

FINAL REGISTRATION REPORT

Part B

Section 9

Ecotoxicology

Detailed summary of the risk assessment

Product code: Acetamipryd 200 SL

Product name(s): -

Chemical active substance:

acetamiprid, 200 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Pestila Sp. z o.o. / Proagri International Sp. z o.o.

Submission date: March 2024

MS Finalisation date: 04.2025; 08.2025; 02.2026

Acetamipryd 200 SL
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Applicant version

Version history

When	What
April 2025	Assessment by zRMS
August 2025	The final Registration Report after the reporting period.
January 2026	Update on Ministry request
February 2026	Assessment new data by z RMS

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9 Ecotoxicology (KCP 10)

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9.1 Critical GAP and overall conclusions

Table 9.1-1: Table of critical GAPs

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Use- No. *	Member state(s)	Crop and/or sit- uation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g saf- ener/ syn- ergist per ha	Conclusion						
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between appli- cations (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 arthro- pods	Soil organisms	Non-target plants
Zonal uses (field or outdoor uses, certain types of protected crops)																				
1	PL	Winter oilseed rape	F	Rape stem weevil (<i>Ceutorhynchus napi</i>) CEUTNA Cabbage stem weevil (<i>Ceutorhynchus palli- dactylus</i>) CEUTQU	broad- cast spraying	BBCH 30-50 Spring, post emergence	1 a) 1 b) 1	N/A	0.25 L/ha a) 0.25 L/ha b) 0.25 L/ha	50 g/ha a) 50 g/ha b) 50 g/ha	200-400 L/ha	N/A	not relevant							
2	PL	Winter oilseed rape	F	Pollen beetle (<i>Bras- sicogethes aeneus</i>) MELIAE	broad- cast spraying	BBCH 50-65 Spring, post emergence	1 a) 1 b) 1	N/A	0.1-0.12 L/ha a) 0.12 L/ha b) 0.12 L/ha	20-24 g /ha a) 24 g /ha b) 24 g /ha	200-400 L/ha	N/A	not relevant							
3	PL	Winter oilseed rape	F	Cabbage seed weevil (<i>Ceutorhynchus ob- strictus</i>) CEUTAS Brassica pod midge (<i>Dasineura brassicae</i>) DASYBR	broad- cast spraying	BBCH 60-69 Spring, post emergence	1 a) 1 b) 1	N/A	0.1-0.12 L/ha a) 0.12 L/ha b) 0.12 L/ha	20-24 g /ha a) 24 g /ha b) 24 g /ha	200-400 L/ha	N/A	not relevant							
4	PL	Potato	F	Colorado beetle (<i>Leptinotarsa decem- lineata</i>) LPTNDE	broad- cast spraying	BBCH 35-75 Spring, post emergence	1 a) 1 b) 1	N/A	0.08-0.12 L/ha a) 0.12 L/ha b) 0.12 L/ha	16-24 g /ha a) 24 g /ha b) 24 g /ha	200-400 L/ha	3	not relevant							
5	PL	Apple	F	Tortix moths (<i>Tortri- cidae sp</i>) TORTSP	broad- cast spraying	BBCH 71-84 Spring, post emergence	2 a) 1 b) 2	7 days	0.118 L/10000m2 LWA	23.6 g/10000m2 LWA	500-900 L/ha	14	Max. 2 x 0.125 L/ha (2 x 25							

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1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
									a) 0.118 L/10000m2 LWA b) 0.236 L/10000m2 LWA	a) 23.6 g/10000m2 LWA b) 47.2 g/10000m2 LWA			g/ha) 10600 LWA							
6	PL	Apple	F	Codling moth (<i>Cydia pomonella</i>) CARPPO	broad-cast spraying	BBCH 71-84 Spring, post emergence	2 a) 1 b) 2	7 days	0.118 L/10000m2 LWA a) 0.118 L/10000m2 LWA b) 0.236 L/10000m2 LWA	23.6 g/10000m2 LWA a) 23.6 g/10000m2 LWA b) 47.2 g/10000m2 LWA	500-900 L/ha	14	Max. 2 x 0.125 L/ha (2 x 25 g/ha) 10600 LWA							
7	PL	Apple	F	Apple sawfly (<i>Hoplocampa testudinea</i>) HOPLTE	broad-cast spraying	BBCH 65-69 Spring, post emergence	1 a) 1 b) 1	N/A	0.073 L/10000m2 LWA a) 0.073 L/10000m2 LWA b) 0.073 L/10000m2 LWA	14.6 g/10000m2 LWA a) 14.6 g/10000m2 LWA b) 14.6 g/10000m2 LWA	500-900 L/ha	14	max. 0.11 L/ha (22 g as/ha) 15000LWA							
8	PL	Apple	F	Aphids (<i>Aphididae</i>) – APXXSP	broad-cast spraying	BBCH 56-84 Spring, post emergence	1 a) 1 b) 1	N/A	0.073 L/10000m2 LWA a) 0.073 L/10000m2 LWA b) 0.073 L/10000m2 LWA	14.6 g/10000m2 LWA a) 14.6 g/10000m2 LWA b) 14.6 g/10000m2 LWA	500-900 L/ha	14	max. 0.11 L/ha (22 g as/ha) 15000LWA							
9	PL	Apple	F	Apple woolly aphid (<i>Eriosoma lanigerum</i>) ERISLA	broad-cast spraying	BBCH 56-84 Spring, post emergence	1 a) 1 b) 1	N/A	0.118 L/10000m2 LWA	23.6 g/10000m2 LWA	500-900 L/ha	14	max. 0.18 L/ha (36 g as/ha) 15000LWA							

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1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
									a) 0.118 L/10000m2 LWA b) 0.118 L/10000m2 LWA	a) 23.6 g/10000m2 LWA b) 23.6 g/10000m2 LWA										
Minor uses according to Article 51 (field uses)																				
10	PL	Spring oilseed rape, Turnip rape		Pollen beetle (<i>Meligethes aeneus</i>) ME-LIAE	Foliar spray	BBCH 50-65 Spring, post emergence	1 a) 1 b) 1	N/A	0.1-0.12 L/ha a) 0.12 L/ha b) 0.12 L/ha	20-24 g /ha a) 24 g /ha b) 24 g /ha	200-400 L/ha	14	not relevant							
11	PL	Spring oilseed rape, Turnip rape	F	Rape stem weevil (<i>Ceutorhynchus napi</i>) –CEUTNA Cabbage stem weevils (<i>Ceutorhynchus palli-dactylus</i>) – CEUTQU	Foliar spray	BBCH 30-50 Spring, post emergence	1 a) 1 b) 1	N/A	0.25 L/ha a) 0.25 L/ha b) 0.25 L/ha	50 g/ha a) 50 g/ha b) 50 g/ha	200-400 L/ha	14	not relevant							
12	PL	Spring oilseed rape, Turnip rape	F	Brassica pod midge (<i>Dasyneura brassicae</i>)- DASYBR Cabbage seed weevil (<i>Ceutorhynchus obstrictus</i>) – CEUTAS	Foliar spray	BBCH 59-71 Spring, post emergence	1 a) 1 b) 1	N/A	0.3 l/ha a) 0.3 l/ha b) 0.3 l/ha	60 g/ha a) 60 g/ha b) 60 g/ha	200-400 L/ha	14	not relevant							
13	PL	Flax- fiber production	F	Cabbage thrips (<i>Thripsangusticeps</i>) - THRIAN; Flax thrips (<i>Thrips lini</i>) - THRILI	Foliar spray	After reaching thresholds or after warning service appeal BBCH 30-61	1 a) 1 b) 1	N/A	0.3 l/ha a) 0.3 l/ha b) 0.3 l/ha	60 g/ha a) 60 g/ha b) 60 g/ha	200-400 L/ha	N/A	not relevant							
14	PL	Common hemp - fiber production	F	Aphids (<i>Aphididae</i>) – APXXSP; Thrips (<i>Thysanoptera</i>) - 1THYSO	Foliar spray	After reaching thresholds or after warning service appeal BBCH 39-59	1 a) 1 b) 1	N/A	0.3 l/ha a) 0.3 l/ha b) 0.3 l/ha	60 g/ha a) 60 g/ha b) 60 g/ha	200-400 L/ha	N/A	not relevant							

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15	PL	Wild apple	F	Aphids (<i>Aphididae</i>) – APXXSP	Foliar spray	BBCH 56-84 Spring, post emergence	1 a) 1 b) 1	N/A	0.073 L/10000m ² LWA a) 0.073 L/10000m ² LWA b) 0.073 L/10000m ² LWA	14.6 g/10000m ² LWA a) 14.6 g/10000m ² LWA b) 14.6 g/10000m ² LWA	500-900 L/ha	14	max. 0.11 L/ha (22 g as/ha) 15000 LWA							
16	PL	Wild apple	F	Codling moth (<i>Cydia pomonella</i>) - CARPPO	Foliar spray	BBCH 71-84 Spring, post emergence	2 a) 1 b) 2	7 days	0.118 L/10000m ² LWA a) 0.118 L/10000m ² LWA b) 0.236 L/10000m ² LWA	23.6 g/10000m ² LWA a) 23.6 g/10000m ² LWA b) 47.2 g/10000m ² LWA	500-900 L/ha	14	Max. 2 x 0.125 L/ha (2 x 25 g/ha) 10600 LWA							
17	PL	Wild apple	F	Pear leaf blister moth (<i>Leucoptera scitella</i>) -LEUCSC	Foliar spray	BBCH 57-69 Spring, post emergence	1 a) 1 b) 1	N/A	0.073 L/10000m ² LWA a) 0.073 L/10000m ² LWA b) 0.073 L/10000m ² LWA	14.6 g/10000m ² LWA a) 14.6 g/10000m ² LWA b) 14.6 g/10000m ² LWA	500-900 L/ha	14	max. 0.11 L/ha (22 g as/ha) 15000 LWA							
18	PL	Wild apple	F	Apple fruit sawfly (<i>Hoplocampa testudinea</i>) - HOPLTE	Foliar spray	BBCH 65-69 Spring, post emergence	1 a) 1 b) 1	N/A	0.073 L/10000m ² LWA a) 0.073 L/10000m ² LWA b) 0.073 L/10000m ² LWA	14.6 g/10000m ² LWA a) 14.6 g/10000m ² LWA b) 14.6 g/10000m ² LWA	500-900 L/ha	14	max. 0.11 L/ha (22 g as/ha) 15000 LWA							

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19	PL	Wild apple	F	Apple leaf midge (<i>Dasineura mali</i>) - DASYMA	Foliar spray	BBCH 59-73 Spring, post emergence	2 a) 1 b) 2	7 days	0.083 L/10000m ² LWA a) 0.083 L/10000m ² LWA b) 1.66 L/10000m ² LWA	16.6 g/10000m ² LWA a) 16.6 g/10000m ² LWA b) 33.2 g/10000m ² LWA	500-900 L/ha	14	Max. 2 x 0.11 L/ha (2 x 22 g/ha) 13000 LWA							
20	PL	Wild apple	F	Bracken clock (<i>Phyllopertha horticola</i>) - PHPHHO	Foliar spray	BBCH 59-73 Spring, post emergence	1 a) 1 b) 1	N/A	0.073 L/10000m ² LWA a) 0.073 L/10000m ² LWA b) 0.073 L/10000m ² LWA	14.6 g/10000m ² LWA a) 14.6 g/10000m ² LWA b) 14.6 g/10000m ² LWA	500-900 L/ha	14	max. 0.11 L/ha (22 g as/ha) 15000 LWA							
21	PL	Pear, Chinese pear	F	Aphids (<i>Aphididae</i>) – APXXSP	Foliar spray	BBCH 56-84 Spring, post emergence	1 a) 1 b) 1	N/A	0.073 L/10000m ² LWA a) 0.073 L/10000m ² LWA b) 0.073 L/10000m ² LWA	14.6 g/10000m ² LWA a) 14.6 g/10000m ² LWA b) 14.6 g/10000m ² LWA	500-900 L/ha	14	max. 0.11 L/ha (22 g as/ha) 15000 LWA							
22	PL	Pear, Chinese pear	F	Tortix moths (<i>Tortricidae sp</i>) TORTSP	Foliar spray	BBCH 71-84 Spring, post emergence	2 a) 1 b) 2	7 days	0.118 L/10000m ² LWA a) 0.118 L/10000m ² LWA b) 0.236 L/10000m ² LWA	23.6 g/10000m ² LWA a) 23.6 g/10000m ² LWA b) 47.2 g/10000m ² LWA	500-900 L/ha	14	Max. 2 x 0.125 L/ha (2 x 25 g/ha) 10600 LWA							

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23	PL	Pear, Chinese pear	F	Codling moth (<i>Cydia pomonella</i>) CARPPO	Foliar spray	BBCH 71-84 Spring, post emergence	2 a) 1 b) 2	7 days	0.118 L/10000m2 LWA a) 0.118 L/10000m2 LWA b) 0.236 L/10000m2 LWA	23.6 g/10000m2 LWA a) 23.6 g/10000m2 LWA b) 47.2 g/10000m2 LWA	500-900 L/ha	14	Max. 2 x 0.125 L/ha (2 x 25 g/ha) 10600 LWA							
24	PL	Pear, Chinese pear	F	Cherry slug saw- fly (<i>Caliroa limacina</i>) - ERICLI	Foliar spray	BBCH 71-84 Spring, post emergence	1 a) 1 b) 1	N/A	0.118 L/10000m2 LWA a) 0.118 L/10000m2 LWA b) 0.118 L/10000m2 LWA	23.6 g/10000m2 LWA a) 23.6 g/10000m2 LWA b) 23.6 g/10000m2 LWA	500-900 L/ha	14	max. 0.135 L/ha (27 g as/ha) 11500LWA							
25	PL	Pear, Chinese pear	F	Pear leaf midge (<i>Dasineura pyri</i>) - DASYPY	Foliar spray	BBCH 71-84 Spring, post emergence	2 a) 1 b) 2	7 days	0.118 L/10000m2 LWA a) 0.118 L/10000m2 LWA b) 0.236 L/10000m2 LWA	23.6 g/10000m2 LWA a) 23.6 g/10000m2 LWA b) 47.2 g/10000m2 LWA	500-900 L/ha	14	Max. 2 x 0.125 L/ha (2 x 25 g/ha) 10600 LWA							
26	PL	Pear, Chinese pear	F	Apple bud weevil (<i>Anthonomus piri</i>) - ANTHPY	Foliar spray	BBCH 51-59 Spring, post emergence	1 a) 1 b) 1	N/A	0.083 L/10000m2 LWA a) 0.083 L/10000m2 LWA b) 0.083 L/10000m2 LWA	16.6 g/10000m2 LWA a) 16.6 g/10000m2 LWA b) 16.6 g/10000m2 LWA	500-900 L/ha	14	max. 0.125 L/ha (25 g as/ha) 15000LWA							
27	PL	Pear, Chinese pear		Pear psylla (<i>Cacopsylla pyri</i>) - PSYLPI;	Foliar spray	BBCH 51-71 Spring, post emergence	2 a) 1 b) 2	7 days	0.083 L/10000m2 LWA	16.6 g/10000m2 LWA	500-900 L/ha	14	Max. 2 x 0.11 L/ha (2 x 22							

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				Pear sucker (<i>Cacopsylla pyrisuga</i>) - PSYLPY; Pear psyllid (<i>Cacopsylla pyricola</i>) - PSYLPC					a) 0.083 L/10000m2 LWA b) 1.66 L/10000m2 LWA	a) 16.6 g/10000m2 LWA b) 33.2 g/10000m2 LWA			g/ha) 13000 LWA							
28	PL	Quince, Medlar	F	Aphids (<i>Aphididae</i>) – APXXSP	Foliar spray	BBCH 56-84 Spring, post emergence	1 a) 1 b) 1	N/A	0.073 L/10000m2 LWA a) 0.073 L/10000m2 LWA b) 0.073 L/10000m2 LWA	14.6 g/100N/A00m2 LWA a) 14.6 g/10000m2 LWA b) 14.6 g/10000m2 LWA	500-900 L/ha	14	max. 0.11 L/ha (22 g as/ha) 15000LWA							
29	PL	Quince, Medlar	F	Codling moth (<i>Cydia pomonella</i>) CARPPO	Foliar spray	BBCH 71-84 Spring, post emergence	2 a) 1 b) 2	7 days	0.118 L/10000m2 LWA a) 0.118 L/10000m2 LWA b) 0.236 L/10000m2 LWA	23.6 g/10000m2 LWA a) 23.6 g/10000m2 LWA b) 47.2 g/10000m2 LWA	500-900 L/ha	14	Max. 2 x 0.125 L/ha (2 x 25 g/ha) 10600 LWA							
30	PL	Plum	F	Aphids (<i>Aphididae</i>) – APXXSP	Foliar spray	BBCH 56-84 Spring, post emergence	1 a) 1 b) 1	N/A	0.073 L/10000m2 LWA a) 0.073 L/10000m2 LWA b) 0.073 L/10000m2 LWA	14.6 g/1N/A0000m2 LWA a) 14.6 g/10000m2 LWA b) 14.6 g/10000m2 LWA	500-900 L/ha	14	max. 0.11 L/ha (22 g as/ha) 15000LWA							
31	PL	Plum	F	Plum fruit sawfly (<i>Hoplocampa minuta</i>) -HOPLMI; Plum sawfly (<i>Hop- locampa flava</i>) -	Foliar spray	BBCH 69-84	1 a) 1 b) 1	N/A	0.073 L/10000m2 LWA	14.6 g/10000m2 LWA	500-900 L/ha	14	max. 0.11 L/ha (22 g as/ha) 15000LWA							

