

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**Table 9.6-12: Foraging in the field margin - chronic risk for adult honeybees and honeybee larvae from oral exposure**

Species (life stage)	Endpoint	BBCH	Ef	SV	TWA	ETR <sub>oral</sub>	Trigger value
<b>OSR 1 x 0.17418 kg prod./ha; BBCH 10-21 and 30-70</b>							
Honeybee (adult)	LDD <sub>50</sub> = 4.5 µg prod./bee/day	10 - 19 20 – 39 40 – 69 ≥ 70	0.0092	2.9	0.72	0.001	0.03
Honeybee (larvae)	NOED = 2.0 µg prod./larvae	10 - 19 20 – 39 40 – 69 ≥ 70	0.0092	2.2	0.85	0.00	0.2
<b>Cereals 1 x 0.17418 kg prod./ha; BBCH 37-75</b>							
Honeybee (adult)	LDD <sub>50</sub> = 4.5 µg prod./bee/day	30-39 40-69 ≥ 70	0.0092	2.9	0.72	0.001	0.03
Honeybee (larvae)	NOED = 2.0 µg prod./larvae	30-39 40-69 ≥ 70	0.0092	2.2	0.85	0.00	0.2
<b>Sugar beet 1 x 0.17418 kg prod./ha; BBCH 12-19</b>							
Honeybee (adult)	LDD <sub>50</sub> = 4.5 µg prod./bee/day	10 – 39	0.0092	2.9	0.72	0.001	0.03
Honeybee (larvae)	NOED = 2.0 µg prod./larvae	10-39	0.0092	2.2	0.85	0.00	0.2

SV: Shortcut value; Ef: exposure factor; TWA: time weighted average; ETR: Exposure toxicity ratio. ETR values shown in **bold** are greater than the relevant trigger, indicating a potential concern. SUW: sideward/upward spray; DW: downward spray.

The first-tier risk assessment for the exposure scenario “foraging in the field margin” demonstrates an acceptable risk for adult honeybees and honeybee larvae for all proposed uses of CHR/I/ADEL 280 SC, at all relevant BBCH stages.

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**Table 9.6-13: Foraging the following year on a permanent crop or succeeding crop for annual crops - chronic risk for adult honeybees and honeybee larvae from oral exposure**

Species (life stage)	Endpoint	BBCH	Ef	SV	TWA	ETR <sub>oral</sub>	Trigger value
<b>OSR 1 x 0.17418 kg prod./ha; BBCH 10-21 and 30-70</b>							
Honeybee (adult)	LDD <sub>50</sub> = 4.5 µg prod./bee/day	10 - 19 20 – 39 40 – 69 ≥ 70	1	0.54	0.72	0.015	0.03
Honeybee (larvae)	NOED = 2.0 µg prod./larvae	10 - 19 20 – 39 40 – 69 ≥ 70	1	0.4	0.85	0.03	0.2
<b>Cereals 1 x 0.17418 kg prod./ha; BBCH 37-75</b>							
Honeybee (adult)	LDD <sub>50</sub> = 4.5 µg prod./bee/day	30-39 40 – 69 ≥ 70	1	0.54	0.72	0.015	0.03
Honeybee (larvae)	NOED = 2.0 µg prod./larvae	30-39 40 – 69 ≥ 70	1	0.4	0.85	0.03	0.2
<b>Sugar beet 1 x 0.17418 kg prod./ha; BBCH 12-19</b>							
Honeybee (adult)	LDD <sub>50</sub> = 4.5 µg prod./bee/day	10-39	1	0.54	0.72	0.015	0.03
Honeybee (larvae)	NOED = 2.0 µg prod./larvae	10-39	1	0.4	0.85	0.03	0.02

SV: Shortcut value; Ef: exposure factor; TWA: time weighted average; ETR: Exposure toxicity ratio. ETR values shown in **bold** are greater than the relevant trigger, indicating a potential concern. SUW: sideward/upward spray; DW: downward spray.

The first-tier risk assessment for the “next crop” exposure scenario demonstrates an acceptable chronic risk for adult honeybees and honeybee larvae for all proposed uses of CHR/I/ADEL 280 SC, at all relevant BBCH stages.

### 9.6.2.2 Higher-tier risk assessment for bees (tunnel test, field studies)

According to SANCO/6504/VI/99-final 17 October 2002 for deltamethrin Repellent effect noted in all studies:

#### Field studies:

Slight increase in mortality in 4/6 replications at 7.5 g/ha; in older studies no adverse effect level up to 8.75 g/ha; at 10-20 g/ha increased mortality in some trials but not in others; severe effects at 35 g/ha.

#### Tunnel in the field:

No adverse effect level 6.25 g/ha; slightly increased mortality at 12.5 g as/ha.

#### Cage study in the field:

RT25 (residual time required to reduce activity and bring mortality down to 25%) < 8 hours.

Therefore, NOAEL considered to be 6.25 g as/ha



### 9.6.3 Effects on bumble bees

Not required.

### 9.6.4 Effects on solitary bees

Not available.

### 9.6.5 Overall conclusions

All hazard quotients (HQ) are considerably less than 50, indicating that CHR/I/ADEL 280 SC applied at the maximum use rate in all intended uses poses low risk to bees.

#### Review Comments:

The evaluation of the acute risk for bees was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002). The submitted risk assessment, based on laboratory studies, has been accepted. It can therefore be concluded that there will be negligible acute risk associated with the exposure of *Apis mellifera* to CHR/I/ADEL 280 SC.

The data requirements in accordance with Commission Regulation (EU) No 284/2013 for the chronic toxicity to adult honeybees and honeybee larvae are fulfilled.

The risk assessment based on the EFSA Guidance (2013) is not yet approved. Nevertheless, some CEU countries require evaluation according to EFSA 2013. This approach is still not harmonised, but it was discussed at the last meeting of the Central Zone in the field of ecotoxicology (Warsaw, 12.2023), where it was agreed to present an assessment in the Core in accordance with EFSA 2013.

The evaluation of the acute and chronic risk for bees was performed by zRMS in accordance with the recommendations of the “EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees)” (EFSA Journal 2013;11(7):3295; hereafter referred to as EFSA/2013/3295). Refinement of risk, where required, has been left to the national level.

## 9.7 Effects on arthropods other than bees (KCP 10.3.2)

### 9.7.1 Toxicity data

Studies on the toxicity to non-target arthropods have been carried out with acetamiprid and deltamethrin. Full details of these studies are provided in the respective EU DAR and related documents as well as in Appendix 2 of this document (new studies).

Effects on non-target arthropods of CHR/I/ADEL 280 SC were not evaluated as part of the EU assessment of acetamiprid and deltamethrin. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

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**Table 9.7-1: Endpoints and effect values relevant for the risk assessment for non-target arthropods**

Species	Substance	Exposure System	Results	Reference
Typhlodromus pyri (protonymphs)	CHR/I/ADEL 280 SC	Extended laboratory test disc leaves (2D)	LR <sub>50</sub> = 0.003053 L [prod]/ha which is equivalent to 3.32 g [prod]/ha ER <sub>50</sub> > 0.0000313 L [prod]/ha which is equivalent to 0.0341 g [prod]/ha	M. Grzesica, Study Code: B-09-20
Aphidius rhopalosiphi (adults)	CHR/I/ADEL 280 SC	Extended laboratory test barley plants (3D)	LR <sub>50</sub> = 0.095 L [prod]/ha which is equivalent to 103.42 g [prod]/ha ER <sub>50</sub> > 0.16 L [prod]/ha	M. Grzesica, Study code: B-10-20
Chrysoperla carnea	CHR/I/ADEL 280 SC	Extended laboratory test Leaf disc (2D)	LR <sub>50</sub> = 0.072 L [prod]/ha which is equivalent to 78.3 g [prod]/ha ER <sub>50</sub> > 0.04 L [prod]/ha	M. Knapik, Study code: B-13-21
Coccinella septempunctata L.	CHR/I/ADEL 280 SC	Extended laboratory test Leaf disc (2D)	LR <sub>50</sub> = 0.00068 L/ha which is equivalent to 0.74 g [prod]/ha ER <sub>50</sub> > 0.0005 L [prod]/ha	M. Knapik, Study code: B-12-21
Coccinella septempunctata L.	CHR/I/ADEL 280 SC	Aged - Residue Extended laboratory	0.08 L prod./ha 0 DAT 7.5% pre-imaginal mortality 12 DAT 0% pre-imaginal mortality	White-Hall, Ch. Study code: CHR-22-02
<b>Field or semi-field tests</b>				

## 9.7.2 Risk assessment

The evaluation of the risk for non-target arthropods was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002), and in consideration of the recommendations of the guidance document ESCORT 2.

### 9.7.2.1 Risk assessment for in-field exposure

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group winter cereals also covers the risk for non-target arthropods from all other intended uses (see

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9.1.2).

**Table 9.7-2: First- and higher-tier assessment of the in-field risk for non-target arthropods due to the use of CHR/I/ADEL 280 SC**

<b>Intended use</b>	Winter oilseed rape/winter cereals/ sugrbeet		
<b>Active substance/product</b>	CHR/I/ADEL 280 SC		
<b>Application rate (g/ha)</b>	1 x 174.18		
<b>MAF</b>	1		
<b>Test species</b> Tier I	<b>LR<sub>50</sub> (lab.)</b> (g/ha)	<b>PER<sub>in-field</sub></b> (g/ha)	<b>HQ<sub>in-field</sub></b> criterion: HQ ≤ 1
<i>Typhlodromus pyri</i>	3.32	174.18	52.46
<i>Aphidius rhopalosiphi</i>	103.42		1.68
<i>Chrysoperla carnea</i>	78.3		2.23
<i>Coccinella septempunctata</i> L.	0.74		235.4
<b>Test species</b> Tier II	<b>ER<sub>50</sub> (lab.)</b> (L/ha)	<b>PER<sub>in-field</sub></b> (L/ha)	<b>HQ<sub>in-field</sub></b> criterion: HQ ≤ 1
<i>Typhlodromus pyri</i>	> 0.0000313	0.16	<5111.8
<i>Aphidius rhopalosiphi</i>	>0.16		<1
<i>Chrysoperla carnea</i>	>0.04		<4
<i>Coccinella septempunctata</i> L.	>0.0005		320
<i>Typhlodromus pyri</i>	> 0.0000313	0.08	<2555.9
<i>Aphidius rhopalosiphi</i>	>0.16		<0.5
<i>Chrysoperla carnea</i>	>0.04		<2
<i>Coccinella septempunctata</i> L.	>0.0005		160

MAF: Multiple application factor; PER: Predicted environmental rate; HQ: Hazard quotient; DALT: Days after last treatment.  
Criteria values shown in bold breach the relevant trigger.

\* If an LR<sub>50</sub> or ER<sub>50</sub> from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

### 9.7.2.2 Risk assessment for off-field exposure

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use covers the risk for non-target arthropods from all intended uses(see 9.1.2).

**Table 9.7-3: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of CHR/I/ADEL 280 SC**

<b>Intended use</b>	Winter oilseed rape/winter cereals/ sugrbeet
<b>Active substance/product</b>	CHR/I/ADEL 280 SC
<b>Application rate (g/ha)</b>	174.18 (0.16 L/ha)
<b>MAF</b>	1
<b>vdf</b>	1 (Tier 2)

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Test species Tier I	LR <sub>50</sub> (lab.) (g/ha)	Drift rate	PER <sub>off-field</sub> (g/ha)	CF	HQ <sub>off-field</sub> criterion: HQ ≤ 1
<i>Typhlodromus pyri</i>	3.32	00277	0.4825	5	0.7267
<i>Aphidius rhopalosiphi</i>	103.42				0.2333
<i>Chrysoperla carnea</i>	78.3				0.308
<i>Coccinella septempunctata L.</i>	0.74				32.6
Test species Tier II	LR <sub>50</sub> (lab.) (L/ha)	Drift rate	PER <sub>off-field</sub> (L/ha)	CF	HQ <sub>off-field</sub> criterion: HQ ≤ 1
<i>Typhlodromus pyri</i>	> 0.0000313	00277	0.0004432	5	<70.80
<i>Aphidius rhopalosiphi</i>	>0.16		0.0044320		<0.139
<i>Chrysoperla carnea</i>	>0.04		0.0004432		<0.055
<i>Coccinella septempunctata L.</i>	>0.0005		0.0004432		<4.432

MAF: Multiple application factor; vdf: Vegetation distribution factor; (corr.) PER: (corrected) Predicted environmental rate; CF: Correction factor; HQ: Hazard quotient. Criteria values shown in bold breach the relevant trigger.

\* If an LR<sub>50</sub> or ER<sub>50</sub> from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

**Table 9.7-4: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of CHR/I/ADEL 280 SC**

<b>Intended use</b>		Winter oilseed rape/winter cereals/ sugrbeet			
<b>Active substance/product</b>		CHR/I/ADEL 280 SC			
<b>Application rate (g/ha)</b>		0.08 L/ha			
<b>MAF</b>		1			
<b>vdf</b>		1 (Tier 2)			
Test species Tier II	LR <sub>50</sub> (lab.) (L/ha)	Drift rate	PER <sub>off-field</sub> (L/ha)	CF	HQ <sub>off-field</sub> criterion: HQ ≤ 1
<i>Typhlodromus pyri</i>	> 0.0000313	00277	0.0002216	5	<35.39
<i>Aphidius rhopalosiphi</i>	>0.16		0.0022160		<0.069
<i>Chrysoperla carnea</i>	>0.04		0.0002216		<0.028
<i>Coccinella septempunctata L.</i>	>0.0005		0.0002216		<2.216

MAF: Multiple application factor; vdf: Vegetation distribution factor; (corr.) PER: (corrected) Predicted environmental rate; CF: Correction factor; HQ: Hazard quotient. Criteria values shown in bold breach the relevant trigger.

\* If an LR<sub>50</sub> or ER<sub>50</sub> from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

### 9.7.2.3 Additional higher-tier risk assessment

Aged residue study is ongoing

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The intention of the bioassay programme was to demonstrate that residues of the test item did not result in unacceptable effects in two consecutive bioassays (i.e. demonstrating that corrected pre-imaginal mortality was  $\leq 50\%$  and that certain fecundity and fertility criteria were met).

### Results

The results of the mortality assessments are summarised below.

Bioassay initiated	Treatment	Test-item rate (L/ha)	% pre-imaginal mortality <sup>a)</sup>	Corrected % pre-imaginal mortality <sup>b)</sup>
0 DAT	Control	-	10.0	-
	CHR/I/ADEL 280 SC	0.08	7.5	-2.8
	Toxic reference	-	97.5*	97.2
12 DAT	Control	-	0.0	-
	CHR/I/ADEL 280 SC	0.08	0.0	0.0

a) For each bioassay, pre-imaginal mortality in the test item treatment and the toxic reference treatment was compared to the control using Fisher's exact binomial test (one-sided,  $>$  control,  $\alpha = 0.05$ ). An asterisk (\*) indicates where differences were significant.

b) Corrected mortalities were calculated using Abbott's formula. A positive value indicates an increase and a negative value a decrease in mortality, relative to the control.

The results of the reproduction assessments are summarised below.

Bioassay initiated	Treatment	Test-item rate (L/ha)	Mean no. eggs/♀/ day	Mean % egg viability	Mean no. viable eggs/♀/ day
0 DAT	Control	-	20.0	54.4	10.9
	CHR/I/ADEL 280 SC	0.08	17.2	37.4	6.4
12 DAT	Control	-	22.2	68.8	15.3
	CHR/I/ADEL 280 SC	0.08	24.3	56.4	13.7

In the 0 and 12 DAT bioassays, the mean numbers of viable eggs produced in all the treatments evaluated was  $\geq 2.0$  eggs/female/day. This threshold is currently viewed as being indicative of no harmful treatment effects.

### Conclusions

The effects of both fresh and aged foliar residues of CHR/I/ADEL 280 SC on the ladybird beetle, *Coccinella septempunctata*, were evaluated under extended laboratory conditions. When applied at a rate equivalent to 0.08 L test item/ha, fresh residues (0-day-old) of CHR/I/ADEL 280 SC and the subsequent bioassay evaluating 12-day-old foliar residues of CHR/I/ADEL 280 SC, showed no unacceptable effects on either the survival, or the subsequent reproductive capacity of the ladybirds.

### **Review Comments:**

The applicant submitted an aged residue extended laboratory study only for the dose rate of 0.08 L/ha. Therefore, for the dose of 0.16 L/ha the in-field risk for non-target arthropods is considered unacceptable until the required data is submitted.

According to the available extended (Tier 2) laboratory studies the lowest LR<sub>50</sub> is for *Coccinella septempunctata*, but the ER<sub>50</sub> for *Typhlodromus pyri* is the lowest one. Nevertheless, it should be noted that on the basis of the obtained results for *T. pyri* the ER<sub>50</sub> value could not be estimated. The mean Rr after 14 days of exposure to CHR/I/ADEL 280 SC at the rates of 0.0078, 0.0313, 0.125, 0.5 and 2.0 mL/ha were 3.7, 3.0, 2.2, 1.9 and 3.5 eggs/female, respectively. The percentages of reproduction reduction (Pr) caused by test item at the rates of 0.0078, 0.0313, 0.125, 0.5 and 2.0 mL/ha were 19.6, 35.5, 52.6, 58.0 and 24.6%, respectively.

Furthermore, the LR<sub>50</sub> for *Coccinella septempunctata* is almost a factor of 5 lower than the one for *Typhlodromus pyri*. Taking to consideration that *Coccinella septempunctata* has a one of the longer life cycle, the mortality of adult is crucial.

Therefore, aged residue extended laboratory study for *Coccinella septempunctata* has been considered as sufficient higher tier data, and the in-field risk for non-target arthropods is considered acceptable for application dose rate of 0.08 L/ha.

#### **9.7.2.4 Risk mitigation measures**

In order to reduce the off-field exposure, risk mitigation measures can be implemented. These correspond to unsprayed in-field buffer strips of a given width and/or the usage of drift reducing nozzles. The results of the risk assessment using typical mitigation measures (no-spray buffer zones of 5 or 10 m; drift-reducing nozzles with reduction by 50 %, 75 %, or 90 %) are summarised in the following table.

**Table 9.7-4: Risk assessment for non-target terrestrial plants due to the use of CHR/H/NTF considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles)**

Intended-use	Winter oilseed rape/winter cereals/ sugarbeet
Active substance/product	CHR/I/ADEL 280 SC
Application rate (g/ha)	174.18
MAF	+
vdF	+(Tier 1)

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Buffer-strip (m)	Drift rate (%)	PER <sub>off-field</sub> (g/ha)	PER <sub>off-field</sub> 50 % drift red. (g/ha)	PER <sub>off-field</sub> 75 % drift red. (g/ha)	PER <sub>off-field</sub> 90 % drift red. (g/ha)
1	2.77	4.825	2.413	1.206	0.4825
5	0.57	0.9928	0.4964	0.2482	0.09928
10	0.29	0.5051	0.2526	0.1263	0.05051
15	0.20	0.3484	0.1742	0.0871	0.03484
20	0.15	0.2613	0.1307	0.06533	0.02613
30	0.10	0.1742	0.0871	0.0436	0.01742
40	0.07	0.1219	0.06095	0.03048	0.01219
Toxicity value ER <sub>50</sub> = 0.74 g/ha CF = 5		HQ criterion: HQ < 1			
1		32.6	16.30	8.15	3.26
5		6.71	3.35	1.68	0.67
10		3.41	1.71	0.85	0.34
15		2.35	1.18	0.59	0.24
20		1.77	0.88	0.44	0.18
30		1.18	0.59	0.29	0.12
40		0.82	0.41	0.21	0.08

Intended use		Winter oilseed rape/winter cereals/ sugrbeet			
Active substance/product		CHR/I/ADEL 280 SC			
Application rate (mL/ha)		160			
MAF		1			
vdf		10			
Buffer strip (m)	Drift rate (%)	PER <sub>off-field</sub> (mL/ha)	PER <sub>off-field</sub> 50 % drift red. (mL/ha)	PER <sub>off-field</sub> 75 % drift red. (mL/ha)	PER <sub>off-field</sub> 90 % drift red. (mL/ha)
10	0.29	0.0464	0.0232	0.0116	0.00464
15	0.20	0.032	0.016	0.008	0.0032
20	0.15	0.024	0.012	0.006	0.0024
30	0.10	0.016	0.008	0.004	0.0016
40	0.07	0.0112	0.0056	0.0028	0.00112
50	0.06	0.0096	0.0048	0.0024	0.00096
75	0.04	0.0064	0.0032	0.0016	0.00064
Toxicity value ER <sub>50</sub> > 0.0313 mL/ha CF = 5		HQ criterion: HQ < 1			
10		7.41	3.71	1.85	0.74

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15	<b>5.11</b>	<b>2.56</b>	<b>1.28</b>	0.51
20	<b>3.83</b>	<b>1.92</b>	0.96	-
30	<b>2.56</b>	<b>1.28</b>	0.64	-
40	<b>1.79</b>	0.89	-	-
50	<b>1.53</b>	0.77	-	-
75	1.02 <sup>#</sup>	0.51	-	-

MAF: Multiple application factor; vdf: Vegetation distribution factor; (corr.) PER: (corrected) Predicted environmental rate; CF: Correction factor; HQ: Hazard quotient. Criteria values shown in bold breach the relevant trigger.

\* If an LR<sub>50</sub> or ER<sub>50</sub> from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

# accepted as ER<sub>50</sub> is far below value of 50%

**Table 9.7-6: Risk assessment for non-target terrestrial plants due to the use of CHR/H/NTF considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles)**

<b>Intended use</b>		Winter oilseed rape/winter cereals/ sugrbeet			
<b>Active substance/product</b>		CHR/I/ADEL 280 SC			
<b>Application rate (mL/ha)</b>		80			
<b>MAF</b>		1			
<b>vdf</b>		10			
<b>Buffer strip (m)</b>	<b>Drift rate (%)</b>	<b>PER<sub>off-field</sub> (mL/ha)</b>	<b>PER<sub>off-field</sub> 50 % drift red. (mL/ha)</b>	<b>PER<sub>off-field</sub> 75 % drift red. (mL/ha)</b>	<b>PER<sub>off-field</sub> 90 % drift red. (mL/ha)</b>
5	0.57	0.0456	0.0228	0.0114	0.00456
10	0.29	0.0232	0.0116	0.0058	0.00232
15	0.20	0.016	0.008	0.004	0.0016
20	0.15	0.012	0.006	0.003	0.00012
30	0.10	0.008	0.004	0.002	0.0008
40	0.07	0.0056	0.0028	0.0014	0.00056
<b>Toxicity value</b>		<b>HQ</b>			
ER <sub>50</sub> > 0.0313 mL/ha CF = 5		<b>criterion: HQ &lt; 1</b>			
5		<b>7.28</b>	<b>3.64</b>	<b>1.82</b>	0.73
10		<b>3.71</b>	<b>1.85</b>	0.93	-
15		<b>2.56</b>	<b>1.28</b>	0.64	-
20		<b>1.92</b>	0.96	-	-
30		<b>1.28</b>	0.64	-	-
40		0.89	-	-	-

MAF: Multiple application factor; vdf: Vegetation distribution factor; (corr.) PER: (corrected) Predicted environmental rate; CF: Correction factor; HQ: Hazard quotient. Criteria values shown in bold breach the relevant trigger.

\* If an LR<sub>50</sub> or ER<sub>50</sub> from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.



### 9.7.3 Overall conclusions

The in-field HQ values for exposure to maximum residues on leaves for *Aphidius rhopalosiphi* and *Coccinella septempunctata* L. falls above the ESCORT 2 trigger value, and, therefore triggers further assessment. Such assessment was made for CHR/I/ADEL 280 SC with aged residues study.

**CHR/I/ADEL 280 SC applied at the maximum use rates poses no risk to non-target arthropods with use:**

- ~~40 meters buffer zone~~
- ~~20 meter buffer zone with 50, 75 or 90% nozzles reduction~~
- ~~10 meters buffer zone with 75 or 90% nozzles reduction~~
- ~~5 meters buffer zone with 90 % nozzles reduction~~

#### Review Comments:

For the application rate of 0.16 L/ha, based on currently available data, it was not possible to demonstrate an acceptable in-field risk for non-target arthropods. Therefore, the Applicant modified the product's application pattern by including a lower application rate of 0.08 L/ha.

For application rate of 0.08 L/ha, the in-field risk for non-target arthropods is acceptable. For higher application rate an unacceptable risk is considered.

Based on the results of the conducted risk assessment it can be concluded that no off-field risk for non-target arthropods is expected from use of CHR/I/ADEL 280 SC. Following mitigation measures are required:

1. Application rate of 0.16 L/ha
  - 75 meters buffer zone
  - 40 meter buffer zone with 50% nozzles reduction
  - 20 meters buffer zone with 75% nozzles reduction
  - 10 meters buffer zone with 90% nozzles reduction
2. Application rate of 0.08 L/ha
  - 40 meters buffer zone
  - 20 meter buffer zone with 50% nozzles reduction
  - 10 meters buffer zone with 75% nozzles reduction
  - 5 meters buffer zone with 90% nozzles reduction

## 9.8 Effects on non-target soil meso- and macrofauna (KCP 10.4)

### 9.8.1 Toxicity data

Studies on the toxicity to earthworms and other non-target soil organisms (meso- and macrofauna) have been carried out with acetamiprid and its relevant metabolite. Full details of these studies are provided in the respective EU DAR and related documents as well as in Appendix 2 of this document (new studies).

