FINAL REGISTRATION REPORT

Part B

Section 9

Ecotoxicology

Detailed summary of the risk assessment

Product code: SHA5500A

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

Chemical active substance:

Acetamiprid, 200 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: April 2020

MS Finalisation date: December 2020, July 2021

Version history

When	What
October 2020	Assessment by ZRMS-PL
November 2020	Updated risk assessment by the applicant for additional uses in orchards
December 2020	Finalisation of the evaluation by zRMS.
July 2021	The final version prepared by zRMS after commenting period.

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9 Ecotoxicology (KCP 10)

9.1 Critical GAP and overall conclusions

Table 9.1-1: Table of critical GAPs

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: devel-opmental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g saf-ener/ synergist per ha	**Conclusion**						
					Method / Kind	Timing / Growth stage of crop & season	Max. num-ber a) per use b) per crop/ season	Min. inter-val between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water 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	CEU	**Oilseed Rape**	F	Pollen Beetle (*Meli-gethes aeneus)*	Foliar spray	At pest presence. Before BBCH 69	a) 1 b) 1	NA	a) 0.2 b) 0.2	a) 0.04 b) 0.04	200-600	28	-							
2	CEU	**Pome fruits**	F	Aphids	Foliar spray	~~At pest presence, Before BBCH 59 and~~ from BBCH 69	a) 1-2 b) 1-2	14	a) 0.18***-~~0.25~~ b) 0.36***-~~0.5~~	a)0.036***-~~0.05~~ b) 0.72***-~~0.10~~	900-1000	14	-							

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

** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

*** ~~Due to comments on efficacy section about possible reduction of rate additional calculations are presented.~~

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/m³ 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

zRMS comments after commentin period, June 2021:

It should be noted that the initialy GAP Table for intended uses included early and late applications in orchards for max application rate of 2 x 50 g a.s./ha.
However, in meantime tha applicant reduced tha application rate from 2 x 50 g a.s./ha to 1-2 x 36 g a.s./ha in orchards and limited the growth stage to BBCH >69.
Therefore, only the **late application in orchards** with lower rates :1-2 x 36 g a.s./ha, with 14 d interval and BBCH >69 was considered by zRMS in updaded B9 Section, July 2021.
The risk assessment for higher doses evaluated before commenting period was shadowed for transparency.

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 amphi bians) (KCP 10.1.3)

The risk assessment for birds has been done. The TER_A values are greater than the Annex VI trigger of 10, indicating low acute risk to birds from Acetamiprid following application of ~~Zuxion~~ Asset ~~-~~at all proposed label rates. The TER_{LT} values are greater than the Annex VI trigger of 5, indicating low long-term risk to birds from Acetamiprid following application of ~~Zuxion~~ Asset at all proposed label rates. The risk for drinking water exposure is acceptable and effect of secondary poisoning is not expected.
The risk assessment for mammals has been done. The TER_A values are greater than the Annex VI trigger of 10, indicating low acute risk to mammals from Acetamiprid following application of ~~Zuxion –~~Assetat all proposed label rates~~.~~ The TER_{LT} values after refinement of PD, DF, ftwa and MAF parameters were ~~below~~ above the Annex VI trigger of 5, indicating an acceptable a long-term risk to herbivorouse mammals – vole from Acetamiprid following application of ~~Zuxion –~~Asset in pome fruits for late application. at doses such as: . at all proposed label rates. After the ftwa, MAF and DF refinement,
The risk for drinking water exposure is acceptable and effect of secondary poisoning is not expected.

Effects on aquatic organisms (KCP 10.2)

The risk to aquatic organisms for the metabolites were assessed as low at FOCUS step 1 and step 2 for the representative use on oilseed rape and pome/stone fruits.

After Step 3 calculations, for the intended uses, calculated PEC/RAC ratios did indicate an unacceptable risk for the most sensitive group of aquatic organisms (risk for sediment dwelling organism as characterised by an NOEC for *Chironomus riparius* of 0.235 µg/L in connection with an assessment factor of 10) in several FOCUS Steps 1-3 scenarios.
Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies for application rate for oilseed rape (1 x40 g a.s./ha) and for orchards for lower doses (early and late 1 x 40 g a.s./ha (covers 1 x 36 g a.s./ha) and 2 x 36 g a.s./ha).
According to EFSA, a mesocosms study was used for the refinement for application rates of 2 x 50 g a.s./ha for early and late application in orchards.
Based on the results of the risk assessment at step 4, the following conclusions regarding buffer zones, vegetative buffer strips and nozzles reduction may be drawn:

Pome/stone fruits (early application) – SPe 3: *To protect aquatic organisms respect an unsprayed vegetated buffer zone of 10 5 m to surface water bodies with 90% of nozzles reduction OR an unsprayed vegetated buffer zone of 15 m to surface water bodies with 75% of nozzles reduction OR an unsprayed*

vegetated buffer zone of 20 m to surface water bodies with 50% of nozzles reduction OR an unsprayed vegetated buffer zone of 30 m to surface water bodies.

***Pome/stone fruits (late application) - SPe 3**: To protect aquatic organisms respect an unsprayed vegetated buffer zone of 5 m to surface water bodies with 90% of nozzles reduction OR an unsprayed vegetated buffer zone of 10 m to surface water bodies with 50% of nozzles reduction OR an unsprayed vegetated buffer zone of 15 m to surface water bodies.*

No calculations for max. appliacton 2 x 50 g a.s./ha in orchards based on FOCUS Step 4 PEC_{SW} and NOEC for *Chironomus riparius* of 0.235 µg/L was provided by the applicant.
Therefore, in this case further refinement is needed.

Further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies for with calculations of the PECsw with FOCUS STEP 4 program for lower doses in orchards (1 x 40 g a.s./ha and 2 x 36 g a.s./ha) and for oilseed rape (1 x40 g a.s./ha) indicated the acceptable risk when following risk mitigation measures are applied:

Orchards (early application. 2 x 36 g a.s./ha)

- D3 ditch: 20 m no-spray buffer zone + 95% of nozzles reduction or 30 m no-spray buffer zone + 90% of nozzles reduction or 40 m no-spray buffer zone + 75% of nozzles reduction or 50 m no-spray buffer zone.
- D4 pond: 5 m no-spray buffer zone + 95% of nozzles reduction or 10 m no-spray buffer zone + 90% of nozzles reduction or 15 m no-spray buffer zone + 75% of nozzles reduction or 20 m no-spray buffer zone + 50% of nozzles reduction or 50 m no-spray buffer zone.
- D4 stream:20 m no-spray buffer zone + 95% of nozzles reduction or 30 m no-spray buffer zone + 90% of nozzles reduction or 40 m no-spray buffer zone + 75% of nozzles reduction or 50 m no-spray buffer zone + 50% of nozzles reduction.
- D5 pond: 5 m no-spray buffer zone + 95% of nozzles reduction or 10 m no-spray buffer zone + 90% of nozzles reduction or 15 m no-spray buffer zone + 75% of nozzles reduction or 30 m no-spray buffer zone.
- D5 stream: 20 m no-spray buffer zone + 95% of nozzles reduction or 30 m no-spray buffer zone + 90% of nozzles reduction or 40 m no-spray buffer zone + 75% of nozzles reduction or 50 m no-spray buffer zone+ 50% of nozzles reduction.
- R1 pond:5 m no-spray buffer zone + 95% of nozzles reduction or 10 m no-spray buffer zone + 90% of nozzles reduction or 15 m no-spray buffer zone + 75% of nozzles reduction or 30 m no-spray buffer zone.
- R1 stream: 20 m no-spray buffer zone +20m vegetative strip + 95% of nozzles reduction or 30 m no-spray buffer zone +20m vegetative strip + 75% of nozzles reduction or 40 m no-spray buffer zone +20m vegetative strip + 50% of nozzles reduction or 50 m no-spray buffer zone +20m vegetative strip.
- R2 stream: 20 m no-spray buffer zone + 95% of nozzles reduction or 30 m no-spray buffer zone + 90% of nozzles reduction or 40 m no-spray buffer zone + 75% of nozzles reduction or 50 m no-spray buffer zone+ 50% of nozzles reduction.
- R3 stream: 20 m no-spray buffer zone +20m vegetative strip + 95% of nozzles reduction or 30 m no-spray buffer zone +20m vegetative strip + 90% of nozzles reduction or 40 m no-spray buffer zone +20m vegetative strip + 75% of nozzles reduction or 50 m no-spray buffer zone +20m vegetative strip + 50% of nozzles reduction.
- R4 stream: 20 m no-spray buffer zone +20m vegetative strip + 95% of nozzles reduction or 30 m no-spray buffer zone +20m vegetative strip + 90% of nozzles reduction or 40 m no-spray buffer zone +20m vegetative strip + 75% of nozzles reduction or 50 m no-spray buffer zone +20m vegetative strip + 50% of nozzles reduction.

Orchards (late application application, 2 x 36 g a.s./ha)

- D3 ditch: 10 m no-spray buffer zone + 95% of nozzles reduction or 15 m no-spray buffer zone + 90% of nozzles reduction or 30 m no-spray buffer zone + 75% of nozzles reduction or 40 m no-spray buffer zone + 50% of nozzles reduction.
- D4 pond: 5 m no-spray buffer zone + 90% of nozzles reduction or 10 m no-spray buffer zone + 75% of nozzles reduction or 15 m no-spray buffer zone + 50% of nozzles reduction or 20 m no-spray buffer zone.
- D4 stream: 10 m no-spray buffer zone + 95% of nozzles reduction or 15 m no-spray buffer zone + 90% of nozzles reduction or 30 m no-spray buffer zone + 75% of nozzles reduction or 40 m no-spray buffer zone + 50% of nozzles reduction.
- D5 pond: 5 m no-spray buffer zone + 95% of nozzles reduction or 10 m no-spray buffer zone + 75% of nozzles reduction or 15 m no-spray buffer zone + 50% of nozzles reduction or 20 m no-spray buffer zone.
- D5 stream: 15 m no-spray buffer zone + 95% of nozzles reduction or 20 m no-spray buffer zone + 90% of nozzles reduction or 30 m no-spray buffer zone + 75% of nozzles reduction or 40 m no-spray buffer zone + 50% of nozzles reduction.
- R1 pond: 5 m no-spray buffer zone + 90% of nozzles reduction or 10 m no-spray buffer zone + 75% of nozzles reduction or 15 m no-spray buffer zone + 50% of nozzles reduction or 30 m no-spray buffer zone.
- R1 stream: 10 m no-spray buffer zone +10m vegetative strip + 95% of nozzles reduction or 20 m no-spray buffer zone +20m vegetative strip + 90% of nozzles reduction or 30 m no-spray buffer zone +20m vegetative strip + 75% of nozzles reduction or 40 m no-spray buffer zone +20m vegetative strip + 50% of nozzles reduction or 50 m no-spray buffer zone +20m vegetative strip.
- R2 stream: 15 m no-spray buffer zone + 95% of nozzles reduction or 20 m no-spray buffer zone + 90% of nozzles reduction or 30 m no-spray buffer zone + 75% of nozzles reduction or 40 m no-spray buffer zone+ 50% of nozzles reduction.
- R3 stream: 15 m no-spray buffer zone + 95% of nozzles reduction or 20 m no-spray buffer zone + 90% of nozzles reduction or 30 m no-spray buffer zone + 75% of nozzles reduction or 40 m no-spray buffer zone + 50% of nozzles reduction.
- R4 stream: 10 m no-spray buffer zone +10m vegetative strip + 95% of nozzles reduction or 20 m no-spray buffer zone +20m vegetative strip + 75% of nozzles reduction or 30 m no-spray buffer zone +20m vegetative strip + 50% of nozzles reduction or 40 m no-spray buffer zone +20m vegetative strip.

It should be noted that risk mitigation measures for application dose 2 x 36 g a.s/ha presented above covers the risk mitigation measures for application dose 1x36 g a.s./ha in orchards (early and late applications).
However, the final risk mitigation measures for relevant scenarios should be considered at MSs level.

Winter oilseed rape

- D2 ditch: scenario is not relevant under CEU conditions.
- D2 stream: scenario is not relevant under CEU conditions.
- D3 ditch: 5 m no-spray buffer zone + 75% of nozzles reduction or 10 m no-spray buffer zone + 50% of nozzles reduction or 20 m no-spray buffer zone.
- D4 stream: 5 m no-spray buffer zone + 75% of nozzles reduction or 10 m no-spray buffer zone + 50% of nozzles reduction or 20 m no-spray buffer zone.
- D5 stream: 5 m no-spray buffer zone + 75% of nozzles reduction or 10 m no-spray buffer zone + 50% of nozzles reduction.
- R1 stream: 5 m no-spray buffer zone + 75% of nozzles reduction or 10 m no-spray buffer zone + 50% of nozzles reduction or 15 m no-spray buffer zone.
- R3 stream: 20 m no-spray buffer zone + 20 m vegetative filter strip.

Summer oilseed rape

- D1 ditch: scenario is not relevant under CEU conditions.
- D1 stream: scenario is not relevant under CEU conditions.
- D3 ditch: 5 m no-spray buffer zone + 75% of nozzles reduction or 10 m no-spray buffer zone + 50% of nozzles reduction or 20 m no-spray buffer zone.
- D4 stream: 5 m no-spray buffer zone + 75% of nozzles reduction or 10 m no-spray buffer zone + 50% of nozzles reduction or 20 m no-spray buffer zone.
- D5 stream: 5 m no-spray buffer zone + 75% of nozzles reduction or 10 m no-spray buffer zone + 50% of nozzles reduction or 20 m no-spray buffer zone.
- R1 stream: 5 m no-spray buffer zone + 75% of nozzles reduction or 10 m no-spray buffer zone + 50% of nozzles reduction or 15 m no-spray buffer zone.

~~***Applicant update Nov 2020 (2x180 g f.p./ha , equivalent to 2x36 g a.s./ha):***~~

~~***Winter oilseed rape – SPe 3:*** *To protect aquatic organisms respect an unsprayed vegetated buffer zone of 20 m to surface water bodies.*~~

~~***Summer oilseed rape – SPe 3:*** *To protect aquatic organisms respect an unsprayed buffer zone of 5 m to surface water bodies with 75% of nozzles reduction OR an unsprayed buffer zone of 10 m to surface water bodies with 50% of nozzles reduction OR an unsprayed buffer zone of 20 m to surface water bodies.*~~

~~***Pome/stone fruits (early application) – SPe 3:*** *To protect aquatic organisms respect an unsprayed vegetated buffer zone of 20 m to surface water bodies with 95% of nozzles reduction OR an unsprayed buffer zone of 30 m with 20m of vegetative strip to surface water bodies with 90% of nozzles reduction OR an unsprayed buffer zone of 40 m with 20m of vegetative strip to surface water bodies with 75% of nozzles reduction OR an unsprayed buffer zone of 50 m with 20m of vegetative strip to surface water bodies with 50% of nozzles reduction.*~~

~~***Pome/stone fruits (late application) – SPe 3:*** *To protect aquatic organisms respect an unsprayed buffer zone of 15 m with 10m of vegetative strip to surface water bodies with 95% of nozzles reduction OR an unsprayed vegetated buffer zone of 20 m to surface water bodies with 90% of nozzles reduction OR an unsprayed buffer zone of 30 m with 20m of vegetative strip to surface water bodies with 75% of nozzles reduction OR an unsprayed buffer zone of 40 m with 20m of vegetative strip to surface water bodies with 50% of nozzles reduction OR an unsprayed buffer zone of 50 m with 20m of vegetative strip to surface water bodies.*~~

The risk to aquatic organisms for the metabolites were assessed as low at FOCUS step 1 and step2 for the representative use on oilseed rape and pome/stone fruits.

After Step 3 calculations, for the intended uses, calculated PEC/RAC ratios did indicate an unacceptable risk for the most sensitive group of aquatic organisms (risk for sediment dwelling organism as characterised by an NOEC for *Chironomus riparius* of 0.235 µg/L in connection with an assessment factor of 10) in several FOCUS Steps 1-3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies.

~~According to EFSA, a mesocosms study was used for the refinement. Based on the results of the risk assessment at step 4, the following conclusions regarding buffer zones, vegetative buffer strips and nozzles reduction may be drawn:~~

~~***Pome/stone fruits (early application) – SPe 3:*** *To protect aquatic organisms respect an unsprayed vege-*

~~*tated buffer zone of 5 m to surface water bodies with 90% of nozzles reduction OR an unsprayed vegetated buffer zone of 15 m to surface water bodies with 75% of nozzles reduction OR an unsprayed vegetated buffer zone of 20 m to surface water bodies with 50% of nozzles reduction OR an unsprayed vegetated buffer zone of 30 m to surface water bodies.*~~

~~***Pome/stone fruits (late application) - SPe 3**: To protect aquatic organisms respect an unsprayed vegetated buffer zone of 5 m to surface water bodies with 90% of nozzles reduction OR an unsprayed vegetated buffer zone of 10 m to surface water bodies with 50% of nozzles reduction OR an unsprayed vegetated buffer zone of 15 m to surface water bodies.*~~

Applicant update-Nov 2020 (2x180 g f.p./ha , equivalent to 2x36 g a.s./ha):

***Winter oilseed rape* - SPe 3**: *To protect aquatic organisms respect an unsprayed vegetated buffer zone of 20 m to surface water bodies.*

***Summer oilseed rape* - SPe 3**: *To protect aquatic organisms respect an unsprayed buffer zone of 5 m to surface water bodies with 75% of nozzles reduction OR an unsprayed buffer zone of 10 m to surface water bodies with 50% of nozzles reduction OR an unsprayed buffer zone of 20 m to surface water bodies.*

***Pome/stone fruits (early application) - SPe 3**: To protect aquatic organisms respect an unsprayed vegetated buffer zone of 20 m to surface water bodies with 95% of nozzles reduction OR an unsprayed buffer zone of 30 m with 20m of vegetative strip to surface water bodies with 90% of nozzles reduction OR an unsprayed buffer zone of 40 m with 20m of vegetative strip to surface water bodies with 75% of nozzles reduction OR an unsprayed buffer zone of 50 m with 20m of vegetative strip to surface water bodies with 50% of nozzles reduction.*

***Pome/stone fruits (late application) - SPe 3**: To protect aquatic organisms respect an unsprayed buffer zone of 15 m with 10m of vegetative strip to surface water bodies with 95% of nozzles reduction OR an unsprayed vegetated buffer zone of 20 m to surface water bodies with 90% of nozzles reduction OR an unsprayed buffer zone of 30 m with 20m of vegetative strip to surface water bodies with 75% of nozzles reduction OR an unsprayed buffer zone of 40 m with 20m of vegetative strip to surface water bodies with 50% of nozzles reduction OR an unsprayed buffer zone of 50 m with 20m of vegetative strip to surface water bodies.*

ZRMS comments:

The relevant predicted environmental concentrations in water (PEC_{sw}) for risk assessments were taken from Part B Section 8 (Environmental Fate).
The risk assessment was based on the PECsw values (STEP 1-3) and the results of laboratory toxicity testing with aquatic organism.
After Step 3 calculations, for the intended uses, calculated PEC/RAC ratios did indicate an unacceptable risk for the most sensitive group of aquatic organisms (risk for sediment dwelling organism as characterised by an NOEC for *Chironomus riparius* of 0.235 µg/L in connection with an assessment factor of 10) in several FOCUS Steps 1-3 scenarios. Therefore, further PEC/RAC ratios were calculated based on
FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies were provided for oilseed rape (appl. dose 1 x40 g a.s./ha) and orchards (early and late application for 1 x 40 (covers 1 x 36 g a.s./ha) and for app.dose 2 x 36 g a.s./ha).
~~It should be noted the for max application dose: 2 x 50 g a.s/ha for use in orchards the PEC/RACratio based on NOEC of 0.235 L µg/L in connection with an assessment factor of 10 and with consideration of~~

~~the PECsw with FOCUS STEP 4, should be provided to concluded acceptable risk.~~

The risk assessment based on PEC/RAC values with calculations of the PECsw with FOCUS STEP 4 program for lower doses in orchards and oilseed rape indicated the acceptable risk when following risk mitigation measures are applied:

Orchards (early application. 2 x 36 g a.s./ha)

- D3 ditch: 20 m no-spray buffer zone + 95% of nozzles reduction or 30 m no-spray buffer zone + 90% of nozzles reduction or 40 m no-spray buffer zone + 75% of nozzles reduction or 50 m no-spray buffer zone.
- D4 pond: 5 m no-spray buffer zone + 95% of nozzles reduction or 10 m no-spray buffer zone + 90% of nozzles reduction or 15 m no-spray buffer zone + 75% of nozzles reduction or 20 m no-spray buffer zone + 50% of nozzles reduction or 50 m no-spray buffer zone.
- D4 stream:20 m no-spray buffer zone + 95% of nozzles reduction or 30 m no-spray buffer zone + 90% of nozzles reduction or 40 m no-spray buffer zone + 75% of nozzles reduction or 50 m no-spray buffer zone + 50% of nozzles reduction.
- D5 pond: 5 m no-spray buffer zone + 95% of nozzles reduction or 10 m no-spray buffer zone + 90% of nozzles reduction or 15 m no-spray buffer zone + 75% of nozzles reduction or 30 m no-spray buffer zone.
- D5 stream: 20 m no-spray buffer zone + 95% of nozzles reduction or 30 m no-spray buffer zone + 90% of nozzles reduction or 40 m no-spray buffer zone + 75% of nozzles reduction or 50 m no-spray buffer zone+ 50% of nozzles reduction.
- R1 pond:5 m no-spray buffer zone + 95% of nozzles reduction or 10 m no-spray buffer zone + 90% of nozzles reduction or 15 m no-spray buffer zone + 75% of nozzles reduction or 30 m no-spray buffer zone.
- R1 stream: 20 m no-spray buffer zone +20m vegetative strip + 95% of nozzles reduction or 30 m no-spray buffer zone +20m vegetative strip + 75% of nozzles reduction or 40 m no-spray buffer zone +20m vegetative strip + 50% of nozzles reduction or 50 m no-spray buffer zone +20m vegetative strip.
- R2 stream: 20 m no-spray buffer zone + 95% of nozzles reduction or 30 m no-spray buffer zone + 90% of nozzles reduction or 40 m no-spray buffer zone + 75% of nozzles reduction or 50 m no-spray buffer zone+ 50% of nozzles reduction.
- R3 stream: 20 m no-spray buffer zone +20m vegetative strip + 95% of nozzles reduction or 30 m no-spray buffer zone +20m vegetative strip + 90% of nozzles reduction or 40 m no-spray buffer zone +20m vegetative strip + 75% of nozzles reduction or 50 m no-spray buffer zone +20m vegetative strip + 50% of nozzles reduction.
- R4 stream: 20 m no-spray buffer zone +20m vegetative strip + 95% of nozzles reduction or 30 m no-spray buffer zone +20m vegetative strip + 90% of nozzles reduction or 40 m no-spray buffer zone +20m vegetative strip + 75% of nozzles reduction or 50 m no-spray buffer zone +20m vegetative strip + 50% of nozzles reduction.

Orchards (late application application, 2 x 36 g a.s./ha)

- D3 ditch: 10 m no-spray buffer zone + 95% of nozzles reduction or 15 m no-spray buffer zone + 90% of nozzles reduction or 30 m no-spray buffer zone + 75% of nozzles reduction or 40 m no-spray buffer zone + 50% of nozzles reduction.
- D4 pond: 5 m no-spray buffer zone + 90% of nozzles reduction or 10 m no-spray buffer zone + 75% of nozzles reduction or 15 m no-spray buffer zone + 50% of nozzles reduction or 20 m no-spray buffer zone.
- D4 stream: 10 m no-spray buffer zone + 95% of nozzles reduction or 15 m no-spray buffer zone + 90% of nozzles reduction or 30 m no-spray buffer zone + 75% of nozzles reduction or 40 m no-spray buffer zone + 50% of nozzles reduction.
- D5 pond: 5 m no-spray buffer zone + 95% of nozzles reduction or 10 m no-spray buffer zone +

75% of nozzles reduction or 15 m no-spray buffer zone + 50% of nozzles reduction or 20 m no-spray buffer zone.
- D5 stream: 15 m no-spray buffer zone + 95% of nozzles reduction or 20 m no-spray buffer zone + 90% of nozzles reduction or 30 m no-spray buffer zone + 75% of nozzles reduction or 40 m no-spray buffer zone + 50% of nozzles reduction.
- R1 pond: 5 m no-spray buffer zone + 90% of nozzles reduction or 10 m no-spray buffer zone + 75% of nozzles reduction or 15 m no-spray buffer zone + 50% of nozzles reduction or 30 m no-spray buffer zone.
- R1 stream: 10 m no-spray buffer zone +10m vegetative strip + 95% of nozzles reduction or 20 m no-spray buffer zone +20m vegetative strip + 90% of nozzles reduction or 30 m no-spray buffer zone +20m vegetative strip + 75% of nozzles reduction or 40 m no-spray buffer zone +20m vegetative strip + 50% of nozzles reduction or 50 m no-spray buffer zone +20m vegetative strip.
- R2 stream: 15 m no-spray buffer zone + 95% of nozzles reduction or 20 m no-spray buffer zone + 90% of nozzles reduction or 30 m no-spray buffer zone + 75% of nozzles reduction or 40 m no-spray buffer zone+ 50% of nozzles reduction.
- R3 stream: 15 m no-spray buffer zone + 95% of nozzles reduction or 20 m no-spray buffer zone + 90% of nozzles reduction or 30 m no-spray buffer zone + 75% of nozzles reduction or 40 m no-spray buffer zone + 50% of nozzles reduction.
- R4 stream: 10 m no-spray buffer zone +10m vegetative strip + 95% of nozzles reduction or 20 m no-spray buffer zone +20m vegetative strip + 75% of nozzles reduction or 30 m no-spray buffer zone +20m vegetative strip + 50% of nozzles reduction or 40 m no-spray buffer zone +20m vegetative strip.

It should be noted that risk mitigation measures for application dose 2 x 36 g a.s/ha (late applications) presented above covers the risk mitigation measures for application dose 1x36 g a.s./ha in orchards (late applications). However, the final risk mitigation measures for relevant scenarios should be considered at MSs level.

Winter oilseed rape

- D2 ditch: scenario is not relevant under CEU conditions.
- D2 stream: scenario is not relevant under CEU conditions.
- D3 ditch: 5 m no-spray buffer zone + 75% of nozzles reduction or 10 m no-spray buffer zone + 50% of nozzles reduction or 20 m no-spray buffer zone.
- D4 stream: 5 m no-spray buffer zone + 75% of nozzles reduction or 10 m no-spray buffer zone + 50% of nozzles reduction or 20 m no-spray buffer zone.
- D5 stream: 5 m no-spray buffer zone + 75% of nozzles reduction or 10 m no-spray buffer zone + 50% of nozzles reduction.
- R1 stream: 5 m no-spray buffer zone + 75% of nozzles reduction or 10 m no-spray buffer zone + 50% of nozzles reduction or 15 m no-spray buffer zone.
- R3 stream: 20 m no-spray buffer zone + 20 m vegetative filter strip.

Summer oilseed rape

- D1 ditch: scenario is not relevant under CEU conditions.
- D1 stream: scenario is not relevant under CEU conditions.
- D3 ditch: 5 m no-spray buffer zone + 75% of nozzles reduction or 10 m no-spray buffer zone + 50% of nozzles reduction or 20 m no-spray buffer zone.
- D4 stream: 5 m no-spray buffer zone + 75% of nozzles reduction or 10 m no-spray buffer zone + 50% of nozzles reduction or 20 m no-spray buffer zone.
- D5 stream: 5 m no-spray buffer zone + 75% of nozzles reduction or 10 m no-spray buffer zone + 50% of nozzles reduction or 20 m no-spray buffer zone.
- R1 stream: 5 m no-spray buffer zone + 75% of nozzles reduction or 10 m no-spray buffer zone + 50% of nozzles reduction or 15 m no-spray buffer zone.

Effects on bees (KCP 10.3.1)

The risk assessment for bees has been done. All the hazard quotients are considerably less than 50, indicating that the active substances pose a low risk to bees. Therefore a low risk to bees is expected from the application of ~~Zuxion~~ Asset at all proposed label rates.

According to Commission regulation (EU) No 284/2013, point 10.3.1. (Effects on bees) the Applicant provided the chronic test on bees for formulated product and chronic test for larvae for a.s acetamiprid.
Thus, concerned Member States must decide on the consideration of data requirements and the risk assessment at national level.

Effects on arthropods other than bees (KCP 10.3.2)

The results of the risk assessment for non-target arthropods showed an acceptable in-field and off-field risk after the application of Acetamiprid 20% SG. A potential of recovery of the in-field area have been demonstrate in a short period of time. In addition, an acceptable off-field risk was obtained with the application of the following risk mitigation measures:

Oilseed rape – Spe3 (1x 40 g a.s./ha)*: To protect non-target arthropods respect an unsprayed buffer zone of 10 m to non-agricultural land OR an unsprayed buffer zone of 5 m to non-agricultural land with 50% of nozzles reduction OR no buffer zone to non-agricultural land with 90% of nozzles reduction.*

~~***Pome/stone fruits (early application, 2 x 50 ga.s./ha) – Spe3****: To protect non-target arthropods respect an unsprayed buffer zone of 50 m to non-agricultural land OR an unsprayed buffer zone of 40 m to non-agricultural land with 50% of nozzles reduction OR an unsprayed buffer zone of 30m to non-agricultural land with 75% of nozzles reduction.*~~

~~***Pome/stone fruits (late application, 2 x 50 g a.s./ha) – Spe3****: To protect non-target arthropods respect an unsprayed buffer zone of 40 m to non-agricultural land OR an unsprayed buffer zone of 30 m to non-agricultural land with 50% of nozzles reduction OR an unsprayed buffer zone of 20m to non-agricultural land with 75% of nozzles reduction OR an unsprayed buffer zone of 15m to non-agricultural land with 90% of nozzles reduction.*~~

~~***Pome/stone fruits (early application, 1 x 36 g a.s./ha) – Spe3:*** *To protect non-target arthropods respect an unsprayed buffer zone of 40 m to non-agricultural land OR an unsprayed buffer zone of 30 m to non-agricultural land with 50% of nozzles reduction OR an unsprayed buffer zone of 15 and20 m to non-agricultural land with 90% of nozzles reduction*~~.

~~***Pome/stone fruits (late application, 1 x 36 g a.s./ha) – Spe3****: To protect non-target arthropods respect an unsprayed buffer zone of 30 m to non-agricultural land OR an unsprayed buffer zone of 20 m to non-agricultural land with 50% of nozzles reduction OR an unsprayed buffer zone of 15m to non-agricultural land with 75% of nozzles reduction OR an unsprayed buffer zone of 10m to non-agricultural land with 90% of nozzles reduction.*~~

~~***Pome/stone fruits (early application, 2 x 36 g a.s./ha) – Spe3****: To protect non-target arthropods respect an unsprayed buffer zone of 50 m to non-agricultural land OR an unsprayed buffer zone of 40 m to non-agricultural land with 50% of nozzles reduction OR an unsprayed buffer zone of 30m to non-agricultural land with 75% of nozzles reduction OR an unsprayed buffer zone of 20m to non-agricultural land with 90% of nozzles reduction.*~~

Pome/stone fruits (late application, 1-2 x 36 g a.s./ha)– Spe3*: To protect non-target arthropods respect an unsprayed buffer zone of 30 m to non-agricultural land OR an unsprayed buffer zone of 20 m to non-agricultural land with 50% of nozzles reduction OR an unsprayed buffer zone of 15m to non-agricultural land with 75% of nozzles reduction OR an unsprayed buffer zone of 10m to non-agricultural land with 90% of nozzles reduction.*

~~*Applicant update Nov 2020*~~

~~***Pome/stone fruits (early application) – Spe3:** To protect non-target arthropods respect an unsprayed buffer zone of 50 m to non-agricultural land OR an unsprayed buffer zone of 40 m to non-agricultural land with 50% of nozzles reduction OR an unsprayed buffer zone of 30m to non-agricultural land with 75% of nozzles reduction OR an unsprayed buffer zone of 20m to non-agricultural land with 90% of nozzles reduction.*~~

~~***Pome/stone fruits (late application) – Spe3:** To protect non-target arthropods respect an unsprayed buffer zone of 40 m to non-agricultural land OR an unsprayed buffer zone of 30 m to non-agricultural land with 50% of nozzles reduction OR an unsprayed buffer zone of 20m to non-agricultural land with 75% of nozzles reduction OR an unsprayed buffer zone of 10m to non-agricultural land with 90% of nozzles reduction.*~~

9.1.1.6 Effects on non-target soil meso- and macrofauna (KCP 10.4), The risk assessment for earthworms has been done. All the chronic TER values are much higher than the Annex VI long-term trigger value of 5, indicating that ~~Zuxion~~ Asset poses low chronic risk to earthworms when applied according to the proposed use rates.

9.1.1.7 Effects on soil microbial activity (KCP 10.5)

The risk assessment for earthworms has been done. All the chronic TER values are much higher than the Annex VI long-term trigger value of 5, indicating that ~~Zuxion~~ Asset poses low chronic risk to earthworms when applied according to the proposed use rates.

The risk assessment for earthworms has been done. The risk to soil microbial processes from the proposed uses of Zuxion is considered to be acceptable when applied according to the proposed use rates.

The risk assessment for earthworms has been done. The risk to soil microbial processes from the proposed uses of Zuxion is considered to be acceptable when applied according to the proposed use rates.

ZRMS comments:

SHA5500A/~~Zuxion~~ Asset has no significant effect on soil micro-organisms at 0.267 mg a.s./kg dry soil. Based on it, can be concluded that **SHA5500A/~~Zuxion~~** Asset under field conditions, use at the proposed rates poses no unacceptable risk to non-target soil micro-organisms.

Effects on non-target terrestrial plants (KCP 10.6)

The risk assessment for non-target plants has been done. The risk to non-target plants for Zuxion is considered to be acceptable when applied according to the proposed use rates.

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

Not required.

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).

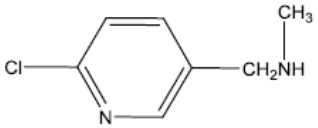
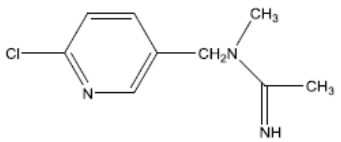
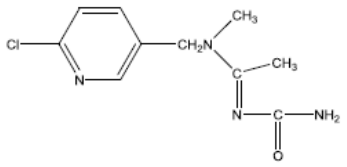
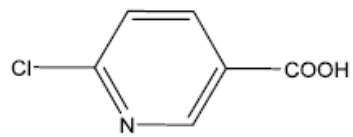
Table 9.1-2: Critical use pattern of Zuxion grouped according to criterion

Grouping according to criterion			
Group	**Intended uses**	**relevant use parameters for grouping**	**relevant parameter or value for sorting**
Oilseed rape	Oisleed rape	1 application, 0.2 L./ha	Before BBCH 69
Orchard	Pome fruits	1-2 applications,0.18 ~~– 0.25 L./ha~~	~~Before BBCH 59 and~~ from BBCH 69

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 ~~Zuxion~~ Asset 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-1-4		156.61	Soil: 53.9 % Water: 12.3% Sediment: 30.7%	Aquatic organims and soil organisms
IM-1-5		197.66	Soils: 20.02%	Aquatic organims and soil organisms
IM-1-2		240.69	Soils: 36.02%	Aquatic organims and soil organisms
IC-0		157.55	Soils: 10.2% Water: 26.15% Sediment: 3.32%	Aquatic organims and soil organisms

9.2 Effects on birds (KCP 10.1.1)

9.2.1 Toxicity data

Avian toxicity studies have been carried out with Acetamiprid. Full details of these studies are provided in the respective EU DAR.

Effects on birds of ~~Zuxion~~ Asset were not evaluated as part of the EU assessment of Acetamiprid. The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

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_{50} = 98 mg/kg bw/d	EFSA Journal 2016;14(11):4610
Colinus virginianus (Bobwhite quail)	Acetamiprid	Acute	LD_{50} > 100 mg/kg bw/d	EFSA Journal 2016;14(11):4610
Poephila guttata (zebra finch)	Acetamiprid	Acute	LD_{50} = 5.7 mg/kg bw/d	EFSA Journal 2016;14(11):4610
Geometric mean	Acetamiprid	Acute	**LD_{50} = 38.2 mg/kg bw/d**	EFSA Journal 2016;14(11):4610
	Acetamiprid	Long-term	**LD_{50}/10 = 3.8 mg/kg bw/d**	EFSA Journal 2016;14(11):4610
Anas platyrhynchos (mallard duck)	Acetamiprid	Reproductive toxicity	NOAEL = 9.5 mg/kg bw/d	EFSA Journal 2016;14(11):4610

Justification for new endpoints

The EU agreed endpoints are uses for the risk assessment.

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.

Table 9.2-2: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of ~~Zuxion~~ Asset in oilseed rape

Intended use	Oilseed rape
Active substance/product	Acetamiprid

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_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Oilseed rape late – late (with seeds) (BBCH 30-99)	Small insectivorous bird "dunnock"	7.4	1.0	0.30	129.05
Oilseed rape early (shoots) (BBCH 10-19)	Large herbivorous bird "goose"	39.0	1.0	1.56	24.49
Oilseed rape BBCH 10 - 29	Small omnivorous bird "lark"	24.0	1.0	0.96	39.79
Oilseed rape BBCH 30 - 39	Small omnivorous bird "lark"	7.2	1.0	0.29	132.64
Oilseed rape BBCH ≥ 40	Small omnivorous bird "lark"	6.0	1.0	0.24	159.17
Oilseed rape BBCH 10 – 19	Medium herbivorous/granivorous bird "pigeon"	55.6	1.0	2.22	17.18
Oilseed rape BBCH 20 – 29	Medium herbivorous/granivorous bird "pigeon"	4.0	1.0	0.16	238.75
Oilseed rape BBCH 30 – 39	Medium herbivorous/granivorous bird "pigeon"	2.4	1.0	0.10	397.92
Oilseed rape BBCH ≥ 40	Medium herbivorous/granivorous bird "pigeon"	2.0	1.0	0.08	477.50
Oilseed rape BBCH 10 – 19	Small insectivorous bird "wagtail"	10.9	1.0	0.44	87.61
Oilseed rape BBCH 20 – 29	Small insectivorous bird "wagtail"	7.7	1.0	0.31	124.03

Reprod. toxicity (mg/kg bw/d)	3.8
TER criterion	5

Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Oilseed rape late – late (with seeds) (BBCH 30-99)	Small insectivorous bird "dunnock"	2.7	1.0 × 0.53	0.06	66.39
Oilseed rape early (shoots) (BBCH 10-19)	Large herbivorous bird "goose"	15.9	1.0 × 0.53	0.34	11.27
Oilseed rape BBCH 10 - 29	Small omnivorous bird "lark"	10.9	1.0 × 0.53	0.23	16.44
Oilseed rape BBCH 30 - 39	Small omnivorous bird "lark"	3.3	1.0 × 0.53	0.07	54.32
Oilseed rape BBCH ≥ 40	Small omnivorous bird "lark"	2.7	1.0 × 0.53	0.06	66.39
Oilseed rape BBCH 10 – 19	Medium herbivorous/granivorous bird "pigeon"	22.7	1.0 × 0.53	0.48	7.90

Oilseed rape BBCH 20 – 29	Medium herbivorous/granivorous bird "pigeon"	3.5	1.0 × 0.53	0.07	51.21
Oilseed rape BBCH 30 – 39	Medium herbivorous/granivorous bird "pigeon"	1.1	1.0 × 0.53	0.02	162.95
Oilseed rape BBCH ≥ 40	Medium herbivorous/granivorous bird "pigeon"	0.9	1.0 × 0.53	0.02	199.16
Oilseed rape BBCH 10 – 19	Small insectivorous bird "wagtail"	5.9	1.0 × 0.53	0.13	30.38
Oilseed rape BBCH 20 – 29	Small insectivorous bird "wagtail"	2.8	1.0 × 0.53	0.06	64.02

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 9.2-3: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of Zuxion-Asset- in pome fruits

Intended use	**Pome fruits**				
Active substance/product	Acetamiprid				
Application rate (g/ha)	2 x 50				
Acute toxicity (mg/kg bw)	38.2				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Orchards	"Indicator species for screening"	46.8	1.2	2.81	13.60
Reprod. toxicity (mg/kg bw/d)	3.8				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Orchards	"Indicator species for screening"	18.2	1.4 × 0.53	0.68	5.63

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.

Applicant update-Nov 2020 (2x180 g f.p./ha , equivalent to 2x36 g a.s./ha):

~~Risk assessment for birds considering the reduction of application rate for comments from efficacy is performed below:~~

Table 9.2-4: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of ~~Zuxion~~ Asset in pome fruits

Intended use	**Pome fruits**				
Active substance/product	Acetamiprid				
Application rate (g/ha)	2 x 36				
Acute toxicity (mg/kg bw)	38.2				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Orchards	"Indicator species for screening"	46.8	1.2	2.02	18.9

Reprod. toxicity (mg/kg bw/d)	3.8				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Orchards	"Indicator species for screening"	18.2	1.4 × 0.53	0.49	7.8

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.

9.2.2.2 Higher-tier risk assessment

Not relevant.

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).

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 (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/kg).

With a K(f)oc of 106.5, Acetamiprid belongs to the group of less sorptive substances. Here, the assessment for the use group orchard also covers the risk for birds for all other intended uses in group oilseed rape.

Effective application rate (g/ha)	=	70			
Acute toxicity (mg/kg bw)	=	38.2	quotient	=	1.83
Reprod. toxicity (mg/kg bw/d)	=	3.8	quotient	=	18.42

9.2.2.4 Effects of secondary poisoning

The log P_{ow} of Acetamiprid amounts to 0.80 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.

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

The risk assessment for birds has been done. The TER_A values are greater than the Annex VI trigger of 10, indicating low acute risk to birds from Acetamiprid following application of ~~Zuxion~~ Asset at all proposed label rates. The TER_{LT} values are greater than the Annex VI trigger of 5, indicating low long-term risk to birds from Acetamiprid following application of ~~Zuxion~~ Asset at all proposed label rates. The risk for drinking water exposure is acceptable and effect of secondary poisoning is not expected.

ZRMS comments:

The acute and chronic risks of SHA5500A/ ~~Zuxion~~ Asset to birds were assessed from toxicity exposure ratios between toxicity endpoints, estimated from study with active ingredients, and maximum residues occurring on food items. No acute toxicity test with the formulation was required.

All TER values exceed the relevant triggers indicating that SHA5500A/ ~~Zuxion~~ Asset 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 birds from secondary poisoning is not required.

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.

Effects on mammals of ~~Zuxion~~ Asset~~-~~ 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 Section 6 (Mammalian Toxicology) of this report.

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

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

Species	Substance	Exposure System	Results	Reference
Rats	Acetamiprid	Oral acute	**LD_{50} = 146 mg/kg bw**	EFSA Journal 2016;14(11):4610
Rats	Acetamiprid	Long-term [90-d study]	NOAEL = 12.4 mg/kg d	EFSA Journal 2016;14(11):4610
Rats	Acetamiprid	Long-term [developmental	**NOAEL = 2.5 mg/kg d**	EFSA Journal 2016;14(11):4610

Species	Substance	Exposure System	Results	Reference
		neurotoxicity study]		

9.3.1.1 Justification for new endpoints

The EU agreed endpoints are uses for the risk assessment.

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 ~~Zuxion~~ Asset in oilseed rape

Intended use **Active substance/product** **Application rate (g/ha)**	Oilseed rape Acetamiprid 1 x 40				
Acute toxicity (mg/kg bw) **TER criterion**	146 10				
Crop scenario **Growth stage**	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Oilseed rape	"Indicator species for screening"	118.4	1	4.74	30.83
Reprod. toxicity (mg/kg bw/d) **TER criterion**	2.5 5				
Crop scenario **Growth stage**	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Oilseed rape BBCH 10 - 19	Small insectivorous mammal "shrew"	4.2	1 × 0.53	0.09	28.08
Oilseed rape BBCH ≥ 20	Small insectivorous mammal "shrew"	1.9	1 × 0.53	0.04	62.07
Oilseed rape BBCH ≥ 40	Small herbivorous mammal "vole	18.1	1 × 0.53	0.38	6.52
Oilseed rape All season	Large herbivorous mammal "lagomorph"	14.3	1 × 0.53	0.30	8.25
Oilseed rape BBCH 10 - 29	Small omnivorous mammal "mouse"	7.8	1 × 0.53	0.17	15.12
Oilseed rape BBCH 30 - 39	Small omnivorous mammal "mouse"	2.3	1 × 0.53	0.05	51.27

Oilseed rape BBCH ≥ 40	Small omnivorous mammal “mouse”	1.9	1 × 0.53	0.04	62.07

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 ~~Zuxion~~ Asset~~-~~ in pome fruits

Intended use **Active substance/product** **Application rate (g/ha)**	Pome fruits, BBCH >69 Acetamiprid ~~2 x 50~~, 2 x36*				
Acute toxicity (mg/kg bw) **TER criterion**	146 10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Orchard	“Indicator species for screening”	136.4	1.2	8.18 5.89	17.84 24.8*
Reprod. toxicity (mg/kg bw/d) **TER criterion**	2.5 5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
~~Orchard Application crop directed BBCH <10 or not crop directed~~	~~Small insectivorous mammal “shrew”~~	~~1.9~~	~~1.4 × 0.53~~	~~0.07~~	~~35.47~~
~~Orchard Application crop directed BBCH <10 or not crop directed~~	~~Small herbivorous mammal "vole”~~	~~72.3~~	~~1.4 × 0.53~~	~~2.68~~	~~**0.93**~~
~~Orchard Application crop directed BBCH 10–19~~	~~Small herbivorous mammal "vole”~~	~~57.8~~	~~1.4 × 0.53~~	~~2.14~~	~~**1.17**~~
~~Orchard Application crop directed BBCH 20–40~~	~~Small herbivorous mammal "vole”~~	~~43.4~~	~~1.4 × 0.53~~	~~1.61~~	~~**1.55**~~
Orchard Application crop directed BBCH ≥ 40	Small herbivorous mammal "vole”	21.7	1.4 × 0.53	0.81 0.58	**3.11** 4.31*
Orchard Fruit stage BBCH 71-79 currants	Frugivorous mammal "dormouse"	22.7	1.4 × 0.53	0.84 0.6	**2.97** 4.16*
~~Orchard Application crop directed BBCH <10 or not crop directed~~	~~Large herbivorous mammal “lagomorph”~~	~~14.3~~	~~1.4 × 0.53~~	~~0.53~~	~~**4.71**~~

~~Orchard Application crop directed BBCH 10- 19~~	~~Large herbivorous mammal "lagomorph"~~	~~11.5~~	~~1.4 × 0.53~~	~~0.43~~	~~5.86~~
~~Orchard Application crop directed BBCH 20- 40~~	~~Large herbivorous mammal "lagomorph"~~	~~8.6~~	~~1.4 × 0.53~~	~~0.32~~	~~7.84~~
Orchard Application crop directed BBCH ≥ 40	Large herbivorous mammal "lagomorph"	4.3	1.4 × 0.53	0.16 0.11	15.67 22.72*
~~Orchard Application crop directed BBCH <10 or not crop directed~~	~~Small omnivorous mammal "mouse"~~	~~7.8~~	~~1.4 × 0.53~~	~~0.29~~	~~8.64~~
~~Orchard Application crop directed BBCH 10- 19~~	~~Small omnivorous mammal "mouse"~~	~~6.2~~	~~1.4 × 0.53~~	~~0.23~~	~~10.87~~
Application crop directed BBCH 20- 40	Small omnivorous mammal "mouse"	4.7	1.4 × 0.53	0.17 0.12	14.34 20.83*
Orchard Application crop directed BBCH ≥ 40	Small omnivorous mammal "mouse"	2.3	1.4 × 0.53	0.09 0.06	29.30 41.66*

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.
*the TER for rate 2x 36 g a.s./ha

9.3.2.2 Higher-tier risk assessment

TER_a values are greater than the Annex VI trigger of 10, indicating that ~~Zuxion~~ Asset presents no unacceptable acute risk to mammals.

TER_{lt} values are greater than the trigger of 5 except for the species "vole", "dormouse" and "lagomorph" in pome fruits, indicating a potential unacceptable long-term risk to mammals. Further refinements are therefore required.

Deposition factor (DF)

~~Zuxion~~ Asset will be applied directly to crop. Since grass will be covered by the crop, an interception by the crop has to be taken into account. In addition, the Applicant considers that the leaves cover the fruits that are in the tree at the time of application. Moreover, the frugivorous mammals will be fed mostly fruits that are on the ground. Therefore, the Applicant considers that a deposition factor for the refinement is justified.

According to the interception values of EFSA Journal 2014;12(5):3662[1], for pome fruits, an interception factor of 60% should be considered as highest worst case. Therefore, for the refinement of the risk a deposition factor of 0.4 should be applied for small herbivorous and frugivorous mammals.

[1] EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil.

DT50

In the Tier I assessment, the default foliar DT_{50} is 10 days. However, the foliar DT_{50} was refined considering the available information from decline residue trials and according to *Conclusion of Peer review of the pesticide risk assessment of the active substance acetamiprid* (EFSA Journal 2016;14(11):4610*)*, a refined residue for dicotic portion of the diet based on a geomean value of DT_{50} of 2.3 days was considered for the refinement of "vole".

TWA

In the Tier I, the default twa value used is 0.53. However, since the DT_{50} is lower than 10 days, the twa value was recalculated considering the geomean DT_{50} of 2.3 days and the resulting value is 0.23 for "vole". which will be used in the higher-tier assessment.

MAF

Considering the the geomean DT_{50} of 2.3 days, the MAF was re-calculated considering the formula of the EFSA/2009/1438, and the resulting MAF was 1.01. This value was used for the refinement.

Table 9.3-4: Higher-tier assessment of long-term risk for mammals due to the use of ~~Zuxion~~ Asset in pomefruits– refined parameters (*) are further described and justified in the text

Intended use	Pome fruits						
Active substance/product	Acetamiprid						
Application rate (g/ha)	2 x 50						
Reprod. toxicity (mg/kg bw/d)	2.5						
TER criterion	5						
Focal species	**Food category, % in diet**	**FIR/bw**	**RUD_m × DF (mg/kg food)**	**MAF_m* × TWA***	**PT***	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Common vole (*Microtus arvalis*)	Grass + cereals	1.33	54.2[1] × 0.4[2]	1.01[3] × 0.23[3]	1.0	0.33	7.46
Rabbit (*Oryctolagus cuniculus*)	**Non-grass herbs**	**0.50**	**28.7[1] × 0.4[2]**	**1.4 × 0.53**	**1.0**	**0.21**	**11.74**
Garden dormouse (Eliomys quercinus)	100% fruit	1.16	19.5[1] × 0.4[2]	1.4 × 0.53	1.0	0.34	7.45

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

[1] According to Appendix A of EFSA/2009/1438.

[2] An interception factor of 60% is considered as highest worst case according to according to the interception values of EFSA Journal 2014;12(5):3662.

[3] Values of MAF_m and ftwa obtained from calculated DT_{50} from decline residue trials (please refer to *Conclusion of Peer review of the pesticide risk assessment of the active substance acetamiprid, EFSA Journal 2016;14(11):4610*).

Moreover, there are many reasons why the risk assessment for vole is considered to be covered through the assessment of other small mammalian species:

- High fecundity and population recuperation of the vole.
- Primary source of food outside crops fields for the vole.
- Necessity of population control measures since the vole is considered a crop pest when high population levels are reached.
- Other agricultural techniques being also means of population control.

In addition, orchards are intensively managed crops, besides the use of pesticides particularly mechanical husbandry activities such as mowing, mulching and pruning take place. Based in generic studies and literatura data, intensively managed orchards by mowing, mulching and herbicidal weeding pose adverse habitat conditions for the common vole and are therefore considered only as secondary habitats for this species. Orchards are mulched regularly during the vegetation season reducing the vegetation height which increases the predation risk being orchards are a secondary habitat for voles.

Therefore, the exposure of common voles to plant protection products within orchards is not ecologically relevant for the persistence of the populations. Since the exposure of common voles to plant protection products in orchards is not ecologically relevant for the survival and reproduction of the populations, the Wood mouse (*Apodemus syvalticus*) and the European hare (*Lepus europaeus*) were identified as suitable focal species in pome fruits. Same findings were reported in studies already evaluated by EFSA (*EFSA Journal 2010;8(11):1904)*.

Applicant update-Nov 2020

~~The following options have been considered by the Applicant according to comments from efficacy.~~

Option 1 (1 x 40 g a.s./ha and application from BBCH 69)

Application rate and BBCH
According to the proposed GAP, a reduction from 2 to 1 application is proposed by the Applicant.
In addition, application from BBCH 69 is defended by the Applicant. This approach was considered for the risk assessment performed below.

Deposition factor (DF)
According to the interception values of EFSA Journal 2014;12(5):3662[2], for pome fruits, an interception factor of 65% should be considered from BBCH 69. Therefore, for the refinement of the risk a deposition factor of 0.35 should be applied for small herbivorous and frugivorous mammals.

PD
As a further refinement of the risk of vole in tomat**o**, the PD refinement was considered. A PD refinement is commented by Netherlands[3] and a proposal of refinement is given. The refinement is based on the studies by Rinke (1991) "*Percentage of volume versus number of species: availability and intake of grasses and forbs in microtus arvalis. Folia zoological 40 (2): 143-151*" and by Lüthi, M. *et al* (2010) "*Nutritional ecology of Microtus arvalis* (*Pallas, 1779) in sown wild flower fields and quasi-natural habitats. Revue Suisse de Zoologia 117 (4): 811-828*".

In the study of Rinke (1991) the stomach content of 363 individuals (186 females and 177 males) trapped on five plots of permanent meadow in central Hessia (Germany) were analyzed. The study investigated the vole feeding preferences (mono *vs.* dicot). In the study voles showed a preference for dicots, with the majority of voles (all seasons, sexes, ages) showing > 80% dicot material in stomach contents.