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1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
				HOPFLFL					a) 0.073 L/10000m2 LWA b) 0.073 L/10000m2 LWA	a) 14.6 g/10000m2 LWA b) 14.6 g/10000m2 LWA										
32	PL	Plum	F	Plum fruit moth (<i>Laspeyresia fune- brana</i>) - LASPFU	Foliar spray	BBCH 71-81 Spring, post emergence	2 a) 1 b) 2	7 days	0.118 L/10000m2 LWA a) 0.118 L/10000m2 LWA b) 0.236 L/10000m2 LWA	23.6 g/10000m2 LWA a) 23.6 g/10000m2 LWA b) 47.2 g/10000m2 LWA	500-900 L/ha	14	Max. 2 x 0.125 L/ha (2 x 25 g/ha) 10600 LWA							
33	PL	Plum	F	European brown scale (<i>Parthenoleca- nium corni</i>) - LECACO	Foliar spray	BBCH 56-59	1 a) 1 b) 1	N/A	0.073 L/10000m2 LWA a) 0.073 L/10000m2 LWA b) 0.073 L/10000m2 LWA	14.6 g/10000m2 LWA a) 14.6 g/10000m2 LWA b) 14.6 g/10000m2 LWA	500-900 L/ha	14	max. 0.11 L/ha (22 g as/ha) 15000LWA							
34	PL	Plum	F	Apple brown tortrix (<i>Pandemis heparana</i>) -PANDHE; Reticu- lated tortrix (<i>Adox- ophyes orana</i>) - CAPURE; European leaf roller (<i>Archips rosana</i>) - CACORO; Whelk (<i>Tortricidae</i>) - 1TORTF; and other leaf caterpillars	Foliar spray	BBCH 51-87	2 a) 1 b) 2	7 days	0.083 L/10000m2 LWA a) 0.083 L/10000m2 LWA b) 1.66 L/10000m2 LWA	16.6 g/10000m2 LWA a) 16.6 g/10000m2 LWA b) 33.2 g/10000m2 LWA	500-900 L/ha	14	Max. 2 x 0.11 L/ha (2 x 22 g/ha) 13000 LWA							

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1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
35	PL	Peach Nectarine Apricot	F	Aphids (<i>Aphididae</i>) – APXXSP	Foliar spray	BBCH 56-84 Spring, post emergence	1 a) 1 b) 1	N/A	0.073 L/10000m2 LWA a) 0.073 L/10000m2 LWA b) 0.073 L/10000m2 LWA	14.6 g/10000m2 LWA a) 14.6 g/10000m2 LWA b) 14.6 g/10000m2 LWA	500-900 L/ha	14	max. 0.11 L/ha (22 g as/ha) 15000LWA							
36	PL	Peach Nectarine Apricot	F	Apple brown tortrix (<i>Pandemis heparana</i>) -PANDHE; Reticu- lated tortrix (<i>Adox- ophyes orana</i>) - CAPURE; European leaf roller (<i>Archips ro- sana</i>) - CACORO; Whelk (<i>Tortricidae</i>) - 1TORTF; and other leafcaterpillars	Foliar spray	BBCH 51-65	2 a) 1 b) 2	7 days	0.083 L/10000m2 LWA a) 0.083 L/10000m2 LWA b) 1.66 L/10000m2 LWA	16.6 g/10000m2 LWA a) 16.6 g/10000m2 LWA b) 33.2 g/10000m2 LWA	500-900 L/ha	14	Max. 2 x 0.11 L/ha (2 x 22 g/ha) 13000 LWA							
37	PL	Sour cherry, sweet cherry	F	Aphids (<i>Aphididae</i>) – APXXSP	Foliar spray	BBCH 56-84 Spring, post emergence	1 a) 1 b) 1	N/A	0.073 L/10000m2 LWA a) 0.073 L/10000m2 LWA b) 0.073 L/10000m2 LWA	14.6 g/10000m2 LWA a) 14.6 g/10000m2 LWA b) 14.6 g/10000m2 LWA	500-900 L/ha	14	max. 0.11 L/ha (22 g as/ha) 15000LWA							
38	PL	Sour cherry, sweet cherry	F	Cherry fruit moth (<i>Argyresthia ephip- piella</i>) - ARGYEP	Foliar spray	BBCH 51-59	1 a) 1 b) 1	N/A	0.083 L/10000m2 LWA a) 0.083 L/10000m2 LWA b) 0.083 L/10000m2 LWA	16.6 g/10000m2 LWA a) 16.6 g/10000m2 LWA b) 16.6 g/10000m2 LWA	500-900 L/ha	14	max. 0.125 L/ha (25 g as/ha) 15000LWA							

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1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
39	PL	Sour cherry, sweet cherry	F	Cherry-stone weevil (<i>Anthonomus rectirostris</i>) - ANTHRE	Foliar spray	BBCH 57-65 Spring, post emergence	1 a) 1 b) 1	N/A	0.073 L/10000m2 LWA a) 0.073 L/10000m2 LWA b) 0.073 L/10000m2 LWA	14.6 g/10000m2 LWA a) 14.6 g/10000m2 LWA b) 14.6 g/10000m2 LWA	500-900 L/ha	14	max. 0.11 L/ha (22 g as/ha) 15000LWA							
40	PL	Sweet Cherry Sour Cherry	F	Apple brown tortrix (<i>Pandemis heparana</i>) - PANDHE; Reticulated tortrix (<i>Adoxophyes orana</i>) - CAPURE; European leaf roller (<i>Archips rosana</i>) - CACORO; Whelk (<i>Tortricidae</i>) - 1TORTF; and other leafcaterpillars	Foliar spray	BBCH 51-65	2 a) 1 b) 2	7 days	0.083 L/10000m2 LWA a) 0.083 L/10000m2 LWA b) 1.66 L/10000m2 LWA	16.6 g/10000m2 LWA a) 16.6 g/10000m2 LWA b) 33.2 g/10000m2 LWA	500-900 L/ha	14	Max. 2 x 0.11 L/ha (2 x 22 g/ha) 13000 LWA							
41	PL	Tomato	G	Glasshouse white- fly (<i>Trialeurodes vaporariorum</i>) – TRIAVA;	Foliar spray	BBCH 20-89	1	N/A	0.30 L/ha	60g/ha	300-750 L/ha	3	not relevant							
42	PL	Aubergine/egg-plant	G	Common cotton thrips (<i>Thrips tabaci</i>) – THRITB;	Foliar spray	BBCH 20-89	1	N/A	0.30 L/ha	60g/ha	300-750 L/ha	3	not relevant							
43	PL	Pepper	G	Western grass thrips (<i>Frankliniella occidentalis</i>) - FRANOC; Leaf miner (<i>Phytomyza sp.</i>) -PHYYPSP; Aphids (<i>Aphididae</i>) – APXXSP; Lygus bug (<i>Lygus sp.</i>) - LYGUSP; Flea beetle (<i>Psyllides</i>) - IPSYIG	Foliar spray	BBCH 20-89	1	N/A	0.30 L/ha	60g/ha	300-750 L/ha	3	not relevant							

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1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
44	PL	Walnuts	F	Aphids (<i>Aphididae</i>) – APXXSP	Foliar spray	BBCH 51-65	2 a) 1 b) 2	10 days	0.083 L/10000m2 LWA a) 0.083 L/10000m2 LWA b) 1.66 L/10000m2 LWA	16.6 g/10000m2 LWA a) 16.6 g/10000m2 LWA b) 33.2 g/10000m2 LWA	500-900 L/ha	14	Max. 2 x 0.11 L/ha (2 x 22 g/ha) 13000 LWA							
45	PL	Hazelnuts	F	Aphids (<i>Aphididae</i>) – APXXSP; , Hazelnut weevil (<i>Curculio nucum</i>) - CURCNU; (<i>Oberea linearis</i>) - OBERLI; European brown scale (<i>Parthenolecanium corni</i>) - LECACO; , Reticulated tortrix (<i>Adoxophyes orana</i>) - CAPURE; European leaf roller (<i>Archips rosana</i>) - CACORO; other tortrix and other leaf caterpillars	Foliar spray	BBCH 51-65	2 a) 1 b) 2	7 days	0.083 L/10000m2 LWA a) 0.083 L/10000m2 LWA b) 1.66 L/10000m2 LWA	16.6 g/10000m2 LWA a) 16.6 g/10000m2 LWA b) 33.2 g/10000m2 LWA	500-900 L/ha	14	Max. 2 x 0.11 L/ha (2 x 22 g/ha) 13000 LWA							
46	PL	Common osier, Purple willow	F	Aphids (<i>Aphididae</i>) – APXXSP, Balsam poplar leaf beetle (<i>Chrysomela populi</i>) - CHRSPQ; (<i>Chrysomelasaliceti</i>)- CHRSSA, Blue willow beetle (<i>Phratora vulgatissima</i>) - PHRRVU; Brassy willow leaf beetle (<i>Phratora vitellinae</i>) -	Foliar spray	BBCH 51-69	2 a) 1 b) 2	7 days	0.083 L/10000m2 LWA a) 0.083 L/10000m2 LWA b) 1.66 L/10000m2 LWA	16.6 g/10000m2 LWA a) 16.6 g/10000m2 LWA b) 33.2 g/10000m2 LWA	200-750 L/ha	N/A	Max. 2 x 0.11 L/ha (2 x 22 g/ha) 13000 LWA							

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1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
				PHRRVI; Cream- bordered green pea moth (<i>Earias clorana</i>) - EARICH; Gall midge (<i>Dasineura marginemtorquens</i>) - RHABMA																
47	PL	Forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations; Christmas trees grown on plantations	F	Aphids (<i>Aphididae</i>) – APXXSP, Springtails (<i>Collembola</i>) - ICOLLO; Larch case-bearer (<i>Coleophora laricella</i>) - COLELA	Foliar spray	BBCH 11-69	1 a) 1 b) 1	N/A	0.133 L/10000m2 LWA a) 0.133 L/10000m2 LWA b) 0.133 L/10000m2 LWA	26.6 g/10000m2 LWA a) 26.6 g/10000m2 LWA b) 26.6 g/10000m2 LWA	200-400 L/ha	N/A	Max. 0.19 L/ha (38 g/ha) 14000 LWA							

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

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

Explanation for column 15 – 21 “Conclusion”

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

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Remarks table:	<div> <div> <p>(1) Numeration necessary to allow references</p> <p>(2) Use official codes/nomenclatures of EU</p> <p>(3) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (<i>e.g.</i> fumigation of a structure)</p> <p>(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</p> <p>(5) Scientific names <u>and</u> EPPO-Codes of target pests/diseases/ weeds or when relevant the common names of the pest groups (<i>e.g.</i> 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</p> <p>(6) Method, <i>e.g.</i> high volume spraying, low volume spraying, spreading, dusting, drench Kind, <i>e.g.</i> overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated</p> </div> <div> <p>(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</p> <p>(8) The maximum number of application possible under practical conditions of use must be provided</p> <p>(9) Minimum interval (in days) between applications of the same product.</p> <p>(10) For specific uses other specifications might be possible, <i>e.g.</i>: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products</p> <p>(11) The dimension (g, kg) must be clearly specified. (Maximum) dose of as per treatment (usually g, kg or L product / ha).</p> <p>(12) If water volume range depends on application equipments (<i>e.g.</i> ULVA or LVA) it should be mentioned under “application: method/kind”.</p> <p>(13) PHI - minimum pre-harvest interval</p> <p>(14) Remarks may include: Extent of use/economic importance/restrictions</p> </div> </div>
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9.1.1 Overall conclusions

9.1.1.1

9.1.1.2 zRMS comments: **Accepted.**

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

Birds

Effects on birds for Acetamipryd 200 SL were not evaluated as part of the EU review of acetamiprid. However further data on Acetamipryd 200 SL is not relevant as data for the active substance on toxicity to birds are considered essential. It is possible to extrapolate from data for the active substance. Therefore, all relevant data were assessed in the EU review. Risk assessments for Acetamipryd 200 SL with the proposed use pattern and EU agreed endpoints have been provided and are considered adequate.

The risk assessment for effects on birds was carried out according to the latest guidance for risk assessment for birds and mammals EFSA Journal 2009; 7(12): 1438.

The acute and reproductive risks of Acetamipryd 200 SL to birds were assessed from toxicity exposure ratios between EU agreed toxicity endpoints, estimated from studies with active substance, as well as SV_{90} and SV_m .

Drinking water exposure leaf scenario has not been performed since Acetamipryd 200 SL is not intended to be applied on leafy vegetables forming heads or crop plants with comparable water collecting structures at principal growth stage 4 or later. Drinking water exposure puddle scenario has not been performed since the ratios of effective application rates to relevant endpoints do not exceed 50 ($Koc < 500$ L/kg).

Exposure for earthworm-eating birds and fish-eating birds via secondary poisoning was not required since $\log P_{ow}$ of acetamiprid are below the trigger value of 3.

The TER values where applicable exceed the trigger values of 10 for acute and 5 for reproductive and long-term risk, thus indicating no unacceptable risk to birds from the proposed use of Acetamipryd 200 SL. No risk management measures are required.

The application of Acetamipryd 200 SL to tomatoes, aubergine and paprika (uses. 41-43) is limited to greenhouses, risk assessment is not required.

Terrestrial vertebrates (other than birds)

Effects on mammals for Acetamipryd 200 SL were not evaluated as part of the EU review of acetamiprid. However further data on Acetamipryd 200 SL is not relevant as data for the active substance on toxicity to mammals are considered essential. It is possible to extrapolate from data for the active substance. Therefore,

all relevant data were assessed in the EU review. Risk assessments for Acetamipryd 200 SL with the proposed use pattern and EU agreed endpoints have been provided and are considered adequate.

The risk assessment for effects on terrestrial vertebrates other than birds was carried out according to the latest guidance for risk assessment for birds and mammals EFSA Journal 2009; 7(12): 1438.

The acute and reproductive risks of Acetamipryd 200 SL to mammals were assessed from toxicity exposure ratios between EU agreed toxicity endpoints, estimated from studies with active substance, as well as SV_{90} and SV_m .

Drinking water exposure puddle scenario has not been performed since the ratios of effective application rates to relevant endpoints do not exceed 50 ($Koc < 500 \text{ L/kg}$).

Exposure for earthworm-eating mammals and fish-eating mammals via secondary poisoning was not required since $\log P_{ow}$ of acetamiprid are below the trigger value of 3.

The TER values where applicable exceed the trigger values of 10 for acute and 5 for reproductive and long-term risk, thus indicating no unacceptable risk to mammals from the proposed use. No risk management measures are required.

The application of Acetamipryd 200 SL to tomatoes, aubergine and paprika (uses. 41-43) is limited to greenhouses, risk assessment is not required.

9.1.1.4 Effects on aquatic organisms (KCP 10.2)

Effects on aquatic organisms for Acetamipryd 200 SL were not evaluated as part of the EU review of acetamiprid. Acute toxicity studies of Acetamipryd 200 SL to invertebrates and algae were submitted in this dossier.

Risk assessments for Acetamipryd 200 SL with the proposed use pattern was carried out according to the latest guidance for risk assessment for aquatic organisms in edge-of-field surface water EFSA Journal 2013; 11(7):3290.

PEC_{sw}/RAC values were calculated with PEC_{sw} values obtained for active substance and its metabolites calculated in Steps 1, 2, 3 and 4 were below the 1 for acute and long-term risk indicating no unacceptable risk to aquatic organisms for most scenarios provided appropriate risk mitigations measures are applied. For scenarios with PEC/RAC above 1 safe use has not been confirmed so further risk mitigations from and risk refinement is required at national level. Risk mitigation for particular country are proposed in respective Part A.

The application of Acetamipryd 200 SL to tomatoes, aubergine and paprika (uses. 41-43) is limited to greenhouses, risk assessment is not required.

Classification of ACETAMIPRYD 200 SL was done on the basis of formulation test results as well as active substance properties. The proposed classification of the product Acetamipryd 200 SL is:

Aquatic Chronic 1, H410

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9.1.1.5

9.1.1.6 zRMS comments: The evaluation of the risk for aquatic 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” (EFSA Journal 2013;11(7):3290).

The PEC_{sw} calculations for acetamiprid have been approved for applications proposed in GAP. PEC_{sw} and PEC_{sed} calculations were carried out according to the FOCUS recommendations.

The relevant predicted environmental concentrations in water (PEC_{sw}) for risk assessments covering the proposed use pattern are taken from Part B Section 8 (Environmental Fate). Details on PEC_{sw} calculations for acetamiprid and formulation **PIORUN 200 SL** are included in Section B8.

Since not all relevant to the central zone scenarios are defined for the evaluated crops, the surrogate crops were considered by the Applicant in simulations.

Step 4 simulations were performed according to recommendations of the FOCUS work group on landscape and mitigation, FOCUS TOXSWA v5.5.3, ECPA SWAN v5.0.1, VFSmod.

The acceptability of proposed risk mitigation measures should be taken at MSs level.

PL

For Poland D3, D4 and R1 scenarios are relevant so it can be concluded that **PIORUN 200 SL** in accordance with GAP does not pose unacceptable risk to aquatic organisms under condition following risk mitigations measures are applied:

To protect aquatic organisms respect 10m unsprayed vegetated buffer zone to surface water bodies in case of spring oilseed rape and turnip rape sprayed with 0.25-0.3 L/ha.	Use no: 11, 12
To protect aquatic organisms respect 5m unsprayed buffer zone to surface water bodies in case of flax-fiber production and common hemp fiber production sprayed with 0.3 L/ha.	Use no: 13, 14
To protect aquatic organisms respect 5m unsprayed buffer zone to surface water bodies + 90% drift reduction nozzles or 15m unsprayed buffer zone to surface water bodies + 50% drift reduction nozzles or 20m unsprayed buffer zone to surface water bodies in case of orchards, walnuts, hazelnuts, common osier and purple willow sprayed with 0.11-0.18 L/ha.	Use no: 7-9, 15, 17-21, 26-28, 30, 31, 33-40, 44-46
To protect aquatic organisms respect 5m unsprayed buffer zone to surface water bodies + 90% drift reduction nozzles or 15m unsprayed buffer zone to surface water bodies + 75% drift reduction nozzles bodies in case of forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations, Christmas trees grown on plantations sprayed with 0.19 L/ha.	Use no: 47
To protect aquatic organisms respect 5m unsprayed buffer zone to surface water bodies + 50% drift reduction nozzles or 10m unsprayed buffer zone to surface water bodies in case of orchards sprayed with 2 x 0.125 L/ha.	Use no: 5, 6, 16, 22-25, 29, 32

In case of winter oilseed rape (uses no. 1-3), spring oilseed rape and turnip rape (uses no. 10) as well as potato (use no. 4) no risk mitigations measures are required.