Effects on earthworms and other non-target soil organisms (meso- and macrofauna) of CHR/I/ADEL 280 SC were not evaluated as part of the EU assessment of acetamiprid and deltamethrin. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

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**Table 9.8-1: Endpoints and effect values relevant for the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna)**

Species	Substance	Exposure System	Results	Reference
<i>Eisenia fetida</i>	CHR/I/ADEL 280 SC	Mixed into substrate 28 d, chronic 10 % peat content	NOEC $\geq$ 1.80mg/kg dw EC <sub>10</sub> = 5.91 mg prod./kg dw	M. Wołany, Study code: G-71-20
<i>Hypoaspis aculeifer</i>	CHR/I/ADEL 280 SC	Mixed into substrate 14 d, chronic 5 % peat content	EC <sub>10</sub> ; reproduction = 9.6 mg prod./kg dw NOEC <sub>reproduction</sub> = 18 mg/kg dw soil	M. Wołany, Study code: G-73-20
<i>Folsomia candida</i>	CHR/I/ADEL 280 SC	Mixed into substrate 14 d, chronic 5 % peat content	NOEC = 0.953 mg/kg dw soil EC <sub>10</sub> ; reproduction = 1.0 mg prod./kg dw	A. Cooper, Study code: CHR-21-09
<i>Eisenia fetida</i>	IM-1-5	Chronic	NOEC = 62.5 mg metabolite/kg d.w. soil	EFSA Journal 2016;14(11):4610
<i>Folsomia candida</i>	IM-1-5	Mortality and reproduction 28d	NOEC repr = 12.5 mg/kg dw soil NOEC mortality = 62.7 mg/kg dw soil	EFSA Journal 2016;14(11):4610
<b>Field studies</b>				
N/A				
<b>Litter bag test</b>				
N/A				

\* Considering the similar acute toxicity as IM-1-5, the much lower persistence than IM-1-5, and the fact that IM-1-4 is structurally farther removed from the parent acetamiprid, IM-1-4 is not expected to be more toxic to earthworms than metabolite IM-1-5 or the parent acetamiprid. In addition, metabolites IM-1-2 and IC-0 also show similar acute toxicity as IM-1-5 and are less persistent. All of these metabolites are expected to have formed in the field study.

According to SANCO/6504/VI/99-final 17 October 2002 deltamethrin does not have any chronic studies for earthworm, *folsomia candida* and *hypoaspis aculeifer*.

## 9.8.2 Risk assessment

The evaluation of the risk for earthworms and other non-target soil organisms (meso- and macrofauna) was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

### 9.8.2.1 First-tier risk assessment

The relevant PEC<sub>soil</sub> for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, Table 8.7-3. According to the assessment of environmental-fate data, multi-annual accumulation in soil is considered for IM-1-5.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the

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use CHR/I/ADEL 280 SC on sugar beets which also covers the risk for earthworms and other non-target soil organisms (meso- and macrofauna) from all other intended uses (see 9.1.2) as the highest PECs were taken into account in the risk assessment.

**Table 9.8-2: First-tier assessment of the acute and chronic risk for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use of CHR/I/ADEL 280 SC in sugar beet**

Intended use	Sugar beet		
Chronic effects on earthworms			
Product/active substance	NOEC (mg/kg dw)	PEC <sub>soil</sub> (mg/kg dw)	TER <sub>lt</sub> (criterion TER ≥ 5)
Acetamiprid	≥0.76	0.0427	17.80
CHR/I/ADEL 280 SC	1.8	0.1858 0.1852	9.69 9.7
IM-1-5	62.5	0.040 0.0076	1562.5 8223.7
Chronic effects on other soil macro- and mesofauna			
Product/active substance	NOEC (mg/kg dw)	PEC <sub>soil</sub> (mg/kg dw)	TER <sub>lt</sub> (criterion TER ≥ 5)
Hypoaspis aculeifer CHR/I/ADEL 280 SC	18 9.6	0.1858 0.1852	96.89 51.84
Folsomia Candida CHR/I/ADEL 280 SC	0.953	0.1858 0.1852	5.13 5.14

TER values shown in bold fall below the relevant trigger.

According to the EFSA Journal 2016;14(11);4610 the metabolites IM-1-2, IC-0 and IM-1-4 show similar acute toxicity and lower persistence than IM-1-5. Therefore the risk assessment for earthworms and other soil macroorganisms is covered by the risk assessment from an active substance and IM-1-5.

### 9.8.2.2 Higher-tier risk assessment

Not relevant.

### 9.8.3 Overall conclusions

**The chronic risk to earthworms and other non-target soil organisms (meso- and macrofauna) was assessed as low for CHR/I/ADEL 280 SC in a first-tier risk assessment.**

#### Review Comments:

The long-term risks of CHR/I/ADEL 280 SC to soil meso- and macro-organisms were assessed from toxicity exposure ratios between toxicity endpoints and maximum PEC<sub>soil</sub>. The relevant predicted environmental concentrations in soil (PEC<sub>soil</sub>) for risk assessments covering the proposed use pattern are taken from Part B Section 8 (Environmental Fate).

Based on performed risk assessment it can be concluded that there will be negligible risk associated with the exposure of beneficial soil organisms to CHR/I/ADEL 280 SC following proposed use pattern.

## 9.9 Effects on soil microbial activity (KCP 10.5)

### 9.9.1 Toxicity data

Studies on effects soil microorganisms have been carried out with acetamiprid and deltamethrin. Full details of these studies are provided in the respective EU DAR and related documents as well as in Appendix 2 of this document (new studies).

Effects on soil microorganisms of CHR/I/ADEL 280 SC were not evaluated as part of the EU assessment of acetamiprid and deltamethrin. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

**Table 9.9-1: Endpoints and effect values relevant for the risk assessment for soil microorganisms**

Endpoint	Substance	Exposure System	Results	Reference
N-mineralisation	CHR/I/ADEL 280 SC	28 d, aerobic soil type	On the basis of the results, it was concluded that CHR/I/ADEL 280 SC at the concentrations corresponding to the PEC: 0.93 mg test item/kg dry weight of soil (i.e. 0.21 mg of acetamiprid + 0.03 mg of deltamethrin/kg dry weight of soil) and 5x PEC: 4.64 mg of the test item/kg dry weight of soil (i.e. 1.05 mg of acetamiprid + 0.13 mg of deltamethrin/kg dry weight of soil) did not have any long-term adverse effects on the process of nitrogen transformation in aerobic surface soils.	P. Pieczka, Study code: G-74-20
N-mineralisation	Deltamethrin	28d, aerobic soil type	500 mg a.s./kg dry soil: No effect	SANCO/6504/VI/99-final 17 October 2002

### 9.9.2 Risk assessment

The evaluation of the risk for soil microorganisms was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services

(SANCO/10329/2002 rev 2 (final), October 17, 2002).  
 The relevant PEC<sub>soil</sub> for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, Table 8.7-3 and were already used in the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna)(see 9.8).  
 To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use CHR/I/ADEL 280 SC on sugar beet covers the risk for the soil microorganisms from all other intended uses in groups(see 9.1.2).

**Table 9.9-2:                   Assessment of the risk for effects on soil micro-organisms due to the use of CHR/I/ADEL 280**

Intended use	Sugar beet		
N-mineralisation			
Product/active substance	Max. conc. with effects ≤ 25 % (mg/kg dw)	PEC <sub>soil</sub> (mg/kg dw)	Risk acceptable?
CHR/I/ADEL 280 SC	On the basis of the rults, it was concluded that CHR/I/ADEL 280 SC at the concentrations corresponding to the PEC: 0.93 mg test item/kg dry weight of soil (i.e. 0.21 mg of acetamiprid + 0.03 mg of deltamehtrin/kg dry weight of soil) and 5x PEC: 4.64 mg of the test item/kg dry weight of soil (i.e. 1.05 mg of acetamiprid + 0.13 mg of deltamethrin/kg dry weight of soil) did not have any long-term adverse effects on the process of nitrogen transformation in aerobic surface soils.	<del>0.1858</del> 0.1852	yes
Deltamethrin	500 mg a.s./kg dry soil: No effect	<del>0.0427</del> 0.0051	yes

**9.9.3                   Overall conclusions**

The Predicted Environmental Concentrations of the formulation CHR/I/ADEL 280 SC and its active substance acetamiprid and deltamethrin in soil are below the concentrations at which no unacceptable effects (< 25%) regarding the soil microbial activity were observed after 28 days or more of exposure, indicating that the proposed use of CHR/I/ADEL 280 SC poses an acceptable risk to soil microorganisms.

<p><b>Review Comments:</b></p> <p>Based on the results of the conducted first tier risk assessment it can be concluded that no risk for soil micro-organisms is expected from use of CHR/I/ADEL 280 SC.</p>
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## 9.10 Effects on non-target terrestrial plants (KCP 10.6)

### 9.10.1 Toxicity data

Studies on the toxicity to non-target terrestrial plants have been carried out with acetamiprid and deltamethrin. Full details of these studies are provided in the respective EU DAR and related documents as well as in Appendix 2 of this document (new studies).

Effects on non-target terrestrial plants of CHR/I/ADEL 280 SC were not evaluated as part of the EU assessment of acetamiprid and deltamethrin. New data submitted with this application are listed in Appendix 1 summarised in Appendix 2.

**Table 9.10-1: Endpoints and effect values relevant for the risk assessment for non-target terrestrial plants**

Species	Substance	Exposure System	Results	Reference
<i>Pisum sativum</i> <i>Helianthus annuus</i> <i>Linum usitatissimum</i> <i>Daucus carota</i> <i>Allium cepa</i> <i>Zea mays</i>	CHR/I/ADEL 280 SC	21 d Seedling emergence	ER50 > 160 ml prod/ha which is equivalent to 174.18 g prod/ha	P. Pieczka, Study code: G-76-20
<i>Pisum sativum</i> <i>Helianthus annuus</i> <i>Linum usitatissimum</i> <i>Daucus carota</i> <i>Allium cepa</i> <i>Zea mays</i>	CHR/I/ADEL 280 SC	21 d Vegetative vigour	ER50 > 160 ml prod/ha which is equivalent to 174.18 g prod/ha	M. Wolany, Study code: G-75-20

m: monocotyledonous; d: dicotyledonous

### 9.10.2 Risk assessment

#### 9.10.2.1 Tier-1 risk assessment (based screening data)

Not relevant.

#### 9.10.2.2 Tier-2 risk assessment (based on dose-response data)

The risk assessment is based on the “Guidance Document on Terrestrial Ecotoxicology”, (SANCO/10329/2002 rev.2 final, 2002). It is restricted to off-field situations, as non-target plants are non-crop plants located outside the treated area.

~~To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use CHR/I/ADEL in sugar beets which is also covers the risk for non-target terrestrial plants from all other intended uses.~~

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**Table 9.10-2: Assessment of the risk for non-target plants due to the use of CHR/I/ADEL 280 SC**

<b>Intended use</b>	Sugarbeets			
<b>Active substance/product</b>	CHR/I/ADEL 280 SC			
<b>Application rate (g a.s./ha)</b>	174.18 (160 mL/ha)			
<b>MAF</b>	1			
<b>Test species</b>	<b>ER<sub>50</sub> (g/ha)</b>	<b>Drift rate</b>	<b>PER<sub>off-field</sub> (g/ha)</b>	<b>TER criterion: TER ≥ 5</b>
<i>Pisum sativum</i> <i>Helianthus annuus</i> <i>Linum usitatissimum</i> <i>Daucus carota</i> <i>Allium cepa</i> <i>Zea mays</i>	ER <sub>50</sub> > 160 ml prod/ha which is equivalent to 174.18 g prod/ha	0.0277	4.83	36.06

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

### 9.10.2.3 Higher-tier risk assessment

Not relevant.

### 9.10.2.4 Risk mitigation measures

Not required.

## 9.10.3 Overall conclusions

Based on the predicted rates of CHR/I/ADEL 280 SC in off-field areas, the TER values describing the risk for non-target plants following exposure to CHR/I/ADEL 280 SC according to the GAP of the formulation CHR/I/ADEL 280 SC achieve the acceptability criteria  $TER \geq 5$ , with applying buffer zone of 1m mitigation measures.

### Review Comments:

Based on the risk assessment it can be concluded that the proposed use of CHR/I/ADEL 280 SC poses no unacceptable risk to non-target plants, if applied according to the recommended use pattern. Particular precautions to reduce the environmental concentrations resulting from CHR/I/ADEL 280 SC applications are not required for the protection of terrestrial non-target plants.

## 9.11 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)

Not relevant.

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## **9.12            Monitoring data (KCP 10.8)**

Not required.

## **9.13            Classification and Labelling**

Aquatic Chronic 1, H410  
Aquatic Acute 1, H400

Pictogram: GHS09

Signal Word: Warning

Hazard statement:

H410 – Very toxic to aquatic life with long lasting effects.

H400 – Very toxic to aquatic life

Precautionary statements:

P391 – Collect spillage.

P501 – Dispose of contents/container in accordance with applicable regulations

EUH401: To avoid risks to human health and the environment, comply with the instructions for use.



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## Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

### List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.2/01	M. Czarnecka	2020	CHR/I/ADEL 280 SC Daphnia magna, Acute Immobilisation Test Study code: W/54/19 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna. Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Chemirol Sp. z o.o.
KCP 10.2/02	M. Czarnecka	2021	Acetamiprid + Deltametryna (250+30) SC (CHR/I/ADEL 280 SC) Anabaena flos-aquae UTEX B 1444 Growth inhibition test Study code: W-49-20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna. Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Chemirol Sp. z o.o.
KCP 10.2/04	M. Czarnecka	2021	Acetamiprid + Deltametryna (250+30) SC (CHR/I/ADEL 280 SC) Chironomus sp., Acute Immobilisation Test Study code: W-48-20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna.	N	Chemirol Sp. z o.o.

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<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>
			Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished		
KCP 10.3/01	M. Grzesica	2020	CHR/I/ADEL 280 SC Honeybees ( <i>Apis mellifera</i> L.) Acute Oral Toxicity Test Study code: B-11-20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna. Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Chemiroł Sp. z o.o.
KCP 10.3/02	M. Grzesica	2020	CHR/I/ADEL 280 SC Honeybees ( <i>Apis mellifera</i> L.) Acute Contact Toxicity Test Study code: B-12-20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna. Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Chemiroł Sp. z o.o.
KCP 10.3/03	M. Grzesica	2020	An extended laboratory test for evaluating the effects of CHR/I/ADEL 280 SC on the predatory mite, <i>Typhlodromus pyri</i> (Sch.) Study code: B-09-20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna. Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Chemiroł Sp. z o.o.
KCP 10.3/04	M. Grzesica	2020	An extended laboratory test for evaluating the effects of CHR/I/ADEL 280 SC on the parasitic wasp, <i>Aphidius rhopalosiphii</i> (De Stefani-Perez) Study code: B-10-20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna. Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland GLP	N	Chemiroł Sp. z o.o.

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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
			Unpublished		
KCP 10.3/05	M. Knapik	2021	An extended laboratory test for evaluating effects of CHR/I/ADEL 280 SC on the ladybird beetle, <i>Coccinella septempunctata</i> (L.) Study code: B-12-21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna. Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Chemiroł Sp. z o.o.
KCP 10.3/06	M. Knapik	2021	An extended laboratory test for evaluating effects of CHR/I/ADEL 280 SC on the green lacewing, <i>Chrysoperla carnea</i> (Steph.) Study code: B-13-21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna. Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Chemiroł Sp. z o.o.
KCP 10.3/07	T. Ansaloni	2021	CHR/I/ADEL 280SC: Honey Bee ( <i>Apis mellifera</i> L.) Chronic Oral Toxicity Test (10-Day Feeding) under Laboratory Conditions Study code: S21-05567 Eurofins Trialcamp S.L.U. Polígon Industrial l'Alter, Avda. Antic Regne de València, 25, 46290 Alcàsser (Valencia), Spain GLP Unpublished	N	Chemiroł Sp z o.o.
KCP 10.3/08	T. Ansaloni	2021	CHR/I/ADEL 280SC: Honey Bee ( <i>Apis mellifera</i> L.) Larval Toxicity Test following Repeated Exposure under laboratory conditions Study code: S21-05568 Eurofins Trialcamp S.L.U. Polígon Industrial l'Alter, Avda. Antic Regne de València, 25, 46290 Alcàsser (Valencia), Spain GLP	N	Chemiroł Sp z o.o.

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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
			Unpublished		
KCP 10.3/09	Ch. White-Hall	2022	CHR/I/ADEL 280 SC – A Series of Aged-Residue Extended Laboratory Tests to Determine Effects on the Ladybird Beetle, <i>Coccinella septempunctata</i> (Coleoptera: Coccinellidae) Study code: CHR-22-02 Mambo-Tox Part of Cawood 2 venture Road University Science Park Southampton SO16 7 NP, UK. GLP Unpublished	N	Chemirool Sp. z o.o.
KCP 10.4/01	M. Wolany	2021	Acetamiprid + Deltametryna (250+30) SC (CHR/I/ADEL 280 SC) Earthworm reproduction test ( <i>Eisenia andrei</i> ) Study code: G-71-20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna. Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Chemirool Sp. z o.o.
KCP 10.4/02	A. Cooper		CHR/I/ADEL 280 SC – A Laboratory Study to Determine the Effects of Fresh Residues on the Springtail <i>Folsomia candida</i> (Collembola, Isotomidae) in an Artificial Soil Substrate Study code: CH-21-09 Mambo-Tox, A Division of Cawood Scientific Ltd., 2 Venture Road, University Science Park, Southampton SO16 7NP, UK GLP Unpublished	N	Chemirool Sp. z o.o.
KCP 10.4/03	M. Wolany	2021	Acetamiprid + Deltametryna (250+30) SC (CHR/I/ADEL 280 SC) Predatory mite ( <i>Hypoaspis</i> ( <i>Geolaelaps</i> ) <i>aculeifer</i> ) reproduction test in soil Study code: G-73-20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna. Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Chemirool Sp. z o.o.

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<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>
KCP 10.5/01	P. Pieczka	2021	Acetamiprid + Deltametryna (250+30) SC (CHR/I/ADEL 280 SC) Soil Microorganisms: Nitrogen Transformation Test Study code: G-74-20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna. Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Chemiroł Sp. z o.o.
KCP 10.6//01	P. Pieczka	2021	Acetamiprid + Deltametryna (250+30) SC (CHR/I/ADEL 280 SC) Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test Study code: G-76-20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna. Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Chemiroł Sp. z o.o.
KCP 10.6/02	M. Wolany	2021	Acetamiprid + Deltametryna (250+30) SC (CHR/I/ADEL 280 SC) Terrestrial Plant Test: Vegetative Vigour Test Study code: G-75-20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna. Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Chemiroł Sp. z o.o.

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

<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>
KCP 10.1.1		1994b	NI-25: Acute oral toxicity (LD50) to the Bobwhite Quail Report No: RD-9434N GLP Not published	Y	Nippon Soda
KCP 10.1.1		2011	Acetamiprid: An acute oral toxicity study with the zebra finch (Poephila guttata) Report No: RD-02175 GLP Not published	Y	Nippon Soda
KCP 10.1.1		2012	Acetamiprid Technical Grade: Dietary toxicity test in zebra finch(Poephila guttata) Report No: RD-02389 GLP Not published	Y	Nippon Soda
KCP 10.1.1		2014	Acetamiprid: Reproductive Toxicity Test with the Mallard Duck (Anas platyrhynchos) Report No: RD-02797 GLP Not published	Y	Nippon Soda
KCP 10.2		1995	Acetamiprid - Acute Toxicity Study in Carp. , Report No: RD-9549 GLP Not published	Y	Nippon Soda
KCP 10.2		1998b	Acetamiprid technical - acute toxicity to sheepshead minnow (Cyprinodon variegatus) under flow-through conditions Report No: RD-00726 GLP Not published	Y	Nippon Soda
KCP 10.1.2		2013	Acetamiprid: Amphibian metamorphosis assay for the detection of the thyroid active substances Report No: RD-02574 GLP Not published	Y	Nippon Soda

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<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>
KCP 10.1.1		1994a	NI-25 -Acute oral toxicity (LD50) to the mallard duck. Report No: RD-9435N GLP Not published	Y	Nippon Soda
KCP 10.1.1		1994c	NI-25 -Sub-acute Dietary toxicity (LC50) to the mallard duck. Report No: RD-09437N GLP Not published	Y	Nippon Soda
KCP 10.1.1		1994d	NI-25 -Sub-acute Dietary toxicity (LC50) to the bobwhite quail. Report No: RD-09436N GLP Not published	Y	Nippon Soda
KCP 10.1.1		1999	Reproduction study with Acetamiprid in the mallard duck (Anas platyrhynchos) Report No: RD-09990 GLP Not published	Y	Nippon Soda
KCP 10.1.1		1997	Reproduction study with Acetamiprid in the bobwhite quail (Colinus virginianus) Report No: RD-09930N GLP Not published	Y	Nippon Soda
KCP 10.2		1997a	NI-25 -Acute toxicity study in Rainbow trout. Report No: RD-09637N GLP Not published	Y	Nippon Soda
KCP 10.2		1997a	Acetamiprid - Acute toxicity (96 hrs) to bluegill (Lepomis macrochirus) under flow through conditions. Report No: RD-00232 GLP Not published	Y	Nippon Soda
KCP 10.2		1998	IM-1-4 -Acute toxicity study in Rainbow trout (Oncorhynchus mykiss) under semi-static conditions. Report No: RD-9938 GLP	Y	Nippon Soda

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<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>
			Not published		
KCP 10.2		1997	Acetamiprid -Early life stage toxicity test to Fathead minnow ( <i>Pimephales promelas</i> ). Report No: RD-00255 GLP Not published	Y	Nippon Soda
KCP 10.2	Putt, A.E.	2003a	Acetamiprid technical - Acute toxicity to midge ( <i>Chironomus riparius</i> ) under static conditions. Springborn Smithers Laboratories, NC, USA Nippon-Soda Report No: RD-03144 GLP Not published	N	Nippon Soda
KCP 10.2	Putt, A.E.	2003b	Acetamiprid technical - Acute toxicity to gammarids ( <i>Gammarus fasciatus</i> ) under static conditions. Springborn Smithers Laboratories, NC, USA Nippon-Soda Report No: RD-03143 GLP Not published	N	Nippon Soda
KCP 10.2	Putt, A.E.	1998b	Acetamiprid technical - Acute toxicity to mysids ( <i>Mysidopsis bahia</i> ) under flow-through conditions Springborn Laboratories, Inc. Nippon-Soda Report No: RD-00720 GLP Not published	N	Nippon Soda
KCP 10.2	Kley, A. & Wydra, V.	2012a	Acute toxicity of IM-1-2 to larvae of <i>Chironomus riparius</i> in a static 48-hours immobilisation test Ibacon GmbH, Rossdorf, Germany Project No. 67741251 Nippon-Soda Report No: RD-02374 GLP Not published	N	Nippon Soda
KCP 10.2	Kley, A. & Wydra, V.	2012b	Acute toxicity of IC-0 to larvae of <i>Chironomus riparius</i> in a static 48-hours immobilisation test Ibacon GmbH, Rossdorf, Germany Nippon-Soda Report No: RD-02375 GLP Not published	N	Nippon Soda



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<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>
KCP 10.2	Kley, A. & Wydra, V.	2012c	Acute toxicity of IB-1-1 to larvae of Chironomus riparius in a static 48-hours immobilisation test Ibacon GmbH, Rossdorf, Germany Nippon-Soda Report No: RD-02373 GLP Not published	N	Nippon Soda
KCP 10.2	Putt, A.E.	1998c	IM-1-4 Acute toxicity to mysids (Mysidopsis bahia) under static conditions Springborn Laboratories, Inc. Nippon-Soda Report No: RD-00719 GLP Not published	N	Nippon Soda
KCP 10.2	Hoberg, J.R.	1997a	Acetamiprid technical - toxicity to the freshwater blue-green alga, Anabaena flos-aquae. Springborn Smithers Laboratories, NC, USA, Nippon-Soda Report No: RD-00154 GLP Not published	N	Nippon Soda
KCP 10.2	Saika, O.	1997b	NI-25 -Acute toxicity study in Daphnids. Nippon Soda Co., Odawara Research Center, Japan. Nippon-Soda Report No: RD-09765 GLP Not published	N	Nippon Soda
KCP 10.2	Mc Elligott A.	1997a	IM-1-4 -Acute toxicity (48 hours) to Daphnids under semi-static conditions. Rhone-Poulenc Secteur Agro, Sophia, Antipolis, France. Nippon-Soda Report No: RD-9939 GLP Not published	N	Nippon Soda
KCP 10.2	Mc Elligott A.	1997b	IM-1-2 -Acute toxicity (48 hours) to Daphnids under semi-static conditions. Rhone-Poulenc Secteur Agro, Sophia, Antipolis, France. Nippon-Soda Report No: RD-9940 GLP	N	Nippon Soda

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<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>
			Not published		
KCP 10.2	Mc Elligott A.	1997c	IC-0 -Acute toxicity (48 hours) to Daphnids under semi-static conditions. Rhone-Poulenc Secteur Agro, Sophia, Antipolis, France. Nippon-Soda Report No: RD-9936 GLP Not published	N	Nippon Soda
KCP 10.2	Mc Elligott A.	1998	IB-I-I -Acute toxicity (48 hours) to Daphnids under semi-static conditions. Rhone-Poulenc Secteur Agro, Sophia, Antipolis, France. Nippon-Soda Report No: RD-9941 GLP Not published	N	Nippon Soda
KCP 10.2	Saito, S.	2002	IM-1-5 (N1-((6-chloro-3-pyridyl)methyl)-N1-methylacetamidine): Acute toxicity to Daphnia magna. Aventis CropScience Nippon-Soda Report No: RD-II02414 GLP Not published	N	Nippon Soda
KCP 10.2	Putt, A.E.	2001	IM-1-4 Acute toxicity to midge Chironomus riparius under static conditions Generated by:: Springborn Smithers Laboratories, NC, USA, Nippon-Soda Report No: RD-01034 GLP Not published	N	Nippon Soda
KCP 10.2	Putt, A.E.	2003c	IM-1-5 - Acute Toxicity to Midge (Chironomus riparius) Under Static Conditions. Source : Aventis CropScience Nippon-Soda Report No: RD-03060 GLP Not published	N	Nippon Soda
KCP 10.2	Suteau, P.	1997b	Acetamiprid -Daphnia magna Life cycle (21 day static renewal) Chronic toxicity study. Rhone-Poulenc Secteur Agro, Sophia, Antipolis, France.	N	Nippon Soda