Diet of common voles (%) – Rinke 1991

Season	Monocotyledons (% volume)	Dicotyledonos (% volume)	No. of voles
Spring	24	76	23
Summer	25	75	152
Autum	48	52	188

[2] EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil.
[3] Evaluation Manual for the authorization of plant protection products according to Regulation (EC) No 1107/2009 Chapter 7, version 2.2; April 2017

Total	36	64	363

In the study of Lüthi et al., 2010 the diet of the common vole in monocot and dicot dominated fields was studied. In the sown wild flower areas vegetation cover was mainly dicot (79%, 81.6% and 79% in the three fields, respectivley) and in the quasi natural habitat the cover was mainly monocots (82.5, 92.5 and 47.5%).

Diet of common voles (%) – Lüthi et al., 2010

Sown wild flower fields	**Field 1**	**Field 2**	**Field 3**	**Average**
Dicots	16.3	31.8	11.2	19.6
Monocots	43.1	36.5	53.3	44.3
Seeds	14.8	16.5	27.0	19.4
Other (roots)	25.8	15.2	8.5	16.6
Natural quasi habitat				
Dicots	17.1	6.2	9.6	11.0
Monocots	67.7	81.9	66.0	71.0
Seeds	6.6	8.4	17.0	10.7
Other (roots)	8.56	3.5	7.4	7.4

Dicot dominated fields (agricultural crops, etc): 50% non-grass herbs and 50% grass and cereals

Monocot dominated underground (grasslands, orchards, etc): 25% non-grass herbs and 75% grass and cereals.

The approach is considered appropriate for the refinement of the chronic risk assessmente for vole. Therefore, for the refinement of the risk in pome fruits, a PD of 0.25 for non-grass herbs and 0.75 for grass and cereals will be used.

FIR/bw

For the food category grass and cereals, the FIR/bw value of 1.33, given by EFSA/2009/1438 was used. For the food category non-grass herbs, FIR/bw value was calculated. Default values given by EFSA/2009/1438 were used for the estimation of FIR and a bw value of 25 g for common vole given in EFSA/2009/1439 was used. The resulting values were: FIR = 40.433; FIR/bw = 1.62.

Table 9.3-5: Higher-tier assessment of the long-term/reproductive risk for mammals due to the use of ~~Zuxion~~ Asset in pome fruits– refined parameters (*) are further described and justified in the text

Intended use	Pome fruits
Active substance/product	Acetamiprid
Application rate (g/ha)	1 x 40
Reprod. toxicity (mg/kg bw/d)	2.5
TER criterion	5

Focal species	**Food category, % in diet**	**FIR/bw**	**RUD_m× DF* (mg/kg food)**	**MAF_m × TWA**	**PT**	**PD***	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Common vole (*Microtus arvalis*)	75% grass and cereals	1.33	54.2[1] × 0.35[1]	1.0 x 0.53	1.0	0.75*	0.09	5.1
BBCH ≥ 69	25% non-grass herbs	1.62	28.7[1] x 0.35[1]	1.0 x 0.53	1.0	0.25*	0.40	

	Total	0.49	

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.
[1]According to Appendix A of EFSA/2009/1438.
[2] An interception factor of 65% is considered as highest worst case according to according to the interception values of EFSA Journal 2014;12(5):3662.

Option 2 (2 x 36 g a.s./ha)

Focal species and PD

According to *EFSA Scientific Report (2006) 61, 1-70, Conclusion on the peer review of pyrimethanil*, typical small herbivores like voles of the genus *Microtus* are considered not to be representative inhabitants of apple orchards. The bank vole (*Clethrionomys glareolus*) was chosen as relevant species. Based on a study on seasonal diet composition (Abt & Bock 1998: "Seasonal variations of diet composition in farmland field mice *Apodemus* spp. and bank voles *Clethrionomys glareolus*", Acta Theriologica 43: 379-389), the representative summer diet of bank voles consists of approx. **60 % grains/seeds, 20 % green plant material and 20 % invertebrates**. Although one might suppose a high dependence of diet composition on the availability of food items in the habitat and many cereal grains were available at the investigated study site, the authors state that "Proportions of primary food items, i.e. seeds, tend to be similar in different food habitats". In addition, as diet composition of wood mice in orchards is not known, EFSA agreed to use the bank vole as a focal species and hence the PD of 0.2/0.6/0.2 for short grass/seeds/large insects respectively to refine the risk, since it also covers the risk to wood mouse.

Refinement of FIR/bw

A FIR/bw corresponding to modified diet of Wood mouse was calculated in accordance to the EFSA GD

Table 9.3-6: Calculation of FIR for Bank vole

Species	Body weight (g)	Diet item	Daily energy expenditure, DEE [kJ/d]	Food energy, FE [kJ/d]	Moisture content, MC [%]	Assimilation efficiency, AE [%]	FIR	FIR/bw
Bank vole (*Clethrionomys glareolus*)	25	Short grass	58.44	17.6	76.4	47	33.343	1.33
		Seeds	58.44	18.4	14.7	84	4.937	0.20
		Large insects	58.44	22.7	68.8	87	10.564	0.42

Therefore, the resulting TER_{LT} values are given in the tables below.

Table 9.3-7: Higher-tier assessment of the long-term/reproductive risk for mammals due to the use of ~~Zuxion~~ Asset ~~in~~ in pome fruits– refined parameters (*) are further described and justified in the text

Intended use	Pome fruits							
Active substance/product	Acetamiprid							
Application rate (g/ha)	2 x 36							
Reprod. toxicity (mg/kg bw/d)	2.5							
TER criterion	5							
Focal species	**Food category, % in diet**	**FIR/bw**	**RUD_m× DF***	**MAF_m × TWA**	**PT**	**PD***	**DDD_m (mg/kg bw/d)**	**TER_{lt}**

			(mg/kg food)					
Bank vole (*Clethrionomys glareolus*) BBCH ≥ 40	20% short grass	1.33	54.2[1] × 0.4[1]	1.4 x 0.53	1.0	0.20*	0.15	11.7
	60% seeds	0.20	40.2[1] x 0.4[1]	1.4 x 0.53	1.0	0.60*	0.05	
	20% large insects	0.42	3.5[1] × 1.0	1.4 x 0.53	1.0	0.20*	0.01	
						Total	0.21	

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.
[1] According to Appendix A of EFSA/2009/1438.
[2] An interception factor of 60% is considered as highest worst case according to according to the interception values of EFSA Journal 2014;12(5):3662.

zRMS comments:

~~The applicant provided higher tier refinements to address the risk to vole, lagomorph and garden dormouse for max application doses 2 x 50 g a.s./ha and for lower doses: 2 x 36 g a.s./ha and 1 x 40 g a.s./ha to vole with refined parameters.~~

The refined risk assessment provided by the applicant for vole for all proposed uses was verified by zRMS and corrected according to information provided for vole in orchards (for application rate of 1 x 36 g and 2 x 36 g a.s./ha) presented in the DAR in acetamiprid as the worst case scenario.

It should be noted that the applicant referred also to the study by Rinke (1990): Percentage of volume versus number of species: Availablity and intake of grasses and forbs in *microtus arvalis*. Folia zoologica 40 (2): 143-151 which was evaluated in the DAR. It was concluded that the study cannot be used to determine a quantitative PD (mono versus dicotyledonous plant matter), however, it can be used to determine that the actual diet of the common vole typically contains both monocotyledons and dicotyledons and that dicots will comprise ≥50% of the diet under normal circumstances,

For this reason the chronic risk assessment the diet on 50 % monocots and 50 % dicots was considered during renewal of the a.s.-acetamiprid and this PD value was taken into account in this dossier.

In addition, refined parameters such as :DF of 0.35, ftwa=0.16 based on DT_{50} of 2.8 days and refined MAF of 1.01 for dicot plants for two application with 14 days interval agreed at EFSA Conclusion 2016 was use in the risk assessment for BBCH>69 in orchards.

The applicant proposed also use bank vole in the refined risk assessment in orchards.

However, during evaluation of acetamiprid the RMS notes that the bank vole diet is significantly different than that of the common vole, in that it is more frugivorous/granivorous/insectivorous than herbivorous, thus the RMS does not consider the bank vole to be representative of a small herbivorous mammal.

The risk assessmmet according to recommendation given in EFSA Conclusion 2016 for a.s.- acetamiprid is provided in the Tables below:

Table 9.3-8: Higher-tier assessment of long-term risk for mammals due to the use of ~~Zuxion~~ Asset in pomefruits–refined parameters for application dose of 1 x 36 g a.s./ha.

Intended use	Pome fruits
Active substance/product	Acetamiprid
Application rate (g a.s./ha)	1 x 36, **BBCH >69**
Reprod. toxicity (mg/kg bw/d)	2.5
TER criterion	5

Focal species	**Food category, % in diet**	**FIR/bw**	**RUD_m× DF*** (mg/kg food)	**MAF_m × TWA**	**PT**	**PD**	**DDD_m** (mg/kg bw/d)	**TER_{lt}**
Common vole (*Microtus arvalis*) BBCH ≥ 69	50% monocot	1.46	54.2 × 0.35[1]	1.0 x 0.53	1.0	0.5	0.26	6.25
	50% dicots		28.7x 0.35[1]	1.0 x 0.53	1.0	0.5	0.14	
						Total	0.4	

FIR/bw: Food intake rate per body weight; **FIR was calculated by ZRMS, using PD 50% monocot/50% dicot.**
RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger. **FIR was calculated by ZRMS, using PD50% monocot and 50% dicot.**

Table 9.3-9: Higher-tier assessment of long-term risk for mammals due to the use of ~~Zuxion~~ Asset in pomefruits – refined parameters for application dose of 2 x 0.036 kg a.s./ha.

Intended use	Pome fruits
Active substance/product	Acetamiprid
Application rate (g a.s./ha)	2 x 36, **BBCH >69**
Reprod. toxicity (mg/kg bw/d)	2.5
TER criterion	5

Focal species	**Food category, % in diet**	**FIR/bw**	**RUD_m× DF** (mg/kg food)	**MAF_m × TWA**	**PT**	**PD***	**DDD_m** (mg/kg bw/d)	**TER_{lt}**
Common vole (*Microtus arvalis*) BBCH ≥ 69	50% monocot	~~1.47~~ 1.46	54.2× 0.35	1.4 x 0.53	1.0	0.5	0.37	6.09
	50% dicots		x 28.7[1] x 0.35[1]	1.01x0.16	1.0	0.5	0.043	
			Total				0.41	

FIR/bw: Food intake rate per body weight; **FIR was calculated by ZRMS, using PD 50% monocot and 50% dicot.**
RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio.

The risk assessment for vole is considered acceptable for application rate of 1-2 x 0.036 kg a.s./ha.

~~**Table 9.3-10: Higher-tier assessment of long-term risk for mammals due to the use of Zuxion Asset in pome fruits–refined parameters for application dose of 2 x50 g a.s./ha**~~

~~**Intended use**~~	~~Pome fruits~~
~~Active substance/product~~	~~Acetamiprid~~
~~Application rate (g a.s./ha)~~	~~2 x 50, 14 day interval, **BBCH> 69**~~
~~**Reprod. toxicity (mg/kg bw/d)**~~	~~2.5~~

~~TER criterion~~			~~5~~						
~~Focal species~~	~~Food category, % in diet~~	~~FIR/bw~~	~~RUD_m x DF (mg/kg food)~~	~~MAF_m x TWA*~~	~~PT~~	~~PD~~	~~DDD_m (mg/kg bw/d~~	~~DDD_m (mg/kg bw/d) sum~~	~~TER_{lt}~~
~~Common vole (*Microtus arvalis*)~~	~~50% monocot~~	~~1.46~~	~~54.2 × 0.35~~	~~1.4x 0.53~~	~~1.0~~	~~0.5~~	~~0.51~~	~~0.57~~	~~**4.38**~~
	~~50% dicots~~		~~28.7 x 0.35~~	~~1.01 x 0.16~~	~~1.0~~	~~0.5~~	~~0.06~~		

Table 9.3.10: Higher-tier assessment of long-term risk for mammals due to the use of Asset in pomefruits.

Intended use	Pome fruits, **BBCH > 69**						
Active substance/product	Acetamiprid						
Application rate (g/ha)	2 x 36						
Reprod. toxicity (mg/kg bw/d)	2.5						
TER criterion	5						
Focal species	**Food category, % in diet**	**FIR/bw**	**RUD_m × DF (mg/kg food)**	**MAF_m* × TWA***	**PT***	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Rabbit (*Oryctolagus cuniculus*)	**Non-grass herbs**	0.50	28.7[1] × 0.4[2]	1.4 × 0.53	1.0	0.15	16.66
Garden dormouse (Eliomys quercinus)	100% fruit	1.16	19.5[1] × 0.4[2]	1.4 × 0.53	1.0	0.24	10.42

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.
[1] According to Appendix A of EFSA/2009/1438.
[2] An interception factor of 60% is considered as highest worst case according to according to the interception values of EFSA Journal 2014;12(5):3662. **During the commenting period the HU did not accept the DF of 0.4 for frugivorous mammals.Therfore,in opinion od zRMS further refinmant should be considered at MSs level.**
[3] Values of MAF_m and ftwa obtained from calculated DT_{50} from decline residue trials (please refer to *Conclusion of Peer review of the pesticide risk assessment of the active substance acetamiprid, EFSA Journal 2016;14(11):4610*).

The risk assessment for rabbit for single application dose at 2 x 36 g a.s./ha for rabbit and garden dormouse is considered acceptable when DF is applied.

Table 9.3.10-1: Higher-tier assessment of long-term risk for mammals due to the use of Asset in pomefruits for application of 1 x 36 g a.s./ha

Intended use	Pome fruits						
Active substance/product	Acetamiprid						
Application rate (g/ha)	1 x 36						
Reprod. toxicity (mg/kg bw/d)	2.5						
TER criterion	5						
Focal species	**Food category, % in diet**	**FIR/bw**	**RUD_m × DF (mg/kg food)**	**MAF_m* × TWA***	**PT***	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Rabbit (*Oryctolagus cuniculus*)	**Non-grass herbs**	0.50	28.7[1 2]	1 × 0.53	1.0	0.27	9.25

Garden dormouse (Eliomys quercinus)	100% fruit	1.16	19.5[1]	1 × 0.53	1.0	0.43	5.81

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.
[1] According to Appendix A of EFSA/2009/1438.

The risk assessment for rabbit for single application dose at 1 x 36 g a.s./ha for rabbit and garden dormouse is considered acceptable.

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 (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/kg).

With a K(f)oc of 106.5, Acetamiprid belongs to the group of less sorptive substances. Here, the assessment for the use group orchard also covers the risk for mammals for all other intended uses in group oilseed rape.

Effective application rate (g/ha)	=	70			
Acute toxicity (mg/kg bw)	=	146	quotient	=	0.48
Reprod. toxicity (mg/kg bw/d)	=	2.5	quotient	=	28.00

9.3.2.4 Effects of secondary poisoning

The log P_{ow} of Acetamiprid amounts to 0.80 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.

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

The risk assessment for mammals has been done. The TER_A values are greater than the Annex VI trigger of 10, indicating low acute risk to mammals from Acetamiprid following application of ~~Zuxion~~ Asset at all proposed label rates. The TER_{LT} values were below than the Annex VI trigger of 5, indicating a long-term risk to mammals from Acetamiprid following application of ~~Zuxion~~ Asset at all proposed label rates. After the ftwa, MAF and DF refinement, the risk was considered acceptable. The risk for drinking water exposure is acceptable and effect of secondary poisoning is not expected.

ZRMS comments:

The acute risks of SHA5500A/ ~~Zuxion~~ Asset to mammals were assessed from toxicity exposure ratios between toxicity endpoints, estimated from study with active ingredients, and maximum residues occurring on food items. No acute toxicity test with the formulation was required.

Refined TER_{LT} values exceed the relevant triggers, ~~except species~~ for vole-small herbivorous mammals in orchards and frugivorous mammal following use for ~~max application rates of 2 x 50g a.s./ha at rate of~~ 2 x 36 g a.s./ha at BBCH>69, indicating ~~needs for further refinement at national level.~~ an acceptable risk for mammals

For ~~remained uses in orchards and~~ oilseed rape the acute and long term risk for mammals is considered an acceptable.

Evaluation of exposing to mammals through the drinking water demonstrated the acceptable risk.

The risk to earthworm- and fish-eating mammals from secondary poisoning is not required.

9.4 Effects on other terrestrial vertebrate wildlife (reptiles and amphi bians) (KCP 10.1.3)

Not relevant.

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 and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on aquatic organisms of ~~Zuxion~~ Asset 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 regarding the active substance is in line with the results of Acetamiprid and deviates from the results of the formulation 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
Fish				
Oncorhynchus mykiss	Acetamiprid	96 h, s	LC_{50} > 100 mg a.s./L (nom)	EFSA Journal 2016;14(11):4610
Lepomis macrochirus	Acetamiprid	96, f	LC_{50} > 119.3 mg a.s./L (mm)	EFSA Journal 2016;14(11):4610
Cyprinodon variegatus	Acetamiprid	96, f	**LC_{50} > 100 mg a.s./L (nom)**	EFSA Journal 2016;14(11):4610
Oncorhynchus mykiss	IM-1-4	96 h, ss	LC_{50} = 98.1 mg a.s./L (mm)	EFSA Journal 2016;14(11):4610
Pimephales promelas	Acetamiprid	35 d, f	**$NOEC_{hatch}$ = 9.4 mg a.s./L (mm)** $EC10_{hatch}$ = >150 mg a.s./L(mm)	EFSA Journal 2016;14(11):4610
Aquatic invertebrates				
Daphnia magna	Acetamiprid	48 h, s	EC_{50} = 49.8 mg a.s./L (mm)	EFSA Journal 2016;14(11):4610
Daphnia magna	EXP60707A	48 h, s	EC_{50} > 31.8 mg a.s./L (mm)	EFSA Journal 2016;14(11):4610
Chironomus riparius	Acetamiprid	48 h, s	EC_{50} = 0.0207 mg a.s./L (mm)	EFSA Journal 2016;14(11):4610
Gammarus fasciatus	Acetamiprid	96 h, s	EC_{50} = 0.1 mg a.s./L (mm)	EFSA Journal 2016;14(11):4610
Mysidopsis bahia	Acetamiprid	96 h, f	EC_{50} = 0.066 mg a.s./L (mm)	EFSA Journal 2016;14(11):4610
Gammarus pulex	Acetamiprid	96 h, s	EC_{50} = 0.050 mg a.s./L (mm)	EFSA Journal 2016;14(11):4610
Simulium latigonium	Acetamiprid	96 h, s	EC_{50} = 0.0037 mg a.s./L (mm)	EFSA Journal 2016;14(11):4610
Geometric mean aquatic insects	Acetamiprid		**EC_{50} = 0.0085 mg a.s./L (mm)**	EFSA Journal 2016;14(11):4610
Chironomus riparius	Acetamiprid 20% SP	72 h, s	EC_{50} = 0.0196 mg a.s./L((mm))	EFSA Journal 2016;14(11):4610
Daphnia magna	IM-1-4	48 h, s	EC_{50} = 43.9 mg a.s./L	EFSA Journal 2016;14(11):4610
Mysidopsis bahia	IM-1-4	48 h, s	EC_{50} = 19 mg a.s./L	EFSA Journal 2016;14(11):4610
Chironomus riparius	IM-1-4	48 h, s	LC_{50} = 76 mg a.s./L	EFSA Journal 2016;14(11):4610
Daphnia magna	IM-1-2	48 h, s	EC_{50} = 99.8 mg a.s./L	EFSA Journal 2016;14(11):4610
Chironomus riparius	IM-1-2	48 h, s	EC_{50} = 15.0 mg a.s./L	EFSA Journal 2016;14(11):4610

Species	Substance	Exposure System	Results	Reference
Daphnia magna	IC-0	48 h, s	EC_{50} > 95.1 mg a.s./L	EFSA Journal 2016;14(11):4610
Chironomus riparius	IC-0	48h, s	EC_{50} > 100 mg a.s./L	EFSA Journal 2016;14(11):4610
Daphnia magna	IM-1-5	48 h, s	EC_{50} = 25 mg a.s./L	EFSA Journal 2016;14(11):4610
Chironomus riparius	IM-1-5	48 h, s	EC_{50} = 68 mg a.s./L	EFSA Journal 2016;14(11):4610
Daphnia magna	IM-1-5	21 d, s	NOEC = 26 mg a.s./L	EFSA Journal 2016;14(11):4610
Daphnia magna	IB-1-1	48 h, s	EC_{50} > 100.8 mg a.s./L	EFSA Journal 2016;14(11):4610
Daphnia magna	Acetamiprid	21 d, s	NOEC = 5 mg a.s./L(mm) **EC_{10} = 2.96 mg a.s./L(mm)**	EFSA Journal 2016;14(11):4610
Algae				
Scenedesmus subspicatus	Acetamiprid	72 h, s	EC_{50} > 98.3 mg a.s./L (mm)	EFSA Journal 2016;14(11):4610
Anabaena flos-aquae	Acetamiprid	120 h, s	**EC_{50} > 1.3 mg a.s./L (mm)**	EFSA Journal 2016;14(11):4610
Scenedesmus subspicatus	Acetamiprid 20% SP	72 h, s	E_bC_{50} > 19.6 mg a.s./L (mm)	EFSA Journal 2016;14(11):4610
Sediment-dwelling organisms				
Chironomus riparius	Acetamiprid	28d, s	NOEC = 0.00096 mg a.s./L (mm) ; **EC_{10} = 0.000235 mg a.s./L (mm)**	EFSA Journal 2016;14(11):4610
Higher plant				
Lemna gibba	Acetamiprid	14 d, s	**EC_{50} > 1 mg a.s./L**	EFSA Journal 2016;14(11):4610
Amphibians				
Xenopis laevis	Acetamiprid	21 d, f	**Growth = 2.6 mg a.s./L (mm)**	EFSA Journal 2016;14(11):4610
Higher-tier studies (micro- or mesocosm studies)				

Species	Substance	Exposure System	Results	Reference
Further testing on aquatic organisms Outdoor mesocosm study: Effect assessment on macroinvertebrates, zooplankton, phytoplankton, periphyton and macrophytes in outdoor mesocosms. Test substance: Acetamiprid 20 SG (Mospilan 20 SG). 2 applications with a 14 day interval. Study duration: 82 days. Treatment rates: 0.5, 1.1, 2.6 and 6.0 µg a.s./L. Endpoints: NOEC and NOEAEC <0.5 µg/L based on class 5B effects on Naididae at 0.5-6.0 µg/L . Considering however the uncertainty associated with the findings for Naididae (not expected to be more sensitive than insects based on mode of action; relatively low numbers in control, although MDD was low) the reported conclusion by the study author NOEC based on class 2 effects to derive the ETO-RAC 1.1 µg/L; NOEAEC to derive ERO-RAC 1.1 µg/L based on class 5B effects on Cloeon dipterum at 2.6 µg/L) could be acceptable in case the findings for Naididae in the present study are negated by prolonged toxicity laboratory studies (e.g. at least 28 days duration) with representative taxa of Naididae. Potential endocrine disrupting properties (Annex Part A, point 8.2.3) The mammalian toxicology data was considered, along with the amphibian metamorphosis assay and the fish early life-stage test. These data do not indicate an endocrine-system-specific pathway of toxicity (i.e. systemic toxicity is indicated, as opposed to direct interaction with estrogen, androgen or thyroidal systems). **zRMS comments: LoA is needed to use this study in the risk assessment**.				

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 – ~~Zuxion~~ Asset

Species	Substance	Exposure System	Results	Reference
Oncorhynchus mykiss	~~Zuxion~~ Asset	96 h, s	**LC_{50} = 46.67 mg f.p./L** (9.474 mg a.s./L)	KCP 10.2.1-01 xxx, 2017 W/12/17
Daphnia magna	~~Zuxion~~ Asset	48 h, s	**EC_{50} = 69.18 mg f.p./L**	KCP 10.2.1-02 xxx, 2017 W/14/17
Pseudokirchneriella subcapitata	~~Zuxion~~ Asset	72 h	**E_rC_{50} = 677.92 mg f.p./L** (137.619 mg a.s./L) E_yC_{50} = 172.87 mg f.p./L (35.092 mg a.s./L)	KCP 10.2.1-03 xxx, 2017 W/13/17

Species	Substance	Exposure System	Results	Reference
Lemna gibba	~~Zuxion~~ Asset	7d, ss	Frond number : **E_rC_{50} = 330.02 mg f.p./L** (66.994 mg a.s./L) E_yC_{50} = 175.87 mg f.p./L (35.701 mg a.s./L) Dry weight E_rC_{50} >1000 mg f.p./L (>203 mg a.s./L) E_yC_{50} = 262.21 mg f.p./L (53.230 mg a.s./L)	KCP 10.2.1-04 xxx, A. 2017 W/15/17
Chironomus riparius	~~Zuxion~~ Asset	48h, s	**EC_{50} = 0.104 mg f.p./L**	KCP 10.2.1-05 Angayarkanni, V. 2018 4343/2018
Higher-tier studies (micro- or mesocosm studies)				
-				

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

9.5.1.1 Justification for new endpoints

The EU agreed endpoints for Acetamiprid are used for the assessments and the endpoints for Zuxion are from the new studies

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_{SW} for risk assessments covering the proposed use pattern and the resulting PEC/RAC ratios are presented in the table below.

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

Table 9.5-3: 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 ~~Zuxion~~ Asset in winter oilseed rape

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants acute**	**Amphibi-ans**
Test species		***Cyprinodon variegatus***	***Pimephales promelas***	**Geomean of EC_{50} of 2 aquatic insect species**	***Daphnia magna***	***Scenedes-mus. sub-spicatus***	***Chironomus riparius***	***Lemna gibba***	***Xenopis laevis***
Endpoint (µg/L)		LC_{50} > 100000	NOEC -9400	EC_{50} 8.5	EC_{10} 2960	E_rC_{50}/E_yC_{50} > 1300	NOEC 0.235	EC_{50} 1000	NOEC 2600
AF		100	10	100	10	10	10	10	10
RAC (µg/L)		>1000	940	0.085	296	>130	0.0235	100	260
FOCUS Sce-nario	**PEC $_{gl\text{-}max}$ (µg/L)**								
Step 1									
	12.10	<0.012	0.013	**142.353**	0.041	<0.093	**514.894**	0.121	0.047
Step 2									
S-Europe	0.41	<0.001	<0.001	**4.824**	0.001	0.003	**17.447**	0.004	0.002
N-Europe	0.51	0.001	0.001	**6.000**	0.002	0.004	**21.702**	0.005	0.002
Step 3									
D2/ditch	0.257	<0.001	<0.001	**3.024**	0.001	0.002	**10.936**	0.003	0.001
D2/stream	0.229	<0.001	<0.001	**2.694**	0.001	0.002	**9.745**	0.002	0.001
D3/ditch	0.255	<0.001	<0.001	**3.000**	0.001	0.002	**10.851**	0.003	0.001
D4/pond	0.009	<0.001	<0.001	0.106	<0.001	<0.001	0.383	<0.001	<0.001
D4/stream	0.219	<0.001	<0.001	**2.576**	0.001	0.002	**9.319**	0.002	0.001
D5/pond	0.009	<0.001	<0.001	0.106	<0.001	<0.001	0.383	<0.001	<0.001
D5/stream	0.237	<0.001	<0.001	**2.788**	0.001	0.002	**10.085**	0.002	0.001

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Aquatic plants acute	Amphibi-ans
R1/pond	0.009	<0.001	<0.001	0.106	<0.001	<0.001	0.383	<0.001	<0.001
R1/stream	0.168	<0.001	<0.001	**1.976**	0.001	0.001	**7.149**	0.002	0.001
R3/stream	0.320	<0.001	<0.001	**3.024**	0.001	0.002	**10.936**	0.003	0.001

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

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 ~~Zuxion~~ Asset in summer oilseed rape

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. pro-longed	Aquatic plants acute	Amphibi-ans
Test species		***Cyprinodon variegatus***	***Pimephales promelas***	**Geomean of EC_{50} of 2 aquatic insect species**	***Daphnia magna***	***Scenedesmus. subspicatus***	***Chironomus riparius***	***Lemna gibba***	***Xenopis laevis***
Endpoint (µg/L)		LC_{50} > 100000	NOEC -9400	EC_{50} 8.5	EC_{10} 2960	E_rC_{50}/E_yC_{50} > 1300	NOEC 0.235	EC_{50} 1000	NOEC 2600
AF		100	10	100	10	10	10	10	10
RAC (µg/L)		>1000	940	0.085	296	>130	0.0235	100	260
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**								
Step 1									
	12.10	<0.012	0.013	**142.353**	0.041	<0.093	**514.894**	0.121	0.047
Step 2									
S-Europe	0.41	<0.001	<0.001	**4.824**	0.001	0.003	**17.447**	0.004	0.002
N-Europe	0.46	<0.001	<0.001	**5.412**	0.002	0.004	**19.574**	0.005	0.002

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Aquatic plants acute	Amphibians
Step 3									
D1/ditch	0.257	<0.001	<0.001	**3.024**	0.001	0.002	**10.936**	0.003	0.001
D1/stream	0.224	<0.001	<0.001	**2.635**	0.001	0.002	**9.532**	0.002	0.001
D3/ditch	0.254	<0.001	<0.001	**2.988**	0.001	0.002	**10.809**	0.003	0.001
D4/pond	0.009	<0.001	<0.001	0.106	<0.001	<0.001	0.383	<0.001	<0.001
D4/stream	0.208	<0.001	<0.001	**2.447**	0.001	0.002	**8.851**	0.002	0.001
D5/pond	0.009	<0.001	<0.001	0.106	<0.001	<0.001	0.383	<0.001	<0.001
D5/stream	0.201	<0.001	<0.001	**2.365**	0.001	0.002	**8.553**	0.002	0.001
R1/pond	0.009	<0.001	<0.001	0.106	<0.001	<0.001	0.383	<0.001	<0.001
R1/stream	0.167	<0.001	<0.001	**1.965**	0.001	0.001	**7.106**	0.002	0.001

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

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 Zuxion in pome fruits (single/ multiple applications)-early application 2 x 250 g f.p/ha, equivalent to 2 x 50 g a.s./ha)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Aquatic plants acute	Amphibians
Test species		*Cyprinodon variegatus*	*Pimephales promelas*	Geomean of EC_{50} of 2 aquatic insect species	*Daphnia magna*	*Scenedesmus. subspicatus*	*Chironomus riparius*	*Lemna gibba*	*Xenopis laevis*
Endpoint (µg/L)		LC_{50} > 100000	NOEC -9400	EC_{50} 8.5	EC_{10} 2960	E_rC_{50}/E_yC_{50} > 1300	NOEC 0.235	EC_{50} 1000	NOEC 2600
AF		100	10	100	10	10	10	10	10

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Aquatic plants acute	Amphibians
RAC (µg/L)		>1000	940	0.085	296	>130	0.0235	100	260
FOCUS Scenario	PEC $_{gl-max}$ (µg/L)								
Step 1									
	19.54/39.07	0.020/0.039	0.021/0.042	**229.882/459.647**	0.066/0.132	<0.150/0.301	**831.489/1662.553**	0.195/0.391	0.075/0.150
Step 2									
S-Europe	4.87/7.05	0.005/0.007	0.005/0.008	**57.294/82.941**	0.016/0.024	<0.037/0.054	**207.234/300.000**	0.049/0.071	0.019/0.027
N-Europe	4.87/7.05	0.005/0.007	0.005/0.008	**57.294/82.941**	0.016/0.024	<0.037/0.054	**207.234/300.000**	0.049/0.071	0.019/0.027
Step 3									
D3/ditch	3.884/3.343	0.004/0.003	0.004/0.004	**45.694/39.329**	0.013/0.011	0.030/0.026	**165.277/142.255**	0.039/0.003	0.015/0.004
D4/pond	0.236/0.318	<0.001/<0.001	<0.001/<0.001	**2.776/3.741**	0.001/0.001	0.002/0.002	**10.043/13.532**	0.002/<0.001	0.001/<0.001
D4/stream	3.742/3.380	0.004/0.003	0.004/0.004	**44.024/39.765**	0.013/0.011	0.029/0.026	**159.234/143.830**	0.037/0.003	0.014/0.004
D5/pond	0.236/0.367	<0.001/<0.001	<0.001/<0.001	**2.776/4.318**	0.001/0.001	0.002/0.003	**10.043/15.617**	0.002/<0.001	0.001/<0.001
D5/stream	3.852/3.582	0.004/0.004	0.004/0.004	**45.318/42.141**	0.013/0.012	0.030/0.028	**163.915/152.426**	0.039/0.004	0.015/0.004
R1/pond	0.236/0.359	<0.001/<0.001	<0.001/<0.001	**2.776/4.224**	0.001/0.001	0.002/0.003	**10.043/15.277**	0.002/<0.001	0.001/<0.001
R1/stream	3.140/2.681	0.003/0.003	0.003/0.003	**36.941/31.541**	0.011/0.009	0.024/0.021	**133.617/114.085**	0.031/0.003	0.012/0.003
R2/stream	4.160/3.557	0.004/0.004	0.004/0.004	**48.941/41.847**	0.014/0.012	0.032/0.027	**177.021/151.362**	0.042/0.004	0.016/0.004
R3/stream	4.443/3.793	0.004/0.004	0.005/0.004	**52.271/44.624**	0.015/0.013	0.034/0.029	**189.064/161.404**	0.044/0.004	0.017/0.004
R4/stream	3.159/2.697	0.003/0.003	0.003/0.003	**37.165/31.729**	0.011/0.009	0.024/0.021	**134.426/114.766**	0.032/0.003	0.012/0.003

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

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 ~~Zuxion~~ Asset in pome fruits (single/ multiple applications)-late application 2 x 250 g f.p/ha, equivalent to 2 x 50 g a.s./ha)

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants acute**	**Amphibians**
Test species		***Cyprinodon variegatus***	***Pimephales promelas***	**Geomean of EC_{50} of 2 aquatic insect species**	***Daphnia magna***	***Scenedesmus. subspicatus***	***Chironomus riparius***	***Lemna gibba***	***Xenopis laevis***
Endpoint (µg/L)		LC_{50} > 100000	NOEC -9400	EC_{50} 8.5	EC_{10} 2960	E_rC_{50}/E_yC_{50} > 1300	NOEC 0.235	EC_{50} 1000	NOEC 2600
AF		100	10	100	10	10	10	10	10
RAC (µg/L)		>1000	940	0.085	296	>130	0.0235	100	260
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**								
Step 1									
	17.29/34.58	0.017/0.017	0.018/0.018	**203.412/203.412**	0.058/0.058	0.133/0.133	**735.745/735.745**	0.173/0.173	0.067/0.067
Step 2									
S-Europe	2.62/3.35	0.003/0.003	0.003/0.003	**30.824/30.824**	0.009/0.009	0.020/0.020	**111.489/111.489**	0.026/0.026	0.010/0.010
N-Europe	2.62/3.35	0.000/0.000	0.000/0.000	**5.412/5.412**	0.002/0.002	0.004/0.004	**19.574/19.574**	0.005/0.005	0.002/0.002
Step 3									
D3/ditch	1.838/1.458	0.002/0.001	0.002/0.002	**21.624/17.153**	0.006/0.005	0.014/0.011	**78.213/62.043**	0.018/0.001	0.007/0.002
D4/pond	0.082/0.116	<0.001/<0.001	<0.001/<0.001	0.965/**1.365**	<0.001/<0.001	0.001/0.001	**3.489/4.936**	0.001/<0.001	<0.001/<0.001
D4/stream	1.842/1.477	0.002/0.001	0.002/0.002	**21.671/17.376**	0.006/0.005	0.014/0.011	**78.383/62.851**	0.018/0.001	0.007/0.002
D5/pond	0.082/0.118	<0.001/<0.001	<0.001/<0.001	0.965/**1.388**	<0.001/<0.001	0.001/0.001	**3.489/5.021**	0.001/<0.001	<0.001/<0.001
D5/stream	1.990/1.594	0.002/0.002	0.002/0.002	**23.412/18.753**	0.007/0.005	0.015/0.012	**84.681/67.830**	0.020/0.002	0.008/0.002
R1/pond	0.082/0.124	<0.001/<0.001	<0.001/<0.001	0.965/**1.459**	<0.001/<0.001	0.001/0.001	**3.489/5.277**	0.001/<0.001	<0.001/<0.001

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Aquatic plants acute	Amphibians
R1/stream	1.411/1.130	0.001/0.001	0.002/0.001	**16.600/13.294**	0.005/0.004	0.011/0.009	**60.043/48.085**	0.014/0.001	0.005/0.001
R2/stream	1.892/1.515	0.002/0.002	0.002/0.002	**22.259/17.824**	0.006/0.005	0.015/0.012	**80.511/64.468**	0.019/0.002	0.007/0.002
R3/stream	1.989/1.593	0.002/0.002	0.002/0.002	**23.400/18.741**	0.007/0.005	0.015/0.012	**84.638/67.787**	0.020/0.002	0.008/0.002
R4/stream	1.379/1.130	0.001/0.001	0.001/0.001	**16.224/13.294**	0.005/0.004	0.011/0.009	**58.681/48.085**	0.014/0.001	0.005/0.001

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

Applicant update-Nov 2020 (2x180 g f.p./ha , equivalent to 2x36 g a.s./ha):

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 Zuxion in pome fruits (single/ multiple applications)-early application

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Aquatic plants acute	Amphibians
Test species		*Cyprinodon variegatus*	*Pimephales promelas*	Geomean of EC_{50} of 2 aquatic insect species	*Daphnia magna*	*Scenedesmus. subspicatus*	*Chironomus riparius*	*Lemna gibba*	*Xenopis laevis*
Endpoint (µg/L)		LC_{50} > 100000	NOEC ~9400	EC_{50} 8.5	EC_{10} 2960	E_rC_{50}/E_yC_{50} > 1300	NOEC 0.235	EC_{50} 1000	NOEC 2600
AF		100	10	100	10	10	10	10	10
RAC (µg/L)		>1000	940	0.085	296	>130	0.0235	100	260
FOCUS Scenario	PEC $_{gl\text{-}max}$ (µg/L)								
Step 3									
D3/ditch	2.796/2.407	0.003/0.002	0.003/0.003	**32.894/28.318**	0.009/0.008	0.022/0.019	**118.979/102.426**	0.028/0.002	0.011/0.003
D4/pond	0.170/0.229	<0.001/<0.001	<0.001/<0.001	**2.000/2.694**	0.001/0.001	0.001/0.002	**7.234/9.745**	0.002/<0.001	0.001/<0.001

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Aquatic plants acute	Amphibians
D4/stream	2.694/2.434	0.003/0.002	0.003/0.003	**31.694/28.635**	0.009/0.008	0.021/0.019	**114.638/103.574**	0.027/0.002	0.010/0.003
D5/pond	0.170/0.264	<0.001/<0.001	<0.001/<0.001	**2.000/3.106**	0.001/0.001	0.001/0.002	**7.234/11.234**	0.002/<0.001	0.001/<0.001
D5/stream	2.774/2.579	0.003/0.003	0.003/0.003	**32.635/30.341**	0.009/0.009	0.021/0.020	**118.043/109.745**	0.028/0.003	0.011/0.003
R1/pond	0.170/0.258	<0.001/<0.001	<0.001/<0.001	**2.000/3.035**	0.001/0.001	0.001/0.002	**7.234/10.979**	0.002/<0.001	0.001/<0.001
R1/stream	2.261/1.930	0.002/0.002	0.002/0.002	**26.600/22.706**	0.008/0.007	0.017/0.015	**96.213/82.128**	0.023/0.002	0.009/0.002
R2/stream	2.995/2.561	0.003/0.003	0.003/0.003	**35.235/30.129**	0.010/0.009	0.023/0.020	**127.447/108.979**	0.030/0.003	0.012/0.003
R3/stream	3.199/2.731	0.003/0.003	0.003/0.003	**37.635/32.129**	0.011/0.009	0.025/0.021	**136.128/116.213**	0.032/0.003	0.012/0.003
R4/stream	2.274/1.942	0.002/0.002	0.002/0.002	**26.753/22.847**	0.008/0.007	0.017/0.015	**96.766/82.638**	0.023/0.002	0.009/0.002

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

Table 9.5-8: 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 ~~Zuxion~~ Asset in pome fruits (single/ multiple applications)-late application

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants acute**	**Amphibians**
Test species		***Cyprinodon variegatus***	***Pimephales promelas***	**Geomean of EC_{50} of 2 aquatic insect species**	***Daphnia magna***	***Scenedesmus. subspicatus***	***Chironomus riparius***	***Lemna gibba***	***Xenopis laevis***
Endpoint (µg/L)		LC_{50} > 100000	NOEC -9400	EC_{50} 8.5	EC_{10} 2960	E_rC_{50}/E_yC_{50} > 1300	NOEC 0.235	EC_{50} 1000	NOEC 2600
AF		100	10	100	10	10	10	10	10
RAC (µg/L)		>1000	940	0.085	296	>130	0.0235	100	260
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**								
Step 3									

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Aquatic plants acute	Amphibians
D3/ditch	1.323/1.050	0.001/0.001	0.001/0.001	**15.565/12.353**	0.004/0.004	0.010/0.008	**56.298/44.681**	0.013/0.001	0.005/0.001
D4/pond	0.059/0.084	<0.001/<0.001	<0.001/<0.001	0.694/0.988	<0.001/<0.001	<0.001/0.001	**2.511/3.574**	0.001/<0.001	<0.001/<0.001
D4/stream	1.326/1.064	0.001/0.001	0.001/0.001	**15.600/12.518**	0.004/0.004	0.010/0.008	**56.426/45.277**	0.013/0.001	0.005/0.001
D5/pond	0.059/0.085	<0.001/<0.001	<0.001/<0.001	0.694/1.000	<0.001/<0.001	<0.001/0.001	**2.511/3.617**	0.001/<0.001	<0.001/<0.001
D5/stream	1.433/1.148	0.001/0.001	0.002/0.001	**16.859/13.506**	0.005/0.004	0.011/0.009	**60.979/48.851**	0.014/0.001	0.006/0.001
R1/pond	0.059/0.089	<0.001/<0.001	<0.001/<0.001	0.694/**1.047**	<0.001/<0.001	<0.001/0.001	**2.511/3.787**	0.001/<0.001	<0.001/<0.001
R1/stream	1.016/0.814	0.001/0.001	0.001/0.001	**11.953/9.576**	0.003/0.003	0.008/0.006	**43.234/34.638**	0.010/0.001	0.004/0.001
R2/stream	1.362/1.091	0.001/0.001	0.001/0.001	**16.024/12.835**	0.005/0.004	0.010/0.008	**57.957/46.426**	0.014/0.001	0.005/0.001
R3/stream	1.432/1.147	0.001/0.001	0.002/0.001	**16.847/13.494**	0.005/0.004	0.011/0.009	**60.936/48.809**	0.014/0.001	0.006/0.001
R4/stream	0.993/0.814	0.001/0.001	0.001/0.001	**11.682/9.576**	0.003/0.003	0.008/0.006	**42.255/34.638**	0.010/0.001	0.004/0.001

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

For the intended uses, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for sediment dwelling organism as characterised by an NOEC for *Chironomus riparius* of 0.235 µg/L in connection with an assessment factor of 10) in several FOCUS Steps 1-3 scenarios.

Mesocosms study:

According to *Conclusion of Peer review of the pesticide risk assessment of the active substance acetamiprid* (EFSA Journal 2016;14(11):4610), a mesocosm study was available to refine the risk assessment. This study was conducted with the insecticide Acetamiprid 20 SG (nominal 20% w/w acetamiprid) in outdoor mesocosms including sediment in order to assess the biological effects on macroinvertebrates, zooplankton, phytoplankton, periphyton and macrophytes. The endpoint selected was a NOEC of 1.1 µg a.s./L. Furthermore, to account for uncertainties related to species belonging to *Naididae*, which were observed to be sensitive at the selected endpoint, the highest assessment factor (AF) of 3 was proposed and further data were considered necessary to address the effects on *Naididae*. Therefore a **RAC of 0.37** µg a.s./L was obtained and used in the refinement of the risk assessment.

Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{sw} considering reduced exposure of surface water bodies. The refinement only was performed in FOCUS scenarios where risk was identified in step 3 considering the RAC from mesocosms study.

Table 9.5-9: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Acetamiprid based on FOCUS Step 4 calculations and toxicity data for mesocosms study with mitigation of spray drift and run-off for the use of Zuxion in pome fruits (single/ multiple applications) early application

Intended use **Active substance** **Application rate (g a.s./ha)**		Pome fruit (early application) Acetamiprid 2 x 50				
Nozzle reduction	Vegetative strip (m)	None				
	No spray buffer (m)	5	10	15	20	30
None	D3 ditch	3.051/2.577	1.874/1.523	0.843/0.836	0.429/0.394	0.164/0.136
50 %		1.526/1.289	0.937/0.761	0.422/0.418	0.214/0.197	-/-
75 %		0.763/0.644	0.468/0.381	0.211/0.209	-/-	-/-
90 %		0.305/0.258	0.187/0.152	-/-	-/-	-/-
None	D4 stream	3.216/2.870	1.974/1.695	0.888/0.931	0.451/0.439	0.173/0.151
50 %		1.608/1.435	0.987/0.848	0.444/0.465	0.226/0.219	-/-
75 %		0.804/0.717	0.494/0.424	0.222/0.233	-/-	-/-
90 %		0.322/0.287	0.197/0.170	-/-	-/-	-/-
None	D5 stream	3.311/3.041	2.032/1.797	0.914/0.986	0.465/0.465	0.178/0.160
50 %		1.655/1.521	1.016/0.898	0.457/0.493	0.232/0.233	-/-
75 %		0.827/0.760	0.508/0.449	0.229/0.247	-/-	-/-
90 %		0.331/0.304	0.203/0.180	-/-	-/-	-/-
None	R1 stream	2.699/2.276	1.657/1.345	0.745/0.738	0.379/0.348	0.145/0.120
50 %		1.349/1.138	0.828/0.672	0.373/0.369	0.189/-	-/-
75 %		0.674/0.569	0.414/0.336	0.186/-	-/-	-/-

Intended use		Pome fruit (early application)				
Active substance		Acetamiprid				
Application rate (g a.s./ha)		2 x 50				
Nozzle reduction	Vegetative strip (m)	None				
	No spray buffer (m)	5	10	15	20	30
90 %		0.270/0.228	0.166/-	-/-	-/-	-/-
None	R2-stream	3.575/3.019	2.195/1.784	0.988/0.979	0.502/0.462	0.192/0.159
50 %		1.787/1.510	1.097/0.892	0.494/0.490	0.251/0.231	-/-
75 %		0.893/0.755	0.549/0.446	0.247/0.245	-/-	-/-
90 %		0.358/0.302	0.220/0.178	-/-	-/-	-/-
None	R3-stream	3.818/3.220	2.344/1.902	1.055/1.044	0.536/0.492	0.205/0.169
50 %		1.908/1.610	1.172/0.951	0.527/0.522	0.268/0.246	-/-
75 %		0.954/0.805	0.586/0.476	0.264/0.261	-/-	-/-
90 %		0.382/0.322	0.234/0.190	-/-	-/-	-/-
None	R4-stream	2.715/2.289	1.666/1.353	0.750/0.743	0.381/0.350	0.146/0.120
50 %		1.357/1.145	0.833/0.676	0.375/0.371	0.191/-	-/-
75 %		0.678/0.572	0.417/0.338	0.187/-	-/-	-/-
90 %		0.272/0.229	0.167/-	-/-	-/-	-/-

RAC		**PEC/RAC ratio**				
0.37						
None	D3-ditch	**8.246/6.965**	**5.065/4.116**	**2.278/2.259**	**1.159/1.065**	0.443/0.368
50 %		**4.124/3.484**	**2.532/2.057**	**1.141/1.130**	0.578/0.532	-/-
75 %		**2.062/1.741**	**1.265/1.030**	0.570/0.565	-/-	-/-
90 %		0.824/0.697	0.505/0.411	-/-	-/-	-/-
None	D4-stream	**8.692/7.757**	**5.335/4.581**	**2.400/2.516**	**1.219/1.186**	0.468/0.408
50 %		**4.346/3.878**	**2.668/2.292**	**1.200/1.257**	0.611/0.592	-/-
75 %		**2.173/1.938**	**1.335/1.146**	0.600/0.630	-/-	-/-
90 %		0.870/0.776	0.532/0.459	-/-	-/-	-/-
None	D5-stream	**8.949/8.219**	**5.492/4.857**	**2.470/2.665**	**1.257/1.257**	0.481/0.432
50 %		**4.473/4.111**	**2.746/2.427**	**1.235/1.332**	0.627/0.630	-/-
75 %		**2.235/2.054**	**1.373/1.214**	0.619/0.668	-/-	-/-
90 %		0.895/0.822	0.549/0.486	-/-	-/-	-/-
None	R1-stream	**7.295/6.151**	**4.478/3.635**	**2.014/1.995**	**1.024**/0.941	0.392/0.324
50 %		**3.646/3.076**	**2.238/1.816**	**1.008**/0.997	0.511/-	-/-
75 %		**1.822/1.538**	**1.119**/0.908	0.503/-	-/-	-/-
90 %		0.730/0.616	0.449/-	-/-	-/-	-/-
None	R2-stream	**9.662/8.159**	**5.932/4.822**	**2.670/2.646**	**1.357/1.249**	0.519/0.430
50 %		**4.830/4.081**	**2.965/2.411**	**1.335/1.324**	0.678/0.624	-/-

Intended use		Pome fruit (early application)				
Active substance		Acetamiprid				
Application rate (g a.s./ha)		2 x 50				
Nozzle reduction	Vegetative strip (m)	None				
	No spray buffer (m)	5	10	15	20	30
75 %		**2.414/2.041**	**1.484/1.205**	0.668/0.662	-/-	-/-
90 %		0.968/0.816	0.595/0.481	-/-	-/-	-/-
None	R3 stream	**10.319/8.703**	**6.335/5.141**	**2.851/2.822**	**1.449/1.330**	0.554/0.457
50 %		**5.157/4.351**	**3.168/2.570**	**1.424/1.411**	0.724/0.665	-/-
75 %		**2.578/2.176**	**1.584/1.286**	0.714/0.705	-/-	-/-
90 %		**1.032**/0.870	0.632/0.514	-/-	-/-	-/-
None	R4 stream	**7.338/6.186**	**4.503/3.657**	**2.027/2.008**	**1.030**/0.946	0.395/0.324
50 %		**3.668/3.095**	**2.251/1.827**	**1.014/1.003**	0.516/-	-/-
75 %		**1.832/1.546**	**1.127**/0.914	0.505/-	-/-	-/-
90 %		0.735/0.619	0.451/-	-/-	-/-	-/-

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

Table 9.5-10: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Acetamiprid based on FOCUS Step 4 calculations and toxicity data for mesocosms study with mitigation of spray drift and run-off for the use of Zuxion in pome fruits (single/ multiple applications) late application

Intended use		Pome fruit (late application)			
Active substance		Acetamiprid			
Application rate (g a.s./ha)		2 x 50			
Nozzle reduction	Vegetative strip (m)	None			
	No spray buffer (m)	5	10	15	20
None	D3 ditch	1.240/1.014	0.554/0.487	0.280/0.239	-/-
50 %		0.620/0.507	0.277/0.244	-/-	-/-
75 %		0.310/0.254	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-
None	D4 stream	1.437/1.176	0.642/0.565	0.324/0.276	-/-
50 %		0.719/0.588	0.321/0.282	-/-	-/-
75 %		0.359/0.294	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-
None	D5 stream	1.553/1.268	0.694/0.609	0.351/0.298	-/-
50 %		0.777/0.634	0.347/0.305	-/-	-/-

Intended use		Pome fruit (late application)			
Active substance		Acetamiprid			
Application rate (g a.s./ha)		2 x 50			
Nozzle reduction	Vegetative strip (m)	None			
	No spray buffer (m)	5	10	15	20
75 %		0.388/0.317	-/-	-/-	-/-
90 %		0.155/-	-/-	-/-	-/-
None	R1 stream	1.101/0.899	0.492/0.432	0.249/0.242	-/-
50 %		0.551/0.450	0.246/0.242	-/-	-/-
75 %		0.275/0.242	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-
None	R2 stream	1.476/1.205	0.660/0.579	0.333/0.283	-/-
50 %		0.738/0.603	0.330/0.289	-/-	-/-
75 %		0.369/0.301	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-
None	R3 stream	1.552/1.268	0.694/0.609	0.350/0.298	-/-
50 %		0.776/0.634	0.347/0.304	-/-	-/-
75 %		0.388/0.317	-/-	-/-	-/-
90 %		0.155/-	-/-	-/-	-/-
None	R4 stream	1.077/0.899	0.481/0.432	0.243/0.274	-/-
50 %		0.538/0.450	0.241/0.274	-/-	-/-
75 %		0.269/0.274	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-
RAC (µg/L)		**PEC/RAC ratio**			
0.37					
None	D3 ditch	**3.351/2.741**	**1.497/1.316**	0.757/0.646	-/-
50 %		**1.676/1.370**	0.749/0.659	-/-	-/-
75 %		0.838/0.686	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-
None	D4 stream	**3.884/3.178**	**1.735/1.527**	0.876/0.746	-/-
50 %		**1.943/1.589**	0.868/0.762	-/-	-/-
75 %		0.970/0.795	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-
None	D5 stream	**4.197/3.427**	**1.876/1.646**	0.949/0.805	-/-
50 %		**2.100/1.714**	0.938/0.824	-/-	-/-
75 %		**1.049**/0.857	-/-	-/-	-/-
90 %		0.419/-	-/-	-/-	-/-
None	R1 stream	**2.976/2.430**	**1.330/1.168**	0.673/0.654	-/-

Intended use		Pome fruit (late application)			
Active substance		Acetamiprid			
Application rate (g a.s./ha)		2 x 50			
Nozzle reduction	Vegetative strip (m)	None			
	No spray buffer (m)	5	10	15	20
50 %		**1.489/1.216**	0.665/0.654	-/-	-/-
75 %		0.743/0.654	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-
None	R2-stream	**3.989/3.257**	**1.784/1.565**	0.900/0.765	-/-
50 %		**1.995/1.630**	0.892/0.781	-/-	-/-
75 %		0.997/0.814	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-
None	R3-stream	**4.195/3.427**	**1.876/1.646**	0.946/0.805	-/-
50 %		**2.097/1.714**	0.938/0.822	-/-	-/-
75 %		**1.049**/0.857	-/-	-/-	-/-
90 %		0.419/-	-/-	-/-	-/-
None	R4-stream	**2.911/2.430**	**1.300/1.168**	0.657/0.741	-/-
50 %		**1.454/1.216**	0.651/0.741	-/-	-/-
75 %		0.727/0.741	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-

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

Applicant update-Nov 2020 (2x180 g f.p./ha , equivalent to 2x36 g a.s./ha):

~~According to recommendation from zRMS in comments on Nov 2020, mesocosms study has not been considered in the risk assessment~~. The Applicant proposes a risk assessment taking into account the lowest endpoint from sediment dwelling organism as characterised by an NOEC for *Chironomus riparius* of 0.235 µg/L in connection with an assessment factor of 10 RAC. New risk mitigation measures are proposed by the Applicant:

Table 9.5-11: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Acetamiprid based on FOCUS Step 4 calculations and toxicity data for sediment dwelling organism with mitigation of spray drift and run-off for the use of ~~Zuxion~~ Asset in winter oilseed rape

Intended use		Winter oilseed rape					
Active substance		Acetamiprid					
Application rate (g a.s./ha)		1 x 40					
Nozzle reduction	Vegetative strip (m)	None				10	20
	No spray buffer (m)	5	10	15	20	10	20
None	D2 ditch	0.070	0.044	0.044	-	-	-
50 %		0.044	0.044	-	-	-	-
75 %		0.044	-	-	-	-	-
90%		-	-	-	-	-	-
None	D2 stream	0.083	0.044	0.030	0.028	-	-
50 %		0.042	0.028	0.028	-	-	-
75 %		0.030	0.028	-	-	-	-
90%		0.028	-	-	-	-	-
None	D3 ditch	0.069	0.037	0.025	0.019	-	-
50 %		0.035	0.018	0.013	-	-	-
75 %		0.017	-	-	-	-	-
90%		-	-	-	-	-	-
None	D4 stream	0.080	0.042	0.029	0.022	-	-
50 %		0.040	0.021	0.015	-	-	-
75 %		0.020	-	-	-	-	-
90%		-	-	-	-	-	-
None	D5 stream	0.086	0.046	0.031	0.024	-	-
50 %		0.043	0.0229	0.016	0.012	-	-
75 %		0.022	-	-	-	-	-
90%		-	-	-	-	-	-
None	R1 stream	0.061	0.032	0.022	0.017	-	-
50 %		0.031	0.016	0.011	-	-	-
75 %		0.015	-	-	-	-	-
90%		-	-	-	-	-	-

Intended use		Winter oilseed rape					
Active substance		Acetamiprid					
Application rate (g a.s./ha)		1 x 40					
Nozzle reduction	Vegetative strip (m)	None				10	20
	No spray buffer (m)	5	10	15	20	10	20
None	R3 stream	0.320	-	-	-	0.083	0.0236
50 %		-	-	-	-	-	-
75 %		-	-	-	-	-	-
90%		-	-	-	-	-	-
RAC (µg/L)		**PEC/RAC ratio**					
0.0235							
None	D2 ditch	**2.979**	**1.872**	**1.872**	-	-	-
50 %		**1.872**	**1.872**	-	-	-	-
75 %		**1.872**	-	-	-	-	-
90%		-	-	-	-	-	-
None	D2 stream	**3.532**	**1.872**	**1.277**	**1.191**	-	-
50 %		**1.787**	**1.191**	**1.191**	-	-	-
75 %		**1.277**	**1.191**	-	-	-	-
90%		**1.191**	-	-	-	-	-
None	D3 ditch	**2.936**	**1.574**	**1.064**	0.809	-	-
50 %		**1.489**	0.766	0.553	-	-	-
75 %		0.723	-	-	-	-	-
90%		-	-	-	-	-	-
None	D4 stream	**3.404**	**1.787**	**1.234**	0.936	-	-
50 %		**1.702**	0.894	0.638	-	-	-
75 %		0.851	-	-	-	-	-
90%		-	-	-	-	-	-
None	D5 stream	**3.660**	**1.957**	**1.319**	**1.021**	-	-
50 %		**1.830**	0.974	0.681	0.511	-	-
75 %		0.936	-	-	-	-	-
90%		-	-	-	-	-	-
None	R1 stream	**2.596**	**1.362**	0.936	0.723	-	-
50 %		**1.319**	0.681	0.468	-	-	-
75 %		0.638	-	-	-	-	-
90%		-	-	-	-	-	-
None	R3 stream	**13.617**	-	-	-	**3.532**	**1.004**
50 %		-	-	-	-	-	-
75 %		-	-	-	-	-	-

Intended use		Winter oilseed rape					
Active substance		Acetamiprid					
Application rate (g a.s./ha)		1 x 40					
Nozzle reduction	Vegetative strip (m)	None				10	20
	No spray buffer (m)	5	10	15	20	10	20
90%		-	-	-	-	-	-

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

The outcome of this tiered assessment is that no unacceptable risk to aquatic organisms is expected when the following mitigation measures are applied:

- D2 ditch: scenario is not relevant under CEU conditions.
- D2 stream: scenario is not relevant under CEU conditions.
- D3 ditch: 5 m no-spray buffer zone + 75% of nozzles reduction or 10 m no-spray buffer zone + 50% of nozzles reduction or 20 m no-spray buffer zone.
- D4 stream: 5 m no-spray buffer zone + 75% of nozzles reduction or 10 m no-spray buffer zone + 50% of nozzles reduction or 20 m no-spray buffer zone.
- D5 stream: 5 m no-spray buffer zone + 75% of nozzles reduction or 10 m no-spray buffer zone + 50% of nozzles reduction.
- R1 stream: 5 m no-spray buffer zone + 75% of nozzles reduction or 10 m no-spray buffer zone + 50% of nozzles reduction or 15 m no-spray buffer zone.
- R3 stream: 20 m no-spray buffer zone + 20 m vegetative filter strip.