A product PIORUN 200 SL in ecotoxicology section approved for uses 41-43 only in greenhouses with a durable structure, isolated from the ground.

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The application of **PIORUN 200 SL** to tomatoes, aubergine and paprika (uses. 41-43) is limited to greenhouses, risk assessment is not required.

Final risk mitigation measures should be considered at MSs level.

New data was accepted.

9.1.1.7 Effects on bees (KCP 10.3.1)

Effects on bees for Acetamipryd 200 SL were not evaluated as part of the EU review of acetamiprid. Toxicity studies of Acetamipryd 200 SL to bees were submitted in this dossier.

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

The risks of Acetamipryd 200 SL to honeybees was assessed from Hazard Quotients (HQ) and Exposure Toxicity Ratio (ETR) between toxicity endpoints, estimated from acute oral and contact studies with active ingredients and formulated product as well as the maximum single application rate.

All the hazard quotients were considerably less than the respective triggers, indicating that Acetamipryd 200 SL in accordance with GAP poses a low risk to bees. No risk management measures are required.

The application of Acetamipryd 200 SL to tomatoes, aubergine and paprika (uses. 41-43) is limited to greenhouses, risk assessment is not required.

9.1.1.8 Effects on arthropods other than bees (KCP 10.3.2)

Effects on non-target arthropods for Acetamipryd 200 SL were not evaluated as part of the EU review of acetamiprid. Toxicity studies of Acetamipryd 200 SL to non-target arthropods were submitted in this dossier.

Risk assessments for Acetamipryd 200 SL with the proposed use pattern was carried out according to the guidance for risk assessment for arthropods “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 in-field and off-field risk of Acetamipryd 200 SL to non-target arthropods was evaluated by comparison of % effects rate with derived from laboratory tests as well as in-field and off-field predicted rate. No risk was determined in-field and off-field after application of Acetamipryd 200 SL in accordance with GAP. No risk management measures are required.

The application of Acetamipryd 200 SL to tomatoes, aubergine and paprika (uses. 41-43) is limited to greenhouses, risk assessment is not required.

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

Effects on earthworms and other soil micro-organisms for Acetamipryd 200 SL were not evaluated as part of the EU review of acetamiprid. The toxicity studies to earthworm and *Hypoaspis aculeifer* as well as nitrogen transformation test for Acetamipryd 200 SL were submitted in this dossier.

Risk assessments for Acetamipryd 200 SL with the proposed use pattern was carried out according to the guidance for risk assessment for terrestrial ecotoxicology “Guidance Document on Terrestrial Ecotoxicology”, (SANCO/10329/2002 rev.2 final, 2002).

Earthworms, *Hypoaspis aculeifer* and *Folsomia candida*

The risk of Acetamipryd 200 SL to earthworms, *Hypoaspis aculeifer* and *Folsomia candida* was assessed from toxicity exposure ratio (TER) between the selected toxicity endpoints for metabolite IM-1-5 s and the formulated product Acetamipryd 200 SL as well as the maximum soil PECs.

The chronic TER values were greater than the trigger of 5, indicating an acceptable risk to earthworms, *Hypoaspis aculeifer* and *Folsomia candida* following application of Acetamipryd 200 SL in accordance with GAP. No risk management measures are required.

Micro-organisms

The risk of Acetamipryd 200 SL to soil micro-organisms was evaluated by comparison of no-effect concentration in soil, derived from laboratory tests for the formulated product Acetamipryd 200 SL with the maximum soil PECs.

According to the performed risk assessment it was assessed that the application of Acetamipryd 200 SL 01 in accordance with GAP does not pose unacceptable risk to soil micro-organisms. No risk management measures are required.

The application of Acetamipryd 200 SL to tomatoes, aubergine and paprika (uses. 41-43) is limited to greenhouses, risk assessment is not required.

9.1.1.10 Effects on non-target terrestrial plants (KCP 10.6)

Effects on non-target terrestrial plants for Acetamipryd 200 SL were not evaluated as part of the EU review of acetamiprid. The studies on seedling emergence and vegetative vigour for Acetamipryd 200 SL were submitted in this dossier.

The risk of Acetamipryd 200 SL to non-target plants was assessed from toxicity exposure ratios between toxicity endpoints for the formulation Acetamipryd 200 SL and off-field predicted environmental rate. The TER values were greater than the trigger of 5, indicating an acceptable risk to non-target terrestrial plants following application of Acetamipryd 200 SL in accordance with GAP. No risk management measures are required.

The application of Acetamipryd 200 SL to tomatoes, aubergine and paprika (uses. 41-43) is limited to greenhouses, risk assessment is not required.

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

Not relevant.

9.1.2 Grouping of intended uses for risk assessment

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

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Table 9.1-2: Critical use pattern of Acetamipryd 200 SL grouped according to crop group

Grouping according to criterion			
Critical Use	Covered Uses	Relevant use parameters for grouping	Relevant parameter or value for sorting
Birds & Mammals			
oilseed rape (use no: 12)	1-3, 10-14	Scenario: rape Rate: 1 × 60 g/ha	-
potato (use no. 4)	4	Scenario: potato Rate: 1 × 24 g/ha	-
orchards and ornamentals/nursery (use no. 5, 47)	5-8, 15-23, 25-40, 44- 46	Scenario: orchards and ornamentals/nursery Rate: 2 × 25 g/ha and 1 × 38 g/ha	-
Aquatic organisms			
winter rape (use no: 1)	1	Scenario: winter rape Rate: 1 × 50 g/ha BBCH 30-50	-
winter rape (use no: 2)	2, 3	Scenario: winter rape Rate: 1 × 24 g/ha BBCH 50-69	-
winter rape (use no: 13)	13, 14	Scenario: winter rape Rate: 1 × 60 g/ha BBCH 30-61	-
spring rape (use no: 10)	10	Scenario: spring rape Rate: 1 × 24 g/ha BBCH 50-65	-
spring rape (use no: 11)	11	Scenario: spring rape Rate: 1 × 50 g/ha BBCH 30-50	-
spring rape (use no: 12)	12	Scenario: spring rape Rate: 1 × 60 g/ha BBCH 59-71	-
potato (use no. 4)	4	Scenario: potato Rate: 1 x 24 g as/ha BBCH 35-75	-
orchards, early application (use no: 7)	7, 8, 15, 17, 18, 20, 21, 28, 30, 31, 33, 35, 37, 39	Scenario: orchards, early application Rate: 1 x 22 g as/ha BBCH 56-84	-
orchards, late application (use no: 7)		Scenario: orchards, late application Rate: 1 x 22 g as/ha BBCH 56-84	-
orchards, early application (use no: 9)	9	Scenario: orchards, early application Rate: 1 x 36 g as/ha BBCH 56-84	-
orchards, late application (use no: 9)		Scenario: orchards, late application Rate: 1 x 36 g as/ha BBCH 56-84	-

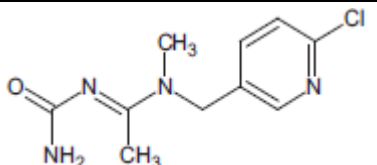
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orchards, early application (use no: 47)	47	Scenario: orchards, early application Rate: 1 x 38 g as/ha BBCH 11-69	-
orchards, early application (use no: 19)	19, 26, 27, 34, 36, 38, 40, 44-46	Scenario: orchards, early application Rate: 2 x 22 g as/ha BBCH 51-73	-
orchards, late application (use no: 5)	5, 6, 16, 22-25, 29, 32	Scenario: orchards, late application Rate: 2 x 25 g as/ha BBCH 71-84	-
Bees			
oilseed rape (use no: 12)	1-47	Max. single rate: 60 g as/ha	-
Arthropods – in-field exposure			
oilseed rape (use no: 12)	1-47	In-field: max. effective rate: 0.3 L/ha	-
Arthropods – off-field exposure			
orchards (use no. 5)	1-47	Off-field: max. drift rate: 0.125 L/ha x MAF 1.7 x drift 25.63%,,,	-
Soil macro-organisms and micro-organisms			
orchards (use no. 5)	1-47	Max. PECs	-
Non-target plants			
orchards (use no. 5)	1-47	max. drift rate: 0.125 L/ha x MAF 1.7 x drift 25.63%	-
zRMS comments: Critical use pattern of Acetamipryd 200 SL grouped according to crop group in risk assessment was accepted by zRMS.			

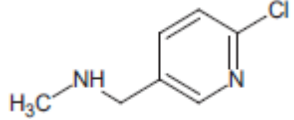
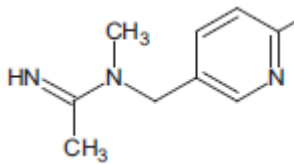
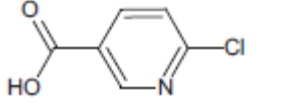
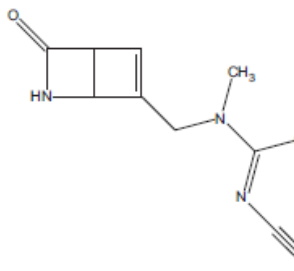
9.1.3 Consideration of metabolites

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 Acetamipryd 200 SL is indicated in the table.

Table 9.1-3 Metabolites of acetamiprid

Metabolite	Chemical structure	Molar mass	Maximum occurrence in compartments	Risk assessment required?
IM-1-2		240.69	Maximum in soil: 55% Maximum in water/sediment: 13.4%	Soil: yes Water/sediment: yes

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Metabolite	Chemical structure	Molar mass	Maximum occurrence in compartments	Risk assessment required?
IM-1-4		156.61	Maximum in soil: 72% Maximum in water/sediment: 81.5% (aerobic mineralisation study)	Soil: yes Water/sediment: yes
IM-1-5		197.66	Maximum in soil: 20% (calcareous soils only)	Soil: yes Water/sediment: yes
IC-0 6-chloronicotinic acid (IV-0)		157.55	Maximum in soil: 11.3% Maximum in water/sediment: 29.5%	Soil: yes Water/sediment: yes
IB-1-1		204.23	Maximum in water/sediment: 35% (aqueous photochemical degradation)	Soil: no Water/sediment: yes
zRMS comments: Accepted.				

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 RAR and related documents.

Effects on birds of Acetamipryd 200 SL were not evaluated as part of the EU assessment of acetamiprid. However, the provision of further data on the Acetamipryd 200 SL is not considered essential, because it is possible to extrapolate data from the active substance. Additionally, vertebrates' studies should be avoided.

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
<i>Anas platyrhynchos</i> (mallard duck)	acetamiprid	Acute	LD ₅₀ = 98 mg/kg bw	EFSA Journal 2016;14(11):4610

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Species	Substance	Exposure System	Results	Reference
<i>Colinus virginianus</i> (bobwhite quail)	acetamiprid	Acute	LD ₅₀ > 100 mg/kg bw	EFSA Journal 2016;14(11):4610
<i>Poephila guttata</i> (zebra finch)	acetamiprid	Acute	LD ₅₀ = 5.7 mg/kg bw	EFSA Journal 2016;14(11):4610
Geometric mean	acetamiprid	Acute	LD₅₀ = 38.2 mg/kg bw	EFSA Journal 2016;14(11):4610
	acetamiprid	Long-term	LD₅₀ /10 = 3.8 mg/kg bw	EFSA Journal 2016;14(11):4610
<i>Anas platyrhynchos</i> (mallard duck)	acetamiprid	Long-term	NOAEL = 9.5 mg/kg bw/d	EFSA Journal 2016;14(11):4610

9.2.1.1 Justification for new endpoints

Not relevant. No new endpoints were used.

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.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the screening assessment for the use no. 4 (potato), 5 (orchards), 47 (ornamentals/nursery) and 12 (oilseed rape) also covers the risk for birds from all other intended uses (see 9.1.2).

Table 9.2-2: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of Acetamipryd 200 SL in oilseed rape (use no. 12)

Intended use	oilseed rape (use no: 12)				
Active substance/product	acetamiprid				
Acute toxicity (mg/kg bw)	38.2				
TER criterion	10				
Crop scenario	Indicator/generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a
Growth stage					
Screening assessment					
oilseed rape	Small omnivorous bird	158.8	1	9.53	4.01

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appl. rate: 60 g as/ha covered uses no: 1-3, 10-14					
First-tier assessment					
oilseed rape BBCH 30-71 appl. rate: 60 g as/ha covered uses no: 1-3, 10-14	Small insectivorous bird “dunnoch” BBCH 30-99	7.4	1	0.44	86.82
	Small omnivorous bird “lark” BBCH 30-39	7.2	1	0.43	88.84
	Small omnivorous bird “lark” BBCH ≥ 40	6.0	1	0.36	106.11
	Medium herbivorous/ granivorous bird “pigeon” BBCH 30-39	2.4	1	0.14	272.86
	Medium herbivorous/ granivorous bird “pigeon” BBCH ≥ 40	2.0	1	0.12	318.33
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}
Screening assessment					
oilseed rape BBCH 30-71 appl. rate: 60 g as/ha covered uses no: 1-3, 10-14	Small omnivorous bird	64.8	1 x 0.53	2.06	1.84
First-tier assessment					
oilseed rape BBCH 30-71 appl. rate: 60 g as/ha covered uses no: 1-3, 10-14	Small insectivorous bird “dunnoch” BBCH 30-99	2.7	1 x 0.53	0.09	42.22
	Small omnivorous bird “lark” BBCH 30-39	3.3	1 x 0.53	0.1	38
	Small omnivorous bird “lark” BBCH ≥ 40	2.7	1 x 0.53	0.09	42.22
	Medium herbivorous/ granivorous bird “pigeon” BBCH 30-39	1.1	1 x 0.53	0.03	126.67
	Medium herbivorous/ granivorous bird “pigeon” BBCH ≥ 40	0.9	1 x 0.53	0.03	126.67

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 Acetamiprid 200 SL in potato (use no. 4)

Intended use	potato (use no. 4)
Active substance/product	acetamiprid

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Acute toxicity (mg/kg bw)		38.2			
TER criterion		10			
Crop scenario	Indicator/generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a
Growth stage					
Screening assessment					
potato appl. rate: 24 g as/ha covered uses no: 4	Small omnivorous bird	158.8	1	3.81	10.03
Reprod. toxicity (mg/kg bw/d)		3.8			
TER criterion		5			
Crop scenario	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}
Growth stage					
Screening assessment					
potato appl. rate: 24 g as/ha covered uses no: 4	Small omnivorous bird	64.8	1 x 0.53	0.82	4.63
First-tier assessment					
potato BBCH 35-75 appl. rate: 24 g as/ha covered uses no: 4	Small omnivorous bird “lark” BBCH 10-39	10.9	1 x 0.53	0.14	27.14
	Small omnivorous bird “lark” BBCH ≥ 40	3.3	1 x 0.53	0.04	95
	Small insectivorous bird “wagtail” BBCH ≥ 20	9.7	1 x 0.53	0.12	31.67

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

Table 9.2-4: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of Acetamiprid 200 SL in orchards (use no. 5) and ornamentals (use no. 47)

Intended use		orchards (use no. 5) and ornamentals (use no. 47)			
Active substance/product		acetamiprid			
Acute toxicity (mg/kg bw)		38.2			
TER criterion		10			
Crop scenario	Indicator/generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a
Growth stage					
Screening assessment					
orchards and ornamentals/nursery appl. rate: 2 x 25 g covered use no: 5-8, 15-23, 25-40, 44-46	small insectivorous bird	46.8	1.4	1.64	23.29
orchards and ornamentals/nursery appl. rate: 38 g	small insectivorous bird	46.8	1	1.78	21.46

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covered use no: 9, 24, 47					
Reprod. toxicity (mg/kg bw/d)	3.8				
TER criterion	5				
Crop scenario	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}
Growth stage					
Screening assessment					
orchards and ornamentals/nursery appl. rate: 2 x 25 g covered use no: 5-8, 15-23, 25-40, 44-46	small insectivorous bird	18.2	1.6 x 0.53	0.39	9.74
orchards and ornamentals/nursery appl. rate: 38 g covered use no: 9, 24, 47	small insectivorous bird	18.2	1 x 0.53	0.37	10.27

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 acute and reproductive first-tier TER values for birds exceed the relevant trigger values of 10 and 5, respectively, indicating no unacceptable acute and reproductive risk following applications of Acetamipryd 200 SL according to proposed GAP.

<p>zRMS comments: The risk envelope approach in risk assessment for birds was accepted by zRMS. The toxicity endpoints used in risk assessment for birds was accepted by zRMS:</p> <p>Acute: geomeanLD₅₀ = 38.2 mg/kg bw</p> <p>Long-term: geomeanLD_{50/10} = 3.8 mg/kg bw/d</p> <p>The acute and chronic risks of PIORUN 200 SL 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.</p> <p>All TER values exceed the relevant triggers indicating that PIORUN 200 SL does not pose an unacceptable risk to birds following applications according to recommended use pattern.</p> <p>Evaluation of exposing to birds through the drinking water demonstrated the acceptable risk.</p> <p>The risk to earthworm- and fish-eating birds from secondary poisoning is not required.</p>
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9.2.2.2 Higher-tier risk assessment

Not relevant.