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<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>
			Nippon-Soda Report No: RD-00235 GLP Not published		
KCP 10.2	Putt, A.E.	2003d	IM-1-5 - Full life-cycle toxicity test with water fleas, Daphnia magna, under static-renewal conditions. Springborn Smithers Laboratories, NC, USA, Nippon-Soda Report No: RD-03057 GLP, not published	N	Nippon Soda
KCP 10.2	Mc Elligott, A.	1999	Acetamiprid -Toxicity to the sediment dwelling chironomid larvae (Chironomus riparius) Rhone-Poulenc Secteur Agro, Sophia, Antipolis, France. Nippon-Soda Report No: RD-II02191 GLP Not published	N	Nippon Soda
KCP 10.2	Suteau, P.	1996a	Acetamiprid -Freshwater algal growth inhibition study (72 hours) (Scenedesmus subspicatus) Rhone-Poulenc Secteur Agro, Sophia, Antipolis, France. Nippon-Soda Report No: RD-09931 GLP Not published	N	Nippon Soda
KCP 10.2	Hoberg, J.R.	1997b	Acetamiprid technical -Toxicity to duckweed, Lemna gibba. Springborn Laboratories, Inc. USA. Nippon-Soda Report No: RD-00223 GLP Not published	N	Nippon Soda
KCP 10.3.1	Harkin, S.	2014	Acetamiprid – Chronic toxicity test for adult honeybees (Apis mellifera L.) The Food and Environment Research Agency, York, UK. Nippon-Soda Report No: RD-02928 GLP Not published	N	Nippon Soda
KCP	Harkin, S.	2015	Acetamiprid: In vitro chronic toxicity to larval stage honeybee (Apis mellifera L.)	N	Nippon Soda

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<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>
10.3.1			The Food and Environment Research Agency, York, UK. Nippon-Soda Report No: RD-02929 GLP Not published		
KCP 10.3.1	Collins, M.K.	1997	Evaluation of toxicity of residues of Acetamiprid (NI-25) on alfalfa to honey bees ( <i>Apis mellifera</i> L.) (Hymenoptera, Apidae) Landis International, Valdosta, GA Nippon-Soda Report No: RD-00017 GLP Not published	N	Nippon Soda
KCP 10.3.2	Schmitzer, S.	2003	Effects of IM 1-5 on the Reproduction of Rove beetles <i>Aleochara bilineata</i> in the laboratory. Aventis CropScience Nippon-Soda Report No: RD-03101 GLP: yes Published: no	N	Nippon Soda
KCP 10.4	Johnson, A.J.	1994	NI-25 Acute toxicity (LC50) to Earthworm ( <i>Eisenia foetida</i> ). Huntingdon Research Center, U.K. Nippon-Soda Report No: RD-09520N GLP Not published	N	Nippon Soda
KCP 10.4	Wetton, P.M.	1999a	IM-1-4 Acute toxicity to Earthworm ( <i>Eisenia foetida</i> ). Safepharm Laboratories Ltd, U.K. Nippon-Soda Report No: RD-00780 GLP Not published	N	Nippon Soda
KCP 10.4	Lühns, U.	2002a	Acute toxicity (14 days) of IM-1-2 to the earthworm <i>Eisenia fetida</i> in artificial soil. Aventis CropScience Nippon-Soda Report No : B004154 GLP Not published	N	Nippon Soda

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<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>
KCP 10.4	Wetton, P.M.	1999b	IC-0 - Acute toxicity to Earthworm (Eisenia foetida). Safepharm Laboratories Ltd, U.K. Nippon-Soda Report No: RD-00781 GLP: Yes Not published	N	Nippon Soda
KCP 10.4	Rogers, M.	2002	IM-1-5: Acute toxicity (LC50) to the earthworm Huntingdon Life Sciences, Ltd. Nippon-Soda Report No: RD-II 02451 GLP Not published	N	Nippon Soda
KCP 10.4	Lühns, U.	2003	Effects of IM-1-5 on reproduction and growth of earthworms Eisenia fetida in artificial soil. Source : Aventis CropScience Report No: C029229, Document No. RD-03096 GLP Not published	N	Nippon Soda
KCP 10.4	Klein, S. & Rosenkraus, B.	2003	Effects of IM -1-5 on Reproduction of the Collembola Folsomia Candida in Artificial Soil IBACON, Germany Nippon-Soda Report No: RD-03058 GLP Not published	N	Nippon Soda
KCP 10.5	Forster, J.	1997	A laboratory assessment of the effects of NI-25 on soil microflora respiration & nitrogen transformations according to EPPO Bulletin 24, 1-16 (1994). Chemex International plc. Nippon-Soda Report No: RD-09942 GLP Not published	N	Nippon Soda
KCP 10.6	Hatano, R.	1999	Insecticidal activity of NI-25 metabolites Nippon Soda Co., Odawara Research Center, Japan.	N	Nippon Soda

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<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>
			Nippon-Soda Report No: RD-9617N2 GLP Not published		
KCP 10.6	Mead, C.	1999	Acetamiprid: assessment of the inhibitory effect on the respiration of activated sewage sludge. Safepharm Laboratories Ltd, U.K. Nippon-Soda Report No: RD-00221 GLP Not published	N	Nippon Soda
KCP 10.1	Martens, R. Schafer, D.	1999	Estimation of half-life of residues on leafy crops. Report No. C005514 (RCS 99/012) Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany GLP/GEP: not relevant unpublished	N	AgroEvo
KCP 10.2	Schanne, C. Van der Kolk, J.	2001	[14C]-Deltamethrin Formulated as Emulsifiable Concentrate (25 g/L Deltamethrin): Outdoor Aquatic Microcosm Study of the Ecological Effects and Environmental Fate. Report No. C015510 Springborn Laboratories, Horn, Switzerland GLP, unpublished	N	AgroEvo
KCP 10.2	Schanne, C.	2001	Statement of the Study Director to the Final Report (C015510) RE: Section 3.5 Macrophyte Biomass Assessment and Stocking of the Enclosures with Elodea spec. Report No. C017935 Springborn Laboratories, Horn, Switzerland GLP/GEP: not relevant unpublished	N	AgroEvo
KCP 10.2	Schanne, C.	2001	Statement of the Study Director to the Final Report (C015510) RE: Page 106. Supplementary Information concerning Chironomidae Type 1 (Ablatesmya spec) and Chironomidae Type 4 Corynoneura spec, Orthocladinae). Report No. C017934	N	AgroEvo

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<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>
			Springborn Laboratories, Horn, Switzerland GLP/GEP: not relevant unpublished		
KCP 10.2	xxxxxxx	1993	Deltamethrin - The Chronic Toxicity to the Fathead Minnow (Pimephales promelas) during a Full Life-Cycle Exposure. Report No. 4607 xxxxxxxxxxxxxxxxxx GLP, unpublished	Y	AgroEvo
KCP 10.2	Putt, E.E.	1999	Deltamethrin _[14C]-labelled_ - Acute toxicity to Daphnids (Daphnia magna) under flow-through conditions. Report No. C003959 Springborn Laboratories, Wareham, Massachusetts GLP, unpublished	N	AgroEvo
KCP 10.2	Putt, A.E.	2000	Decis EC 25 g/L - Acute Toxicity to Gammarids (Gammarus fasciatus) Under Flow-Through Conditions. Report No. C006608 Springborn Laboratories, Wareham, Massachusetts GLP, unpublished	N	AgroEvo
KCP 10.2	Putt, A.E.	2000	Decis EC 25 g/L (AE F032640 00 EC03 B003) - Acute Toxicity to Gammarids (Gammarus fasciatus) in a Sediment- Water System. Report No. C009363 Springborn Laboratories, Wareham, Massachusetts GLP, unpublished	N	AgroEvo
KCP 10.2	Gries, T. Van der Kolk, J.	2001	14C]-Deltamethrin Formulated as Emulsifiable Concentrate (25 g/L Deltamethrin): Acute toxicity test with fresh water isopods (Asellus aquaticus) under semi-static conditions. Report No. C015003 Springborn Laboratories, Horn, Switzerland GLP, unpublished	N	AgroEvo

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<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>
KCP 10.2	Heusel, R. Gildemeister, H. Gosch, H.	1998	Chronic toxicity to the sediment dwelling chironomid larvae <i>Chironomus riparius</i> Report No. A74315 Study Id. CE96/126 Hoechst Scherung AgrEvo GmbH, Frankfurt am Main GLP, unpublished	N	AgroEvo
KCP 10.3	Nengel, S.	1998	Assessment of Side Effects of AE F032640 00 EC03 B003 on the Honey Bee ( <i>Apis mellifera</i> L.) in the Field Following Application during Bee-Flight. Report No. C002768 Study code: 98299/01-BFEU Arbeitsgemeinschaft GAB Biotechnologie GmbH & IEU Umweltanalytik GmbH, Niefern-Öschelbronn GLP, unpublished	N	AgroEvo
KCP 10.3	Brown, K.C. Selby, K.A.	2000	An evaluation of the effects of field and drift rates of 6% EG (emulsifiable granule) formulation of deltamethrin (AE F032640 00EG06) on the epigeal nontarget arthropod fauna in a cereal field in England. Report No. C008877 (ER-99-KCB114) Ecotox Limited, Tavistock, Devon, England GLP, unpublished	N	AgroEvo
KCP 10.3	Aldershof, S.	2001	Evaluating effects of AE F032640 00 EC03 B007 applications on predatory mites (Acari: Phytoseiidae) and other nontarget arthropod species in the field (apple orchards, Portugal). Report No. C014857 MITOX, Amsterdam, The Netherlands, and IMPACTEST, Lda, Lisboa, Portugal GLP, unpublished	N	AgroEvo
KCP 10.4	Hoxter, K.A. Smith, G.J.	1993	Deltamethrin technical: An Acute Toxicity Study with the Earthworm in an Artificial Soil Substrate. Report No. 239109 Wildlife International LTD, USA GLP, unpublished	N	AgroEvo
KCP 10.4	Frings, H. Bock, K.D.	1994	Deltamethrin: technical substance. Investigating the effect of the microbial activity in soil (short term effects on aerobic soil respiration in accordance with BBA, VI, 1-1, 2nd edition)	N	AgroEvo



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<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>
			Report No. DE93036 Hoechst AG, Agriculture Div. GLP, unpublished		
KCP 10.4	Frings, H. Bock, K.D.	1994	Deltamethrin; technical substance. Investigating the effect on the nitrogen cycle in soil (in accordance with BBA, VI, 1-1, 2nd edition) Report No. DE93038 Hoechst AG, Agriculture Div. GLP, unpublished	N	AgroEvo

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>

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**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</b> <b>Company Report No.</b> <b>Source (where different from company)</b> <b>GLP or GEP status</b> <b>Published or not</b>	<b>Vertebrate study</b> <b>Y/N</b>	<b>Owner</b>

## **Appendix 2 Detailed evaluation of the new studies**

### **A 2.1 KCP 10.1 Effects on birds and other terrestrial vertebrates**

#### **A 2.1.1 KCP 10.1.1 Effects on birds**

##### **A 2.1.1.1 KCP 10.1.1.1 Acute oral toxicity**

No additional studies were performed.

##### **A 2.1.1.2 KCP 10.1.1.2 Higher tier data on birds**

No additional studies were performed.

#### **A 2.1.2 KCP 10.1.2 Effects on terrestrial vertebrates other than birds**

No additional studies were performed.

##### **A 2.1.2.1 KCP 10.1.2.1 Acute oral toxicity to mammals**

No additional studies were performed.

##### **A 2.1.2.2 KCP 10.1.2.2 Higher tier data on mammals**

No additional studies were performed.

#### **A 2.1.3 KCP 10.1.3 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians)**

No additional studies were performed.

### **A 2.2 KCP 10.2 Effects on aquatic organisms**

#### **A 2.2.1 KCP 10.2.1 Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes**

##### **A 2.2.1.2. Study 1**

Comments of zRMS:	The study was conducted to OECD guideline 202 and according to the principles of GLP. No deviations to the guideline were noted. All validity criteria were met. The study is considered to be reliable and suitable for the risk assessment.
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Reference:	KCP 10.2
Report	CHR/I/ADEL 280 SC Daphnia magna, Acute Immobilisation Test, Study code: W/54/19, 2020, M. Czarnecka
Guideline(s):	according to the OECD Guideline No. 202 (2004)/EU method C.2.
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	-

**Materials and methods:**

Test item: CHR/I/ADEL 280 SC; batch no. 05.08.2019, the (determined) content of acetamiprid: 245.4 g/L; the (determined) content of deltamethrin: 30.7 g/L; density at 20°C: 1.0886 g/cm<sup>3</sup>; manufacturing date: August 05, 2019, expiry date: August 05,2021.

Test organism: Daphnia magna Straus (< 24 h old at exposure initiation); not first brood progeny; neonates collected from a laboratory culture cultivated at the Łukasiewicz Research Network - Institute of Industrial Organic Chemistry, Branch Pszczyna.

Test design: Semi-static test (48 h of exposure with renewal after 24h); 4 replicates per test item concentration and the control; 5 Daphnia magna in each replicate.

Nominal test item concentrations: 20, 9.1, 4.13, 1.88, 0.85, 0.39, 0.18, 0.080, 0.036, 0.017, 0.008, 0.003, 0.0016, and 0.0007 mg/L plus the control.

Test conditions:  
 Temperature: 19.4 – 20.5°C; pH of the control: 7.48 – 7.72;dissolved oxygen concentration in the control: 7.6 – 8.3 mg/L; daily cycle 16 h light : 8 h dark; fluorescent light source; no feeding; no aeration; medium: Elendt M7.

Statistics: Probit method calculations and analyses by: Fisher’s Exact Binomial Test with Bonferroni Correction.

Chemical determinations:  
 The concentrations of acetamiprid and deltamethrin were determined with the validated high performance liquid chromatographic method with DAD detection.

Endpoint values: EC50/48 h, NOEC/48 h, and LOEC/48 h.

**Results and discussions**

The concentrations of acetamiprid and deltamethrin were chemically analysed the validated high performance liquid chromatographic method with DAD detection. Samples of all fresh test item concentrations and the control were analysed at exposure initiation and during renewal (spent). Moreover,

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fresh and spent samples of the highest test item concentration of 20 mg/L and the test item concentration of 0.0016 mg/L plus the control at renewal and at exposure termination were chemically analyzed. However, the content of acetamiprid in the test item concentration of 0.0007 mg/L is below LoQ value, whereas the content of deltamethrin in the test item concentrations of 0.008, 0.003, 0.0016, and 0.0007 mg/L is below LoQ value. In fresh samples at exposure initiation and at the renewal, the determined concentrations of acetamiprid were in the range of 103.2 – 114.0% and the concentrations of deltamethrin were in the range of 92.1 – 114.5% of the nominal concentration. The results confirm that the test item concentrations were prepared correctly. In spent samples at renewal and at exposure termination, the determined concentrations of acetamiprid were in the range of 104.4 – 119.5% and the determined concentrations of deltamethrin were in the range of 41.3 – 89.0% of the nominal concentration. Therefore, the concentrations of acetamiprid were stable under test conditions and the concentrations of deltamethrin were not stable during 24 h under test conditions. The results showed that concentrations of deltamethrin were lower than 80% of nominal concentrations during the exposure. Therefore, the concentrations of deltamethrin were not stable under test conditions. Hence, the geometric means of determined concentrations of deltamethrin were calculated for the renewal according to the formula below:

$$\text{Mean concentration} = \text{antilog} \left( \frac{1}{2(t_n - t_1)} \sum_{i=1}^{n-1} [(\log(\text{conc}_i) + \log(\text{conc}_{i+1})) \times (t_{i+1} - t_i)] \right)$$

where:

t1= initial time < t2 <... tn = final time

conc1 = initial concentration, conc2, ..., concn=final concentration

conc1 = initial concentration

conc2 = concentration after 24 h of exposure

In order to calculate the geometric means of determined concentrations of deltamethrin for the test item concentrations of 0.008, 0.003, 0.0016, and 0.0007 mg/L, the LoD values for deltamethrin (i.e. 0.000126 mg/L) were taken for calculations because the active ingredient was not detected.

Table 11. Concentration and stability of deltamethrin, definitive test

Nominal test item concentration [mg/L]	Control	0.0007	0.0016	0.003	0.008	0.017	0.036	0.080	0.18	0.39	0.85	1.88	4.13	9.1	20	Day of sampling
Nominal concentration of deltamethrin [mg/L]	0.000	0.00002	0.000046	0.000086	0.000228	0.000485	0.001026	0.00228	0.00513	0.01112	0.02423	0.0536	0.1177	0.2594	0.570	
Geometric mean of determined concentration of deltamethrin* [mg/L]	—	0.0001*	0.0001*	0.0001*	0.0002*	0.0003	0.0010	0.0023	0.0041	0.0080	0.0161	0.0364	0.0832	0.1736	0.4058	
Average determined concentration of deltamethrin (n=3) in samples collected [mg/L]	< LoD	< LoQ	< LoQ	< LoQ	0.0002	0.0005	0.0012	0.0026	0.0052	0.0112	0.0228	0.0494	0.1142	0.2424	0.5783	at exposure initiation (fresh)
% of the nominal concentration	—	—	—	—	97.4	103.8	112.2	114.5	101.8	100.5	94.3	92.1	97.1	93.5	101.5	
Average determined concentration deltamethrin (n=3) in samples collected [mg/L]	< LoD	< LoQ	< LoQ	< LoQ	< LoQ	0.0002	0.0008	0.0020	0.0033	0.0057	0.0114	0.0268	0.0606	0.1243	0.2848	after 24 h of exposure (spent, 24h old)
% of the nominal concentration	—	—	—	—	—	41.3	82.5	89.0	64.1	51.3	47.0	50.0	51.5	47.9	50.0	
Average determined concentration of deltamethrin (n=3) in samples collected [mg/L]	< LoD	—	< LoQ	—	—	—	—	—	—	—	—	—	—	—	0.5786	after 24 h of exposure (fresh)
% of the nominal concentration	—	—	—	—	—	—	—	—	—	—	—	—	—	—	101.5	
Average determined concentration of deltamethrin (n=3) in samples collected [mg/L]	< LoD	—	< LoQ	—	—	—	—	—	—	—	—	—	—	—	0.3320	exposure termination
% of the nominal concentration	—	—	—	—	—	—	—	—	—	—	—	—	—	—	58.2	

\*geometric mean was calculated according to the formula [10]

LoQ = 0.015 mg test item/L (0.00042 mg deltamethrin/L); LoD = 0.0045 mg test item/L (0.000126 mg deltamethrin /L)

\*in order to calculate the geometric means of determined concentrations of deltamethrin for the test item concentrations of 0.008, 0.003, 0.0016, and 0.0007 mg/L, the LoD values for deltamethrin (0.000126 mg/L) were taken for calculations.

— no value

## Conclusions:

Endpoint values [mg/L]	Time of exposure	
	24 h	48 h
EC <sub>50</sub>	14.66 (6.04 – 60.99)	11.66 (2.98 – 134.87)
EC <sub>20</sub>	0.80 (0.36 – 1.65)	0.05 (0.01 – 0.16)
EC <sub>10</sub>	0.17 (0.05 – 0.38)	0.003 (0.0002 – 0.014)
LOEC	1.88	0.85
NOEC	0.85	0.39

Calculations were made according to [7], [SOP/W/68].  
 ( - ) - 95% confidence interval

The endpoint values were determined based on the nominal test item concentrations. The endpoint values were calculated with a probit method. The lowest observed effect concentration (LOEC) and the no observed effect concentration (NOEC) were estimated on the basis of statistical analysis. To make calculations and to conduct statistical analysis, the ToxRat Professional commercial software was used.. The median concentration causing 50% immobilisation of *Daphnia magna* after 24 h of exposure, i.e. the EC<sub>50</sub>/24 h value is 14.66 mg/L (95% confidence interval 6.04 – 60.99). The EC<sub>20</sub>/24 h value is 0.80 mg/L (95% confidence interval 0.36 – 1.65). The EC<sub>10</sub>/24 h value is 0.17 mg/L (95% confidence interval 0.05 – 0.38). The median concentration causing 50% immobilisation of *Daphnia magna* after 48 h of exposure, i.e. the EC<sub>50</sub>/48 h value is 11.66 mg/L (95% confidence interval 2.98 – 134.87). The EC<sub>20</sub>/48 h value is 0.05 mg/L (95% confidence interval 0.01 – 0.16). The EC<sub>10</sub>/48 h value is 0.003 mg/L (95% confidence interval 0.0002 – 0.014). The data on immobilisation of the *Daphnia magna* at exposure termination were analysed using Fisher's Exact Binomial Test with Bonferroni Correction, which showed significant differences between the nominal test item concentrations in the range of 0.85 – 20 mg/L and the control. Therefore, the LOEC/48 h value is 0.85 mg/L and the NOEC/48 h value 0.39 mg/L.

**The validity criteria:**

In the definitive test, the validity criteria were met according to the OECD Guideline No. 202 (2004):

- the percentage of immobilisation of *Daphnia magna* in the control was 0% (criterion: not more than 10%),
- the dissolved oxygen concentrations in the test vessels were within the range of 7.4 – 8.5 mg/L (criterion: not less than 3 mg/L).

**A 2.2.1.3. Study 2**

Comments of zRMS:	The study was conducted to OECD guideline 201 and according to the principles of GLP. No deviations to the guideline were noted. All validity criteria were met. The study is considered to be reliable and suitable for the risk assessment.
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Reference: KCP 10.2/02

Report Acetamiprid + Deltametryna (250+30) SC (CHR/I/ADEL 280 SC) *Anabaena flos-aquae* UTEX B 1444 Growth inhibition test, Study code:W-49-20, M. Czarnecka

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Guideline(s):	according to the OECD Guideline No. 201 (2006)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	-

#### Materials and methods:

Test item: Acetamiprid + Deltametryna (250+30) SC (CHR/I/ADEL 280SC); batch no. 05.08.2019, the (determined) content of acetamiprid: 245.4 g/L; the (determined) content of deltamethrin: 30.7 g/L; density at 20°C: 1.0886 g/cm<sup>3</sup>; manufacturing date: August 05, 2019, expiry date: August 05,2021

Test system: The freshwater cyanobacteria, *Anabaena flos-aquae* (Lyng.) Bréb UTEX B 1444 cultivated at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna, Department of Ecotoxicological Studies, Laboratory of Aquatic Organisms Toxicology. The culture was obtained from the Culture Collection of Algae at the University of Texas at Austin, USA.

Test design: 72 hours of exposure; three replicates per each test item concentration; six replicates per the control; initial cyanobacterial cell density: 1 x 10<sup>4</sup> cells/mL.

Nominal test item concentrations:  
 1000, 312.5, 97.7, 30.5, 9.5 mg/L plus the control

Test conditions: Temperature: 21.8 – 22.3°C; pH of the control: 7.51 – 7.60; mean light intensity: 3288 - 3428 lux; constant illumination and shaking; medium: AAP.

Chemical determinations:  
 The concentrations of acetamiprid and deltamethrin were determined with the validated high performance liquid chromatographic method with DAD detection.

Statistics: Probit method calculations and analyses by: Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Williams Multiple Sequential t-test Procedure

Endpoint values: ErC<sub>50</sub>/72 h, EyC<sub>50</sub>/72 h, NOEC/72 h, LOEC/72 h.

#### Results and discussion:

The concentrations of acetamiprid and deltamethrin were chemically analysed the validated high performance liquid chromatographic method with DAD detection. Samples of each treatment were collected at exposure initiation and at exposure termination. At exposure initiation, the determined concentrations of acetamiprid were in the range of 92.0 – 94.6% and the concentrations of deltamethrin were in the range of 87.0 – 105.2% of the nominal concentration. The results confirm that the test item concentrations were prepared correctly. At exposure termination, the determined concentrations of acetamiprid were in the range of 91.5 – 92.9% and the determined concentrations of deltamethrin were in the range of 63.5 – 94.8% of the nominal concentration. Therefore, the concentrations of acetamiprid were

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stable under test conditions and the concentrations of deltamethrin were not stable under test conditions. The results showed that concentrations of deltamethrin were lower than 80% of nominal concentrations after 72 hours of the exposure. Therefore, the concentrations of deltamethrin were not stable under test conditions. Hence, the geometric means of determined concentrations of deltamethrin were calculated according to the below formula:

$$\text{Mean concentration} = \text{antilog} \left( \frac{1}{2(t_n - t_1)} \sum_{i=1}^{n-1} [(\log(\text{conc}_1) + \log(\text{conc}_2)) \times (t_n - t_1)] \right)$$

where:

t1= initial time

tn = final time

conc1 = initial concentration

conc2 = final concentration

**Table 13. Concentration and stability of acetamiprid, definitive test**

Nominal test item concentration [mg/L]	Nominal concentration of acetamiprid [mg/L]	Average determined concentration of acetamiprid (n=3) in samples collected [mg/L]			
		at exposure initiation	[%] of nominal concentration	at exposure termination	[%] of nominal concentration
Control	0.000	< LoD	–	< LoD	–
9.5	2.141	2.011	93.9	1.979	92.4
30.5	6.875	6.343	92.3	6.317	91.9
97.7	22.022	20.819	94.5	20.143	91.5
312.5	70.44	66.62	94.6	64.99	92.3
1000	225.40	207.33	92.0	209.36	92.9

LoQ = 0.0015 mg test item/L (0.000338 mg acetamiprid/L)

LoD = 0.00045 mg test item/L (0.000101 mg acetamiprid /L)

– no value



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**Table 14. Concentration and stability of deltamethrin, definitive test**

Nominal test item concentration [mg/L]	Nominal concentration of deltamethrin [mg/L]	Geometric mean of determined deltamethrin concentration [mg/L]*	Average determined concentration of deltamethrin (n=3) in samples collected			
			at exposure initiation [mg/L]	[%] of nominal concentration	at exposure termination [mg/L]	[%] of nominal concentration
Control	0.000	–	< LoD	–	< LoD	–
9.5	0.268	0.23	0.273	101.9	0.196	73.2
30.5	0.860	0.70	0.905	105.2	0.546	63.5
97.7	2.755	2.55	2.816	102.2	2.305	83.7
312.5	8.813	8.42	8.49	96.3	8.35	94.8
1000	28.200	24.0	24.53	87.0	23.49	83.3

LoQ = 0.015 mg test item/L (0.00042 mg deltamethrin/L)

LoD = 0.0045 mg test item/L (0.000126 mg deltamethrin/L)

\*geometric mean was calculated according to the formula [10]

– no value

**Endpoint values**

The endpoint values are based on the nominal test item concentrations. The EC<sub>x</sub> values were calculated with a probit method. The lowest observed effect concentration (LOEC) and the no observed effect concentration (NOEC) were estimated on the basis of statistical analyzes. To conduct statistical analyses, the ToxRat Professional commercial software was used. The median test item concentration causing 50% inhibition of the average specific growth rate of *Anabaena flos-aquae*, i.e. the ErC<sub>50</sub>/72 h value is 582.11 mg/L (95% confidence interval: 403.84 – 965.90). The ErC<sub>20</sub>/72 h value is 131.76 mg/L (95% confidence interval: 58.22 – 204.72) and the ErC<sub>10</sub>/72 h value is 60.60 mg/L (95% confidence interval: 17.34 – 110.97). Statistical tests based on the growth rate data were the Shapiro-Wilk's Test on Normal Distribution which confirmed normal distribution of the data, the Levene's Test on Variance Homogeneity (with Residuals) which showed that the variances were homogeneous. The Williams Multiple Sequential t-test Procedure showed significant differences between the test item concentrations in the range of 312.5 - 1000 mg/L and the control. Therefore, the LOEC/72 h value is 312.5 mg/L and the NOEC/72 h value is 97.7 mg/L. The median test item concentration causing 50% yield inhibition of *Anabaena flos-aquae*, i.e. the EyC<sub>50</sub>/72 h value is 180.08 mg/L (95% confidence interval: 134.20 – 241.08). The EyC<sub>20</sub>/72 value is 91.44 mg/L (95% confidence interval: 49.23 – 124.60) and EyC<sub>10</sub>/72 h value is 64.17 mg/L (95% confidence interval: 27.27 – 94.33). Statistical tests based on the yield data were the Shapiro-Wilk's Test on Normal Distribution which confirmed normal distribution of the data, the Levene's Test on Variance Homogeneity (with Residuals) which showed that the variances were homogeneous. The Williams Multiple Sequential t-test Procedure showed significant differences between the test item concentrations in the range of 30.5 - 1000 mg/L and the control. Therefore, the LOEC/72 h value is 30.5 mg/L and the NOEC/72 h value is 9.5 mg/L.