Table 9.5-12: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Acetamiprid based on FOCUS Step 4 calculations and toxicity data for sediment dwelling organism with mitigation of spray drift and run-off for the use of ~~Zuxion~~ Asset in summer oilseed rape

Intended use		Summer oilseed rape			
Active substance		Acetamiprid			
Application rate (g a.s./ha)		1 x 40			
Nozzle reduction	Vegetative strip (m)	None			
	No spray buffer (m)	5	10	15	20
None	D1 ditch	0.070	0.037	0.025	0.019
50 %		0.035	0.019	0.013	-
75 %		0.018	-	-	-
None	D1 stream	0.082	0.043	0.030	0.0226
50 %		0.041	0.022	0.015	-
75 %		0.021	-	-	-
None	D3 ditch	0.069	0.036	0.025	0.020

Intended use		Summer oilseed rape			
Active substance		Acetamiprid			
Application rate (g a.s./ha)		1 x 40			
Nozzle reduction	Vegetative strip (m)	None			
	No spray buffer (m)	5	10	15	20
50 %		0.034	0.018	0.012	-
75 %		0.017	-	-	-
None	D4 stream	0.076	0.040	0.027	0.021
50 %		0.038	0.020	0.014	-
75 %		0.019	-	-	-
None	D5 stream	0.074	0.039	0.027	0.020
50 %		0.037	0.020	0.013	-
75 %		0.018	-	-	-
None	R1 stream	0.061	0.032	0.022	-
50 %		0.031	0.016	-	-
75 %		0.015	-	-	-
RAC (µg/L)					
0.0235		**PEC/RAC ratio**			
None	D1 ditch	**2.979**	**1.574**	**1.064**	0.809
50 %		**1.489**	0.809	0.553	-
75 %		0.766	-	-	-
None	D1 stream	**3.489**	**1.830**	**1.277**	0.962
50 %		**1.745**	0.936	0.638	-
75 %		0.894	-	-	-
None	D3 ditch	**2.936**	**1.532**	**1.064**	0.851
50 %		**1.447**	0.766	0.511	-
75 %		0.723	-	-	-
None	D4 stream	**3.234**	**1.702**	**1.149**	0.894
50 %		**1.617**	0.851	0.596	-
75 %		0.809	-	-	-
None	D5 stream	**3.149**	**1.660**	**1.149**	0.851
50 %		**1.574**	0.851	0.553	-
75 %		0.766	-	-	-
None	R1 stream	**2.596**	**1.362**	0.936	-
50 %		**1.319**	0.681	-	-
75 %		0.638	-	-	-

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

The outcome of this tiered assessment is that no unacceptable risk to aquatic organisms is expected when the following mitigation measures are applied:

- D1 ditch: scenario is not relevant under CEU conditions.
- D1 stream: scenario is not relevant under CEU conditions.
- D3 ditch: 5 m no-spray buffer zone + 75% of nozzles reduction or 10 m no-spray buffer zone + 50% of nozzles reduction or 20 m no-spray buffer zone.
- D4 stream: 5 m no-spray buffer zone + 75% of nozzles reduction or 10 m no-spray buffer zone + 50% of nozzles reduction or 20 m no-spray buffer zone.
- D5 stream: 5 m no-spray buffer zone + 75% of nozzles reduction or 10 m no-spray buffer zone + 50% of nozzles reduction or 20 m no-spray buffer zone.
- R1 stream: 5 m no-spray buffer zone + 75% of nozzles reduction or 10 m no-spray buffer zone + 50% of nozzles reduction or 15 m no-spray buffer zone.

ZRMS comments:

For the intended uses in oilseed rape at rate 1 x 40 g a.s./ha, PEC/RAC ratio with calculations of the PEC_{sw} with FOCUS STEP 4 program and NOEC for *Chironomus riparius* of 0.235 µg/L in connection with an assessment factor of 10, indicated the acceptable risk when following risk mitigation measures are applied.

Winter oilseed rape

- D2 ditch: scenario is not relevant under CEU conditions.
- D2 stream: scenario is not relevant under CEU conditions.
- D3 ditch: 5 m no-spray buffer zone + 75% of nozzles reduction or 10 m no-spray buffer zone + 50% of nozzles reduction or 20 m no-spray buffer zone.
- D4 stream: 5 m no-spray buffer zone + 75% of nozzles reduction or 10 m no-spray buffer zone + 50% of nozzles reduction or 20 m no-spray buffer zone.
- D5 stream: 5 m no-spray buffer zone + 75% of nozzles reduction or 10 m no-spray buffer zone + 50% of nozzles reduction.
- R1 stream: 5 m no-spray buffer zone + 75% of nozzles reduction or 10 m no-spray buffer zone + 50% of nozzles reduction or 15 m no-spray buffer zone.
- R3 stream: 20 m no-spray buffer zone + 20 m vegetative filter strip.

Summer oilseed rape

- D1 ditch: scenario is not relevant under CEU conditions.
- D1 stream: scenario is not relevant under CEU conditions.
- D3 ditch: 5 m no-spray buffer zone + 75% of nozzles reduction or 10 m no-spray buffer zone + 50% of nozzles reduction or 20 m no-spray buffer zone.
- D4 stream: 5 m no-spray buffer zone + 75% of nozzles reduction or 10 m no-spray buffer zone + 50% of nozzles reduction or 20 m no-spray buffer zone.
- D5 stream: 5 m no-spray buffer zone + 75% of nozzles reduction or 10 m no-spray buffer zone + 50% of nozzles reduction or 20 m no-spray buffer zone.
- R1 stream: 5 m no-spray buffer zone + 75% of nozzles reduction or 10 m no-spray buffer zone + 50% of nozzles reduction or 15 m no-spray buffer zone.

Table 9.5-13: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Acetamiprid based on FOCUS Step 4 calculations and toxicity data for sediment dwelling organism with mitigation of spray drift and run-off for the use of Zuxion in pome/stone fruits (single/ multiple applications)-early application

Intended use		Pome/stone fruits (early application)										
Active substance		Acetamiprid										
Application rate (g a.s./ha)		2 x 36										
Nozzle reduction	Vegetative strip (m)	None							20			
	No spray buffer (m)	5	10	15	20	30	40	50	20	30	40	50
None	D3 ditch	-/-	-/-	-/-	0.309/0.284	0.118/0.098	0.059/0.046	0.034/0.025	-/-	-/-	-/-	-/-
50 %		-/-	-/-	-/-	0.154/0.142	0.059/0.049	0.030/0.0227	0.017/0.013	-/-	-/-	-/-	-/-
75 %		-/-	-/-	-/-	0.077/0.071	0.029/0.024	0.015/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	0.031/0.028	0.012/0.010	-/-	-/-	-/-	-/-	-/-	-/-
95 %		-/-	-/-	-/-	0.015/0.014	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 pond	0.191/0.257	0.105/0.146	0.055/0.076	0.034/0.044	0.016/0.019	-/-	-/-	-/-	-/-	-/-	-/-
50 %		0.096/0.128	0.052/0.072	0.028/0.038	0.017/0.022	-/-	-/-	-/-	-/-	-/-	-/-	-/-
75 %		0.048/0.064	0.026/0.036	0.014/0.019	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		0.019/0.026	0.010/0.014	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
95 %		-/0.013	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 stream	-/-	-/-	-/-	0.325/0.316	0.124/0.109	0.063/0.051	0.037/0.028	-/-	-/-	-/-	-/-
50 %		-/-	-/-	-/-	0.163/0.158	0.062/0.054	0.031/0.025	0.018/0.014	-/-	-/-	-/-	-/-
75 %		-/-	-/-	-/-	0.081/0.079	0.031/0.027	0.017/0.013	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	0.033/0.032	0.012/0.011	-/-	-/-	-/-	-/-	-/-	-/-
95 %		-/-	-/-	-/-	0.016/0.016	-/-	-/-	-/-	-/-	-/-	-/-	-/-

Intended use		Pome/stone fruits (early application)										
Active substance		Acetamiprid										
Application rate (g a.s./ha)		2 x 36										
Nozzle reduction	Vegetative strip (m)	None							20			
	No spray buffer (m)	5	10	15	20	30	40	50	20	30	40	50
None	D5 pond	0.191/0.297	0.105/0.168	0.055/0.088	0.034/0.051	0.016/0.022	-/-	-/-	-/-	-/-	-/-	-/-
50 %		0.096//0.148	0.052/0.084	0.028/0.044	0.017/0.025	-/-	-/-	-/-	-/-	-/-	-/-	-/-
75 %		0.048/0.074	0.026/0.042	0.014/0.022	-/0.013	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		0.019/0.030	0.010/0.017	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
95 %		-/0.015	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D5 stream	-/-	-/-	-/-	0.335/0.335	0.128/0.115	0.064/0.054	0.038/0.030	-/-	-/-	-/-	-/-
50 %		-/-	-/-	-/-	0.167/0.167	0.064/0.058	0.032/0.027	0.019/0.015	-/-	-/-	-/-	-/-
75 %		-/-	-/-	-/-	0.084/0.084	0.032/0.029	0.016/0.013	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	0.033/0.034	0.013/0.0122	-/-	-/-	-/-	-/-	-/-	-/-
95 %		-/-	-/-	-/-	0.017/0.017	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 pond	0.191/0.290	0.105/0.164	0.055/0.086	0.034/0.049	0.016/0.022	-/-	-/-	-/-	-/-	-/-	-/-
50 %		0.096/0.145	0.052/0.082	0.028/0.043	0.017/0.025	-/-	-/-	-/-	-/-	-/-	-/-	-/-
75 %		0.048/0.072	0.026/0.041	0.014/0.022	-/0.012	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		0.019/0.029	0.010/0.016	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
95 %		-/0.014	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	-/-	-/-	-/-	0.273/0.251	0.104/0.086	0.053/0.042	0.031/0.042	-/0.251	-/0.086	-/0.040	-/0.022
50 %		-/-	-/-	-/-	0.136/0.125	0.052/0.043	0.026/0.042	0.015/-	-/0.125	-/0.043	-/0.020	-/-
75 %		-/-	-/-	-/-	0.068/0.063	0.026/0.042	0.013/-	-/-	-/0.063	-/0.022	-/-	-/-
90 %		-/-	-/-	-/-	0.027/0.042	0.010/0.042	-/-	-/-	-/0.025	-/-	-/-	-/-

Intended use		Pome/stone fruits (early application)										
Active substance		Acetamiprid										
Application rate (g a.s./ha)		2 x 36										
Nozzle reduction	Vegetative strip (m)	None							20			
	No spray buffer (m)	5	10	15	20	30	40	50	20	30	40	50
95 %		-/-	-/-	-/-	0.014/0.042	-/-	-/-	-/-	-/0.013	-/-	-/-	-/-
None	R2 stream	-/-	-/-	-/-	0.361/0.333	0.138/0.114	0.070/0.055	0.041/0.030	-/-	-/-	-/-	-/-
50 %		-/-	-/-	-/-	0.181/0.166	0.069/0.057	0.035/0.027	0.020/0.015	-/-	-/-	-/-	-/-
75 %		-/-	-/-	-/-	0.090/0.083	0.035/0.029	0.017/0.013	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	0.036/0.033	0.014/0.013	-/-	-/-	-/-	-/-	-/-	-/-
95 %		-/-	-/-	-/-	0.018/0.017	-/	-/-	-/-	-/-	-/-	-/-	-/-
None	R3 stream	-/-	-/-	-/-	0.386/0.355	0.148/0.122	0.074/0.057	0.044/0.032	0.386/0.355	0.148/0.122	0.074/0.057	0.044/0.031
50 %		-/-	-/-	-/-	0.193/0.177	0.074/0.061	0.037/0.029	0.025/0.025	0.192/0.177	0.074/0.061	0.037/0.028	0.022/0.016
75 %		-/-	-/-	-/-	0.096/0.089	0.037/0.031	0.025/0.025	-/-	0.096/0.089	0.037/0.031	0.019/0.014	-/-
90 %		-/-	-/-	-/-	0.039/0.036	0.025/0.025	-/-	-/-	0.039/0.035	0.015/0.012	-/-	-/-
95 %		-/-	-/-	-/-	0.025/0.025	0.025/0.025	-/-	-/-	0.019/0.018	-/-	-/-	-/-
None	R4 stream	-/-	-/-	-/-	0.274/0.252	0.105/0.087	0.079/0.080	0.079/0.080	0.274/0.252	0.105/0.087	0.053/0.040	0.031/0.022
50 %		-/-	-/-	-/-	0.137/0.126	0.079/0.080	0.079/0.080	-/-	0.137/0.126	0.052/0.043	0.026/0.020	0.017/-
75 %		-/-	-/-	-/-	0.079/0.080	0.079/0.080	-/-	-/-	0.069/0.063	0.026/0.022	0.017/-	-/-
90 %		-/-	-/-	-/-	0.079/0.080	-/-	-/-	-/-	0.027/0.025	0.017/-	-/-	-/-
95 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	0.017/0.017	-/-	-/-	-/-
RAC (µg/L) 0.0235		**PEC/RAC ratio**										
None	D3 ditch	-/-	-/-	-/-	**13.149/12.085**	**5.021/4.170**	**2.511/1.957**	**1.447/1.064**	-/-	-/-	-/-	-/-

Intended use		Pome/stone fruits (early application)										
Active substance		Acetamiprid										
Application rate (g a.s./ha)		2 x 36										
Nozzle reduction	Vegetative strip (m)	None							20			
	No spray buffer (m)	5	10	15	20	30	40	50	20	30	40	50
50 %		-/-	-/-	-/-	**6.553/6.043**	**2.511/2.085**	**1.277**/0.966	0.723/0.553	-/-	-/-	-/-	-/-
75 %		-/-	-/-	-/-	**3.277/3.021**	**1.234/1.021**	0.638/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	**1.319/1.191**	0.511/0.426	-/-	-/-	-/-	-/-	-/-	-/-
95 %		-/-	-/-	-/-	0.638/0.596	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 pond	**8.128/10.936**	**4.468/6.213**	**2.340/3.234**	**1.447/1.872**	0.681/0.809	-/-	-/-	-/-	-/-	-/-	-/-
50 %		**4.085/5.447**	**2.213/3.064**	**1.191/1.617**	0.723/0.936	-/-	-/-	-/-	-/-	-/-	-/-	-/-
75 %		**2.043/2.723**	**1.106/1.532**	0.596/0.809	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		0.809/**1.106**	0.426/0.596	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
95 %		-/0.553	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 stream	-/-	-/-	-/-	**13.830/13.447**	**5.277/4.638**	**2.681/2.170**	**1.574/1.191**	-/-	-/-	-/-	-/-
50 %		-/-	-/-	-/-	**6.936/6.723**	**2.638/2.298**	**1.319/1.064**	0.766/0.596	-/-	-/-	-/-	-/-
75 %		-/-	-/-	-/-	**3.447/3.362**	**1.319/1.149**	0.723/0.553	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	**1.404/1.362**	0.511/0.468	-/-	-/-	-/-	-/-	-/-	-/-
95 %		-/-	-/-	-/-	0.681/0.681	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D5 pond	**8.128/12.638**	**4.468/7.149**	**2.340/3.745**	**1.447/2.170**	0.681/0.936	-/-	-/-	-/-	-/-	-/-	-/-
50 %		**4.085/6.298**	**2.213/3.574**	**1.191/1.872**	0.723/**1.064**	-/-	-/-	-/-	-/-	-/-	-/-	-/-
75 %		**2.043/3.149**	**1.106/1.787**	0.596/0.936	-/0.553	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		0.809/**1.277**	0.426/0.723	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
95 %		-/0.638	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-

Intended use		Pome/stone fruits (early application)										
Active substance		Acetamiprid										
Application rate (g a.s./ha)		2 x 36										
Nozzle reduction	Vegetative strip (m)	None							20			
	No spray buffer (m)	5	10	15	20	30	40	50	20	30	40	50
None	D5 stream	-/-	-/-	-/-	**14.255/14.255**	**5.447/4.894**	**2.723/2.298**	**1.617/1.277**	-/-	-/-	-/-	-/-
50 %		-/-	-/-	-/-	**7.106/7.106**	**2.723/2.468**	**1.362/1.149**	0.809/0.638	-/-	-/-	-/-	-/-
75 %		-/-	-/-	-/-	**3.574/3.574**	**1.362/1.234**	0.681/0.553	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	**1.404/1.447**	0.553/0.519	-/-	-/-	-/-	-/-	-/-	-/-
95 %		-/-	-/-	-/-	0.723/0.723	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 pond	**8.128/12.340**	**4.468/6.979**	**2.340/3.660**	**1.447/2.085**	0.681/0.936	-/-	-/-	-/-	-/-	-/-	-/-
50 %		**4.085/6.170**	**2.213/3.489**	**1.191/1.830**	0.723/**1.064**	-/-	-/-	-/-	-/-	-/-	-/-	-/-
75 %		**2.043/3.064**	**1.106/1.745**	0.596/0.936	-/0.511	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		0.809/**1.234**	0.426/0.681	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
95 %		-/0.596	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	-/-	-/-	-/-	**11.617/10.681**	**4.426/3.660**	**2.255/1.787**	**1.319/1.787**	**-/10.681**	**-/3.660**	**-/1.702**	-/0.936
50 %		-/-	-/-	-/-	**5.787/5.319**	**2.213/1.830**	**1.106/1.787**	0.638/**1.787**	**-/5.319**	**-/1.830**	-/0.851	-/-
75 %		-/-	-/-	-/-	**2.894/2.681**	**1.106/1.787**	0.553/**1.787**	-/-	**-/2.681**	-/0.936	-/-	-/-
90 %		-/-	-/-	-/-	**1.149/1.787**	0.426/**1.787**	-/-	-/-	**-/1.064**	-/-	-/-	-/-
95 %		-/-	-/-	-/-	0.596/**1.787**	-/-	-/-	-/-	-/0.553	-/-	-/-	-/-
None	R2 stream	-/-	-/-	-/-	**15.362/14.170**	**5.872/4.851**	**2.979/2.340**	**1.745/1.277**	-/-	-/-	-/-	-/-
50 %		-/-	-/-	-/-	**7.702/7.064**	**2.936/2.426**	**1.489/1.149**	0.851/0.638	-/-	-/-	-/-	-/-
75 %		-/-	-/-	-/-	**3.830/3.532**	**1.489/1.234**	0.723/0.553	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	**1.532/1.404**	0.596/0.553	-/-	-/-	-/-	-/-	-/-	-/-

Intended use		Pome/stone fruits (early application)										
Active substance		Acetamiprid										
Application rate (g a.s./ha)		2 x 36										
Nozzle reduction	Vegetative strip (m)	None							20			
	No spray buffer (m)	5	10	15	20	30	40	50	20	30	40	50
95 %		-/-	-/-	-/-	0.766/0.723	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R3 stream	-/-	-/-	-/-	**16.426/15.106**	**6.298/5.191**	**3.149/2.426**	**1.872/1.362**	**16.426/15.106**	**6.298/5.191**	**3.149/2.426**	**1.872/1.319**
50 %		-/-	-/-	-/-	**8.213/7.532**	**3.149/2.596**	**1.574/1.234**	**1.064/1.064**	**8.170/7.532**	**3.149/2.596**	**1.574/1.191**	0.936/0.681
75 %		-/-	-/-	-/-	**4.085/3.787**	**1.574/1.319**	**1.064/1.064**	-/-	**4.085/3.787**	**1.574/1.319**	0.809/0.596	-/-
90 %		-/-	-/-	-/-	**1.660/1.532**	**1.064/1.064**	-/-	-/-	**1.660/1.489**	0.638/0.511	-/-	-/-
95 %		-/-	-/-	-/-	**1.064/1.064**	**1.064/1.064**	-/-	-/-	0.809/0.766	-/-	-/-	-/-
None	R4 stream	-/-	-/-	-/-	**11.660/10.723**	**4.468/3.702**	**3.362/3.404**	**3.362/3.404**	**11.660/10.723**	**4.468/3.702**	**2.255/1.702**	**1.319**/0.936
50 %		-/-	-/-	-/-	**5.830/5.362**	**3.362/3.404**	**3.362/3.404**	-/-	**5.830/5.362**	**2.213/1.830**	**1.106**/0.851	0.723/-
75 %		-/-	-/-	-/-	**3.362/3.404**	**3.362/3.404**	-/-	-/-	**2.936/2.681**	**1.106**/0.936	0.723/-	-/-
90 %		-/-	-/-	-/-	**3.362/3.404**	-/-	-/-	-/-	**1.149/1.064**	0.723/-	-/-	-/-
95 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	0.723/0.723	-/-	-/-	-/-

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

The outcome of this tiered assessment is that no unacceptable risk to aquatic organisms is expected when the following mitigation measures are applied:

- D3 ditch: 20 m no-spray buffer zone + 95% of nozzles reduction or 30 m no-spray buffer zone + 90% of nozzles reduction or 40 m no-spray buffer zone + 75% of nozzles reduction or 50 m no-spray buffer zone.
- D4 pond: 5 m no-spray buffer zone + 95% of nozzles reduction or 10 m no-spray buffer zone + 90% of nozzles reduction or 15 m no-spray buffer zone + 75% of nozzles reduction or 20 m no-spray buffer zone + 50% of nozzles reduction or 50 m no-spray buffer zone.
- D4 stream:20 m no-spray buffer zone + 95% of nozzles reduction or 30 m no-spray buffer zone + 90% of nozzles reduction or 40 m no-spray buffer zone + 75% of nozzles reduction or 50 m no-spray buffer zone + 50% of nozzles reduction.
- D5 pond: 5 m no-spray buffer zone + 95% of nozzles reduction or 10 m no-spray buffer zone + 90% of nozzles reduction or 15 m no-spray buffer zone +

75% of nozzles reduction or 30 m no-spray buffer zone.

- D5 stream: 20 m no-spray buffer zone + 95% of nozzles reduction or 30 m no-spray buffer zone + 90% of nozzles reduction or 40 m no-spray buffer zone + 75% of nozzles reduction or 50 m no-spray buffer zone+ 50% of nozzles reduction.
- R1 pond:5 m no-spray buffer zone + 95% of nozzles reduction or 10 m no-spray buffer zone + 90% of nozzles reduction or 15 m no-spray buffer zone + 75% of nozzles reduction or 30 m no-spray buffer zone.
- R1 stream: 20 m no-spray buffer zone +20m vegetative strip + 95% of nozzles reduction or 30 m no-spray buffer zone +20m vegetative strip + 75% of nozzles reduction or 40 m no-spray buffer zone +20m vegetative strip + 50% of nozzles reduction or 50 m no-spray buffer zone +20m vegetative strip.
- R2 stream: 20 m no-spray buffer zone + 95% of nozzles reduction or 30 m no-spray buffer zone + 90% of nozzles reduction or 40 m no-spray buffer zone + 75% of nozzles reduction or 50 m no-spray buffer zone+ 50% of nozzles reduction.
- R3 stream: 20 m no-spray buffer zone +20m vegetative strip + 95% of nozzles reduction or 30 m no-spray buffer zone +20m vegetative strip + 90% of nozzles reduction or 40 m no-spray buffer zone +20m vegetative strip + 75% of nozzles reduction or 50 m no-spray buffer zone +20m vegetative strip + 50% of nozzles reduction.
- R4 stream: 20 m no-spray buffer zone +20m vegetative strip + 95% of nozzles reduction or 30 m no-spray buffer zone +20m vegetative strip + 90% of nozzles reduction or 40 m no-spray buffer zone +20m vegetative strip + 75% of nozzles reduction or 50 m no-spray buffer zone +20m vegetative strip + 50% of nozzles reduction.

Table 9.5-14: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Acetamiprid based on FOCUS Step 4 calculations and toxicity data for sediment dwelling organism with mitigation of spray drift and run-off for the use of Zuxion in pome/stone fruits (single/ multiple applications)-late application

Intended use		Pome/stone fruits (late application)											
Active substance		Acetamiprid											
Application rate (g a.s./ha)		2 x 36											
Nozzle reduction	Vegetative strip (m)	None							10	20			
	No spray buffer (m)	5	10	15	20	30	40	50	10	20	30	40	50
None	D3 ditch	-/-	0.399/0.351	0.202/0.172	0.123/0.100	0.061/0.046	0.037/0.026	0.025/0.017	-/-	-/-	-/-	-/-	-/-
50 %		-/-	0.200/0.175	0.101/0.086	0.062/0.050	0.031/0.023	0.019/0.013	0.013/-	-/-	-/-	-/-	-/-	-/-
75 %		-/-	0.100/0.088	0.050/0.043	0.031/0.025	0.015/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-

Intended use		Pome/stone fruits (late application)											
Active substance		Acetamiprid											
Application rate (g a.s./ha)		2 x 36											
Nozzle reduction	Vegetative strip (m)	None							10	20			
	No spray buffer (m)	5	10	15	20	30	40	50	10	20	30	40	50
90 %		-/-	0.040/0.035	0.020/0.017	0.013/0.010	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
95 %		-/-	0.020/0.018	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 pond	0.068/0.09	0.038/0.052	0.024/0.032	0.017/0.022	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
50 %		0.034/0.04	0.019/0.026	0.012/0.016	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
75 %		0.017/0.02	-/0.013	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/0.009	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
95 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 stream	-/-	0.462/0.406	0.234/0.199	0.142/0.155	0.071/0.053	0.043/0.031	0.029/0.020	-/-	-/-	-/-	-/-	-/-
50 %		-/-	0.231/0.203	0.117/0.099	0.071/0.058	0.035/0.027	0.022/0.015	0.015/-	-/-	-/-	-/-	-/-	-/-
75 %		-/-	0.116/0.102	0.058/0.050	0.036/0.029	0.018/0.013	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	0.046/0.041	0.023/0.020	0.014/0.012	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
95 %		-/-	0.023/0.020	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D5 pond	0.068/0.09	0.038/0.053	0.024/0.032	0.017/0.022	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
50 %		0.034/0.04	0.019/0.027	0.012/0.016	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
75 %		0.017/0.02	-/0.013	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/0.010	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
95 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D5 stream	-/-	0.500/0.438	0.252/0.215	0.154/0.125	0.077/0.057	0.047/0.033	0.032/0.022	-/-	-/-	-/-	-/-	-/-

Intended use		Pome/stone fruits (late application)											
Active substance		Acetamiprid											
Application rate (g a.s./ha)		2 x 36											
Nozzle reduction	Vegetative strip (m)	None							10	20			
	No spray buffer (m)	5	10	15	20	30	40	50	10	20	30	40	50
50 %		-/-	0.250/0.219	0.126/0.107	0.077/0.062	0.038/0.029	0.023/0.017	0.016/-	-/-	-/-	-/-	-/-	-/-
75 %		-/-	0.125/0.110	0.063/0.054	0.039/0.031	0.019/0.014	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	0.050/0.044	0.025/0.021	0.015/0.012	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
95 %		-/-	0.025/0.022	0.013/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 pond	0.068/0.10	0.038/0.058	0.025/0.038	0.020/0.028	-/0.019	-/-	-/-	-/-	-/-	-/-	-/-	-/-
50 %		0.034/0.54	0.022/0.033	0.017/0.023	-/0.018	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
75 %		0.020/0.03	-/0.020	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/0.017	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
95 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	-/-	0.354/0.311	0.179/0.169	0.122/0.169	-/-	-/-	-/-	0.354/0.311	0.109/0.088	0.054/0.041	0.033/0.023	0.022/-
50 %		-/-	0.178/0.169	0.122/0.169	-/-	-/-	-/-	-/-	0.177/0.156	0.055/0.044	0.027/0.020	0.016/-	-/-
75 %		-/-	0.122/0.169	-/-	-/-	-/-	-/-	-/-	0.089/0.078	0.027/0.022	0.014	-/-	-/-
90 %		-/-	0.122/-	-/-	-/-	-/-	-/-	-/-	0.035/0.031	0.011/-	-/-	-/-	-/-
95 %			-/-	-/-	-/-	-/-	-/-	-/-	0.018/0.016	-/-	-/-	-/-	-/-
None	R2 stream	-/-	0.475/0.417	0.240/0.204	0.147/0.118	0.073/0.055	0.044/0.031	0.030/0.020	-/-	-/-	-/-	-/-	-/-
50 %		-/-	0.238/0.208	0.120/0.102	0.073/0.059	0.036/0.027	0.022/0.016	0.015/-	-/-	-/-	-/-	-/-	-/-
75 %		-/-	0.119/0.104	0.060/0.060	0.037/0.030	0.018/0.014	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	0.048/0.042	0.024/0.024	0.015/0.012	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-

Intended use		Pome/stone fruits (late application)											
Active substance		Acetamiprid											
Application rate (g a.s./ha)		2 x 36											
Nozzle reduction	Vegetative strip (m)	None							10	20			
	No spray buffer (m)	5	10	15	20	30	40	50	10	20	30	40	50
95 %		-/-	0.024/0.021	0.012/0.010	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R3 stream	-/-	0.475/0.417	0.240/0.204	0.154/0.125	0.077/0.057	0.047/0.033	0.032/0.022	-/-	-/-	-/-	-/-	-/-
50 %		-/-	0.238/0.208	0.126/0.107	0.077/0.062	0.038/0.029	0.023/0.017	0.016/-	-/-	-/-	-/-	-/-	-/-
75 %		-/-	0.125/0.110	0.063/0.054	0.039/0.031	0.019/0.014	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	0.050/0.044	0.025/0.021	0.015/0.012	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
95 %		-/-	0.025/0.022	0.013/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R4 stream	-/-	0.346/0.311	0.175/0.193	0.107/0.193	0.053/-	0.032/-	0.022/-	-/0.311	-/0.088	-/0.041	-/0.023	-/-
50 %		-/-	0.173/0.193	0.087/0.193	0.053/-	0.027/-	0.018/-	-/-	-/0.155	-/0.044	-/0.020	-/-	-/-
75 %		-/-	0.087/0.193	0.044/-	0.027/-	0.018/-	-/-	-/-	-/0.078	-/0.022	-/-	-/-	-/-
90 %		-/-	0.035/-	0.018/-	0.018/-	-/-	-/-	-/-	-/0.031	-/-	-/-	-/-	-/-
95 %		-/-	0.018/-	-/-	-/-	-/-	-/-	-/-	-/0.016	-/-	-/-	-/-	-/-
RAC 0.0235		**PEC/RAC ratio**											
None	D3 ditch	-/-	**16.979/14.93**	**8.596/7.319**	**5.234/4.255**	**2.596/1.957**	**1.574/1.106**	**1.064**/0.723	-/-	-/-	-/-	-/-	-/-
50 %		-/-	**8.511/7.447**	**4.298/3.660**	**2.638/2.128**	**1.319**/0.979	0.809/0.553	0.553/-	-/-	-/-	-/-	-/-	-/-
75 %		-/-	**4.255/3.745**	**2.128/1.830**	**1.319/1.064**	0.638/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	**1.702/1.489**	0.851/0.723	0.553/0.426	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
95 %		-/-	0.851/0.766	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-

Intended use		Pome/stone fruits (late application)											
Active substance		Acetamiprid											
Application rate (g a.s./ha)		2 x 36											
Nozzle reduction	Vegetative strip (m)	None							10	20			
	No spray buffer (m)	5	10	15	20	30	40	50	10	20	30	40	50
None	D4 pond	**2.894/4.04**	**1.617/2.213**	**1.021/1.362**	0.723/0.936	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
50 %		**1.447/2.04**	0.809/**1.106**	0.511/0.681	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
75 %		0.723/**1.02**	-/0.553	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/0.383	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
95 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 stream	-/-	**19.660/17.27**	**9.957/8.468**	**6.043/6.596**	**3.021/2.255**	**1.830/1.319**	**1.234**/0.851	-/-	-/-	-/-	-/-	-/-
50 %		-/-	**9.830/8.638**	**4.979/4.213**	**3.021/2.468**	**1.489/1.149**	0.936/0.638	0.638/-	-/-	-/-	-/-	-/-	-/-
75 %		-/-	**4.936/4.340**	**2.468/2.128**	**1.532/1.234**	0.766/0.553	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	**1.957/1.745**	0.979/0.851	0.596/0.511	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
95 %		-/-	0.979/0.851	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D5 pond	**2.894/4.12**	**1.617/2.255**	**1.021/1.362**	0.723/0.936	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
50 %		**1.447/2.08**	0.809/**1.149**	0.511/0.681	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
75 %		0.723/**1.02**	-/0.553	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/0.426	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
95 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D5 stream	-/-	**21.277/18.63**	**10.723/9.149**	**6.553/5.319**	**3.277/2.426**	**2.000/1.404**	**1.362**/0.936	-/-	-/-	-/-	-/-	-/-
50 %		-/-	**10.638/9.319**	**5.362/4.553**	**3.277/2.638**	**1.617/1.234**	0.979/0.723	0.681/-	-/-	-/-	-/-	-/-	-/-
75 %		-/-	**5.319/4.681**	**2.681/2.298**	**1.660/1.319**	0.809/0.596	-/-	-/-	-/-	-/-	-/-	-/-	-/-

Intended use		Pome/stone fruits (late application)											
Active substance		Acetamiprid											
Application rate (g a.s./ha)		2 x 36											
Nozzle reduction	Vegetative strip (m)	None							10	20			
	No spray buffer (m)	5	10	15	20	30	40	50	10	20	30	40	50
90 %		-/-	**2.128/1.872**	**1.064**/0.894	0.638/0.511	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
95 %		-/-	**1.064**/0.936	0.553/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 pond	**2.894/4.25**	**1.617/2.468**	**1.064/1.617**	0.851/**1.191**	-/0.809	-/-	-/-	-/-	-/-	-/-	-/-	-/-
50 %		**1.447/22.9**	0.936/**1.404**	0.723/0.979	-/0.766	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
75 %		0.851/**1.31**	-/0.851	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/0.723	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
95 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	-/-	**15.064/13.23**	**7.617/7.191**	**5.191/7.191**	-/-	-/-	-/-	**15.064/13.23**	**4.638/3.745**	**2.298/1.745**	**1.404**/0.979	0.936/-
50 %		-/-	**7.574/7.191**	**5.191/7.191**	-/-	-/-	-/-	-/-	**7.532/6.638**	**2.340/1.872**	**1.149**/0.851	0.681/-	-/-
75 %		-/-	**5.191/7.191**	-/-	-/-	-/-	-/-	-/-	**3.787/3.319**	**1.149**/0.936	0.596/0.596	-/-	-/-
90 %		-/-	**5.191/7.191**	-/-	-/-	-/-	-/-	-/-	**1.489/1.319**	0.468/-	-/-	-/-	-/-
95 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	0.766/0.681	-/-	-/-	-/-	-/-
None	R2 stream	-/-	**20.213/17.74**	**10.213/8.681**	**6.255/5.021**	**3.106/2.340**	**1.872/1.319**	**1.277**/0.851	-/-	-/-	-/-	-/-	-/-
50 %		-/-	**10.128/8.851**	**5.106/4.340**	**3.106/2.511**	**1.532/1.149**	0.936/0.681	0.638/-	-/-	-/-	-/-	-/-	-/-
75 %		-/-	**5.064/4.426**	**2.553/2.553**	**1.574/1.277**	0.766/0.596	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	**2.043/1.787**	**1.021/1.021**	0.638/0.511	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
95 %		-/-	**1.021**/0.894	0.511/0.426	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R3 stream	-/-	**20.213/17.74**	**10.213/8.681**	**6.553/5.319**	**3.277/2.426**	**2.000/1.404**	**1.362**/0.936	-/-	-/-	-/-	-/-	-/-

Intended use		Pome/stone fruits (late application)											
Active substance		Acetamiprid											
Application rate (g a.s./ha)		2 x 36											
Nozzle reduction	Vegetative strip (m)	None							10	20			
	No spray buffer (m)	5	10	15	20	30	40	50	10	20	30	40	50
50 %		-/-	**10.128/8.851**	**5.362/4.553**	**3.277/2.638**	**1.617/1.234**	0.979/0.723	0.681/-	-/-	-/-	-/-	-/-	-/-
75 %		-/-	**5.319/4.681**	**2.681/2.298**	**1.660/1.319**	0.809/0.596	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	**2.128/1.872**	**1.064**/0.894	0.638/0.511	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
95 %		-/-	**1.064**/0.936	0.553/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R4 stream	-/-	**14.723/13.23**	**7.447/8.213**	**4.553/8.213**	**2.255/8.213**	**1.362/8.213**	0.936/**8.213**	**-/13.234**	**-/3.745**	**-/1.745**	-/0.979	-/-
50 %		-/-	**7.362/8.213**	**3.702/8.213**	**2.255/8.213**	**1.149/8.213**	0.766/**8.213**	-/-	**-/6.596**	**-/1.872**	-/0.851	-/-	-/-
75 %		-/-	**3.702/8.213**	**1.872/8.213**	**1.149/8.213**	0.766/**8.213**	-/-	-/-	**-/3.319**	-/0.936	-/-	-/-	-/-
90 %		-/-	**1.489**/-	0.766/**8.213**	0.766/**8.213**	-/-	-/-	-/-	**-/1.319**	-/-	-/-	-/-	-/-
95 %		-/-	0.766/-	-/-	-/-	-/-	-/-	-/-	-/0.681	-/-	-/-	-/-	-/-

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

The outcome of this tiered assessment is that no unacceptable risk to aquatic organisms is expected when the following mitigation measures are applied:

- D3 ditch: 10 m no-spray buffer zone + 95% of nozzles reduction or 15 m no-spray buffer zone + 90% of nozzles reduction or 30 m no-spray buffer zone + 75% of nozzles reduction or 40 m no-spray buffer zone + 50% of nozzles reduction.
- D4 pond: 5 m no-spray buffer zone + 90% of nozzles reduction or 10 m no-spray buffer zone + 75% of nozzles reduction or 15 m no-spray buffer zone + 50% of nozzles reduction or 20 m no-spray buffer zone.
- D4 stream: 10 m no-spray buffer zone + 95% of nozzles reduction or 15 m no-spray buffer zone + 90% of nozzles reduction or 30 m no-spray buffer zone + 75% of nozzles reduction or 40 m no-spray buffer zone + 50% of nozzles reduction.
- D5 pond: 5 m no-spray buffer zone + 95% of nozzles reduction or 10 m no-spray buffer zone + 75% of nozzles reduction or 15 m no-spray buffer zone + 50% of nozzles reduction or 20 m no-spray buffer zone.

- D5 stream: 15 m no-spray buffer zone + 95% of nozzles reduction or 20 m no-spray buffer zone + 90% of nozzles reduction or 30 m no-spray buffer zone + 75% of nozzles reduction or 40 m no-spray buffer zone + 50% of nozzles reduction.
- R1 pond: 5 m no-spray buffer zone + 90% of nozzles reduction or 10 m no-spray buffer zone + 75% of nozzles reduction or 15 m no-spray buffer zone + 50% of nozzles reduction or 30 m no-spray buffer zone.
- R1 stream: 10 m no-spray buffer zone +10m vegetative strip + 95% of nozzles reduction or 20 m no-spray buffer zone +20m vegetative strip + 90% of nozzles reduction or 30 m no-spray buffer zone +20m vegetative strip + 75% of nozzles reduction or 40 m no-spray buffer zone +20m vegetative strip + 50% of nozzles reduction or 50 m no-spray buffer zone +20m vegetative strip.
- R2 stream: 15 m no-spray buffer zone + 95% of nozzles reduction or 20 m no-spray buffer zone + 90% of nozzles reduction or 30 m no-spray buffer zone + 75% of nozzles reduction or 40 m no-spray buffer zone+ 50% of nozzles reduction.
- R3 stream: 15 m no-spray buffer zone + 95% of nozzles reduction or 20 m no-spray buffer zone + 90% of nozzles reduction or 30 m no-spray buffer zone + 75% of nozzles reduction or 40 m no-spray buffer zone + 50% of nozzles reduction.
- R4 stream: 10 m no-spray buffer zone +10m vegetative strip + 95% of nozzles reduction or 20 m no-spray buffer zone +20m vegetative strip + 75% of nozzles reduction or 30 m no-spray buffer zone +20m vegetative strip + 50% of nozzles reduction or 40 m no-spray buffer zone +20m vegetative strip.

ZRMS comments:
For the intended uses in orchards, PEC/RAC ratio with calculations of the PEC_{sw} with FOCUS STEP 4 program and NOEC for *Chironomus riparius* of 0.235 µg/L in connection with an assessment factor of 10, indicated the acceptable risk when following risk mitigation measures are applied.

Orchards (early application. 2 x 36 g a.s./ha)

- D3 ditch: 20 m no-spray buffer zone + 95% of nozzles reduction or 30 m no-spray buffer zone + 90% of nozzles reduction or 40 m no-spray buffer zone + 75% of nozzles reduction or 50 m no-spray buffer zone.
- D4 pond: 5 m no-spray buffer zone + 95% of nozzles reduction or 10 m no-spray buffer zone + 90% of nozzles reduction or 15 m no-spray buffer zone + 75% of nozzles reduction or 20 m no-spray buffer zone + 50% of nozzles reduction or 50 m no-spray buffer zone.
- D4 stream:20 m no-spray buffer zone + 95% of nozzles reduction or 30 m no-spray buffer zone + 90% of nozzles reduction or 40 m no-spray buffer zone + 75% of nozzles reduction or 50 m no-spray buffer zone + 50% of nozzles reduction.
- D5 pond: 5 m no-spray buffer zone + 95% of nozzles reduction or 10 m no-spray buffer zone + 90% of nozzles reduction or 15 m no-spray buffer zone + 75% of nozzles reduction or 30 m no-spray buffer zone.
- D5 stream: 20 m no-spray buffer zone + 95% of nozzles reduction or 30 m no-spray buffer zone + 90% of nozzles reduction or 40 m no-spray buffer zone + 75% of nozzles reduction or 50 m no-spray buffer zone+ 50% of nozzles reduction.
- R1 pond:5 m no-spray buffer zone + 95% of nozzles reduction or 10 m no-spray buffer zone + 90% of nozzles reduction or 15 m no-spray buffer zone + 75% of nozzles reduction or 30 m no-spray buffer zone.
- R1 stream: 20 m no-spray buffer zone +20m vegetative strip + 95% of nozzles reduction or 30 m no-spray buffer zone +20m vegetative strip + 75% of nozzles reduction or 40 m no-spray buffer zone +20m vegetative strip + 50% of nozzles reduction or 50 m no-spray buffer zone +20m vegetative strip.

- R2 stream: 20 m no-spray buffer zone + 95% of nozzles reduction or 30 m no-spray buffer zone + 90% of nozzles reduction or 40 m no-spray buffer zone + 75% of nozzles reduction or 50 m no-spray buffer zone+ 50% of nozzles reduction.
- R3 stream: 20 m no-spray buffer zone +20m vegetative strip + 95% of nozzles reduction or 30 m no-spray buffer zone +20m vegetative strip + 90% of nozzles reduction or 40 m no-spray buffer zone +20m vegetative strip + 75% of nozzles reduction or 50 m no-spray buffer zone +20m vegetative strip + 50% of nozzles reduction.

  R4 stream: 20 m no-spray buffer zone +20m vegetative strip + 95% of nozzles reduction or 30 m no-spray buffer zone +20m vegetative strip + 90% of nozzles reduction or 40 m no-spray buffer zone +20m vegetative strip + 75% of nozzles reduction or 50 m no-spray buffer zone +20m vegetative strip + 50% of nozzles

Orchards (late application application, 2 x 36 g a.s./ha)

- D3 ditch: 10 m no-spray buffer zone + 95% of nozzles reduction or 15 m no-spray buffer zone + 90% of nozzles reduction or 30 m no-spray buffer zone + 75% of nozzles reduction or 40 m no-spray buffer zone + 50% of nozzles reduction.
- D4 pond: 5 m no-spray buffer zone + 90% of nozzles reduction or 10 m no-spray buffer zone + 75% of nozzles reduction or 15 m no-spray buffer zone + 50% of nozzles reduction or 20 m no-spray buffer zone.
- D4 stream: 10 m no-spray buffer zone + 95% of nozzles reduction or 15 m no-spray buffer zone + 90% of nozzles reduction or 30 m no-spray buffer zone + 75% of nozzles reduction or 40 m no-spray buffer zone + 50% of nozzles reduction.
- D5 pond: 5 m no-spray buffer zone + 95% of nozzles reduction or 10 m no-spray buffer zone + 75% of nozzles reduction or 15 m no-spray buffer zone + 50% of nozzles reduction or 20 m no-spray buffer zone.
- D5 stream: 15 m no-spray buffer zone + 95% of nozzles reduction or 20 m no-spray buffer zone + 90% of nozzles reduction or 30 m no-spray buffer zone + 75% of nozzles reduction or 40 m no-spray buffer zone + 50% of nozzles reduction.
- R1 pond: 5 m no-spray buffer zone + 90% of nozzles reduction or 10 m no-spray buffer zone + 75% of nozzles reduction or 15 m no-spray buffer zone + 50% of nozzles reduction or 30 m no-spray buffer zone.
- R1 stream: 10 m no-spray buffer zone +10m vegetative strip + 95% of nozzles reduction or 20 m no-spray buffer zone +20m vegetative strip + 90% of nozzles reduction or 30 m no-spray buffer zone +20m vegetative strip + 75% of nozzles reduction or 40 m no-spray buffer zone +20m vegetative strip + 50% of nozzles reduction or 50 m no-spray buffer zone +20m vegetative strip.
- R2 stream: 15 m no-spray buffer zone + 95% of nozzles reduction or 20 m no-spray buffer zone + 90% of nozzles reduction or 30 m no-spray buffer zone + 75% of nozzles reduction or 40 m no-spray buffer zone+ 50% of nozzles reduction.
- R3 stream: 15 m no-spray buffer zone + 95% of nozzles reduction or 20 m no-spray buffer zone + 90% of nozzles reduction or 30 m no-spray buffer zone + 75% of nozzles reduction or 40 m no-spray buffer zone + 50% of nozzles reduction.
- R4 stream: 10 m no-spray buffer zone +10m vegetative strip + 95% of nozzles reduction or 20 m no-spray buffer zone +20m vegetative strip + 75% of nozzles reduction or 30 m no-spray buffer zone +20m vegetative strip + 50% of nozzles reduction or 40 m no-spray buffer zone +20m vegetative strip.

It should be noted that risk mitigation for application dose 2 x 36 g a.s/ha presented above covers the risk mitigation for application doses 1x36 g a.s./ha. However, final risk mitigation should be considered at MSs level.