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9.2.2.3 Drinking water exposure

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

Leaf scenario

Since Acetamipryd 200 SL is not a product for spray applications / not intended to be applied on leafy vegetables forming heads or crop plants with comparable water collecting structures at principal growth stage 4 or later, the leaf scenario does not have to be considered.

Puddle scenario

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

With a $K(f)_{oc}$ of 106.5 (arithmetic mean), acetamiprid belongs to the group of less sorptive substances.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use no. 12 (oilseed rape) also covers the risk for birds from all other intended uses (see 9.1.2).

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 since the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances ($K_{oc} < 500$ L/kg).

Effective application rate (g/ha) =	60 (worst case)		
Acute toxicity (mg/kg bw) =	38.2	quotient =	1.57
Reprod. toxicity (mg/kg bw/d) =	3.8	quotient =	15.79
zRMS comments: Accepted.			

9.2.2.4 Effects of secondary poisoning

The log P_{ow} of acetamiprid amounts to 0.8 at 25 °C (neutral pH) 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.

zRMS comments: Accepted.

Risk assessment for fish-eating birds via secondary poisoning

Not required.

zRMS comments: Accepted.

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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

All the TER values exceed the trigger values of 10 for acute and 5 for reproductive/long-term risk. Acetamipryd 200 SL does not pose unacceptable risk to birds following application in accordance with GAP. No risk management measures are required.

zRMS comments: The risk envelope approach in risk assessment for birds was accepted by zRMS.
 All TER values exceed the relevant triggers indicating that **PIORUN 200 SL** 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 RAR and related documents.

Effects on mammals of Acetamipryd 200 SL were not evaluated as part of the EU assessment of acetamiprid. However, the provision of further data on the Acetamipryd 200 SL is not considered essential, because it is possible to extrapolate data from the active substance. Additionally, vertebrates' studies should be avoided.

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
Rat	acetamiprid	Acute	LD₅₀ = 146 mg/kg bw	EFSA Journal 2016;14(11):4610
Rat	acetamiprid	Long-term 90-d study	NOAEL = 12.4 mg/kg bw	EFSA Journal 2016;14(11):4610
Rat	acetamiprid	Long-term Developmental	NOAEL = 2.5 mg/kg bw	EFSA Journal 2016;14(11):4610

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Species	Substance	Exposure System	Results	Reference
		neurotoxicity study		
zRMS comments: The toxicity endpoints used in risk assessment for mammals was accepted by zRMS.				

9.3.1.1 Justification for new endpoints

Not relevant. No new endpoints were used.

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).

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.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the screening assessment for the use no. 4 (potato), 5 (orchards), 47 (ornamentals/nursery) and 12 (oilseed rape) also covers the risk for mammals from all other intended uses (see 9.1.2).

Table 9.3-2: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of Acetamiprid 200 SL in oilseed rape (use no: 12)

Intended use		oilseed rape (use no: 12)				
Active substance/product		acetamiprid				
Acute toxicity (mg/kg bw)		146				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Growth stage						
Screening assessment						
oilseed rape appl. rate: 60 g as/ha covered uses no: 1-3, 10-14	Small herbivorous mammal	118.4	1	7.10	20.56	
Reprod. toxicity (mg/kg bw/d)		2.5				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{lt}	
Growth stage						
Screening assessment						
oilseed rape appl. rate: 60 g as/ha covered uses no: 1-3,	Small herbivorous mammal	48.3	1 x 0.53	1.54	1.62	

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10-14					
First-tier assessment					
oilseed rape BBCH 30-69 appl. rate: 50 g as/ha covered uses no: 1-3, 10-11	Small insectivorous mammal “shrew” BBCH ≥ 20	1.9	1 x 0.53	0.05	50
	small herbivorous mammal “vole” BBCH ≥ 40	18.1	1 x 0.53	0.48	5.21
	Large herbivorous mammal “lagomorph” all season	14.3	1 x 0.53	0.38	6.58
	Small omnivorous mammal “mouse” BBCH 30-39	2.3	1 x 0.53	0.06	41.67
	Small omnivorous mammal “mouse” BBCH ≥ 40	1.9	1 x 0.53	0.05	50
oilseed rape BBCH 30-71 appl. rate: 60 g as/ha covered uses no: 12- 14	Small insectivorous mammal “shrew” BBCH ≥ 20	1.9	1 x 0.53	0.06	41.67
	small herbivorous mammal “vole” BBCH ≥ 40	18.1	1 x 0.53	0.58	4.31
	Large herbivorous mammal “lagomorph” all season	14.3	1 x 0.53	0.45	5.56
	Small omnivorous mammal “mouse” BBCH 30-39	2.3	1 x 0.53	0.07	35.71
	Small omnivorous mammal “mouse” BBCH ≥ 40	1.9	1 x 0.53	0.06	41.67

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 Acetamiprid 200 SL in potato (use no: 4)

Intended use		potato (use no: 4)			
Active substance/product		acetamiprid			
Application rate (g/ha)		24			
Acute toxicity (mg/kg bw)		146			
TER criterion		10			
Crop scenario	Indicator/generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a
Growth stage					
Screening assessment					
potato appl. rate: 24 g as/ha covered uses no: 4	Small herbivorous mammal	118.4	1	2.84	51.41
Reprod. toxicity (mg/kg bw/d)		2.5			
TER criterion		5			
Crop scenario	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}
Growth stage					
Screening assessment					

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potato appl. rate: 24 g as/ha covered uses no: 4	Small herbivorous mammal	48.3	1 x 0.53	0.61	4.10
First-tier assessment					
potato BBCH 35-75 appl. rate: 24 g as/ha covered uses no: 4	Small insectivorous mammal “shrew” BBCH ≥ 20	1.9	1 x 0.53	0.02	125
	small herbivorous mammal “vole” BBCH ≥ 40	21.7	1 x 0.53	0.28	8.93
	Large herbivorous mammal “lagomorph” BBCH 10-40	14.3	1 x 0.53	0.18	13.89
	Large herbivorous mammal “lagomorph” BBCH ≥ 40	4.3	1 x 0.53	0.05	50
	Small omnivorous mammal “mouse” BBCH 10-39	7.8	1 x 0.53	0.1	25
	Small omnivorous mammal “mouse” BBCH ≥ 40	2.3	1 x 0.53	0.03	83.33

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 9.3-4: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of Acetamiprid 200 SL in orchards (use no. 5) and ornamentals (use no. 47)

Intended use		orchards (use no. 5) and ornamentals (use no. 47)				
Active substance/product		acetamiprid				
Acute toxicity (mg/kg bw)		146				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Growth stage						
Screening assessment						
orchards and ornamentals/nursery appl. rate: 2 x 25 g covered use no: 5-8, 15-23, 25-40, 44-46	Small herbivorous mammal	136.4	1.4	4.77	30.61	
orchards and ornamentals/nursery appl. rate: 38 g covered use no: 9, 24, 47	Small herbivorous mammal	136.4	1	5.18	28.19	
Reprod. toxicity (mg/kg bw/d)	2.5					
TER criterion	5					
Crop scenario	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{lt}	
Growth stage						
Screening assessment						
orchards appl. rate: 2 x 25 g	Small herbivorous mammal	72.3	1.6 x 0.53	1.53	1.63	

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covered use no: 5-8, 15-23, 25-40, 44-46					
orchards and ornamentals/nursery appl. rate: 38 g covered use no: 9, 24, 47	Small herbivorous mammal	72.3	1 x 0.53	1.46	1.71
First-tier assessment					
orchards BBCH 51-84 appl. rate: 2 x 25 g covered uses no: 5-8, 15-23, 25-40, 44-46	Small herbivorous mammal “vole” BBCH ≥ 40	21.7	1.6 x 0.53	0.46	5.43
	Frugivorous mammal “dormouse” BBCH 71-79	22.7	1.6 x 0.53	0.48	5.21
	Large herbivorous mammal “lagomorph” BBCH ≥ 40	4.3	1.6 x 0.53	0.09	27.78
	Small omnivorous mammal “mouse” BBCH ≥ 40	2.3	1.6 x 0.53	0.05	50
orchards BBCH 56-84 appl. rate: 1 x 36 g covered uses no: 9, 24, 47	Small herbivorous mammal “vole” BBCH ≥ 40	21.7	1 x 0.53	0.41	6.1
	Frugivorous mammal “dormouse” BBCH 71-79	22.7	1 x 0.53	0.43	5.81
	Large herbivorous mammal “lagomorph” BBCH ≥ 40	4.3	1 x 0.53	0.08	31.25
	Small omnivorous mammal “mouse” BBCH ≥ 40	2.3	1 x 0.53	0.04	62.5

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 acute screening and reproductive first-tier TER values for mammals exceed the relevant trigger values of 10 and 5, respectively, indicating no unacceptable acute and reproductive risk following applications of Acetamipryd 200 SL according to proposed GAP except vole (uses no: 12-14) for which higher tier risk assessment is required.

zRMS comments: The risk envelope approach in risk assessment for mammals was accepted by zRMS. The toxicity endpoints used in risk assessment for mammals was accepted by zRMS:

Rat

Acute LD₅₀ = 146 mg/kg bw

Long-term NOAEL = 2.5 mg/kg bw

The acute and chronic risks of **PIORUN 200 SL** 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.

All TER values exceed the relevant triggers indicating that **PIORUN 200 SL** does not pose an unacceptable risk to mammals following applications according to recommended use pattern except vole (uses no: 12-14). The refinement risk assessment is required.

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.

9.3.2.2 Higher-tier risk assessment

The higher-tier reproductive risk assessment for small herbivorous mammal “vole” is conducted according to recommendations of EFSA/2009/1438.

Small herbivorous mammal “vole”

In accordance with CTGB Evaluation Manual for the Authorisation of plant protection products according to Regulation (EC) No 1107/2009, Chapter 7 Ecotoxicology: terrestrial; birds and mammals. version 2.2; April 2017, the proportion of vole’s diet in the chronic risk assessment should be 25% of dicotyledons and 75% of monocotyledons. However, at EU level it was agreed that voles diet consisting of 50% monocotyledons and 50% of dicotyledons may be used. Regarding above risk assessment was performed for both diets.

The calculation of food energy of total mixed diet for common vole and food intake rate per body weight for common voles consuming either 25% of dicotyledons and 75% of monocotyledons or 50% monocotyledons and 50% of dicotyledons are in table below.

Table 9.3-5: Food energy of total mixed diet and food intake rate per body weight for common vole

Parameter		Diet			
		25% of dicotyledons 75% of monocotyledons		50% of dicotyledons 50% of monocotyledons	
		Grass ce- real shoots	Non-grass herbs	Grass ce- real shoots	Non-grass herbs
Fraction of food item in mixed diet	PDi fresh (%)	75	25	50	50
Food energy of food item [i] in mixed diet	FE (kJ/dry g)	17.6	17.8	17.6	17.8
Moisture content of food item [i] in mixed diet	MC (%)	76.4	88.1	76.4	88.1
Assimilation efficiency of food item [i] in mixed diet	AE (%)	47	76	47	76
Food energy of food item in diet	FE _{item,fresh} (kJ/g fw)	1.464	0.402	0.976	0.805
Food energy of total mixed diet	FE _{total,fresh} (kJ/g fw)	1.866		1.781	
Body weight of vole	BW (g)	25		25	
Daily energy expenditure	DDE (kJ)	65.1			
Food intake rate	FIR _{total fresh} (g fw/d)	34.887		36.552	
Food intake rate / body weight	FIR/BW (g fw/g bw/d)	1.395		1.462	

Additionally, in refinement risk assessment shortcut values of median RUD for dicotyledons of 28.7 mg/kg food and monocotyledons of 54.2 mg/kg food in accordance with Appendix A of EFSA Journal 2009; 7(12): 1438, deposition factor (DF) of 0.2 (BBCH 30) for oilseed rape and 0.4 (BBCH 11) for ornamentals (surrogate for nurseries and forest) were applied in accordance with EFSA Journal 2014;12(5):3662 as well as TWA of 0.16 based on DT₅₀ = 2.3 days in accordance with EFSA Journal 2016;14(11):4610.

Table 9.3-6: Higher-tier assessment of the long-term/reproductive risk for herbivorous mammals due to the use of ASA-01 in oilseed rape (use no. 12)

Intended use	oilseed rape (use no: 12)
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Active substance/product		acetamiprid					
Application rate (g/ha)		60					
Chronic toxicity (mg/kg bw)		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}
Diet: 25% of dicotyledons and 75% of monocotyledons							
oilseed rape BBCH 30-71 appl. rate: 60 g as/ha covered uses no: 12-14	dicotyledons, 25%	1.395	28.7 x 1	1 x 0.16	1	0.06	
	monocotyledons, 75%	1.395	54.2 x 0.2	1 x 0.53	1	0.24	
	whole diet					0.3	8.33
Diet: 50% of dicotyledons and 50% of monocotyledons							
oilseed rape BBCH 30-71 appl. rate: 60 g as/ha covered uses no: 12-14	dicotyledons, 50%	1.462	28.7 x 1	1 x 0.16	1	0.13	
	monocotyledons, 50%	1.462	54.2 x 0.2	1 x 0.53	1	0.17	
	whole diet					0.30	8.33

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.

The higher-tier reproductive TER values for herbivorous mammals exceed the relevant trigger value of 5, indicating no unacceptable reproductive risk following applications of Acetamipryd 200 SL according to proposed GAP.

zRMS comments: The risk envelope approach in risk assessment for mammals was accepted by zRMS.
The refinement risk assessment for vole is accepted by zRMS.
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.

9.3.2.3 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

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

With a $K(f)_{oc}$ of 106.5 (arithmetic mean), acetamiprid belongs to the group of less sorptive substances.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use no. 12 (oilseed rape) also covers the risk for mammals from all other intended uses (see 9.1.2).

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 since the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances ($K_{oc} < 500 \text{ L/kg}$).

Effective application rate (g/ha) =	60 (worst case)		
Acute toxicity (mg/kg bw) =	146	quotient =	0.41
Reprod. toxicity (mg/kg bw/d) =	2.5	quotient =	24
zRMS comments: Accepted.			

9.3.2.4 Effects of secondary poisoning

The log P_{ow} of acetamiprid amounts to 0.8 at 25°C (neutral pH) 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.

zRMS comments: Accepted.

Risk assessment for fish-eating mammals via secondary poisoning

Not required.

zRMS comments: Accepted.

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

All the TER values exceed the trigger values of 10 for acute and 5 for reproductive/long-term risk. Acetamipryd 200 SL does not pose unacceptable risk to mammals following application in accordance with GAP. No risk management measures are required.

zRMS comments: The risk envelope approach in risk assessment for mammals was accepted by zRMS. All TER values exceed the relevant triggers indicating that **PIORUN 200 SL** does not pose an unacceptable risk to mammals following applications according to recommended use pattern except vole (uses no: 12-14). The refinement risk assessment is required. The refinement risk assessment for mammals was accepted by zRMS. The refinement risk assessment for vole should be considered by MSs level. 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 amphibians) (KCP 10.1.3)

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 RAR and related documents.

Effects on aquatic organisms of Acetamipryd 200 SL were not evaluated as part of the EU assessment of acetamiprid. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

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

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

Species	Substance	Exposure System	Results	Reference
Fish - acute				
<i>Oncorhynchus mykiss</i>	acetamiprid	96 h, s	LC₅₀ > 100 mg as/L_{nom}	EFSA Journal 2016;14(11):4610
<i>Lepomis macrochirus</i>	acetamiprid	96 h, f	LC ₅₀ > 119.3 mg as/L _{mm}	EFSA Journal 2016;14(11):4610
<i>Cyprinodon variegatus</i>	acetamiprid	96 h, f	LC ₅₀ = 100 mg as/L _{nom}	EFSA Journal 2016;14(11):4610
<i>Oncorhynchus mykiss</i>	metabolite IM-1-4	96 h, ss	LC₅₀ > 98.1 mg as/L	EFSA Journal 2016;14(11):4610

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Fish - chronic				
<i>Pimephales promelas</i>	acetamiprid	35 d, f	NOEC = 9.4 mg as/L_{mm} EC ₁₀ > 150 mg as/L _{mm}	EFSA Journal 2016;14(11):4610
Amphibians - chronic				
<i>Xenopus laevis</i>	acetamiprid	21 d, f	NOEC_{growth} = 2.6 mg as/L_{mm}	EFSA Journal 2016;14(11):4610
Aquatic invertebrates - acute				
<i>Daphnia magna</i>	acetamiprid	48 h, s	EC ₅₀ = 49.8 mg as/L _{mm}	EFSA Journal 2016;14(11):4610
<i>Chironomus riparius</i>	acetamiprid	48 h, s	EC ₅₀ = 0.0207 mg as/L _{mm}	EFSA Journal 2016;14(11):4610
<i>Gammarus fasciatus</i>	acetamiprid	48 h, s	EC ₅₀ = 0.10 mg as/L _{mm}	EFSA Journal 2016;14(11):4610
<i>Mysidopsis bahia</i>	acetamiprid	48 h, f	EC ₅₀ = 0.066 mg as/L _{mm}	EFSA Journal 2016;14(11):4610
<i>Gammarus pulex</i>	acetamiprid	48 h, s	EC ₅₀ = 0.050 mg as/L _{mm}	EFSA Journal 2016;14(11):4610
<i>Simulium latigonium</i>	acetamiprid	48 h, s	EC ₅₀ = 0.0037 mg as/L _{mm}	EFSA Journal 2016;14(11):4610
Geometric mean aquatic insects	acetamiprid	-	EC₅₀ = 0.0085 mg as/L_{mm}	EFSA Journal 2016;14(11):4610
<i>Daphnia magna</i>	Metabolite IM-1-2	48 h, ss	EC ₅₀ > 99.8 mg/L	EFSA Journal 2016;14(11):4610
<i>Chironomus riparius</i>	Metabolite IM-1-2	48 h, s	EC₅₀ = 15.0 mg/L	EFSA Journal 2016;14(11):4610
<i>Daphnia magna</i>	Metabolite IM-1-4	48 h, ss	EC ₅₀ = 43.9 mg/L	EFSA Journal 2016;14(11):4610
<i>Mysidopsis bahia</i>	Metabolite IM-1-4	48 h, s	EC₅₀ = 19 mg/L	EFSA Journal 2016;14(11):4610
<i>Chironomus riparius</i>	Metabolite IM-1-4	48 h, s	EC ₅₀ = 76.0 mg/L	EFSA Journal 2016;14(11):4610
<i>Daphnia magna</i>	Metabolite IM-1-5	48 h, s	EC₅₀ = 25 mg/L	EFSA Journal 2016;14(11):4610
<i>Chironomus riparius</i>	Metabolite IM-1-5	48 h, s	EC ₅₀ = 68 mg/L	EFSA Journal 2016;14(11):4610
<i>Daphnia magna</i>	Metabolite IC-0	48 h, ss	EC₅₀ > 95.1 mg/L	EFSA Journal 2016;14(11):4610
<i>Chironomus riparius</i>	Metabolite IC-0	48 h, s	EC ₅₀ > 100 mg/L	EFSA Journal 2016;14(11):4610
<i>Daphnia magna</i>	Metabolite IB-1-1	48 h, ss	EC ₅₀ > 100.8 mg/L	EFSA Journal 2016;14(11):4610
<i>Chironomus riparius</i>	Metabolite IB-1-1	48 h, s	EC₅₀ > 100 mg/L	EFSA Journal 2016;14(11):4610
Aquatic invertebrates – chronic				