**The validity criteria:**

In the definitive test, the following validity criteria specified in the OECD Guideline No.201 (2006) were met:

- the biomass in the control increased by a factor of 20.1 within the 72-hour test period (criterion: at least a 16-fold growth),
- the coefficient of variation of the mean specific growth rate after the 72-hour test period (exposure initiation – exposure termination) in the control culture was 2.7% (criterion: it must not exceed 10%).
- the mean coefficient of variation for the section-by-section growth rate in the control culture was 31% (criterion: it must not exceed 35%).

**A 2.2.2 KCP 10.2.2 Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms**

**A 2.2.2.1. Study 1**

Comments of zRMS:	The study was conducted to OECD Guideline 235 and according to the principles of GLP. No deviations to the guideline were noted. All validity criteria were met. The study is considered to be reliable and suitable for the risk assessment.
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Reference:	KCP 10.2/04
Report	Acetamiprid + Deltametryna (250+30) SC (CHR/I/ADEL 280 SC) Chironomus sp., Acute Immobilisation Test, Study code: W-48-20, M. Czarnecka
Guideline(s):	according to the OECD Guideline No. 235 (2011)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	-

**Materials and methods:**

Test item: Acetamiprid + Deltametryna (250+30) SC (CHR/I/ADEL 280 SC); batch no. 05.08.2019, the (determined) content of acetamiprid: 245.4 g/L; the (determined) content of deltamethrin: 30.7 g/L; density at 20°C: 1.0886 g/cm<sup>3</sup>; manufacturing date: August 05, 2019, expiry date: August 05, 2021.

Test system: First instar larvae of freshwater dipteran midge Chironomus riparius Meigen 1804 (two-four days after hatching) collected from a laboratory culture cultivated at the Łukasiewicz Research Network - Institute of Industrial Organic Chemistry Branch Pszczyna.

Test design: Semi-static test (48 h of exposure with renewal after 24h); 4 replicates per test item concentration and the control; 5 larvae in each replicate.

Nominal test item concentrations: 1.0, 0.45, 0.21, 0.09, 0.04, and 0.019 mg/L plus the control.

Test conditions: Temperature: 19.5 – 20.6°C; pH of the control: 7.30 – 7.79; dissolved oxygen concentration in the control: 8.4 – 8.7 mg/L; daily cycle 16 h light : 8 h dark; fluorescent light source; mean light intensity: 681 lux; no feeding; no aeration; medium: Elendt M7.

Statistics: Probit method calculations and analyses by: Tarone's Test

Procedure, Multiple Sequentially-rejective Chi<sup>2</sup>-2x2 Test with Bonferroni Correction.

Chemical determinations: The concentrations of acetamiprid and deltamethrin were determined with the validated high performance liquid chromatographic method with DAD detection.

Endpoint values: EC<sub>50</sub>/48 h, NOEC/48 h, LOEC/48 h.

**Results and discussion:**

The concentrations of acetamiprid and deltamethrin were chemically analysed using the validated high performance liquid chromatographic method with DAD detection. Samples of all fresh test item

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concentrations and the control were analysed at exposure initiation and during renewal (spent). Moreover, fresh and spent samples of the highest test item concentration of 1.0 mg/L and the test item concentration of 0.019 mg/L plus the control at renewal and at exposure termination were chemically analyzed. In fresh samples at exposure initiation and at the renewal, the determined concentrations of acetamiprid were in the ranges of 101.2 – 113.1% and the concentrations of deltamethrin were in the ranges of 101.5 – 120% of the nominal concentration. The results confirm that the test item concentrations were prepared correctly. In spent samples at the renewal and at exposure termination, the determined concentrations of acetamiprid were in the ranges of 100.7 – 109.8% and the determined concentrations of deltamethrin were in the ranges of 40.4 – 53.8% of the nominal concentration. Therefore, the concentrations of acetamiprid were stable under test conditions, whereas the concentrations of deltamethrin were not stable during 24 h under test conditions. Moreover, during the renewal in spent samples for the test item concentration of 0.019 mg/L, the analysed concentrations of deltamethrin were below the LoD value. The results are presented in Tables 10-11. The results showed that concentrations of deltamethrin were lower than 80% of nominal concentrations during the exposure. Therefore, the concentrations of deltamethrin were not stable under test conditions. Hence, the geometric means of determined concentrations of deltamethrin were calculated for the renewal according to the formula below:

where:

$t_1$  = initial time <  $t_2$  < ...  $t_n$  = final time

conc1 = initial concentration, conc2, ..., concn = final concentration

conc1 = initial concentration

conc2 = concentration after 24 h of exposure

In order to calculate the geometric mean of determined concentration of deltamethrin for the test item concentration of 0.019 mg/L, the LoD value for deltamethrin (i.e. 0.000126 mg/L)

**Table 10. Concentration and stability of acetamiprid, definitive test**

Nominal test item concentration [mg/L]	Control	0.019	0.04	0.09	0.21	0.45	1.0	Day of sampling
Nominal concentration of acetamiprid [mg/L]	0.000	0.0043	0.0090	0.0203	0.047	0.10	0.23	
Average determined concentration of acetamiprid (n=3) in samples collected [mg/L]	< LoD	0.0045	0.0102	0.0217	0.048	0.103	0.228	at exposure initiation (fresh)
[%] of the nominal concentration	–	105.1	113.1	107.0	100.6	101.5	101.2	
Average determined concentration of acetamiprid (n=3) in samples collected [mg/L]	< LoD	0.0045	0.0099	0.0216	0.048	0.104	0.227	after 24 h of exposure (spent, 24h old)
[%] of the nominal concentration	–	105.1	109.8	106.5	101.7	102.5	100.7	
Average determined concentration of acetamiprid (n=3) in samples collected [mg/L]	< LoD	0.0047	–	–	–	–	0.2338	after 24 h of exposure (fresh)
[%] of the nominal concentration	–	109.7	–	–	–	–	103.7	
Average determined concentration of acetamiprid (n=3) in samples collected [mg/L]	< LoD	0.0046	–	–	–	–	0.2295	exposure termination
[%] of the nominal concentration	–	107.4	–	–	–	–	101.8	

LoQ = 0.0015 mg test item/L (0.000338 mg acetamiprid/L)

LoD = 0.00045 mg test item/L (0.000101 mg acetamiprid /L)

– no value

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Table 11. Concentration and stability of deltamethrin, definitive test

Nominal test item concentration [mg/L]	Control	0.019	0.04	0.09	0.21	0.45	1.0	Day of sampling
Nominal concentration of deltamethrin [mg/L]	0.000	0.00054	0.00113	0.0025	0.0059	0.0127	0.0282	
Geometric mean of determined concentration of deltamethrin [mg/L]*	–	0.0003*	0.0008	0.0018	0.0041	0.0088	0.0206	
Average determined concentration of deltamethrin (n=3) in samples collected [mg/L]	< LoD	0.000563	0.001243	0.002635	0.00620	0.01288	0.03251	at exposure initiation (fresh)
[%] of the nominal concentration	–	105.1	110.2	103.8	104.7	101.5	115.3	
Average determined concentration of deltamethrin (n=3) in samples collected [mg/L]	< LoD	< LoD	0.000456	0.001212	0.00270	0.00600	0.01309	after 24 h of exposure (spent, 24h old)
[%] of the nominal concentration	–	–	40.4	47.8	45.6	47.3	46.4	
Average determined concentration of deltamethrin (n=3) in samples collected [mg/L]	< LoD	0.000643	–	–	–	–	0.032257	after 24 h of exposure (fresh)
[%] of the nominal concentration	–	120.0	–	–	–	–	114.4	
Average determined concentration of deltamethrin (n=3) in samples collected [mg/L]	< LoD	< LoD	–	–	–	–	0.015180	exposure termination
[%] of the nominal concentration	–	–	–	–	–	–	53.8	

\*geometric mean was calculated according to the formula [10]

LoQ = 0.015 mg test item/L (0.00042 mg deltamethrin/L)

LoD = 0.0045 mg test item/L (0.000126 mg deltamethrin /L)

\*in order to calculate the geometric mean of the determined concentration of deltamethrin for the test item concentration of 0.0019 mg/L, the LoD value for deltamethrin (0.000126 mg/L) was taken for calculations.

– no value

**Conclusion:**

Endpoint values [mg/L]	Time of exposure	
	24 h	48 h
EC <sub>50</sub>	n.d.	0.106 (0.075 – 0.149)
EC <sub>20</sub>	n.d.	0.039 (0.022 – 0.057)
EC <sub>10</sub>	n.d.	0.023 (0.011 – 0.037)
LOEC	>1.0	0.09
NOEC	≥1.0	0.04

Calculations were made according to [7], [SOP/W/68].

(-) - 95% confidence interval

n.d. – not determined

The endpoint values were determined based on the nominal test item concentrations. The endpoint values were calculated with a probit method. The lowest observed effect concentration (LOEC) and the no observed effect concentration (NOEC) were estimated on the basis of statistical analysis. To make calculations and to conduct statistical analysis, the ToxRat Professional commercial software was used.. The EC<sub>10</sub>/24 h, EC<sub>20</sub>/24 h, and EC<sub>50</sub>/48 h values were not determined. The LOEC/24 h value appeared to be higher than 1.0 mg/L and the NOEC/24 h value appeared to be higher than or equal to 1.0 mg/L. The median concentration causing 50% immobilisation of *Chironomus riparius* after 48 h of exposure, i.e. the EC<sub>50</sub>/48 h value is 0.106 mg/L (95% confidence interval 0.075 – 0.149). The EC<sub>20</sub>/48 h value is 0.039 mg/L (95% confidence interval 0.022 – 0.057). The EC<sub>10</sub>/48 h value is 0.023 mg/L (95% confidence interval 0.011 – 0.037)..

**The validity criteria:**

In the definitive test, the following validity criteria specified in the OECD Guideline No. 235 (2011) were

met:  
 – the immobilisation of *Chironomus riparius* larvae in the control was 10% (criterion: not more than 15%),  
 – the dissolved oxygen concentrations in the test vessels were within the range of 8.3 – 8.8 mg/L (criterion: not less than 3 mg/L).

**A 2.2.3                      KCP 10.2.3                      Further testing on aquatic organisms**

No additional studies were performed.

**A 2.3                              KCP 10.3      Effects on arthropods**

**A 2.3.1                          KCP 10.3.1                      Effects on bees**

**A 2.3.1.1                      KCP 10.3.1.1                      Acute toxicity to bees**

**A 2.3.1.1.1                      KCP 10.3.1.1.1                      Acute oral toxicity to bees**

Comments of zRMS:	The study was conducted to OECD 213 and according to the principles of GLP. No deviations to the guideline were noted. All validity criteria were met. The study is considered to be reliable and suitable for the risk assessment.
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Reference:	KCP 10.3/01
Report	CHR/I/ADEL 280 SC Honeybees ( <i>Apis mellifera</i> L.) Acute Oral Toxicity Test, Study code: B-11-20, M. Grzesica
Guideline(s):	according to the OECD Guideline for the Testing of Chemicals No. 213 (1998) and the EU Method C.16. (2008)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

**Materials and methods**

Test item:

name: Acetamiprid + Deltametryna (250 + 30) SC  
 producer's code: CHR/I/ADEL 280 SC  
 active substance: 245.4 g/L of acetamiprid 30.7 g/L of deltamethrin  
 batch number: 05.08.20191  
 sample identification: 219080603208  
 manufacturing date: 05.08.2019  
 expiry date: 05.08.2021

Biological test system:

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the honeybee. *Apis mellifera* L. strain: carnica  
 source: an apiary at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch  
 Pszczyna, Department of Ecotoxicological Studies  
 age: approximately 3 weeks

Test design:

–test item:

exposure time: 96 hours  
 number of doses: 5 doses and a control  
 number of replicates: 3 replicates  
 number of bees: 10 bees/replicate

–reference item:

exposure time: 24 hours  
 number of doses: 3 doses  
 number of replicates: 3 replicates  
 number of bees: 10 bees/replicate

Test item doses:

1.25, 2.5, 5.0, 10.0 and 20.0 µg test item/bee and a control (0.0 µg/bee)

Reference item doses: 0.1, 0.2 and 0.4 µg a.i./bee

Test conditions:

temperature: 25 – 27°C, relative air humidity: 55 – 62%  
 place: a dark room

Endpoints:

–honeybee mortality after 24, 48, 72 and 96 hours of exposure  
 –LD50/24, 48, 72 and 96h of the test item  
 –LD50/24h of the reference item (dimethoate)

Statistical method: regression analysis using the log-probit method

### Results and discussion:

After 24 hours of the exposure there were no dead bees in the control group. The percentage of mortality in the groups exposed to the test item at the rates of 1.25, 2.5, 5.0, 10.0 and 20.0 µg/bee were 3.3, 0.0, 0.0, 6.7 and 73.3%, respectively. After 48 hours of the exposure, mortality of the control group was 6.7%. The percentage of mortality in the groups exposed to the test item at the rates of 1.25, 2.5, 5.0, 10.0 and 20.0 µg/bee, after Abbott's correction were 0.0, 0.0, 0.0, 14.3 and 92.9%, respectively. After 72 hours of the exposure, mortality of the control group was 6.7%. The percentage of mortality in the groups exposed to the test item at the rates of 1.25, 2.5, 5.0, 10.0 and 20.0 µg/bee, after Abbott's correction, were 7.1, 7.1, 10.7, 21.4 and 96.4%, respectively. After 96 hours of the exposure, mortality of the control group was 10.0%. The percentage of mortality in the groups exposed to the test item at the rates of 1.25, 2.5, 5.0, 10.0 and 20.0 µg/bee, after Abbott's correction, were 11.1, 14.8, 7.4, 22.2 and 96.3%, respectively. The median lethal dose LD50/24 h is equal to 17.5 µg/honeybee (confidence limits: n.d.). The median lethal dose LD50/48 h is equal to 13.4 µg/honeybee (confidence limit: 11.9 – 25.2 µg/honeybee). The median lethal dose LD50/72 h is equal to 10.9 µg/honeybee (confidence limits: n.d.). The median lethal dose LD50/96 h is equal to 10.8 µg/honeybee (confidence limits: n.d.).

Reduction [%] in food consumption calculated using the formula of Abbott (1925)  
 presented below [6]:

$$C = \left( 1 - \frac{nT}{nK} \right) \times 100$$

C: reduction of food consumption [%].

nT: the amount of sucrose solution consumed by bees exposed to the test item.

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nK: the amount of sucrose solution consumed by control bees.

The reduction during 4, 24, 48, 72 and 96 h ranged from 1.87 to 99.25% as compared to the control group. The median lethal dose of dimethoate (LD<sub>50</sub> oral) after 24 hours determined with the log-probit method is 0.23 µg a.i./bee (confidence limits: 0.18 – 0.31),

**Table 4. Honeybee mortality and the LD<sub>50</sub> after 24 hours of exposure – definitive test**

Dose [µg/bee]	Number of tested bees [no.]	Mortality					LD <sub>50</sub> [µg/bee]
		Number of dead bees [no.]			Total		
		replicates					
		I	II	III	[no.]	[%]	
0.0 (Control)	30	0	0	0	0	0.0	17.5 (n.d.)
1.25	30	0	0	1	1	3.3	
2.5	30	0	0	0	0	0.0	
5.0	30	0	0	0	0	0.0	
10.0	30	1	0	1	2	6.7	
20.0	30	7	8	7	22	73.3	

**Table 5. Honeybee mortality and the LD<sub>50</sub> after 48 hours of exposure – definitive test**

Dose [µg/bee]	Number of tested bees [no.]	Mortality						LD <sub>50</sub> [µg/bee]
		Number of dead bees [no.]			Total			
		replicates						
		I	II	III	[no.]	[%]	[%] <sup>c</sup>	
0.0 (Control)	30	0	2	0	2	6.7	–	13.4 (11.85 – 15.21)**
1.25	30	1	0	1	2	6.7	0.0	
2.5	30	0	1	0	1	3.3	0.0	
5.0	30	0	0	1	1	3.3	0.0	
10.0	30	3	0	3	6	20.0	14.3	
20.0	30	10	8	10	28	93.3	92.9	

<sup>c</sup>: mortality corrected according Abbott's formula [6]

\*\* : the LD<sub>50</sub> (with 95% confidence limits) was calculated with the log-probit method (ToxRat Professional 3.3.0 computer [SOP/B/67]).

**Table 6. Honeybee mortality and the LD<sub>50</sub> after 72 hours of exposure – definitive test**

		Mortality						LD <sub>50</sub> [µg/bee]
Dose [µg/bee]	Number of tested bees [no.]	Number of dead bees [no.]			Total			
		replicates						
		I	II	III	[no.]	[%]	[%] <sup>c</sup>	
0.0 (Control)	30	0	2	0	2	6.7	–	10.9 (n.d.)
1.25	30	1	0	3	4	13.3	7.1	
2.5	30	2	1	1	4	13.3	7.1	
5.0	30	2	1	2	5	16.7	10.7	
10.0	30	3	2	3	8	26.7	21.4	
20.0	30	10	9	10	29	96.7	96.4	

<sup>c</sup>: mortality corrected according Abbott's formula [6]



**Table 7. Honeybee mortality and the LD50 after 96 hours of exposure – definitive test**

Definitive test		Mortality						LD <sub>50</sub> [µg/bee]
Dose [µg/bee]	Number of tested bees [no.]	Number of dead bees [no.]			Total			
		replicates						
		I	II	III	[no.]	[%]	[%] <sup>c</sup>	
0.0 (Control)	30	0	2	1	3	10.0	–	10.8 (n.d.)
1.25	30	1	2	3	6	20.0	11.1	
2.5	30	2	3	2	7	23.3	14.8	
5.0	30	2	1	2	5	16.7	7.4	
10.0	30	3	3	3	9	30.0	22.2	
20.0	30	10	9	10	29	96.7	96.3	

The definitive test was performed between 27 – 31.05.2020

<sup>c</sup>: mortality corrected according Abbott's formula [6]

#### The validity criteria:

The following validity criteria were met during the test:

- the average mortality for the control was 10.0% at the end of the experiment (criterion: it must not exceed 10%).
- the LD50/24 h of the reference item (dimethoate) was 0.23 µg a.i./bee (criterion: 0.18 – 0.31 µg a.i./bee).

## STUDY 2

Comments of zRMS:	The study was conducted to OECD 214 and according to the principles of GLP. No deviations to the guideline were noted. All validity criteria were met. The study is considered to be reliable and suitable for the risk assessment.
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Reference:	KCP 10.3/02
Report	CHR/I/ADEL 280 SC Honeybees ( <i>Apis mellifera</i> L.) Acute Contact Toxicity Test, Study code: B-12-20, M. Grzesica
Guideline(s):	according to the OECD Guideline for the Testing of Chemicals No. 214 (1998) and the EU Method C.17. (2008)
Deviations:	no
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

#### Materials and methods

Test item:

name: Acetamiprid + Deltametryna (250 + 30) SC

CHR/I/ADEL 280 SC/ ADEL 280 SC, PYRIFOS ADE 280 SC.  
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producer's code: CHR/I/ADEL 280 SC  
 active substances: 245.4 g/L of acetamiprid, 30.7 g/L of deltamethrin  
 batch number: 05.08.20191  
 sample identification: 219080603208  
 manufacturing date: 05.08.2019  
 expiry date: 05.08.2021

Biological test system:  
 the honeybee, *Apis mellifera* L.,  
 strain: carnica  
 source: an apiary at the Institute of Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna, Department of Ecotoxicological Studies  
 age: approximately 3 weeks

Test design:  
 –test item:  
 exposure time: 96 hours  
 number of doses: 5 doses and a control  
 number of replicates: 3 replicates  
 number of bees: 10 bees/replicate

–reference item:  
 exposure time: 24 hours  
 number of doses: 3 doses  
 number of replicates: 3 replicates  
 number of bees: 10 bees/replicate

Test item doses: 3.125, 6.25, 12.5, 25.0 and 50.0 µg test item/bee and a control (0.0 µg/bee)

Reference item doses: 0.1, 0.2 and 0.4 µg a.i./bee

Test conditions:  
 temperature: 25 – 27°C, relative air humidity: 57 – 62%  
 place: a dark room

Endpoints:  
 –honeybee mortality after 24, 48, 72 and 96 hours of exposure  
 –LD50/24h, LD50/48h, LD50/72h and LD50/96h of the test item  
 –LD50/24h of the reference item (dimethoate)

Statistical method: regression analysis using the log-probit method

**Results and discussion:**

Mortality of the control group after 4, 24, 48, and 72 hours of exposure was 0.0%. The mortality percentages of the bees treated with the test item at the doses of 3.125, 6.25, 12.5, 25.0 and 50.0 µg/honeybee after 24 hours of exposure were 10.0, 43.3, 66.7, 90.0 and 93.3%, respectively. The mortality percentages of the bees treated with the test item at the doses of 3.125, 6.25, 12.5, 25.0 and 50.0 µg/honeybee after 48 hours of exposure were 10.0, 43.3, 66.7, 90.0 and 96.7%, respectively. The mortality percentages of the bees treated with the test item at the doses of 25.0 and 50.0 µg/honeybee after 72 hours of exposure were 13.3, 43.3, 70.0, 90.0 and 96.7 %, respectively.

Mortality of the control group after 96 hours of exposure was 6.7%. The mortality percentages (corrected using the formula of Abbott [10]) of the bees treated with the test item at the doses of 3.125, 6.25, 12.5, 25.0 and 50.0 µg/honeybee after 96 hours of exposure were 7.1, 39.3, 71.4, 96.4 and 100.0 %, respectively.

A dose-effect curve showing the influence of the test item on mortality of the introduced honeybees as observed after 24, 48, 72 and 96 hours is given in Figure 1 – 4.

The median lethal doses (LD50 oral) after 24, 48, 72 and 96 hours of exposure are 8.48 µg test item/bee (confidence limits: 6.53 – 10.72), 8.31 µg test item /bee (confidence limits: 6.51 – 10.37), 7.86 µg test item /bee (confidence limits: 6.08 – 9.86) and 7.96 µg test item /bee (confidence limits: 6.55 – 9.60) µg test item /bee, respectively.

Abnormal behavioural effects are presented in Table 11.

Mortality of the bees treated with the reference item after 4 and 24 h are presented in Tables 12 and 13. A dose-effect curve showing the influence of the reference item on mortality of honeybees after 24 hours of exposure is given in Figure 5. The median lethal dose of dimethoate (LD50/24 h) determined with the log-probit method is 0.23 µg/bee (confidence limits: 0.19 – 0.28) (Table 13).

#### The validity criteria:

The following validity criteria were met during the test:

- the average mortality for the control was 6.7% after 96 h (criterion: it must not exceed 10%),
- the LD50/24 h of the reference item (dimethoate) was 0.23 µg a.i./bee (criterion: 0.10 – 0.30 µg a.i./bee).

### A 2.3.1.1.2 KCP 10.3.1.1.2 Acute contact toxicity to bees

#### Study 1

Reference:	KCP-10.3/02
Report	CHR/I/ADEL 280 SC Honeybees ( <i>Apis mellifera</i> L.) Acute-Contact-Toxicity Test, Study-code: B-12-20, M. Grzesica
Guideline(s):	according to the OECD Guideline for the Testing of Chemicals No. 214 (1998) and the EU Method C.17. (2008)
Deviations:	no
GLP:	Yes
Acceptability:	Yes
Duplication (if-vertebrate-study)	No

#### Materials and methods

Test item:

name: Acetamiprid + Deltametryna (250 + 30) SC

producer's code: CHR/I/ADEL 280 SC

active substances: 245.4 g/L of acetamiprid, 30.7 g/L of deltamethrin

batch number: 05.08.20191

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sample identification: 219080603208  
 manufacturing date: 05.08.2019  
 expiry date: 05.08.2021

Biological test system:  
 the honeybee, *Apis mellifera* L.,  
 strain: carnica  
 source: an apiary at the Institute of Lukaszewicz Research Network—Institute of Industrial Organic  
 Chemistry, Branch Pszczyna, Department of Ecotoxicological Studies  
 age: approximately 3 weeks

Test design:

~~test item:~~

exposure time: 96 hours  
 number of doses: 5 doses and a control  
 number of replicates: 3 replicates  
 number of bees: 10 bees/replicate

~~reference item:~~

exposure time: 24 hours  
 number of doses: 3 doses  
 number of replicates: 3 replicates  
 number of bees: 10 bees/replicate

Test item doses: 3.125, 6.25, 12.5, 25.0 and 50.0 µg test item/bee and a control (0.0 µg/bee)

Reference item doses: 0.1, 0.2 and 0.4 µg a.i./bee

Test conditions:

temperature: 25—27°C, relative air humidity: 57—62%  
 place: a dark room

Endpoints:

~~honeybee mortality after 24, 48, 72 and 96 hours of exposure~~  
~~LD50/24h, LD50/48h, LD50/72h and LD50/96h of the test item~~  
~~LD50/24h of the reference item (dimethoate)~~

Statistical method: regression analysis using the log probit method

**Results and discussion:**

Mortality of the control group after 4, 24, 48, and 72 hours of exposure was 0.0%. The mortality percentages of the bees treated with the test item at the doses of 3.125, 6.25, 12.5, 25.0 and 50.0 µg/honeybee after 24 hours of exposure were 10.0, 43.3, 66.7, 90.0 and 93.3%, respectively. The mortality percentages of the bees treated with the test item at the doses of 3.125, 6.25, 12.5, 25.0 and 50.0 µg/honeybee after 48 hours of exposure were 10.0, 43.3, 66.7, 90.0 and 96.7%, respectively. The mortality percentages of the bees treated with the test item at the doses of 25.0 and 50.0 µg/honeybee after 72 hours of exposure were 13.3, 43.3, 70.0, 90.0 and 96.7 %, respectively. Mortality of the control group after 96 hours of exposure was 6.7%. The mortality percentages (corrected using the formula of Abbott) of the bees treated with the test item at the doses of 3.125, 6.25, 12.5, 25.0 and 50.0 µg/honeybee after 96 hours of exposure were 7.1, 39.3, 71.4, 96.4 and 100.0 %, respectively. The median lethal doses (LD50-oral) after 24, 48, 72 and 96

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hours of exposure are 8.48 µg test item/bee (confidence limits: 6.53—10.72), 8.31 µg test item /bee (confidence limits: 6.51—10.37), 7.86 µg test item /bee (confidence limits: 6.08—9.86) and 7.96 µg test item /bee (confidence limits: 6.55—9.60) µg test item /bee, respectively.