Metabolites

Table 9.5-15: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for the metabolite IM-1-2 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of ~~Zuxion~~ Asset –in winter oilseed rape

Group		**Inverteb. acute**	**Sed. dwell. prolonged**
Test species		***Daphnia magna***	***Chironomus riparius***
Endpoint (µg/L)		LC_{50} 99800	EC_{50} 15000
AF		100	10
RAC (µg/L)		998	1500
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**		
Step 1			
	9.23	0.0092	0.0062
Step 2			
S-Europe	0.36	0.0004	0.0002
N-Europe	0.26	0.0003	0.0002

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

Table 9.5-16: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for the metabolite IM-1-2 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of ~~Zuxion~~ Asset in summer oilseed rape

Group		**Inverteb. acute**	**Sed. dwell. prolonged**
Test species		***Daphnia magna***	***Chironomus riparius***
Endpoint (µg/L)		LC_{50} 99800	EC_{50} 15000
AF		100	10
RAC (µg/L)		998	1500
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**		
Step 1			
	9.23	0.0092	0.0062
Step 2			

Group		**Inverteb. acute**	**Sed. dwell. prolonged**
S-Europe	0.46	0.0005	0.0003
N-Europe	0.26	0.0003	0.0002

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

Table 9.5-17: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for the metabolite IM-1-2 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of Zuxion (single/ multiple applications) in pome/stone fruits – early application (worst case)

Group		**Inverteb. acute**	**Sed. dwell. prolonged**
Test species		***Daphnia magna***	***Chironomus riparius***
Endpoint (µg/L)		LC_{50} 99800	EC_{50} 15000
AF		100	10
RAC (µg/L)		998	1500
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**		
Step 1			
	12.16/24.32	0.0122/0.0244	0.0062
Step 2			
S-Europe	1.01/1.50	0.0010/0.0010	0.0007/0.0007
N-Europe	1.35/1.84	0.0014/0.0014	0.0009/0.0009

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

Table 9.5-18: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for the metabolite IM-1-4 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of ~~Zuxion~~ Asset in winter oilseed rape

Group		**Fish acute**	**Inverteb. acute**	**Sed. dwell. prolonged**
Test species		***Oncorhynchus mykiss***	***Mysidopsis bahia***	***Chironomus riparius***
Endpoint (µg/L)		LC_{50} 98100	EC_{50} 19000	NOEC 76000
AF		100	100	10
RAC (µg/L)		981	190	7600

Group		**Fish acute**	**Inverteb. acute**	**Sed. dwell. prolonged**
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**			
Step 1				
	11.77	0.012	0.062	0.002
Step 2				
S-Europe	1.15	0.001	0.006	<0.001
N-Europe	0.83	0.001	0.004	<0.001

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

Table 9.5-19: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for the metabolite IM-1-4 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of ~~Zuxion~~ Asset in summer oilseed rape

Group		**Fish acute**	**Inverteb. acute**	**Sed. dwell. prolonged**
Test species		***Oncorhynchus mykiss***	***Mysidopsis bahia***	***Chironomus riparius***
Endpoint (µg/L)		LC_{50} 98100	EC_{50} 19000	NOEC 76000
AF		100	100	10
RAC (µg/L)		981	190	7600
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**			
Step 1				
	11.77	0.012	0.062	0.002
Step 2				
S-Europe	1.47	0.001	0.008	<0.001
N-Europe	0.83	0.001	0.004	<0.001

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

Table 9.5-20: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for the metabolite IM-1-4 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of Zuxion (single/ multiple applications) in pome/stone fruits – early application (worst case)

Group		**Fish acute**	**Inverteb. acute**	**Sed. dwell. prolonged**

Group		Fish acute	Inverteb. acute	Sed. dwell. prolonged
Test species		*Oncorhynchus mykiss*	*Mysidopsis bahia*	*Chironomus riparius*
Endpoint (µg/L)		LC_{50} 98100	EC_{50} 19000	NOEC 76000
AF		100	100	10
RAC (µg/L)		981	190	7600
FOCUS Scenario	PEC $_{gl\text{-}max}$ (µg/L)			
Step 1				
-	17.19/34.39	0.018/0.035	0.090/0.181	0.002/0.005
Step 2				
S-Europe	4.54/7.22	0.005/0.005	0.024/0.024	0.001/0.001
N-Europe	3.46/5.68	0.004/0.004	0.018/0.018	<0.001/<0.001

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

Table 9.5-21: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for the metabolite IC-0 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of ~~Zuxion~~ Asset in winter oilseed rape

Group		**Inverteb. acute**	**Sed. dwell. prolonged**
Test species		***Daphnia magna***	***Chironomus riparius***
Endpoint (µg/L)		EC_{50} 95100	EC_{50} >100000
AF		100	10
RAC (µg/L)		951	10000
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**		
Step 1			
	3.39	0.004	<0.001
Step 2			
S-Europe	0.19	<0.001	<0.001
N-Europe	0.15	<0.001	<0.001

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

Table 9.5-22: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for the metabolite IC-0 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of ~~Zuxion~~ Asset in summer oilseed rape

Group		**Inverteb. acute**	**Sed. dwell. prolonged**

Group		**Inverteb. acute**	**Sed. dwell. prolonged**
Test species		***Daphnia magna***	***Chironomus riparius***
Endpoint (µg/L)		EC_{50} 95100	EC_{50} >100000
AF		100	10
RAC (µg/L)		951	10000
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**		
Step 1			
	3.39	0.004	<0.001
Step 2			
S-Europe	0.23	<0.001	<0.001
N-Europe	0.15	<0.001	<0.001

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

Table 9.5-23: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for the metabolite IC-0 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of Zuxion (single/ multiple applications) in pome/stone fruits – early application (worst case)

Group		Inverteb. acute	Sed. dwell. prolonged
Test species		*Daphnia magna*	*Chironomus riparius*
Endpoint (µg/L)		EC_{50} 95100	EC_{50} >100000
AF		100	10
RAC (µg/L)		951	10000
FOCUS Scenario	PEC $_{gl\text{-}max}$ (µg/L)		
Step 1			
	5.14/10.27	0.005/0.011	0.001/0.001
Step 2			
S-Europe	1.18/1.86	0.001/0.001	<0.001/<0.001
N-Europe	1.05/1.72	0.001/0.001	<0.001/<0.001

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

Table 9.5-24: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for the metabolite IM-1-5 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of ~~Zuxion~~ Asset in winter oilseed rape

Group		**Inverteb. acute**	**Inverteb. prolonged**	**Sed. dwell. prolonged**

Group		**Inverteb. acute**	**Inverteb. prolonged**	**Sed. dwell. prolonged**
Test species		***Daphnia magna***	***Daphnia magna***	***Chironomus riparius***
Endpoint (µg/L)		EC_{50} 25000	NOEC 26000	NOEC 68000
AF		100	10	10
RAC (µg/L)		250	2600	6800
FOCUS Scenario	**PEC gl-max (µg/L)**			
Step 1				
	1.65	0.007	0.001	<0.001
Step 2				
S-Europe	0.30	0.001	<0.001	<0.001
N-Europe	0.20	0.001	<0.001	<0.001

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

Table 9.5-25: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for the metabolite IM-1-5 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of ~~Zuxion~~ Asset –in summer oilseed rape

Group		**Inverteb. acute**	**Inverteb. prolonged**	**Sed. dwell. prolonged**
Test species		***Daphnia magna***	***Daphnia magna***	***Chironomus riparius***
Endpoint (µg/L)		EC_{50} 25000	NOEC 26000	NOEC 68000
AF		100	10	10
RAC (µg/L)		250	2600	6800
FOCUS Scenario	**PEC gl-max (µg/L)**			
Step 1				
	1.65	0.007	0.001	<0.001
Step 2				
S-Europe	0.39	0.002	<0.001	<0.001
N-Europe	0.20	0.001	<0.001	<0.001

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

Table 9.5-26: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for the metabolite IM-1-5 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of Zuxion (single/ multiple applications) in pome fruits – early application (worst case)

Group		Inverteb. acute	Inverteb. prolonged	Sed. dwell. prolonged
Test species		*Daphnia magna*	*Daphnia magna*	*Chironomus riparius*
Endpoint (µg/L)		EC_{50} 25000	NOEC 26000	NOEC 68000
AF		100	10	10
RAC (µg/L)		250	2600	6800
FOCUS Scenario	PEC $_{gl-max}$ (µg/L)			
Step 1				
	2.06/4.12	0.008/0.016	0.001/0.002	<0.001/0.001
Step 2				
S-Europe	0.66/1.30	0.003/0.003	<0.001/<0.001	<0.001/<0.001
N-Europe	0.33/0.65	0.001/0.001	<0.001/<0.001	<0.001/<0.001

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

Table 9.5-27: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for the metabolite IB-1-1 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of ~~Zuxion~~ Asset in winter oilseed rape

Group		**Inverteb. acute**	**Sed. dwell. prolonged**
Test species		***Daphnia magna***	***Chironomus riparius***
Endpoint (µg/L)		EC_{50} 100800	NOEC >100000
AF		100	10
RAC (µg/L)		1008	>10000
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**		
Step 1			
	4.32	0.004	<0.001
Step 2			
S-Europe	0.23	<0.001	<0.001
N-Europe	0.19	<0.001	<0.001

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

Table 9.5-28: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for the metabolite IB-1-1 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of ~~Zuxion~~ Asset in summer oilseed rape

Group		**Inverteb. acute**	**Sed. dwell. prolonged**
Test species		***Daphnia magna***	***Chironomus riparius***
Endpoint (µg/L)		EC_{50} 100800	NOEC >100000
AF		100	10
RAC (µg/L)		1008	>10000
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**		
Step 1			
	4.32	0.004	<0.001
Step 2			
S-Europe	0.26	<0.001	<0.001
N-Europe	0.19	<0.001	<0.001

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

Table 9.5-29: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for the metabolite IB-1-1 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of ~~Zuxion~~ Asset (single/ multiple applications) in pome fruits – early application (worst case)

Group		**Inverteb. acute**	**Sed. dwell. prolonged**
Test species		***Daphnia magna***	***Chironomus riparius***
Endpoint (µg/L)		EC_{50} 100800	NOEC >100000
AF		100	10
RAC (µg/L)		1008	>10000
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**		
Step 1			
	6.79/13.58	0.007/0.013	0.001/0.001
Step 2			
S-Europe	1.78/2.91	0.002/0.002	<0.001/<0.001
N-Europe	1.65/2.79	0.002/0.002	<0.001/<0.001

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

9.5.3 Overall conclusions

The risk to aquatic organisms for the metabolites were assessed as low at FOCUS step 1 and step2 for the representative use on oilseed rape and pome/stone fruits.

After Step 3 calculations, for the intended uses, calculated PEC/RAC ratios did indicate an unacceptable risk for the most sensitive group of aquatic organisms (risk for sediment dwelling organism as characterised by an NOEC for *Chironomus riparius* of 0.235 µg/L in connection with an assessment factor of 10) in several FOCUS Steps 1-3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies.

~~According to EFSA, a mesocosms study was used for the refinement. Based on the results of the risk assessment at step 4, the following conclusions regarding buffer zones, vegetative buffer strips and nozzles reduction may be drawn:~~

~~***Pome/stone fruits (early application) - SPe 3**: To protect aquatic organisms respect an unsprayed vegetated buffer zone of 5 m to surface water bodies with 90% of nozzles reduction OR an unsprayed vegetated buffer zone of 15 m to surface water bodies with 75% of nozzles reduction OR an unsprayed vegetated buffer zone of 20 m to surface water bodies with 50% of nozzles reduction OR an unsprayed vegetated buffer zone of 30 m to surface water bodies.*~~

~~***Pome/stone fruits (late application) - SPe 3**: To protect aquatic organisms respect an unsprayed vegetated buffer zone of 5 m to surface water bodies with 90% of nozzles reduction OR an unsprayed vegetated buffer zone of 10 m to surface water bodies with 50% of nozzles reduction OR an unsprayed vegetated buffer zone of 15 m to surface water bodies.*~~

Applicant update-Nov 2020 (2x180 g f.p./ha , equivalent to 2x36 g a.s./ha):

***Winter oilseed rape* - SPe 3**: *To protect aquatic organisms respect an unsprayed vegetated buffer zone of 20 m to surface water bodies.*

***Summer oilseed rape* - SPe 3**: *To protect aquatic organisms respect an unsprayed buffer zone of 5 m to surface water bodies with 75% of nozzles reduction OR an unsprayed buffer zone of 10 m to surface water bodies with 50% of nozzles reduction OR an unsprayed buffer zone of 20 m to surface water bodies.*

***Pome/stone fruits (early application) - SPe 3**: To protect aquatic organisms respect an unsprayed vegetated buffer zone of 20 m to surface water bodies with 95% of nozzles reduction OR an unsprayed buffer zone of 30 m with 20m of vegetative strip to surface water bodies with 90% of nozzles reduction OR an unsprayed buffer zone of 40 m with 20m of vegetative strip to surface water bodies with 75% of nozzles reduction OR an unsprayed buffer zone of 50 m with 20m of vegetative strip to surface water bodies with 50% of nozzles reduction.*

***Pome/stone fruits (late application) - SPe 3**: To protect aquatic organisms respect an unsprayed buffer zone of 15 m with 10m of vegetative strip to surface water bodies with 95% of nozzles reduction OR an unsprayed vegetated buffer zone of 20 m to surface water bodies with 90% of nozzles reduction OR an unsprayed buffer zone of 30 m with 20m of vegetative strip to surface water bodies with 75% of nozzles reduction OR an unsprayed buffer zone of 40 m with 20m of vegetative strip to surface water bodies with 50% of nozzles reduction OR an unsprayed buffer zone of 50 m with 20m of vegetative strip to surface water bodies.*

ZRMS comments:

The relevant predicted environmental concentrations in water (PEC_{sw}) for risk assessments were taken from Part B Section 8 (Environmental Fate).
The risk assessment was based on the PECsw values (STEP 1-3) and the results of laboratory toxicity testing with aquatic organism.
After Step 3 calculations, for the intended uses, calculated PEC/RAC ratios did indicate an unacceptable risk for the most sensitive group of aquatic organisms (risk for sediment dwelling organism as characterised by an NOEC for *Chironomus riparius* of 0.235 µg/L in connection with an assessment factor of 10) in several FOCUS Steps 1-3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies were provided for oilseed rape (appl. dose 1 x40 g a.s./ha) and orchards (early and late application for 1 x 40 (covers 1 x 36 g a.s./ha) and for app.dose 2 x 36 g a.s./ha).
~~It should be noted the for max application dose: 2 x 50 g a.s/ha for use in orchards the PEC/RACratio based on NOEC of 0.235 L µg/L in connection with an assessment factor of 10 and with consideration of the PECsw with FOCUS STEP 4, should be provided to concluded acceptable risk.~~

The risk assessment based on PEC/RAC values with calculations of the PECsw with FOCUS STEP 4 program for lower doses in orchards and oilseed rape indicated the acceptable risk when following risk mitigation measures are applied:

Orchards (early application. 2 x 36 g a.s./ha)

- D3 ditch: 20 m no-spray buffer zone + 95% of nozzles reduction or 30 m no-spray buffer zone + 90% of nozzles reduction or 40 m no-spray buffer zone + 75% of nozzles reduction or 50 m no-spray buffer zone.
- D4 pond: 5 m no-spray buffer zone + 95% of nozzles reduction or 10 m no-spray buffer zone + 90% of nozzles reduction or 15 m no-spray buffer zone + 75% of nozzles reduction or 20 m no-spray buffer zone + 50% of nozzles reduction or 50 m no-spray buffer zone.
- D4 stream:20 m no-spray buffer zone + 95% of nozzles reduction or 30 m no-spray buffer zone + 90% of nozzles reduction or 40 m no-spray buffer zone + 75% of nozzles reduction or 50 m no-spray buffer zone + 50% of nozzles reduction.
- D5 pond: 5 m no-spray buffer zone + 95% of nozzles reduction or 10 m no-spray buffer zone + 90% of nozzles reduction or 15 m no-spray buffer zone + 75% of nozzles reduction or 30 m no-spray buffer zone.
- D5 stream: 20 m no-spray buffer zone + 95% of nozzles reduction or 30 m no-spray buffer zone + 90% of nozzles reduction or 40 m no-spray buffer zone + 75% of nozzles reduction or 50 m no-spray buffer zone+ 50% of nozzles reduction.
- R1 pond:5 m no-spray buffer zone + 95% of nozzles reduction or 10 m no-spray buffer zone + 90% of nozzles reduction or 15 m no-spray buffer zone + 75% of nozzles reduction or 30 m no-spray buffer zone.
- R1 stream: 20 m no-spray buffer zone +20m vegetative strip + 95% of nozzles reduction or 30 m no-spray buffer zone +20m vegetative strip + 75% of nozzles reduction or 40 m no-spray buffer zone +20m vegetative strip + 50% of nozzles reduction or 50 m no-spray buffer zone +20m vegetative strip.
- R2 stream: 20 m no-spray buffer zone + 95% of nozzles reduction or 30 m no-spray buffer zone + 90% of nozzles reduction or 40 m no-spray buffer zone + 75% of nozzles reduction or 50 m no-spray buffer zone+ 50% of nozzles reduction.
- R3 stream: 20 m no-spray buffer zone +20m vegetative strip + 95% of nozzles reduction or 30 m no-spray buffer zone +20m vegetative strip + 90% of nozzles reduction or 40 m no-spray buffer zone +20m vegetative strip + 75% of nozzles reduction or 50 m no-spray buffer zone +20m vegetative strip + 50% of nozzles reduction.
- R4 stream: 20 m no-spray buffer zone +20m vegetative strip + 95% of nozzles reduction or 30 m no-spray buffer zone +20m vegetative strip + 90% of nozzles reduction or 40 m no-spray buffer zone +20m vegetative strip + 75% of nozzles reduction or 50 m no-spray buffer zone +20m vege-

tative strip + 50% of nozzles reduction.

Orchards (late application application, 2 x 36 g a.s./ha)

- D3 ditch: 10 m no-spray buffer zone + 95% of nozzles reduction or 15 m no-spray buffer zone + 90% of nozzles reduction or 30 m no-spray buffer zone + 75% of nozzles reduction or 40 m no-spray buffer zone + 50% of nozzles reduction.
- D4 pond: 5 m no-spray buffer zone + 90% of nozzles reduction or 10 m no-spray buffer zone + 75% of nozzles reduction or 15 m no-spray buffer zone + 50% of nozzles reduction or 20 m no-spray buffer zone.
- D4 stream: 10 m no-spray buffer zone + 95% of nozzles reduction or 15 m no-spray buffer zone + 90% of nozzles reduction or 30 m no-spray buffer zone + 75% of nozzles reduction or 40 m no-spray buffer zone + 50% of nozzles reduction.
- D5 pond: 5 m no-spray buffer zone + 95% of nozzles reduction or 10 m no-spray buffer zone + 75% of nozzles reduction or 15 m no-spray buffer zone + 50% of nozzles reduction or 20 m no-spray buffer zone.
- D5 stream: 15 m no-spray buffer zone + 95% of nozzles reduction or 20 m no-spray buffer zone + 90% of nozzles reduction or 30 m no-spray buffer zone + 75% of nozzles reduction or 40 m no-spray buffer zone + 50% of nozzles reduction.
- R1 pond: 5 m no-spray buffer zone + 90% of nozzles reduction or 10 m no-spray buffer zone + 75% of nozzles reduction or 15 m no-spray buffer zone + 50% of nozzles reduction or 30 m no-spray buffer zone.
- R1 stream: 10 m no-spray buffer zone +10m vegetative strip + 95% of nozzles reduction or 20 m no-spray buffer zone +20m vegetative strip + 90% of nozzles reduction or 30 m no-spray buffer zone +20m vegetative strip + 75% of nozzles reduction or 40 m no-spray buffer zone +20m vegetative strip + 50% of nozzles reduction or 50 m no-spray buffer zone +20m vegetative strip.
- R2 stream: 15 m no-spray buffer zone + 95% of nozzles reduction or 20 m no-spray buffer zone + 90% of nozzles reduction or 30 m no-spray buffer zone + 75% of nozzles reduction or 40 m no-spray buffer zone+ 50% of nozzles reduction.
- R3 stream: 15 m no-spray buffer zone + 95% of nozzles reduction or 20 m no-spray buffer zone + 90% of nozzles reduction or 30 m no-spray buffer zone + 75% of nozzles reduction or 40 m no-spray buffer zone + 50% of nozzles reduction.
- R4 stream: 10 m no-spray buffer zone +10m vegetative strip + 95% of nozzles reduction or 20 m no-spray buffer zone +20m vegetative strip + 75% of nozzles reduction or 30 m no-spray buffer zone +20m vegetative strip + 50% of nozzles reduction or 40 m no-spray buffer zone +20m vegetative strip.

It should be noted that risk mitigation measures for application dose 2 x 36 g a.s/ha (late applications) presented above covers the risk mitigation measures for application dose 1x36 g a.s./ha in orchards (late applications). However, the final risk mitigation measures for relevant scenarios should be considered at MSs level.

Winter oilseed rape

- D2 ditch: scenario is not relevant under CEU conditions.
- D2 stream: scenario is not relevant under CEU conditions.
- D3 ditch: 5 m no-spray buffer zone + 75% of nozzles reduction or 10 m no-spray buffer zone + 50% of nozzles reduction or 20 m no-spray buffer zone.
- D4 stream: 5 m no-spray buffer zone + 75% of nozzles reduction or 10 m no-spray buffer zone + 50% of nozzles reduction or 20 m no-spray buffer zone.
- D5 stream: 5 m no-spray buffer zone + 75% of nozzles reduction or 10 m no-spray buffer zone + 50% of nozzles reduction.
- R1 stream: 5 m no-spray buffer zone + 75% of nozzles reduction or 10 m no-spray buffer zone + 50% of nozzles reduction or 15 m no-spray buffer zone.

- R3 stream: 20 m no-spray buffer zone + 20 m vegetative filter strip.

Summer oilseed rape

- D1 ditch: scenario is not relevant under CEU conditions.
- D1 stream: scenario is not relevant under CEU conditions.
- D3 ditch: 5 m no-spray buffer zone + 75% of nozzles reduction or 10 m no-spray buffer zone + 50% of nozzles reduction or 20 m no-spray buffer zone.
- D4 stream: 5 m no-spray buffer zone + 75% of nozzles reduction or 10 m no-spray buffer zone + 50% of nozzles reduction or 20 m no-spray buffer zone.
- D5 stream: 5 m no-spray buffer zone + 75% of nozzles reduction or 10 m no-spray buffer zone + 50% of nozzles reduction or 20 m no-spray buffer zone.
- R1 stream: 5 m no-spray buffer zone + 75% of nozzles reduction or 10 m no-spray buffer zone + 50% of nozzles reduction or 15 m no-spray buffer zone.

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.

Effects on bees of Zuxion were not evaluated as part of the EU assessment of Acetamiprid. New data submitted with this application are listed in **Błąd! Nie można odnaleźć źródła odwołania.** and summarised in Appendix 2.

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

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

Species	Substance	Exposure System	Results	Reference
Apis mellifera	preparation EXP 60707A	Oral	**LD_{50} = 8.85 µg/bee**	EFSA Journal 2016;14(11):4610
Apis mellifera	preparation EXP 60707A	Contact	**LD_{50} = 9.26 µg/bee**	EFSA Journal 2016;14(11):4610
Bombus terrestris	preparation EXP 60707A	Contact	LD_{50} >100 µg/bee	EFSA Journal 2016;14(11):4610
Apis mellifera	Acetamiprid	Chronic, 10 d	LC_{50} = 11.7 µg/bee	EFSA Journal 2016;14(11):4610
Apis mellifera	Acetamiprid	Bee brood development	EC_{10} = 1.3 µg/larva/developmental period (total dose over 6 days feeding)	EFSA Journal 2016;14(11):4610
Apis mellifera	Acetamiprid	Sub-lethal effects (behavioural and reproductive)	NOEC hypopharyngeal glands not available	EFSA Journal 2016;14(11):4610

Species	Substance	Exposure System	Results	Reference
Apis mellifera	Zuxion	Oral	**LD_{50} = 25.8 µg f.p./bee** (equivalent to 5.28 µg a.s./bee)	KCP10.3.1.1.1 Elzbieta Kulec-Polszczyca, 2016, B/100/15
Apis mellifera	Zuxion	Contact	**LD_{50} = 130.5 µg/bee** (equivalent to 26.8 µg a.s./bee)	KCP10.3.1.1.2 Elzbieta Kulec-Polszczyca, 2016, B/101/15
Apis mellifera	Zuxion	Chronic, 10 d	LDD_{50} = 16.33 µg f.p./bee (equivalent to 3.33 µg a.s./bee) NOEDD = 6.39 µg f.p./bee (equivalent to 1.30 µg a.s./bee)	KCP10.3.1.2 Gimeno, I. 2019 TRC17-065BA
Apis mellifera	Acetamiprid	Larval, repeated exposure, 22 d	NOED = 0.80 µg as/larva EC_{50} >5.00 µg as/larva	KCP10.3.1.3 Gimeno, I., 2019, S18-05066
Higher-tier studies (tunnel test, field studies)				
Semi-field test (Cage and tunnel test) Five acceptable semi-field studies. Application during full flowering and bee flight at 1x 100-120 g a.s./ha, one study had an additional application one week before introduction of the bees. Generally, transient reduced foraging activity was seen. No increased mortality. No clear brood effects. Details per study are shown below: Due to concerns identified regarding the robustness and reliability of the semi-field and field studies, they could not be used to draw any conclusion, and in particular to exclude potential chronic effects and effects on the brood development. Field tests Two acceptable field studies (one on two locations). Application during full flowering and bee flight at 1x 50-75 g a.s./ha. Transient reduced foraging activity in one study. Transient increased mortality. No brood effects.				

9.6.1.1 Justification for new endpoints

The EU agreed endpoints for Acetamiprid are used for the assessments and the endpoints for Zuxion are from the new studies

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).

9.6.2.1 Hazard quotients for bees

Table 9.6-2: First-tier assessment of the risk for bees due to the use of Zuxion in Oilseed rape

Intended use	Oilseed rape
Active substance	Acetamiprid

Application rate (g/ha)	1 x 40		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	8.85	40	4.52
Contact toxicity	9.26		4.32
Product	Zuxion		
Application rate (g/ha)	1 x 200		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	25.8	200	7.75
Contact toxicity	130.5		1.53

Q_{HO}, Q_{HC}: Hazard quotients for oral and contact exposure. Q_H values shown in bold breach the relevant trigger.

Table 9.6-3: First-tier assessment of the risk for bees due to the use of Zuxion in pome fruits

Intended use	Pome fruits		
Active substance	Acetamiprid		
Application rate (g/ha)	2 x 50		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	8.85	50	5.65
Contact toxicity	9.26		5.40
Product	Zuxion		
Application rate (g/ha)	2 x 250		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	25.8	250	9.69
Contact toxicity	130.5		1.92

Q_{HO}, Q_{HC}: Hazard quotients for oral and contact exposure. Q_H values shown in bold breach the relevant trigger.

Applicant update-Nov 2020 (2x180 g f.p./ha , equivalent to 2x36 g a.s./ha):

Table 9.6-4: First-tier assessment of the risk for bees due to the use of Zuxion in pome fruits

Intended use	Pome fruits		
Active substance	Acetamiprid		
Application rate (g/ha)	2 x 36		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	8.85	36	4.07
Contact toxicity	9.26		3.89
Product	Zuxion		
Application rate (g/ha)	2 x 180		

Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	25.8	180	6.98
Contact toxicity	130.5		1.38

Q_{HO}, Q_{HC}: Hazard quotients for oral and contact exposure. Q_H values shown in bold breach the relevant trigger.

ZRMS comments:

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).

The submitted risk assessment, based on laboratory studies, has been accepted.

According to Commission regulation (EU) No 284/2013, point 10.3.1. (Effects on bees) the Applicant provided the chronic test on bees for formulated product and chronic test for larvae only for a.s - acetamiprid.

Thus, concerned Member States must decide on the consideration of data requirements and the risk assessment at national level.

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

Not relevant.

9.6.3 Effects on bumble bees

Not required.

9.6.4 Effects on solitary bees

Not required.

9.6.5 Overall conclusions

The risk assessment for bees has been done. All the hazard quotients are considerably less than 50, indicating that the active substances pose a low risk to bees. Therefore a low risk to bees is expected from the application of Zuxion at all proposed label rates.

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 representative formulation. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on non-target arthropods of Zuxion were not evaluated as part of the EU assessment of Acetam-

iprid. 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 are in line with the results of the EU review process.

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)	EXP 607070A (Acetamiprid 200 g/kg)	Laboratory test glass plates (2D)	Mortality: 100 % at 90 g/ha and 180 g/ha No eggs	EFSA Journal 2016;14(11):4610
Aphidius rhopalosiphi (adults)	EXP 607070A (Acetamiprid 200 g/kg)	Laboratory test glass plates (2D)	Mortality: 100 % at 200 g/ha and 400 g/ha No fecundity	EFSA Journal 2016;14(11):4610
Coccinella septempunctata L. (3 days old larvae)	EXP 607070A (Acetamiprid 200 g/kg)	Laboratory test glass plates (2D)	Mortality: 100 % at 90 g/ha and 180 g/ha No fecundity	EFSA Journal 2016;14(11):4610
Poecilus cupreus L. (adult)	EXP 607070A (Acetamiprid 200 g/kg)	Laboratory test glass plates (2D)	Mortality: 3.3 % at 200 g/ha and 400 g/ha Feedig rate: 0.17% LR_{50} > 400 g s.a./ha	EFSA Journal 2016;14(11):4610
Typhlodromus pyri (protonymphs)	EXP 607070A (Acetamiprid 200 g/kg)	Extended laboratory test, (2D). 14 d	Mortality: 20.5% at 10 g a.s./ha 43.8% at 18 g a.s./ha 34.1% at 32 g a.s./ha 82.6% at 57 g a.s./ha 94.2% at 100 g a.s./ha LR_{50} = 29.7 g a.s./ha Reproduction: No statistically significant effects on the reproductive performance at rates up to 32 g as/ha	EFSA Journal 2016;14(11):4610

Species	Substance	Exposure System	Results	Reference
Aphidius rhopalosiphi (adults)	EXP 607070A (Acetamiprid 200 g/kg)	Extended laboratory test barley plants (3D), 48h	Mortality: 0.0% at 0.207 g a.s./ha 9.4% at 0.621 g a.s./ha 53.1% at 1.86 g a.s./ha 87.5% at 5.59 g a.s./ha 93.8% at 16.8 g a.s./ha LR_{50} = 2.00 g a.s./ha Reproduction: No statistically significant effects on the reproductive performance at rates up to 1.86 g as/ha	EFSA Journal 2016;14(11):4610
Typhlodromus pyri (protonymphs)	~~**Zuxion**~~ **Asset**	Extended laboratory test bean leaves (2D)	**LR_{50} = 25 g f.p./ha (5.1 g a.s./ha)** **ER_{50} = 18.4 g f.p./ha (3.8 g a.s./ha)**	KCP 10.3.2.2-01 Elzbieta Kulec-Polszczyca, 2016, B/98/15
Aphidius rhopalosiphi (adults)	~~**Zuxion**~~ **Asset**	Extended laboratory test barley plants (3D)	**LR_{50} = 11.4 g f.p./ha (2.3 g a.s./ha)** **ER_{50} > 5.2 g f.p./ha (> 1 g a.s./ha)**	KCP 10.3.2.2-02 Elzbieta Kulec-Polszczyca, 2016, B/99/15
Typhlodromus pyri (protonymphs)	EXP 607070A (Acetamiprid 200 g/kg)	Aged-residue test Apple trees (3D)	Mortality at 13 g a.s./ha: -1.1 % at day 0 Mortality at 100 g a.s./ha: 39.1 % at day 0 Sublethal effects at 13 g a.s./ha: 6.2% at day 0 Sublethal effects at 100 g a.s./ha: n.a at day 0 -1.1% at day 7	EFSA Journal 2016;14(11):4610

Species	Substance	Exposure System	Results	Reference
Aphidius rhopalosiphi (adults)	EXP 607070A (Acetamiprid 200 g/kg)	Aged-residue test Apple trees (3D)	Mortality at 13 g a.s./ha: 90 % at day 0 10.3% at day 7 Mortality at 100 g a.s./ha: 70 % at day 0 31.6% at day 14 Sublethal effects at 13 g a.s./ha: n.a. % at day 0 42.4% at day 7 Sublethal effects at 100 g a.s./ha: 54.7% at day 7 20.7% at day 14	EFSA Journal 2016;14(11):4610
Coccinella septempunctata L. (3 days old larvae)	EXP 607070A (Acetamiprid 200 g/kg)	Aged-residue test Apple trees (3D)	Mortality at 13 g a.s./ha: 42.9 % at day 0 Mortality at 100 g a.s./ha: 95.9% at day 0 45.8% at day 7 Sublethal effects at 13 g a.s./ha: n.a at day 0 -16.4% at day 7 Sublethal effects at 100 g a.s./ha: 14.4% at day 28	EFSA Journal 2016;14(11):4610
Chrysoperla carnea. (larvae)	EXP 607070A (Acetamiprid 200 g/kg)	Aged-residue test Apple trees (3D)	Mortality at 13 g a.s./ha: 2.3 % at day 0 Mortality at 100 g a.s./ha: 16.3% at day 0 Sublethal effects at 13 g a.s./ha: 2.4% at day 0 Sublethal effects at 100 g a.s./ha: 6.6% at day 0	EFSA Journal 2016;14(11):4610

Species	Substance	Exposure System	Results	Reference
Typhlodromus pyri (protonymphs)	~~**Zuxion**~~ **Asset**	Aged-residue test Apple leaves	Corrected mortality at 40 g a.s./ha*: 9.4 % at day 0 1.2 % at day 14 -1.4% at day 28 Corrected mortality at 85 g a.s./ha: 11.8 % at day 0 3.5% at day 14 1.9% at day 28 Sublethal effects at 40 g a.s./ha*: 5.6% at day 0 4.2% at day 14 1.7% at day 28 Sublethal effects at 85 g a.s./ha*: 22.2% at day 0 11.5% at day 14 -2.6% at day 28	KCP 10.3.2.2-03 Luna, F., 2018, TRC17-087BA
Aphidius rhopalosiphi (adults)	~~**Zuxion**~~ **Asset**	Aged-residue test Apple trees (3D)	Mortality at 40 g a.s./ha: 100 % at day 0 100% at day 21 16.67% at day 42 0.00% at day 55 Mortality at 85 g a.s./ha: 100 % at day 0 96.67% at day 21 73.33% at day 42 30.00% at day 55 Sublethal effects at 40 g a.s./ha*: n.a. at day 0 n.a. at day 21 5.37% at day 42 -25.01% at day 55 Sublethal effects at 85 g a.s./ha*: n.a. at day 0 n.a. at day 21 n.a. at day 42 -42.75% at day 55	KCP 10.3.2.2-04 Varela, S., 2017, TRC17-086BA

Species	Substance	Exposure System	Results	Reference
Chrysoperla carnea. (larvae)	~~**Zuxion**~~ **Asset**	Aged-residue test Apple leaves	Corrected mortality at 40 g a.s./ha: 33.89% at day 0 0.00% at day 21 8.73% at day 42 Corrected mortality at 85 g a.s./ha*: 75.00% at day 0 4.71% at day 21 -3.17% at day 42 Sublethal effects (fertility) at 40 g a.s./ha: ~~10~~0% at day 0 ~~10~~0% at day 21 ~~10~~0% at day 42 Sublethal effects (fertility) at 85 g a.s./ha: n.a. at day 0 ~~10~~0% at day 21 ~~10~~0% at day 42	KCP 10.3.2.2-05 Luna, F., 2018, TRC17-088BA
Coccinella septempunctata L. (3 days old larvae)	~~**Zuxion**~~ **Asset**	Aged-residue test Apple leaves	Corrected mortality at 40 g a.s./ha*: 87.18% at day 0 -5.56% at day 21 -11.43% at day 42 Corrected mortality at 85 g a.s./ha*: 94.87% at day 0 -5.41% at day 21 -5.71% at day 42 Sublethal effects (Fertile. eggs per female per day) at 40 g a.s./ha**: n.a. at day 0 8.89 at day 21 9.88 at day 42 Sublethal effects (Fertile. eggs per female per day) at 85 g a.s./ha**: n.a. at day 0 11.80 at day 21 12.03 at day 42	KCP 10.3.2.2-06 Luna, F., 2018, TRC17-089BA

*Negative value indicates an increase compared to the control.
**More than 2 fertile eggs per female per day is considered a normal reproductive output for the control treatment
In grey values corrected by ZRMS-PL

9.7.1.1 Justification for new endpoints

The used endpoints were the EU agreed one and the new endpoints of the formulation Zuxion. The results of the studies with Zuxion show that the toxicity is similar to the toxicity of the representative formulation; therefore, it is justified to refer to the DAR studies.

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

Table 9.7-2: First- and higher-tier assessment of the in-field risk for non-target arthropods due to the use of ~~Zuxion~~ Asset in oilseed rape

Intended use	Oilseed rape		
Active substance/product	Acetamiprid/Zuxion		
Application rate (g/ha)	1 x 40 (a.s.) – 1 x 200 (formulation)		
MAF	1		
~~**Test species Tier I**~~	~~**LR_{50} (lab.) (g a.s./ha)**~~	~~**$PER_{in\text{-}field}$ (g a.s./ha)**~~	~~**$HQ_{in\text{-}field}$ criterion: HQ ≤ 2**~~
~~*Typhlodromus pyri*~~	~~< 90~~	~~40~~	~~>0.44~~
~~*Aphidius rhopalosiphi*~~	~~< 200~~	~~40~~	~~>0.20~~
~~*Coccinella septempunctata*~~	~~< 90~~	~~40~~	~~>0.44~~
~~*Poecilus cupreus*~~	~~> 400~~	~~40~~	~~<0.1~~
Test species Higher-tier	**Rate with ≤ 50 % effect* (g f.p./ha)**	**$PER_{in\text{-}field}$ (g f.p./ha)**	**$PER_{in\text{-}field}$ below rate with ≤ 50 % effect?**
Typhlodromus pyri	LR_{50} = 25 g/ha ER_{50} = 18.4 g/ha	200	**no**
Aphidius rhopalosiphi	LR_{50} = 11.4 g/ha ER_{50} > 5.2 g/ha	200	**no**
Test species Higher-tier	**Rate with ≤ 50 % effect (g a.s./ha) at DALT**	**$PER_{in\text{-}field}$ (g a.s./ha)**	**$PER_{in\text{-}field}$ below rate with ≤ 50 % effect?**
Typhlodromus pyri	85 (0 DALT)	40	yes
Aphidius rhopalosiphi	85 (55 DALT)	40	yes
Coccinella septempunctata	85 (21 DALT)	40	yes
Chrysoperla carnea	85 (21 DALT)	40	yes

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_{50} or ER_{50} from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

Table 9.7-3: First- and higher-tier assessment of the in-field risk for non-target arthropods due to the use of ~~Zuxion~~ Asset ~~-~~in pome fruits

Intended use	Pome fruits
Active substance/product	Acetamiprid/Zuxion
Application rate (g/ha)	2 x 50 (a.s.) – 2 x 250 (formulation)
MAF	1.7 (foliar)

~~**Test species**~~ ~~**Tier I**~~	~~**LR_{50} (lab.)**~~ ~~**(g a.s./ha)**~~	~~**$PER_{in\text{-}field}$**~~ ~~**(g a.s./ha)**~~	~~**$HQ_{in\text{-}field}$**~~ ~~**criterion: HQ ≤ 2**~~
~~*Typhlodromus pyri*~~	~~< 90~~	~~85~~	~~>0.94~~
~~*Aphidius rhopalosiphi*~~	~~< 200~~	~~85~~	~~>0.43~~
~~*Coccinella septempunctata*~~	~~< 90~~	~~85~~	~~>0.94~~
~~*Poecilus cupreus*~~	~~> 400~~	~~85~~	~~<0.21~~
Test species **Higher-tier**	**Rate with ≤ 50 % effect*** **(g f.p./ha)**	**$PER_{in\text{-}field}$** **(g f.p./ha)**	**$PER_{in\text{-}field}$ below rate with ≤ 50 % effect?**
Typhlodromus pyri	LR_{50} = 25 g/ha ER_{50} = 18.4 g/ha	340	**no**
Aphidius rhopalosiphi	LR_{50} = 11.4 g/ha ER_{50} > 5.2 g/ha	340	**no**
Test species **Higher-tier**	**Rate with ≤ 50 % effect** **(g a.s./ha) at DALT**	**$PER_{in\text{-}field}$** **(g a.s./ha)**	**$PER_{in\text{-}field}$ below rate with ≤ 50 % effect?**
Typhlodromus pyri	85 (0 DALT)	85	yes
Aphidius rhopalosiphi	85 (55 DALT)	85	yes
Coccinella septempunctata	85 (21 DALT)	85	yes
Chrysoperla carnea	85 (21 DALT)	85	yes

~~**Intended use**~~	~~Pome fruits~~
~~**Active substance/product**~~	~~Acetamiprid/Zuxion~~
~~**Application rate (g/ha)**~~	~~2 x 50 (a.s.) – 2 x 250 (formulation) [2 x 20** (a.s.) – 2 x 100** (formulation)]~~
~~**MAF**~~	~~1.9 (soil)~~

~~**Test species**~~ ~~**Tier I**~~	~~**LR_{50} (lab.)**~~ ~~**(g a.s./ha)**~~	~~**$PER_{in\text{-}field}$**~~ ~~**(g a.s./ha)**~~	~~**$HQ_{in\text{-}field}$**~~ ~~**criterion: HQ ≤ 2**~~
~~*Typhlodromus pyri*~~	~~< 90~~	~~38~~	~~>0.42~~
~~*Aphidius rhopalosiphi*~~	~~< 200~~	~~38~~	~~>0.19~~
~~*Coccinella septempunctata*~~	~~< 90~~	~~38~~	~~>0.42~~
~~*Poecilus cupreus*~~	~~> 400~~	~~38~~	~~<0.10~~
~~**Test species**~~ ~~**Higher-tier**~~	~~**Rate with ≤ 50 % effect***~~ ~~**(g f.p./ha)**~~	~~**$PER_{in\text{-}field}$**~~ ~~**(g f.p./ha)**~~	~~**$PER_{in\text{-}field}$ below rate with ≤ 50 % effect?**~~
~~*Typhlodromus pyri*~~	~~LR_{50} = 25 g/ha~~ ~~ER_{50} = 18.4 g/ha~~	~~190~~	~~**no**~~
~~*Aphidius rhopalosiphi*~~	~~LR_{50} = 11.4 g/ha~~ ~~ER_{50} > 5.2 g/ha~~	~~190~~	~~**no**~~
~~**Test species**~~ ~~**Higher-tier**~~	~~**Rate with ≤ 50 % effect**~~ ~~**(g a.s./ha) at DALT**~~	~~**$PER_{in\text{-}field}$**~~ ~~**(g a.s./ha)**~~	~~**$PER_{in\text{-}field}$ below rate with ≤ 50 % effect?**~~
~~*Typhlodromus pyri*~~	~~85 (0 DALT)~~	~~38~~	~~yes~~

~~*Aphidius rhopalosiphi*~~	~~85 (55 DALT)~~	~~38~~	~~yes~~
~~*Coccinella septempunctata*~~	~~85 (21 DALT)~~	~~38~~	~~yes~~
~~*Chrysoperla carnea*~~	~~85 (21 DALT)~~	~~38~~	~~yes~~

~~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_{50} or ER_{50} from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

~~**rate with a 60% of interception at the BBCH indicated in the GAP. According to the interception values of FOCUS (2012)[4].~~

Two extended studies were submitted with this application to support this application, one with *T. pyri* and the other on with *A. rhopalosiphi*. The risk assessment performed with those studies showed that there would be in-field risk in oilseed rape and pome/stone fruits for both species.

In addition, the Applicant wishes to refer to aged residue studies which were conducted with *T. pyri*, *A. rhopalosiphi* and two additional species, *C. septempunctata* and *C. carnea*. The results of the aged residue studies showed that at a rate of 85 g a.s./ha, higher or equal than the $PEC_{in\text{-}field}$, the effects on mortality and reproduction in those species were ≤ 50% at 0 d for *T. pyri*, at 55 d for *A. rhopalosiphi*, and at 21 d for *Coccinella septempunctata* and *C. carnea*,. Therefore, the potential of recolonization of the in-field area is expected in a short period of time.

Hence, it can be concluded, based on the risk assessment presented above, that the in-field risk to non-target arthropods is considered acceptable after the application of Acetamiprid 20% SG since a potential of recolonisation is expected after a short period of time.

[4] FOCUS (2012) "Focus groundwater scenarios in the EU review of active substances" Report of the FOCUS Groundwater Scenarios Workgroup, EC Document Reference Sanco/321/2000 rev.2, 202 pp.

Applicant update-Nov 2020 (2x180 g f.p./ha , equivalent to 2x36 g a.s./ha):

In-field risk assessment considering the reduction of application rate for comments from efficacy is performed below:

Table 9.7-4: First- and higher-tier assessment of the in-field risk for non-target arthropods due to the use of ~~Zuxion~~ Asset in pome fruits

Intended use	Pome fruits		
Active substance/product	Acetamiprid/Zuxion		
Application rate (g/ha)	2 x 36 (a.s.) – 2 x 180 (formulation)		
MAF	1.7 (foliar)		
~~**Test species Tier I**~~	~~**LR_{50} (lab.) (g a.s./ha)**~~	~~**$PER_{in-field}$ (g a.s./ha)**~~	~~**$HQ_{in-field}$ criterion: HQ ≤ 2**~~
~~*Typhlodromus pyri*~~	~~< 90~~	~~61.20~~	~~>0.68~~
~~*Aphidius rhopalosiphi*~~	~~< 200~~	~~61.20~~	~~>0.31~~
~~*Coccinella septempunctata*~~	~~< 90~~	~~61.20~~	~~>0.68~~
~~*Poecilus cupreus*~~	~~> 400~~	~~61.20~~	~~<0.15~~
Test species Higher-tier	**Rate with ≤ 50 % effect* (g f.p./ha)**	**$PER_{in-field}$ (g f.p./ha)**	**$PER_{in-field}$ below rate with ≤ 50 % effect?**
Typhlodromus pyri	LR_{50} = 25 g/ha ER_{50} = 18.4 g/ha	306.00	**no**
Aphidius rhopalosiphi	LR_{50} = 11.4 g/ha ER_{50} > 5.2 g/ha	306.00	**no**
Test species Higher-tier	**Rate with ≤ 50 % effect (g a.s./ha) at DALT**	**$PER_{in-field}$ (g a.s./ha)**	**$PER_{in-field}$ below rate with ≤ 50 % effect?**
Typhlodromus pyri	85 (0 DALT)	61.20	yes
Aphidius rhopalosiphi	85 (55 DALT)	61.20	yes
Coccinella septempunctata	85 (21 DALT)	61.20	yes
Chrysoperla carnea	85 (21 DALT)	61.20	yes
Intended use	Pome fruits		
Active substance/product	Acetamiprid/Zuxion		
Application rate (g/ha)	2 x 36 (a.s.) – 2 x 180 (formulation) [2 x 14.4** (a.s.) – 2 x 72** (formulation)]		
MAF	1.9 (soil)		
Test species Tier I	**LR_{50} (lab.) (g a.s./ha)**	**$PER_{in-field}$ (g a.s./ha)**	**$HQ_{in-field}$ criterion: HQ ≤ 2**
Typhlodromus pyri	< 90	27.36	>0.30
Aphidius rhopalosiphi	< 200	27.36	>0.14
Coccinella septempunctata	< 90	27.36	>0.30
Poecilus cupreus	> 400	27.36	<0.07
Test species Higher-tier	**Rate with ≤ 50 % effect* (g f.p./ha)**	**$PER_{in-field}$ (g f.p./ha)**	**$PER_{in-field}$ below rate with ≤ 50 % effect?**
Typhlodromus pyri	LR_{50} = 25 g/ha ER_{50} = 18.4 g/ha	136.80	**no**

Aphidius rhopalosiphi	LR_{50} = 11.4 g/ha ER_{50} > 5.2 g/ha	136.80	**no**
Test species Higher-tier	**Rate with ≤ 50 % effect (g a.s./ha) at DALT**	**$PER_{in-field}$ (g a.s./ha)**	**$PER_{in-field}$ below rate with ≤ 50 % effect?**
Typhlodromus pyri	85 (0 DALT)	27.36	yes
Aphidius rhopalosiphi	85 (55 DALT)	27.36	yes
Coccinella septempunctata	85 (21 DALT)	27.36	yes
Chrysoperla carnea	85 (21 DALT)	27.36	yes

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_{50} or ER_{50} from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.
**rate with a 60% of interception at the BBCH indicated in the GAP. According to the interception values of FOCUS (2012)

ZRMS comments:

In-field 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.

Two extended studies were submitted with this application to support this application, one with *T. pyri* and the other on with *A. rhopalosiphi*. The risk assessment performed with those studies showed that there would be in-field risk in oilseed rape and pome/stone fruits for both species.

In addition, the Applicant performed aged residue studies conducted with *T. pyri*, *A. rhopalosiphi* and two additional species, *C. septempunctata* and *C. carnea*. The results of the aged residue studies showed that at a rate of 85 g a.s./ha, higher or equal than the $PEC_{in-field}$, the effects on mortality and reproduction in those species were ≤ 50% at 0 d for *T. pyri*, at 55 d for *A. rhopalosiphi*, and at 21 DAL for *Coccinella septempunctata* and *C. carnea*. Therefore, the potential of recolonization of the in-field area is concluded. Therefore, the risk for non target anthropods in –field is considered as an acceptable.

9.7.2.2 Risk assessment for off-field exposure

Table 9.7-5: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of Zuxion in oilseed rape

Intended use	Oilseed rape
Active substance/product	Acetamiprid/~~Zuxion~~ Assel
Application rate (g/ha)	1 x 200 (formulation)
MAF	1
vdf	10 (2D only)/ 1 (3D only)

Test species Higher-tier	Rate with ≤ 50 % effect* (g f.p./ha)	Drift rate	$PER_{off-field}$ (g f.p./ha)	CF	corr. $PER_{off-field}$ below rate with ≤ 50 % effect?
Typhlodromus pyri	LR_{50} = 25 g/ha ER_{50} = 18.4 g/ha	2.77	0.554	5	yes
Aphidius rhopalosiphi	LR_{50} = 11.4 g/ha ER_{50} > 5.2 g/ha	2.77	5.54	5	**no**

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_{50} or ER_{50} from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

Table 9.7-6: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of Zuxion in pome fruits

Intended use	Pome fruits
Active substance/product	Acetamiprid/~~Zuxion~~ Asset
Application rate (g/ha)	2 x 250 (formulation)
MAF	1.7 (foliar)
vdf	10 (2D only)/ 1 (3D only)

Test species Higher-tier	Rate with ≤ 50 % effect* (g/ha)	Drift rate	$PER_{off-field}$ (g/ha)	CF	corr. $PER_{off-field}$ below rate with ≤ 50 % effect?
Typhlodromus pyri	LR_{50} = 25 g/ha ER_{50} = 18.4 g/ha	25.53	10.85	5	**no**
Aphidius rhopalosiphi	LR_{50} = 11.4 g/ha ER_{50} > 5.2 g/ha	25.53	108.50	5	**no**

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_{50} or ER_{50} from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

The off-field risk performed showed risk in oilseed rape for *A. rhopalosiphi* and in pome fruits for *A. rhopalosiphi* and *T. pyri*.

Applicant update-Nov 2020 (2x180 g f.p./ha , equivalent to 2x36 g a.s./ha):

Off-field risk assessment considering the reduction of application rate for comments from efficacy is performed below:

Table 9.7-7: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of Zuxion in pome fruits

Intended use	Pome fruits
Active substance/product	Acetamiprid/~~Zuxion~~ Asset
Application rate (g/ha)	2 x 180 (formulation)
MAF	1.7 (foliar)
vdf	10 (2D only)/ 1 (3D only)

Test species Higher-tier	**Rate with ≤ 50 % effect* (g/ha)**	**Drift rate**	**$PER_{off-field}$ (g/ha)**	**CF**	**corr. $PER_{off-field}$ below rate with ≤ 50 % effect?**
Typhlodromus pyri	LR_{50} = 25 g/ha ER_{50} = 18.4 g/ha	25.53	7.81	5	**no**
Aphidius rhopalosiphi	LR_{50} = 11.4 g/ha ER_{50} > 5.2 g/ha	25.53	78.12	5	**no**

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_{50} or ER_{50} from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

ZRMS comments:

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.

The off-field risk performed showed risk in oilseed rape for *A. rhopalosiphi* and in pome fruits for A. rhopalosiphi and T. pyri.

Therefore, further refinement off -field risk was needed for two indicator species.

The proposed risk mitigation measures was provided in the Tables below:

9.7.2.3 Additional higher-tier risk assessment

Not required.

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 9.7-8: Assessment of the off-field risk for non-target arthropods due to the use of ~~Zuxion~~ Asset in oilseed rape considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles)

Intended use		Oilseed rape			
Active substance/product		~~Zuxion~~ Asset			
Application rate (g/ha)		1 x 200 (formulation)			
MAF		1			
vdf		1 (3D only)			
Buffer strip (m)	**Drift rate (%)**	**corr. $PER_{off-field}$ (g f.p./ha)**	**corr. $PER_{off-field}$ 50 % drift red. (g f.p./ha)**	**corr. $PER_{off-field}$ 75 % drift red. (g f.p/ha)**	**corr. $PER_{off-field}$ 90 % drift red. (g f.p./ha)**
1	2.77	27.70	13.85	6.93	2.77
5	0.57	5.70	2.85	-	-
10	0.29	2.90	-	-	-
Higher-tier toxicity value		**corr. $PER_{off-field}$ below rate with ≤ 50 % effect**			
ER_{50} > 5.2 g/ha					
1		**No**	**No**	**No**	Yes
5		**No**	Yes	-	-
10		Yes	-	-	-

MAF: Multiple application factor; PER: Predicted environmental rates; HQ: Hazard quotient; Criteria values shown in bold breach the relevant trigger.