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<i>Daphnia magna</i>	acetamiprid	21 d, ss	NOEC = 5 mg as/L _{mm} EC₁₀ = 2.96 mg as/L_{mm}	EFSA Journal 2016;14(11):4610
<i>Daphnia magna</i>	Metabolite IM-1-5	21 d, ss	NOEC_{rep} = 26 mg/L	EFSA Journal 2016;14(11):4610
Sediment dwelling organisms				
<i>Chironomus riparius</i>	acetamiprid	28 d, s	NOEC _{emerg} = 0.00096 mg as/L _{mm} EC_{10emerg} = 0.000235 mg as/L_{mm}	EFSA Journal 2016;14(11):4610
Algae				
<i>Scenedesmus subspicatus</i>	acetamiprid	72 h, s	E _b C ₅₀ / E _r C ₅₀ > 98.3 mg as/L _{mm}	EFSA Journal 2016;14(11):4610
<i>Anabaena flos-aquae</i>	acetamiprid	120 h, s	EC₅₀ >1.3 mg as/L_{mm}	EFSA Journal 2016;14(11):4610
Higher plant				
<i>Lemna gibba</i>	acetamiprid	14 d, s	Fronds number EC₅₀ > 1.0 mg as/L_{mm}	EFSA Journal 2016;14(11):4610
Higher-tier studies (micro- or mesocosm studies)				
<p>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 as/L.</p> <p>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.</p>				

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 – Acetamipryd 200 SL

Species	Substance	Exposure System	Results	Reference
<i>Daphnia magna</i>	Acetamipryd 200 SL	48 h, s	EC ₅₀ = 951.7 mg/L _{nom} (164.1 mg as/ L _{nom}) LOEC = 1000 mg/ L _{nom} (172.4 mg as/ L _{nom}) NOEC = 500 mg/L _{nom} (86.2 mg as/ L _{nom})	Czarnecka M/ 2022/ Study code: W-11-22 KCP 10.2.1.2/01
<i>Pseudokirchneriella subcapitata</i>	Acetamipryd 200 SL	72 h, s	E _r C ₅₀ = 151.3 mg/L _{nom} (26.1 mg as/L) E _y C ₅₀ = 25.1 mg/L _{nom} (4.4 mg as/L) LOEC = 30.5 mg/ L _{nom} (5.3 mg as/ L _{nom}) NOEC = 9.5 mg/L _{nom} (1.6 mg as/ L _{nom})	Czarnecka M/ 2022/ Study code: W-12-22 KCP 10.2.1.3/01
Higher-tier studies (micro- or mesocosm studies)				

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Species	Substance	Exposure System	Results	Reference
Not relevant.				

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

zRMS comments: The toxicity endpoints for acetamiprid and aquatic organisms used in risk assessment was accepted by zRMS. The toxicity endpoints for formulation **PIORUN 200 SL** and *Daphnia magna* and *Pseudokirchneriella subcapitata* was accepted by zRMS.

9.5.1.1 Justification for new endpoints

New endpoints are provided for the formulated product Acetamipryd 200 SL. Details of studies and results are included in Table 9.5-2. Summary of the studies is included in Appendix II. Additional studies are required according to Regulation (EC) No. 284/2013.

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.

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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 Acetamipryd 200 SL to winter rape (1 × 50 g as/ha, BBCH 30-50) (use no. 1)

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. pro- longed	Algae	Higher plants	Sed. dwell. prolonged	Amphibians	Mesocosm
Test species		<i>Cyprinodon variegatus</i>	<i>Pimephales promelas</i>	Geomean.	<i>Daphnia magna</i>	<i>Anabaena flos-aquae</i>	<i>Lemna gibba</i>	<i>Chironomus riparius</i>	<i>Xenopus laevis</i>	-
Endpoint (µg/L)		LC ₅₀ 100 000	NOEC 9 400	EC ₅₀ 8.5	NOEC 2 960	EC ₅₀ 1 300	EC ₅₀ 1 000	NOEC 0.235	NOEC 2 600	NOEC/NOEAEC 1.1
AF		100	10	100	10	10	10	10	10	3
RAC (µg/L)		1000	940	0.085	296	130	100	0.0235	260	0.37
FOCUS Scenario	PEC _{gl-max} (µg/L)									
Step 1										
-	15.1312	0.02	0.02	178.01	0.05	0.12	0.15	643.88	0.06	40.90
Step 2										
N-Europe	0.5129	0.00	0.00	6.03	0.00	0.00	0.01	21.83	0.00	1.39
S-Europe	0.6430	0.00	0.00	7.56	0.00	0.00	0.01	27.36	0.00	1.74
Step 3										
D2/ditch	0.3210	0.00	0.00	3.78	0.00	0.00	0.00	13.66	0.00	0.87
D2/stream	0.2856	0.00	0.00	3.36	0.00	0.00	0.00	12.15	0.00	0.77
D3/ditch	0.3161	0.00	0.00	3.72	0.00	0.00	0.00	13.45	0.00	0.85
D4/pond	0.01094	0.00	0.00	0.13	0.00	0.00	0.00	0.47	0.00	0.03
D4/stream	0.2511	0.00	0.00	2.95	0.00	0.00	0.00	10.69	0.00	0.68

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Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. pro- longed	Algae	Higher plants	Sed. dwell. prolonged	Amphibians	Mesocosm
D5/pond	0.01093	0.00	0.00	0.13	0.00	0.00	0.00	0.47	0.00	0.03
D5/stream	0.2524	0.00	0.00	2.97	0.00	0.00	0.00	10.74	0.00	0.68
R1/pond	0.01093	0.00	0.00	0.13	0.00	0.00	0.00	0.47	0.00	0.03
R1/stream	0.2084	0.00	0.00	2.45	0.00	0.00	0.00	8.87	0.00	0.56
R3/stream	0.3391	0.00	0.00	3.99	0.00	0.00	0.00	14.43	0.00	0.92

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 (use no. 1), calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive groups of aquatic organisms (*Daphnia magna* and *Chironomus riparius*) in most of FOCUS Steps 1-3 scenarios. Therefore, additional risk with RAC based on mesocosm studies has been performed where all PEC/RAC values were below 1 indicating no unacceptable risk. No risk mitigation measures are required.

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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 Acetamipryd 200 SL to winter rape (1 × 24 g as/ha, BBCH 50-69) (use no. 2, 3)

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. pro- longed	Algae	Higher plants	Sed. dwell. prolonged	Amphibians	Mesocosm
Test species		<i>Cyprinodon variegatus</i>	<i>Pimephales promelas</i>	Geomean.	<i>Daphnia magna</i>	<i>Anabaena flos-aquae</i>	<i>Lemna gibba</i>	<i>Chironomus riparius</i>	<i>Xenopus laevis</i>	-
Endpoint (µg/L)		LC ₅₀ 100 000	NOEC 9 400	EC ₅₀ 8.5	NOEC 2 960	EC ₅₀ 1 300	EC ₅₀ 1 000	NOEC 0.235	NOEC 2 600	NOEC/NOEAEC 1.1
AF		100	10	100	10	10	10	10	10	3
RAC (µg/L)		1000	940	0.085	296	130	100	0.0235	260	0.37
FOCUS Scenario	PEC _{gl-max} (µg/L)									
Step 1										
-	7.2630	0.01	0.01	85.45	0.02	0.06	0.07	309.06	0.03	19.63
Step 2										
N-Europe	0.2358	0.00	0.00	2.77	0.00	0.00	0.00	10.03	0.00	0.64
S-Europe	0.2878	0.00	0.00	3.39	0.00	0.00	0.00	12.25	0.00	0.78
Step 3										
D2/ditch	0.1541	0.00	0.00	1.81	0.00	0.00	0.00	6.56	0.00	0.42
D2/stream	0.1371	0.00	0.00	1.61	0.00	0.00	0.00	5.83	0.00	0.37
D3/ditch	0.1521	0.00	0.00	1.79	0.00	0.00	0.00	6.47	0.00	0.41
D4/pond	0.005248	0.00	0.00	0.06	0.00	0.00	0.00	0.22	0.00	0.01
D4/stream	0.1168	0.00	0.00	1.37	0.00	0.00	0.00	4.97	0.00	0.32
D5/pond	0.005249	0.00	0.00	0.06	0.00	0.00	0.00	0.22	0.00	0.01

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Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. pro- longed	Algae	Higher plants	Sed. dwell. prolonged	Amphibians	Mesocosm
D5/stream	0.1233	0.00	0.00	1.45	0.00	0.00	0.00	5.25	0.00	0.33
R1/pond	0.006778	0.00	0.00	0.08	0.00	0.00	0.00	0.29	0.00	0.02
R1/stream	0.2449	0.00	0.00	2.88	0.00	0.00	0.00	10.42	0.00	0.66
R3/stream	0.1406	0.00	0.00	1.65	0.00	0.00	0.00	5.98	0.00	0.38

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 (use no. 2, 3), calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive groups of aquatic organisms (*Daphnia magna* and *Chironomus riparius*) in most of FOCUS Steps 1-3 scenarios. Therefore, additional risk with RAC based on mesocosm studies has been performed where all PEC/RAC values were below 1 indicating no unacceptable risk. No risk mitigation measures are required.

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Table 9.5-5: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for acetamiprid for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of Acetamipryd 200 SL to winter rape (1 × 60 g as/ha, BBCH 30-61) (use no. 13, 14)

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. pro- longed	Algae	Higher plants	Sed. dwell. prolonged	Amphibians	Mesocosm
Test species		<i>Cyprinodon variegatus</i>	<i>Pimephales promelas</i>	Geomean.	<i>Daphnia magna</i>	<i>Anabaena flos-aquae</i>	<i>Lemna gibba</i>	<i>Chironomus riparius</i>	<i>Xenopus laevis</i>	-
Endpoint (µg/L)		LC ₅₀ 100 000	NOEC 9 400	EC ₅₀ 8.5	NOEC 2 960	EC ₅₀ 1 300	EC ₅₀ 1 000	NOEC 0.235	NOEC 2 600	NOEC/NOEAEC 1.1
AF		100	10	100	10	10	10	10	10	3
RAC (µg/L)		1000	940	0.085	296	130	100	0.0235	260	0.37
FOCUS Scenario	PEC _{gl- max} (µg/L)									
Step 1										
-	18.1574	0.02	0.02	213.62	0.06	0.14	0.18	772.66	0.07	49.07
Step 2										
N-Europe	0.6155	0.00	0.00	7.24	0.00	0.00	0.01	26.19	0.00	1.66
S-Europe	0.7715	0.00	0.00	9.08	0.00	0.01	0.01	32.83	0.00	2.09
Step 3										
D2/ditch	0.3852	0.00	0.00	4.53	0.00	0.00	0.00	16.39	0.00	1.04
D2/stream	0.3427	0.00	0.00	4.03	0.00	0.00	0.00	14.58	0.00	0.93
D3/ditch	0.3794	0.00	0.00	4.46	0.00	0.00	0.00	16.14	0.00	1.03
D4/pond	0.01312	0.00	0.00	0.15	0.00	0.00	0.00	0.56	0.00	0.04
D4/stream	0.3013	0.00	0.00	3.54	0.00	0.00	0.00	12.82	0.00	0.81

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Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. pro- longed	Algae	Higher plants	Sed. dwell. prolonged	Amphibians	Mesocosm
D5/pond	0.01312	0.00	0.00	0.15	0.00	0.00	0.00	0.56	0.00	0.04
D5/stream	0.3029	0.00	0.00	3.56	0.00	0.00	0.00	12.89	0.00	0.82
R1/pond	0.01312	0.00	0.00	0.15	0.00	0.00	0.00	0.56	0.00	0.04
R1/stream	0.2501	0.00	0.00	2.94	0.00	0.00	0.00	10.64	0.00	0.68
R3/stream	0.4113	0.00	0.00	4.84	0.00	0.00	0.00	17.50	0.00	1.11

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 (use no. 13, 14), calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive groups of aquatic organisms (*Daphnia magna* and *Chironomus riparius*) in most of FOCUS Steps 1-3 scenarios. Therefore, additional risk with RAC based on mesocosm studies has been performed where most PEC/RAC values were below 1 indicating no unacceptable risk. However, for scenarios D2 ditch, D3 ditch and R3 stream further risk assessment with Step 4 PECsw was performed.

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Table 9.5-6: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for acetamiprid based on FOCUS Step 4 calculations and toxicity data for mesocosm with mitigation of spray drift and run-off for the use of Acetamipryd 200 SL winter rape (1 × 60 g as/ha, BBCH 30-61) (use no. 13, 14)

Intended use		winter rape						
Active substance		acetamiprid						
Application rate (g as/ha)		1 × 60						
Nozzle reduction	Vegetated filter strip (m)	None	None	None	None	None	10 (VFS)	20 (VFS)
	No-spray buffer (m)	1/3	5	10	15	20	10	20
None	D2/ditch	0.3852	0.1045	0.09213	0.09213	-	0.09213	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	D3/ditch	0.3794	0.1029	0.05453	0.03727	-	0.05453	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	R3 stream	0.4113	0.4113	0.4113	0.4113	-	0.06811	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
RAC (µg/L)								
0.37		PEC/RAC ratio						
None	D2/ditch	1.04	0.28	0.25	0.25	-	0.25	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	D3/ditch	1.03	0.28	0.15	0.1	-	0.15	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	R3 stream	1.11	1.11	1.11	1.11	-	0.18	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-

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90 %		-	-	-	-	-	-	-
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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 (use no. 13, 14), calculated Step 4 PEC/RAC ratios for scenarios D2 ditch, D3 ditch and R3 stream were below 1 indicating no unacceptable risk provided appropriate risk mitigation measures are applied.

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Table 9.5-7: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for acetamiprid for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of Acetamipryd 200 SL to spring rape (1 × 24 g as/ha, BBCH 50-65) (use no. 10)

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. pro-longed	Algae	Higher plants	Sed. dwell. prolonged	Amphibians	Mesocosm
Test species		<i>Cyprinodon variegatus</i>	<i>Pimephales promelas</i>	Geomean.	<i>Daphnia magna</i>	<i>Anabaena flos-aquae</i>	<i>Lemna gibba</i>	<i>Chironomus riparius</i>	<i>Xenopus laevis</i>	-
Endpoint (µg/L)		LC ₅₀ 100 000	NOEC 9 400	EC ₅₀ 8.5	NOEC 2 960	EC ₅₀ 1 300	EC ₅₀ 1 000	NOEC 0.235	NOEC 2 600	NOEC/NOEAEC 1.1
AF		100	10	100	10	10	10	10	10	3
RAC (µg/L)		1000	940	0.085	296	130	100	0.0235	260	0.37
FOCUS Scenario	PEC _{gl-max} (µg/L)									
Step 1										
-	7.2630	0.01	0.01	85.45	0.02	0.06	0.07	309.06	0.03	19.63
Step 2										
N-Europe	0.2358	0.00	0.00	2.77	0.00	0.00	0.00	10.03	0.00	0.64
S-Europe	0.2878	0.00	0.00	3.39	0.00	0.00	0.00	12.25	0.00	0.78
Step 3										
D1/ditch	0.1539	0.00	0.00	1.81	0.00	0.00	0.00	6.55	0.00	0.42
D1/stream	0.1346	0.00	0.00	1.58	0.00	0.00	0.00	5.73	0.00	0.36
D3/ditch	0.1527	0.00	0.00	1.80	0.00	0.00	0.00	6.50	0.00	0.41
D4/pond	0.005252	0.00	0.00	0.06	0.00	0.00	0.00	0.22	0.00	0.01
D4/stream	0.1316	0.00	0.00	1.55	0.00	0.00	0.00	5.60	0.00	0.36

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Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. pro- longed	Algae	Higher plants	Sed. dwell. prolonged	Amphibians	Mesocosm
D5/pond	0.005253	0.00	0.00	0.06	0.00	0.00	0.00	0.22	0.00	0.01
D5/stream	0.1419	0.00	0.00	1.67	0.00	0.00	0.00	6.04	0.00	0.38
R1/pond	0.02570	0.00	0.00	0.30	0.00	0.00	0.00	1.09	0.00	0.07
R1/stream	0.2646	0.00	0.00	3.11	0.00	0.00	0.00	11.26	0.00	0.72

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 (use no. 10), calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive groups of aquatic organisms (*Daphnia magna* and *Chironomus riparius*) in most of FOCUS Steps 1-3 scenarios. Therefore, additional risk with RAC based on mesocosm studies has been performed where all PEC/RAC values were below 1 indicating no unacceptable risk. No risk mitigation measures are required.