The median lethal dose of dimethoate (LD<sub>50</sub>/24 h) determined with the log-probit method is 0.23 µg/bee (confidence limits: 0.19—0.28).

**Table 7. Honeybee mortality and the LD<sub>50</sub> after 24 hours of exposure – definitive test**

Dose [µg/bee]	Number of tested bees [no.]	Mortality					LD <sub>50</sub> [µg/bee]
		Number of dead bees [no.] replicates			Total		
		I	II	III	[no.]	[%]	
0.0 (Control)	30	0	0	0	0	0.0	8.48* (6.53 – 10.72)
3.125	30	1	1	1	3	10.0	
6.25	30	3	7	3	13	43.3	
12.5	30	6	8	6	20	66.7	
25.0	30	9	9	9	27	90.0	
50.0	30	10	9	9	28	93.3	

\*: the LD<sub>50</sub> (with 95% confidence limits) was calculated with the log-probit method (ToxRat Professional 3.3.0. computer [SOP/B/67]).

**Table 8. Honeybee mortality and the LD<sub>50</sub> after 48 hours of exposure – definitive test**

Dose [µg/bee]	Number of tested bees [no.]	Mortality					LD <sub>50</sub> [µg/bee]
		Number of dead bees [no.] replicates			Total		
		I	II	III	[no.]	[%]	
0.0 (Control)	30	0	0	0	0	0.0	8.31* (6.51 – 10.37)
3.125	30	1	1	1	3	10.0	
6.25	30	3	7	3	13	43.3	
12.5	30	6	8	6	20	66.7	
25.0	30	9	9	9	27	90.0	
50.0	30	10	9	10	29	96.7	

\*: the LD<sub>50</sub> (with 95% confidence limits) was calculated with the log-probit method (ToxRat Professional 3.3.0. computer [SOP/B/67]).

**Table 9. Honeybee mortality and the LD<sub>50</sub> after 72 hours of exposure – definitive test**

Dose [µg/bee]	Number of tested bees [no.]	Mortality					LD <sub>50</sub> [µg/bee]
		Number of dead bees [no.] replicates			Total		
		I	II	III	[no.]	[%]	
0.0 (Control)	30	0	0	0	0	0.0	7.86* (6.08 – 9.86)
3.125	30	1	1	2	4	13.3	
6.25	30	3	7	3	13	43.3	
12.5	30	6	8	7	21	70.0	
25.0	30	9	9	9	27	90.0	
50.0	30	10	9	10	29	96.7	

\*: the LD<sub>50</sub> (with 95% confidence limits) was calculated with the log-probit method (ToxRat Professional 3.3.0. computer [SOP/B/67]).

**Table 10. Honeybee mortality and the LD50 after 96 hours of exposure – definitive test**

Dose [µg/bee]	Number of tested bees [no.]	Mortality						LD <sub>50</sub> [µg/bee]
		Number of dead bees [no.] replicates			Total			
		I	II	III	[no.]	[%]	[%] <sup>a</sup>	
0.0 (Control)	30	0	1	1	2	6.7	–	7.96* (6.55 – 9.60)
3.125	30	1	1	2	4	13.3	7.1	
6.25	30	3	7	3	13	43.3	39.3	
12.5	30	7	8	7	22	73.3	71.4	
25.0	30	10	9	10	29	96.7	96.4	
50.0	30	10	10	10	30	100.0	100.0	

The definitive test was performed between 28.05 – 01.06.2020

<sup>a</sup>: mortality corrected using the formula of Abbott [10]

\*: the LD50 (with 95% confidence limits) was calculated with the log-probit method (ToxRat Professional 3.3.0. computer [SOP/B/67]).

**The validity criteria:**

The following validity criteria were met during the test:

- the average mortality for the control was 6.7% after 96 h (criterion: it must not exceed 10%);
- the LD50/24 h of the reference item (dimethoate) was 0.23 µg a.i./bee (criterion: 0.10 – 0.30 µg a.i./bee);

**A 2.3.1.2 KCP 10.3.1.2. Chronic toxicity to bees**

Comments of zRMS:	The study was conducted to OECD 245 and according to the principles of GLP. No deviations to the guideline were noted. All validity criteria were met. The study is considered to be reliable and suitable for the risk assessment.
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**Reference:**

KCP 10.3/07

**Report**

CHR/I/ADEL 280SC: Honey Bee (Apis mellifera L.) Chronic Oral Toxicity Test (10-Day Feeding) under Laboratory Conditions, Study code: S21-05567, T. Ansaloni

**Guideline(s):**

Based on OECD test No. 245 Guideline for the Testing of Chemicals: Honey bee (Apis mellifera L.), Chronic Oral Toxicity Test – 10 Day Feeding (9 October 2017).  
 SANTE/2020/12830, rev.1

**Deviations:**

no

**GLP:**

Yes

**Acceptability:**

Yes

**Duplication  
(if vertebrate study)**

No

**Materials and methods**

**Test item:**

Test item: CHR/I/ADEL 280SC material

Batch code: 221070802802

Active ingredients: acetamiprid and deltamethrin

Density: 1.0885 g/cm<sup>3</sup>

Content of a.i. determined by certificate of analysis: acetamiprid 245.1 g/L,  
 deltamethrin 30.5 g/L.

Reference item: BAS 152 65 I

Batch code: 10248664A

Active ingredient: dimethoate

Content of a.i. determined by certificate of analysis: 409 g/L

Test species: *Apis mellifera* L. young adult worker bees (newly hatched; 1 to 2 days old).

Place of test: Eurofins Trialcamp S.L.U., Polígon Industrial l'Alter, Avda. Antic Regne de València, 25,  
 46290 Alcàsser (Valencia), Spain.

Test design: ten days dose response test including one control group, 5 test item concentrations, one concentration of the reference item; 5 replicates with 10 bees each per treatment group. Mortality and behavioural abnormalities were assessed daily over the test duration. Five additional test units without bees with full food syringes containing pure 50 % (w/v) aqueous sucrose solution for evaluation of the evaporation. Test concentrations: 1 control group (negative control C), 5 test item groups with 67.23, 107.56, 172.10, 275.36 and 440.58 mg test item/kg feeding solution, 1 reference item group with 0.90 mg dimethoate/kg feeding solution. Endpoints: LC10/LDD10, LC20/LDD20, LC50/LDD50 and NOEC/NOEDD on exposure at day 10, where possible.

**Test conditions:**

Air temperature: Min / Max: 32.4 / 33.7 °C (target 33 ± 2 °C)

Relative air humidity: Min / Max: 52.6 / 65.8 % (target 50 – 70 %)

Photoperiod: 24 h darkness, except during application and assessments.

Dates of work: 29 Jul – 08 Aug 2021.

Statistics: Statistical calculations were made with MS Excel 2016 and the statistical program ToxRatPro® Version 3.3.0.

In order to determine the NOEC / NOED and the LOEC / LOED values, a Step-down Rao-Scott-Cochran-Armitage Test Procedure ( $\alpha = 0.05$ , one sided greater) was used. The estimation of the LCx /LDDx values with this regression analysis was performed by means of Weibull regression analysis.

Analytical verification: Analytical Phase was performed to verify the concentration of the samples taken. For the analytical dose verification, acetamiprid and deltamethrin residues were determined.

Results of the Analytical Phase are shown in section 6.2 and detailed information is included in the Analytical Phase Report in Annex 2.

**RESULTS:**

Samples of the test item treatments gave recoveries within the 80 - 120 % of the nominal concentrations (actual 100 % - 117 %). Samples of the untreated control gave results below the limit of detection. Therefore, all endpoints are based on nominal concentrations. Validity criterion for the negative control C (untreated 50 % (w/v) aqueous sucrose solution) was fulfilled (mortality < 15% after 10 days of exposure), with 10.0 % mean mortality after 10 days of continuous exposure. In the reference item group, the validity criterion was fulfilled with 100.00 % mortality after 10 days of continuous exposure. Since validity criteria were fulfilled, the test was considered valid. The overall mean daily consumption of feeding solution was 18.1 mg/bee/day in the control group C. The overall mean daily consumption of feeding solution for the test item concentrations of 67.23, 107.56, 172.10, 275.36 and 440.58 mg t.i./kg feeding solution was 14.6, 15.9, 16.5, 17.5 and 20.9 mg/bee/day, respectively. The overall mean daily consumption of feeding solution in the reference item treatment group was 13.1 mg/bee/day. The mean daily uptake for the test item



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concentrations of 67.23, 107.56, 172.10, 275.36 and 440.58 mg t.i./kg feeding solution was 0.98, 1.71, 2.85, 4.82 and 9.21 µg test item/bee/day, equivalent to 0.22, 0.38, 0.64, 1.08 and 2.07 µg acetamiprid/bee/day and 0.03, 0.05, 0.08, 0.13 and 0.26 µg deltamethrin/bee/day, respectively. In the test item groups of 0.98, 1.71, 2.85, 4.82 and 9.21 consumed µg test item/bee/day cumulative mortalities of 2.0, 6.0, 12.0, 68.0, and 100.0 % were observed, respectively, at the final assessment after 10 days of exposure. Symptoms of intoxication (affected bees) were observed at the highest test item concentration starting on the first assessment day, and increasing numbers of affected bees were observed progressively in time at the other test item concentrations, with the exception of lowest (T1), for which no affected bees were observed throughout the study. No symptoms of intoxication were observed for the control group throughout the study.

Results of the test and main endpoints are resumed in the table below:

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Cumulative mortality, overall mean consumption of feeding solution, feeding dose (DD), accumulated mean uptake of test item, NOEDD/NOEC and LDDx/LCx.

Treatment	10 day cumulative mortality	Abbot's transformed mortality	Overall mean consumption of feeding solution	Feeding dose <sup>1</sup>	Accumulated mean uptake of test item
Control(s):					
	[%]	[%]	[mg/bee/day]	-	-
C (0)	10.0	-	18.1	-	-
Reference item: Dimethoate [µg a.i./kg feeding solution]					
	[%]	[%]	[mg/bee/day]	[µg a.i./bee/day]	[µg a.i./bee]
R (0.90)	100.0	100.0	13.1	0.012	0.097
Test item: CHR//ADEL 280SC material [mg test item/kg feeding solution]					
	[%]	[%]	[mg/bee/day]	[µg t.i./bee/day]	[µg t.i./bee]
T1 (67.23)	2.0	-8.9	14.6	0.98	9.83
T2 (107.56)	6.0	-4.4	15.9	1.71	17.06
T3 (172.10)	12.0	2.2	16.5	2.85	28.45
T4 (275.36)	68.0	64.4	17.5	4.82	48.16
T5 (440.58)	100.0	100.0	20.9	9.21	73.67
	µg/bee/day				
	test item	acetamiprid <sup>2</sup>		deltamethrin <sup>2</sup>	
NOEDD <sup>3</sup>	2.85	0.64		0.08	
LDD <sub>10</sub> [95% CI] <sup>4</sup>	3.25 [2.86 - 3.53]	0.73 [0.64 - 0.79]		0.09 [0.08 - 0.10]	
LDD <sub>20</sub> [95% CI] <sup>4</sup>	3.70 [3.37 - 3.95]	0.83 [0.76 - 0.89]		0.10 [0.09 - 0.11]	
LDD <sub>50</sub> [95% CI] <sup>4</sup>	4.50 [4.24 - 4.81]	1.01 [0.95 - 1.08]		0.13 [0.12 - 0.13]	
	mg/kg feeding solution				
	test item <sup>2</sup>	acetamiprid <sup>2</sup>		deltamethrin <sup>2</sup>	
NOEC <sup>3</sup>	172.10	38.75		4.82	
LC <sub>10</sub> (95% CI) <sup>4</sup>	194.22 [172.41 - 209.74]	43.73 [38.82 - 47.23]		5.44 [4.83 - 5.88]	
LC <sub>20</sub> (95% CI) <sup>4</sup>	218.30 [200.33 - 232.02]	49.16 [45.11 - 52.24]		6.12 [5.61 - 6.50]	
LC <sub>50</sub> (95% CI) <sup>4</sup>	260.46 [246.43 - 275.57]	58.65 [55.49 - 62.05]		7.30 [6.91 - 7.72]	

<sup>1</sup>Based on actual measured consumption of feeding solution

<sup>2</sup>Calculated on the basis of the content declared in the Certificate of Analysis acetamiprid: 245.1 g/L, deltamethrin 30.5 g/L) and the test item density (1.0885 g/cm<sup>3</sup>)

<sup>3</sup>Step-down Rao-Scott-Cochran-Armitage Test Procedure ( $\alpha = 0.05$ , one sided greater)

<sup>4</sup>Weibull regression analysis

## Conclusion:

The chronic toxicity test of CHR/I/ADEL 280SC material was tested under laboratory conditions over a period of 10 days.

The actual concentrations of the active ingredients acetamiprid and deltamethrin in the test item feeding solutions were within the range of 20 % of the nominal concentrations. The resulting endpoints of this Chronic Oral Toxicity Test (10-Day Feeding) to the Honey Bee, *Apis mellifera* L. with the test item CHR/I/ADEL 280SC are presented below:

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<b>NOEC</b>	172.10 mg t.i./kg feeding solution
<b>NOEDD</b>	2.85 µg t.i./bee/day
<b>LC<sub>10</sub></b>	194.22 mg t.i./kg feeding solution
<b>LDD<sub>10</sub></b>	3.25 µg t.i./bee/day
<b>LC<sub>20</sub></b>	218.30 mg t.i./kg feeding solution
<b>LDD<sub>20</sub></b>	3.70 µg t.i./bee/day
<b>LC<sub>50</sub></b>	260.46 mg t.i./kg feeding solution
<b>LDD<sub>50</sub></b>	4.50 µg t.i./bee/day

All validity criteria were met and the sensitivity of the test organisms was confirmed. Accordingly, the study was deemed valid.

#### The validity criteria:

The study is considered valid because:

- Mean mortality in the control group was ≤ 15% at the end of the test (actual 10.0 %).
- Mean mortality in the reference item group was ≥ 50 % at the end of the test (actual 100.0 %)

#### A 2.3.1.3 KCP 10.3.1.3 Effects on honey bee development and other honey bee life stages

<b>Comments of zRMS:</b>	The study was conducted to OECD 239 and according to the principles of GLP. No deviations to the guideline were noted. All validity criteria were met. The study is considered to be reliable and suitable for the risk assessment.
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Reference: KCP 10.3/08

Report CHR/I/ADEL 280SC: Honey Bee (*Apis mellifera* L.) Larval Toxicity Test following Repeated Exposure under laboratory conditions, Study code: S21-05568, T. Ansaloni

Guideline(s): ENV/JM/MONO (2016) 34: Guidance Document on Honey bee (*Apis mellifera*) Larval Toxicity Test, Repeated Exposure (OECD 239).  
SANTE/2020/12830, rev.1 (2021)

Deviations: no

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study) No

#### Materials and methods

Test item:

Test item: CHR/I/ADEL 280SC material

Batch code: 05.08.2019

Active ingredients: acetamiprid and deltamethrin

Density: 1.0885 g/cm<sup>3</sup>

Content of a.i. determined by certificate of analysis: acetamiprid 245.1 g/L,  
deltamethrin 30.5 g/L.

BAS 152 I

Batch code: COD-002332

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Active substance: dimethoate

Content (analysed): 98.2 % (w/w)

Storage conditions: stored refrigerated in the original container at  $\leq 25^{\circ}\text{C}$ .

**Test organisms:** Honey bee (*Apis mellifera* L.), synchronized first instar (L1) larvae not older than 30 hours at grafting time.

**Source:** Commercial beehives from the in-house Test Facility stock, adequately fed, healthy, queen-right and as far as possible disease-free. The hives from which the larvae were obtained had not been previously exposed to any chemical treatments within four weeks of test initiation.

**Preparation of test organisms and larvae collection:**

At D-3, to provide known-aged eggs (and subsequent larvae), queens from at least three colonies were confined in a single frame with empty cells of their own hive by using an excluder cage.

At D-2, and maximum 30 hours after confinement, queens were released. Frames containing eggs were left in the excluder cages until hatching (D1). Three frames from different hives, containing the highest number of synchronized larvae, were selected for grafting in the laboratory.

**Test design:** Dose response test with duration of 21 days from grafting on day 1 to the final assessment on day 22. From day 3 until day 6 of the test, 5 different concentrations of CHR/I/ADEL 280SC were applied to the larvae of the test item groups and one single concentration of the reference item was applied to the larvae of the reference item group. Both test and reference item were supplied in diet B and C. The daily feeding volume increased progressively from 20  $\mu\text{L}$  to 50  $\mu\text{L}$  diet per larva over the application period. The cumulative feeding volume from day 3 until day 6 of 140  $\mu\text{L}$  diet per larva was considered for the calculation of the cumulative doses per larva. One control group was included in the test. The control group was exposed to identical exposure conditions of the treatments and for the same period of time. Each treatment group consisted of 48 larvae: 16 from each of three different colonies (each colony representing one replicate). Larval mortality assessments were done on days 4, 5, 6, 7, and 8. The presence of uneaten food was qualitatively recorded on day 8. Assessments of mortality during pupation phase were done on days 15 and 22. Emergence rate was also recorded on day 22.

**Test concentrations and doses:**

Control: C: control group (untreated diet).

Test Item: 3.25, 6.49, 12.99, 25.97 and 51.95 mg t.i./kg diet equivalent to 0.73, 1.46, 2.92, 5.85, and 11.70 mg acetamiprid/kg diet and 0.09, 0.18, 0.36, 0.73 and 1.46 mg deltamethrin/kg diet.

Based on the

cumulative application volume of 140  $\mu\text{L}$ /larva, the corresponding cumulative doses were 0.50, 1.00, 2.00, 4.00 and 8.00  $\mu\text{g}$  t.i./larva equivalent to 0.113, 0.225, 0.450, 0.901 and 1.801  $\mu\text{g}$  acetamiprid/larva and 0.014, 0.028, 0.056, 0.112 and 0.224  $\mu\text{g}$  deltamethrin/larva.

Reference item: R: 48.0 mg dimethoate/kg diet (equivalent to 7.39  $\mu\text{g}$  dimethoate/larva, cumulative).

**Endpoints:** NOEC/NOED, LOEC/LOED and EC<sub>10,20,50</sub>/ED<sub>10,20,50</sub> for adult emergence, where possible.

**Test conditions:**

Air Temperature: Min: 31.7\* / Max: 34.9  $^{\circ}\text{C}$

Relative humidity: Min: 52.3\* / Max: 97.9 %

\* Short-term deviation (less than 2 hours)

Exposure to light: constant darkness except during feeding and assessments.

**Dates of work:** 19 Jul 2021 to 11 Nov 2021 (Experimental Biological Phase start to Experimental Analytical Phase end dates)

**Sampling:** Treated diet samples of the lowest (T1) and highest (T5) test item concentrations were taken daily directly after preparation; all samples were placed in the freezer at < -18 °C until shipment.

#### **Analytical verification:**

An analytical study was performed as a phase of this multisite study. Test item residues were determined to verify the content of the active ingredients in the treated diet of the lowest (T1) and highest (T5) test item concentrations from day 3 to day 6. Results of the Analytical Phase are shown in section 6.2 and detailed information is included in Annex 2 in the Analytical Phase Report. The measured concentrations (corrected for the procedural recoveries) of the active ingredients in all the analysed samples were within  $\pm 20$  % nominal concentrations for the treatment solutions, with the exception of deltamethrin in treatment T1 at D5, for which recovery was 75 %. Nevertheless, since recovery of acetamiprid for the same treatment and on the same day was 104 %, it is considered that the relatively low recovery for deltamethrin does not reflect the real concentration in the analyzed sample. In addition, no effect was observed at this concentration level, and therefore the relatively low recovery of deltamethrin is considered uninfluential. Consequently, the concentrations of the test item were sufficiently confirmed and the endpoints are based on nominal concentrations.

**Statistics:** Statistical calculations were made with MS Excel 2016 and the statistical program ToxRatPro® Version 3.3.0.

In order to determine the NOEC / NOED and the LOEC / LOED values, a Stepdown Rao-Scott-Cochran-Armitage Test Procedure ( $\alpha = 0.05$ , one sided greater) was used.

Even though a statistically significant dose/response was found ( $p(F) \leq 0.05$ ) by means of Weibull analysis, the estimation of the ED<sub>x</sub> values with this regression analysis is considered unreliable due to the low goodness of fit probability ( $p(\chi^2) < 0.01$ ) and the non determination of some of the 95 % CI. The ED<sub>50</sub>/EC<sub>50</sub> values were determined by means of Moving Averages Computation. Since corrected mortality for treatment T3 at 22D was lower than 10 %, the EC<sub>10</sub>/20 /ED<sub>10</sub>/20 values were empirically estimated to be higher than this treatment level.

#### **RESULTS:**

On day 8, the cumulative larval mortality in the control group (C) was 4.17 %. On day 22, the adult emergence rate was 93.75 %. Therefore, the validity criteria for the control group were met for both test periods (the D8 mortality was lower than 15.00 % and the D22 emergence rate was greater than 70.00 %, across all replicates). Moreover, cumulative mortality in the Reference Item group also met the validity criteria (> 50 % at day 8, actual value 85.42 %). On day 8, no individuals with presence of uneaten food were observed. At the end of the test, in the final assessment of the emergence on day 22, no emerged bees were recorded as being affected (i.e. malformation). The Effects of CHR/I/ADEL 280SC on Honey Bee (*Apis mellifera* L.) Larvae from Repeated Exposure.

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Treatment Group [mg t.i./kg diet]	Cumulative Mortality [%]						
	D4	D5	D6	D7	D8	D15	D22
C [0]	0.00	2.08	2.08	4.17	4.17	6.25	6.25
T1 [3.25]	0.00	0.00	2.08	4.17	4.17	12.50	12.50
T2 [6.49]	2.08	8.33	8.33	8.33	10.42	16.67	16.67
T3 [12.99]	0.00	2.08	2.08	2.08	2.08	14.58	14.58
T4 [25.97]	20.83	22.92	22.92	22.92	22.92	29.17	29.17
T5 [51.95]	33.33	62.50	72.92	75.00	75.00	85.42	87.50
R [48.00] <sup>a</sup>	27.08	54.17	70.83	79.17	85.42	95.83	97.92

<sup>a</sup> For the reference item, the value indicate the amount of active substance (dimethoate)

t.i.: test item (CHR/I/ADEL 280SC)

Treatment Group [mg t.i./kg diet]	Corrected Mortality [%] <sup>a</sup>						
	D4	D5	D6	D7	D8	D15	D22
T1 [3.25]	0.00	-2.13	0.00	0.00	0.00	6.67	6.67
T2 [6.49]	2.08	6.38	6.38	4.35	6.52	11.11	11.11
T3 [12.99]	0.00	0.00	0.00	-2.17	-2.17	8.89	8.89
T4 [25.97]	20.83	21.28	21.28	19.57	19.57	24.44	24.44
T5 [51.95]	33.33	61.70	72.34	73.91	73.91	84.44	86.67

<sup>a</sup> Corrected for control mortality according Abbott modified by Schneider-Orelli. Negative values represent lower mortality compared to the control group.

t.i.: test item (CHR/I/ADEL 280SC)

### Conclusion:

The repeated exposure of CHR/I/ADEL 280SC to honey bee (*Apis mellifera* L.) was tested under laboratory conditions over a period of 22 days. All validity criteria were met and sensitivity of the test organisms was confirmed. Accordingly, the study was deemed valid.

The measured concentrations (corrected for the procedural recoveries) of the active ingredients in all the analysed samples were within  $\pm 20$  % nominal concentrations for the treatment solutions, with the exception of deltamethrin in treatment T1 at D5, for which recovery was 75 %. Nevertheless, since recovery of acetamiprid for the same treatment and on the same day was 104 %, it is considered that the relatively low recovery for deltamethrin does not reflect the real concentration in the analyzed sample. In addition, no effect was observed at this concentration level, and therefore the relatively low recovery of deltamethrin is considered uninfluential. Consequently, the concentrations of the test item were sufficiently confirmed and the endpoints are based on nominal concentrations. The endpoints of the study are summarised in the following table. Endpoints at Emergence on day 22 (D22):

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Endpoints	Concentration			Dose		
	mg t.i./kg diet	mg a.i.1/kg diet	mg a.i.2/kg diet	µg t.i./larva	µg a.i.1/larva	µg a.i.2/larva
NOEC/NOED	12.99	2.92	0.36	2.00	0.450	0.056
LOEC/LOED	25.97	5.85	0.73	4.00	0.901	0.112
EC <sub>10</sub> / ED <sub>10</sub> *	> 12.99	> 2.92	> 0.36	> 2.000	> 0.450	> 0.056
EC <sub>20</sub> / ED <sub>20</sub> *	> 12.99	> 2.92	> 0.36	> 2.000	> 0.450	> 0.056
EC <sub>50</sub> / ED <sub>50</sub> [95 % CI]**	34.53 [30.30-39.34]	7.78 [6.82-8.86]	0.97 [0.85-1.10]	5.32 [4.67-6.06]	1.20 [1.05-1.36]	0.15 [0.13-0.17]

t.i.: test item (CHR/I/ADEL 280SC)

a.i.1: active ingredient 1 (acetamiprid). a.i. 2: active ingredient 2 (deltamethrin)

\* Empirically estimated

\*\* Mean averages computation

Active ingredients equivalences were determined based on acetamiprid and deltamethrin content declared in the Certificate of Analysis.