Table 9.7-9: Assessment of the off-field risk for non-target arthropods due to the use of ~~Zuxion~~ Asset in pome fruits (early application) considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles)

Intended use		Pome fruits (early application)			
Active substance/product		~~Zuxion~~ Asset			
Application rate (g/ha)		2 x 250 (formulation)			
MAF		~~1.7~~ 1			
vdf		1 (3D only)			
Buffer strip (m)	**Drift rate (%)**	**corr. $PER_{off-field}$ (g f.p./ha)**	**corr. $PER_{off-field}$ 50 % drift red. (g f.p./ha)**	**corr. $PER_{off-field}$ 75 % drift red. (g f.p/ha)**	**corr. $PER_{off-field}$ 90 % drift red. (g f.p./ha)**
1	~~25.53~~ 29.20	~~542.51~~ 365.00	~~271.26~~ 182.50	~~135.63~~ 91.25	~~54.25~~ 36.50
5	~~16.87~~ 19.89	~~358.49~~ 248.63	~~179.24~~ 124.31	~~89.62~~ 62.16	~~35.85~~ 24.86
10	~~9.61~~ 11.81	~~204.21~~ 147.63	~~102.11~~ 73.81	~~51.05~~ 36.91	~~20.42~~ 14.76
15	~~5.61~~ 5.55	~~119.21~~ 69.38	~~59.61~~ 34.69	~~29.80~~ 17.34	~~11.92~~ 6.94
20	~~2.59~~ 2.77	~~55.04~~ 34.63	~~27.52~~ 17.31	~~13.76~~ 8.66	~~5.50~~ 3.46

30	~~0.87~~ 1.04	~~18.49~~ 13.00	~~9.24~~ 6.50	~~4.62~~ 3.25	~~1.85~~ 1.30
40	~~0.40~~ 0.52	~~8.50~~ 6.50	~~4.25~~ 3.25	-	-
50	~~0.22~~ 0.30	~~4.68~~ 3.75	-	-	-
Higher-tier toxicity value ER_{50} > 5.2 g/ha		**corr. $PER_{off-field}$ below rate with ≤ 50 % effect**			
1		**No**	**No**	**No**	**No**
5		**No**	**No**	**No**	**No**
10		**No**	**No**	**No**	**No**
15		**No**	**No**	**No**	**No**
20		**No**	**No**	**No**	~~**No**~~ Yes
30		**No**	**No**	Yes	-
40		**No**	Yes	-	-
50		Yes	-	-	-

MAF: Multiple application factor; PER: Predicted environmental rates; HQ: Hazard quotient; Criteria values shown in bold breach the relevant trigger.

Table 9.7-10: Assessment of the off-field risk for non-target arthropods due to the use of ~~Zuxion-Asset~~ in pome fruits (late application) considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles)

Intended use		Pome fruits (late application)			
Active substance/product		~~Zuxion-Asset~~			
Application rate (g/ha)		2 x 250 (formulation)			
MAF		~~1.7~~ 1			
vdf		1 (3D only)			
Buffer strip (m)	**Drift rate (%)**	**corr. $PER_{off-field}$ (g f.p./ha)**	**corr. $PER_{off-field}$ 50 % drift red. (g f.p./ha)**	**corr. $PER_{off-field}$ 75 % drift red. (g f.p/ha)**	**corr. $PER_{off-field}$ 90 % drift red. (g f.p./ha)**
1	12.13 15.73	257.76 196.63	128.88 98.31	64.44 49.16	25.78 19.66
5	6.81 8.41	144.71 105.13	72.36 52.56	36.18 26.28	14.47 10.51
10	3.11 3.60	66.09 45.00	33.04 22.50	16.52 11.25	6.61 4.50
15	1.58 1.81	33.58 22.63	16.79 11.31	8.39 5.66	3.36 2.26
20	0.90 1.09	19.13 13.63	9.56 6.81	4.78 3.40	-
30	0.40 0.54	8.50 6.75	4.25 3.38	-	-
40	0.23 0.32	4.89 4.00	-	-	-

Higher-tier toxicity value ER_{50} > 5.2 g/ha	**corr. $PER_{off-field}$ below rate with ≤ 50 % effect**			
1	**No**	**No**	**No**	**No**
5	**No**	**No**	**No**	**No**
10	**No**	**No**	**No**	~~**No**~~ Yes
15	**No**	**No**	**No**	Yes
20	**No**	**No**	Yes	-
30	**No**	Yes	-	-
40	Yes	-	-	-

MAF: Multiple application factor; PER: Predicted environmental rates; HQ: Hazard quotient; Criteria values shown in bold breach the relevant trigger.

The results of the risk assessment for non-target arthropods showed an acceptable off-field risk after the application of Acetamiprid 20% SG with the following risk mitigation measures.

Oilseed rape: A buffer zone of 10 m or 5m with 50% of nozzles reduction or no buffer zone with 90% of nozzles reduction, are required.

Pome fruits (early application): A buffer zone of 50m or 40m with 50% of nozzles reduction or 30m with 75% of nozzles reduction or 20m with 90% of nozzles reduction, are required.

Pome fruits (late application): A buffer zone of 40m or 30m with 50% of nozzles reduction or 20m with 75% of nozzles reduction or 10~~5~~m with 90% of nozzles reduction, are required.

Applicant update-Nov 2020 (2x180 g f.p./ha , equivalent to 2x36 g a.s./ha):

Off-field risk assessment ~~considering the reduction of application rate for comments from efficacy~~ is performed below~~:~~

Table 9.7-9: Assessment of the off-field risk for non-target arthropods due to the use of in ~~Zuxion-Asset~~ pome fruits (early application) considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles)

Intended use		Pome fruits (early application)			
Active substance/product		~~Zuxion-Asset~~			
Application rate (g/ha)		2 x 180 (formulation)			
MAF		~~1.7~~ 1			
vdf		1 (3D only)			
Buffer strip (m)	**Drift rate (%)**	**corr. $PER_{off-field}$ (g f.p./ha)**	**corr. $PER_{off-field}$ 50 % drift red. (g f.p./ha)**	**corr. $PER_{off-field}$ 75 % drift red. (g f.p/ha)**	**corr. $PER_{off-field}$ 90 % drift red. (g f.p./ha)**
1	25.53 ~~29.20~~	390.61 ~~262.80~~	195.30 ~~131.40~~	97,65 ~~65.70~~	39,06 ~~26.28~~
5	16.87 ~~19.89~~	258.11 ~~179.01~~	129.06 ~~89.51~~	64,53 ~~44.75~~	25,81 ~~17.90~~
10	9.61 ~~11.81~~	147.03 ~~106.29~~	73.52 ~~53.15~~	36,76 ~~26.57~~	14,70 ~~10.63~~

15	5.61 5.55	85.83 49.95	42.92 24.98	21.46 12.49	8,58 5.00
20	2.59 2.77	39.63 24.98	19.81 12.47	9,91 5.23	3,96 2.49
30	0.87 1.04	13.31 9.10	6.66 4.55	3,33 2.27	1,33 0.91
40	0.40 0.52	6.12 4.68	3.06 2.34	1,53 1.17	0,61 0.47
50	0.22 0.30	3.37 2.70	1.68 1.35	0,84 0.68	0,34 0.27
Higher-tier toxicity value ER_{50} > 5.2 g/ha		**corr. $PER_{off-field}$ below rate with ≤ 50 % effect**			
1		**no**	**no**	**no**	**no**
5		**no**	**no**	**no**	**no**
10		**no**	**no**	**no**	**no**
15		**no**	**no**	**no**	~~**no**~~ yes
20		**no**	**no**	**no**	yes
30		**no**	~~**no**~~ yes	yes	yes
40		~~**no**~~ yes	yes	yes	yes
50		yes	yes	yes	yes

MAF: Multiple application factor; PER: Predicted environmental rates; HQ: Hazard quotient; Criteria values shown in bold breach the relevant trigger.

Table 9.7-10: Assessment of the off-field risk for non-target arthropods due to the use of ASSET ~~ZUXION~~ in pome fruits (early application) considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles)

Intended use **Active substance/product** **Application rate (g/ha)** **MAF** **vdf**		Pome fruits (early application) ASSET ~~ZUXION~~ **1 x 180 (formulation)** 1. 1 (3D only)			
Buffer strip (m)	**Drift rate (%)**	**corr. $PER_{off-field}$ (g f.p./ha)**	**corr. $PER_{off-field}$ 50 % drift red. (g f.p./ha)**	**corr. $PER_{off-field}$ 75 % drift red. (g f.p/ha)**	**corr. $PER_{off-field}$ 90 % drift red. (g f.p./ha)**
1	~~25.53~~ 29.20	~~229.77~~ 262.80	~~114.88~~ 131.40	~~57.44~~ 65.70	~~22.98~~ 26.28
5	~~16.87~~ 19.89	~~151.83~~ 179.01	~~75.92~~ 89.51	~~37.96~~ 44.75	~~15.18~~ 17.90
10	~~9.61~~ 11.81	~~86.49~~ 106.29	~~43.25~~ 53.15	~~21.62~~ 26.57	~~8.65~~ 10.63
15	~~5.61~~ 5.55	~~50.49~~ 49.95	~~25.25~~ 24.98	~~12.62~~ 12.49	~~5.05~~ 5.00

20	~~2.59~~ 2.77	~~23.31~~ 24.93	~~11.65~~ 12.47	~~5.83~~ 6.23	~~2.33~~ 2.49
30	~~0.87~~ 1.04	~~7.83~~ 9.36	~~3.92~~ 4.68	~~1.96~~ 2.34	~~0.78~~ 0.94
40	~~0.40~~ 0.52	~~3.60~~ 4.68	~~2.12~~ 2.34	~~0.90~~ 1.17	~~0.36~~ 0.47
50	~~0.22~~ 0.30	~~1.98~~ 2.70	1.17 1.35	~~0.49~~ 0.68	~~0.20~~ 0.27
Higher-tier toxicity value ER_{50} > 5.2 g/ha		**corr. $PER_{off-field}$ below rate with ≤ 50 % effect**			
1		**no**	**no**	**no**	**no**
5		**no**	**no**	**no**	**no**
10		**no**	**no**	**no**	**no**
15		**no**	**no**	**no**	yes
20		**no**	**no**	**no**	yes
30		**no**	yes	yes	yes
40		yes	yes	yes	yes
50		yes	yes	yes	yes

MAF: Multiple application factor; PER: Predicted environmental rates; HQ: Hazard quotient; Criteria values shown in bold breach the relevant trigger.

Table 9.7-11: Assessment of the off-field risk for non-target arthropods due to the use of i ~~Zuxion~~ Asset in pome fruits (late application) considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles)

Intended use		Pome fruits (late application)			
Active substance/product		Zuxion Asset			
Application rate (g/ha)		2 x 180 (formulation)			
MAF		~~1.7~~ 1			
vdf		1 (3D only)			
Buffer strip (m)	**Drift rate (%)**	**corr. $PER_{off-field}$ (g f.p./ha)**	**corr. $PER_{off-field}$ 50 % drift red. (g f.p./ha)**	**corr. $PER_{off-field}$ 75 % drift red. (g f.p/ha)**	**corr. $PER_{off-field}$ 90 % drift red. (g f.p./ha)**
1	12.13 15.73	185.59 141.57	92.79 70.79	46.40 35.39	18.56 14.16
5	6.81 8.41	104.19 75.69	52.10 37.85	26.05 18.92	10.42 7.57
10	3.11 3.60	47.58 32.40	23.79 16.20	11.90 8.10	4.76 3.24
15	1.58 1.81	24.17 16.29	12.09 8.15	6.04 4.07	2.42 1.63
20	0.90 1.09	13.77 9.81	6.89 4.91	3.44 2.45	1.38 0.98
30	0.40	6.12	3.06	1.53	0.61

	0.54	4.86	2.43	1.22	0.49
40	0.23 0.32	3.52 2.88	1.76 1.44	0.88 0.72	0.35 0.29
Higher-tier toxicity value ER_{50} > 5.2 g/ha		**corr. $PER_{off-field}$ below rate with ≤ 50 % effect**			
1		**no**	**no**	**no**	**no**
5		**no**	**no**	**no**	**no**
10		**no**	**no**	**no**	yes
15		**no**	**no**	~~**no**~~ yes	yes
20		**no**	~~**no**~~ yes	yes	yes
30		~~**no**~~ yes	yes	yes	yes
40		yes	yes	yes	yes

MAF: Multiple application factor; PER: Predicted environmental rates; HQ: Hazard quotient; Criteria values shown in bold breach the relevant trigger.

~~Risk mitigation measures are considered due to the reduction of application rate for comments from efficacy is performed below:~~

Pome fruits (early application): A buffer zone of ~~50m or~~ 40m ~~with 50% of nozzles reduction~~ or 30m with ~~75~~0% of nozzles reduction or ~~20~~15m with 90% of nozzles reduction, are required.

Pome fruits (late application): A buffer zone of ~~40m or~~ 30m ~~with 50% of nozzles reduction~~ or 20m with ~~75~~0% of nozzles reduction or 15m with 75% of nozzles reduction or 10m with 90% of nozzles reduction, are required.

Table 9.7-12: Assessment of the off-field risk for non-target arthropods due to the use of ~~Zuxion~~ Asset in pome fruits (late application) considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles)

Intended use		Pome fruits (late application)			
Active substance/product		~~Zuxion~~ Asset			
Application rate (g/ha)		1 x 180 (formulation)			
MAF		1.			
vdf		1 (3D only)			
Buffer strip (m)	**Drift rate (%)**	**corr. $PER_{off-field}$ (g f.p./ha)**	**corr. $PER_{off-field}$ 50 % drift red. (g f.p./ha)**	**corr. $PER_{off-field}$ 75 % drift red. (g f.p/ha)**	**corr. $PER_{off-field}$ 90 % drift red. (g f.p./ha)**
1	~~12.13~~ 15.73	~~109.17~~ 141.57	~~54.58~~ 70.79	~~27.29~~ 35.39	~~10.92~~ 14.16
5	~~6.81~~ 8.41	~~61.29~~ 75.69	~~30.65~~ 37.85	~~15.32~~ 18.92	~~6.13~~ 7.57
10	~~3.11~~ 3.60	~~27.99~~ 32.40	~~13.99~~ 16.20	~~7.00~~ 8.10	~~**2.80**~~ **3.24**
15	~~1.58~~	~~14.22~~	~~7.11~~	~~**3.55**~~	~~**1.42**~~

	1.81	16.29	8.15	**4.07**	**1.63**
20	~~0.90~~ 1.09	~~8.10~~ 9.81	~~**4.05**~~ **4.91**	~~**2.02**~~ **2.45**	~~**0.81**~~ **0.98**
30	~~0.40~~ 0.54	~~**3.60**~~ **4.86**	~~**1.80**~~ **2.43**	~~**0.90**~~ **1.22**	~~**0.36**~~ **0.49**
40	~~0.23~~ 0.32	~~**2.07**~~ **2.88**	~~**1.04**~~ **1.44**	~~**0.52**~~ **0.72**	~~**0.21**~~ **0.29**

Higher-tier toxicity value ER_{50} > 5.2 g/ha	**corr. $PER_{off-field}$ below rate with ≤ 50 % effect**			
1	**no**	**no**	**no**	**no**
5	**no**	**no**	**no**	**no**
10	**no**	**no**	**no**	yes
15	**no**	**no**	yes	yes
20	**no**	yes	yes	yes
30	yes	yes	yes	yes
40	yes	yes	yes	yes

MAF: Multiple application factor; PER: Predicted environmental rates; HQ: Hazard quotient; Criteria values shown in bold breach the relevant trigger.

Pome fruits (1 x 36 g a.s./ha late application): A buffer zone of 30m or 20m with ~~7~~50% of nozzles reduction or 15m with 75% of nozzles reduction or 10m with 90% of nozzles reduction, are required.

9.7.3 Overall conclusions

The results of the risk assessment for non-target arthropods showed an acceptable in-field and off-field risk after the application of Acetamiprid 20% SG. A potential of recovery of the in-field area have been demonstrate in a short period of time. In addition, an acceptable off-field risk was obtained with the application (2 x 50 g a.s./ha). with risk mitigation measures.
The application rate of 2x 50 g a.s./ha is not considered further as the applicant during evaluation changed tha GAP and reduce the the proposed uses in orchrds to 1-2 36 g a.s./ha with BBCH>69.
Therefore, the following risk mitigation measures are required:

Oilseed rape – Spe3*: To protect non-target arthropods respect an unsprayed buffer zone of 10 m to non-agricultural land OR an unsprayed buffer zone of 5 m to non-agricultural land with 50% of nozzles reduction OR no buffer zone to non-agricultural land with 90% of nozzles reduction.*

~~***Pome/stone fruits (early application) – Spe3****: To protect non-target arthropods respect an unsprayed buffer zone of 50 m to non-agricultural land OR an unsprayed buffer zone of 40 m to non-agricultural land with 50% of nozzles reduction OR an unsprayed buffer zone of 30m to non-agricultural land with 75% of nozzles reduction or an unsprayed buffer zone of 20m to non-agricultural land with 90% of nozzles reduction.~~*

~~***Pome/stone fruits (late application) – Spe3****: To protect non-target arthropods respect an unsprayed buffer zone of 40 m to non-agricultural land OR an unsprayed buffer zone of 30 m to non-agricultural land with 50% of nozzles reduction OR an unsprayed buffer zone of 20m to non-agricultural land with 75% of nozzles reduction OR an unsprayed buffer zone of 1~~*

Applicant update-Nov 2020 (2x180 g f.p./ha , equivalent to 2x36 g a.s./ha):

Pome/stone fruits (early application)– Spe3*: To protect non-target arthropods respect an unsprayed buffer zone of ~~50 m to non-agricultural land OR an unsprayed buffer zone of~~ 40 m to non-agricultural land ~~with 50% of nozzles reduction~~ OR an unsprayed buffer zone of 30m to non-agricultural land with ~~75~~50% of nozzles reduction OR an unsprayed buffer zone of ~~20~~15m to non-agricultural land with 90% of nozzles reduction.*

Pome/stone fruits (late application)– Spe3*: To protect non-target arthropods respect an unsprayed buffer zone of ~~40 m to non-agricultural land OR an unsprayed buffer zone of~~ 30 m to non-agricultural land ~~with 50% of nozzles reduction~~ OR an unsprayed buffer zone of 20m to non-agricultural land with ~~75~~50% of nozzles reduction OR an unsprayed buffer zone of 15m to non-agricultural land with 75% of nozzles reduction OR 10m to non-agricultural land with 90% of nozzles reduction.*

ZRMS comments:

The results of the risk assessment for non-target arthropods showed an acceptable off-field risk after the application of Acetamiprid 20% SG with the following risk mitigation measures.

Oilseed rape (appicatio dose 1 x 40 g a.s./ha) – Spe3*: To protect non-target arthropods respect an unsprayed buffer zone of 10 m to non-agricultural land OR an unsprayed buffer zone of 5 m to non-agricultural land with 50% of nozzles reduction OR no buffer zone to non-agricultural land with 90% of nozzles reduction.*

~~***Pome/stone fruits (early application 2 x 50 g a.s./ha) – Spe3****: To protect non-target arthropods respect an unsprayed buffer zone of 50 m to non-agricultural land OR an unsprayed buffer zone of 40 m to non-agricultural land with 50% of nozzles reduction OR an unsprayed buffer zone of 30m to non-agricultural land with 75% of nozzles reduction or an unsprayed buffer zone of 20m to non-agricultural land with 90% of nozzles reduction.~~*

~~***Pome/stone fruits (late application, 2 x 50 g a.s./ha) – Spe3****: To protect non-target arthropods respect an unsprayed buffer zone of 40 m to non-agricultural land OR an unsprayed buffer zone of 30 m to non-agricultural land with 50% of nozzles reduction OR an unsprayed buffer zone of 20m to non-agricultural land with 75% of nozzles reduction OR an unsprayed buffer zone of 10m to non-agricultural land with 90% of nozzles reduction.~~*

~~***Pome/stone fruits (early application, 2 x 36 g a.s./ha)– Spe3****: To protect non-target arthropods respect an unsprayed buffer zone of 50 m to non-agricultural land OR an unsprayed buffer zone of 40 m to non-agricultural land with 50% of nozzles reduction OR an unsprayed buffer zone of 30m to non-agricultural land with 75% of nozzles reduction OR an unsprayed buffer zone of 20m to non-agricultural land with 90% of nozzles reduction.~~*

Pome/stone fruits (late application, 2 x 36 g a.s./ha)– Spe3*: To protect non-target arthropods respect an unsprayed buffer zone of ~~40 m to non-agricultural land OR an unsprayed buffer zone of~~ 30 m to non-agricultural land ~~with 50% of nozzles reduction~~ OR an unsprayed buffer zone of 20m to non-agricultural land with ~~75~~50% of nozzles reduction OR an unsprayed buffer zone of 15m to non-agricultural land with 75% of nozzles reduction OR an unsprayed buffer zone of 10m to non-agricultural land with 90% of nozzles reduction.*

~~In addition zRMS calculated the risk mitigation measures for application rate of **1 x 36 g a.s./ha** for early and late application in orchards.~~
~~The results of the risk assessment for non-target arthropods showed an acceptable off-field risk when:~~

Pome/stone fruits (early application, 1 x 36 g a.s./ha)– Spe3: To protect non-target arthropods respect an unsprayed buffer zone of 40 m to non-agricultural land OR an unsprayed buffer zone of 30 m to non-agricultural land with 50% of nozzles reduction OR an unsprayed buffer zone of 15 and20 m to non-agricultural land with 90% of nozzles reduction.

***Pome/stone fruits (late application, 1 x 36 g a.s./ha)– Spe3**: To protect non-target arthropods respect an unsprayed buffer zone of 30 m to non-agricultural land OR an unsprayed buffer zone of 20 m to non-agricultural land with 50% of nozzles reduction OR an unsprayed buffer zone of 15m to non-agricultural land with 75% of nozzles reduction OR an unsprayed buffer zone of 10m to non-agricultural land with 90% of 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 metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on earthworms and other non-target soil organisms (meso- and macrofauna) of ~~Zuxion~~ Asset 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.

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
Eisenia fetida	IM-1-5	Chronic	NOEC = 62.5 mg metabolite/kg d.w. soil E/LC_{10} = > 62.5	EFSA Journal 2016;14(11):4610
Eisenia fetida	~~Zuxion~~ Asset	Mixed into substrate 4 weeks, chronic	**NOEC = 5.6 mg/kg dry soil(equivalent to 1.1 mg a.s./kg dw soil)**	KCP 10.4.1.1 Gierbuszewska, A. 2017 G/187/15
Folsomia candida	Acetamiprid 20 SG	Mixed into substrate 28 d, chronic 5 % peat content	$NOEC_{mortality}$ = 0.49 mg a.s./kg soil d.w. LC_{10} = 0.82 mg a.s./kg soil d.w. **$NOEC_{reproduction}$ = 0.27 mg a.s./kg soil d.w.** EC_{10} = 0.47 mg a.s./kg soil d.w.	EFSA Journal 2016;14(11):4610

Species	Substance	Exposure System	Results	Reference
Folsomia candida	IM-1-5	Mixed into substrate 28 d, chronic	$NOEC_{mortality}$ = 62.7 mg/kg dw soil No EC values could be calculated as there were no effects below the highest tested value. **$NOAEC_{reproduction}$ = 12.5 mg/kd dw soil** No EC values were calculated as the data were not appropriate for modelling.	EFSA Journal 2016;14(11):4610
Folsomia candida	~~Zuxion~~ Asset	Mixed into substrate 28d, chronic	**NOEC = 1.39 mg f.p./kg dw soil (equivalent to 0.28 mg a.s./kg dw soil)** EC_{10} = 1.91 mg f.p./kg dw soil (equivalent to 0.39 mg a.s./kg dw soil)	KCP 10.4.2.1-01 Angayarkanni, V. 2019 4344/2018
Hypoaspis aculeifer	Acetamiprid 20 SG	Mixed into substrate 14 d, chronic 5 % peat content	$NOEC_{mortality\ and\ reproduction}$ = 180 mg a.s./kg soil d.w. LC_{50} = > 180 mg a.s./kg soil d.w. **EC_{10} = 50.8 mg a.s./kg soil d.w.**	EFSA Journal 2016;14(11):4610
Hypoaspis aculeifer	~~Zuxion~~ Asset	Mixed into substrate 14d, Acute	**EC_{50}> 1000 mg/kg dw(equivalent to 204 mg a.s./kg dw soil)**	KCP 10.4.2.1-02 Lozano Garcia, J. 2017 TRC17-096BA
Field studies				

Species	Substance	Exposure System	Results	Reference
Higher tier testing (e.g. modelling or field studies) An earthworm field study was performed with the formulation Acetamiprid 20 SG. Two applications of 25, 50 and 80 g a.s./ha with a 7 day interval were sprayed onto bare soil in Althen, Germany. 20 plots of 10 x 10m, separated by 2m strips, with 4 replicates, were used. A toxic reference (Nutdazim 50 Flow, 500 g/L carbendazim nominal) was applied to the reference plot(s) at the same time as the first test substance application (28 April 2009). The temperature during first application was 20-23 ºC and in the 3 days after the first application 6 mm rainfall occurred. The temperature during second application was 8-11 ºC, and 5.5 mm rainfall occurred in the 3 days post application. Temperatures varied from 8.7 to 17.4 ºC and soil moisture was 10.7 – 16.8% during soil sampling. Analytical sampling occurred after application and before irrigation. 5 subsamples of soil were taken per plot, which were pooled to one specimen. The analytical method was acceptable. Earthworm sampling took place 2 weeks before application (14 April 2009), 1 month after first application (1 May 2009), 6 months after first application (12 October 2009) and 1 year after first application (26 April 2010). On each sampling occasion the soil surface was monitored to check for dead earthworms, in two 1m strips in the middle of a plot. 4 sub-plots of 0.25m2 per plot were sampled in the middle 6 x 6m of the plots, to a depth of 20 cm per sample. The results show that none of the acetamiprid treatments cause significant effects (>50%) on total abundance or biomass, as compared to the control. In the middle and high acetamiprid treatments of 50 and 80 g a.s./ha, a decline in abundance and biomass is present at the 1st sampling after application, both when compared to the control and to pre-treatment sampling. This effect is generally <50% as compared to the control and no dose-related differences are seen 6 months and 1 year after treatment. Individual species show occasional significant decreases in biomass at either 1 or 6 months, but the differences are no longer present after 1 year. **Acetamiprid 20 SG at rates up to 80 g a.s./ha did not cause any adverse effects >50% on total earthworm abundance and biomass.**				
Litter bag test				
-				

Justification for new endpoints

The used endpoints were the EU agreed one and the new endpoints of the formulation ~~Zuxion~~ Asset .

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).

First-tier risk assessment

The relevant PEC_{soil} 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 the metabolite IM-1-5.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group pome fruits also covers the risk for earthworms and other non-target soil organisms (meso- and macrofauna) for the use on oilseed rape.

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 ~~Zuxion~~ Asset in pome fruits (worst case)

Intended use	Pome/stone fruits		
Chronic effects on earthworms			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
IM-1-5	62.5	0.042	1488.10
~~Zuxion~~ Asset	5.6	0.267	20.97
~~Zuxion~~* Asset as acetamiprid	1.1	0.039	28.21
Chronic effects on other soil macro- and mesofauna			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Acetamiprid 20 SG *(Folsomia candida)*	0.27	0.039	6.92
IM-1-5 *(Folsomia candida)*	12.5	0.042	297.62
~~Zuxion~~ Asset (*Folsomia candida*)	1.39	0.267	5.21
~~Zuxion~~ Asset* (*Folsomia candida*) as acetamiprid	0.28	0.039	7.18
Acetamiprid 20 SG (*Hypoaspis aculeifer*)	50.8	0.039	1302.56
~~Zuxion~~ Asset (*Hypoaspis aculeifer*)	1000	0.267	3745.32
~~Zuxion*~~Asset- (*Hypoaspis aculeifer*) as acetamiprid	204	0.039	5230.77

TER values shown in bold fall below the relevant trigger.
* Risk assessment based on an endpoint expressed as mg as/kg dw from ~~Zuxion~~/ Asset-study.

Applicant update-Nov 2020 (2x180 g f.p./ha , equivalent to 2x36 g a.s./ha):

Chronic risk assessment for earthworms and other soil macro- and mesofauna considering the reduction of application rate for comments from efficacy is performed below:

Table 9.8-3: 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 ~~Zuxion~~ Asset in pome fruits (worst case)

Intended use	Pome/stone fruits		
Chronic effects on earthworms			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
~~Zuxion~~ Asset	5.6	0.192	29.17

~~Zuxion*~~ Asset	1.1	0.028	39.29
Chronic effects on other soil macro- and mesofauna			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Acetamiprid 20 SG *(Folsomia candida)*	0.27	0.028	9.64
~~Zuxion~~ (*Folsomia candida*) Asset	1.39	0.192	7.24
~~Zuxion~~ Asset * (*Folsomia candida*) acetamiprid	0.28	0.028	10.00
Acetamiprid 20 SG (*Hypoaspis aculeifer*)	50.8	0.028	1814.29
~~Zuxion~~ (*Hypoaspis aculeifer*)	1000	0.192	5208.33
~~Zuxion~~ Asset * (*Hypoaspis aculeifer*) acetamiprid	204	0.028	7285.71

TER values shown in bold fall below the relevant trigger.
* Risk assessment based on an endpoint expressed as mg as/kg dw from ~~Zuxion~~ Asset ~~s~~tudy.

ZRMS comments:

The long-term risks of SHA5500A/~~Zuxion~~ Asset to earthworms and soil meso -and macro-organisms were assessed from toxicity exposure ratios between toxicity endpoints and maximum PEC_{soil}.

The relevant predicted environmental concentrations in soil **(PEC_{soil})** for risk assessments covering the proposed use pattern are taken from Part B Section 8 (Environmental Fate).

Safe use of **SHA5500A/~~Zuxion~~** Asset were confirmed based on TER_{LT} calculations for active substances, their metabolites and for formulation.

9.8.2.2 Higher-tier risk assessment

Not relevant.

9.8.3 Overall conclusions

The risk assessment for earthworms has been done. All the chronic TER values are much higher than the Annex VI long-term trigger value of 5, indicating that ~~Zuxion~~ Asset poses low chronic risk to earthworms when applied according to the proposed use rates.

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. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on soil microorganisms of ~~Zuxion~~ Asset 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 deviates from the results of the EU review process. Justifications are provided below.

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

Endpoint	Substance	Exposure System	Results	Reference
N-mineralisation	Acetamiprid 20G	28 d, aerobic	No statistically significant effects > ± 25% compared to control control when acetamiprid is applied at 0.2 Kg a.s./ha	EFSA Journal 2016;14(11):4610
N-mineralisation	Acetamprid 20% SG	28 d, aerobic	Nitrate formation rate 1.733 mg f.p./kg soil dw -2.4 %	KCP 10.5.1 Aneta Gierbuszewska, 2016, G/186/15
C-mineralisation	Acetamprid 20% SG	28 d, aerobic soil type	CO_2 formation 1.733 mg f.p./kg soil dw 2.6 %	KCP 10.5.2 Aneta Gierbuszewska, 2016, G/185/15

9.9.1.1 Justification for new endpoints

The EU agreed endpoints for Acetamiprid are used for the assessments and the endpoints for Zuxion are from the new studies.

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_{soil} 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).

Here, the assessment for the use pome fruit also covers the risk for the soil microorganisms for use

oilseed rape.

Table 9.9-2: Assessment of the risk for effects on soil micro-organisms due to the use of ~~Zuxion~~ Asset in pome fruits (worst case)

Intended use	Pome fruits		
N-mineralisation			
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**Risk acceptable?**
~~Zuxion~~ Asset	1.733 (at 28 d)	0.267	yes
C-mineralisation			
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**Risk acceptable?**
~~Zuxion Asset~~	1.733 (at 28 d)	0.267	yes

Applicant update-Nov 2020 (2x180 g f.p./ha , equivalent to 2x36 g a.s./ha):

Risk assessment for soil microorganisms considering the reduction of application rate for comments from efficacy is performed below:

Table 9.9-3: Assessment of the risk for effects on soil micro-organisms due to the use of Zuxion in pome fruits (worst case)

Intended use	Pome fruits		
N-mineralisation			
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**Risk acceptable?**
~~Zuxion~~ Asset	1.733 (at 28 d)	0.192	yes
C-mineralisation			
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**Risk acceptable?**
~~Zuxion~~ Asset	1.733 (at 28 d)	0.192	yes

9.9.3 Overall conclusions

The risk assessment for earthworms has been done. The risk to soil microbial processes from the proposed uses of Zuxion is considered to be acceptable when applied according to the proposed use rates.

ZRMS comments:

SHA5500A/~~Zuxion~~ Asset has no significant effect on soil micro-organisms at 0.267 mg a.s./kg dry soil. Based on it, can be concluded that **SHA5500A/~~Zuxion~~** Asset under field conditions, use at the proposed rates poses no unacceptable risk to non-target soil micro-organisms.

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 not been carried out with Acetamiprid. Effects on non-target terrestrial plants of ~~Zuxion~~ Asset were not evaluated as part of the EU assessment of Acetamiprid. New data submitted with this application are listed in Appendix 1 summarised in Appendix 2.

The selection of studies and endpoints for the risk assessment deviates from the results of the EU review process. Justifications are provided below.

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

Species	Substance	Exposure System	Results	Reference
Cucumber[1)], cabbage[2)], corn[2)], lettuce[2)], oat[2)], onion[2)], perennial ryegrass[2)], soybean[2)], tomato[2)], turnip[2)]	Acetamiprid 20G	Seedling emergence	[1)]ER_{50}> 650 g a.s./ha [2)]ER_{50} > 700 g a.s./ha	EFSA Journal 2016;14(11):4610
	Acetamiprid 20G	Vegetative vigour	[1)]ER_{50}>500 g a.s./ha [2)]ER_{50}>500 g a.s./ha	EFSA Journal 2016;14(11):4610
Helianthus annuus *Sinapis alba* *Pisum sativum* *Solanum lycopersicon* *Allium cepa* *Avena sativa*	~~Zuxion~~ Asset	14 d Seedling emergence	ER_{50} emergence > 500 g a.s./ha ER_{50} plant weight > 500 g a.s./ha ER_{50} plant height > 500 g a.s./ha	KCP 10.6.2-01 Aneta Gierbuszewska, 2016, G/190/15
Helianthus annuus *Sinapis alba* *Pisum sativum* *Solanum lycopersicon* *Allium cepa* *Avena sativa*	~~Zuxion~~ Asset	21 d Vegetative vigour	ER_{50} emergence > 500 g a.s./ha ER_{50} plant weight > 500 g a.s./ha ER_{50} plant height > 500 g a.s./ha	KCP 10.6.2-02 Aneta Gierbuszewska, 2016, G/191/15

m: monocotyledonous; d: dicotyledonous

9.10.1.1 Justification for new endpoints

As there is no EU agreed endpoints, new studies have been used to define new endpoints.

9.10.2 Risk assessment

Tier-1 risk assessment (based screening data)

Not relevant.

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

The risk assessment is based on the "Guidance Document on Terrestrial Ecotoxicology", (SAN-CO/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.

Table 9.10-2: Assessment of the risk for non-target plants due to the use of ~~Zuxion~~ Asset ~~–~~ in oilseed rape

Intended use	Oilseed rape			
Active substance/product	Acetamiprid			
Application rate (g a.s./ha)	1 x 40			
MAF	1			
Test species	**ER_{50} (g a.s./ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (g a.s./ha)**	**TER criterion: TER ≥ 5**
Helianthus annuus *Sinapis alba* *Pisum sativum* *Solanum lycopersicon* *Allium cepa* *Avena sativa*	>500	2.77	1.108	>451

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

Table 9.10-3: Assessment of the risk for non-target plants due to the use of ~~Zuxion~~ Asset ~~–~~ in pome fruits

Intended use	Pome fruits			
Active substance/product	Acetamiprid			
Application rate (g a.s./ha)	2 x 50			
MAF	1.7			
Test species	**ER_{50} (g a.s./ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (g a.s./ha)**	**TER criterion: TER ≥ 5**
Helianthus annuus *Sinapis alba* *Pisum sativum* *Solanum lycopersicon* *Allium cepa* *Avena sativa*	>500	25.53	21.70	>23

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

Applicant update-Nov 2020 (2x180 g f.p./ha , equivalent to 2x36 g a.s./ha):

Risk assessment for non-target plants considering the reduction of application rate for comments from efficacy is performed below:

Table 9.10-4: Assessment of the risk for non-target plants due to the use of ~~Zuxion~~ Asset in pome fruits

Intended use	Pome fruits, BBCH>69			
Active substance/product	Acetamiprid			
Application rate (g a.s./ha)	2 x 36			
MAF	~~1.7~~ 1			
Test species	**ER_{50} (g a.s./ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (g a.s./ha)**	**TER criterion: TER ≥ 5**
Helianthus annuus *Sinapis alba* *Pisum sativum* *Solanum lycopersicon* *Allium cepa* *Avena sativa*	>500	~~25.53~~ 15.73	~~15.62~~ 5.66	>32 88.34

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

ZRMS comments:

The risk assessment is based on the "Guidance Document on Terrestrial Ecotoxicology", (SANCO/10329/2002 rev.2 final, 2002).

Based on the risk assessment it can be concluded that the proposed use of 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 **SHA5500A/~~Zuxion~~ Asset**–applications are not required for the protection of terrestrial non-target plants.

9.10.2.3 Higher-tier risk assessment

Not relevant.

Risk mitigation measures

No risk mitigation needed.

9.10.3 Overall conclusions

The risk assessment for non-target plants has been done. The risk to non-target plants for ~~Zuxion~~ Asset is considered to be acceptable when applied according to the proposed use rates.

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

Not relevant.

9.12 Monitoring data (KCP 10.8)

Not relevant.

9.13 Classification and Labelling

	Acetamiprid 20% SG
Common Name	~~Zuxion~~ Asset
Classification and proposed labelling	
With regard to ecotoxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	Hazard classes (s), categories: Aquatic Acute 1 Code(s) for hazard pictogram(s): GHS09 Signal word: Warning Hazard statement(s): H410: Very toxic to aquatic life **with long lasting effects** Precautionary statement~~: P273~~, P391, P501

ZRMS comments:

We agree with the proposed classification and labelling for **SHA5500A/Zaxion.**
Acute 1, H400, Chronic 1, H410
Hazard statement(s): H410: Very toxic to aquatic life with long lasting effects

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 10.2.1-01	xxx	2017	Acetamiprid 20% SG Rainbow trout Acute toxicity test xxx, W/12/17 GLP Unpublished	Y	Sharda Cropchem Limited
KCP 10.2.1-02	xxx	2017	Acetamiprid 20% SG *Daphnia magna*, acute immobilization test xxx, W/14/17 GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.2.1-03	xxx	2017	Acetamiprid 20% SG *Pseudokirchneriella subcapitata* SAG 61.81 Growth inhibition test xxx, W/13/17 GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.2.1-04	xxx,	2017	Acetamiprid 20% SG. *Lemna gibba* CPCC 310, Growth inhibition test xxx, W/15/17 GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.2.1-05	Angayarkanni, V.	2018	Acute Immobilization Effect of Acetamiprid 20% SG on *Chironomus riparius* BIOSCIENCE RESEARCH FOUNDATION, Study nº 4343/2018 GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.3.1.1.1	Elzbieta Kulec-Ploszczyca	2016	Acetamiprid 20% SG, Honeybees (*Apis mellifera* L.), Acute Oral Toxicity Test Institute of Industrial Organic Chemistry, B/100/15 GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.3.1.1.2	Elzbieta Kulec-Ploszczyca	2016	Acetamiprid 20% SG, Honeybees (*Apis mellifera* L.), Acute Contact Toxicity Test Institute of Industrial Organic Chemistry, B/101/15 GLP Unpublished	N	Sharda Cropchem Limited

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 10.3.1.2	Gimeno, I.	2019	Acetamiprid 20 % SG – Chronic Oral Toxicity Test (10-Day Feeding) to the Honey Bee, *Apis mellifera* L. under Laboratory Conditions Trialcamp S.L.U, TRC17-065BA GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.3.1.3	Gimeno, I.	2019	Acetamiprid Technical – Honey Bee (*Apis mellifera* L.) Larval Toxicity Test following Repeated Exposure under laboratory conditions Trialcamp S.L.U, S18-05066 GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.3.2.2-01	Elzbieta Kulec-Ploszczyca	2016	An extended laboratory test for evaluating the effects of Acetamiprid 20% SG on the predatory mite, *Typhlodromus pyri* (Sch.) Institute of Industrial Organic Chemistry, B/98/15 GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.3.2.2-02	Elzbieta Kulec-Ploszczyca	2016	An extended laboratory test for evaluating the effects of Acetamiprid 20% SG on the parasitic wasp, *Aphidius rhopalosiphi* (De Stefani - Perez) Institute of Industrial Organic Chemistry, B/99/15 GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.3.2.2-03	Luna, F.	2018	Aged residue test with the formulation “Acetamiprid 20 % SG” on the predatory mite *Typhlodromus pyri* (Acari: Phytoseiidae) Trialcamp S.L.U, TRC17-087BA GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.3.2.2-04	Varela, S.	2017	Aged residue test with the formulation “Acetamiprid 20% SG” on the parasitic wasp *Aphidius rhopalosiphi* (Hymenoptera: Braconidae) Trialcamp S.L.U, TRC17-086BA GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.3.2.2-05	Luna, F.	2018	Aged residue test with the formulation “Acetamiprid 20% SG” on *Chrysoperla carnea* (Neuroptera: Chrysopidae) Trialcamp S.L.U, TRC17-088BA GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.3.2.2-06	Luna, F.	2018	Aged residue test with the formulation “Acetamiprid 20% SG” on *Coccinella septempunctata* L. (Coleoptera: Coccinellidae) Trialcamp S.L.U, TRC17-089BA GLP Unpublished	N	Sharda Cropchem Limited

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 10.4.1.1	Aneta Gierbuszewska	2017	ACETAMIPRID 20% SG Earthworm Reproduction Test *(Eisenia fetida)* Institute of Industrial Organic Chemistry, G/187/15 GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.4.2.1-01	Angayarkanni, V.	2019	Effect of Acetamiprid 20% SG on the reproduction of the collembolans (*Folsomia candida*) in artificial soil 4344/2018 GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.4.2.1-02	Josep Lozano Garcia	2017	ACETAMIPRID 20% SG Effects on the Reproductive Output of the Predatory Soil Mite *Hypoaspis (Geolaelaps) aculeifer* Canestrini (Acari: Laelapidae) in Artificial Soil Trialcamp S.L.U, TRC17-096BA GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.5.1	Aneta Gierbuszewska	2016	ACETAMIPRID 20% SG Soil Microorganisms: Nitrogen Transformation Test Institute of Industrial Organic Chemistry, G/186/15 GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.5.2	Aneta Gierbuszewska	2016	ACETAMIPRID 20% SG Soil Microorganisms: Carbon Transformation Test Institute of Industrial Organic Chemistry, G/185/15 GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.6.2-01	Aneta Gierbuszewska	2016	ACETAMIPRID 20% SG Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test Institute of Industrial Organic Chemistry, G/190/15 GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.6.2-02	Aneta Gierbuszewska	2016	ACETAMIPRID 20% SG Terrestrial Plant Test: Vegetative Vigour Test Institute of Industrial Organic Chemistry, G/191/15 GLP Unpublished	N	Sharda Cropchem Limited

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

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

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

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

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

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

Appendix 2 Detailed evaluation of the 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 new data submitted.

A 2.1.1.2 KCP 10.1.1.2 Higher tier data on birds

No new data submitted.

A 2.1.2 KCP 10.1.2 Effects on terrestrial vertebrates other than birds

A 2.1.2.1 KCP 10.1.2.1 Acute oral toxicity to mammals

No new data submitted.

A 2.1.2.2 KCP 10.1.2.2 Higher tier data on mammals

No new data submitted.

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

No new data submitted.

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

Comments of zRMS:

The study is considered acceptable. All validity criteria were met.

- In the control, the mortality of fish should not exceed 10 per cent (or one fish if less than ten fish are used). The mortality of fish in the control was 0%.
- The dissolved oxygen concentration should be higher than 60 per cent of air saturation value-

throughout exposure.

The dissolved oxygen concentration was in the range of 92 – 99% of air saturation value.

At exposure initiation the determined concentration of acetamiprid was in the range of 95.63 – 98.58% of the nominal concentration. At exposure termination the determined concentration of acetamiprid was in the range of 95.51 – 99.69% of the nominal concentration.

Agreed endpoint:

96 h LC_{50} =46.67 mg product/L (nom.)

KCP 10.2.1-01

Acetamiprid 20% SG, Rainbow trout Acute toxicity test, 2017, W/12/17

OECD Guideline for the Testing of Chemicals No. 203 (1992)

No

Yes

Yes

Materials and methods

Test item: Acetamiprid 20% SG, the content of active ingredient: 20.3% w/w, manufacturing date: 15 February 2015, expiry date: 15 January 2019, batch No.: SWEPL-10035.
Test organism: Rainbow trout (Oncorhynchus mykiss), age: approximately 5 months**,** average weight: 1.03 g ± 0.11 g, average body length: 4.4 cm ± 0.30 cm,supplier: The culture of the salmonidae fish in xxx).
Test design: Static system (96 hours), one replicate of seven fish for each test item concentration and the control, fish loading: 0.72 g/L.
Nominal test item concentrations: 100, 50, 25, 12.5, 6.25 mg/L plus the control.
Nominal concentration of acetamiprid in the test item: 20.300, 10.150, 5.075, 2.538, 1.269 mg/L plus the control.
Test conditions: Temperature: 14.1 – 14.5oC; pH of the control: 7.23 – 7.57; oxygen concentration in the control: 96 – 98% of the air saturation value; dailycycle: 16 h day : 8 h night, no feeding, constant aeration.
Endpoint values: LC50, LOEC, and NOEC.

Results and discussions

In the definitive test the rainbow trout were exposed to the test item concentrations of 100, 50, 25,12.5, 6.25 mg/L plus the control for 96 h in a static test design.
The temperature was in a range of 14.1 – 14.5°C. Therefore, the temperature variationwas up to 0.4°C during the 96 hours of exposure.
The pH values measured during exposure were in the range of 7.22 – 7.63. The dissolvedoxygen concentration was in the range of 92 – 99% of air saturation value.
During exposure observations for mortality and for symptoms of intoxication were conducted after 3, 6, 24, 48, 72 and 96 h of exposure.
During exposure no mortality of fish and no symptoms of intoxication were observed in the controland in test item concentrations of 6.25 and 12.5 mg/L.

In the test item concentration of 25 mg/L after 72 h of exposure loss of equilibrium, non-typicalpigmentation for one fish and unbalanced swimming, respiratory problems for three fish were reported. After 96 h of exposure two fish were dead, unbalanced swimming for one fish, respiratoryproblems for two fish were observed.
In the test item concentration of 50 mg/L after 6 h of exposure unbalanced swimming for one fish andnon-typical pigmentation for three fish were reported. After 24 h and 48 h of exposure unbalancedswimming, respiratory problems for one fish and non-typical pigmentation for seven fish wereobserved. After 72 h of exposure loss of equilibrium, unbalanced swimming for one fish, respiratoryproblems for two fish, non-typical pigmentation for seven fish were observed. After 96 h of exposuretwo fish were dead, unbalanced swimming, respiratory problems for two fish, non-typicalpigmentation for five were observed.
In the test item concentration of 100 mg/L after 6 h of exposure unbalanced swimming for two fish,respiratory problems for five fish, non-typical pigmentation for seven fish were reported. After 24 h ofexposure unbalanced swimming for two fish, respiratory problems and non-typical pigmentation forseven fish were observed. After 48 h of exposure loss of equilibrium for one fish, unbalancedswimming for two fish, respiratory problems and non-typical pigmentation for seven fish werereported. After 72 h of exposure two fish were dead, unbalanced swimming for one fish, respiratoryproblems and non-typical pigmentation for five fish were observed. After 96 h of exposure all fishwere dead.

Results of the chemical determinations

The concentrations of acetamiprid were chemically determined using a validated liquidchromatographic method with DAD detection [SOP/C/61]. Samples of each test item concentrationand the control collected at exposure initiation and at exposure termination were chemicallyanalyzed.
At exposure initiation the determined concentration of acetamiprid was in the range of 95.63 –98.58% of the nominal concentration. The results confirm that the test item concentrations wereprepared correctly.
At exposure termination the determined concentration of acetamiprid was in the range of 95.51 –99.69% of the nominal concentration. Therefore, the concentration of acetamiprid was stable undertest conditions.

Endpoint values

The endpoint values were determined based on the nominal test item concentrations and nominalconcentration of acetamiprid in the test item [1]. The LC50 values were calculated with a probitmethod. 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 conductstatistical analysis, the ToxRat Professional commercial software was used.
The endpoint values determined based on the nominal test item concentrations:
The median concentration causing 50% mortality of rainbow trout after 96 hours of exposure
LC50/96 h value is 46.67 mg/L (95% confidence interval 30.63 – 75.68).
The STUDENT-t test for Homogeneous Variances with Bonferroni-Holm Adjustment performed with
data for mortality at 96 h showed a significant difference between the test item concentrations of 25,50, 100 mg/L compared with the control. Therefore, the LOEC/96 h value is 25 mg/L, the NOEC/96 hvalue is 12.5 mg/L.
The endpoint values determined based on the nominal concentrations of acetamiprid in the test item:
The median concentration causing 50% mortality of rainbow trout after 96 hours of exposureLC50/96 h value is 9.474 mg/L (95% confidence interval 6.219 – 15.363).
The STUDENT-t test for Homogeneous Variances with Bonferroni-Holm Adjustment performed withdata for mortality at 96 h showed a significant difference between the test item concentrations of5.075, 10.150, 20.300 mg/L compared with the control. Therefore, the LOEC/96 h value is5.075 mg/L, the NOEC/96 h value is 2.538 mg/L.

Table: Endpoint values based on the nominal test item concentrations and mortality of fish definitive test

Endpoint value Time of exposure [mg/L]	Time of exposure			
	24 h	**48 h**	**72 h**	**96 h**
LC50	n.d.	n.d.	> 100	46.67 (30.63 – 75.68)
NOEC	≥ 100	≥ 100	50*	12.5*
LOEC	> 100	> 100	100	25*

(–) 95% confidence interval
n.d. – not determined
* STUDENT-t test for Homogeneous Variances with Bonferroni-Holm Adjustment

Table: Endpoint values based on the nominal concentrations of acetamiprid in the test item– definitive test

Endpoint value Time of exposure [mg/L]	Time of exposure			
	24 h	**48 h**	**72 h**	**96 h**
LC50	n.d.	n.d.	>20.300	9.474 (6.219 – 15.363)
NOEC	≥20.300	≥20.300	10.150*	2.538*
LOEC	>20.300	>20.300	20.300	5.075*

(–) 95% confidence interval
n.d. – not determined
* STUDENT-t test for Homogeneous Variances with Bonferroni-Holm Adjustment

Conclusion

The endpoint values based on the mortality of rainbow trout after 96 hours of exposure to the nominal test item concentrations in a static design:
The LC50/96 h is 46.67 mg/L (30.63 – 75.68).
The NOEC/96 h is 12.5 mg/L.
The LOEC/96 h is 25 mg/L.

The endpoint values determined based on the nominal concentrations of acetamiprid in the test item and mortality of fish:
The LC50/96 h is 9.474 mg/L (6.219 – 15.363).
The NOEC/96 h is 2.538 mg/L.
The LOEC/96 h is 5.075 mg/L.

Comments of zRMS:

The study is considered acceptable. All validity criteria were met.

- The immobilization 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 9.1 – 9.8 mg/L (criterion: not less than 3 mg/L).

At exposure initiation the determined concentration of acetamiprid was in the range of 94.16 – 98.74% of the nominal concentration. At exposure termination the determined concentration of acetamiprid was in therange of 90.77 – 98.88% of the nominal concentration.

Agreed endpoints:

Endpoint values based on nominal test item concentrations.

Endpoint value [mg/L]	Time of exposure	
	24 h	48 h
EC50	193.54 (154.22 – 245.48)	69.18 (n.d.)
EC20	113.82 (79.49 – 143.90)	62.50 (n.d.)
EC10	86.24 (53.95 – 113.42)	59.27 (n.d.)
LOEC	125	62.5
NOEC	62.5	31.25

(-) the 95% confidence interval
n.d. – not determined

Endpoint values based on the nominal concentrations of acetamiprid in the test item.

Endpoint value [mg/L]	Time of exposure	
	24 h	48 h
EC50	39.288 (31.307 – 49.833)	14.075 (n.d.)
EC20	23.106 (16.137 – 29.213)	12.688 (n.d.)
EC10	17.507 (10.952 – 23.025)	12.018 (n.d.)
LOEC	25.375	12.688
NOEC	12.688	6.344

(-) the 95% confidence interval
n.d. – not determined

Reference: KCP 10.2.1-02

Report Acetamiprid 20% SG, Daphnia magna, acute immobilization test, 2017, W/14/17

Guideline(s): OECD Guideline for the Testing of Chemicals No. 202 (2004)

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods

Test item: Acetamiprid 20% SG, the content of active ingredient: 20.3% w/w, manufacturing date: 15 February 2015, expiry date: 15 January 2019, batch No.: SWEPL-10035.
Test organism:*Daphnia magna* Straus (< 24 h old at exposure initiation); not first brood progeny; neonates collected from a laboratory culture cultivated at the Institute of Industrial Organic Chemistry, Branch Pszczyna, Department of Ecotoxicology, Laboratory of Aquatic Toxicology.
Test design: Static test (exposure: 48 h); four replicates per treatment, five *Daphnia magna* in each replicate.
Nominal test item concentration: 500, 250, 125, 62.5 and 31.25 mg/L plus the control.
Nominal concentration of acetamiprid in the test item: 101.500, 50.750, 25.375, 12.688, 6.344 mg/L plus the control.
Test conditions: Temperature: 19.8 – 21.2ºC; pH of the control: 7.68 – 7.69; dissolved oxygen concentration in the control: 9.4 – 9.7 mg/L; daily cycle: 16 h light : 8 h dark; fluorescent light source; no feeding; no aeration. Chemical determinations: The concentration of acetamiprid was determined with validated liquid chromatographic method with DAD detection.
Statistics: Probit method calculations and analysis by Step-down Cochran-Armitage Test Procedure.
Endpoint values: EC50, NOEC and LOEC.

Results and discussions

The recorded temperature during exposure was in the range of 19.8 – 21.2ºC and constant within1.4ºC. The measured pH values at exposure initiation were in the range of 7.68 – 7.73 andat exposure termination were in the range of 7.69 – 7.77. The measured dissolved oxygenconcentrations at exposure initiation were in the range of 9.4 – 9.8 mg/L and at exposure terminationwere in the range of 9.1 – 9.4 mg/L.
In the control and in the test item concentration of 31.25 mg/L no immobilization of *Daphnia magna*was observed during exposure. At exposure termination in the test item concentrations of 62.5, 125,250 and 500 mg/L immobilization of *Daphnia magna* was 20, 100, 100, 100% respectively.