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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 Acetamipryd 200 SL to spring rape (1 × 50 g/ha, BBCH 30-50) (use no. 11)

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. pro- longed	Algae	Higher plants	Sed. dwell. prolonged	Amphibians	Mesocosm
Test species		<i>Cyprinodon variegatus</i>	<i>Pimephales promelas</i>	Geomean.	<i>Daphnia magna</i>	<i>Anabaena flos-aquae</i>	<i>Lemna gibba</i>	<i>Chironomus riparius</i>	<i>Xenopus laevis</i>	-
Endpoint (µg/L)		LC ₅₀ 100 000	NOEC 9 400	EC ₅₀ 8.5	NOEC 2 960	EC ₅₀ 1 300	EC ₅₀ 1 000	NOEC 0.235	NOEC 2 600	NOEC/NOEAEC 1.1
AF		100	10	100	10	10	10	10	10	3
RAC (µg/L)		1000	940	0.085	296	130	100	0.0235	260	0.37
FOCUS Scenario	PEC _{gl-max} (µg/L)									
Step 1										
-	15.1312	0.02	0.02	178.01	0.05	0.12	0.15	643.88	0.06	40.90
Step 2										
N-Europe	0.5129	0.00	0.00	6.03	0.00	0.00	0.01	21.83	0.00	1.39
S-Europe	0.6430	0.00	0.00	7.56	0.00	0.00	0.01	27.36	0.00	1.74
Step 3										
D1/ditch	0.3213	0.00	0.00	3.78	0.00	0.00	0.00	13.67	0.00	0.87
D1/stream	0.2805	0.00	0.00	3.30	0.00	0.00	0.00	11.94	0.00	0.76
D3/ditch	0.3180	0.00	0.00	3.74	0.00	0.00	0.00	13.53	0.00	0.86
D4/pond	0.01094	0.00	0.00	0.13	0.00	0.00	0.00	0.47	0.00	0.03
D4/stream	0.2741	0.00	0.00	3.22	0.00	0.00	0.00	11.66	0.00	0.74
D5/pond	0.01094	0.00	0.00	0.13	0.00	0.00	0.00	0.47	0.00	0.03

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Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. pro- longed	Algae	Higher plants	Sed. dwell. prolonged	Amphibians	Mesocosm
D5/stream	0.2956	0.00	0.00	3.48	0.00	0.00	0.00	12.58	0.00	0.80
R1/pond	0.07677	0.00	0.00	0.90	0.00	0.00	0.00	3.27	0.00	0.21
R1/stream	0.5610	0.00	0.00	6.60	0.00	0.00	0.01	23.87	0.00	1.52

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 use (use no. 11), calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive groups of aquatic organisms (*Daphnia magna* and *Chironomus riparius*) in most of FOCUS Steps 1-3 scenarios. Therefore, additional risk with RAC based on mesocosm studies has been performed where most PEC/RAC values were below 1 indicating no unacceptable risk. However, for scenario R1 stream further risk assessment with Step 4 PEC_{sw} was performed.

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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 mesocosm with mitigation of spray drift and run-off for the use of Acetamipryd 200 SL spring rape (1 × 50 g/ha, BBCH 30-50) (use no. 11)

Intended use		spring rape						
Active substance		acetamiprid						
Application rate (g as/ha)		1 × 50						
Nozzle reduction	Vegetated filter strip (m)	None	None	None	None	None	10 (VFS)	20 (VFS)
	No-spray buffer (m)	1/3	5	10	15	20	10	20
None	R1 stream	0.5610	0.5610	0.5610	0.5610	-	0.04062	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
RAC (µg/L)								
0.37		PEC/RAC ratio						
None	R1 stream	1.52	1.52	1.52	1.52	-	0.11	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-

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 use (use no. 11), calculated Step 4 PEC/RAC ratios for scenario R1 stream were below 1 indicating no unacceptable risk provided appropriate risk mitigation measures are applied.

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Table 9.5-10: 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 Acetamipryd 200 SL to spring rape (1 × 60 g/ha, BBCH 59-71) (use no. 12)

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. pro- longed	Algae	Higher plants	Sed. dwell. prolonged	Amphibians	Mesocosm
Test species		<i>Cyprinodon variegatus</i>	<i>Pimephales promelas</i>	Geomean.	<i>Daphnia magna</i>	<i>Anabaena flos-aquae</i>	<i>Lemna gibba</i>	<i>Chironomus riparius</i>	<i>Xenopus laevis</i>	-
Endpoint (µg/L)		LC ₅₀ 100 000	NOEC 9 400	EC ₅₀ 8.5	NOEC 2 960	EC ₅₀ 1 300	EC ₅₀ 1 000	NOEC 0.235	NOEC 2 600	NOEC/NOEAEC 1.1
AF		100	10	100	10	10	10	10	10	3
RAC (µg/L)		1000	940	0.085	296	130	100	0.0235	260	0.37
FOCUS Scenario	PEC _{gl- max} (µg/L)									
Step 1										
-	18.1574	0.02	0.02	213.62	0.06	0.14	0.18	772.66	0.07	49.07
Step 2										
N-Europe	0.5894	0.00	0.00	6.93	0.00	0.00	0.01	25.08	0.00	1.59
S-Europe	0.7195	0.00	0.00	8.46	0.00	0.01	0.01	30.62	0.00	1.94
Step 3										
D1/ditch	0.3855	0.00	0.00	4.54	0.00	0.00	0.00	16.40	0.00	1.04
D1/stream	0.3366	0.00	0.00	3.96	0.00	0.00	0.00	14.32	0.00	0.91
D3/ditch	0.3816	0.00	0.00	4.49	0.00	0.00	0.00	16.24	0.00	1.03
D4/pond	0.01313	0.00	0.00	0.15	0.00	0.00	0.00	0.56	0.00	0.04
D4/stream	0.3289	0.00	0.00	3.87	0.00	0.00	0.00	14.00	0.00	0.89

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Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. pro- longed	Algae	Higher plants	Sed. dwell. prolonged	Amphibians	Mesocosm
D5/pond	0.01313	0.00	0.00	0.15	0.00	0.00	0.00	0.56	0.00	0.04
D5/stream	0.3547	0.00	0.00	4.17	0.00	0.00	0.00	15.09	0.00	0.96
R1/pond	0.09331	0.00	0.00	1.10	0.00	0.00	0.00	3.97	0.00	0.25
R1/stream	0.6829	0.00	0.00	8.03	0.00	0.01	0.01	29.06	0.00	1.85

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 (use no. 12), calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive groups of aquatic organisms (*Daphnia magna* and *Chironomus riparius*) in most of FOCUS Steps 1-3 scenarios. Therefore, additional risk with RAC based on mesocosm studies has been performed where all PEC/RAC values were below 1 indicating no unacceptable risk. No risk mitigation measures are required.

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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 mesocosm with mitigation of spray drift and run-off for the use of Acetamipryd 200 SL to spring rape (1 × 60 g/ha, BBCH 59-71) (use no. 12)

Intended use		spring rape						
Active substance		acetamiprid						
Application rate (g as/ha)		1 × 60						
Nozzle reduction	Vegetated filter strip (m)	None	None	None	None	None	10 (VFS)	20 (VFS)
	No-spray buffer (m)	1/3	5	10	15	20	10	20
None	D1/ditch	0.3855	0.1050	0.05598	0.03847	-	0.05598	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	D3/ditch	0.3816	0.1035	0.05486	0.03749	-	0.05486	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	R1/stream	0.6829	0.6829	0.6829	0.6829	-	0.04875	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
RAC (µg/L)								
0.37		PEC/RAC ratio						
None	D1/ditch	1.04	0.28	0.15	0.1	-	0.15	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	D3/ditch	1.03	0.28	0.15	0.1	-	0.15	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	R1/stream	1.85	1.85	1.85	1.85	-	0.13	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-

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90 %		-	-	-	-	-	-	-
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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 use (use no. 12), calculated Step 4 PEC/RAC ratios for scenarios D1 ditch, D3 ditch and R1 stream were below 1 indicating no unacceptable risk provided appropriate risk mitigation measures are applied.

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Table 9.5-12: 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 Acetamipryd 200 SL to potato (1 x 24 g as/ha, BBCH 35-75) (use no. 4)

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. pro- longed	Algae	Higher plants	Sed. dwell. prolonged	Amphibians	Mesocosm
Test species		<i>Cyprinodon variegatus</i>	<i>Pimephales promelas</i>	Geomean.	<i>Daphnia magna</i>	<i>Anabaena flos-aquae</i>	<i>Lemna gibba</i>	<i>Chironomus riparius</i>	<i>Xenopus laevis</i>	-
Endpoint (µg/L)		LC ₅₀ 100 000	NOEC 9 400	EC ₅₀ 8.5	NOEC 2 960	EC ₅₀ 1 300	EC ₅₀ 1 000	NOEC 0.235	NOEC 2 600	NOEC/NOEAEC 1.1
AF		100	10	100	10	10	10	10	10	3
RAC (µg/L)		1000	940	0.085	296	130	100	0.0235	260	0.37
FOCUS Scenario	PEC _{gl- max} (µg/L)									
Step 1										
-	7.2630	0.01	0.01	85.45	0.02	0.06	0.07	309.06	0.03	19.63
Step 2										
N-Europe	0.2878	0.00	0.00	3.39	0.00	0.00	0.00	12.25	0.00	0.78
S-Europe	0.3919	0.00	0.00	4.61	0.00	0.00	0.00	16.68	0.00	1.06
Step 3										
D3/ditch	0.1258	0.00	0.00	1.48	0.00	0.00	0.00	5.35	0.00	0.34
D4/pond	0.005081	0.00	0.00	0.06	0.00	0.00	0.00	0.22	0.00	0.01
D4/stream	0.09460	0.00	0.00	1.11	0.00	0.00	0.00	4.03	0.00	0.26
D6/ditch	0.1254	0.00	0.00	1.48	0.00	0.00	0.00	5.34	0.00	0.34
R1/pond	0.02575	0.00	0.00	0.30	0.00	0.00	0.00	1.10	0.00	0.07

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Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. pro- longed	Algae	Higher plants	Sed. dwell. prolonged	Amphibians	Mesocosm
R1/stream	0.1841	0.00	0.00	2.17	0.00	0.00	0.00	7.83	0.00	0.50
R2/stream	0.1171	0.00	0.00	1.38	0.00	0.00	0.00	4.98	0.00	0.32
R3/stream	0.2723	0.00	0.00	3.20	0.00	0.00	0.00	11.59	0.00	0.74

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 use (use no. 4), calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive groups of aquatic organisms (*Daphnia magna* and *Chironomus riparius*) in most of FOCUS Steps 1-3 scenarios. Therefore, additional risk with RAC based on mesocosm studies has been performed where all PEC/RAC values were below 1 indicating no unacceptable risk. No risk mitigation measures are required.

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Table 9.5-13: 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 Acetamipryd 200 SL to orchards, early application (1 × 22 g as/ha, BBCH 56-84) (use no. 7, 8, 15, 17, 18, 20, 21, 28, 30, 31, 33, 35, 37, 39)

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. pro- longed	Algae	Higher plants	Sed. dwell. prolonged	Amphibians	Mesocosm
Test species		<i>Cyprinodon variegatus</i>	<i>Pimephales promelas</i>	Geomean.	<i>Daphnia magna</i>	<i>Anabaena flos-aquae</i>	<i>Lemna gibba</i>	<i>Chironomus riparius</i>	<i>Xenopus laevis</i>	-
Endpoint (µg/L)		LC ₅₀ 100 000	NOEC 9 400	EC ₅₀ 8.5	NOEC 2 960	EC ₅₀ 1 300	EC ₅₀ 1 000	NOEC 0.235	NOEC 2 600	NOEC/NOEAEC 1.1
AF		100	10	100	10	10	10	10	10	3
RAC (µg/L)		1000	940	0.085	296	130	100	0.0235	260	0.37
FOCUS Scenario	PEC _{gl-max} (µg/L)									
Step 1										
-	8.5965	0.01	0.01	101.14	0.03	0.07	0.09	365.81	0.03	23.23
Step 2										
N-Europe	2.1411	0.00	0.00	25.19	0.01	0.02	0.02	91.11	0.01	5.79
S-Europe	2.1411	0.00	0.00	25.19	0.01	0.02	0.02	91.11	0.01	5.79
Step 3										
D3/ditch	1.714	0.00	0.00	20.16	0.01	0.01	0.02	72.94	0.01	4.63
D4/pond	0.1039	0.00	0.00	1.22	0.00	0.00	0.00	4.42	0.00	0.28
D4/stream	1.817	0.00	0.00	21.38	0.01	0.01	0.02	77.32	0.01	4.91
D5/pond	0.1039	0.00	0.00	1.22	0.00	0.00	0.00	4.42	0.00	0.28
D5/stream	1.857	0.00	0.00	21.85	0.01	0.01	0.02	79.02	0.01	5.02

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Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. pro- longed	Algae	Higher plants	Sed. dwell. prolonged	Amphibians	Mesocosm
R1/pond	0.1039	0.00	0.00	1.22	0.00	0.00	0.00	4.42	0.00	0.28
R1/stream	1.392	0.00	0.00	16.38	0.00	0.01	0.01	59.23	0.01	3.76
R2/stream	1.866	0.00	0.00	21.95	0.01	0.01	0.02	79.40	0.01	5.04
R3/stream	1.949	0.00	0.00	22.93	0.01	0.01	0.02	82.94	0.01	5.27
R4/stream	1.361	0.00	0.00	16.01	0.00	0.01	0.01	57.91	0.01	3.68

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 (use no. 7, 8, 15, 17, 18, 20, 21, 28, 30, 31, 33, 35, 37, 39), calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive groups of aquatic organisms (*Daphnia magna* and *Chironomus riparius*) in most of FOCUS Steps 1-3 scenarios. Therefore, additional risk with RAC based on mesocosm studies has been performed where some PEC/RAC values were below 1 indicating no unacceptable risk. However, for scenarios D3 ditch, D4 stream, D5 stream, R1 stream, R2 stream, R3 stream and R4 stream further risk assessment with Step 4 PEC_{sw} was performed.

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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 mesocosm with mitigation of spray drift and run-off for the use of Acetamipryd 200 SL in orchards, early application (1 × 22 g as/ha, BBCH 56-84) (use no. 7, 8, 15, 17, 18, 20, 21, 28, 30, 31, 33, 35, 37, 39)

Intended use		orchards						
Active substance		acetamiprid						
Application rate (g as/ha)		1 × 22						
Nozzle reduction	Vegetated filter strip (m)	None	None	None	None	None	10 (VFS)	20 (VFS)
	No-spray buffer (m)	1/3	5	10	15	20	10	20
None	D3/ditch	1.714	1.347	0.8271	0.3721	0.1891	0.8271	0.1891
50 %		-	0.6736	0.4137	0.1861	-	-	-
75 %		-	0.3368	0.2068	0.09305	-	-	-
90 %		-	0.1347	0.08271	0.03721	-	-	-
None	D4/stream	1.817	1.561	0.9586	0.4312	0.2192	0.9586	0.2192
50 %		-	0.7807	0.4793	0.2156	-	-	-
75 %		-	0.3903	0.2397	0.1078	-	-	-
90 %		-	0.1561	0.09586	0.04312	-	-	-
None	D5/stream	1.857	1.595	0.9797	0.4406	0.2240	0.9797	0.2240
50 %		-	0.7978	0.4898	0.2204	-	-	-
75 %		-	0.3989	0.2449	0.1102	-	-	-
90 %		-	0.1595	0.09797	0.04406	-	-	-
None	R1/stream	1.392	1.196	0.7346	0.3304	0.1680	0.7346	0.1680
50 %		-	0.5982	0.3673	0.1652	-	-	-
75 %		-	0.2991	0.1837	0.1418	-	-	-
90 %		-	0.1418	0.1418	0.1418	-	-	-
None	R2/stream	1.866	1.603	0.9846	0.4429	0.2252	0.9846	0.2252
50 %		-	0.8019	0.4923	0.2215	-	-	-
75 %		-	0.4009	0.2462	0.1107	-	-	-
90 %		-	0.1603	0.09846	0.04429	-	-	-
None	R3/stream	1.949	1.674	1.028	0.4624	0.2351	1.028	0.2351
50 %		-	0.8372	0.5140	0.2313	-	-	-
75 %		-	0.4186	0.2570	0.1156	-	-	-
90 %		-	0.1674	0.1028	0.04624	-	-	-

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None	R4/stream	1.361	1.169	0.7180	0.3229	0.1642	0.7180	0.1642
50 %		-	0.5847	0.3590	0.2032	-	-	-
75 %		-	0.2924	0.2032	0.2032	-	-	-
90 %		-	0.2032	0.2032	0.2032	-	-	-
RAC (µg/L)								
0.37		PEC/RAC ratio						
None	D3/ditch	4.63	3.64	2.24	1.01	0.51	2.24	0.51
50 %		-	1.82	1.12	0.5	-	-	-
75 %		-	0.91	0.56	0.25	-	-	-
90 %		-	0.36	0.22	0.1	-	-	-
None	D4/stream	4.91	4.22	2.59	1.17	0.59	2.59	0.59
50 %		-	2.11	1.3	0.58	-	-	-
75 %		-	1.05	0.65	0.29	-	-	-
90 %		-	0.42	0.26	0.12	-	-	-
None	D5/stream	5.02	4.31	2.65	1.19	0.61	2.65	0.61
50 %		-	2.16	1.32	0.6	-	-	-
75 %		-	1.08	0.66	0.3	-	-	-
90 %		-	0.43	0.26	0.12	-	-	-
None	R1/stream	3.76	3.23	1.99	0.89	0.45	1.99	0.45
50 %		-	1.62	0.99	0.45	-	-	-
75 %		-	0.81	0.5	0.38	-	-	-
90 %		-	0.38	0.38	0.38	-	-	-
None	R2/stream	5.04	4.33	2.66	1.2	0.61	2.66	0.61
50 %		-	2.17	1.33	0.6	-	-	-
75 %		-	1.08	0.67	0.3	-	-	-
90 %		-	0.43	0.27	0.12	-	-	-
None	R3/stream	5.27	4.52	2.78	1.25	0.64	2.78	0.64
50 %		-	2.26	1.39	0.63	-	-	-
75 %		-	1.13	0.69	0.31	-	-	-
90 %		-	0.45	0.28	0.12	-	-	-
None	R4/stream	3.68	3.16	1.94	0.87	0.44	1.94	0.44
50 %		-	1.58	0.97	0.55	-	-	-
75 %		-	0.79	0.55	0.55	-	-	-
90 %		-	0.55	0.55	0.55	-	-	-

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 (use no. 7, 8, 15, 17, 18, 20, 21, 28, 30, 31, 33, 35, 37, 39), calculated Step 4 PEC/RAC ratios for scenarios D3 ditch, D4 stream, D5 stream, R1 stream, R2 stream, R3 stream and R4 stream were

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below 1 indicating no unacceptable risk provided appropriate risk mitigation measures are applied.