#### The validity criteria:

The study was considered valid since validity criteria for both control and reference item were met.

Control The cumulative larval mortality from day 3 (D3) until day 8 (D8) was ≤ 15 % across all replicates (actual value 4.17 %). On day 22 (D22) the adult emergence rate was ≥ 70 % across all replicates (actual value 93.75 %).

Reference The cumulative larval mortality was ≥ 50 % across all replicates on day 8 (D8) (actual value 85.42 %).

#### A 2.3.1.4 KCP 10.3.1.4 Sub-lethal effects

No additional studies were performed.

#### A 2.3.1.5 KCP 10.3.1.5 Cage and tunnel tests

#### A 2.3.1.6 KCP 10.3.1.6 Field tests with honeybees

No additional studies were performed.

#### A 2.3.1.7 KCP 10.3.1.6 Non target arthropods studies

##### A 2.3.1.7.1 Study 1

<b>Comments of zRMS:</b>	The study was conducted to the guideline and according to the principles of GLP. All validity criterions were met. The study is considered to be reliable and suitable for the risk assessment.
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Reference:	KCP 10.3/03
Report	An extended laboratory test for evaluating the effects of CHR/I/ADEL 280 SC on the predatory mite, <i>Typhlodromus pyri</i> (Sch.), Study code: B-09-20, M. Grzesica
Guideline(s):	according to the ESCORT 1 (Barrett K.L. et al., 1994) and the ESCORT 2 (Candolfi M.P. et al., 2001) guidance documents and the guidelines developed by the IOBC, BART, and EPPO Joint Initiative (Blümel S. et al., 2000)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

**Materials and methods**

Test item:  
 name: Acetamiprid + Deltametryna (250 + 30) SC  
 producer's code: CHR/I/ADEL 280 SC  
 active substance: 245.4 g/L of acetamiprid, 30.7 g/L of deltamethrin  
 batch number: 05.08.20191  
 sample identification: 219080603208  
 manufacturing date: 05.08.2019  
 expiry date: 05.08.2021

Biological test system:  
 the predatory mite, *Typhlodromus pyri* (Sch.) (Acari: Phytoseiidae)  
 – age:  
 24-hour-old protonymphs  
 – source:  
 a laboratory culture at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna; the culture was augmented from a commercial breeder

Experimental design:  
 7 study groups:

- a control group (0.0 mL/ha)
- CHR/I/ADEL 280 SC at the rates:
  - 2.0 mL/ha
  - 0.5 mL/ha
  - 0.125 mL/ha
  - 0.0313 mL/ha
  - 0.0078 mL/ha
- reference item: Bi 58 Top 400 EC at the rate of 9.0 mL/ha
- number of replicates: 3
- number of mites in each replicate: 20

Test conditions:  
 – temperature:  
 24 – 26°C



CHR/I/ADEL 280 SC/ ADEL 280 SC, PYRIFOS ADE 280 SC.  
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- relative air humidity:  
62 – 75%
- photoperiod:  
16 h light : 8 h dark
- light intensity:  
820 lux

#### Statistical analysis:

Probit analysis using max. likelihood regression, Step-down Cochran-Armitage Test Procedure, Shapiro Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Williams Multiple Sequential t-test Procedure

#### Endpoints:

- mite mortality after 7 days of the treatment
- LR50 and NOERMortality
- reproduction reduction (Pr) after 14 days of the treatment
- ER50 and NOERreproduction

#### Results and discussion:

In the definitive test, mortality of the control group after 7 days of exposure was 0.0%. After 7 days of exposure to CHR/I/ADEL 280 SC at rates of 0.0078, 0.0313, 0.125, 0.5 and 2.0 mL/ha, the percentages of *T. pyri* mortality, were 0.0, 0.0, 8.3, 23.3 and 38.3%, respectively.

There were statistically significant differences in mortality between group treated with the test item at the rates of 0.125, 0.5 and 2.0 mL/ha and the control group (Step-down Cochran-Armitage Test Procedure,  $p(\text{trend}) > \alpha$ ).

On the basis of the obtained mortality results, the LR50 value with 95% confidence limits was calculated. It was 3.053 mL/ha of CHR/I/ADEL 280 SC (95% confidence limits: 1.730 – 7.898). NOERMortality was 0.0313 mL/ha of CHR/I/ADEL 280 SC.

After 7 days of exposure to Bi 58 Top 400 EC at the rate of 9.0 mL/ha mortality was 73.3%. Therefore, the validity criterion specified in the Method description was met. The results obtained in the reference item group showed that the test organisms were sensitive to dimethoate.

The mean reproduction rate (Rr) in the control group was 4.6 eggs/female. The mean Rr after 14 days of exposure to CHR/I/ADEL 280 SC at the rates of 0.0078, 0.0313, 0.125, 0.5 and 2.0 mL/ha were 3.7, 3.0, 2.2, 1.9 and 3.5 eggs/female, respectively. The percentages of reproduction reduction (Pr) caused by test item at the rates of 0.0078, 0.0313, 0.125, 0.5 and 2.0 mL/ha were 19.6, 35.5, 52.6, 58.0 and 24.6%, respectively.

There were statistically significant differences in reproduction between the groups exposed to the test item at the rates of 0.0313, 0.125, 0.5, 2.0 and the control group (Williams Multiple Sequential t-test Procedure,  $|t| > |t^*|$ ).

On the basis of the obtained results the ER50 value could not be estimated. The NOERreproduction appears to be equal 0.0078 mL CHR/I/ADEL 280 SC/ha. The effects of CHR/I/ADEL 280 SC on mortality and reproduction of *Typhlodromus pyri* in the definitive test are summarized in the table.

CHR/I/ADEL 280 SC/ ADEL 280 SC, PYRIFOS ADE 280 SC.

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Study group [application rate]	Parameter (endpoint)					
	Mortality		Reproduction			
Test item rate [mL/ha]	Total [%]	LR <sub>50</sub> [mL/ha]	Test item rate [mL/ha]	Mean number of eqqs/ female (Rr) [no.]	Repro- duction reduction Pr [%]	ER <sub>50</sub> [mL/ha]
Control (0.0)	0.0	3.053  (1.730 – 7.898)*	Control (0.0)	4.6	–	n.d.
0.0078	0.0		0.0078	3.7	19.6	
0.0313	0.0		0.0313 <sup>+</sup>	3.0	35.5	
0.125 <sup>+</sup>	8.3		0.125 <sup>+</sup>	2.2	52.6	
0.5 <sup>+</sup>	23.3		0.5 <sup>+</sup>	1.9	58.0	
2.0 <sup>+</sup>	38.3		2.0 <sup>+</sup>	3.5	24.6	
NOER <sub>mortality</sub> 0.0313 [mL/ha]			NOER <sub>reproduction</sub> 0.0078 [mL/ha]			
Reference item: Bi 58 Top 400 EC						
Reference item [mL/ha]			9.0			
Active ingredient dimethoate [g/ha]			3.6			
Mortality						
Total [%]			73.3			

n.d.: the value could not be determined due to mathematical reasons.

+: statistically significant differences between control and groups exposed to test item; ToxRat Professional 3.3.0. software [12], [SOP/B/67]

\*: 95%-confidence limits

**The validity criteria:**

The following validity criteria were met during the study [3]:

- mortality of the control group was 0.0% on day 7 of exposure (criterion: a maximum of 20%),
- mortality of the mites exposed to the reference item at the rate of 9.0 mL/ha was 73.3% on day 7 of exposure (criterion: from 50 to 100%),
- the mean number of eggs per female in the control group was 4.6 (required:  $\geq 4$  eggs per female)..

**Conclusion:**

Based on the results it can be stated that CHR/I/ADEL 280 SC, at the rates of 0.125, 0.5, and 2.0 mL/ha has significant adverse effect on mortality of the mites. Based on the results it can be stated that CHR/I/ADEL 280 SC, at the rates of 0.0313, 0.125, 0.5 and 2.0 mL/ha has significant adverse effect on reproduction of the mites.

### A 2.3.1.7.2 Study 2

<b>Comments of zRMS:</b>	The study was conducted to the guideline and according to the principles of GLP. All validity criterions were met. The study is considered to be reliable and suitable for the risk assessment.
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Reference:	KCP 10.3/04
Report	An extended laboratory test for evaluating the effects of CHR/I/ADEL 280 SC on the parasitic wasp, <i>Aphidius rhopalosiphi</i> (De Stefani-Perez), Study code: B-10-20, M. Grzesica
Guideline(s):	according to the ESCORT 1 (Barrett K.L. et al., 1994) and the ESCORT 2 (Candolfi M.P. et al., 2001) guidance documents and the guidelines developed by the IOBC, BART, and EPPO Joint Initiative (Mead-Briggs M.A. et al., 2000; Mead-Briggs M.A. et al., 2010)
Deviations:	no
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

#### Materials and methods

Test item:

Name: CHR/I/ADEL 280 SC

Batch number: 05.08.20191

Manufacture date: 05.08.2019

Expiry date: 05.08.2021

Active substance:

245.4 g/L of acetamiprid

30.7 g/L of deltamethrin

Biological test system:

the parasitic wasp, *Aphidius rhopalosiphi* (De Stefani-Perez); Hymenoptera: Braconidae, Aphidinae

– age: adult females (24 – 48 hours after emerging from mummies)

– source: a laboratory-bred culture at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna, the culture was augmented from commercial breeding

Experimental design:

7 study groups:

- a control group (0.0 L/ha)
- CHR/I/ADEL 280 SC at rates:
  - 0.0075 L/ha
  - 0.015 L/ha
  - 0.03 L/ha
  - 0.06 L/ha
  - 0.12 L/ha
- Reference item: Bi 58 Top 400 EC at the rate of 5.0 mL/ha

mortality assessment: 6 replicates/group; 5 females/replicate

CHR/I/ADEL 280 SC/ ADEL 280 SC, PYRIFOS ADE 280 SC.  
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fecundity assessment: 15 replicates/group; 1 females/replicate

Test conditions:

– temperature:

20 – 23°C

– relative air humidity:

65 – 78%

– photoperiod:

16 hours light : 8 hours dark

– light intensity:

mortality and oviposition assessment: 1714 lx

fecundity phase: 5183 lx

Statistical analyses:

– Probit analysis using linear max. likelihood regression,

– Levene's Test on Variance Homogeneity,

– Step-down Cochran-Armitage Test Procedure,

– Shapiro-Wilk's Test on Normal Distribution,

– Williams Multiple Sequential t-test Procedure.

Endpoints:

– wasp mortality after 48 hours of exposure,

– determination of the LR50 and the NOERMortality,

– determination of the ER50 and the NOERfecundity.

– reduction in fecundity (Pr) of the surviving female wasps exposed to CHR/I/ADEL 280 SC, 12 days after the oviposition period

### Results and discussion:

In the definitive test, after 48 hours mortality of the control wasps was 0.0%. Mortality, in the groups treated with CHR/I/ADEL 280 SC at the rates of 0.0075, 0.015, 0.03, 0.06 and 0.12 L/ha were 0.0, 3.3, 10.0, 20.0 and 66.7%, respectively.

At the significance level of 0.05, there were no statistically significant differences in mortality between the wasps exposed to the test item at the rates of 0.0075 and 0.015 L/ha and the control group. At the significance level of 0.05, there were statistically significant differences in mortality between the wasps exposed to the test item at the rates 0.03, 0.06 and 0.12 L/ha and the control group (Step-down Cochran-Armitage Test Procedure,  $p > 0.05$ ).

The LR50 value is 0.095 L/ha (95% confidence limits: 0.074 – 0.140 L/ha) and the NOERMortality is equal to 0.015 L/ha of CHR/I/ADEL 280 SC.

Mortality of the wasps exposed to Bi 58 Top 400 EC at the rate of 5.0 mL/ha was 76.7% after 48 hours. Therefore, the validity criterion specified in the Method description was met [5]. The results showed that the test organisms were sensitive to dimethoate.

The fecundity assessment showed that the mean number of mummies per female in the control group was 6.3. As for the wasps treated with CHR/I/ADEL 280 SC at the rates of 0.0075, 0.015, 0.03 and 0.06 L/ha the mean number of mummies per female were 5.9, 4.8, 4.8 and 4.5, respectively. Fecundity reduction (Pr) in the group treated with the test item at the rates of 0.0075, 0.015, 0.03 and 0.06 L/ha were 7.4, 24.2, 24.2 and 28.4%, respectively.

At the significance level of 0.05, there were no statistically significant differences in fecundity between the wasps exposed to the test item at the rates of 0.0075, 0.015, 0.03 L/ha and the control group. There was statistically significant difference between 0.06 L/ha and the control group (Williams Multiple Sequential t-test Procedure,  $|t| > |t^*|$ ).

The ER50 value is higher than 0.06 L/ha. The NOERfecundity is equal to 0.03 L/ha of the test item. The effects of the test item, CHR/I/ADEL 280 SC on mortality and fecundity of *Aphidius rhopalosiphii* in the extended laboratory test are summarized below.

CHR/I/ADEL 280 SC/ ADEL 280 SC, PYRIFOS ADE 280 SC.  
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Parametr (endpoint)						
Mortality			Fecundity			
Test item [L/ha]	Total	LR <sub>50</sub> [L/ha]	Test item [L/ha]	Mean no. of mummies/ female	Fecundity reduction Pr [%]	ER <sub>50</sub> [L/ha]
	[%]					
Control	0.0	0.095* (0.074 – 0.140)	Control	6.3	–	> 0.16*
0.0075	0.0		0.0075	5.9	7.4	
0.015	3.3		0.015	4.8	24.2	
0.03 <sup>+</sup>	10.0		0.03	4.8	24.2	
0.06 <sup>+</sup>	20.0		0.06 <sup>+</sup>	4.5	28.4	
0.12 <sup>+</sup>	66.7					
NOER <sub>mortality</sub> 0.015 [L/ha]			NOER <sub>fecundity</sub> 0.03 [L/ha]			
Reference item: Bi 58 Top 400 EC						
Reference item [mL/ha]	5.0					
Active ingredient dimethoate [g/ha]	2.0					
Mortality (after 48 h)						
Total [%]	76.7					

\*: statistically significant differences

\*: the ER<sub>50</sub> value is higher than 0.06 L/ha. However, based on ToxRat calculations it could be assumed that theoretical value of ER<sub>50</sub> is 0.16 l/ha

### The validity criteria:

The following validity criteria were met during the study:

- after 48 hours, mortality of the control group was 0.0% (criterion: a maximum of 10.0%),
- after 48 hours, mortality of the group treated with the reference item at the rate of 5.0 mL/ha was 76.7% (criterion: a minimum of 50%),
- all wasps survived the 24-hour oviposition period (criterion: only wasps that survive oviposition can be examined for fecundity),
- the mean number of mummies per female in the control group was 6.3 (criterion: a minimum of 5.0 mummies/female),
- all wasps in the control group gave offspring (criterion: a maximum of 2 females giving no offspring)..

### Conclusion:

On the basis of the obtained mortality results it can be concluded that CHR/I/ADEL 280 SC at the rates of 0.03, 0.06 and 0.12 L/ha has an adverse effect on the mortality of the wasps.

On the basis of the obtained fecundity results it can be concluded that CHR/I/ADEL 280 SC at the rates of 0.0075, 0.015 and 0.03 has no adverse effect on the fecundity of the wasps. The rate 0.06 L/ha has an adverse effect on the fecundity of the wasps..

### A 2.3.1.7.3 Study 3

<b>Comments of zRMS:</b>	The study was conducted to the guideline and according to the principles of GLP. All validity criterions were met. The study is considered to be reliable and suitable for the risk assessment.
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Reference:	KCP 10.3/05
Report	An extended laboratory test for evaluating effects of CHR/I/ADEL 280 SC on the ladybird beetle, <i>Coccinella septempunctata</i> (L.), Study code: B-12-21, M. Knapik
Guideline(s):	according to the ESCORT 1 (Barrett K.L. et al., 1994) and the ESCORT 2 (Candolfi M.P. et al., 2001) guidance documents and the guidelines developed by the IOBC, BART, and EPPO Joint Initiative (Schmuck et al., 2000)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

#### Materials and methods

Test item:

CHR/I/ADEL 280 SC

content: 245.4 g/L of acetamiprid, 30.7 g/L of deltamethrin

batch no.: 05.08.2019

production date: 05.08.2019

expiry date: 05.08.2021

Biological test system:

the ladybird beetle, *C. septempunctata* L. (Arthropoda: Coccinellidae)

– age:

3-day-old larvae

– source:

Beetles was obtained from commercial breeder (Katz Biotech AG, Germany)

Experimental design:

7 study groups:

– a control group (0.0 L/ha)

– CHR/I/ADEL 280 SC at the rates of:

- 0.03125 mL/ha

- 0.125 mL/ha

- 0.5 mL/ha

- 2.0 mL/ha

- 8.0 mL/ha

– Bi 58 Top 400 EC at the rate of 8.0 mL/ha

number of replicates: 40 replicates/group

number of larvae: 1 larva of *Coccinella septempunctata* /replicate

Test conditions:

- temperature:  
23.0 – 27.0°C
- relative air humidity:  
60.1 – 89.9%
- photoperiod:  
16 hours light : 8 hours dark
- light intensity 2742 lx

Statistical analysis:

Logit analysis using linear max. likelihood regression, Step-down Cochran-Armitage Test Procedure

Endpoints:

- preimaginal mortality of the ladybird beetles
- LR50
- NOERMortality
- reproductive performance of the moulted beetles over a period of 14 days (the mean number of fertile eggs/female/day) reproduction reduction (Pr)

**Results and discussion:**

The extended laboratory test involved the evaluation of the effects of the test item, CHR/I/ADEL 280 SC on mortality and reproductive capacity of the ladybird beetle, *Coccinella septempunctata*. In a definitive test, five test item application rates of 0.03125, 0.125, 0.5, 2.0 and 8.0 mL/ha were used.

To assess mortality of the ladybird beetles, *Coccinella septempunctata* L., 3-day-old larvae were exposed to the test item applied to leaf discs. There were 40 replicates of each treated group. Each replicate contained 1 larva of *C. septempunctata* L. The larvae were fed with the fresh aphids, *Acyrtosiphon pisum* until pupation. During the exposure phase, survival, condition and development of the ladybird beetles were regularly assessed until the end of pupation. After emergence of the adults, pre-imaginal mortality was calculated on the basis of the numbers of dead larvae, pupae, and adults which died during emergence.

After completion of mortality assessment, healthy hatched beetles from the control group and from group treated with the test item at the rates of 0.03125, 0.125, 0.5 mL/ha were subjected to evaluate the reproductive performance. To allow egg-laying, adult ladybirds were transferred to separate reproduction units. The beetles had continuous access to food in the form of a honey-water solution (2:1), pine pollen (*Pinus* sp.) and the broad bean plants infested with the aphid, *A. pisum*. Reproductive performance observations, concerning the numbers of eggs laid and their fertility were made over a period of 14 days. To check the relative susceptibility of the test system and the sensitivity of the test method, an insecticide, Bi 58 Top 400 EC (400 g dimethoate/L) was used as a reference item. The rate of the reference item was 8.0 mL/ha. Control beetles had contact with leaf discs sprayed with distilled water. The effects of the test item, CHR/I/ADEL 280 SC on mortality and reproductive capacity of the ladybird beetle, *Coccinella septempunctata* L. in the laboratory test are summarized below.

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Study group	Parameters (endpoints)						
	Mortality			Reproduction			
Test item [mL/ha]	[%]	[%] <sup>a</sup>	LR <sub>50</sub> [mL/ha]	Mean no. of eggs/female/day	Mean no. of fertile eggs/female/day	Reproduction Pr reduction Pr [%]**	ER <sub>50</sub> [mL/ha]
Control (0.0)	7.5	–	0.67965 (0.01897 – 84.76429*)	5.4	3.8	–	> 0.5
0.03125	20.0	13.5		5.9	4.0	-5.3	
0.125+	27.5	21.6		12.1	7.9	-107.9	
0.5+	30.0	24.3		13.3	8.5	-123.7	
2.0+	72.5	70.3		-	-	-	
8.0+	100.0	100.0		-	-	-	
NOER <sub>mortality</sub>	0.03125 [mL/ha]						
Bi 58 Top 400 EC							
Reference item [mL/ha]	100.0	100.0	–				
8.0							

<sup>a</sup>: mortality was corrected according Abbott's equation [1]<sup>+</sup>: statistically significant differences

\* - confidence limits

<sup>\*\*</sup> - The negative values means that in the tested rates there were higher mean numbers of fertile eggs per viable female per day than in the control group**Test validity criteria:**

The following validity criteria were met during the study [6]:

- pre-imaginal mortality of the control group was 7.5% (criterion: a maximum of 30.0%),
- mean corrected mortality of the reference item group was 100.0% (criterion: a minimum of 40%),
- fertility (the mean number of fertile eggs/female/day) in the control group was 3.8 (criterion:  $\geq 2$  fertile eggs/female).

**Conclusion:**

The validity criterion concerning mortality was met, because mortality of the ladybird beetle, *Coccinella septempunctata* L. in the control group was equal to 7.5% ( $\leq 30.0\%$ ). The corrected mortality of the ladybird beetles exposed to the test item at the rates of 0.03125, 0.125, 0.5, 2.0 and 8.0 mL/ha, after Abbott's correction, were 13.5, 21.6, 24.3, 70.3 and 100.0%, respectively.

At the significance level of 0.05, there were statistically significant differences in mortality between the ladybirds exposed to the test item at the rates of 0.125, 0.5, 2.0 and 8.0 mL/ha of CHR/I/ADEL 280 SC and the control group (Step-down Cochran-Armitage Test Procedure, ( $\alpha=0.05$ )). At the significance level of 0.05, there were no statistically significant differences in mortality between the ladybirds exposed to the test item at the rate of 0.03125 mL/ha of CHR/I/ADEL 280 SC and the control group (Step-down Cochran-



CHR/I/ADEL 280 SC/ ADEL 280 SC, PYRIFOS ADE 280 SC.  
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Armitage Test Procedure, ( $\alpha=0.05$ )).

The LR50 value is equal to 0.67965 mL/ha (confidence limits: 0.01897 – 84.76429) of CHR/I/ADEL 280 SC. The NOERMortality is equal to 0.03125 mL/ha of CHR/I/ADEL 280 SC.

The corrected mortality of the ladybird beetles exposed to the reference item at the rate of 8.0 mL of Bi 58 Top 400 EC/ha, after Abbott's correction, was equal to 100.0%. Therefore, the validity criterion was met. The results showed that the insects were sensitive to dimethoate.

The mean number of fertile eggs/female/day in the control group was 5.4 (criterion:  $\geq 2$  eggs/female/day). The mean numbers of fertile eggs/female/day in the group treated with the of CHR/I/ADEL 280 SC at the rates of 0.03125, 0.125 and 0.5 mL/ha were equal to 5.9, 12.1 and 13.3 it refers to -5.3, -107.9 and -123.7% reproduction reduction. The negative values means that in the tested rates there were higher mean numbers of fertile eggs per viable female per day than in the control group.

It can be concluded that CHR/I/ADEL 280 SC at the rates of 0.03125, 0.125 and 0.5 mL/ha had no adverse effect on the reproduction capacity of the ladybird beetle. The ER50 value is above 0.5 mL/ha of CHR/I/ADEL 280 SC..

#### A 2.3.1.7.4 Study 4

<b>Comments of zRMS:</b>	The study was conducted to the guideline and according to the principles of GLP. All validity criteria were met. The study is considered to be reliable and suitable for the risk assessment.
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Reference:	KCP 10.3/06
Report	An extended laboratory test for evaluating effects of CHR/I/ADEL 280 SC on the green lacewing, <i>Chrysoperla carnea</i> (Steph.), Study code: B-13-21, M. Knapik
Guideline(s):	according to the ESCORT 1 (Barrett K.L. et al., 1994) and the ESCORT 2 (Candolfi M.P. et al., 2001) guidance documents and the guidelines developed by the IOBC, BART, and EPPO Joint Initiative (Vogt H. et al., 2000)
Deviations:	No.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

#### Materials and methods

Test item:	CHR/I/ADEL 280 SC content: 245.4 g/L of acetamiprid 30.7 g/L of deltamethrin batch no.: 05.08.2019 production date: 05.08.2019 expiry date: 05.08.2021
Biological test system:	the green lacewing, <i>Chrysoperla carnea</i> (Steph.), Neuroptera: Chrysopidae
– age:	first instars' larvae (3 days old)
– source:	a laboratory culture at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna; the culture was augmented by commercial breeder

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Experimental design:

7 study groups:

- a control group (0.0 L/ha)
- CHR/I/ADEL 280 SC at the rates of
- 0.000625 L/ha
- 0.0025 L/ha
- 0.01 L/ha
- 0.04 L/ha
- 0.16 L/ha
- dimethoate at the rate of 15.0 g/ha

number of replicates: 30 replicates/group

number of larvae: 1 larva of *Chrysoperla carnea* /replicate

Test conditions:

- temperature: 23.0 – 26.3°C
- relative air humidity: 60.1 – 89.9%
- photoperiod: 16 hours light : 8 hours dark
- light intensity: 3003 lux

Statistical analysis:

Logit analysis using linear max. likelihood regression, Step-down Cochran-Armitage Test Procedure

Endpoints:

- cumulative mortality of larvae, pupae, and adults after emergence
- LR50 value
- reproduction of the lacewings:
- fecundity (mean number of eggs/female/day)
- fertility (mean hatching rate)

## Results and discussion:

The extended laboratory test involved the evaluation of the effects of the test item, CHR/I/ADEL 280 SC on mortality and reproductive capacity of the green lacewing, *Chrysoperla carnea*. In a definitive test, five test item application rates of 0.000625, 0.0025, 0.01, 0.04 and 0.16 L/ha were used.

To assess mortality, 3-day-old larvae of *Chrysoperla carnea* were exposed to dry residues of the test item on leaf discs. Eggs of the mill moth *Ephestia kuehniella* were offered as food. After emergence of adults, total mortality was calculated on the basis of the numbers of dead larvae, pupae, and adults which died during emergence. There were 30 replicates of each treated group. Each of them contained 1 larva of *Chrysoperla carnea*.