Results of the chemical determinations
The concentrations of acetamiprid were chemically determined using a validated liquidchromatographic method with DAD detection [SOP/C/61]. Samples of each test item concentrationand the control were collected at exposure initiation and at exposure termination.
At exposure initiation the determined concentration of acetamiprid was in the range of 94.16 –98.74% of the nominal concentration. The results confirm that the test item concentrations werepreprepared correctly. At exposure termination the determined concentration of acetamiprid was in therange of 90.77 – 98.88% of the nominal concentration. Therefore, the concentrations of acetamipridwere stable under test conditions.

Endpoint values
The endpoint values were determined based on the nominal test item concentrations and thenominal concentrations of acetamiprid in the test item.
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-analyzes. To make calculations and to conduct statistical analyzes, the ToxRat Professional commercial software was used.
The endpoint values determined based on the nominal test item concentrations:
The median concentration causing 50% immobilization of *Daphnia magna* after 24 h of exposure,i.e. the EC50/24 h value is 193.54 mg/L (95% confidence interval 154.22 – 245.48). The EC20/24 hvalue is 113.82 mg/L (95% confidence interval 79.49 – 143.90). The EC10/24 h value is 86.24 mg/L(95% confidence interval 53.95 – 113.42).
The median concentration causing 50% immobilization of *Daphnia magna* after 48 h of exposure,i.e. the EC50/48 h value is 69.18 mg/L. The EC20/48 h value is 62.50 mg/L. The EC10/48 h value is 59.27 mg/L.
The data on immobilization of the *Daphnia magna* at exposure termination were analyzed usingStep-down Cochran-Armitage Test Procedure. The test showed a significant difference between thetest item concentrations 500, 250, 125, 62.5 mg/L compared with the control. Therefore, the lowesttest item concentration causing immobilization (LOEC/48 h) is 62.50 mg/L. Therefore, the highesttest item concentration causing no immobilization (NOEC/48 h) is 31.25 mg/L. The endpoint valuesare presented in Table below.
The endpoint values determined based on the nominal concentrations of acetamiprid in the test item:
The median concentration causing 50% immobilization of *Daphnia magna* after 24 h of exposure,i.e. the EC50/24 h value is 39.288 mg/L (95% confidence interval 31.307 – 49.833). The EC20/24 hvalue is 23.106 mg/L (95% confidence interval 16.137 – 29.213). The EC10/24 h value is 17.507 mg/L(95% confidence interval 10.952 – 23.025).
The median concentration causing 50% immobilization of *Daphnia magna* after 48 h of exposure,i.e. the EC50/48 h value is 14.075 mg/L. The EC20/48 h value is 12.688 mg/L. The EC10/48 h value is12.018 mg/L.
The data on immobilization of the *Daphnia magna* at exposure termination were analyzed usingStep-down Cochran-Armitage Test Procedure. The test showed a significant difference between the nominal acetamiprid concentrations in the test item 101.5, 50.75, 25.375, 12.688 mg/L comparedwith the control. Therefore, the lowest nominal acetamiprid concentration in the test item causing immobilization (LOEC/48 h) is 12.688 mg/L. Therefore, the highest nominal acetamipridconcentration in the test item causing no immobilization (NOEC/48 h) is 6.344 mg/L. The endpointvalues are presented in Table below.

Table: Endpoint values based on nominal test item concentrations - definitive test

Endpoint value [mg/L]	Time of exposure	
	24 h	**48 h**
EC50	193.54 (154.22 – 245.48)	69.18 (n.d.)
EC20	113.82 (79.49 – 143.90)	62.50 (n.d.)
EC10	86.24 (53.95 – 113.42)	59.27 (n.d.)
LOEC	125	62.5
NOEC	62.5	31.25

(-) the 95% confidence interval
n.d. – not determined

Table: Endpoint values based on the nominal concentrations of acetamiprid in the test item - definitive test

Endpoint value [mg/L]	Time of exposure	
	24 h	**48 h**
EC50	39.288 (31.307 – 49.833)	14.075 (n.d.)
EC20	23.106 (16.137 – 29.213)	12.688 (n.d.)
EC10	17.507 (10.952 – 23.025)	12.018 (n.d.)
LOEC	25.375	12.688
NOEC	12.688	6.344

(-) the 95% confidence interval
n.d. – not determined

Conclusion

The endpoint values determined based on nominal test item concentrations:
The EC50/48 h is 69.18 mg/L.
The LOEC/48 h value is 62.5 mg/L.
The NOEC/48 h value is 31.25 mg/L.

The endpoint values based on the nominal concentrations of acetamiprid in the test item:
The EC50/48 h is 14.075 mg/L.
The LOEC/48 h value is 12.688 mg/L.
The NOEC/48 h value is 6.344 mg/L.

Comments of zRMS:

The study is considered acceptable. All validity criteria were met.

- The biomass in the control increased by a factor of 133.6 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 0.9%

(criterion: it must not exceed 7%).

- The mean coefficient of variation for the section-by-section growth rate in the control culture was 10.2% (criterion: it must not exceed 35%).

At exposure initiation the determined concentration of acetamiprid was in the range of 89.65 – 97.70% of the nominal concentration. At exposure termination the determined concentration of acetamiprid was in the range of 96.86 – 101.24% of the nominal concentration.

Agreed endpoints:

Endpoint values for growth rate based on the nominal test item concentrations.

Endpoint value [mg/L]	Time of exposure		
	24 h	**48 h**	**72 h**
ErC_{50}	470.87 (394.59 – 571.75)	470.17 (429.74 – 515.97)	677.92 (643.67 – 716.39)
ErC_{20}	186.19 (130.74 – 234.98)	211.04 (179.80 – 239.66)	218.06 (202.26 – 233.37)
ErC_{10}	114.64 (69.11 – 156.77)	138.84 (111.09 – 164.75)	120.52 (107.76 – 133.08)
LOEC	250	250	125
NOEC	125	125	62.5

(-) the 95% confidence interval

Endpoint values for yield based on the nominal test item concentrations.

Endpoint value [mg/L]	Time of exposure		
	24 h	**48 h**	**72 h**
EyC_{50}	283.83 (236.02 – 341.52)	245.49 (224.64 – 268.20)	172.87 (165.68 – 180.36)
EyC_{20}	141.14 (97.70 – 177.01)	161.21 (135.08 – 181.14)	104.20 (97.07 – 110.75)
EyC_{10}	97.96 (58.95 – 131.22)	129.40 (101.34 – 150.75)	79.98 (72.71 – 86.65)
LOEC	250	250	125
NOEC	125	125	62.5

(-) the 95% confidence interval

Endpoint values for growth rate based on the nominal concentrations of <u>acetamiprid</u> in the test item.

Endpoint value [mg/L]	Time of exposure		
	24 h	**48 h**	**72 h**
ErC_{50}	95.587 (80.103 – 116.066)	95.445 (87.237 – 104.742)	137.619 (130.665 – 145.430)
ErC_{20}	37.797 (26.541 – 47.701)	42.841 (36.499 – 48.651)	42.841 (36.499 – 48.651)
ErC_{10}	23.272 (14.030 – 31.825)	28.184 (22.551 – 33.444)	24.465 (21.874 – 27.014)
LOEC	50.750	50.750	25.375
NOEC	25.375	25.375	12.688

(-) the 95% confidence interval

Reference: KCP 10.2.1-03

Report Acetamiprid 20% SG, *Pseudokirchneriella subcapitata* SAG 61.81 Growth inhibition test, 2017, W/13/17

Guideline(s): OECD Guideline for the Testing of Chemicals No. 201 (2006)

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods

Test item: Acetamiprid 20% SG, the content of active ingredient: 20.3% w/w, manufacturing date: 15 February 2015, expiry date: 15 January 2019, batch No.: SWEPL-10035.
Test organism: The unicellular freshwater green algae, *Pseudokirchneriella subcapitata* (Reinsch) Korshikov (syn. *Raphidocelis subcapitata*, *Selenastrum capricornutum* Prinz) SAG 61.81 cultivated at the xxx. The algae were obtained from theCulture Collection of Algae at Göttingen University, Germany.
Test design: 72 hours of exposure; three replicates of each test item concentration and six replicates of the control; initial algal cell density: 1 x 104 cells/mL.
Nominal test item concentrations: 1000, 500, 250, 125, 62.5 mg/L plus the control.
Nominal concentration of acetamiprid in the test item: 203, 101.5, 50.75, 25.375, 12.688 mg/L plus the control.
Test conditions: Temperature: 21.9 – 22.4ºC; pH of the control: 7.51 – 7.92; mean light intensity: 6555 – 6640 lux; constant illumination and shaking; the AAP medium.
Chemical determinations: The concentration of acetamiprid was determined with validated liquid chromatographic method with DAD detection. Statistics: Probit method calculations and analysis by Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Williams Multiple Sequential t-test Procedure.
Endpoint values: ErC50, EyC50, LOEC and NOEC.

Results and discussions

In the definitive test, the algae, *Pseudokirchneriella subcapitata,* with an initial cell density of 1 x 104 cells/mL were exposed to the test item concentrations: 1000, 500, 250, 125 and 62.5 mg/L (with a separation factor of 2.0) plus control.
The recorded temperature was in the range of 21.9 – 22.4ºC with a variation of up to 0.5ºC. This is compliant with the allowed variation during exposure of ± 2.0ºC. The mean light intensity was in the range of 6555 – 6640 lux.
The pH values measured at exposure initiation were in the range of 7.51 – 7.67 and at exposure termination were in the range 7.92 – 8.12.
In the test item concentrations of 62.5, 125 mg/L no differences in shape, size and colour of algae cells were reported as compared to the algae cells in the control. In the test item concentration of 250 mg/L swollen cells were observed as compared to the algae cells in the control. In the test item concentrations 500 and 1000 mg/L deformed cells were reported as compared to the algae cells in the control.
The average specific growth rates and yield were calculated based on the numbers of cells counted at 24, 48 and 72 h of exposure.

Results of the chemical determinations
The concentrations of acetamiprid were chemically determined using a validated liquid chromatographic method with DAD detection. Samples of each test item concentration and the control were collected at exposure initiation and at exposure termination.
At exposure initiation the determined concentration of acetamiprid was in the range of 89.65 – 97.70% of the nominal concentration. The results confirm that the test item concentrations were prepared correctly. At exposure termination the determined concentration of acetamiprid was in the range of 96.86 – 101.24% of the nominal concentration. Therefore, the concentrations of acetamiprid were stable under test conditions.

Endpoint values
The endpoint values were determined on the basis of the nominal test item concentrations and the

nominal concentrations of acetamiprid in the test item. The ErCx and the EyCx values were calculated with the probit method. The lowest observed effect concentration (LOEC) and the no observed effect concentration (NOEC) were estimated on the basis of the results of statistical analyses. To make calculations and to conduct statistical analyses, the ToxRat Professional commercial software was used. The results are given in Tables below.

The endpoint values determined based on the nominal test item concentrations:

The concentration causing a 50% inhibition of the average specific growth rate of *Pseudokirchneriella subcapitata*, i.e. the ErC50/72 h value is 677.92 mg/L (95% confidence interval: 643.67 – 716.39). The ErC20/72 h value is 218.06 mg/L (95% confidence interval: 202.26 – 233.37). The ErC10/72 h value is 120.52 mg/L (95% confidence interval: 107.76 – 133.08).

Statistical tests based on the growth rate data were Shapiro-Wilk's Test on Normal Distribution which confirmed normal distribution of the data, Levene's Test on Variance Homogeneity (with Residuals) showed that the variances were homogeneous and Williams Multiple Sequential t-test Procedure showed significant difference between the nominal test item concentrations in the range of 125 – 1000 mg/L compared with the control. Therefore, the lowest observed effect concentration, i.e. the LOEC/72 h is 125 mg/L and the no observed effect concentration, i.e. the NOEC/72 h is 62.5 mg/L.

The concentration causing a 50% inhibition of yield of *Pseudokirchneriella subcapitata*, i.e. the EyC50/72 h value is 172.87 mg/L (95% confidence interval: 165.68 – 180.36). The EyC20/72 h value is 104.20 mg/L (95% confidence interval: 97.07 – 110.75). The EyC10/72 h value is 79.98 mg/L (95% confidence interval: 72.71 – 86.65).

Statistical tests based on the yield data were Shapiro-Wilk's Test on Normal Distribution which confirmed normal distribution of the data, Levene's Test on Variance Homogeneity (with Residuals) showed that the variances were homogeneous and Williams Multiple Sequential t-test Procedure showed significant difference between the nominal test item concentrations in the range of 125 – 1000 mg/L compared with the control. Therefore, the lowest observed effect concentration, i.e. the LOEC/72 h is 125 mg/L and the no observed effect concentration, i.e. the NOEC/72 h is 62.5 mg/L.

The endpoint values determined based on the nominal concentrations of acetamiprid in the test item:

The concentration causing a 50% inhibition of the average specific growth rate of *Pseudokirchneriella subcapitata*, i.e. the ErC50/72 h value is 137.619 mg/L (95% confidence interval: 130.665 – 145.430). The ErC20/72 h value is 44.265 mg/L (95% confidence interval: 41.058 – 47.374). The ErC10/72 h value is 24.465 mg/L (95% confidence interval: 21.874 – 27.014).

Statistical tests based on the growth rate data were Shapiro-Wilk's Test on Normal Distribution which confirmed normal distribution of the data, Levene's Test on Variance Homogeneity (with Residuals) showed that the variances were homogeneous and Williams Multiple Sequential t-test Procedure showed significant difference between the nominal concentrations of acetamiprid in the range of 25.375 – 203 mg/L compared with the control. Therefore, the lowest observed effect concentration, i.e. the LOEC/72 h is 25.375 mg/L and the no observed effect concentration, i.e. the NOEC/72 h is 12.688 mg/L.

The concentration causing a 50% inhibition of yield of *Pseudokirchneriella subcapitata*, i.e. the EyC50/72 h value is 35.092 mg/L (95% confidence interval: 33.634 – 36.613). The EyC20/72 h value is 21.154 mg/L (95% confidence interval: 19.707 – 22.482). The EyC10/72 h value is 16.236 mg/L (95% confidence interval: 14.761 – 17.591).

Statistical tests based on the yield data were Shapiro-Wilk's Test on Normal Distribution which confirmed normal distribution of the data, Levene's Test on Variance Homogeneity (with Residuals) showed that the variances were homogeneous and Williams Multiple Sequential t-test Procedure showed significant difference between the nominal concentrations of acetamiprid in the range of 25.375 - 203 mg/L compared with the control. Therefore, the lowest observed effect concentration, i.e. the LOEC/72 h is 25.375 mg/L and the no observed effect concentration, i.e. the NOEC/72 h is 12.688 mg/L.

Table: Endpoint values for growth rate based on the nominal test item concentrations, definitive test

Endpoint value [mg/L]	Time of exposure		
	24 h	**48 h**	**72 h**
ErC50	470.87 (394.59 – 571.75)	470.17 (429.74 – 515.97)	677.92 (643.67 – 716.39)
ErC20	186.19 (130.74 – 234.98)	211.04 (179.80 – 239.66)	218.06 (202.26 – 233.37)
ErC10	114.64 (69.11 – 156.77)	138.84 (111.09 – 164.75)	120.52 (107.76 – 133.08)
LOEC	250	250	125
NOEC	125	125	62.5

(-) the 95% confidence interval

Table: Endpoint values for yield based on the nominal test item concentrations, definitive test

Endpoint value [mg/L]	Time of exposure		
	24 h	**48 h**	**72 h**
EyC50	283.83 (236.02 – 341.52)	245.49 (224.64 – 268.20)	172.87 (165.68 – 180.36)
EyC20	141.14 (97.70 – 177.01)	161.21 (135.08 – 181.14)	104.20 (97.07 – 110.75)
EyC10	97.96 (58.95 – 131.22)	129.40 (101.34 – 150.75)	79.98 (72.71 – 86.65)
LOEC	250	250	125
NOEC	125	125	62.5

(-) the 95% confidence interval

Table: Endpoint values for growth rate based on the nominal concentrations of acetamiprid in the test item, definitive test

Endpoint value [mg/L]	Time of exposure		
	24 h	**48 h**	**72 h**
ErC50	95.587 (80.103 – 116.066)	95.445 (87.237 – 104.742)	137.619 (130.665 – 145.430)
ErC20	37.797 (26.541 – 47.701)	42.841 (36.499 – 48.651)	42.841 (36.499 – 48.651)
ErC10	23.272 (14.030 – 31.825)	28.184 (22.551 – 33.444)	24.465 (21.874 – 27.014)
LOEC	50.750	50.750	25.375
NOEC	25.375	25.375	12.688

(-) the 95% confidence interval

Table: Endpoint values for yield based on the nominal concentrations of acetamiprid in the test item, definitive test

Endpoint value [mg/L]	Time of exposure		
	24 h	**48 h**	**72 h**
EyC50	57.618 (47.913 – 69.328)	49.835 (45.601 – 54.444)	35.092 (33.634 – 36.613)
EyC20	28.651 (19.834 – 35.933)	32.724 (27.421 – 36.768)	21.154 (19.707 – 22.482)
EyC10	19.886 (11.968 – 26.638)	26.266 (20.572 – 30.598)	16.236 (14.761 – 17.591)
LOEC	50.750	50.750	25.375
NOEC	25.375	25.375	12.688

(-) the 95% confidence interval

Conclusion

The endpoint values based on the nominal test item concentrations:
The concentration causing a 50% inhibition of the growth rate of *Pseudokirchneriella subcapitata*, i.e. the ErC50/72 h value is 677.92 mg/L (95% confidence interval: 643.67 – 716.39).
The concentration causing a 50% inhibition of yield of *Pseudokirchneriella subcapitata*, i.e. the EyC50/72 h value is 172.87 mg/L (95% confidence interval: 165.68 – 180.36).
The LOEC/72 h value for growth rate and yield is 125 mg/L.
The NOEC/72 h value for growth rate and yield is 62.5 mg/L.

The endpoint values based on the nominal concentrations of acetamiprid in the test item:
The concentration causing a 50% inhibition of the growth rate of *Pseudokirchneriella subcapitata*, i.e. the ErC50/72 h value is 137.619 mg/L (95% confidence interval: 130.665 – 145.430).
The concentration causing a 50% inhibition of yield of *Pseudokirchneriella subcapitata*, i.e. the EyC50/72 h value is 35.092 mg/L (95% confidence interval: 33.634 – 36.613).
The LOEC/72 h value for growth rate and yield is 25.375 mg/L.
The NOEC/72 h value for growth rate and yield is 12.688 mg/L.

Comments of zRMS:

The study is considered acceptable. All validity criteria were met.

- The doubling time of frond number in the control was 1.9 days, criterion: less than 2.5 days (thefactor of frond number in the control between 0 and 7 day was 12.6).
- The average specific growth rate in the control between day 0 and day 7 was 0.362 d-1 (minimum requirement: higher than 0.275 d-1).

In fresh samples the determined concentration of acetamiprid was in the range of 91.43 – 99.37% of the nominal concentration. In spent samples the determined concentration of acetamiprid was in the range of 86.60 – 102.95% of the nominal concentration.

Agreed endpoints:

The endpoint values based on the nominal test item concentrations			
Yield inhibition based on the frond number	**Growth rate inhibition based on the frond number**	**Yield inhibition based on the dry weight**	**Growth rate inhibition based on the dry weight**
175.87 (173.00 – 178.78)	330.02 (315.45 – 345.34)	262.21 (250.63 – 274.37)	> 1000
100.58 (97.97 – 103.12)	144.34 (133.88 – 154.45)	73.15 (67.18 – 79.08)	218.25 (194.04 – 242.07)
75.10 (72.51 – 77.63)	93.68 (84.58 – 102.56)	37.53 (33.33 – 41.80)	73.35 (58.85 – 88.06)
125	125	125	125
62.5	62.5	62.5	62.5

Reference: KCP 10.2.1-04

Report	"Acetamiprid 20% SG *Lemna gibba* CPCC 310, Growth inhibition test". xxx, 2017, W/15/17. xxxx
Guideline(s):	Yes (OECD 221)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test item:

Description:	Acetamiprid 20% SG
Batch number:	SWEPL-10035
A.i. content:	acetamiprid 20.3% w/w

Test system:

Species:	*Lemna gibba*CPCC 310 cultivated at the Institute of Industrial Organic Chemistry, Branch Pszczyna, Department of Ecotoxicology, Laboratory of Aquatic Toxicology
Strain:	-
Age:	-
Source:	Canadian Phycological Culture Center, Department of Biology, University of Waterloo, Canada.
Medium:	20X APP

Experimental conditions:

Temperature:	24.5 – 25.0 °C
pH values:	7.48 – 8.80
Mean light intensity:	7465-7778 lux, illumination constant
Test vessels:	glass crystallizer containing 150 mL of each treatment or control
Initial frond number:	9 (i.e. 3 plants consisting of 3 fronds each)

Experimental period: 7 days

Test design:

Semi-static (7 days); three replicates of each test item concentration; six replicates of the control.
The test item concentrations in definitive test were: 62.5, 125, 250, 500 and 1000 mg/L (12.688, 25.375, 50.75, 101.5, 203 mg a.s./L). The concentrations of acetamiprid was chemically determined with a validated liquid chromatographic method with DAD detection.
The first preliminary test (non GLP) was performed as a static test, the second preliminary test and definitive test were performed as semi-static test. In semi-static design, the test item concentrations and the control were renewed twice and the exposure was 7 days. Each replicate was inoculated with a total of 9 fronds.
The number of fronds in each replicate was counted. In the preliminary test the total number of fronds were counted on days 3 and 5 and at exposure

termination. In the definitive test were counted on days 2 and 4 and at exposure termination. Only visible distinct fronds were counted. At the same time observations of plant development were performed. Growth of plant cultures in the test item concentrations was compared with that in the control. The dry weight of the representative sample of the duckweed culture used as the inoculum was measured after exposure initiation and the dry weight of all plants from each test vessel was measured after exposure termination.
In the first preliminary test, the pH values were measured in each test item concentration and the control before division into replicates at exposure initiation as well as in each test item concentration and the control at exposure termination in pooled replicates. In the second and definitive test, the pH values of the fresh test item concentrations and the control were measured at the exposure initiation and at each renewal, i.e. before the division into replicates. The pH values of the old test item concentrations and the control were measured at each renewal and at the exposure termination (pooled replicates)

Statistics: Calculations were done with the probit method, whereas analysis were conducted with Shapiro-Wilk´s Test on nominal Distribution, the Levene´s Test on variance homogeneity (with Residuals), Williams Multiple Sequential t-test Procedure, Welch-test for Inhomogeneous Variances with Bonferroni-Holm Adjustment.

Results:

In the growth inhibition test on *Lemna gibba,* the endpoint values were determined on the basis of the nominal test item concentrations and the nominal concentrations of acetamiprid in the test item. Results are summarized in the table below:

	The endpoint values based on the nominal test item concentrations			
	Yield inhibition based on the frond number	**Growth rate inhibition based on the frond number**	**Yield inhibition based on the dry weight**	**Growth rate inhibition based on the dry weight**
EyC_{50}/7d/ ErC_{50}/7d (mg/l)	175.87 (173.00 – 178.78)	330.02 (315.45 – 345.34)	262.21 (250.63 – 274.37)	> 1000
EyC_{20}/7d/ ErC_{20}/7d (mg/l)	100.58 (97.97 – 103.12)	144.34 (133.88 – 154.45)	73.15 (67.18 – 79.08)	218.25 (194.04 – 242.07)
EyC_{10}/7d/ ErC_{10}/7d (mg/l)	75.10 (72.51 – 77.63)	93.68 (84.58 – 102.56)	37.53 (33.33 – 41.80)	73.35 (58.85 – 88.06)
LOEC/7d (mg/l)	125	125	125	125
NOEC/7d (mg/l)	62.5	62.5	62.5	62.5

	The endpoint values based on the nominal concentration of acetamiprid in the test item			
	Yield inhibition based on the frond number	**Growth rate inhibition based on the frond number**	**Yield inhibition based on the dry weight**	**Growth rate inhibition based on the dry weight**
EyC_{50}/7d/ ErC_{50}/7d (mg/l)	35.701 (35.119 – 36.293)	66.994 (64.037 – 70.103)	53.230 (50.877 – 55.697)	> 203.000
EyC_{20}/7d/ ErC_{20}/7d (mg/l)	20.417 (19.887 – 20.933)	29.301 (27.177 – 31.352)	14.850 (13.637 – 16.053)	44.305 (39.391 – 49.141)
EyC_{10}/7d/ ErC_{10}/7d (mg/l)	15.246 (14.719 – 15.759)	19.017 (17.169 – 20.819)	7.619 (6.765 – 8.485)	14.890 (11.947 – 17.876)
LOEC/7d (mg/l)	25.375	25.375	25.375	25.375
NOEC/7d (mg/l)	12.688	12.688	12.688	12.688

Comments of zRMS:

The study is considered acceptable. All validity criteria were met.

Agreed endpoints:

Value	As test item concentration	As active substance concentration
EC_{50} (mg/L)	0.105 (0.100 – 0.110)	0.021 (0.020 – 0.022)
LOEC (mg/L)	0.03	0.006
NOEC (mg/L)	0.01	0.003

Reference: KCP 10.2.1 - 05

Report: "Acute immobilization effect of Acetamiprid 20% SG on *Chironomus riparius*". V. Angayarkanni, 2018, 4343/2018

Guideline(s): OECD Guideline No. 235

Deviations: No

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study) No

Materials and methods

Test item:

Description: Acetamiprid 20% SG
Production batch: SCL - 56358
A.i. content: 20.2% w/w

Test system:

Species: *Chironomus riparius*
Strain: -

	Age:	1st Instar larvae
	Source:	Culture maintained at BFR
	Medium:	Elendt M4 (Exposure medium)
Experimental conditions:		
	Temperature:	Range finding: 20.6 – 20.9ºC Main study: 20.5 – 20.9ºC
	pH values:	Range finding: 7.5 – 7.7 Main study: 7.5 – 7.8
	Mean light intensity:	16h light and 8h dark Range finding: 697 – 772 lux Main study: 690 – 833 lux
	Test vessels:	Glass beakers containing the exposure medium
	Replication:	Four replication for range finding/main or definitive test
Experimental period:	48 h	

Test design: A range finding study was conducted using five test concentrations, 0.001, 0.01, 0.1, 10 and 100 mg a.i./L. Each concentration consists of four replicates and each replicate contains five *Chironomus* larvae. Based on the range finding results, the main study was conducted with 0.003, 0.006, 0.013, 0.028, 0.058 and 0.123 mg a.i./L. Each concentration consists of four replicates and each replicate contains five *Chironomus* larvae.
1st instar larvae of Chironomus riparius were collected in glass beakers containing the exposure medium. During the experiment period, feed was not provided, and test vessels were not aerated. The exposure medium and control were filled in the respective beaker. Five larvae were transferred with the help of Pasteur pipette, released into each labelled beaker and covered with glass lid/glass watch/parafilm.
The larvae were observed at 24 and 48 h for immobilization (if there is no movement up to 15 seconds, larvae are considered immobilised). The larvae were also observed for abnormal behaviour and unusual appearance by placing under light box.

Statistics: Probit method calculations with NCSS software 2000.

Results: In the range finding study, immobility at the 24 h observation was 0, 0, 10, 45, 85 and 100% at the control, 0.001, 0.01, 0.1, 10 and 100 mg a.i./L concentrations. Cumulative immobility at the end of 48 h was 0, 0, 35, 100, 100 and % at the same concentrations. *Chironomus* larvae in the control and 0.001 mg a.i./L appeared normal throughout the study period. Immobility at the various test concentration was concentration dependent.
In the main study, cumulative immobility at the end of 48 h observation was 0, 0, 5, 35, 55, 85 and 100% in the *Chironomus* larvae exposed to control, 0.003, 0.006, 0.013, 0.028, 0.058 and 0.123 mg a.i./L concentration. *Chironomus* larvae in the control and 0.003 mg a.i./L appeared normal throughout the study period. The highest concentration exhibited 100% immobility, whereas at the lowest concentration 0% immobility was observed at the end of observation period. Based on the immobility observed, results are summarized in the table below:

Value	As test item concentration	As active substance concentration
EC_{50} (mg/L)	0.105 (0.100 – 0.110)	0.021 (0.020 – 0.022)
LOEC	0.03	0.006

(mg/L)		
NOEC (mg/L)	0.01	0.003

Analytical verification

Stability analysis: The analytical results revealed that the exposed concentration of 100 mg/L and average detected concentration of acetamiprid 20% SG was 98.52% on 0-Hour, 98.65% on 48 Hour analysis, respectively.

Concentration verification analysis: The analytical results revealed that the exposed concentration concentrations (0.003, 0.006, 0.013, 0.028, 0.058 and 0.123 mg a.i./L) and average detected concentrations of Acetamiprid 20% SG were 99.95% for 0.003 mg a.i./L, 101.02% for 0.006 mg a.i./L, 100.48% for 0.013 mg a.i./L, 98.16% for 0.028 mg a.i./L, 99.87 for 0.058 mg a.i./L ad 101.42 for 0.123 mg a.i./L on 0 hour, and 98.83 for 0.003 mg a.i./L, 100.57% for 0.006 mg a.i./L, 101.35% for 0.013 mg a.i./L, 100.63% for 0.028 mg a.i./L, 100.20% for 0.058 mg a.i./L and 99.92 for 0.123 mg a.i./L on 48 hour analysis of Acute Toxicity Effect of Acetamiprid 20% SG on *Chironomus riparius*.

Concentration verification analysis (Potassium Chloride): The analytical results revealed that the exposed concentration (0.125 mg/L, 1.0 mg/L and 4.0 mg/L) and its average detected concentration was 99.54% for 0.125 mg/L, 100.54% for 1.0 mg/L and 98.03% for 4.0 mg/L in 0 hour and 99.54% for 0.125 mg/L, 98.58% for 1.0 mg/L and 100.47% for 4.0 mg/L in 48 hour for Acute Toxicity Effect of Acetamiprid 20% SG on *Chironomus riparius*.

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

No new data submitted.

A 2.2.3 KCP 10.2.3 Further testing on aquatic organisms

No new data submitted.

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 is considered acceptable. All validity criteria were met.

- The average mortality for the total number of controls was 0.0% at the end of the experiment (criterion: it must not exceed 10%)
- The 24-hour LD50 of the reference item (dimethoate) was 0.10 µg/bee (criterion: 0.10 - 0.35 µg a.i./bee).

Agreed endpoints:

48 h LD_{50} = 25.8 µg test item/bee
48 h LD_{50} = 5.28 µg a.i./bee

Reference:	KCP 10.3.1.1.1
Report	Acetamiprid 20% SG, Honeybees (*Apis mellifera* L.), Acute Oral Toxicity Test, 2016, B/100/15
Guideline(s):	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 20% SG; content: 20.5% (w/w) of Acetamiprid as an active ingredient; batch number: SWEPL-10035; manufacturing date: February 15, 2015; expiry date: February 14, 2017
Biological test system :	the honeybee, *Apis mellifera* L.; strain: carnica; source: an apiary at the Institute of Industrial Organic Chemistry, Branch Pszczyna [SOP/B/14]; age: approximately 3 weeks
Test design:	- test item: exposure time: 48 hours; number of doses: 5 doses and a control; number of replicates: 3 replicates containing 10 bees each - reference item: exposure time: 24 hours; number of doses: 3 doses; number of replicates: 3 replicates containing 10 bees each
Test doses:	5.0, 10.0, 20.0, 40.0 and 80.0 µg/bee and a control (0.0 µg/bee)
Reference item doses:	0.03, 0.06, and 0.12 µg a.i./bee
Test conditions:	temperature: 25-26 ºC; relative air humidity: 58-61%; place: a dark room
Endpoints:	- honeybee mortality after 48 hours of the exposure - the LD_{50} value of the test item after 24 and 48 hours - the 24-h LD_{50} value of the reference item (dimethoate)

Results

Dose		Number of tested bees [no.]	Mortality after 48 h		LD_{50} after 48 h	
			Total			
[µg test item/bee]	[µg a.i./bee]		[no.]	[%]	[µg test item/bee]	[µg a.i./bee]
0.0 (Control)		30	0	**0.0**	**25.8** (22.8 - 29.2) *	**5.28** (4.67 - 5.99) *
5.0	**1.0**	30	0	**0.0**		
10.0	**2.1**	30	1	**3.3**		
20.0	**4.1**	30	10	**33.3**		
40.0	**8.2**	30	28	**93.3**		
80.0	**16.4**	30	29	**96.7**		

*: the LD_{50} value with 95% confidence limits was calculated with the log-probit method (Rergres computer software)

Conclusion

Under the experimental conditions, the oral LD_{50} of Acetamiprid 20% SG to bees is 25.8 µg/bee.

A 2.3.1.1.2 KCP 10.3.1.1.2 Acute contact toxicity to bees

Comments of zRMS:

The study is considered acceptable. All validity criteria were met.

- The average mortality for the total number of controls was 0.0% after 96 h (criterion: it must not exceed 10%),
- The 24-hour LD_{50} of the reference item (dimethoate) was 0.27 µg/bee (criterion: 0.10 - 0.30 µg a.i./bee)

Agreed endpoints:

48 h LD_{50} = 130.5 µg test item/bee

48 h LD_{50} = 26.8 µg a.i./bee

Reference:	KCP 10.3.1.1.2
Report	Acetamiprid 20% SG, Honeybees (*Apis mellifera* L.), Acute Contact Toxicity Test, 2016, B/101/15
Guideline(s):	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 20% SG; content: 20.5% (w/w) of Acetamiprid as an active ingredient; batch number: SWEPL-10035; manufacturing date: February 15, 2015; expiry date: February 14, 2017
Biological test system :	the honeybee, *Apis mellifera* L.; strain: carnica; source: an apiary at the Institute of Industrial Organic Chemistry, Branch Pszczyna [SOP/B/14]; 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 containing 10 bees each - reference item: exposure time: 24 hours; number of doses: 3 doses; number of replicates: 3 replicates containing 10 bees each
Test doses:	12.5, 25.0, 50.0, 100.0, and 200.0 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: 25-26 ºC; relative air humidity: 60-62%; place: a dark room
Endpoints:	- honeybee mortality after 96 hours of the exposure - the LD_{50} value of the test item after 24, 48, 72 and 96 hours - the 24-h LD_{50} value of the reference item (dimethoate)

Results and discussions

Dose		**Number of tested bees [no.]**	**Mortality after 96 h**		**LD_{50} after 96 h**	
			Total			
[µg test item/bee]	**[µg a.i./bee]**		**[no.]**	**[%]**	**[µg test item/bee]**	**[µg a.i./bee]**
0.0 (Control)		30	0	**0.0**	**130.5** (69.9 – 243.5) *	**26.8** (14.3 – 49.9) *
12.5	2.6	30	0	**0.0**		
25.0	5.1	30	0	0.0		
50.0	10.3	30	0	0.0		
100.0	20.5	30	14	46.7		
200.0	41.0	30	28	93.3		

*: the LD_{50} value with 95% confidence limits was calculated with the log-probit method (Rergres computer software)

Conclusion

Under the experimental conditions, the contact LD_{50} of Acetamiprid 20% SG to bees is 130.5 µg/bee.

A 2.3.1.2 KCP 10.3.1.2. Chronic toxicity to bees

Comments of zRMS

The study is considered acceptable. All validity criteria were met.

- The mean mortality in the control was ≤ 15 % at the end of the test (actual 8.00 %).
- The mean mortality in the reference item group was ≥ 50 % at the end of the test (actual 100.00 %)

Agreed endpoints:

NOEC[1]	63.03 mg a.s./kg feeding solution
NOEDD[1]	1.30 µg a.s./bee/day
LC_{50} [95 % IC][2]	121.84 (108.22 – 137.39) mg a.s./kg feeding solution
LC_{20} [95 % IC][2]	83.34 (70.05 – 94.83) mg a.s./kg feeding solution
LC_{10} [95 % IC][2]	68.33 (54.79 – 79.58) mg a.s./kg feeding solution
LDD_{50} [95 % IC][2]	3.33 (2.78 – 4.11) µg a.s./bee/day
LDD_{20} [95 % IC][2]	1.84 (1.48 – 2.20) µg a.s./bee/day
LDD_{10} [95 % IC][2]	1.34 (1.02 – 1.65) µg a.s./bee/day

[1]Step-down Rao-Scott-Cochran-Armitage Test Procedure

Reference:	KCP 10.3.1.2
Report	"Acetamiprid 20 % SG – Chronic Oral Toxicity Test (10-Day Feeding) to the Honey Bee, *Apis mellifera* L. under Laboratory Conditions", Ignacio Gimeno, 2019, Study code TRC17-0656BA.
Guideline(s):	Yes, OECD 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).
Deviations:	Not applicable.
GLP:	Yes
Acceptability:	Yes

Materials and methods

The aim of the study was to determine the effects of the test item Acetamiprid 20% SG (Batch SCL-75263) on the honey bee *Apis mellifera* L. from chronic feeding exposure, the median Lethal Concentration (LC_{50}) and the median Lethal Dietary Dose (LDD_{50}) after 10 days of exposure, as well as the No Observed Effect Concentration and the No Observed Effect Dietary Dose (NOEC/NOEDD) were determined.

The test species was honey bee (*Apis mellifera* L.), young adult worker bees (not older than 48 hours) originating from commercial bee hives maintained by Trialcamp S.L.U..

The test was conducted as a dose-response test with an exposure phase duration of 10 days. One control group (negative control), five test item groups and a toxic reference item group were used. Five different concentrations of Acetamiprid 20% SG were applied to the bees in the test item groups, and one single concentration of the reference item was applied to the bees in the toxic reference group. The analyzed content of Acetamiprid was considered for calculation of the test item doses and dimethoate for the reference item dose. Control groups and treated groups were exposed concurrently to identical conditions.

The test concentrations were: 1 control group, 5 test item groups with 15.80, 31.51, 63.03, 126.05 and 252.10 mg a.s/kg diet, equivalent to 1.88, 3.75, 7.50, 15.00 and 30.00 µg a.s./bee/day; 1 reference item group with 0.107 µg dimethoate/bee/day. Five replicates of 10 bees each were used for each group. Mortality and behavioural abnormalities were assessed daily over the 10 days test period.

The test conditions were: Air temperature: Min / Max: 31.9 / 32.8 °C, Relative air humidity: Min / Max: 60.1 % / 75.3 % RH, Exposure to light: Constant darkness except during feeding and assessments.

The LDD_{50}/LC_{50}; LDD_{20}/LC_{20} and LDD_{10}/LC_{10} endpoints were calculated by a Probit analysis using linear max. likelihood regression. For the NOEDD/NOEC, values of mortality for each treatment group were compared to that of the control group using Step-down Cochran-Armitage Test Procedure.

Results and discussions

Table 2.3.1.1.2-1: Cumulative mortality, overall mean consumption of feeding solution, dietary dose (DD), accumulated mean uptake, NOEC, NOEDD, LC_{50} / LDD_{50}, LC_{20} / LDD_{20} and LC_{10} / LDD_{10}

Treatment	10-day cumulative mortaliy (corrected)[1]	Overall mean consumption of feeding solution	Dietary dose (based on actual measured consumption of feeding solution)	Mean accumulated uptake of test item during the test period
	[%]	[µL/bee/day]	[µg a.s./bee/day]	[µg a.s./bee]
Control				
C (0)	8.00 (-)	18.85	-	-
Reference item: dimethoate [µg a.s./bee]				
R (0.107)	100.00 (100.00)	22.71	0.02	0.22
Test item: Acetamiprid 20% SG [mg a.s./kg feeding solution]				
T1 (15.80)	6.00 (-2.17)	21.06	0.40	3.96
T2 (31.51)	4.00 (-4.35)	17.80	0.67	6.68
T3 (6303)	16.00 (8.70)	17.38	1.30	13.03
T4 (126.05)	54.00 (50.00)	20.12	3.02	30.17
T5 (252.10)	96.00 (95.65)	44.25	13.28	132.76
NOEC[1]	63.03 mg a.s./kg feeding solution			
NOEDD[1]	1.30 µg a.s./bee/day			
LC_{50} [95 % IC][2]	121.84 (108.22 – 137.39) mg a.s./kg feeding solution			
LC_{20} [95 % IC][2]	83.34 (70.05 – 94.83) mg a.s./kg feeding solution			
LC_{10} [95 % IC][2]	68.33 (54.79 – 79.58) mg a.s./kg feeding solution			
LDD_{50} [95 % IC][2]	3.33 (2.78 – 4.11) µg a.s./bee/day			
LDD_{20} [95 % IC][2]	1.84 (1.48 – 2.20) µg a.s./bee/day			
LDD_{10} [95 % IC][2]	1.34 (1.02 – 1.65) µg a.s./bee/day			

[1]Step-down Rao-Scott-Cochran-Armitage Test Procedure
[2]Probit analysis using linear max. likelihood regression.

Findings:

- The actual mean concentrations of acetamiprid in all test item feeding solutions were in the range from 94.2 to 101.5 % of the nominal concentrations; therefore results are based on nominal.
- In control group fed with pure 50 % (w/v) aqueous sucrose solution, 8.00% mortality was observed at the final assessment after 10 days.
- The maximum mortality which was observed in the highest test item treatment concentration, 252.10 mg a.s./kg feeding solution was 96.00 % after 10 days.
- At the concentrations of 15.80, 31.51, 63.03, 126.05 and 252.10 mg a.s./kg feeding solution 6.00, 4.00, 16.00, 54.00 and 96.00 % mortality (corrected mortality: - 2.17, -4.35, 8.70, 50.00 and 95.65 %) was observed.

- Bees were recorded as affected, apathetic and moribund in the test item treatment group at 31.51, 63.03, 126.05 and 252.10 mg a.i./kg feeding solution on different assessment days from day 1 until the end of the 10 day test period.
- The overall mean daily consumption of feeding solutions (i.e. the average consumption/bee over 10 days) in the test item concentrations of 15.80, 31.51, 63.03, 126.05 and 252.10 mg a.s./kg feeding solution was 21.06, 17.80, 17.38, 20.12 and 44.25 µL/bee/day, respectively. For the control group 18.85 µL/bee/day. The values of food consumption were corrected for evaporation.
- After 10 days of continuous exposure, the mean accumulated uptake of acetamiprid 20% SG at the test item concentrations of 15.80, 31.51, 63.03, 126.05 and 252.10 mg a.s./kg feeding solution was 3.96, 6.68, 13.03, 30.17 and 132.76 µg a.s./bee, respectively. The corresponding average daily dose (DD) was therefore 0.40, 0.67, 130, 3.02 and 13.28 µg a.s./bee/day.
- The NOEC for mortality after 10 days of continuous exposure was determined to be 63.03 mg a.s./kg feeding solution. The corresponding NOEDD, based on the actual consumption of the feeding solutions, was determined to be 1.30 µg a.s./bee/day.
- After 10 days of continuous exposure, the LC_{50} with 95 % confidence intervals was determined to be 121.84 [108.22 – 137.39] mg a.s./kg feeding solution. The corresponding LDD_{50} with 95 % confidence intervals, based on the actual consumption of the feeding solutions, was determined to be 3.33 [2.78 – 4.11] µg a.s./bee/day.
- After 10 days of continuous exposure, the LC_{20} with 95 % confidence intervals was determined to be 83.34 [70.05 – 94.83] mg a.s./kg feeding solution. The corresponding LDD_{20} with 95 % confidence intervals, based on the actual consumption of the feeding solutions, was determined to be 1.84 [1.48 – 2.20] µg a.s./bee/day.
- After 10 days of continuous exposure, the LC_{10} with 95 % confidence intervals was determined to be 68.33 [54.79 – 79.58] mg a.s./kg feeding solution. The corresponding LDD_{10} with 95 % confidence intervals, based on the actual consumption of the feeding solutions, was determined to be 1.34 [1.02 – 1.65] µg a.s./bee/day.

The following validity criteria were met during the test:

- The mean mortality in the control was ≤ 15 % at the end of the test (actual 8.00 %)
- The mean mortality in the reference item group was ≥50 % at the end of the test (actual 100.00 %)

Conclusion

The chronic toxicity of Acetamiprid 20% SG to honey bees was tested under laboratory conditions over a period of 10 days.

The actual mean concentrations of Acetamiprid in test item feeding solutions were in the range of 94.2 to 101.5 % of the nominal concentrations; therefore results are based on nominal.

The 10-day NOEC was determined to be 63.03 mg a.s./kg feeding solution.

The 10-day NOEDD was determined to be 1.30 µg a.s./bee/day.

The 10-day LC_{50} with 95 % confidence intervals was determined to be 121.84 [108.22 – 137.39] mg a.s./kg feeding solution.

The 10-day LDD_{50} with 95 % confidence intervals was determined to be 3.33 [2.78 – 4.11] µg a.s./bee/day.

The 10-day LC_{20} with 95 % confidence intervals was determined to be 83.34 [70.05 – 94.83] mg a.s./kg feeding solution.

The 10-day LDD_{20} with 95 % confidence intervals was determined to be 1.84 [1.48 – 2.20] µg a.s./bee/day.

The 10-day LC_{10} with 95 % confidence intervals was determined to be 68.33 [54.79 – 79.58] mg a.s./kg feeding solution.

The 10-day LDD_{10} with 95 % confidence intervals was determined to be 1.34 [1.02 – 1.65] µg a.s./bee/day.

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

Comments of zRMS:

The study is considered acceptable. All validity criteria were met.

- Control Mortality: The cumulative larval mortality from day 4 (D4) to the day 8 (D8) was ≤ 15%across all replicates in control group and control solvent group (actual values 4.17 and 0.00 % respectively). On day 22 (D22) the adult emergence rate was ≥ 70% across all replicates (actual value 89.58 % for both control groups).
- Reference Item Mortality: The cumulative larval mortality was ≥ 50 % across all replicates on day 8(D8) and on day 22 (D22) (actual 91.67 and 95.83 % respectively).

Agreed endpoints:

Endpoint	**µg a.s./larva**
22-Day NOED[1]	0.80
22-Day LOED[1]	2.00
22-Day ED_{50} [95 % I.C.]	> 5.00 [not determined]*
Endpoint	**mg a.s./kg diet**
22-Day NOEC[1]	5.20
22-Day LOEC[1]	12.99
22-Day EC_{50} [95 % I.C.]	> 32.47 [not determined]*

1Step-down Cochran-Armitage Test Procedure

*Empirically estimated since no greater mortality than 50% occurred.

Reference:	KCP 10.3.1.3
Report	"Acetamiprid Technical – Honey Bee (*Apis mellifera* L.) Larval Toxicity Test following Repeated Exposure under laboratory conditions", Ignacio Gimeno, 2019, Study code S18-05066
Guideline(s):	Yes, ENV/JM/MONO (2016) 34: Guidance Document on Honey bee (*Apis mellifera*) Larval Toxicity Test, Repeated Exposure (OECD 239).
Deviations:	Yes. The reduction of the relative humidity conditions from 95 ± 5 % to 80 ± 5 % was done on day 7 (D7) of the test instead of on day 8 (D8). The reported deviation to the guideline has no impact on the outcome of the study since validity criteria for both control and control solvent were met..
GLP:	Yes
Acceptability:	Yes

Materials and methods

The objective of this study was to determine the effects of Acetamiprid Technical (batch SCL-59065 on the honey bee larvae, Apis mellifera L., from repeated feeding exposure in an 22 day
in vitro test and to determine the No Observed Effect Dose/Concentration (NOED, NOEC), the Lowest Observed Effect Dose / Concentration (LOED, LOEC) and the corresponding Median Effect Dose/Concentration (ED_{50}, EC_{50}) and any ED_x/EC_x for day 22, where possible.

The test species was honey bee (*Apis mellifera* L.), synchronized first instar (L1) larvae originating from three adequately fed, healthy, as far as possible parasite-free and queen-right colonies.

The test was conducted as a dose response test with a duration of 22 days from grafting on day 1
(D1) to the final assessment on day 22 (D22); from day 3 (D3) until day 6 (D6) of the test, test item (Acetamiprid Technical) and reference item (dimethoate) were dissolved in the appropriate larval diet and provided to larvae once a day. The analysed Acetamiprid content was used to calculate the test item doses and dimethoate content was used to calculate the reference item dose.

The experimental groups were: 1 untreated control group, 1 untreated control solvent group, 5 test item groups and 1 reference item group. The control groups and treated groups were exposed for the same period of time under identical conditions. Each treatment group consisted of 48 larvae from 3 different colonies (each colony representing a replicate); mortality assessments were performed on day 4 (D4), day 5 (D5), day 6 (D6), day 7 (D7), day 8 (D8), day 15 (D15) and day 22 (D22); the presence of uneaten food was qualitatively recorded on day 8 (D8).

The test concentrations were: 1 control group, 1 control solvent group (acetone 0.5 %), 5 test item groups with 0.83, 2.08, 5.20, 12.99 and 32.47 mg a.s./kg diet, equivalent to cumulative doses of 0.13, 0.32, 0.80, 2.00 and 5.00 µg a.s./larva; 1 reference item group with 48.00 mg dimethoate/kg diet, equivalent to a cumulative dose of 7.39 µg dimethoate/larva.

The test conditions were: Air temperature: Min / Max: 27.4 / 35.1 °C; Relative air humidity: Min / Max: 32.0 % / 97.5 % Exposure to light: constant darkness except during feeding and assessments.

Statistical calculations were made with the statistical program ToxRatPro Version 3.2.1. Step-down Cochran-Armitage Test Procedure was used to calculate the 22-Day, NOED / NOEC and LOEC / LOED values. Since no dose tested resulted ≥ 50% mortality, the 22-Day EC_{50} and ED_{50} values were empirically estimated to be greater than the highest nominal diet concentration and dose tested. The 22-Day $EC_{10\,/\,20}$ and $ED_{10\,/\,20}$ values could not be calculated due to the lacking of dose and/or concentration / response.

Results and discussions

Table 2.3.1.1.2-1: Cumulative mortality, overall mean consumption of feeding solution, dietary dose (DD), accumulated mean uptake, NOEC, NOEDD, LOEC, LOEDD, LC_{50} and LDD_{50}

Endpoint	**µg a.s./larva**
22-Day NOED[1]	0.80
22-Day LOED[1]	2.00
22-Day ED_{50} [95 % I.C.]	> 5.00 [not determined]*
Endpoint	**mg a.s./kg diet**
22-Day NOEC[1]	5.20
22-Day LOEC[1]	12.99
22-Day EC_{50} [95 % I.C.]	> 32.47 [not determined]*

[1]Step-down Cochran-Armitage Test Procedure

*Empirically estimated since no greater mortality than 50% occurred.

Findings:

- The actual mean concentrations of Acetamiprid Technical in test item application solutions were 89 and 111 % of the nominal concentrations; therefore results are based on nominal.
- In control and control solvent groups, cumulative larval mortality from day 4 (D4) until day 8 (D8) was 4.17 and 0.00 % respectively. On day 22 (D22), the adult emergence rate in control and control solvent groups was 89.58 % of the initial grafted larvae. Cumulative mortality in the Reference Item treatment group was 91.67 % by D8. Therefore, the validity criteria were met.
- At day 8 (D8) of the test in the test item doses of 0.13, 0.32, 0.80, 2.00 and 5.00 µg a.s./larva, the cumulative mean mortality were; 2.08, 2.08, 2.08, 14.58 and 37.50 % respectively. Larvae with presence of uneaten food were qualitatively observed at the test item dose of 2.00 and 5.00 µg a.s./larva.
- At day 15 (D15) of the test in the test item doses of 0.13, 0.32, 0.80, 2.00 and 5.00 µg a.s./larva, the cumulative mean mortality were 8.33, 14.58, 10.42, 16.67 and 45.83 % respectively.
- In the test item doses of 0.13, 0.32, 0.80, 2.00 and 5.00 µg a.s./larva, the cumulative mean mortalities at 22 days (D22) after grafting were 8.33, 18.75, 16.67, 20.83 and 47.92 % respectively. In consequence the mean emergence rates were 91.67, 81.25, 83.33, 79.17 and 52.08 % respectively. No affected emerged bees were recorded on day 22 (D22).
- The NOEC for mortality at 22 days (D22) after grafting was determined to be 5.20 mg a.s./kg diet. The corresponding NOED was determined to be 0.80 µg a.s./larva. Moreover, LOEC value was determined to be 12.99 mg a.s./kg diet and the corresponding LOED value was determined to be 2.00 µg a.s./larva.
- Regarding EC_{50} / ED_{50} values on day 22, endpoints were empirically estimated to be greater than the highest tested concentration / dose of 32.47 mg a.s./kg diet and 5.00 µg a.s./larva respectively. The corresponding EC_x / ED_x could not be determined due to mathematical reasons.

The following validity criteria were met during the test:

- The cumulative larval mortality from day 4 (D4) to the day 8 (D8) was ≤ 15% across all replicates in control group and control solvent group (actual values 4.17 and 0.00 % respectively). On day 22 (D22) the adult emergence rate was ≥ 70% across all replicates (actual value 89.58 % for both control groups).
- The cumulative larval mortality was ≥ 50 % across all replicates on day 8 (D8) and on day 22 (D22) (actual 91.67 and 95.83 % respectively).

Conclusion

The repeated exposure of Acetamiprid Technical to honey bee larval was tested under laboratory conditions over a period of 22 days.
The actual mean concentrations of Acetamiprid Technical in test item application solutions were 89 and 111 % of the nominal concentrations; therefore results are based on nominal.
The 22-Day NOEC was determined to be 5.20 mg a.s./kg diet.
The 22-Day NOED was determined to be 0.80 µg a.s./larva.
The 22-Day LOEC was determined to be 12.99 mg a.s./kg diet.
The 22-Day LOED was determined to be 2.00 µg a.s./larva.
The 22-Day LC_{50} was empirically estimated to be greater than the highest tested concentration of 32.47 mg a.s./kg diet.
The 22-Day LD_{50} was empirically estimated to be greater than the highest tested dose of 5.00 µg a.s./larva.
The 22-Day ED_{10} / $_{20}$ / EC_{10} / $_{20}$ could not be calculated due to mathematical reason. No significant dose and/or concentration / response was found.
The study was deemed valid since all validity criteria were met.