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Table 9.5-15: 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 Acetamipryd 200 SL to orchards, late application (1 × 22 g as/ha, BBCH 56-84) (use no. 7, 8, 15, 17, 18, 20, 21, 28, 30, 31, 33, 35, 37, 39)

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. pro- longed	Algae	Higher plants	Sed. dwell. prolonged	Amphibians	Mesocosm
Test species		<i>Cyprinodon variegatus</i>	<i>Pimephales promelas</i>	Geomean.	<i>Daphnia magna</i>	<i>Anabaena flos-aquae</i>	<i>Lemna gibba</i>	<i>Chironomus riparius</i>	<i>Xenopus laevis</i>	-
Endpoint (µg/L)		LC ₅₀ 100 000	NOEC 9 400	EC ₅₀ 8.5	NOEC 2 960	EC ₅₀ 1 300	EC ₅₀ 1 000	NOEC 0.235	NOEC 2 600	NOEC/NOEAEC 1.1
AF		100	10	100	10	10	10	10	10	3
RAC (µg/L)		1000	940	0.085	296	130	100	0.0235	260	0.37
FOCUS Scenario	PEC ^{gl-} max (µg/L)									
Step 1										
-	7.6086	0.01	0.01	89.51	0.03	0.06	0.08	323.77	0.03	20.56
Step 2										
N-Europe	1.1532	0.00	0.00	13.57	0.00	0.01	0.01	49.07	0.00	3.12
S-Europe	1.1532	0.00	0.00	13.57	0.00	0.01	0.01	49.07	0.00	3.12
Step 3										
D3/ditch	0.8085	0.00	0.00	9.51	0.00	0.01	0.01	34.40	0.00	2.19
D4/pond	0.03623	0.00	0.00	0.43	0.00	0.00	0.00	1.54	0.00	0.10
D4/stream	0.8103	0.00	0.00	9.53	0.00	0.01	0.01	34.48	0.00	2.19
D5/pond	0.03623	0.00	0.00	0.43	0.00	0.00	0.00	1.54	0.00	0.10
D5/stream	0.8281	0.00	0.00	9.74	0.00	0.01	0.01	35.24	0.00	2.24

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Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. pro- longed	Algae	Higher plants	Sed. dwell. prolonged	Amphibians	Mesocosm
R1/pond	0.03621	0.00	0.00	0.43	0.00	0.00	0.00	1.54	0.00	0.10
R1/stream	0.6210	0.00	0.00	7.31	0.00	0.00	0.01	26.43	0.00	1.68
R2/stream	0.8323	0.00	0.00	9.79	0.00	0.01	0.01	35.42	0.00	2.25
R3/stream	0.8690	0.00	0.00	10.22	0.00	0.01	0.01	36.98	0.00	2.35
R4/stream	0.6070	0.00	0.00	7.14	0.00	0.00	0.01	25.83	0.00	1.64

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 (use no. 7, 8, 15, 17, 18, 20, 21, 28, 30, 31, 33, 35, 37, 39), calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive groups of aquatic organisms (*Daphnia magna* and *Chironomus riparius*) in most of FOCUS Steps 1-3 scenarios. Therefore, additional risk with RAC based on mesocosm studies has been performed where some PEC/RAC values were below 1 indicating no unacceptable risk. However, for scenarios D3 ditch, D4 stream, D5 stream, R1 stream, R2 stream, R3 stream and R4 stream further risk assessment with Step 4 PEC_{sw} was performed.

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Table 9.5-16: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for acetamiprid based on FOCUS Step 4 calculations and toxicity data for mesocosm with mitigation of spray drift and run-off for the use of Acetamipryd 200 SL in orchards, late application (1 × 22 g as/ha, BBCH 56-84) (use no. 7, 8, 15, 17, 18, 20, 21, 28, 30, 31, 33, 35, 37, 39)

Intended use		orchards						
Active substance		acetamiprid						
Application rate (g as/ha)		1 × 22						
Nozzle reduction	Vegetated filter strip (m)	None	None	None	None	None	10 (VFS)	20 (VFS)
	No-spray buffer (m)	1/3	5	10	15	20	10	20
None	D3/ditch	0.8085	0.5458	0.2438	0.1231	0.07525	0.2438	0.07525
50 %		-	0.2729	-	-	-	-	-
75 %		-	0.1364	-	-	-	-	-
90 %		-	0.05458	-	-	-	-	-
None	D4/stream	0.8103	0.6324	0.2826	0.1427	0.08722	0.2826	0.08722
50 %		-	0.3162	-	-	-	-	-
75 %		-	0.1581	-	-	-	-	-
90 %		-	0.06324	-	-	-	-	-
None	D5/stream	0.8281	0.6463	0.2888	0.1458	0.08913	0.2888	0.08913
50 %		-	0.3232	-	-	-	-	-
75 %		-	0.1616	-	-	-	-	-
90 %		-	0.06463	-	-	-	-	-
None	R1/stream	0.6210	0.4846	0.2166	0.1094	0.06684	0.2166	0.06684
50 %		-	0.2423	-	-	-	-	-
75 %		-	0.1212	-	-	-	-	-
90 %		-	0.05744	-	-	-	-	-
None	R2/stream	0.8323	0.6495	0.2903	0.1466	0.08959	0.2903	0.08959
50 %		-	0.3248	-	-	-	-	-
75 %		-	0.1624	-	-	-	-	-
90 %		-	0.06495	-	-	-	-	-
None	R3/stream	0.8690	0.6782	0.3031	0.1530	0.09354	0.3031	0.09354
50 %		-	0.3391	-	-	-	-	-
75 %		-	0.1696	-	-	-	-	-
90 %		-	0.06782	-	-	-	-	-

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None	R4/stream	0.6070	0.4737	0.2117	0.1639	0.06533	0.2117	0.06533
50 %		-	0.2369	-	-	-	-	-
75 %		-	0.1639	-	-	-	-	-
90 %		-	0.1639	-	-	-	-	-
RAC (µg/L)								
0.37		PEC/RAC ratio						
None	D3/ditch	2.19	1.48	0.66	0.33	0.2	0.66	0.2
50 %		-	0.74	-	-	-	-	-
75 %		-	0.37	-	-	-	-	-
90 %		-	0.15	-	-	-	-	-
None	D4/stream	2.19	1.71	0.76	0.39	0.24	0.76	0.24
50 %		-	0.85	-	-	-	-	-
75 %		-	0.43	-	-	-	-	-
90 %		-	0.17	-	-	-	-	-
None	D5/stream	2.24	1.75	0.78	0.39	0.24	0.78	0.24
50 %		-	0.87	-	-	-	-	-
75 %		-	0.44	-	-	-	-	-
90 %		-	0.17	-	-	-	-	-
None	R1/stream	1.68	1.31	0.59	0.3	0.18	0.59	0.18
50 %		-	0.65	-	-	-	-	-
75 %		-	0.33	-	-	-	-	-
90 %		-	0.16	-	-	-	-	-
None	R2/stream	2.25	1.76	0.78	0.4	0.24	0.78	0.24
50 %		-	0.88	-	-	-	-	-
75 %		-	0.44	-	-	-	-	-
90 %		-	0.18	-	-	-	-	-
None	R3/stream	2.35	1.83	0.82	0.41	0.25	0.82	0.25
50 %		-	0.92	-	-	-	-	-
75 %		-	0.46	-	-	-	-	-
90 %		-	0.18	-	-	-	-	-
None	R4/stream	1.64	1.28	0.57	0.44	0.18	0.57	0.18
50 %		-	0.64	-	-	-	-	-
75 %		-	0.44	-	-	-	-	-
90 %		-	0.44	-	-	-	-	-

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 (use no. 7, 8, 15, 17, 18, 20, 21, 28, 30, 31, 33, 35, 37, 39), calculated Step 4 PEC/RAC ratios for scenarios D3 ditch, D4 stream, D5 stream, R1 stream, R2 stream, R3 stream and R4 stream were

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below 1 indicating no unacceptable risk provided appropriate risk mitigation measures are applied.

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Table 9.5-17: 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 Acetamipryd 200 SL to orchards, early application (1 × 36 g as/ha, BBCH 56-84) (use no. 9)

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. pro- longed	Algae	Higher plants	Sed. dwell. prolonged	Amphibians	Mesocosm
Test species		<i>Cyprinodon variegatus</i>	<i>Pimephales promelas</i>	Geomean.	<i>Daphnia magna</i>	<i>Anabaena flos-aquae</i>	<i>Lemna gibba</i>	<i>Chironomus riparius</i>	<i>Xenopus laevis</i>	-
Endpoint (µg/L)		LC ₅₀ 100 000	NOEC 9 400	EC ₅₀ 8.5	NOEC 2 960	EC ₅₀ 1 300	EC ₅₀ 1 000	NOEC 0.235	NOEC 2 600	NOEC/NOEAEC 1.1
AF		100	10	100	10	10	10	10	10	3
RAC (µg/L)		1000	940	0.085	296	130	100	0.0235	260	0.37
FOCUS Scenario	PEC _{gl- max} (µg/L)									
Step 1										
-	14.0670	0.01	0.01	165.49	0.05	0.11	0.14	598.60	0.05	38.02
Step 2										
N-Europe	3.5036	0.00	0.00	41.22	0.01	0.03	0.04	149.09	0.01	9.47
S-Europe	3.5036	0.00	0.00	41.22	0.01	0.03	0.04	149.09	0.01	9.47
Step 3										
D3/ditch	2.805	0.00	0.00	33.00	0.01	0.02	0.03	119.36	0.01	7.58
D4/pond	0.1701	0.00	0.00	2.00	0.00	0.00	0.00	7.24	0.00	0.46
D4/stream	2.974	0.00	0.00	34.99	0.01	0.02	0.03	126.55	0.01	8.04
D5/pond	0.1701	0.00	0.00	2.00	0.00	0.00	0.00	7.24	0.00	0.46
D5/stream	3.039	0.00	0.00	35.75	0.01	0.02	0.03	129.32	0.01	8.21

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Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. pro- longed	Algae	Higher plants	Sed. dwell. prolonged	Amphibians	Mesocosm
R1/pond	0.1700	0.00	0.00	2.00	0.00	0.00	0.00	7.23	0.00	0.46
R1/stream	2.279	0.00	0.00	26.81	0.01	0.02	0.02	96.98	0.01	6.16
R2/stream	3.054	0.00	0.00	35.93	0.01	0.02	0.03	129.96	0.01	8.25
R3/stream	3.189	0.00	0.00	37.52	0.01	0.02	0.03	135.70	0.01	8.62
R4/stream	2.227	0.00	0.00	26.20	0.01	0.02	0.02	94.77	0.01	6.02

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 (use no. 9), calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive groups of aquatic organisms (*Daphnia magna* and *Chironomus riparius*) in most of FOCUS Steps 1-3 scenarios. Therefore, additional risk with RAC based on mesocosm studies has been performed where some PEC/RAC values were below 1 indicating no unacceptable risk. However, for scenarios D3 ditch, D4 stream, D5 stream, R1 stream, R2 stream, R3 stream and R4 stream further risk assessment with Step 4 PEC_{sw} was performed.

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Table 9.5-18: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for acetamiprid based on FOCUS Step 4 calculations and toxicity data for mesocosm with mitigation of spray drift and run-off for the use of Acetamipryd 200 SL in orchards, early application (1 × 36 g as/ha, BBCH 56-84) (use no. 9)

Intended use		orchards						
Active substance		acetamiprid						
Application rate (g as/ha)		1 × 36						
Nozzle reduction	Vegetated filter strip (m)	None	None	None	None	None	10 (VFS)	20 (VFS)
	No-spray buffer (m)	1/3	5	10	15	20	10	20
None	D3/ditch	2.805	2.204	1.353	0.6089	0.3095	1.353	0.3095
50 %		-	1.102	0.6769	0.3045	-	-	-
75 %		-	0.5511	0.3384	0.1522	-	-	-
90 %		-	0.2204	0.1353	0.06089	-	-	-
None	D4/stream	2.974	2.555	1.569	0.7057	0.3588	1.569	0.3588
50 %		-	1.277	0.7845	0.3530	-	-	-
75 %		-	0.6388	0.3923	0.1765	-	-	-
90 %		-	0.2555	0.1569	0.07057	-	-	-
None	D5/stream	3.039	2.611	1.603	0.7212	0.3666	1.603	0.3666
50 %		-	1.305	0.8017	0.3608	-	-	-
75 %		-	0.6528	0.4009	0.1803	-	-	-
90 %		-	0.2611	0.1603	0.07212	-	-	-
None	R1/stream	2.279	1.958	1.202	0.5408	0.2749	1.202	0.2749
50 %		-	0.9787	0.6012	0.2705	-	-	-
75 %		-	0.4895	0.3006	0.2405	-	-	-
90 %		-	0.2405	0.2405	0.2405	-	-	-
None	R2/stream	3.054	2.624	1.611	0.7249	0.3685	1.611	0.3685
50 %		-	1.312	0.8058	0.3626	-	-	-
75 %		-	0.6561	0.4029	0.1812	-	-	-
90 %		-	0.2624	0.1611	0.07249	-	-	-
None	R3/stream	3.189	2.740	1.682	0.7568	0.3847	1.682	0.3847
50 %		-	1.370	0.8413	0.3786	-	-	-
75 %		-	0.6850	0.4207	0.1892	-	-	-
90 %		-	0.2740	0.1682	0.07568	-	-	-
None	R4/stream	2.227	1.914	1.175	0.5286	0.2687	1.175	0.2687

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50 %		-	0.9567	0.5876	0.3421	-	-	-
75 %		-	0.4784	0.3421	0.3421	-	-	-
90 %		-	0.3421	0.3421	0.3421	-	-	-
RAC (µg/L)								
0.37		PEC/RAC ratio						
None	D3/ditch	7.58	5.96	3.66	1.65	0.84	3.66	0.84
50 %		-	2.98	1.83	0.82	-	-	-
75 %		-	1.49	0.91	0.41	-	-	-
90 %		-	0.6	0.37	0.16	-	-	-
None	D4/stream	8.04	6.91	4.24	1.91	0.97	4.24	0.97
50 %		-	3.45	2.12	0.95	-	-	-
75 %		-	1.73	1.06	0.48	-	-	-
90 %		-	0.69	0.42	0.19	-	-	-
None	D5/stream	8.21	7.06	4.33	1.95	0.99	4.33	0.99
50 %		-	3.53	2.17	0.98	-	-	-
75 %		-	1.76	1.08	0.49	-	-	-
90 %		-	0.71	0.43	0.19	-	-	-
None	R1/stream	6.16	5.29	3.25	1.46	0.74	3.25	0.74
50 %		-	2.65	1.62	0.73	-	-	-
75 %		-	1.32	0.81	0.65	-	-	-
90 %		-	0.65	0.65	0.65	-	-	-
None	R2/stream	8.25	7.09	4.35	1.96	1	4.35	1
50 %		-	3.55	2.18	0.98	-	-	-
75 %		-	1.77	1.09	0.49	-	-	-
90 %		-	0.71	0.44	0.2	-	-	-
None	R3/stream	8.62	7.41	4.55	2.05	1.04	4.55	1.04
50 %		-	3.7	2.27	1.02	-	-	-
75 %		-	1.85	1.14	0.51	-	-	-
90 %		-	0.74	0.45	0.2	-	-	-
None	R4/stream	6.02	5.17	3.18	1.43	0.73	3.18	0.73
50 %		-	2.59	1.59	0.92	-	-	-
75 %		-	1.29	0.92	0.92	-	-	-
90 %		-	0.92	0.92	0.92	-	-	-

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 use (use no. 9), calculated Step 4 PEC/RAC ratios for scenarios D3 ditch, D4 stream, D5 stream, R1 stream, R2 stream, R3 stream and R4 stream were below 1 indicating no unacceptable risk provided appropriate risk mitigation measures are applied.