To determine possible adverse effects of the test item on fecundity and fertility of the lacewings, reproductive performance was conducted during 6 days.

Total mortality of the lacewings, the mean number of eggs laid per female lacewing per day, and the mean hatching rate were the endpoints.

To control the sensitivity of the biological test system, an insecticide, dimethoate was used as a reference item. The rate of the reference item was 15.0 g/ha. Control lacewings had contact with discs sprayed with distilled water. The effects of the test item, CHR/I/ADEL 280 SC on mortality and reproductive capacity the green lacewings, *Chrysoperla carnea* (Steph.) in the laboratory test are summarized below.

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Study group [application rate]	Parameter (endpoints)				
	Mortality			Reproduction	
Test item [L/ha]	[%]	[%] <sup>a</sup>	LR <sub>50</sub> [L/ha]	Mean number of eggs/female /day [no.]	Mean hatching rate [%]
Control (0.0)	10.0	-	0.071911	15.3	86.6
0.000625	16.7	7.4		20.3	76.8
0.0025	20.0	11.1		28.6	86.2
0.01	13.3	3.7		14.6	62.9
0.04	26.7	18.5		16.8	83.9
0.16 <sup>+</sup>	86.7	85.2			
NOER <sub>mortality</sub>	0.04 [L/ha]				
Reference item [g/ha]	Dimethoate				
15.0	70.0	66.7	-		

<sup>a</sup>: mortality was corrected according Abbott's equation [1]<sup>+</sup>: statistically significant differences**The validity criteria:**

The following validity criteria were met during the study:

- pre-imaginal mortality of the control group was 10.0% (criterion: a maximum of 20.0%),
- mean mortality of the reference item group was 66.7% (criterion: a minimum of 50%),
- the mean number of eggs per female per day in the control group (fecundity) was 15.3 (criterion:  $\geq 15.0$ ),
- the mean hatching rate in the control group (fertility) was 86.6 (criterion:  $\geq 70\%$ ).

**Conclusion:**

The validity criterion concerning mortality was met, because mortality of the green lacewings, *Chrysoperla carnea* (Steph.) in the control group was 10.0%. The corrected mortality of the green lacewings exposed to the test item at the rates of 0.000625, 0.0025, 0.01, 0.04 and 0.16 L/ha of CHR/I/ADEL 280 SC was 7.4, 11.1, 3.7, 18.5 and 85.2%, respectively.

There were statistically significant differences in mortality of the green lacewings in the groups treated with the test item at the rate of 0.16 L/ha in comparison to the control group. There were no statistically significant differences in mortality of the green lacewings in the groups treated with the test item at the rates of 0.000625, 0.0025, 0.01 and 0.04 L/ha in comparison to the control group (Step-down Cochran-Armitage Test Procedure,  $p(\text{trend}) > \alpha$ , ( $\alpha=0.05$ )).

The LR<sub>50</sub> value is equal to 0.071911 L/ha. The NOER<sub>mortality</sub> value is equal to 0.04 L/ha.

The percentage of mortality of *Ch. carnea* (Steph.) exposed to dimethoate at rate of 15.0 g/ha, after Abbott's corrections, was 66.7%. The results obtained in the reference item group indicated that the biological test

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system was sensitive to dimethoate.

The reproduction in the group treated with the test item at the rate of 0.16 L/ha were not assessed due to mortality higher than 50%.

The mean number of fertile eggs/female/day in the control group was equal to 15.3 (criterion:  $\geq 15.0$ ). The mean numbers of fertile eggs/female/day in the groups treated with CHR/I/ADEL 280 SC at the rates of 0.000625, 0.0025, 0.01 and 0.04 L/ha were equal to 20.3, 28.6, 14.6 and 16.8, respectively. The mean hatching rate in the control group was 86.6% (criterion:  $\geq 70\%$ ). The mean hatching rate in the groups treated with the test item at the rates of 0.000625, 0.0025, 0.01 and 0.04 L/ha were 76.8, 86.2, 62.9 and 83.9%, respectively.

Fecundity reduction (Pr) in the group treated with the test item at the rates 0.000625, 0.0025, 0.01 and 0.04 L/ha were 11.3, 0.5, 27.4 and 3.1%, respectively.

Based on the results, it can be presumed that CHR/I/ADEL 280 SC at the rates of 0.000625, 0.0025 and 0.04 L/ha had no adverse effect on the reproductive performance of the lacewings. CHR/I/ADEL 280 SC at the rate of 0.01 L/ha had adverse effect on the reproductive performance of the lacewings.

Comments of zRMS:	The study was conducted to the guideline and according to the principles of GLP. All validity criterions were met. The study is considered to be reliable and suitable for the risk assessment.
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CHR/I/ADEL 280 SC – A Series of Aged-Residue Extended Laboratory Tests to Determine Effects on the Ladybird Beetle, *Coccinella septempunctata* (Coleoptera: Coccinellidae)

Study code: CHR-22-02

Mambo-Tox Part of Cawood 2 venture Road University Science Park Southampton SO16 7 NP, UK.

**CHR/I/ADEL 280 SC – A Series of Aged-Residue Extended Laboratory Tests to Determine Effects on the Ladybird Beetle, *Coccinella septempunctata* (Coleoptera: Coccinellidae)**

**1. SUMMARY**

Aims

The test item in this study was CHR/I/ADEL 280 SC, a suspension concentrate formulation containing acetamiprid (nominally 250 g/L) and deltamethrin (nominally 30 g/L). The aim of this study was to evaluate the effects of both freshly-dried and field-aged foliar residues of the test item on the ladybird beetle, *Coccinella septempunctata* L. (Coleoptera: Coccinellidae), under extended laboratory test conditions.

Methods

CHR/I/ADEL 280 SC was evaluated at a single application rate, equivalent to 0.08 L test item/ha. The bioassay programme commenced on the day of treatment application, with the test item being compared to a water-treated control. A toxic reference treatment of dimethoate (an EC formulation nominally 400 g a.s./L, applied at a rate of 100 mL/ha) was also included in the initial bioassay only.

Treatments were applied to mature apple trees (*Malus domestica* Borkh., var. Bramley). Applications were made using a hand-held small-plot sprayer fitted with a 2-m-wide spray boom. This was calibrated so that when the boom was moved over the tops of the plants it delivered a volume rate equivalent to 400 L spray solution/ha. Following treatment applications, the apple trees were maintained outdoors, but their foliage was protected from rainfall by suspending a sheet of polythene permeable to UV light above them.

Extended laboratory bioassays were carried out using leaves collected from the treated trees. The first bioassay commenced shortly after residues had dried following the treatment applications, hereafter referred to as 0 days after treatment (0 DAT), and a subsequent bioassay commencing at 12 DAT. Excised leaves were used to line the floor of the test arenas (n = 40 per treatment) into which individual larvae of *C. septempunctata* (4-5 days old) were introduced. The larvae were fed with pea aphids (*Acyrtosiphon pisum* (Harris)) and any pre imaginal mortality of the ladybirds was recorded. A check was then made for sub-lethal effects on the reproductive performance of the adults surviving in the control and the test-item treatment rate in the 0 and 12 DAT bioassays, since the test item resulted in  $\leq 50\%$  corrected pre-imaginal mortality, in each bioassay. For this assessment, the number of eggs produced by the beetles (i.e. a measure of fecundity) was recorded for a 14-day period and the number that hatched (i.e. a measure of fertility) was also assessed.

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The intention of the bioassay programme was to demonstrate that residues of the test item did not result in unacceptable effects in two consecutive bioassays (i.e. demonstrating that corrected pre-imaginal mortality was  $\leq 50\%$  and that certain fecundity and fertility criteria were met).

### Results

The results of the mortality assessments are summarised below.

Bioassay initiated	Treatment	Test-item rate (L/ha)	% pre-imaginal mortality <sup>a)</sup>	Corrected % pre-imaginal mortality <sup>b)</sup>
0 DAT	Control	-	10.0	-
	CHR/I/ADEL 280 SC	0.08	7.5	-2.8
	Toxic reference	-	97.5*	97.2
12 DAT	Control	-	0.0	-
	CHR/I/ADEL 280 SC	0.08	0.0	0.0

a) For each bioassay, pre-imaginal mortality in the test item treatment and the toxic reference treatment was compared to the control using Fisher's exact binomial test (one-sided,  $>$  control,  $\alpha = 0.05$ ). An asterisk (\*) indicates where differences were significant.

b) Corrected mortalities were calculated using Abbott's formula. A positive value indicates an increase and a negative value a decrease in mortality, relative to the control.

The results of the reproduction assessments are summarised below.

Bioassay initiated	Treatment	Test-item rate (L/ha)	Mean no. eggs/♀/day	Mean % egg viability	Mean no. viable eggs/♀/day
0 DAT	Control	-	20.0	54.4	10.9
	CHR/I/ADEL 280 SC	0.08	17.2	37.4	6.4
12 DAT	Control	-	22.2	68.8	15.3
	CHR/I/ADEL 280 SC	0.08	24.3	56.4	13.7

In the 0 and 12 DAT bioassays, the mean numbers of viable eggs produced in all the treatments evaluated was  $\geq 2.0$  eggs/female/day. This threshold is currently viewed as being indicative of no harmful treatment effects.

### Conclusions

The effects of both fresh and aged foliar residues of CHR/I/ADEL 280 SC on the ladybird beetle, *Coccinella septempunctata*, were evaluated under extended laboratory conditions. When applied at a rate equivalent to 0.08 L test item/ha, fresh residues (0-day-old) of CHR/I/ADEL 280 SC and the subsequent bioassay evaluating 12-day-old foliar residues of CHR/I/ADEL 280 SC, showed no unacceptable effects on either the survival, or the subsequent reproductive capacity of the ladybirds.

## **A 2.4 KCP 10.4 Effects on non-target soil meso- and macrofauna**

### **A 2.4.1 KCP 10.4.1 Earthworms**

#### **A 2.4.1.1 KCP 10.4.1.1 Earthworms - sub-lethal effects**

<b>Comments of zRMS:</b>	The study was conducted to OECD 222 the guideline and according to the principles of GLP. All validity criterions were met. The study is considered to be reliable and suitable for the risk assessment.
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Reference:	KCP 10.4/01
Report	Acetamiprid + Deltametryna (250+30) SC (CHR/I/ADEL 280 SC) Earthworm reproduction test ( <i>Eisenia andrei</i> )
Guideline(s):	According to the OECD Guideline No. 222 (2016)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	-
<b>Materials and methods:</b>	
Test item:	Acetamiprid + Deltametryna (250+30) SC (CHR/I/ADEL 280 SC) batch no.: 05.08.2019
Active substances:	acetamiprid: 245.4 g/L deltamethrin: 30.7 g/L
Artificial soil:	10% sphagnum peat, 20% kaolin clay, 70% air-dried quartz sand
Test organism:	the earthworm, <i>Eisenia andrei</i> obtained from a standard laboratory culture cultivated at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna, Department of Ecotoxicological Studies, Laboratory of Soil Organisms Toxicology

Test design:	test duration: 8 weeks; number of replicates: 4
Concentrations of the test item:	replicates/concentration + 8 replicates/control; number of earthworms: 10 earthworms/replicate control, 0.10, 0.18, 0.32, 0.56, 1.00, 1.80, 3.20, 5.60, 10.00, 18.00 and 32.00 mg/kg dry weight of the artificial soil
Test conditions:	temperature: 19.8 – 22.0°C; pH at the beginning of the experiment: 5.76 – 5.88; pH at the end of the experiment: 5.60 – 5.70; soil moisture content at the beginning of the experiment: 19.7 – 21.1% (44.1 – 47.2% of the maximum water holding capacity); soil moisture content at the end of the experiment: 19.2 – 21.1% (43.0 – 47.2% of the maximum water holding capacity); light-dark cycle: 16h : 8h; light intensity at the beginning of the experiment: 594 – 678 lux light intensity at the end of the experiment: 573 – 665 lux
Statistical analysis:	EC10, EC20, EC50, – probit analysis using linear max. likelihood regression, LC50 - logit analysis using linear max. likelihood regression, NOEC (reproduction) – Shapiro-Wilk’s Test on Normal Distribution, Bartlett’s Test Procedure on Variance Homogeneity (with Residuals), Williams Multiple Sequential t-test Procedure, NOEC (survival) – Fisher’s Exact Binomial Test with Bonferroni Correction LOEC: a values suggested by the ToxRat Professional 2.10 statistical computer software
Endpoint:	EC10, EC20, EC50, NOEC, LOEC (reproduction) LC50, NOEC, LOEC (survival)

**Results and discussion:**

At concentrations ranging from 0.10 to 32.00 mg of the test item/kg dry weight of artificial soil, after 4 weeks of exposure to the test item, mortality of the adult earthworms was between 2.5 and 92.5%. As for the control group, mortality of the adult earthworms was equal to 6.3%. The concentration of the test item causing 50% mortality of the adult earthworms (LC50) is equal to 28.65 mg/kg dry weight of the artificial soil (equal to 6.46 mg of acetamiprid and 0.81 mg of deltamethrin/kg dry weight of the artificial soil). No changes in the appearance (morphology) and behaviour of the living adult earthworms were noticed. After 4 weeks of the exposure period of the test item at the concentrations ranging from 0.10 to 32.00 mg/kg dry weight of artificial soil, the body weight increase was between -20.3 and 5.6%. As for the control group, the body weight increase was equal to 1.7%.

**After 8 weeks of the experiment, the obtained results led to the following conclusions:**

After the application of the test item at the concentrations ranging from 0.10 to 18.00 mg/kg dry weight of the artificial soil, the mean number of juveniles was between 52.5 and 186.0 per replicate. At the



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concentration equal to 32.00 mg/kg dry weight of the artificial soil, no juveniles of earthworms were observed. The mean number of juveniles in the control group was equal to 161.5 per replicate.

After 8 weeks of the experiment, it was concluded that Acetamiprid + Deltamethrin (250+30) SC (CHR/I/ADEL 280 SC) had a statistically significant impact on reproduction of the earthworms at the concentrations ranging from 3.20 to 32.00 mg/kg dry weight of the artificial soil.

The endpoint values showing the impact of the test item on reproduction and survival of adult earthworms are presented in the table given below.

Parameter	Value [mg test item/kg dry weight of artificial soil]	Value [mg of acetamiprid/kg dry weight of artificial soil]	Value [mg of deltamethrin/kg dry weight of artificial soil]
EC <sub>10</sub>	5.91 (2.22 – 8.33)	1.33 (0.50 – 1.88)	0.17 (0.06 – 0.24)
EC <sub>20</sub>	7.82 (3.92 – 10.28)	1.76 (0.88 – 2.32)	0.22 (0.11 – 0.29)
EC <sub>50</sub>	13.34 (10.10 – 17.68)	3.01 (2.28 – 3.98)	0.38 (0.28 – 0.50)
NOEC (reproduction)	1.80	0.41	0.05
LOEC (reproduction)	3.20	0.72	0.09
LC <sub>50</sub>	28.65	6.46	0.81
NOEC (survival)	18.00	4.06	0.51
LOEC (survival)	32.00	7.21	0.90

#### Validity criteria:

The results are considered valid because the following criteria were satisfied in the controls:

- each replicate produced from 141 to 189 juveniles (161.5 mean) at the end of the experiment (criterion:  $\geq 30$  juveniles by the end of the experiment),
- the coefficient of variation of reproduction was 11.7% (criterion:  $\leq 30\%$ ),
- adult mortality over the initial 4 weeks of the experiment was 6.3% (criterion:  $\leq 10\%$ ).

#### A 2.4.1.2 KCP 10.4.1.2 Earthworms - field studies

No additional studies were performed.

#### A 2.4.2 KCP 10.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms)

##### A 2.4.2.1 KCP 10.4.2.1 Species level testing

**A 2.4.2.1.1 Study 1**

<b>Comments of zRMS:</b>	The study was conducted to OECD 232 the guideline and according to the principles of GLP. All validity criterions were met. The study is considered to be reliable and suitable for the risk assessment.
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<b>Reference:</b>	KCP 10.4/02
<b>Report</b>	CHR/I/ADEL 280 SC – A Laboratory Study to Determine the Effects of Fresh Residues on the Springtail Folsomia candida (Collembola, Isotomidae) in an Artificial Soil Substrate, Study code: CHR-21-09, A. Cooper
<b>Guideline(s):</b>	OECD Guidelines for Testing Chemicals. Collembolan reproduction test in soil (OECD 232, 2016) ISO Soil quality – Inhibition of reproduction of Collembola (Folsomia candida) by soil contaminants (ISO 11267, 2014)
<b>Deviations:</b>	No
<b>GLP:</b>	Yes
<b>Acceptability:</b>	Yes
<b>Duplication (if vertebrate study)</b>	No

**Materials and methods**

Product code	=	CHR/I/ADEL 280 SC
Formulation type	=	suspension concentrate (SC)
Batch number	=	05.08.2019
Active substance	=	a) acetamiprid                      b) deltamethrin
Nominal content of a.s.	=	a) 250 g/L                              b) 30 g/L
Measured content of a.s.	=	a) 245.4 g/L                          b) 30.7 g/L
Appearance	=	white liquid
Measured density	=	1.0886 g/cm <sup>3</sup>
Date of expiry	=	05 August 2021
Storage at Test Facility	=	ambient laboratory conditions (< 30°C)

A preliminary range-finding bioassay was carried out with five concentrations of the test item and an untreated (water only) control. The endpoints were an assessment of the condition of the introduced springtails at 21 days and an assessment of their reproduction, i.e. the numbers of F1 progeny present 21 days after treatment (DAT).

A definitive bioassay was then carried out using nine treatment concentrations of the test item and an untreated (water only) control. The endpoints were an assessment of the condition of the introduced springtails at 28 days and an assessment of their reproduction, i.e. the numbers of F1 progeny present at 28 DAT.

The intention was to determine values for the lowest-observed-effect concentration (LOEC), the no observed effect concentration (NOEC) with respect to both springtail survival and reproduction. In addition, key effect concentrations (EC<sub>50</sub>, EC<sub>20</sub> and EC<sub>10</sub>) for reproduction, and the median lethal concentration (LC<sub>50</sub>) for the springtails originally introduced, were also to be determined, if the data permitted.

## Results and discussion:

### Aim

The test item in this study is CHR/I/ADEL 280 SC, a suspension concentrate formulation containing acetamiprid (nominally 250 g/L) and deltamethrin (nominally 30 g/L). The aim was to determine, under laboratory test conditions, whether the test item had harmful effects on the survival and reproductive success of adults of the springtail *Folsomia candida* (Willem) (Collembola, Isotomidae).

### Methods

Following a preliminary range-finding bioassay, CHR/I/ADEL 280 SC was evaluated in a definitive test at nine treatment concentrations, equivalent to 10, 5.556, 3.086, 1.715, 0.953, 0.529, 0.294, 0.163 and 0.091 mg test item/kg soil dry weight, which was compared to an untreated (water only) control.

Treatments were incorporated into an artificial soil substrate (containing 5% w/w peat), aliquots of which were then transferred into small, ventilated, glass jars (n = 8 for control; n = 4 for test-item treatment concentrations). For both treatments, the soil moisture content was maintained at 50% ( $\pm$  10%) of the *maximum water-holding capacity* (WHC<sub>max</sub>) throughout the bioassay.

Ten juvenile *F. candida* (11-12 days old) were placed into each arena within approximately 60 minutes of treatment application. As food, granulated dry yeast was added to the soil surface of each test arena, at the beginning of the test and again at 14 days after treatment (DAT). The lids of the arenas were securely fastened during the test with ventilated lids, to allow fresh air into the arenas. The number of both surviving adults and of F1 progeny (i.e. juvenile springtails) in each test arena was assessed at 28 DAT.

The results were used to determine the *lowest-observed-effect concentration* (LOEC) and the *no-observed-effect concentration* (NOEC) for the test item with respect to the assessments of both mortality and reproduction. In addition, a value for the median *lethal concentration* (LC<sub>50</sub>) and the *key effect concentrations* (EC<sub>50</sub>, EC<sub>20</sub> and EC<sub>10</sub>) with respect to reproduction were derived from the results.

### Results

The results of assessments are summarised in Table A. The 28 DAT LC<sub>50</sub> value was 2.024 mg CHR/I/ADEL 280 SC/kg soil dry weight. At 28 DAT, based on the numbers of offspring produced, the EC<sub>50</sub>, EC<sub>20</sub> and EC<sub>10</sub> values were calculated to be 2.475, 1.365 and 1.000 mg CHR/I/ADEL 280 SC/kg soil dry weight, respectively. The NOEC and LOEC values with respect to both springtail survival and reproduction were 0.953 and 1.715 mg CHR/I/ADEL 280 SC/kg soil dry weight, respectively.

CHR/ADEL 280 SC/ ADEL 280 SC, PYRIFOS ADE 280 SC.  
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*Table A. The effects of CHR/ADEL 280 SC on the survival and reproduction of the springtail *Folsomia candida*.*

Treatment	Test item conc. [mg test item/ kg soil dry wt.]	% mortality at 28 DAT <sup>a)</sup>	Mean no. progeny per replicate <sup>b)</sup>	% change in no. progeny, relative to control <sup>c)</sup>
Control	0	15	229	0
CHR/ADEL 280 SC	10.000	90*	0*	100
	5.556	73*	22*	90
	3.086	53*	101*	-56
	1.715	38*	164*	-20
	0.953	23	223	3
	0.529	23	210	8
	0.294	13	312	36
	0.163	18	242	6
	0.091	25	219	4
mg CHR/ADEL 280 SC/kg soil dw				
LC <sub>50</sub> (and 95% CL) <sup>d)</sup>		2.024	(0.937 and 6.803)	
EC <sub>50</sub> (and 95% CL) <sup>e)</sup>		2.475	(1.793 and 3.415)	
EC <sub>20</sub> (and 95% CL) <sup>e)</sup>		1.365	(0.829 and 2.222)	
EC <sub>10</sub> (and 95% CL) <sup>e)</sup>		1.000	(0.517 and 1.915)	

a) Percentage mortality of springtails originally introduced, recorded at 28 days. The test item treatments were compared to the control using step-down Cochran-Armitage test ( $\alpha = 0.05$ , one-sided, > control). An \* indicates a statistically significant difference.

b) The test item treatments were compared to the control by Williams' multiple-sequential t test ( $\alpha = 0.05$ , one-sided, < control). An \* indicates a statistically significant difference.

c) A negative value indicates a decrease, and a positive value an increase, in reproduction, relative to the control data.

d) The median Lethal Concentration (LC<sub>50</sub>) value was calculated by Probit analysis of the data using linear maximum likelihood regression.

e) Specific Effect Concentration (EC<sub>50</sub>, EC<sub>20</sub>, EC<sub>10</sub>) values were calculated using non-linear regression analysis by 3-parameter normal cumulative distribution function.

### Mortality assessments in definitive bioassay

The results of assessments of the mortality of adult springtails during the definitive bioassay are presented in Appendix V and summarised in Table 1.

Table 1. Percentage mortality of adult springtails at 28 DAT in the definitive test.

Treatment	Test item concentration mg CHR/I/ADEL 280 SC/ kg soil dry weight	% mortality at 28 days <sup>a)</sup>
Control	-	15
CHR/I/ADEL 280 SC	10.000	90 *
	5.556	73 *
	3.086	53 *
	1.715	38 *
	0.953	23
	0.529	23
	0.294	13
	0.163	18
	0.091	25
<u>mg CHR/I/ADEL 280 SC/kg soil dry weight</u>		
LC <sub>50</sub> value <sup>b)</sup> (95% confidence limits)	2.024 (0.937 and 6.803)	
NOEC value	0.953	
LOEC value	1.715	

a) Mortality in the test item treatments was compared to the control using step-down Cochran-Armitage test ( $\alpha = 0.05$ , one-sided, > control). An \* indicates a statistically significant difference.

b) The *median Lethal Concentration* value was calculated by Probit analysis of the data using linear maximum likelihood regression.

### Reproduction assessments in definitive bioassay

The results of assessments of the reproduction of the springtails are presented in Appendix V and summarised in Table 3.

Table 3. Number of juvenile springtails produced by 28 DAT in the definitive test.

Treatment	Test item concentration mg CHR/I/ADEL 280 SC/ kg soil dry weight	Mean juveniles per replicate <sup>a)</sup>	% change relative to the control <sup>b)</sup>
Control	-	229	-
CHR/I/ADEL 280 SC	10.000	0 *	-100
	5.556	22 *	-90
	3.086	101 *	-56
	1.715	164 *	-29
	0.953	223	-3
	0.529	210	-8
	0.294	312	36
	0.163	242	6
	0.091	219	-4
<b>mg CHR/I/ADEL 280 SC/kg soil dry weight</b>			
EC <sub>50</sub> value (95% confidence limits)		2.475 (1.793 and 3.415)	
EC <sub>20</sub> value (95% confidence limits)		1.365 (0.829 and 2.222)	
EC <sub>10</sub> value (95% confidence limits)		1.000 (0.517 and 1.915)	
NOEC value		0.953	
LOEC value		1.715	

- a) The mean number of progeny produced per replicate. The test-item treatments were compared to the control using Williams' multiple sequential t-test ( $\alpha = 0.05$ , one-sided, < control). An \* indicates a statistically significant difference.
- b) A negative value indicates a decrease, and a positive value an increase, in reproduction, relative to the control data.
- c) Specific *Effect Concentration* (EC<sub>50</sub>, EC<sub>20</sub> and EC<sub>10</sub>) values were calculated using non-linear regression analysis by 3-parameter normal cumulative distribution function.

### Conclusions

In a laboratory test with CHR/I/ADEL 280 SC and the springtail *Folsomia candida*, the 28-day LC<sub>50</sub> value was 2.024 mg CHR/I/ADEL 280 SC/kg soil dry weight. The 28-day EC<sub>50</sub>, EC<sub>20</sub> and EC<sub>10</sub> values for reproduction were 2.475, 1.365 and 1.000 mg CHR/I/ADEL 280 SC/kg soil dry weight, respectively. The NOEC value with respect to assessments of both adult springtail survival and reproduction was 0.953 mg CHR/I/ADEL 280 SC/kg soil dry weight.

### VALIDITY CRITERIA

According to OECD Guideline 232 (2016), for the test to be deemed valid:

- a) control treatment mortality should not exceed 20% at the end of the test (actual value of control = 15%).