A 2.3.1.4 KCP 10.3.1.4 Sub-lethal effects

No new data submitted.

A 2.3.1.5 KCP 10.3.1.5 Cage and tunnel tests

No new data submitted.

A 2.3.1.6 KCP 10.3.1.6 Field tests with honeybees

No new data submitted.

A 2.3.2 KCP 10.3.2 Effects on arthropods other than bees

A 2.3.2.1 KCP 10.3.2.1 Standard laboratory testing for non-target arthropods

No data submitted.

A 2.3.2.2 KCP 10.3.2.2 Extended laboratory testing, aged residue with non-target arthropods

Comments of zRMS:

The study is considered acceptable. All validity criteria were met.

- The mortality of the control group was 8.3% on day 7 of exposure (criterion: a maximum of 20%).
- The corrected mortality of the mites exposed to the reference item at the rate of 9.0 mL/ha was 89.1% on day 7 of exposure (criterion: a minimum of 50%).
- The mean number of eggs per female in the control group was 5.8(required: ≥ 4 eggs per female).

Agreed endpoints:

Study group [application rate]		Parameter (endpoints)						
		Mortality			Reproduction			
Test item		(%)*	LR_{50}		Mean number of eggs/female (Rr) (no.)	Reproduction reduction Pr (%)	ER_{50}	
(g/ha)[a]	(g a.i./ha)[b]		(g/ha)[a]	(g a.i./ha)[b]			(g/ha)[a]	(g a.i./ha)[b]
Control (0.0)		-	-		5.8	-	-	
4.38	0.90	1.8	25.0 (15.8-45.3)*	5.1 (3.2-9.3)*	6.3	(-8.0)	18.4	3.8
8.75	1.79	23.6+			6.8	(-16.1)		
17.5	3.59	43.6+			4.4	23.9+		
35.0	7.18	52.7+			Not assessed			
70.0	14.35	83.6+						
$NOER_{mortality}$			4.38	0.90	$NOER_{reproduction}$		8.75	1.79
Reference item		-						
(ml/ha)[a]	(g a.i./ha)[b]							
9.0	3.6	89.1	Not determined		Not assessed			

a: [g of the test or mL of the reference item/ha]
b: [g active ingredient/ha]
*: the LR_{50} value (with 95% confidence limits)
+: statistically significant difference

Reference:	KCP 10.3.2.2-01
Report	An extended laboratory test for evaluating the effects of Acetamiprid 20% SG on the predatory mite, *Typhlodromus pyri* (Sch.), 2016, B/98/15
Guideline(s):	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:	Yes: Contrary to what had been planned, the study did not finish in June 2016 but in August 2016. This deviation had no impact on the results.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test item:	name: Acetamiprid 20% SG; content: 20.5% (w/w) of Acetamiprid as an active ingredient; batch number: SWEPL-10035; manufacturing date: February 15, 2015; expiry date: February 14, 2017
Biological test system:	the predatory mite, *Typhlodromus pyri* (Sch.) (Acari: *Phytoseiidae*)
– age:	24-hour-old protonymphs
– source:	a laboratory culture at the Institute of Industrial Organic Chemistry, Branch Pszczyna [SOP/B/33]; the culture was obtained from the Research Institute of Pomology and Floriculture, Skierniewice, Poland
Experimental design:	7 study groups: – a control group (0.0 g/ha) – Acetamiprid 20% SG at the rate of 4.38 g/ha (0.90 g a.i./ha) – Acetamiprid 20% SG at the rate of 8.75 g/ha (1.79 g a.i./ha) – Acetamiprid 20% SG at the rate of 17.5 g/ha (3.59 g a.i./ha) – Acetamiprid 20% SG at the rate of 35.0 g/ha (7.18 g a.i./ha) – Acetamiprid 20% SG at the rate of 70.0 g/ha (14.35 g a.i./ha) Bi 58 Nowy 400 EC at the rate of 9.0 mL/ha (3.6 g a.i./ha) number of replicates: 3; number of mites in each replicate: 20
Test conditions:	
– temperature:	24.0 - 26.0°C
– relative air humidity:	65 - 86%
– photoperiod:	16 h light (816 lux) : 8 h dark
Statistical analysis:	Step-down Cochran-Armitage test procedure, probit analysis, Shapiro-Wilk's test on normal distribution, Levene's test on variance homogeneity, Williams Multiple Sequential t-test procedure,
Endpoints:	– mite mortality after 7 days of the treatment (LR_{50}, $NOER_{mortality}$) – reproduction reduction (Pr) after 14 days of the treatment (ER_{50}, $NOER_{reproduction}$)

Results and discussions

Study group [application rate]	Parameter (endpoints)	
	Mortality	**Reproduction**

Test item		(%)*	LR_{50}		Mean number of eggs/female (Rr) (no.)	Reproduction reduction Pr (%)	ER_{50}	
(g/ha)[a]	(g a.i./ha)[b]		(g/ha)[a]	(g a.i./ha)[b]			(g/ha)[a]	(g a.i./ha)[b]
Control (0.0)		-	-		5.8	-	-	
4.38	0.90	1.8	25.0 (15.8-45.3)*	5.1 (3.2-9.3)*	6.3	(-8.0)	18.4	3.8
8.75	1.79	23.6+			6.8	(-16.1)		
17.5	3.59	43.6+			4.4	23.9+		
35.0	7.18	52.7+			Not assessed			
70.0	14.35	83.6+						
$NOER_{mortality}$			4.38	0.90	$NOER_{reproduction}$		8.75	1.79
Reference item		-						
(ml/ha)[a]	(g a.i./ha)[b]							
9.0	3.6	89.1	Not determined		Not assessed			

a: [g of the test or mL of the reference item/ha]
b: [g active ingredient/ha]
*: the LR50 value (with 95% confidence limits)
+: statistically significant difference

Conclusion

Under the experimental conditions, Acetamiprid 20% SG at the rate of 4.38 g/ha (0.90 g a.i./ha) has no adverse effect on mortality of the mites. However, at the rates of 8.75, 17.5, 35.0, and 70.0 g/ha (1.79, 3.59, 7.18, and 14.35 g a.i./ha) such an effect is observed. Acetamiprid 20% SG at the rates of 4.38 and 8.75 g/ha (0.90 and 1.79 g a.i./ha) has no adverse effect on reproduction of the mites. However, at the rate of 17.5 g/ha (3.59 g a.i./ha) such an effect is observed.

ZRMS comments:

The study is considered acceptable. All validity criteria were met.

- 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 73.3% (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 38.1 (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).

Agreed endpoints:

Study group [application rate]		Parameter (endpoints)						
		Mortality			Fecundity			
Test item		Total (%)*	LR_{50}		Mean no. of mummies/ female	Fecundity reduction Pr (%)	ER_{50}	
(g/ha)[a]	(g a.i./ha)[c]		(g/ha)[a]	(g a.i./ha)[c]			(g/ha)[a]	(g a.i./ha)[c]
Control (0.0)		0.0	-		38.1	-	-	
2.0	0.4	13.3+	11.4* (6.9-16.5)	2.3* (1.4-3.4)	33.5	12.1	> 5.2	> 1.0
5.2	1.0	36.7+			20.4	46.4		
12.8	2.6	63.3+			20.4	46.4		

32.0	6.6	70.0+			Not assessed		
80.0	16.4	90.0+					
$NOER_{mortality}$			< 2.0	< 0.4	$NOER_{fecundity}$	2.0	0.4
Reference item		-					
(ml/ha)[a]	(g a.i./ha)[c]						
5.0	2.0	73.3	Not determined		Not assessed		

a: [g of the test or mL of the reference item/ha]
c: [g active ingredient/ha]
*: the LR50 value (with 95% confidence limits)
+: statistically significant difference

Reference: KCP 10.3.2.1-02

Report An extended laboratory test for evaluating the effects of Acetamiprid 20% SG on the parasitic wasp,Aphidius rhopalosiphi (De Stefani - Perez), 2016, B/99/15

Guideline(s): 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: Acetamiprid 20% SG; content: 20.5% (w/w) of Acetemiprid as an active ingredient; batch number: SWEPL-10035; manufacturing date: February 15, 2015; expiry date: February 14, 2017

Biological test system: the parasitic wasp, *Aphidius rhopalosiphi* (De Stefani-Perez); Hymenoptera: Braconidae, Aphiidinae

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

– source: a laboratory culture at the Institute of Industrial Organic Chemistry, Branch Pszczyna; the culture was obtained from Katz Biotech AG (Baruth, Germany)

Experimental design: 7 study groups:
– a control group (0.0 g/ha)
– Acetamiprid 20% SG at the rate of 2.0 g/ha (0.4 g a.i./ha)
– Acetamiprid 20% SG at the rate of 5.2 g/ha (1.0 g a.i./ha)
– Acetamiprid 20% SG at the rate of 12.8 g/ha (2.6 g a.i./ha)
– Acetamiprid 20% SG at the rate of 32.0 g/ha (6.6 g a.i./ha)
– Acetamiprid 20% SG at the rate of 80.0 g/ha (16.4 g a.i./ha)
– Bi 58 Nowy 400 EC at the rate of 5.0 mL/ha (2.0 g a.i./ha)
number of replicates: 6 replicates/group
number of females: 5 females/replicate

Test conditions:

– temperature: 20-22°C

– relative air humidity: 64-88%

– photoperiod: 16 hours light (mortality assessment and oviposition: 2667 lx; fecundity assessment: 5327 lx) : 8 hours dark

Statistical analysis: Shapiro-Wilk's test on normal distribution, Levene's test on variance

homogeneity, non-parametric Kruskal-Wallis test, step-down Cochran-Armitage test procedure, Weibull analysis using linear max. likelihood regression, Multiple Sequantially-rejective Welsh-t-test after Bonferroni-Holm.

Endpoints:
– wasp mortality after 48 hours of exposure
– determination of the LR_{50} and the $NOER_{mortality}$
– reduction in fecundity (Pr) of surviving female wasps exposed to Acetamiprid 20% SG, recorded 12 days after the oviposition period
– determination of the ER_{50} and the $NOER_{fecundity}$

Results and discussions

Study group [application rate]		**Parameter (endpoints)**						
		Mortality			**Fecundity**			
Test item		**Total (%)***	**LR_{50}**		**Mean no. of mummies/ female**	**Fecundity reduction Pr (%)**	**ER_{50}**	
(g/ha)[a]	**(g a.i./ha)[c]**		**(g/ha)[a]**	**(g a.i./ha)[c]**			**(g/ha)[a]**	**(g a.i./ha)[c]**
Control (0.0)		0.0	-		38.1	-	-	
2.0	0.4	13.3+	11.4* (6.9-16.5)	2.3* (1.4-3.4)	33.5	12.1	> 5.2	> 1.0
5.2	1.0	36.7+			20.4	46.4		
12.8	2.6	63.3+			20.4	46.4		
32.0	6.6	70.0+			Not assessed			
80.0	16.4	90.0+						
$NOER_{mortality}$			< 2.0	< 0.4	$NOER_{fecundity}$		2.0	0.4
Reference item		-						
(ml/ha)[a]	(g a.i./ha)[c]							
5.0	2.0	73.3	Not determined		Not assessed			

a: [g of the test or mL of the reference item/ha]
c: [g active ingredient/ha]
*: the LR50 value (with 95% confidence limits)
+: statistically significant difference

Conclusion

Under the experimental conditions, Acetamiprid 20% SG at all the tested rates i.e. 2.0, 5.2, 12.8, 32.0, and 80.0 g/ha (0.4, 1.0, 2.6, 6.6, and 16.4 g a.i./ha) has an adverse effect on mortality of the wasps. Acetamiprid 20% SG at the rate of 2.0 g/ha (0.4 g a.i./ha) has no adverse effect on fecundity of the wasps. However, at the rate of 5.2 g/ha (1.0 g a.i./ha) such an effect is observed.

Comments of zRMS:

The study is considered acceptable. All validity criteria were met.

Mortality in the control treatment did not exceed 20 %.

Mortality in the reference treatment was in a range from 50 % to 100 %.

More than 4 eggs per female in the control treatments were achieved.

- Maximum mortality in the control was 15.0 %
- Mortality (corrected to control) in the toxic reference was 100 % with fresh and dry residues

(exposure of 0 DAA) and in the other exposures performed, 14 and 28 after the first application.

- More than 4 eggs per female in the control treatments were achieved (actual values ranged be-

tween 6.0 and 9.5 eggs per female)

Agreed endpoints:

Code	Treatment	Rate	Exposure					
			0 DAA(1)		14 DAA		28 DAA	
		[kg a.s./ha]	e/f(2)	[%] R	e/f	[%] R	e/f	[%] R(3)
C	Control (water)	-	6.0	-	6.5	-	9.5	-
T1	Acetamiprid 20 % SG	0.040	5.7	5.6	6.5	4.2	9.3	1.7
T2		0.085	4.7 SD	22.2	5.8	11.5	9.8	-2.6

(1): DAA = Days after application; "e/f"= eggs per female (mean); [%] R = Reduction [%]
(2): SD = significantly different compared to the control (T-Test, 1-sided smaller, α=0.05)
(3): Negative value indicates an increase relative to the control

Reference: KCP 10.3.2.2-03

Report "Aged residue test with the formulation Acetamiprid 20 % SG on the predatory mite *Typhlodromus pyri* (Acari: Phytoseiidae)". Francisco Luna. 2018. Study code: TRC17-087BA. Trialcamp S.L.U.

Guideline(s): IOBC WPRS/SROP (Blümel S. et al., 2000; Candolfi et al., 2000)

Deviations: Yes. 1. One replicate of the control treatment in the exposure of 28 DAA was studied with 16 individuals instead of 20 individuals since 4 individuals were not found in the first evaluation; 4 individuals escaped by a hole in the leaf. Then, the hole was sealed with glue and the replicate was studied with 16 individuals.
2. Registered humidity in the test site with treated plants was not reliable according to the observed values after unloading the data-logger; several values of 0 and 100 % humidity were obtained. Ambient humidity during the ageing period is possible to be consulted in data climatic conditions from the nearest meteorological station, included in Annex V.

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study) No

Summary

The aim of the study was to evaluate the extent and persistence of effects on the survival and reproduction of the formulation Acetamiprid 20 % SG to *Typhlodromus pyri* Scheuten (Acari: Phytoseiidae), exposing the test organisms to treated apple leaves after different periods of ageing of the residues under outdoors conditions (with a roof closed only when it rains). The effects were evaluated with the rates of 0.040 and 0.085 kg /ha of active substance (a.s.).

Material and methods

Test item: Acetamiprid 20 % SG
Content: 204 g acetamiprid /kg
Batch No.: SCL-68293
Manufacturing date: February 7th, 2017
Expiry date: January 6th, 2019

Biological test system: protonymphs of the parasitoid the predatory mite *T. pyri* Scheuten (Acari: Phytoseiidae)
– Age: Not older than 24 hours from moulting
– Source: From an in-house culture started with supplied eggs by Katz Biotech Ag. (Baruth – Germany)

Experimental design:

Code	Treatment	Application rate [kg a.s./ha](1)	Application rate(2) [kg product /ha]
C	Water (Control)	-	-
T1	Acetamiprid 20% SG	0.040	0.1961
T2		0.085	0.4167
R (A1)*	Deltamethrin 2.5 % EC	0.0122	0.50 L product/ha(3)

(1): "a.s." = active substance; acetamiprid in the test product, deltamethrin in the reference product.
(2): Rate of the formulated product (FP) according to the certificate of analysis: Acetamiprid, 204 g/kg
(3): Reference product at the maximum rate for intended use: 0.5 L FP /ha. It was applied at the beginning of the study (0 DAA) and just before the exposure of 28 DAA. Rate of active substance (0.0122 kg a.s./ha) according to the analysed content: 24.4 g/L.

Apple plants (*Malus domestica*) of the variety GOLDEN were used for trial purposes. Four plots were used with 12 potted plants (for C, T1 and T2) and 23 potted plants (for R) per plot: One plot for water treated control, one plot for each test product rate and one plot for the toxic reference. The treated plot size was 24 m^2 (12 m x 2 m) for the treatments and the plants were arranged in one crop row (0.5 m between plants).

Application was performed using a compressed air knapsack sprayer and one nozzle "Albuz Hollow Cone Yellow ATR-80" simulating an application in field (volume 1000 L/ha), working at pressure of 400 kPa and applying the plants by 2-sides. After application, plants were maintained under outdoors conditions with the use of a translucent roof to cover the crop when it rains to provide natural aging conditions and to avoid the washing-off by rain. The reference product was applied at the same time as the test product and also, after 28 days coinciding with the exposure of aged residue of 28 - days old of the test product. At this time, only 5 potted apple plants were used from among the previous applied 23 trees with the reference product.

In order to select treated leaves with the same age for the different exposures, the youngest leaves were marked to avoid samplings of new (non-treated) or developing leaves (diluted residues) at the exposure periods. A correct application of all leaves available was achieved thanks to the dispersed branching of the plants at the time of the application.

Statistics

Results of 7-d mortality and 7-14-d fecundity (eggs per female) were analysed with the Shapiro-Wilk test for normality of data distribution and with the Levene's test for homoscedasticity. Statistical analysis was performed with data mortality in order to study any significant differences compared to control with the statistic Fisher's exact test (Crosstabs, α=0.05). For reproduction (eggs per female), the non-parametric Mann-Whitney test (exact sig., 1-tailed, α=0.05) or the parametric T-test with Levene's test for equality of variances (α=0.05) were performed in order to study significant differences between the test product treatments and control according to the normality or not of data. No statistical analysis was performed with results in the test reference treatment.

Endpoints

- To study the mortality at 7 days after exposure (lethal effect) to residues on leaves aged for the following periods: 0, 14 and 28 days after application (DAA)
- To study the fecundity of the survivor females during 7 days following exposure to residues on leaves for the aforementioned ageing periods.

Results

Mortality
After each ageing period, 5 leaves were sampled per plot from different plants and transported to the laboratory to prepare the test arenas. After being collected and cut at fragments 2 x 5 cm approximately, the

test units were mounted and then, twenty protonymphs were placed in each arena, with 5 replicates per treatment.

Exposures to the residues (bioassays) were performed 0, 14 and 28 days after application (DAA). The test units were placed into an environmental chamber between 25 ± 2 ºC (actual between 24.7 and 25.4ºC), 60 - 90% RH (actual between 76.3 and 88.3 %), and with a 16:8h L:D photoperiod.

With fresh and dry residues (exposure of 0 DAA) and after the ageing periods of 14 and 28 days, corrected mortality was less than 50 %, i.e. 11.8 % as maximum value at the rate of 0.085 kg a.s./ha with fresh and dry residues.

Mortality in the test product groups of the tested rates of 0.040 and 0.085 kg a.s./ha was not statistically significant higher than control (Fisher's Exact Test, 1-sided greater, α=0.05) at the assessments started in the bioassays started 0, 14 and 28 DAA.

			Exposure					
Code	Treatment	Rate	0 DAA(1)		14 DAA		28 DAA	
		[kg a.s./ha]	% M	[%] Cm	% M	[%]Cm	% M	[%]Cm(2)
C	Control (water)	-	15.0	-	14.0	-	10.3	-
T1	Acetamiprid 20 %	0.040	23.0	9.4	15.0	1.2	9.0	-1.4
T2	SG	0.085	25.0	11.8	17.0	3.5	12.0	1.9
R	Deltamethrin 2.5 %, EC	0.0122	100	100	100	100	100	100

(1): DAA = Days after application; M [%] = Mortality [%]; Cm [%] = Corrected mortality [%]
(2): Negative value indicates a decrease relative to the control

Fecundity

As after 7 days the corrected mortality was ≤ 50 % in the test product groups in all the assayed ageing periods, the fecundity was assessed in the control and test product groups between 7 and 14 days after each exposure (9, 11 and 14 days after each exposure). The test units were placed into an environmental chamber with same climatic conditions that at the mortality period (actual temperature between 24.7 and 26.2ºC and relative humidity between 77.1 and 88.9 %).

The reduction of number of eggs/female was below the ESCORT 2 trigger value of 50 % in the bioassays performed from 0 DAA at the tested rates of 0.040 and 0.085 kg a.s./ha (maximum reduction relative to control was 22.2 % in the treatment of the rate 0.085 kg a.s./ha with fresh and dry residues).

Reproduction performance with the rate of 0.040 kg a.s./ha was not statistically significant affected (T-test and Mann-Whitney test, 1-side smaller, α=0.05) by 0, 14 and 28-day old residues. Reduction on reproduction with the rate of 0.085 kg a.s./ha (22.2 % compared to control with 0-day old residue) was significantly different to control (T-test, 1-side smaller, α=0.05); no significant differences compared to control were observed with 14-day old residues, and the reproduction rate with 28-day old residue in the test product group was even greater than in the control group..

			Exposure					
Code	Treatment	Rate	0 DAA(1)		14 DAA		28 DAA	
		[kg a.s./ha]	e/f(2)	[%] R	e/f	[%] R	e/f	[%] R(3)
C	Control (water)	-	6.0	-	6.5	-	9.5	-
T1	Acetamiprid 20 % SG	0.040	5.7	5.6	6.5	4.2	9.3	1.7
T2		0.085	4.7 SD	22.2	5.8	11.5	9.8	-2.6

(1): DAA = Days after application; "e/f"= eggs per female (mean); [%] R = Reduction [%]
(2): SD = significantly different compared to the control (T-Test, 1-sided smaller, α=0.05)
(3): Negative value indicates an increase relative to the control

Test validity criteria

All mortality and reproduction tests were considered to be valid as:

- Maximum mortality in the control was 15.0 %

- Mortality (corrected to control) in the toxic reference was 100 % with fresh and dry residues (exposure of 0 DAA) and in the other exposures performed, 14 and 28 after the first application.
- More than 4 eggs per female in the control treatments were achieved (actual values ranged between 6.0 and 9.5 eggs per female)

Conclusion

Based on the results of the present study it can be concluded that residues of the test product Acetamiprid 20 % SG applied up to the rate of 0.085 kg a.s./ha causes mortality less than 50 % compared to the control and has less than 50 % reduction on the reproduction of *T. pyri* from the day of the application with fresh and dry residues.

Comments of zRMS

The study is considered acceptable. All validity criteria were met.

Mortality in the control treatment did not exceed 10 %

Mortality in the reference treatment was in the range 50 % - 100 % until the exposure of 55 DAA

Wasps in the control produced a minimum of 5 mummies per female and no more than two wasps in the control produced 0 mummies.

- 0 DAA: 0 % mortality was observed in the control group and 63.33 % corrected mortality was observed in the reference product group.
- 21 DAA: 0 % mortality was observed in the control group and 100.00 % corrected mortality was observed in the reference product group.
- 42 DAA: 0 % mortality was observed in the control group and 66.67 % corrected mortality was observed in the reference product group.
- Wasps in the control treatment produced an average of 12.20 mummies per female over a 24-hours period.

Agreed endpoints:

	[%] Mortality (2)				[%] Corrected Mortality (3)			
Treatment(1)	**Exposure +0DAA**	**Exposure +21 DAA**	**Exposure +42 DAA**	**Exposure +55 DAA**	**Exposure +0DAA**	**Exposure +21 DAA**	**Exposure +42 DAA**	**Exposure +55 DAA**
C ; Water Control	0.00	0.00	0.00	0.00	--	--	--	--
Acetamiprid 20% SG at 0.040 kg as/ha	100.00	100.00	16.67	0.00	100.00 SD	100.00 SD	16.67 SD	0.00
Acetamiprid 20% SG at 0.085 kg as/ha	100.00	96.67	73.33	30.00	100.00 SD	96.67 SD	73.33 SD	30.00 SD
Deltamethrin 2.5% EC at 0.5 L product/ha	63.33	100.00	66.67	90.00	63.33	100.00	66.67	90.00

(1): Rate of the test product in kg/ha of the active substance (as).
(2): DAA = Days after application.
(3): Negative value indicates a decrease compared to the control.
SD: Statistically significantly increased compared to control (Fisher's Exact Test, one-sided greater, $p \leq 0.05$)

	m/f (Average)(2)				[%] R(3)			
Treatment (1)	**Exposure +0DAA**	**Exposure +21 DAA**	**Exposure +42 DAA**	**Exposure +55 DAA**	**Exposure +0DAA**	**Exposure +21 DAA**	**Exposure +42 DAA**	**Exposure +55 DAA**
C ; Water Control	Not studied	Not studied	12.20	15.79	--	--	--	
Acetamiprid 20% SG at 0.040 kg as/ha	Not studied	Not studied	11.55	19.73	--	--	5.37	-25.01
Acetamiprid 20% SG at 0.085 kg as/ha	Not studied	Not studied	Not studied	22.53	--	--	--	-42.75

(1): Rate of the test product in kg/ha of the active substance (as).
(2): DAA = Days after application; "m/f"= mummies per female;
(3): [%] R= % Reduction relative to control. Negative value indicates an increase compared to the control.
*Actually 55 DAA.

Reference:	KCP 10.3.2.2-04
Report	"Aged residue test with the formulation Acetamiprid 20% SG on the parasitic wasp *Aphidius rhopalosiphi* (Hymenoptera: Braconidae)". Sara Varela. 2017. Study code: TRC17-086BA. Trialcamp S.L.U.
Guideline(s):	ESCORT (Candolfi et al., 2000), IOBC (Mead-Briggs et al. 2010), OECD guideline 54
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Summary
The aim of the study was to evaluate the extent and persistence of effects on the survival and reproduction of the formulation "Acetamiprid 20% SG" to *Aphidius rhopalosiphi* DeStephani Perez (Hymenoptera: Braconidae), exposing the test organisms to treated apple tree branches after different periods of ageing of the residues under outdoors conditions (with a roof closed only when it rains). The effects were evaluated 0, 21, 42 and 55 days after the application of the rates of 0.040 and 0.085 kg/ha of active substance (a.s.).

Material and methods

Test item: Acetamiprid 20% SG: content: 204 g Acetamiprid /kg; Batch No.: SCL-68293; manufacturing date: February 7th, 2017; expiry date: January 6th, 2019.

Biological test system: the parasitoid *A. rhopalosiphi* DeStephani Perez (Hymenoptera: Braconidae)
– Age: adult wasps not older than 48 hours
– Source: Katz Biotech AG, Baruth - Germany

Experimental design:

Treatment code	Product	Rate kg a.s. (1) /ha	Rate kg FP (2) /ha
C	Tap Water	-	-
T1	Acetamiprid 20% SG	0.040	0.1961
T2		0.085	0.4167
R	Deltamethrin 2.5% EC	0.0122	0.5 L product /ha(3)

(1): "a.s." = active substance; acetamiprid.
(2): Rate of the formulated product (FP) according to the certificate of analysis: Acetamiprid, 204 g/kg
(3): Reference product at the maximum rate for intended use: 0.5 L FP /ha. It was applied at the beginning of the study (0 DAA) and just before the exposure of 42 DAA. Rate of active substance (12.2 g a.s./ha) according to the analysed content: 24.4 g/L.

6 replicates/treatment; 5 adults/replicate

Apple trees (*Malus domestica*) of the variety GOLDEN were used for trial purposes. Four plots were used with 12 potted plants (for C, T1 and T2) and 23 potted plants (for R) per plot: One plot for water treated control, one plot for each of the rates of the test product and one plot for the toxic reference. The test

product was sprayed onto the plants simulating typical spray tank applications. The application equipment used was a compressed air knapsack sprayer simulating a commercial application in field (volume 1000 L/ha) and working at pressure of 400 kPa.

In order to select treated leaves in the different exposures, the top of the branches were marked after the application to avoid samplings of hidden leaves (non-treated) or developing leaves (diluted residues) at the exposure periods. A correct application of most of the leaves available was achieved thanks to the dispersed leaves at the time of the application.

After application, plants were maintained outdoors to allow "natural" weathering of the test product residues. The reference product was applied twice, at the same time as the test product (0 days after application-DAA-) and just before the exposure of 42 DAA.

Statistics
Fisher's Exact Binomial Test (one-sided greater) was used to detect significant differences between mortality data. Results of repellence and fecundity were analysed with the Shapiro-Wilk test for normality of data distribution and with the Levene's test for homoscedasticity. Non-parametric Mann-Whitney test (exact sig., 1-tailed, α=0.05) and T-test with Levene's test for equality of variances (α=0.05). Non-parametric Mann-Whitney test (exact sig., 1-tailed, α=0.05) according to the non-normality of data.

Endpoints
- Adult mortality after an exposure of 48 hours (lethal effect) to residues on leaves aged for 0, 21, 42 and 55 days after application (DAA).
- Fecundity of 15 surviving females during 24 hours in presence of their host aphids for the aforementioned ageing periods when mean mortality in the test product group was ≤ 50 % and at least 15 females were survived.

Results
Mortality and repellence
After each ageing period, apple tree branches, with 2-4 leaves, per plot were randomly sampled and transported to the laboratory to prepare the test arenas. Then, 5 female adult wasps were placed in each arena (excised leaf test units) with 6 replicates per treatment.

Exposures to the residues (bioassays) were performed 0, 21, 42 and 55 days after application (DAA). The test units were placed into an environmental chamber between 20 ± 2, 60-90% RH and with a 16:8h L:D photoperiod. The light intensity was checked and it was between 445-622 lux during the mortality phases and it was between 1880-2814 lux during the parasitization phases.

Mortality assessments were carried out after 2, 24 and 48 hours of exposure. Repellency assessments were carried out during the initial 3 hours after their release and after 24 and 48 h when less than 30 % of individuals were settled on plants (after 0DAA and 42 DAA).

After the ageing periods of 0 and 21 days, the corrected mortalities were higher than 50 % at the rates of 0.040 and 0.085 kg as/ha and significantly different in comparison to the control treatment. After 42 days the corrected mortality was lower than 50 % at the rate of 0.040 but significantly different in comparison to the control treatment, while it was higher than 50% at the rate of 0.085 kg as/ha and significantly different in comparison to the control treatment. At the ageing period of 55 days the corrected mortality was lower than 50 % at the rates of 0.040 and 0.085 kg as/ha but it was significantly different in comparison to the control treatment at the rate of 0.085 kg as/ha.

Treatment[1]	[%] Mortality [2]				[%] Corrected Mortality [3]			
	Exposure +0DAA	Exposure +21 DAA	Exposure +42 DAA	Exposure +55 DAA	Exposure +0DAA	Exposure +21 DAA	Exposure +42 DAA	Exposure +55 DAA
C ; Water Control	0.00	0.00	0.00	0.00	--	--	--	--
Acetamiprid 20% SG at 0.040 kg as/ha	100.00	100.00	16.67	0.00	100.00 SD	100.00 SD	16.67 SD	0.00
Acetamiprid 20% SG at 0.085 kg as/ha	100.00	96.67	73.33	30.00	100.00 SD	96.67 SD	73.33 SD	30.00 SD
Deltamethrin 2.5% EC at 0.5 L product/ha	63.33	100.00	66.67	90.00	63.33	100.00	66.67	90.00

(1): Rate of the test product in kg/ha of the active substance (as).
(2): DAA = Days after application.
(3): Negative value indicates a decrease compared to the control.
SD: Statistically significantly increased compared to control (Fisher's Exact Test, one-sided greater, $p \leq 0.05$)

Fecundity

If after 48 hours the corrected mortality was ≤ 50 % and at least 15 females were survived in the test product group, which was the case after 42 (at 0.040 kg/ha of a.s.) and 55 (at 0.040 and 0.085 kg/ha of a.s.) days of ageing, the reproductive capacity was assessed in the control and test product groups confining 15 females individually over untreated barley plants infested with the host cereal aphids, *Rhopalosiphum padi*. The females were removed after 24 hours and the aphid-infested plants were left for a further 10 (for exposure at 42 DAA) and 11 (for exposure at 55 DAA) days before the numbers of aphid mummies that had developed were assessed. The test units were placed into an environmental chamber at similar climatic conditions that at the mortality period (between 20 ± 2 and with a 16:8h L:D photoperiod). It was not considered necessary to regulate humidity during the reproduction phases. The light intensity was checked and it was between those ranges required in the study plan: 4000-20000 lux during the development of mummies (actual minimum-maximum values: 4603-7672 lux).

The reproductive capacity was assessed in the control and test product groups after 42 (at 0.040 kg as/ha) and 55 (at 0.040 and 0.085) kg as/ha days of ageing because less than 50 % mortality and more than 15 females were obtained.

Reproduction performance at the tested rates of the test product 0.040 and 0.085 kg as/ha were below the ESCORT 2 trigger value of 50 % from the exposures of 42 and 55 DAA. No significantly differences were detected with the number of females at 42 (Mann-Whitney test, exact sig., 1-tailed, α=0.05). At the exposure of 55 DAA, the number of mummies per female was higher at the two rates of the test product than the detected in the control group.

Treatment [1]	m/f (Average)[2]				[%] R[3]			
	Exposure +0DAA	Exposure +21 DAA	Exposure +42 DAA	Exposure +55 DAA	Exposure +0DAA	Exposure +21 DAA	Exposure +42 DAA	Exposure +55 DAA
C ; Water Control	Not studied	Not studied	12.20	15.79	--	--	--	
Acetamiprid 20% SG at 0.040 kg as/ha	Not studied	Not studied	11.55	19.73	--	--	5.37	-25.01
Acetamiprid 20% SG at 0.085 kg as/ha	Not studied	Not studied	Not studied	22.53	--	--	--	-42.75

(1): Rate of the test product in kg/ha of the active substance (as).
(2): DAA = Days after application; "m/f"= mummies per female;
(3): [%] R= % Reduction relative to control. Negative value indicates an increase compared to the control.
*Actually 55 DAA.

Test validity criteria

All mortality and reproduction tests were considered to be valid as:

- 0 DAA: 0 % mortality was observed in the control group and 63.33 % corrected mortality was observed in the reference product group.

- 21 DAA: 0 % mortality was observed in the control group and 100.00 % corrected mortality was observed in the reference product group.
- 42 DAA: 0 % mortality was observed in the control group and 66.67 % corrected mortality was observed in the reference product group. Wasps in the control treatment produced an average of 12.20 mummies per female over a 24-hours period. Furthermore, zero values were not observed in the control treatment.
- 55 DAA: 0 % mortality was observed in the control group and 90.00 % corrected mortality was observed in the reference product group. Wasps in the control treatment produced an average of 15.79 mummies per female over a 24-hours period. Furthermore, zero values were not observed in the control treatment.

Conclusion

To determine the extent and persistence of effects on mortality and fecundity on the parasitoid *A. rhopalosiphi* after the application of 0.040 and 0.085 kg as/ha, equivalent to 0.1961 and 0.4167 kg of formulated product/ha respectively, an aged residue study was performed. Potted apple plants were treated and maintained under outdoors conditions to provide natural aging conditions, except washing-off by rain. Assessments were performed with residues aged for 0, 21, 42 and 55 days.

This study performed on *A. rhopalosiphi* after the application of the test product Acetamiprid 20% SG indicates that, at the application rate of 0.040 kg as/ha, the lethal and sub-lethal effects were < 50% relative to the control from 42-day old residue. At such rate, significant differences compared to control with mortality results were observed after the exposures of 0, 21 and 42-day old residue and no significant differences were detected at 55 -day old residue. At the application rate of 0.040 kg as/ha no significant differences compared to control with fecundity results were observed in the exposures of 42 and 55-day old residue.

At the application rate of 0.085 kg as/ha, the lethal and sub-lethal effects were < 50% relative to the control from 55-day old. At such rate, significant differences compared to control with mortality results were observed after the exposures of 0, 21, 42 and 55-day old residue. At the application rate of 0.085 kg as/ha the number of mummies per female observed in the exposure of 55-day old residue was higher than the one detected in the control group.

According to the significant differences compared to control, effects of repellence were detected with 0-day old residues during the initial 3 hours at the two rates of the test item group. However, no statistically significant effects were detected after 24 and 48 hours or at the following ageing periods.

Based on the results of this study performed on *A. rhopalosiphi* after the application of Acetamiprid 20% SG, it can be concluded that at the rate of 0.040 kg as/ha, equivalent to 0.1961 kg of formulated product/ha, 42-day old residues will not adversely affect mortality and will not impact reproduction (less than 50% reduction). At the rate of 0.085 kg as/ha, equivalent to 0.4167 kg of formulated product/ha, 55-day old residues will not adversely affect mortality and will not impact reproduction (less than 50% reduction).

Comments of zRMS

The study is considered acceptable. All validity criteria were met.

Maximum acceptable cumulative mortality (dead larvae and pupae and adults dying during emergence or not successfully moulted): required ≤ 20%.

Reproduction: Fecundity (mean number of eggs per female per day): ≥ 15.

Fertility (mean hatching rate): required ≥ 70%.

The level of mortality in the reference product treatment should be ≥ 50% at every exposure in order to demonstrate the correct application of the products and to confirm that the test system is suitable.

In the current study:

- Maximum mortality in the control was 14.29 % (exposure of 0 DAA).
- More than 15 eggs per female per day in the control treatments were achieved (actual values ranged between 21.2 and 26.3 eggs per female per day.
- More the 70 % of emergence of larvae from eggs (fertility) was obtained in the control treatments (actual value was 100 % in the exposures performed: 0, 21 and 42 DAA).
- Mortality (corrected to control) in the toxic reference was greater than 50 % at the performed exposures (actual minimum mortality was 53.60 % corrected to control).

Agreed endpoints:

Mortality values [%]

Code	Treatment	Rate [g a.s./ha]	Exposure					
			0 DAA(1)		21 DAA		42 DAA	
			[%]M(2)	[%] Cm	[%]M	[%] Cm	[%]M	[%]Cm
C	Control (water)	--	14.29	--	13.79	--	10.00	--
T1	Test Product Acetamiprid 20% SG	40.0	43.33 SD	33.89	13.79	0.00	17.86	8.73
T2		85.0	78.57 SD	75.00	17.86	4.71	7.14	-3.17
R (A1)* / R (A2)*	Reference (Deltamethrin 2.5 % EC)	12.20	70.00	65.00	60.00	53.60	70.00	66.67

(1): DAA = Days after application; M [%] = Mortality [%]; Cm [%] = Corrected mortality [%]

(2): SD = statistically significant different compared to the control (Fisher's Exact Test, 1-sided greater, α=0.05)

(3): Negative value indicates a decrease relative to the control

* A1=Application at the same time as the test product; A2=Application at 42 DAA.

Reproduction results; Fecundity and fertility

Code	Treatment	Rate [g a.s./ha]	Exposure					
			0 DAA		21 DAA		42 DAA	
			Fec. (1)	Fert. (2)	Fec. (1)	Fert. (2)	Fec. (1)	Fert. (2)
C	Control (water)	--	23.8	100	26.3	100	21.2	100
T1	Acetamiprid 20% SG	40.0	2.0*	100	24.2	100	19.7	100
T2		85.0	Not assayed(3)		24.5	100	21.5	100

(1): DAA = Days after application

(2): Fec.: Fecundity; mean eggs per female per day. Fert.: Mean eggs viability [%]

(*): The fecundity value below 15 eggs per female (2.0) in treatment T1 in the exposure of 0 DAA is considered as an effect of the test product on reproduction capacity.

(3): Reproduction capacity was not assessed, since corrected juvenile mortality with the test product was higher than 50 %

Reference:	KCP 10.3.2.2-05
Report	"Aged residue test with the formulation "Acetamiprid 20% SG" on *Chrysoperla carnea* (Neuroptera: Chrysopidae)". Francisco Luna. 2018. Study code: TRC17-088BA. Trialcamp S.L.U.
Guideline(s):	ESCORT workshops for higher tier testing (Barrett et al., 1994 and Candolfi et al., 2000). The method was based on guidelines proposed by Vogt et al., 2000.
Deviations:	Yes. 1. Relative humidity was registered with values outside of the ranges established in the Study Plan, 60-90 % for longer than 2 hours. No negative effects were observed in the study since the validity criteria were achieved in the control treatment. 2. Registered humidity in the test site with treated plants was not reliable according to the observed values after unloading the data-logger; several values of 0 and 100 % humidity were obtained. Ambient humidity during the ageing period is possible to be consulted in data climatic conditions from the nearest meteorological station, included in Annex V. The above mentioned deviations were considered by the Study Director to have not had any adverse effect on the outcome of the study.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Summary

The aim of the study was to evaluate the extent and persistence of effects on the survival and reproduction of the formulation "Acetamiprid 20% SG" to *Chrysoperla carnea* (Neuroptera: Chrysopidae), exposing the test organisms to treated apple leaves after different periods of ageing of the residues under outdoors conditions (with a roof closed only when it rains). The effects were evaluated with the rates of 0.040 and 0.085 kg/ha of active substance (a.s.).

Application was performed on Apple plants (*Malus domestica*) of the variety GOLDEN with a compressed air knapsack sprayer and one nozzle simulating an application in field. First instar larvae of *Chrysoperla carnea* (2-3 days old) were isolated and exposed to the different aged residues on leaves.The larvae were continuously exposed to the residue on the leaves until, at least 5 days after formation of pupae. Thirty larvae per treatment were individually confined within test units.

Viable adults from each treatment (control and test product) were used to study fecundity and fertility. Adults emerging within this discrete time period were housed in one box per treatment group. Fecundity assessments began seven days after eggs were first observed in the control treatment.

Larval mortality was assessed from the same day of the exposure (approximately 2 h after the exposure) to the completion of pupation of the larvae and emergence of adults. When corrected pre-adult mortality in the test product treatments was less than 50 %, reproduction (fecundity and fertility) was studied.

To control the sensitivity of the biological test system and the relative susceptibility of the test method, Deltamethrin 2.5 % EC was used as a reference item. The reference item was applied at a rate of 0.5 L/ha (equivalent to 12.20 g a.s./ha). A water control was also tested.

Material and methods

Test item: Acetamiprid 20% SG
Content: 204 g acetamiprid / kg
Batch No.: SCL-68293
Manufacturing date: February 7th, 2017
Expiry date: January 6th, 2019.

Biological test system: green lacewing (*Chrysoperla carnea*)
– age: 2-3 days old
– source: A batch of eggs came from the supplier "Sautter & Stepper"

Experimental design: 4 test groups:
– Control (0 L product/ha)
– Acetamiprid 20% SG at a rate of 40.0 g a.s./ha
– Acetamiprid 20% SG at a rate of 85g a.s./ha
– Deltamethrin 2.5 % EC at a rate of 12.20 g a.s./ha
30 larvae/group. Viable adults from each treatment emerged within a period of seven days were used to study fecundity and fertility

Exposure	Test periods	Temperature(1) [ºC]	Relative Humidity(2) [%]	Light intensity [Lux] Photoperiod 16:8 hours
0 DAA	Mortality(1)	24.6 - 25.7	78.1 - 96.8	1653 - 2226
	Reproduction(2)	24.6 - 25.9	81.8 - 94.2	1154 - 1288
21 DAA	Mortality	24.6 - 25.9	78.1 - 95.7	1704 - 2835
	Reproduction	24.6 - 25.8	81.8 - 96.0	1112 - 1246
42 DAA	Mortality	24.6 - 25.8	79.2 - 96.0	1642 - 2762
	Reproduction	24.6 - 25.7	54.3 - 94.5	1257 - 1911

(1): Mortality period: Pre-adult or juvenile mortality; up to the completion of adult emergence.

(2): Reproduction period: Since the last emerged adult until the last assessment of fertility (viable eggs).

Statistics: Statistical analysis was performed with data mortality in order to study any significant differences compared to control with the statistic Fisher's exact test (Crosstabs, α=0.05).
The reproductive performance data were not analysed; the obtained values with fecundity and fertility were compared to the threshold values for control treatment: 15 eggs/female/day and 70% hatching rate.
No statistical analysis was performed with results in the test reference treatment.

Endpoints:

- To study the juvenile or pre-imaginal mortality (up to the completion of adult emergence) after several exposures to residues on leaves aged for the following periods: 0, 21 and 42 days after application (DAA).
- To study the reproduction of the survivor females for the aforementioned ageing periods, when possible.

Results

Mortalities in the control were below 20% at the end of exposures of 0, 21 and 42 DAA (actual maximum value was 14.29 % in the exposure of 0 DAA). In addition, reproductive performances in the control were above 15 eggs per female per day and above 70 % viability of eggs at the fecundity and fertility assessments 0, 21 and 42 DAA (actual minimum value of fecundity was 21.2 eggs per female per day in the

exposure of 42 DAA and always 100% emergence of larvae). A corrected mortality greater than 50 % was obtained with the toxic reference in the studied exposures (53.60 % as minimum corrected mortality). Regarding this information, the sensitivity of the test species and the suitability of the test system was confirmed and the study can be regarded to be valid.
With fresh and dry residues (exposure of 0 DAA) and after the ageing periods of 21 and 42 days of the test product at the rate of 0.040 kg a.s/ha, corrected mortality was less than 50 % i.e. 33.89, 0.0 and 8.73 % respectively. Statistically significant different to control was the mortality obtained with fresh and dry residues (Fisher's exact Test, 1-sided greater, α=0.05).
Mortality in the test product group of the rate 0.085 kg a.s./ha was higher than 50 % (75.00 % corrected mortality) at the assessment started with fresh and dry residues (exposure of 0 DAA) and statistically significant higher than control (Fisher's exact Test, 1-sided greater, α=0.05). No lethal effects were observed in the exposures of 21 and 42 DAA; 4.71 and -3.17 % corrected mortality respectively.
The mortalities for the different assayed treatments until completion of adult emergence are detailed in the table below.

Table 10.3.2.2-05-01. Mortality values [%]

Code	Treatment	Rate [g a.s./ha]	Exposure					
			0 DAA(1)		21 DAA		42 DAA	
			[%]M(2)	[%] Cm	[%]M	[%] Cm	[%]M	[%]Cm
C	Control (water)	--	14.29	--	13.79	--	10.00	--
T1	Test Product Acetamiprid 20% SG	40.0	43.33 SD	33.89	13.79	0.00	17.86	8.73
T2		85.0	78.57 SD	75.00	17.86	4.71	7.14	-3.17
R (A1)* / R (A2)*	Reference (Deltamethrin 2.5 % EC)	12.20	70.00	65.00	60.00	53.60	70.00	66.67

(1): DAA = Days after application; M [%] = Mortality [%]; Cm [%] = Corrected mortality [%]

(2): SD = statistically significant different compared to the control (Fisher's Exact Test, 1-sided greater, α=0.05)

(3): Negative value indicates a decrease relative to the control

* A1=Application at the same time as the test product; A2=Application at 42 DAA.

Table 10.3.2.2-05-02. Reproduction results; Fecundity and fertility

Code	Treatment	Rate [g a.s./ha]	Exposure					
			0 DAA		21 DAA		42 DAA	
			Fec. (1)	Fert. (2)	Fec. (1)	Fert. (2)	Fec. (1)	Fert. (2)
C	Control (water)	--	23.8	100	26.3	100	21.2	100
T1	Acetamiprid 20% SG	40.0	2.0*	100	24.2	100	19.7	100
T2		85.0	Not assayed(3)		24.5	100	21.5	100

(1): DAA = Days after application

(2): Fec.: Fecundity; mean eggs per female per day. Fert.: Mean eggs viability [%]

(*): The fecundity value below 15 eggs per female (2.0) in treatment T1 in the exposure of 0 DAA is considered as an effect of the
test product on reproduction capacity.

(3): Reproduction capacity was not assessed, since corrected juvenile mortality with the test product was higher than 50 %

Test validity criteria

The validity criteria for the water treated control have been fixed as follows (Vogt H. et al., 2000, SOP 9.1.17)

- Water control: Maximum acceptable cumulative mortality (dead larvae and pupae and adults dying during emergence or not successfully moulted): ≤ 20%.
- Water control: Reproduction:

o Fecundity (mean number of eggs per female per day): ≥ 15.
o Fertility (mean hatching rate): ≥ 70%.

The level of mortality in the reference product treatment should be ≥ 50% at every exposure in order to demonstrate the correct application of the products and to confirm that the test system is suitable.

Conclusion

To determine the extent and persistence of effects on mortality and reproductive capacity on the green lacewing *Chrysoperla carnea* after the application of 0.040 and 0.085 kg a.s./ha (equivalent to 0.1961 and 0.4167 kg product/ha respectively) an aged residue study was performed. Potted apple plants were treated and maintained under outdoors conditions to provide natural aging conditions, except washing-off by rain. Assessments were performed with residues aged for 0, 21 and 42 days.

Lethal effects less than the threshold of 50 % (50 % effect compared to the control) were observed after exposure to 0, 21 and 42-day old residues with the tested rate 0.040 kg a.s./ha of the test product. Mortality in the test product group of the rate 0.085 kg a.s./ha was higher than 50 % (75.00 % corrected mortality) at the assessment started with fresh and dry residues (exposure of 0 DAA).

Significant differences compared to control (Fisher's exact Test) with mortality results were observed in the exposure of 0-day old residue (fresh and dry residues) at the tested rates of 0.040 and 0.085 kg a.s./ha, and no significant lethal effects were recorded after exposure to residues aged for 21 and 42 days.

Fecundity (eggs female per day) was less than 15 eggs per female per day (considered a normal fecundity value for the control treatment) in the test product group of the rate 0.040 kg a.s./ha when larvae were exposed to fresh and dry residues; the obtained fecundity value was 2.0 eggs per female per day.

Therefore, based on the results of this study performed on *Chrysoperla carnea* after the application of Acetamiprid 20% SG it can be concluded that at a rate of 0.040 kg a.s./ha with fresh and dry residues (0-day old residues) will not cause mortality greater than 50 % and will not impact reproduction after 21days of the application. The test product at the rate of 0.085 kg a.s./ha will not adversely affect mortality and will not impact reproduction after 21-day old residue.

Comments of zRMS

The study is considered acceptable. All validity criteria were met.

Maximum acceptable cumulative mortality (dead larvae and pupae, adults dying during emergence): ≤30 %.

Reproduction output (mean number of eggs per viable female per day) ≥2.

Mortality in the reference product treatment higher than 50 % at the planned exposures.

In the current study:

- Maximum mortality in the control was 12.50 % (exposure of 42 DAA).
- More than 2 fertile eggs per female in the control treatments were achieved (actual values ranged between 5.84 and 6.63 fertile eggs per female per day.
- Mortality (corrected to control) in the toxic reference was 100 %, 69.44 and 100 % at 0, 21 and 42-day old residues respectively.

Agreed endpoints:

Mortality.

Code	Treatment	Rate	Exposure					
			0 DAA(1)		21 DAA		42 DAA	
		[kg a.s./ha]	[%]M(2)	[%]Cm	[%]M	[%]Cm(3)	[%]M	[%]Cm(3)
C	Control (water)	-	2.50	-	10.00	-	12.50	-
T1	Acetamiprid 20% SG	0.040	87.50 SD	87.18	5.00	-5.56	2.50	-11.43
T2		0.085	95.00 SD	94.87	5.13	-5.41	7.50	-5.71

R (A1)* **R (A2)***	Deltamethrin 2.5 % EC	0.0122	100	100	72.50	69.44	100	100

(1): DAA = Days after application; M [%] = Mortality [%]; Cm [%] = Corrected mortality [%]

(2): SD = statistically significant different compared to the control (Fisher's Exact Test, 1-sided greater, α=0.05)

(3): Negative values indicate a decrease relative to the control

* A1=Application at the same time as the test product; A2=Application at 42 DAA.

Reproduction capacity (fertile eggs per female and day).

			Exposure		
Code	Treatment	Rate [kg a.s./ha]	0 DAA(1) [Fertile. Eggs / female / day]	21 DAA [Fertile. Eggs / female / day]	42 DAA [Fertile. Eggs / female / day]
C	Control (water)	-	Not assayed(2)	6.63	5.84
T1	Acetamiprid 20% SG	0.040	Not assayed(2)	8.89	9.88
T2		0.085	Not assayed(2)	11.80	12.03

(1): DAA = Days after application

(2): Reproduction capacity was not assessed when corrected juvenile mortality with the test product was higher than 50 %

Reference: KCP 10.3.2.2-06

Report "Aged residue test with the formulation Acetamiprid 20% SG on *Coccinella septempunctata* L. (Coleoptera: Coccinellidae)". Francisco Luna. 2018. Study code: TRC17-089BA. Trialcamp S.L.U.

Guideline(s): ESCORT (Barrett et al., 1994; Candolfi et al., 2000), OECD 54, IOBC WPRS/SROP (Schmuck R. et al., 2000)

Deviations: Yes. 1. Larval mortality was assessed from the same day of each exposure (2 hours after the exposures) and at least every working day to the completion of the adult stage, with exception of one day due to a mistake, 21st of July (Friday), in the mortality assessments for the exposure of 21 DAA. The units were fed and this lack of evaluation does not affect the final results of mortality.
2. Relative humidity was registered with values outside of the ranges established in the Study Plan, 60-90 %, for longer than 2 hours continuously. These deviations affected to the reproduction period during the exposure of 21 DAA and both mortality and reproduction periods during the exposure of 42 DAA (between August 11th and September 19th 2017). No negative effects were observed in the study since the validity criteria were achieved in the control treatment (for mortality assessments at 21 and 42 DAA, 10.00 and 12.50% mortality, respectively; for reproductive performance assessments 21 and 42 DAA, 6.63 and 5.84 fertile eggs per female per day, respectively).
3. Registered humidity in the test site with treated plants was not reliable according to the observed values after unloading the data-logger; several values of 0 and 100 % humidity were obtained. Ambient humidity during the ageing period is possible to be consulted in data climatic conditions from the nearest meteorological station, included in Annex V.
4. Two – four rubber bands were used to fix the ring to the Petri dish with the leaflets instead of 2 - 3 rubber bands as the Study Plan indicates.