- b) the mean number of juveniles recorded in the control treatment should be at least 100 per replicate at the end of the test (actual value of control in test = 229).
- c) the coefficient of variation of reproduction in the control should not exceed 30% (actual value in control = 28.3%).

Thus, all of these criteria were met.

It also recommended that the efficiency of the method used to extract the springtails in this test should be > 95%. In a separate test, reported by the Test Facility in April 2019, this was determined to be 100% for the adult springtails and 99.3% for the juvenile springtails (Cooper, 2019).

#### A 2.4.2.1.2 Study 2

Comments of zRMS:	<p>The study was conducted to OECD 226 the guideline and according to the principles of GLP. All validity criterions were met. The study is considered to be reliable and suitable for the risk assessment.</p> <p>Agreed endpoints:</p> <p>EC<sub>10; reproduction</sub> = 9.6 mg prod./kg dw</p> <p>NOEC<sub>reproduction</sub> = 18 mg/kg dw soil</p>
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Reference:	KCP 10.4/03
Report	Acetamiprid + Deltametryna (250+30) SC (CHR/I/ADEL 280 SC) Predatory mite (Hypoaspis (Geolaelaps) aculeifer) reproduction test in soil, Study code: G -73-20, P Pieczka
Guideline(s):	according to the OECD Guideline No. 226 (2008)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

#### Materials and methods

Test item:  
 Acetamiprid + Deltametryna (250+30) SC  
 (CHR/I/ADEL 280 SC)  
 batch number: 05.08.2019  
 Active substance:  
 acetamiprid: 245.4 g/L  
 deltamethrin: 30.7 g/L

Artificial soil:

5% sphagnum peat, 20% kaolin clay, and 75% air-dried industrial sand

Test organism:

the predatory mites, *Hypoaspis* (*Geolaelaps*) *aculeifer* (adult female mites from a synchronized culture) obtained from a standard laboratory culture at the Łukasiewicz Research Network - Institute of Industrial Organic Chemistry Branch Pszczyna, Department of Ecotoxicological Studies, Laboratory of Soil Organisms Toxicology. The mites were introduced 7 – 14 days after becoming adult.

Test design:

test duration: 14 days

number of replicates: 4 replicates / concentration + 8 replicates / control; number of mites: 10 mites / replicate

Concentrations of the

test item:

a control, 0.56, 1.00, 1.80, 3.20, 5.60, 10.00, 18.00, 32.00, 56.00, 100.00, 180.00 and 320.00 mg test item/kg dry weight of the artificial soil.

Test conditions:

temperature: 19.8 – 22.0°C

pH at the beginning of the test: 5.51 – 5.61

pH at the end of the test: 5.81 – 5.89

soil moisture content at the beginning of the test: 12.9 – 13.5%  
 (41.3 – 43.2% of the maximum water holding capacity)

soil moisture content in the middle of the test: 12.6 – 13.6%  
 (40.3 – 43.5% of the maximum water holding capacity)

soil moisture content at the end of the test: 12.7 – 13.7%  
 (40.6 – 43.8% of the maximum water holding capacity)

light-dark cycle: 16 h light and 8 h dark

light intensity at the beginning of the test: 496 – 520 lux

light intensity at end of the test: 562 – 603 lux

Statistical analysis: EC10, EC20, EC50 – a probit analysis using linear max. likelihood regression

LC10, LC20, LC50 – a probit analysis using linear max. likelihood regression

NOEC:

- offspring number – Shapiro-Wilk's Test on Normal Distribution,  
 Bartlett's Test Procedure on Variance Homogeneity, Williams

Multiple Sequential t-test Procedure

- survival – Fisher's Exact Binomial Test with Bonferroni

Correction



Endpoints: EC10, EC20, EC50, NOEC  
 LC10, LC20, LC50, NOEC

### Results and discussion:

The aims of the study were to assess the impact of Acetamiprid + Deltametryna (250+30) SC (CHR/I/ADEL 280 SC) on reproduction of the predatory mite, *Hypoaspis* (*Geolaelaps*) *aculeifer* and to determine the EC10, EC20, EC50, and NOEC.

Twelve concentrations of the test item were used. These included: 0.56, 1.00, 1.80, 3.20, 5.60, 10.00, 18.00, 32.00, 56.00, 100.00, 180.00 and 320.00 mg/kg dry weight of the artificial soil. Each concentration was divided into four replicates. There was also an untreated control group divided into eight replicates. The test item in the form of aqueous suspension was mixed with the artificial soil. The control artificial soil was mixed with deionized water alone. The experiment lasted 14 days. After that, the mites were extracted from the artificial soil (48-hour extraction). The numbers of adults and juveniles were determined separately.

Mortality of the predatory mites exposed to the test item at the concentrations ranging from 0.56 to 320.00 mg/kg dry weight of the artificial soil was between 5.0% and 32.5%. Mortality of the control group was equal to 5.0%.

After the application of the test item at the concentrations ranging from 0.56 to 320.00 mg/kg dry weight of the artificial soil the mean number of juveniles was between 24.3 – 94.0 per replicate. The mean number of juveniles in the control group was equal to 97.9 per replicate.

The results are summarized in the table given below.

Concentration [mg/kg dry weight of the artificial soil]	Adult mites		Number of juveniles (mean)
	Number of tested mites	Number of dead mites after 14 days	
<b>Control</b>	80	4	97.9
<b>0.56</b>	40	2	92.3
<b>1.00</b>	40	2	87.5
<b>1.80</b>	40	4	90.3
<b>3.20</b>	40	2	85.3
<b>5.60</b>	40	4	94.0
<b>10.00</b>	40	4	92.0
<b>18.00</b>	40	4	86.3
<b>32.00</b>	40	3	69.0
<b>56.00</b>	40	3	59.5
<b>100.00</b>	40	6	47.5
<b>180.00</b>	40	10	34.3
<b>320.00</b>	40	13	24.3

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Endpoint	Value [mg/kg dry weight of the artificial soil]	Value [mg of acetamiprid/kg dry weight of the artificial soil]	Value [mg of deltamethrin/ kg dry weight of the artificial soil]
<b>EC<sub>10</sub></b>	<b>9.6</b> (4.6 – 15.3)	<b>2.2</b> (1.0 – 3.5)	<b>0.3</b> (0.1 – 0.4)
<b>EC<sub>20</sub></b>	<b>21.1</b> (12.7 – 29.7)	<b>4.7</b> (2.9 – 6.7)	<b>0.6</b> (0.4 – 0.8)
<b>EC<sub>50</sub></b>	<b>94.4</b> (72.6 – 127.4)	<b>21.3</b> (16.4 – 28.7)	<b>2.7</b> (2.0 – 3.6)
<b>NOEC (reproduction)</b>	<b>18.00</b>	<b>4.1</b>	<b>0.5</b>
<b>LC<sub>10</sub></b>	<b>71.6</b> (19.1 – >320.0)	<b>16.1</b> (4.3 – >72.1)	<b>2.0</b> (0.5 – >9.0)
<b>LC<sub>20</sub></b>	<b>196.7</b> (43.4 – >320.0)	<b>44.4</b> (9.8 – >72.1)	<b>5.5</b> (1.2 – >9.0)
<b>LC<sub>50</sub></b>	<b>&gt; 320.0</b>	<b>&gt; 72.1</b>	<b>&gt; 9.0</b>
<b>NOEC (survival)</b>	<b>100.0</b>	<b>22.5</b>	<b>2.8</b>

**VALIDITY CRITERIA**

The results are considered valid because the following criteria were satisfied in the control:

- mean adult mortality: 5.0% (criterion:  $\leq 20\%$ ),  
the mean number of juveniles per vessel at the end of the test: 97.9 (criterion:  $\geq 50$  juveniles at the end of the test),
- the coefficient of variation for the number of juveniles: 10.6 % (criterion:  $\leq 30\%$ ).

**A 2.4.2.2 KCP 10.4.2.2 Higher tier testing**

No additional studies were performed.

**A 2.5 KCP 10.5 Effects on soil nitrogen transformation**

Comments of zRMS:	The study was conducted to OECD 216 the guideline and according to the principles of GLP. All validity criterions were met. The study is considered to be reliable and suitable for the risk assessment.
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Reference: KCP 10.5

Report Acetamiprid + Deltametryna (250+30) SC (CHR/I/ADEL 280 SC)  
Soil Microorganisms: Nitrogen Transformation Test, Study code: G-74-20,  
P. Pieczka

Guideline(s): according to the OECD Guideline No. 216 (2000)/EU Method C.21)

Deviations: No

GLP: Yes

Acceptability: Yes

Duplication                      No  
 (if vertebrate study)

**Materials and methods**

Test material:  
 Acetamiprid + Deltametryna (250+30) SC (CHR/I/ADEL 280 SC)  
 batch no.: 05.08.2019  
 Active substance:  
 acetamiprid: 245.4 g/L  
 deltamethrin: 30.7 g/L

Soil:  
 Agricultural soil collected from a place belonging to the Łukasiewicz Research Network - Institute of Industrial Organic Chemistry Branch Pszczyna.

Test design:  
 Three portions of soil (3 x 1500 g), i.e. one control group and two treated groups. Every portion was divided into three replicates (3 x 500 g). The soil was enriched with the organic substrate, i.e. lucerne at dose of 5 g/kg dry weight of soil. Test duration: 42 days.

Concentrations of the test item:  
 control;  
 PEC: 0.93 mg test item/kg dry weight of soil (i.e. 0.21 mg of acetamiprid + 0.03 mg of deltamethrin/kg dry weight of soil);  
 5 x PEC: 4.64 mg of the test item / kg dry weight of soil (i.e. 1.05 mg of acetamiprid + 0.13 mg of deltamethrin/kg dry weight of soil)

Test conditions:  
 temperature: 18.8 – 21.5°C,  
 soil moisture: 44.9 – 50.0% of the maximum water holding capacity, incubation in darkness

Endpoints:  
 The concentration of nitrate [mg/kg dry soil] after 0, 7, 14, 28 and 42 days of incubation.  
 The nitrate formation rate [mg/kg dry weight of soil/day] for selected time intervals of soil incubation, i.e. 0 – 7, 0 – 14, 0 – 28, 0 - 42 days.  
 Percent deviation from the control in nitrate formation rate calculated for selected time intervals i.e. 0 – 7, 0 – 14, 0 – 28, 0 - 42 days

Statistical analysis:  
 - Shapiro-Wilk's test on Normal Distribution  
 - Levene's Test on Variance Homogeneity (with Residuals)  
 - Williams Multiple Sequential t-test Procedure

**Results and discussion:**

The aim of the study was to detect long-term adverse effects of Acetamiprid + Deltametryna (250+30) SC (CHR/I/ADEL 280 SC) on the processes of nitrogen transformation in aerobic surface soils.  
 The freshly collected agricultural soil was used in the experiment. It was manually cleared of large objects and sieved to a particle size of 2 mm.  
 Two concentrations of the test item were used in the experiment:  
 - PEC: 0.93 mg test item/kg dry weight of soil (i.e. 0.21 mg of acetamiprid + 0.03 mg of deltamethrin/kg dry weight of soil)

- 5 x PEC: 4.64 mg of the test item / kg dry weight of soil (i.e. 1.05 mg of acetamiprid + 0.13 mg of deltamethrin/kg dry weight of soil)

The treated and the control soils were divided into three replicates.

On days 0, 7, 14, 28 and 42 of incubation, soil samples were collected to determine the quantities of nitrate.

The method involves a measurement of the nitrates ions concentration in a soil extract obtained by using deionised water. The pH/ION 7320 digital meter and the NO 800 nitrate electrode were used.

The nitrate formation rate in each treated group was compared with that in the control, and the percent deviation of the treated from the control was calculated.

On 28 day of analysis the percent deviation from the control calculated on the basis of the nitrate formation rate of the soil treated with the test item at the concentration corresponding to the PEC exceeded 25%, therefore, according to the OECD No. 216, EU Method C.21 and the study plan, the experiment was continued.

The difference in the nitrate formation rate between the control soil and the ones treated with the test item at the concentrations corresponding to the PEC: 0.93 mg test item/kg dry weight of soil (i.e. 0.21 mg of acetamiprid + 0.03 mg of deltamethrin/kg dry weight of soil) and 5xPEC: 4.64 mg of the test item / kg dry weight of soil (i.e. 1.05 mg of acetamiprid + 0.13 mg of deltamethrin/kg dry weight of soil) did not exceed 25% on 42 day of analysis.

**Validity criteria:**

The coefficients of variation (CV) in the control group were 5.2, 10.7, 0.7, 2.2 and 1.3%, after 0, 7, 14, 28 and 42 days of incubation. The validity criterion was met, because the variation between replicate control samples is less than 15%.

**Conclusion:**

On the basis of the results, it was concluded that Acetamiprid + Deltametryna (250+30) SC (CHR/I/ADEL 280 SC) at the concentrations corresponding to the PEC: 0.93 mg test item/kg dry weight of soil (i.e. 0.21 mg of acetamiprid + 0.03 mg of deltamethrin/kg dry weight of soil) and 5 x PEC: 4.64 mg of the test item / kg dry weight of soil (i.e. 1.05 mg of acetamiprid + 0.13 mg of deltamethrin/kg dry weight of soil) did not have any long-term adverse effects on the process of nitrogen transformation in aerobic surface soils..

**A 2.6 KCP 10.6 Effects on terrestrial non-target higher plants**

**A 2.6.1 KCP 10.6.1 Summary of screening data**

No additional studies were performed.

**A 2.6.2 KCP 10.6.2 Testing on non-target plants**

**A 2.6.2.1.1 Study 1**

Comments of zRMS:	The study was conducted to OECD 208 the guideline and according to the principles of GLP. All validity criterions were met. The study is considered to be reliable and suitable for the risk assessment.
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### A 2.6.2.1.2

Reference:	KCP 10.6/01
Report	Acetamiprid + Deltametryna (250+30) SC (CHR/I/ADEL 280 SC) Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test, Study code: G-76-20, P. Pieczka
Guideline(s):	according to the OECD Guideline No. 208 (2006)
Deviations:	No.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

#### Materials and methods

##### Test item:

Acetamiprid + Deltametryna (250+30) SC  
 (CHR/I/ADEL 280 SC)  
 batch number: 05.08.2019  
 active substances: acetamiprid: 245.4 g/L  
 deltamethrin: 30.7 g/L

##### Test species:

pea (*Pisum sativum*), sunflower (*Helianthus annuus*), flax (*Linum usitatissimum*), carrot (*Daucus carota*), onion (*Allium cepa*), corn (*Zea mays*)

##### Soil:

Sandy loam

##### Study design:

number of rates: 5 + control; number of replicates/rate: 4 (carrot, flax, onion) or 7 (pea, sunflower) or 10 (corn). The total number of seeds per application rate – 20 (carrot, flax, onion, corn) or 21 (pea, sunflower).  
 test termination: 14 days after the emergence of 50% of the control seedlings

##### Application rates:

- a control,
  - 10 mL of the test item /ha (2.5 g of acetamiprid + 0.3 g of deltamethrin/ha),
  - 20 mL of the test item /ha (4.9 g of acetamiprid + 0.6 g of deltamethrin/ha)
  - 40 mL of the test item /ha (9.8 g of acetamiprid + 1.2 g of deltamethrin/ha)
  - 80 mL of the test item /ha (19.6 g of acetamiprid + 2.5 g of deltamethrin/ha)
  - 160 mL of the test item /ha (39.3 g of acetamiprid + 4.9 g of deltamethrin/ha)
- volume of deionized water used to prepare the highest rate corresponded to 300 L water/ha

##### Test conditions:

temperature: 17.4 – 24.9°C, humidity: 50.1 – 79.5%, lighting: 16 h light : 8 h dark; light intensity: 92.37 – 172.7 µE/m<sup>2</sup>/s; carbon dioxide concentration: 332 – 363 ppm

##### Statistical analysis:

ER25, ER50 – probit analysis

NOER:

CHR/I/ADEL 280 SC/ ADEL 280 SC, PYRIFOS ADE 280 SC.

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In order to determine the NOER values for the emergence the Fisher's Exact Binomial Test with Bonferroni Correction was used,

In order to determine the NOER values for the shoot length at the end of the experiment (shoots cut down above the ground) and for the plant weight at the end of the experiment (shoots cut down above the ground), the following statistical tests were used:

Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Williams Multiple Sequential t-test Procedure or Welch t-test for Inhomogeneous Variances with Bonferroni-Holm Adjustment

Endpoints:

ER25, ER50, NOER

#### Results and discussion:

The study, aimed at evaluating the effect of Acetamiprid + Deltametryna (250+30) SC (CHR/I/ADEL 280 SC) on seedling emergence and seedling growth of 6 terrestrial plants, was conducted on 4 dicotyledonous and 2 monocotyledonous species. The test item was sprayed onto the soil surface. For each species, five application rates were used. There was also a concurrent control group. Seeds of the test plant species were sown in plastic pots. There were 3 (pea, sunflower) or 5 (carrot, flax, onion) or 2 (corn) seeds/pot. The experiment was conducted in a special room. Suitable environmental conditions for each test species were provided. During the experiment, the plants were observed for emergence (every day and then every 2 – 3 days) and visual phytotoxicity (after 7 and 14 days). The experiment finished 14 days after the emergence of 50% of the control seedlings. At the end of the experiment, the number of surviving plants was determined. Next, the plants were cut down, measured, dried to a constant weight at 60°C, and weighed. The results concerning the emergence, the shoot length, and the dry weight were statistically analyzed in order to determine the ER25, ER50, and NOER.

The ER<sub>50</sub> and NOER values determined on the basis of plants number at the end of the experiment, shoot length and shoot dry weight measurements expressed as mL of the test item/ha for all test species are given below.

	Pea <i>Pisum sativum</i>	Sunflower <i>Helianthus annuus</i>	Flax <i>Linum usitatissimum</i>	Carrot <i>Daucus carota</i>	Onion <i>Allium cepa</i>	Corn <i>Zea mays</i>
<b>Plant number at the end of the experiment</b>						
ER <sub>50</sub>	>160	>160	>160	>160	>160	>160
NOER	≥160	≥160	≥160	≥160	≥160	≥160
<b>Shoot length (plants without roots)</b>						
ER <sub>50</sub>	>160	>160	>160	>160	>160	>160
NOER	≥160	≥160	≥160	≥160	≥160	≥160
<b>Plant dry weight (plants without roots)</b>						
ER <sub>50</sub>	>160	>160	>160	>160	>160	>160
NOER	≥160	≥160	≥160	≥160	≥160	≥160

On the basis of the obtained results it was proved that the test item i.e. Acetamiprid + Deltametryna (250+30) SC (CHR/I/ADEL 280 SC) had no influence on the plant number, shoot length and shoot dry weight of the all tested plant species at the end of the experiment. The phytotoxic symptoms were not observed.

#### Validity criteria

On the basis of the obtained results, it was stated that the following validity criteria of the study aimed at evaluating the impact of Acetamiprid + Deltametryna (250+30) SC (CHR/I/ADEL 280 SC) on seedling emergence and seedling growth of terrestrial plants were met:

- the seedling emergence in the control (validity criterion: at least 70%) was as follows:  
 100.0% – pea,  
 100.0% – sunflower,  
 100.0% – flax,  
 100.0% – carrot,  
 100.0% – onion,  
 90.0% – corn,
- the mean survival of the emerged control seedlings was 100% for pea, carrot, flax, red clover, onion and corn (validity criterion: 90%);
- the control seedlings did not exhibit any visible phytotoxic effects;
- environmental conditions for all plants of the same species were identical.

**A 2.6.2.1.3 Study 2**

Comments of zRMS:	The study was conducted to OECD 227 the guideline and according to the principles of GLP. All validity criterions were met. The study is considered to be reliable and suitable for the risk assessment.
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Reference:	KCP 10.6/02
Report	Acetamiprid + Deltametryna (250+30) SC (CHR/I/ADEL 280 SC) Terrestrial Plant Test: Vegetative Vigour Test, Study code: G-75-20, 2021
Guideline(s):	according to the OECD Guideline No. 227 (2006)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

**Materials and methods**

Test Item:	Acetamiprid + Deltametryna (250+30) SC (CHR/I/ADEL 280 SC) batch number: 05.08.2019 active substances: acetamiprid: 245.4 g/L deltamethrin: 30.7 g/L
Test species:	pea ( <i>Pisum sativum</i> ), sunflower ( <i>Helianthus annuus</i> ), carrot ( <i>Daucus carota</i> ), flax ( <i>Linum usitatissimum</i> ), onion ( <i>Allium cepa</i> ), corn ( <i>Zea mays</i> )
Test Design:	number of rates: 5 + control; number of replicates/rate: 7 (pea, sunflower), 4 (carrot, flax, onion) or 10 (corn). The total number of plants per application rate – 21 (pea, sunflower) or 20 (carrot, flax, onion, corn) ; exposure period: 21 days after the spraying
Endpoints:	ER25, ER50, NOER
Test Concentration:	- a control, - 10.0 mL of the test item /ha (2.5 g of acetamiprid + 0.3 g of deltamethrin/ha), - 20.0 mL of the test item /ha (4.9 g of acetamiprid + 0.6 g of deltamethrin/ha),

- 40.0 mL of the test item /ha (9.8 g of acetamiprid + 1.2 g of deltamethrin/ha),
  - 80.0 mL of the test item /ha (19.6 g of acetamiprid + 2.5 g of deltamethrin/ha),
  - 160.0 mL of the test item /ha (39.3 g of acetamiprid + 4.9 g of deltamethrin/ha).
- volume of deionized water used to prepare the highest rate corresponded to 300 L spraying liquid/ha.

Test Conditions: temperature: 17.4 – 24.9°C, humidity: 50.1 – 79.5%, lighting: 16 h light : 8 h dark; light intensity: 96.02 – 248.4  $\mu\text{E}/\text{m}^2/\text{s}$ ; carbon dioxide concentration: 317–370 ppm

### Results and discussion:

The study, aimed at evaluating the effect of Acetamiprid + Deltametryna (250+30) SC (CHR/I/ADEL 280 SC) on vegetative vigour of 6 terrestrial plants, was conducted on 4 dicotyledonous and 2 monocotyledonous species. Seeds of the test plant species were sown in plastic pots (6 seeds/pot for pea and sunflower; 10 seeds/pot for carrot, flax, onion and 4 seeds/pot for corn). The plants were grown to the 2- to 4- true leaf stage. Then, some of them were removed. As a result, the number of plants per pot as well as the total number of plants per concentration were:

- pea: 3 plants/pot – 21 plants/application rate (7 pots/application rate);
- sunflower: 3 plants/pot – 21 plants/application rate (7 pots/application rate);
- carrot: 5 plants/pot – 20 plants/ application rate (4 pots/ application rate);
- flax: 5 plants/pot – 20 plants/ application rate (4 pots/ application rate);
- onion: 5 plants/pot – 20 plants/ application rate (4 pots/ application rate);
- corn: 2 plants/pot – 20 plants/ application rate (10 pots/ application rate).

The pot is defined as a replicate. The test item was sprayed onto the plants. For each species, five application rates were used. Untreated control group was conducted simultaneously. The treated and the control groups were divided into four replicates for carrot, flax and onion; 7 replicates for pea and sunflower; 10 replicates for corn. The experiment was conducted in a plant growth room where suitable environmental conditions for each test species were provided. During the experiment, the plants were observed for visual phytotoxicity (7, 14 and 21 days after the test item application). The experiment finished 21 days after the spraying. At the end of the experiment, the number of surviving plants was counted. Next, the plants were cut down, and the lengths of their shoots were determined. Finally, they were dried at 60°C to a constant weight and weighed.

The results concerning the shoot length, the dry weight, and the number of plants at the end of the experiment were statistically analyzed to determine the ER25, ER50 and NOER..



The ER<sub>50</sub> and NOER values determined on the basis of plants number at the end of the experiment, shoot length and shoot dry weight measurements expressed as mL of the test item/ha for all test species are given below.

	<b>Pea</b> <i>Pisum sativum</i>	<b>Sunflower</b> <i>Helianthus annuus</i>	<b>Carrot</b> <i>Daucus carota</i>	<b>Flax</b> <i>Linum usitatissimum</i>	<b>Onion</b> <i>Allium cepa</i>	<b>Corn</b> <i>Zea mays</i>
<b>Plant number at the end of the experiment</b>						
<b>ER<sub>50</sub></b>	>160.0	>160.0	>160.0	>160.0	>160.0	>160.0
<b>NOER</b>	>160.0	>160.0	>160.0	>160.0	>160.0	>160.0
<b>Shoot length (plants without roots)</b>						
<b>ER<sub>50</sub></b>	>160.0	>160.0	>160.0	>160.0	>160.0	>160.0
<b>NOER</b>	≥160.0	≥160.0	≥160.0	≥160.0	≥160.0	≥160.0
<b>Plant dry weight (plants without roots)</b>						
<b>ER<sub>50</sub></b>	>160.0	>160.0	>160.0	>160.0	>160.0	>160.0
<b>NOER</b>	≥160.0	≥160.0	≥160.0	≥160.0	≥160.0	≥160.0

On the basis of the obtained results it was proved that the test item i.e. Acetamiprid + Deltametryna (250+30) SC (CHR/I/ADEL 280 SC) had no influence on the plant number, shoot length and shoot dry weight of the all tested plant species at the end of the experiment.

The phytotoxic symptoms in cultivation of pea, sunflower, carrot, flax, onion and corn were not observed.

#### Validity criteria

On the basis of the obtained results, it was stated that the following validity criteria of the study aimed at evaluating the impact of Acetamiprid + Deltametryna (250+30) SC (CHR/I/ADEL 280 SC) on vegetative vigour of terrestrial plants were met:

- the seedling emergence of plants (validity criterion: at least 70%) was as follows:

81.0 – 88.1 – pea,

76.2 – 85.7 – sunflower,

85.0 – 97.5 – carrot,

87.5 – 95.0 – flax,

85.0 – 95.0 – onion,

90.0 – 95.0 – corn,

- the mean plant survival of the control was 100% for all tested species (validity criterion: at least 90%),

- the control plants did not exhibit any visible phytotoxic symptoms,

- environmental conditions for all plants belonging to the same species were identical.

CHR/I/ADEL 280 SC/ ADEL 280 SC, PYRIFOS ADE 280 SC.  
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No additional studies were performed.

**A 2.7                    KCP 10.7 Effects on other terrestrial organisms (flora and fauna)**

No additional studies were performed.

**A 2.8                    KCP 10.8 Monitoring data**

No additional studies were performed.