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study) No

Summary

The aim of the study was to evaluate the extent and persistence of effects on the survival and reproduction of the formulation "Acetamiprid 20% SG" to *Coccinella septempunctata* L. (Coleoptera: Coccinellidae), exposing the test organisms to treated apple leaves after different periods of ageing of the residues under outdoors conditions (with a roof closed only when it rains). The effects were evaluated with the rates of 0.040 and 0.085 kg/ha of active substance (a.s.). A water treated control and a toxic reference (Deltamethrin 2.5 % EC at 0.5 L/ha = 0.0122 kg a.s./ha) were also part of the study. Four plots were used with 12 potted plants (for control, T1 and T2) and 23 potted plants (for reference item) per plot: One plot for water treated control, one plot for each of the rates of the test product and one plot for the toxic reference. The water volume was 1000 L/ha.

After each ageing period, at least 40 leaves were sampled per plot and transported to the laboratory to prepare the test arenas. Larvae of *C. septempunctata* L. (3-5 days old) were isolated and exposed to the different aged residues on leaves. The larvae were continuously exposed to the residue on the leaves until the pupae had moulted to adults. Forty larvae per treatment were individually confined within test units. Exposures to the residues (bioassays) were performed 0, 21 and 42 days after application (DAA).

Mortality assessments were carried out daily except weekends and the number of dead larvae/pupae was recorded together. Pupation and hatching of the adults were recorded. The number of dead larvae and the number of pupae that fail to develop into adults were combined and the value used to calculate the total juvenile mortality.

The sub-lethal effects on the reproductive performance of the emerging adults was evaluated when possible (corrected mortality < 50 %), with 8 synchronisations of egg laying (24-h periods) in two weeks to calculate the eggs per female and day (fecundity rate) and the larvae emerging from eggs to calculate the percentage of viable eggs (fertility rate). It was not possible with the test product groups in the exposure to fresh and dry residues (0 DAA).

Material and methods

Test item: Acetamiprid 20% SG
Content: 204 g acetamiprid / kg
Batch No.: SCL-68293
Manufacturing date: February 7th, 2017
Expiry date: January 6th, 2019.

Biological test system: The aphid predator, *C. septempunctata* L. (Stephens)(Coleoptera: Coccinellidae)
– Age: Larvae 3-5 days old
– Source: From an in-house culture started with supplied adults from Katz Biotech Ag. (Baruth – Germany).

Application:
- Plot size: 24 m^2 for the treatments.
  Plants in one row (0.5 m between plants).
- Working pressure: 400 Kpa
- Aging conditions: Application by 2-sides

Outdoors conditions (translucent roof to cover the crop)

Experimental design

Code	Treatment	Application rate [kg a.s./ha]	Application rate(1) [kg product /ha]
C	Water (Control)	-	-
T1	"Acetamiprid 20% SG"	0.040	0.1961
T2		0.085	0.4167
R (A1)*	Deltamethrin 2.5 % EC	0.0122(2)	0.50 L product/ha
R (A2)*			

(1): Rates of the formulated product according to the analytical certificate: Acetamiprid 204 g/kg.

(2): Rate of active substance of the reference product according to the analytical certificate: Deltamethrin 24.4 g/L.

* A1=Application at the same time as the test product; A2=Application at 42 DAA

The larvae, 40 / treatment and 1 larvae / unit, were continuously exposed to the residue on the leaf until they developed into adults. They were fed every working day with fresh aphids (*Acyrthosiphon pisum*).

Climatic conditions and light intensity

Exposure	Test periods	Temperature (1) (min-max) [ºC]	Relative humidity (2) (mean min-max) [%]	Light intensity (min-max) [Lux] Photo-period 16:8 hours L:D
0 DAA	Mortality(1)	24.7 - 25.8	77.8 - 88.6	1363 - 1411
	Reproduction(2)	--(3)	--(3)	--(3)
21 DAA	Mortality	24.7 - 26.2	54.4 - 92.4	1519 - 1601
	Reproduction	24.7 - 25.8	85.5 - 94.4	1818 - 2216
42 DAA	Mortality	24.7 - 26.2	54.4(4) - 94.4	1123 - 1360
	Reproduction	24.7 - 25.6	84.3 - 94.4	2457 - 2961

(1): Mortality period: Pre-adult or juvenile mortality, up to the completion of adult emergence.

(2): Reproduction period: Since the last emerged adult until the last assessment of fertility (viable eggs).

(3): Reproductive performance was not assessed because juvenile corrected mortality was greater than 50 %.

(4): Relative humidity below 60% was not registered for longer than 2 hours continuously.

Statistics: Statistical analysis was performed with data mortality of the exposure of 0 DAA in order to study any significant differences compared to control with the statistic Fisher's exact test (one-sided greater, α=0.05). Mortality even less than in the control treatment was observed in the exposures of 21 DAA and 42 DAA with both rates of the test product, so no statistical analysis was considered necessary with these data.

The reproductive performance data were not analysed; the obtained value with fecundity and fertility were compared to the threshold values for control: 2 viable (or fertile) eggs/female/day.

No statistical analysis was performed with results in the test reference treatment.

Endpoints:

- To study the juvenile or pre-imaginal mortality (up to the completion of adult emergence) after several exposures to residues on leaves aged for the following periods: 0, 21 and 42 days after application (DAA).
- To study the reproduction of the survivor females for the aforementioned ageing periods, when possible

Results

Based on mortalities being less than 30 % at the end of all exposure periods in the control groups (actual maximum value was 12.50 % in the exposure of 42 DAA), reproductive performances above 2 fertile eggs per female per day at the performed fecundity and fertility assessments in the control (actual minimum value was 5.84 fertile eggs per female in the exposure of 42 DAA) and a corrected mortality to control greater than 50 % in the toxic reference in all the exposures (minimum corrected mortality of 69.44 %), the sensitivity of the test species and the suitability of the test system was confirmed and the study can be regarded to be valid.

Mortality in the test product group of both 0.040 and 0.085 kg a.s./ha rates at the assessment started with fresh and dry residues (exposure of 0 DAA) was higher than 50 % (87.18 % and 94.87 % corrected mortality relative to the control, respectively). These mortalities in the test product groups were statistically significant higher than control (Fisher's exact Test, 1-sided greater, α=0.05).

After the ageing periods of 21 and 42 days of the test product at the rates of 0.040 and 0.085 kg a.s/ha, corrected mortality was less than 50 %; even the mortality values in the test product groups were below those found in the control groups (ranging from 2.50 to 7.50 % mortality)

Code	Treatment	Rate	Exposure					
			0 DAA(1)		21 DAA		42 DAA	
		[kg a.s./ha]	[%]M(2)	[%]Cm	[%]M	[%]Cm(3)	[%]M	[%]Cm(3)
C	Control (water)	-	2.50	-	10.00	-	12.50	-
T1	Acetamiprid 20% SG	0.040	87.50 SD	87.18	5.00	-5.56	2.50	-11.43
T2		0.085	95.00 SD	94.87	5.13	-5.41	7.50	-5.71
R (A1)*	Deltamethrin 2.5 % EC	0.0122	100	100	72.50	69.44	100	100
R (A2)*								

(1): DAA = Days after application; M [%] = Mortality [%]; Cm [%] = Corrected mortality [%]

(2): SD = statistically significant different compared to the control (Fisher's Exact Test, 1-sided greater, α=0.05)

(3): Negative values indicate a decrease relative to the control

* A1=Application at the same time as the test product; A2=Application at 42 DAA.

The reproduction capacity (fertile eggs per female and day) is shown in the following table.

Code	Treatment	Rate [kg a.s./ha]	Exposure		
			0 DAA(1) [Fertile. Eggs / female / day]	21 DAA [Fertile. Eggs / female / day]	42 DAA [Fertile. Eggs / female / day]
C	Control (water)	-	Not assayed(2)	6.63	5.84
T1	Acetamiprid 20% SG	0.040	Not assayed(2)	8.89	9.88
T2		0.085	Not assayed(2)	11.80	12.03

(1): DAA = Days after application

(2): Reproduction capacity was not assessed when corrected juvenile mortality with the test product was higher than 50 %

Reproduction performance was studied for the rates 0.040 and 0.085 kg a.s./ha with aged residues of 21 and 42-day old. As the reproductive output was above 2 fertile eggs per female per day when it was possible to study this parameter (even above the control groups), no effect on the reproduction capacity is considered to have had the test product with the tested rates when mortality was less than 50 %. More than 2 fertile eggs per female per day is considered a normal reproductive output for the control treatment, so the test product is considered harmless in reproduction when these results are obtained.

Based on the results of this study performed on *C. septempunctata* after the application of Acetamiprid 20% SG, it can be concluded that at the rates of 0.040 and 0.085 kg a.s./ha will not adversely affect mortality and will not impact reproduction from 21-day old residue.

Test validity criteria
All mortality and reproduction tests were considered to be valid as:

- Maximum mortality in the control was 12.50 % (exposure of 42 DAA).
- More than 2 fertile eggs per female in the control treatments were achieved (actual values ranged between 5.84 and 6.63 fertile eggs per female per day

Mortality (corrected to control) in the toxic reference was 100 %, 69.44 and 100 % at 0, 21 and 42-day old residues respectively

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

Comments of zRMS:

The study is considered acceptable. All validity criteria were met.

- Each replicate produced 127.3 juveniles (mean) at the end of the experiment (criterion: ≥ 30 juveniles by the end of the experiment).
- The coefficient of variation of reproduction was 11.6% (criterion: ≤ 30%).
- Adult mortality over the initial 4 weeks of the experiment was 0.0% (criterion: ≤ 10%).

Agreed endpoints:

Parameter	Value [mg/kg dry weight of artificial soil]	Value [mg of acetamiprid/kg dry weight of artificial soil]
EC_{10}	11.1 (6.9 – 14.4)	2.3 (1.4 – 2.9)
EC_{20}	15.1 (10.8 – 18.5)	3.1 (2.2 – 3.8)
EC_{50}	27.5 (23.2 – 32.5)	5.6 (4.8 – 6.7)
NOEC	5.6	1.1
LOEC	10.0	2.1
LC_{50}	66.2	13.6

Reference: KCP 10.4.1.1

Report ACETAMIPRID 20% SG
Earthworm Reproduction Test *(Eisenia fetida)*, 2017, G/187/15

Guideline(s): OECD Guideline for the Testing of Chemicals No. 222

Deviations: No

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study) No

Materials and methods

Test item:ACETAMIPRID 20% SG batch number: SWEPL-10035, active substance: acetamiprid – 20.5%(w/w)Artificial soil: 10% sphagnum peat, 20% kaolin clay, 70% industrial sand
Test organism: the earthworm, *Eisenia fetida* obtained from a standard laboratory culture cultivated at the Institute of Industrial Organic Chemistry, Branch Pszczyna, Department of Ecotoxicology, Laboratory of Soil Toxicology [SOP/G/34]
Test design:
Concentrations of the test item: test duration: 8 weeks; number of replicates: 4 replicates/concentration + 8 replicates/control; number of earthworms: 10 earthworms/replicate control, 1.0, 1.8, 3.2, 5.6, 10.0, 18.0, 32.0, 56.0, and 100.0 mg/kg dry soil
Test conditions: temperature: 17 – 19°C; pH at the beginning of the experiment: 5.62 – 5.83; pH at the end of the experiment: 5.52 – 5.62; soil moisture content at the beginning of the experiment: 21.6 – 22.7% (49.24 – 51.75% of the maximum water holding capacity); soil moisture content at the end of the experiment: 21.8 – 23.1% (49.70 – 52.66% of the maximum water holding capacity); light-dark cycle: 16h : 8h; light intensity: 530 – 620 lux Statistical analysis: EC10, EC20, EC50 – the probit method NOEC – the Shapiro-Wilk's Test on Normal Distribution, Bartlett's Test Procedure on Variance Homogeneity, the Williams Multiple Sequential t-test Procedure, Fisher's Exact Binomial Test with Bonferroni Correction (survival)
Endpoints: EC10, EC20, EC50, NOEC

Results and discussions

Mortality of the adult earthworms
After 4 weeks, mortality was observed at the concentrations: 56 mg/kg dr weight of artificial soil (one earthworm) and 100 mg/kg dry weight of artificial soil (all earthworm). After 4 weeks, in the control group mortality was not observed.

Observations of the earthworms
After 4 weeks of the experiment, the treated earthworms at concentrations from 1 to 56 mg/kg dry weight of artificial soil did not exhibit any changes in appearance and behaviour.

Body weights of the living adult earthworms
After the application of the test item at the concentrations ranging from 1 to 56 mg/kg dry soil, the body weight increase was between 26.7 to 47.5%. As for the control group, it was equal to 27.3%.

Impact of the test item on reproduction of the earthworms
· The obtained results made it possible to conclude that ACETAMIPRID 20% SG had a significant impact on reproduction of the earthworms at the concentrations from 10 to 100 mg/kg dry weight of artificial soil.
· The concentration of the test item causing a 10% reduction in the number of juveniles produced within the exposure period **(EC10)** is **11.076 mg/kg dry soil**.
· The concentration of the test item causing a 20% reduction in the number of juveniles produced within the exposure period **(EC20)** is **15.130 mg/kg dry soil**.
· The concentration of the test item causing a 50% reduction in the number of juveniles produced within the exposure period **(EC50)** is **27.480 mg/kg dry soil**.
· The highest concentration at which the test item is observed to have no statistically significant effects on reproduction (**NOEC**) is **5.6 mg/kg dry soil**.
· The lowest concentration at which the test item is observed to have statistically significant effects on reproduction **(LOEC)** is **10.0 mg/kg dry soil**.

Conclusion

Table: Endpoint values determined during the earthworm reproduction test (*Eisenia fetida*).

Parameter	Value [mg/kg dry weight of artificial soil]	Value [mg of acetamiprid/kg dry weight of artificial soil]
EC10	11.1 (6.9 – 14.4)	2.3 (1.4 – 2.9)
EC20	15.1 (10.8 – 18.5)	3.1 (2.2 – 3.8)
EC50	27.5 (23.2 – 32.5)	5.6 (4.8 – 6.7)
NOEC	5.6	1.1
LOEC	10.0	2.1
LC50	66.2	13.6

A 2.4.1.2 KCP 10.4.1.2 Earthworms - field studies

No new data submitted.

A 2.4.2 KCP 10.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms)

Comments of zRMS:	The study is considered acceptable. All validity criteria were met. • Mean adult mortality was 6.3% (criterion: ≤ 20%). • The mean number of juveniles per vessel was 204.9 at the end of the test (criterion: ≥ 100 juveniles at the end of the test), • The coefficient of variation calculated for the number of juveniles was 13.9% (criterion: ≤ 30%) **Agreed endpoints:** EC_{10} =1.91 mg/kg dry weight of the artificial soil (i.e. 0.39 mg acetamiprid/kg dry weight of the artificial soil). EC_{20} =2.64 mg/kg dry weight of the artificial soil (i.e. 0.53 mg acetamiprid/kg dry weight of the artificial soil). EC_{50} =4.87 mg/kg dry weight of the artificial soil (i.e. 0.98 mg acetamiprid/kg dry weight of the artificial soil). **$NOEC_{rep}$=1.39 mg product/kg dws**

Reference: KCP 10.4.2.1-01

Report	"Effect of Acetamiprid 20% SG on reproduction of the collembolans (*Folsomia candida)* in artificial soil." V. Angayarkanni, 2019,4344/2018. BIO-SCIENCE RESEARCH FOUNDATION
Guideline(s):	OECD 232 (2016)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test item:	Acetamiprid 20% SG; Batch code: SCL-56358; active substance: 20.2% w/w
Test species:	*Folsomia candida* from a culture maintained at BFR, India, juveniles (9 - 12 days).
Soil:	5% sphagnum peat; 20% kaolin clay; 75% industrial sand
Study design:	Number of replicates: 4 replicates / concentration + 8 replicates / control Number of collembolans: 10 / replicate Test duration: 28 days
Application rates:	Range finding test: Control, 0.01, 0.1, 1, 10, 100 and 1000 mg test item/kg soil dry weight Dfinitive test: Control, 0.71, 1.00, 1.39, 1.95, 2.73, 3.83, 5.36 and 7.50 mg test item/kg soil dry weight
Test conditions:	Temperature: 19.8 – 22.0℃; humidity: 41.6 – 42.5 % of maximum WHC; lighting: 16 h light: 8 h dark; light intensity: 532 – 644 lux; pH: 5.38 – 5.89
Statistical analysis:	The number of the surviving adults and juvenile collembolans was assessed 4 weeks after introduction. The endpoint values for mortality and reproduction were determined by using Probit analysis in the NCSS (Number Cruncher Statistical System) and one-way ANOVA using Graphpad Prism 8.0.
Endpoints:	EC_{50}, EC_{20}, EC_{10}, NOEC, LOEC LC_{50}

Results and Conclusions

Range finding test:
After 21 days of the experiment, the percentage of mortality of the collembolans in test concentrations ranged from 0.0 to 100.0 %. In contrast, no mortality was observed in the control group. In the case of reproduction, the mean number of juvenile collembolans in test concentrations ranged from 0 to 790.0, whereas in the control group was 787.5. The physiological or pathological symptoms or distinct changes in behavior between the juvenile collembolans from tested concentrations and the control group were not observed.

Definitive test:
After the application of the test item concentrations ranging from 0.71 to 7.50 mg/kg dry weight of the artificial soil, mortality was between 0.0 and 17.5%. As for the control group, it was 0%. The physiological or pathological symptoms or distinct changes in behavior between the juvenile collembolans from tested concentrations and the control group were not observed.
The concentration of the test item causing a 50% mortality of adults within the exposure period (LC_{50}) is >7.50 mg/kg dry weight of the artificial soil (i.e. >1.52 mg acetamiprid/kg dry weight of the artificial soil).

After the application of the test item concentrations ranging from 0.71 to 7.50 mg/kg dry weight of the artificial soil, the mean number of juveniles was between 201.0 and 723.8 per replicate. As for the control group, the number of juveniles was equal to 725.8 per replicate. The physiological or pathological symptoms or distinct changes in behavior between the juvenile collembolans from tested concentrations and the control group were not observed.
The concentration of Acetamiprid 20% SG causing a 10% reduction in the number of juveniles produced within the exposure period (EC_{10}) is equal to 1.91 mg/kg dry weight of the artificial soil (i.e. 0.39 mg acetamiprid/kg dry weight of the artificial soil).
The concentration of Acetamiprid 20% SG causing a 20% reduction in the number of juveniles produced within the exposure period (EC_{20}) is equal to 2.64 mg/kg dry weight of the artificial soil (i.e. 0.53 mg acetamiprid/kg dry weight of the artificial soil).
The concentration of Acetamiprid 20% SG causing a 50% reduction in the number of juveniles produced within the exposure period (EC_{50}) is equal to 4.87 mg/kg dry weight of the artificial soil (i.e. 0.98 mg acetamiprid/kg dry weight of the artificial soil).
The lowest concentration at which Acetamiprid 20% SG is observed to have statistically significant effects on collembolan reproduction (NOEC) is 1.95 mg/kg dry weight of the artificial soil (i.e. 0.39 mg acetamiprid/kg dry weight of the artificial soil).
The highest concentration at which Acetamiprid 20% SG is observed to have statistically significant effects on collembolan reproduction (NOEC) is 1.39 mg/kg dry weight of the artificial soil (i.e. 0.28 mg acetamiprid/kg dry weight of the artificial soil).

Mortality of the adults after 4 weeks of exposure

Treatments	mg prod./ kg dry soil	% Mean Mortality
Control	0.00	0.0
Test item – T1	0.71	0.0
Test item – T2	1.00	2.5
Test item – T3	1.39	0.0
Test item – T4	1.95	0.0
Test item – T5	2.73	2.5
Test item – T6	3.83	0.0
Test item – T7	5.36	0.0
Test item – T8	7.50	17.5*

* statistically significant difference between the control and the treatment group at $p < 0.05$

Reproduction performance

Treatments	mg prod./ kg dry soil	Mean no. of juveniles/vessel	± SD	% reduction in reproduction	CV%*
Control	0.71	725.8	20.4	-	2.8
Test item – T1	1.00	723.8	8.5	0.3	1.2
Test item – T2	1.39	720.8	5.4	0.7	0.8
Test item – T3	1.95	712.5	10.4	1.8	1.5
Test item – T4	2.73	632.0+	16.0	12.9	2.5
Test item – T5	3.83	522.3+	15.0	28.0	2.9
Test item – T6	5.36	471.3+	14.9	35.1	3.2
Test item – T7	7.50	348.8+	10.9	52.0	3.1
Test item – T8	0.71	201.0+	10.2	72.3	5.1

*CV: coefficient of variation
+: statistically significant difference between the control and the treatment group at $p < 0.05$

Comments of zRMS:

The study is considered acceptable. All validity criteria were met.

- Mean mortality of adult females ≤ 20 %, (being 10.00 %)
- Mean number of juveniles per replicate ≥ 50 (being 148.88)
- Coefficient of variation of reproductive output ≤ 30 % (being 19.29)

Agreed endpoints:

Endpoints	[mg t.s./kg sdw] [mg a.i./kg sdw]	[mg t.s./kg sdw] [mg a.i./kg sdw]
NOEC $_{mortality}$	1000.00	204.00
LOEC $_{mortality}$	> 1000.00	> 204.00
NOEC $_{reproductive}$	1000.00	204.00
LOEC reproductive	> 1000.00	> 204.00
EC_{50}	> 1000.00	> 204.00

Reference:	KCP 10.4.2.1-02
Report	ACETAMIPRID 20% SG Effects on the Reproductive Output of the Predatory Soil Mite *Hypoaspis (Geolaelaps) aculeifer* Canestrini (Acari: Laelapidae) in Artificial Soil*)*, 2017, TRC17-096BA
Guideline(s):	OECD Guideline for the Testing of Chemicals No. 226 (2016)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test substance: Acetamiprid 20% SG; Batch number: SCL-68293. Active ingredient: Acetamiprid; Analysed content: 20.4 % (w/w).
Test species:*Hypoaspis aculeifer* Canestrini (Acari, Laelapidae), from in-house culture, adult mites (33 days after starting of the egg-laying for synchronisation).
Test design: Adult females were exposed to the test substance in artificial soil. After 14 days, the survi ing individuals were extracted from the test units. The number of juveniles per test unit and additionally the number of surviving adult females were determined. The reproductive output and the mortality in each test item group were compared to that of the control group. A Dose-response test with 8 different test substance concentrations and 4 replicates each as well as a water control (without test substance) with eight replicates; 10 adult females were exposed per replicate.
Endpoints: LOEC (lowest observed effect concentration) and NOEC (no observed effect concentration) for mortality and reproductive output; EC10, 20, 50 (effect concentration of 10, 20, 50 %) for reproductive output, where possible.
Test substance concentrations:
0 (control), 16.33, 29.40, 52.92, 95.26, 171.47, 308.64, 555.56 and 1000.00 mg test substance/kg soil dry weight. Equivalent to: 3.33, 6.00, 10.80, 19.43, 34.98, 62.96, 113.33 and 204.00 mg Acetamiprid/kg soil dry weight.
Test conditions: Artificial soil with 5 % peat content; soil pH 5.87 to 6.00 at test initiation and pH 5.98 to 6.35 at test termination; water content at test initiation 19.19 % to 20.69 % (corresponding to 44.13 – 47.58 % of the WHCmax), 18.71 % to 20.12 % (corresponding to 43.02 – 46.27 % of the WHCmax) at test termination; temperature during exposure: 19.88 °C to 21.04 °C; 16:8 light:dark cycles (long day conditions), and light intensity 452 lux to 574 lux. Soil analysis Analysis of soil samples correspondent to test substance treatments T1, T5 and T8 at 0, 7 and 14 days after the application for Acetamiprid under an independent GLP study. The Acetamiprid content in samples was determined by HPLC.

Statistics: Calculation of treatment means and standard deviations. Level of significance $\alpha = 0.05$ for each of the tests. Analysis with the Shapiro- Wilk test for normality of data distribution and with the Levene's test for homoscedasticity. Analysis of mortality and reproduction data using the non parametric pair-wise test (Mann-Whitney exact test, $\alpha = 0.05$). The EC10, 20, 50 for reproductive output could not be calculated.

Results and discussions

No statistically significant increase in mortality of *Hypoaspis aculeifer* was detected at any of the test substance concentrations as compared to the control group after 14 days of exposure. Accordingly the LOEC for mortality could not be determined. The NOEC for mortality was determined as 1000.00 mg test substance/kg soil dry weight. No behavioural abnormalities or any pathological symptoms of the test organisms could be observed in the control group and in any of the test substance groups. No statistically significant reduction in the number of juveniles was detected at any of the test substance concentrations as compared to the control group after 14 days of exposure. Accordingly, the LOEC for reproductive output could not be determined.
The NOEC for reproductive output was determined as 1000.00 mg test substance/kg soil dry weight. Since there was no dose-response relationship the EC10, EC20 and EC50 for reproductive output could not be calculated. The EC50 for reproductive output is assumed as > 1000.00 mg test substance/kg soil dry weight.

Table: Mortality and reproductive output of *Hypoaspis aculeifer* after exposure to artificial soil treated with Acetamiprid 20% SG

Treatment group	**Test substance concentration** [mg t.s./kg sdw]	**Mean mortality** [%]	**Mean number of juveniles per replicate**	**Coefficient of variation** [%]	**Reduction in reproductive output** [%] a
Control	0	10.00	148.88	19.29	--
Acetamiprid 20% SG	16.33	7.50	148.00	25.06	0.59
	29.40	12.50	139.50	14.86	6.30
	52.92	17.50	140.25	23.80	5.79
	95.26	2.50	159.75	14.60	-7.30
	171.47	17.50	154.50	8.87	-3.78
	308.64	2.50	144.75	20.71	2.77
	555.56	10.00	157.00	24.24	-5.46
	1000.00	15.00	141.75	27.03	4.79

Endpoints	[mg t.s./kg sdw] [mg a.i./kg sdw]	[mg t.s./kg sdw] [mg a.i./kg sdw]
NOEC mortality	1000.00	204.00
LOEC mortality	> 1000.00	> 204.00
NOEC reproductive output	1000.00	204.00

LOEC reproductive output	> 1000.00	> 204.00
EC50	> 1000.00	> 204.00

The toxic reference item BAS 152 11 I (a.i. dimethoate) was tested in a separate study (TRC16-260BA, issued: 27 October 2016). The EC50 for reproductive output was determined to be 5.13 mg a.i./kg soil dry weight. This is within the target range of 3.0 to 7.0 mg a.i./kg soil dry weight given by the OECD guideline 226 (2016) and hence acceptable sensitivity of the test system was assured.

Conclusion

All validity criteria were met and the sensitivity of the test organisms was confirmed. Accordingly, the study was deemed valid. The LOEC for mortality could not be determined. The NOEC for mortality was determined as 1000.00 mg test substance/kg soil dry weight. The LOEC for reproductive output could not be determined. The NOEC for reproductive output was determined as 1000.00 mg test substance/kg soil dry weight. Since there was no dose-response relationship the EC10, EC20 and EC50 for reproductive output could not be calculated. The EC50 for reproductive output is assumed as > 1000.00 mg test substance/kg soil dry weight.

A 2.4.2.1 10.4.2.1 Species level testing

No new data submitted.

A 2.4.2.2 KCP 10.4.2.2 Higher tier testing

No new data submitted.

A 2.5 KCP 10.5 Effects on soil nitrogen transformation

Comments of zRMS:	The study is considered acceptable. All validity criteria were met. • The coefficients of variation (CV) in the control group were 13.6, 2.0, 0.8, and 1.7%, after 0, 7, 14, and 28 days of incubation The validity criterion was met, because the variation between replicate controlsamples should be less than ± 15%. **Agreed endpoints:** Acetamiprid 20% SG at the concentrations corresponding to the PEC (0.347 mg/kg dry soil = 0.0694 mg of acetamiprid/kg of soil) and 5 x PEC (1.733 mg/kg dry soil = 0.3466 mg of acetamiprid/kg of soil), did not have any long-term adverse effects on the process of nitrogen transformation in aerobic surface soils.

Reference: KCP 10.5.1

Report	ACETAMIPRID 20% SG Soil Microorganisms: Nitrogen Transformation Test, 2016, G/186/15
Guideline(s):	OECD Guideline No. 216 (2000) / EU Method C.21.
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test material:	ACETAMIPRID 20% SG
Soil:	Agricultural soil collected from a place belonging to the 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). Test duration: 28 days.
Concentrations of the test material:	Control; PEC: 0.347 mg/kg dry soil (0.0694 mg of acetamiprid/kg of soil) and 5 x PEC: 1.733 mg/kg dry soil (0.3466 mg of acetamiprid/kg of soil)
Test conditions:	Temperature: 18 – 22°C, soil moisture: 46.3% – 58.1% of the maximum water holding capacity, incubation in darkness.
Endpoints:	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 days 0, 7, 14, and 28 of incubation.
Statistical analysis:	- Shapiro-Wilk's test on Normal Distribution - Levene's Test on Variance Homogenity (with Residuals) - Williams Multiple Sequential t-test

Results and discussions

The difference in the nitrate formation rate between the control soil and the one treated with the test item at the concentrations corresponding to the PEC (0.347 mg/kg dry soil = 0.0694 mg of Acetamiprid/kg of soil) and 5 x PEC (1.733 mg/kg dry soil = 0.3466 mg of Acetamiprid/kg of soil) did not exceed 25% on 28 day of analysis.

Conclusion

Under the experimental conditions, Acetamiprid 20% SG at the concentrations corresponding to the PEC (0.347 mg/kg dry soil = 0.0694 mg of acetamiprid/kg of soil) and 5 x PEC (1.733 mg/kg dry soil = 0.3466 mg of acetamiprid/kg of soil), did not have any long-term adverse effects on the process of nitrogen transformation in aerobic surface soils.

Comments of zRMS:	The study is considered acceptable. All validity criteria were met. • The coefficients of variation (CV) in the control group were 13.6, 2.0, 0.8, and 1.7%, after 0, 7, 14, and 28 days of incubation. The validity criterion was met, because the variation between replicate control samples should be less than ± 15%.

	Agreed endpoints: Acetamiprid 20% SG at the concentrations corresponding to the PEC (0.347 mg/kg of soil = 0.0694 mg of acetamiprid/kg of soil) and 5 x PEC (1.733 mg/kg of soil = 0.3466 mg of acetamiprid/kg of soil), did not have any long-term adverse effects on the process of carbon transformation in aerobic surface soils.

Reference:	KCP 10.5.2
Report	ACETAMIPRID 20% SG Soil Microorganisms: Carbon Transformation Test, 2016, G/185/15
Guideline(s):	OECD Guideline No. 217 (2000) / EU Method C.22.
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test material:	ACETAMIPRID 20% SG
Soil:	Agricultural soil taken from the area belonging to the Institute of Industrial Organic Chemistry, Branch Pszczyna.
Test design:	3 portions of soil weighing 1500 g each: one control group and two groups containing the test item. Every portion was divided into three replicates weighing 500 g each. Test duration: 28 days.
Concentrations of the test material:	Control; PEC: 0.347 mg/kg of soil (0.0694 mg of acetamiprid/kg of soil) and 5 x PEC: 1.733 mg/kg of soil (0.3466 mg of acetamiprid/kg of soil).
Test conditions:	Temperature: 18 – 22 °C, soil moisture: 42.6 – 55.0% of the maximum water holding capacity, incubation in darkness.
Statistical analysis:	in order to determine significance of differences between the control and the treated groups, the Shapiro-Wilk's Test on Normal Distribution, the Levene's Test on Variance Homogeneity, and the William's Multiple Sequential t-test were used.
Endpoints:	the mean respiration rate in the treated soil samples was compared with that in the control, and the percent deviation of the treated from the control was calculated after 0, 7, 14, and 28 days of incubation.

Results and discussions

The difference in the soil respiration rate between the control soil and the one treated with the test item at the concentrations corresponding to the PEC and 5 x PEC did not exceed 25% on any day of analysis.

Conclusion

Under the experimental conditions, Acetamiprid 20% SG at the concentrations corresponding to the PEC (0.347 mg/kg of soil = 0.0694 mg of acetamiprid/kg of soil) and 5 x PEC (1.733 mg/kg of soil = 0.3466 mg of acetamiprid/kg of soil), did not have any long-term adverse effects on the process of carbon 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 new data submitted.

A 2.6.2 KCP 10.6.2 Testing on non-target plants

Comments of zRMS:

The study is considered acceptable. All validity criteria were met.

The seedling emergence in the control was as follows:

95% – sunflower;

85% – white mustard;

90% – pea,

95% – tomato,

95% – onion,

100.0% – oats (validity criterion: at least 70%);

- the mean survival of the emerged control seedlings was 100% (validity criterion: at least 90%);

- the control seedlings did not exhibit any visible phytotoxic effects

- environmental conditions for all plants of the same species were identical

Agreed endpoints:

	Sunflower *Helianthus annuus*	White mustard *Sinapis alba*	Pea *Pisum sativum*	Tomato *Solanum lycopersicon*	Onion *Allium cepa*	Oats *Avena sativa*
Plant number at the end of the experiment						
ER_{10}	> 500.0	> 500.0	> 500.0	> 500.0	210.4	> 500.0
ER_{25}	> 500.0	> 500.0	> 500.0	> 500.0	> 500.0	> 500.0
ER_{50}	> 500.0	> 500.0	> 500.0	> 500.0	> 500.0	> 500.0
NOER	≥ 500.0	≥ 500.0	≥ 500.0	≥ 500.0	≥ 500.0	≥ 500.0
Shoot length (plants without roots)						
ER_{10}	> 500.0	> 500.0	139.8	> 500.0	> 500.0	> 500.0
ER_{25}	> 500.0	> 500.0	> 500.0	> 500.0	> 500.0	> 500.0
ER_{50}	> 500.0	> 500.0	> 500.0	> 500.0	> 500.0	> 500.0
NOER	≥ 500.0	≥ 500.0	32.0	≥ 500.0	≥ 500.0	≥ 500.0
Plant dry weight (plants without roots)						
ER_{10}	> 500.0	> 500.0	451.8	> 500.0	> 500.0	> 500.0
ER_{25}	> 500.0	> 500.0	> 500.0	> 500.0	> 500.0	> 500.0
ER_{50}	> 500.0	> 500.0	> 500.0	> 500.0	> 500.0	> 500.0
NOER	≥ 500.0	≥ 500.0	≥ 500.0	≥ 500.0	≥ 500.0	≥ 500.0

ER_{50}> 500 g a.s./ha for all tested species: (sunflower (*Helianthus annuus*), white mustard (*Sinapis alba*), pea (*Pisum sativum*), tomato (*Solanum lycopersicon*), onion (*Allium cepa*), and oats (*Avena sativa*)

Phytotoxicity:

Oats-plant damage

Application rate [g a.s./ha]	Replicate	Phytotoxic effects Day 7 Mean effects/ replicate [%]	Day 7 Mean effects/ concentration [%]	Day 14 Mean effects/ replicate [%]	Day 14 Mean effects/ concentration [%]
control	1	0	0.0	0	0.0
	2	0		0	
	3	0		0	
	4	0		0	
12.8	1	0	0.0	0	0.0
	2	0		0	
	3	0		0	
	4	0		0	
32.0	1	0	0.0	0	0.0
	2	0		0	
	3	0		0	
	4	0		0	
80.0	1	0	0.0	0	0.0
	2	0		0	
	3	0		0	
	4	0		0	
200.0	1	0	0.0	0	0.0
	2	0		0	
	3	0		0	
	4	0		0	
500.0	1	0	0.0	0	0.0
	2	0		0	
	3	0		0	
	4	0		0	

Onion-plant damage

Application rate [g a.s./ha]	Replicate	Phytotoxic effects			
		Day 7		Day 14	
		Mean effects/ replicate [%]	Mean effects/ concentration [%]	Mean effects/ replicate [%]	Mean effects/ concentration [%]
control	1	0	0.0	0	0.0
	2	0		0	
	3	0		0	
	4	0		0	
12.8	1	0	0.0	0	0.0
	2	0		0	
	3	0		0	
	4	0		0	
32.0	1	0	0.0	0	0.0
	2	0		0	
	3	0		0	
	4	0		0	
80.0	1	0	0.0	0	0.0
	2	0		0	
	3	0		0	
	4	0		0	
200.0	1	0	0.0	0	0.0
	2	0		0	
	3	0		0	
	4	0		0	
500.0	1	0	0.0	0	0.0
	2	0		0	
	3	0		0	
	4	0		0	

Tomato-plant damage

Application rate [g a.s./ha]	Replicate	Phytotoxic effects			
		Day 7		Day 14	
		Mean effects/ replicate [%]	Mean effects/ concentration [%]	Mean effects/ replicate [%]	Mean effects/ concentration [%]
control	1	0	0.0	0	0.0
	2	0		0	
	3	0		0	
	4	0		0	
12.8	1	0	0.0	0	0.0
	2	0		0	
	3	0		0	
	4	0		0	
32.0	1	0	0.0	0	0.0
	2	0		0	
	3	0		0	
	4	0		0	
80.0	1	0	0.0	0	0.0
	2	0		0	
	3	0		0	
	4	0		0	
200.0	1	0	0.0	0	0.0
	2	0		0	
	3	0		0	
	4	0		0	
500.0	1	0	0.0	0	0.0
	2	0		0	
	3	0		0	
	4	0		0	

Pea –plant damage

Application rate [g a.s./ha]	Replicate	Phytotoxic effects			
		Day 7		Day 14	
		Mean effects/ replicate [%]	Mean effects/ concentration [%]	Mean effects/ replicate [%]	Mean effects/ concentration [%]
control	1	0	0.0	0	0.0
	2	0		0	
	3	0		0	
	4	0		0	
12.8	1	0	0.0	0	0.0
	2	0		0	
	3	0		0	
	4	0		0	
32.0	1	0	0.0	0	0.0
	2	0		0	
	3	0		0	
	4	0		0	
80.0	1	0	0.0	0	0.0
	2	0		0	
	3	0		0	
	4	0		0	
200.0	1	0	0.0	0	0.0
	2	0		0	
	3	0		0	
	4	0		0	
500.0	1	0	0.0	0	0.0
	2	0		0	
	3	0		0	
	4	0		0	

White mustard – plant damage

Application rate [g a.s./ha]	Replicate	Phytotoxic effects			
		Day 7		Day 14	
		Mean effects/ replicate [%]	Mean effects/ concentration [%]	Mean effects/ replicate [%]	Mean effects/ concentration [%]
control	1	0	0.0	0	0.0
	2	0		0	
	3	0		0	
	4	0		0	
12.8	1	0	0.0	0	0.0
	2	0		0	
	3	0		0	
	4	0		0	
32.0	1	0	0.0	0	0.0
	2	0		0	
	3	0		0	
	4	0		0	
80.0	1	0	0.0	0	0.0
	2	0		0	
	3	0		0	
	4	0		0	
200.0	1	0	0.0	0	0.0
	2	0		0	
	3	0		0	
	4	0		0	
500.0	1	0	0.0	0	0.0
	2	0		0	
	3	0		0	
	4	0		0	

Sunflower- plant damage

Application rate [g a.s./ha]	Replicate	Phytotoxic effects Day 7 Mean effects/ replicate [%]	Day 7 Mean effects/ concentration [%]	Day 14 Mean effects/ replicate [%]	Day 14 Mean effects/ concentration [%]
control	1	0	0.0	0	0.0
	2	0		0	
	3	0		0	
	4	0		0	
12.8	1	0	0.0	0	0.0
	2	0		0	
	3	0		0	
	4	0		0	
32.0	1	0	0.0	0	0.0
	2	0		0	
	3	0		0	
	4	0		0	
80.0	1	0	0.0	0	0.0
	2	0		0	
	3	0		0	
	4	0		0	
200.0	1	0	0.0	0	0.0
	2	0		0	
	3	0		0	
	4	0		0	
500.0	1	0	0.0	0	0.0
	2	0		0	
	3	0		0	
	4	0		0	

Reference:	KCP 10.6.2-01
Report	ACETAMIPRID 20% SG S Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test, 2016, G/190/15
Guideline(s):	OECD Guideline No. 208 (2006)
Deviations:	Yes: The study finished on September 2016, not on June 2016 as it was planned.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test item:	ACETAMIPRID 20% SG
Test species:	sunflower (*Helianthus annuus*), white mustard (*Sinapis alba*), pea (*Pisum sativum*), tomato (*Solanum lycopersicon*), onion (*Allium cepa*), oats (*Avena sativa*)
Soil:	Sandy loam
Study design:	number of concentrations: 5 concentrations + a control number of replicates: 4 replicates of each concentration and the control number of seeds: 5 seeds/replicate
test termination:	14 days after the emergence of 50% of the control seedlings
Test concentrations:	a control; 12.8; 32.0; 80.0; 200.0, and 500.0 g a.s./ha.
Test conditions:	temperature: 21 – 27°C humidity: 58 – 77% lighting: 16 h light : 8 h dark light intensity: 4320 – 5070 lux carbon dioxide concentration: 343 – 397 ppm
Statistical analysis:	ER_{10}, ER_{25}, ER_{50} – probit analysis NOER: - survival: Multiple Sequentially-rejective Fisher Test After Bonferroni-Holm; - shoot length: Shapiro – Wilk's Test on Normal Distribution, Levene's Test on

	Variance Homogeneity (with Residuals), Multiple Sequentially-rejective Welsht-test After Bonferroni-Holm or Dunnett's Multiple t-test Procedure or Williams Multiple Sequential t-test Procedure; - shoot weight: Shapiro – Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Multiple Sequentially-rejective Median (2x2-Table) Test After Bonferroni-Holm or Williams Multiple Sequential t-test Procedure or Multiple Sequentially-rejective Welsh-t-test After Bonferroni-Holm or Dunnett's Multiple t-test Procedure
Endpoints:	ER_{25}, ER_{50}, NOER

Results and Conclusion

The test item had not an impact on the growth and seedling emergence of the test plant species.
After the application of the test item at the rates ranging from 12.8 to 500.0 g a.s./ha all test plant species, i.e., sunflower (*Helianthus annuus*), white mustard (*Sinapis alba*), pea (*Pisum sativum*), tomato (*Solanum lycopersicon*), onion (*Allium cepa*), and oats (*Avena sativa*) emerged. Shoot length and shoot weight measurements proved that the test item did not inhibit the process of growth of all test species. No phyto-toxic symptoms were observed.

The all ER_{50} were above 500.0 g a.s./ha.

ZRMS comments:

The study is considered acceptable. All validity criteria were met.

The seedling emergence was as follows:

- 92.5 – 97.5% – sunflower;
- 90.0 – 95.0% – white mustard;
- 92.5 – 97.5% – pea,
- 92.5 – 97.5% – tomato,
- 87.5 – 97.5% – onion,
- 95.0 – 100.0% – oats (validity criterion: at least 70%);
- the mean survival of the emerged control seedlings was 100% in case of all species

(validitycriterion: at least 90%),

- the control seedlings did not exhibit any visible phytotoxic symptoms,
- environmental conditions for all plants belonging to the same species were identical

Agreed endpoints:

ER_{10}, ER_{25}, ER_{50} amd NOER (g a.s./ha)

	Sunflower *Helianthus annuus*	White mustard *Sinapis alba*	Pea *Pisum sativum*	Tomato *Solanum lycopersicon*	Onion *Allium cepa*	Oats *Avena sativa*
Plant number at the end of the experiment						
ER_{10}	> 500,0	> 500,0	> 500,0	> 500,0	> 500,0	> 500,0
ER_{25}	> 500,0	> 500,0	> 500,0	> 500,0	> 500,0	> 500,0
ER_{50}	> 500,0	> 500,0	> 500,0	> 500,0	> 500,0	> 500,0
NOER	≥ 500,0	≥ 500,0	≥ 500,0	≥ 500,0	≥ 500,0	≥ 500,0
Shoot length (plants without roots)						
ER_{10}	> 500,0	> 500,0	> 500,0	12,8	> 500,0	> 500,0
ER_{25}	> 500,0	> 500,0	> 500,0	> 500,0	> 500,0	> 500,0
ER_{50}	> 500,0	> 500,0	> 500,0	> 500,0	> 500,0	> 500,0
NOER	≥ 500,0	≥ 500,0	≥ 500,0	12,8	≥ 500,0	≥ 500,0
Plant dry weight (plants without roots)						
ER_{10}	> 500,0	106,9	> 500,0	> 500,0	> 500,0	26,2 (0,2 – 71,7)
ER_{25}	> 500,0	> 500,0	> 500,0	> 500,0	> 500,0	222,3 (88,9 – 960,2*)
ER_{50}	> 500,0	> 500,0	> 500,0	> 500,0	> 500,0	> 500,0
NOER	≥ 500,0	≥ 500,0	≥ 500,0	≥ 500,0	≥ 500,0	12,8

The ER_{10}, ER_{25}, ER_{50} and NOER values were calculated using the ToxRat Professional computer software
*The calculated value lies outside the tested rates range and has to be treated with caution

ER_{50}> 500 g a.s./ha for all tested species: (sunflower (*Helianthus annuus*), white mustard (*Sinapis alba*), pea (*Pisum sativum*), tomato (*Solanum lycopersicon*), onion (*Allium cepa*), and oats (*Avena sativa*)

Phytotoxicity:

Pea – plant damage

Application rate [g a.s./ha]	Replicate	Phytotoxic effects					
		Day 7		Day 14		Day 21	
		Mean effects/ replicate [%]	Mean effects/ application rate [%]	Mean effects/ replicate [%]	Mean effects/ application rate [%]	Mean effects/ replicate [%]	Mean effects/ replicate [%]
control	1	0	0.0	0	0.0	0	0.0
	2	0		0		0	
	3	0		0		0	
	4	0		0		0	
12.8	1	0	0.0	0	0.0	0	0.0
	2	0		0		0	
	3	0		0		0	
	4	0		0		0	
32.0	1	0	0.0	0	0.0	0	0.0
	2	0		0		0	
	3	0		0		0	
	4	0		0		0	
80.0	1	0	0.0	0	0.0	0	0.0
	2	0		0		0	
	3	0		0		0	
	4	0		0		0	
200.0	1	0	0.0	0	0.0	0	0.0
	2	0		0		0	
	3	0		0		0	
	4	0		0		0	
500.0	1	0	0.0	0	0.0	0	0.0
	2	0		0		0	
	3	0		0		0	
	4	0		0		0	

White mustard-plant damage

Application rate [g a.s./ha]	Replicate	Phytotoxic effects					
		Day 7		Day 14		Day 21	
		Mean effects/ replicate [%]	Mean effects/ application rate [%]	Mean effects/ replicate [%]	Mean effects/ application rate [%]	Mean effects/ replicate [%]	Mean effects/ replicate [%]
control	1	0	0.0	0	0.0	0	0.0
	2	0		0		0	
	3	0		0		0	
	4	0		0		0	
12.8	1	0	0.0	0	0.0	0	0.0
	2	0		0		0	
	3	0		0		0	
	4	0		0		0	
32.0	1	0	0.0	0	0.0	0	0.0
	2	0		0		0	
	3	0		0		0	
	4	0		0		0	
80.0	1	0	0.0	0	0.0	0	0.0
	2	0		0		0	
	3	0		0		0	
	4	0		0		0	
200.0	1	0	0.0	0	0.0	0	0.0
	2	0		0		0	
	3	0		0		0	
	4	0		0		0	
500.0	1	0	0.0	0	0.0	0	0.0
	2	0		0		0	
	3	0		0		0	
	4	0		0		0	

Sunflower-plant damage

Application rate [g a.s./ha]	Replicate	Phytotoxic effects					
		Day 7		Day 14		Day 21	
		Mean effects/ replicate [%]	Mean effects/ application rate [%]	Mean effects/ replicate [%]	Mean effects/ application rate [%]	Mean effects/ replicate [%]	Mean effects/ replicate [%]
control	1	0	0.0	0	0.0	0	0.0
	2	0		0		0	
	3	0		0		0	
	4	0		0		0	
12.8	1	0	0.0	0	0.0	0	0.0
	2	0		0		0	
	3	0		0		0	
	4	0		0		0	
32.0	1	0	0.0	0	0.0	0	0.0
	2	0		0		0	
	3	0		0		0	
	4	0		0		0	
80.0	1	0	0.0	0	0.0	0	0.0
	2	0		0		0	
	3	0		0		0	
	4	0		0		0	
200.0	1	0	0.0	0	0.0	0	0.0
	2	0		0		0	
	3	0		0		0	
	4	0		0		0	
500.0	1	0	0.0	0	0.0	0	0.0
	2	0		0		0	
	3	0		0		0	
	4	0		0		0	

Tomato:

Application rate [g a.s./ha]	Replicate	Phytotoxic effects					
		Day 7		Day 14		Day 21	
		Mean effects/ replicate [%]	Mean effects/ application rate [%]	Mean effects/ replicate [%]	Mean effects/ application rate [%]	Mean effects/ replicate [%]	Mean effects/ replicate [%]
control	1	0	0.0	0	0.0	0	0.0
	2	0		0		0	
	3	0		0		0	
	4	0		0		0	
12.8	1	0	0.0	0	0.0	0	0.0
	2	0		0		0	
	3	0		0		0	
	4	0		0		0	
32.0	1	0	0.0	0	0.0	0	0.0
	2	0		0		0	
	3	0		0		0	
	4	0		0		0	
80.0	1	0	0.0	0	0.0	0	0.0
	2	0		0		0	
	3	0		0		0	
	4	0		0		0	
200.0	1	0	0.0	0	0.0	0	0.0
	2	0		0		0	
	3	0		0		0	
	4	0		0		0	
500.0	1	0	0.0	0	0.0	0	0.0
	2	0		0		0	
	3	0		0		0	
	4	0		0		0	

Onion-plant damage

Application rate [g a.s./ha]	Replicate	Phytotoxic effects					
		Day 7		Day 14		Day 21	
		Mean effects/ replicate [%]	Mean effects/ application rate [%]	Mean effects/ replicate [%]	Mean effects/ application rate [%]	Mean effects/ replicate [%]	Mean effects/ replicate [%]
control	1	0	0.0	0	0.0	0	0.0
	2	0		0		0	
	3	0		0		0	
	4	0		0		0	
12.8	1	0	0.0	0	0.0	0	0.0
	2	0		0		0	
	3	0		0		0	
	4	0		0		0	
32.0	1	0	0.0	0	0.0	0	0.0
	2	0		0		0	
	3	0		0		0	
	4	0		0		0	
80.0	1	0	0.0	0	0.0	0	0.0
	2	0		0		0	
	3	0		0		0	
	4	0		0		0	
200.0	1	0	0.0	0	0.0	0	0.0
	2	0		0		0	
	3	0		0		0	
	4	0		0		0	
500.0	1	0	0.0	0	0.0	0	0.0
	2	0		0		0	
	3	0		0		0	
	4	0		0		0	

Oats-plant damage

Application rate [g a.s./ha]	Replicate	Phytotoxic effects					
		Day 7		Day 14		Day 21	
		Mean effects/ replicate [%]	Mean effects/ application rate [%]	Mean effects/ replicate [%]	Mean effects/ application rate [%]	Mean effects/ replicate [%]	Mean effects/ replicate [%]
control	1	0	0.0	0	0.0	0	0.0
	2	0		0		0	
	3	0		0		0	
	4	0		0		0	
12.8	1	0	0.0	0	0.0	0	0.0
	2	0		0		0	
	3	0		0		0	
	4	0		0		0	
32.0	1	0	0.0	0	0.0	0	0.0
	2	0		0		0	
	3	0		0		0	
	4	0		0		0	
80.0	1	0	0.0	0	0.0	0	0.0
	2	0		0		0	
	3	0		0		0	
	4	0		0		0	
200.0	1	0	0.0	5	2.5	10	10.0
	2	0		0		10	
	3	0		5		10	
	4	0		0		10	
500.0	1	5	3.5	10	10.0	15	15.3
	2	2		10		14	
	3	5		10		15	
	4	2		10		17	

Reference: KCP 10.6.2-02

Report ACETAMIPRID 20% SG S Terrestrial Plant Test: Vegetative Vigour Test, 2016, G/191/15

Guideline(s): OECD Guideline No. 227 (2006)

Deviations: Yes: The study finished on September 2016, not on June 2016 as it was planned.

GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test item:	ACETAMIPRID 20% SG
Test species:	sunflower (*Helianthus annuus*), white mustard (*Sinapis alba*), pea (*Pisum sativum*), tomato (*Solanum lycopersicon*), onion (*Allium cepa*), oats (*Avena sativa*)
Soil:	Loam
Study design:	number of rates: 5 application rates + control; number of replicates: 4 replicates/rate and 4 replicates/control; number of seeds: 5 seeds/replicate test termination: 21 days after the spraying;
Test concentrations:	a control; 12.8; 32.0; 80.0; 200.0, and 500.0 g a.s./ha. 400 L water/ha
Test conditions:	temperature: 21 – 28°C; humidity: 53 – 77%; lighting: 16 hours light : 8 hours dark; light intensity: 4320 – 5090 lux; carbon dioxide concentration: 349 – 393 ppm
Statistical analysis:	ER_{10}, ER_{25}, ER_{50} – probit analysis NOER: - shoot length - Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Williams Multiple Sequential t-test Procedure; - shoot weight – Shapiro – Wilk's on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Williams Multiple-Sequential t-test Procedure
Endpoints:	ER_{25}, ER_{50}, NOER

Results and Conclusion

The test item, i.e. ACETAMIPRID 20% SG had not an impact on vegetative vigour of the test plant species. The test item did not cause mortality of all test species.

The all ER_{50} value was above the highest application rate equal to 500.0 g a.s./ha. Dry weight measurements proved that the test item inhibited the process of growth of oats. Shoot length and dry weight measurements proved that the test item did not inhibit the process of growth of sunflower, white mustard, pea, tomato, and onion. Wiltings of oats was observed. No phytotoxic symptoms of other test species were observed.

A 2.6.3 KCP 10.6.3 Extended laboratory studies on non-target plants

No new data submitted.

A 2.7 KCP 10.7 Effects on other terrestrial organisms (flora and fauna)

No new data submitted.

A 2.8 KCP 10.8 Monitoring data

No new data submitted.