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Table 9.5-19: 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 Acetamipryd 200 SL to orchards, late application (1 × 36 g as/ha, BBCH 56-84) (use no. 9)

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. pro- longed	Algae	Higher plants	Sed. dwell. prolonged	Amphibians	Mesocosm
Test species		<i>Cyprinodon variegatus</i>	<i>Pimephales promelas</i>	Geomean.	<i>Daphnia magna</i>	<i>Anabaena flos-aquae</i>	<i>Lemna gibba</i>	<i>Chironomus riparius</i>	<i>Xenopus laevis</i>	-
Endpoint (µg/L)		LC ₅₀ 100 000	NOEC 9 400	EC ₅₀ 8.5	NOEC 2 960	EC ₅₀ 1 300	EC ₅₀ 1 000	NOEC 0.235	NOEC 2 600	NOEC/NOEAEC 1.1
AF		100	10	100	10	10	10	10	10	3
RAC (µg/L)		1000	940	0.085	296	130	100	0.0235	260	0.37
FOCUS Scenario	PEC _{gl- max} (µg/L)									
Step 1										
-	12.4504	0.01	0.01	146.48	0.04	0.10	0.12	529.80	0.05	33.65
Step 2										
N-Europe	1.8870	0.00	0.00	22.20	0.01	0.01	0.02	80.30	0.01	5.10
S-Europe	1.8870	0.00	0.00	22.20	0.01	0.01	0.02	80.30	0.01	5.10
Step 3										
D3/ditch	1.323	0.00	0.00	15.56	0.00	0.01	0.01	56.30	0.01	3.58
D4/pond	0.05929	0.00	0.00	0.70	0.00	0.00	0.00	2.52	0.00	0.16
D4/stream	1.326	0.00	0.00	15.60	0.00	0.01	0.01	56.43	0.01	3.58
D5/pond	0.05929	0.00	0.00	0.70	0.00	0.00	0.00	2.52	0.00	0.16
D5/stream	1.355	0.00	0.00	15.94	0.00	0.01	0.01	57.66	0.01	3.66

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Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. pro- longed	Algae	Higher plants	Sed. dwell. prolonged	Amphibians	Mesocosm
R1/pond	0.05926	0.00	0.00	0.70	0.00	0.00	0.00	2.52	0.00	0.16
R1/stream	1.016	0.00	0.00	11.95	0.00	0.01	0.01	43.23	0.00	2.75
R2/stream	1.362	0.00	0.00	16.02	0.00	0.01	0.01	57.96	0.01	3.68
R3/stream	1.422	0.00	0.00	16.73	0.00	0.01	0.01	60.51	0.01	3.84
R4/stream	0.9932	0.00	0.00	11.68	0.00	0.01	0.01	42.26	0.00	2.68

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 use (use no. 9), calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive groups of aquatic organisms (*Daphnia magna* and *Chironomus riparius*) in most of FOCUS Steps 1-3 scenarios. Therefore, additional risk with RAC based on mesocosm studies has been performed where some PEC/RAC values were below 1 indicating no unacceptable risk. However, for scenarios D3 ditch, D4 stream, D5 stream, R1 stream, R2 stream, R3 stream and R4 stream further risk assessment with Step 4 PEC_{sw} was performed.

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Table 9.5-20: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for acetamiprid based on FOCUS Step 4 calculations and toxicity data for mesocosm with mitigation of spray drift and run-off for the use of Acetamipryd 200 SL in orchards, late application (1 × 36 g as/ha, BBCH 56-84) (use no. 9)

Intended use		orchards						
Active substance		acetamiprid						
Application rate (g as/ha)		1 × 36						
Nozzle reduction	Vegetated filter strip (m)	None	None	None	None	None	10 (VFS)	20 (VFS)
	No-spray buffer (m)	1/3	5	10	15	20	10	20
None	D3/ditch	1.323	0.8928	0.3989	0.2015	0.1231	0.3989	0.1231
50 %		-	0.4464	0.1995	-	-	-	-
75 %		-	0.2232	0.09975	-	-	-	-
90 %		-	0.08928	0.03989	-	-	-	-
None	D4/stream	1.326	1.035	0.4624	0.2335	0.1427	0.4624	0.1427
50 %		-	0.5176	0.2312	-	-	-	-
75 %		-	0.2587	0.1156	-	-	-	-
90 %		-	0.1035	0.04624	-	-	-	-
None	D5/stream	1.355	1.058	0.4726	0.2386	0.1458	0.4726	0.1458
50 %		-	0.5289	0.2363	-	-	-	-
75 %		-	0.2644	0.1181	-	-	-	-
90 %		-	0.1058	0.04726	-	-	-	-
None	R1/stream	1.016	0.7930	0.3544	0.1789	0.1094	0.3544	0.1094
50 %		-	0.3966	0.1772	-	-	-	-
75 %		-	0.1983	0.09692	-	-	-	-
90 %		-	0.09692	0.09692	-	-	-	-
None	R2/stream	1.362	1.063	0.4750	0.2398	0.1466	0.4750	0.1466
50 %		-	0.5316	0.2375	-	-	-	-
75 %		-	0.2657	0.1187	-	-	-	-
90 %		-	0.1063	0.04750	-	-	-	-
None	R3/stream	1.422	1.110	0.4959	0.2504	0.1530	0.4959	0.1530
50 %		-	0.5551	0.2480	-	-	-	-
75 %		-	0.2775	0.1240	-	-	-	-
90 %		-	0.1110	0.04959	-	-	-	-
None	R4/stream	0.9932	0.7751	0.3464	0.2753	0.1069	0.3464	0.1069

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50 %		-	0.3877	0.2753	-	-	-	-
75 %		-	0.2753	0.2753	-	-	-	-
90 %		-	0.2753	0.2753	-	-	-	-
RAC (µg/L) 0.37		PEC/RAC ratio						
None	D3/ditch	3.58	2.41	1.08	0.54	0.33	1.08	0.33
50 %		-	1.21	0.54	-	-	-	-
75 %		-	0.6	0.27	-	-	-	-
90 %		-	0.24	0.11	-	-	-	-
None	D4/stream	3.58	2.8	1.25	0.63	0.39	1.25	0.39
50 %		-	1.4	0.62	-	-	-	-
75 %		-	0.7	0.31	-	-	-	-
90 %		-	0.28	0.12	-	-	-	-
None	D5/stream	3.66	2.86	1.28	0.64	0.39	1.28	0.39
50 %		-	1.43	0.64	-	-	-	-
75 %		-	0.71	0.32	-	-	-	-
90 %		-	0.29	0.13	-	-	-	-
None	R1/stream	2.75	2.14	0.96	0.48	0.3	0.96	0.3
50 %		-	1.07	0.48	-	-	-	-
75 %		-	0.54	0.26	-	-	-	-
90 %		-	0.26	0.26	-	-	-	-
None	R2/stream	3.68	2.87	1.28	0.65	0.4	1.28	0.4
50 %		-	1.44	0.64	-	-	-	-
75 %		-	0.72	0.32	-	-	-	-
90 %		-	0.29	0.13	-	-	-	-
None	R3/stream	3.84	3	1.34	0.68	0.41	1.34	0.41
50 %		-	1.5	0.67	-	-	-	-
75 %		-	0.75	0.34	-	-	-	-
90 %		-	0.3	0.13	-	-	-	-
None	R4/stream	2.68	2.09	0.94	0.74	0.29	0.94	0.29
50 %		-	1.05	0.74	-	-	-	-
75 %		-	0.74	0.74	-	-	-	-
90 %		-	0.74	0.74	-	-	-	-

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 use (use no. 9), calculated Step 4 PEC/RAC ratios for scenarios D3 ditch, D4 stream, D5 stream, R1 stream, R2 stream, R3 stream and R4 stream were below 1 indicating no unacceptable risk provided appropriate risk mitigation measures are applied.

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Table 9.5-21: 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 Acetamipryd 200 SL to orchards, early application (surrogate scenario) (1 × 38 g as/ha, BBCH 11-69) (use no. 47)*

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. pro- longed	Algae	Higher plants	Sed. dwell. prolonged	Amphibians	Mesocosm
Test species		<i>Cyprinodon variegatus</i>	<i>Pimephales promelas</i>	Geomean.	<i>Daphnia magna</i>	<i>Anabaena flos-aquae</i>	<i>Lemna gibba</i>	<i>Chironomus riparius</i>	<i>Xenopus laevis</i>	-
Endpoint (µg/L)		LC ₅₀ 100 000	NOEC 9 400	EC ₅₀ 8.5	NOEC 2 960	EC ₅₀ 1 300	EC ₅₀ 1 000	NOEC 0.235	NOEC 2 600	NOEC/NOEAEC 1.1
AF		100	10	100	10	10	10	10	10	3
RAC (µg/L)		1000	940	0.085	296	130	100	0.0235	260	0.37
FOCUS Scenario	PEC ^{gl-} max (µg/L)									
Step 1										
-	15.6300	0.02	0.02	183.88	0.05	0.12	0.16	665.11	0.06	42.24
Step 2										
N-Europe	3.8929	0.00	0.00	45.80	0.01	0.03	0.04	165.66	0.01	10.52
S-Europe	3.8929	0.00	0.00	45.80	0.01	0.03	0.04	165.66	0.01	10.52
Step 3										
D3/ditch	3.107	0.00	0.00	36.55	0.01	0.02	0.03	132.21	0.01	8.40
D4/pond	0.1889	0.00	0.00	2.22	0.00	0.00	0.00	8.04	0.00	0.51
D4/stream	3.168	0.00	0.00	37.27	0.01	0.02	0.03	134.81	0.01	8.56
D5/pond	0.1889	0.00	0.00	2.22	0.00	0.00	0.00	8.04	0.00	0.51
D5/stream	3.082	0.00	0.00	36.26	0.01	0.02	0.03	131.15	0.01	8.33

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Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. pro- longed	Algae	Higher plants	Sed. dwell. prolonged	Amphibians	Mesocosm
R1/pond	0.1888	0.00	0.00	2.22	0.00	0.00	0.00	8.03	0.00	0.51
R1/stream	2.512	0.00	0.00	29.55	0.01	0.02	0.03	106.89	0.01	6.79
R2/stream	3.328	0.00	0.00	39.15	0.01	0.03	0.03	141.62	0.01	8.99
R3/stream	3.554	0.00	0.00	41.81	0.01	0.03	0.04	151.23	0.01	9.61
R4/stream	2.527	0.00	0.00	29.73	0.01	0.02	0.03	107.53	0.01	6.83

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

* PECsw values were calculated for slightly higher dose (details in dRR Part B8)

For the intended uses (use no. 47), calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive groups of aquatic organisms (*Daphnia magna* and *Chironomus riparius*) in most of FOCUS Steps 1-3 scenarios. Therefore, additional risk with RAC based on mesocosm studies has been performed where some PEC/RAC values were below 1 indicating no unacceptable risk. However, for scenarios D3 ditch, D4 stream, D5 stream, R1 stream, R2 stream, R3 stream and R4 stream further risk assessment with Step 4 PECsw was performed.

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Table 9.5-22: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for acetamiprid based on FOCUS Step 4 calculations and toxicity data for mesocosm with mitigation of spray drift and run-off for the use of Acetamipryd 200 SL in orchards, early application (surrogate scenario) (1 × 38 g as/ha, BBCH 11-69) (use no. 47)*

Intended use		orchards						
Active substance		acetamiprid						
Application rate (g as/ha)		1 × 38						
Nozzle reduction	Vegetated filter strip (m)	None	None	None	None	None	10 (VFS)	20 (VFS)
	No-spray buffer (m)	1/3	5	10	15	20	10	20
None	D3/ditch	3.107	2.441	1.499	0.6743	0.3429	1.499	0.3429
50 %		-	1.221	0.7494	0.3373	-	-	-
75 %		-	0.6102	0.3749	0.1686	-	-	-
90 %		-	0.2441	0.1499	0.06743	-	-	-
None	D4/stream	3.168	2.722	1.671	0.7519	0.3822	1.671	0.3822
50 %		-	1.361	0.8357	0.3761	-	-	-
75 %		-	0.6803	0.4177	0.1880	-	-	-
90 %		-	0.2722	0.1671	0.07519	-	-	-
None	D5/stream	3.082	2.648	1.626	0.7315	0.3718	1.626	0.3718
50 %		-	1.324	0.8130	0.3659	-	-	-
75 %		-	0.6619	0.4063	0.1829	-	-	-
90 %		-	0.2648	0.1626	0.07315	-	-	-
None	R1/stream	2.512	2.158	1.325	0.5963	0.3031	1.325	0.3031
50 %		-	1.079	0.6627	0.2983	-	-	-
75 %		-	0.5396	0.3312	0.1491	-	-	-
90 %		-	0.2158	0.1325	0.05963	-	-	-
None	R2/stream	3.328	2.859	1.756	0.7899	0.4015	1.756	0.4015
50 %		-	1.429	0.8779	0.3951	-	-	-
75 %		-	0.7147	0.4388	0.1975	-	-	-
90 %		-	0.2859	0.1756	0.07899	-	-	-
None	R3/stream	3.554	3.054	1.875	0.8436	0.4288	1.875	0.4288
50 %		-	1.527	0.9376	0.4220	-	-	-
75 %		-	0.7633	0.4686	0.2109	-	-	-
90 %		-	0.3054	0.1875	0.08436	-	-	-

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None	R4/stream	2.527	2.171	1.333	0.5998	0.3049	1.333	0.3049
50 %		-	1.085	0.6666	0.3000	-	-	-
75 %		-	0.5427	0.3332	0.1500	-	-	-
90 %		-	0.2171	0.1333	0.08825	-	-	-
RAC (µg/L)								
0.37		PEC/RAC ratio						
None	D3/ditch	8.4	6.6	4.05	1.82	0.93	4.05	0.93
50 %		-	3.3	2.03	0.91	-	-	-
75 %		-	1.65	1.01	0.46	-	-	-
90 %		-	0.66	0.41	0.18	-	-	-
None	D4/stream	8.56	7.36	4.52	2.03	1.03	4.52	1.03
50 %		-	3.68	2.26	1.02	-	-	-
75 %		-	1.84	1.13	0.51	-	-	-
90 %		-	0.74	0.45	0.2	-	-	-
None	D5/stream	8.33	7.16	4.39	1.98	1	4.39	1
50 %		-	3.58	2.2	0.99	-	-	-
75 %		-	1.79	1.1	0.49	-	-	-
90 %		-	0.72	0.44	0.2	-	-	-
None	R1/stream	6.79	5.83	3.58	1.61	0.82	3.58	0.82
50 %		-	2.92	1.79	0.81	-	-	-
75 %		-	1.46	0.9	0.4	-	-	-
90 %		-	0.58	0.36	0.16	-	-	-
None	R2/stream	8.99	7.73	4.75	2.13	1.09	4.75	1.09
50 %		-	3.86	2.37	1.07	-	-	-
75 %		-	1.93	1.19	0.53	-	-	-
90 %		-	0.77	0.47	0.21	-	-	-
None	R3/stream	9.61	8.25	5.07	2.28	1.16	5.07	1.16
50 %		-	4.13	2.53	1.14	-	-	-
75 %		-	2.06	1.27	0.57	-	-	-
90 %		-	0.83	0.51	0.23	-	-	-
None	R4/stream	6.83	5.87	3.6	1.62	0.82	3.6	0.82
50 %		-	2.93	1.8	0.81	-	-	-
75 %		-	1.47	0.9	0.41	-	-	-
90 %		-	0.59	0.36	0.24	-	-	-

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

* PECsw values were calculated for slightly higher dose (details in dRR Part B8)

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For the intended use (use no. 47), calculated Step 4 PEC/RAC ratios for scenarios D3 ditch, D4 stream, D5 stream, R1 stream, R2 stream, R3 stream and R4 stream were below 1 indicating no unacceptable risk provided appropriate risk mitigation measures are applied.

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Table 9.5-23: 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 Acetamipryd 200 SL to orchards, early application (2 x 22 g as/ha, BBCH 51-73) (use no. 19, 26, 27, 34, 36, 38, 40, 44, 45, 46)*

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. pro- longed	Algae	Higher plants	Sed. dwell. prolonged	Amphibians	Mesocosm
Test species		<i>Cyprinodon variegatus</i>	<i>Pimephales promelas</i>	Geomean.	<i>Daphnia magna</i>	<i>Anabaena flos-aquae</i>	<i>Lemna gibba</i>	<i>Chironomus riparius</i>	<i>Xenopus laevis</i>	-
Endpoint (µg/L)		LC ₅₀ 100 000	NOEC 9 400	EC ₅₀ 8.5	NOEC 2 960	EC ₅₀ 1 300	EC ₅₀ 1 000	NOEC 0.235	NOEC 2 600	NOEC/NOEAEC 1.1
AF		100	10	100	10	10	10	10	10	3
RAC (µg/L)		1000	940	0.085	296	130	100	0.0235	260	0.37
FOCUS Scenario	PEC ^{gl-} max (µg/L)									
Step 1										
-	19.5375	0.02	0.02	229.85	0.07	0.15	0.20	831.38	0.08	52.80
Step 2										
N-Europe	3.7778	0.00	0.00	44.44	0.01	0.03	0.04	160.76	0.01	10.21
S-Europe	3.7778	0.00	0.00	44.44	0.01	0.03	0.04	160.76	0.01	10.21
Step 3										
D3/ditch	1.678	0.00	0.00	19.74	0.01	0.01	0.02	71.40	0.01	4.54
D4/pond	0.1517	0.00	0.00	1.78	0.00	0.00	0.00	6.46	0.00	0.41
D4/stream	1.763	0.00	0.00	20.74	0.01	0.01	0.02	75.02	0.01	4.76
D5/pond	0.1763	0.00	0.00	2.07	0.00	0.00	0.00	7.50	0.00	0.48
D5/stream	1.904	0.00	0.00	22.40	0.01	0.01	0.02	81.02	0.01	5.15

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Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. pro- longed	Algae	Higher plants	Sed. dwell. prolonged	Amphibians	Mesocosm
R1/pond	0.1606	0.00	0.00	1.89	0.00	0.00	0.00	6.83	0.00	0.43
R1/stream	1.351	0.00	0.00	15.89	0.00	0.01	0.01	57.49	0.01	3.65
R2/stream	1.807	0.00	0.00	21.26	0.01	0.01	0.02	76.89	0.01	4.88
R3/stream	1.904	0.00	0.00	22.40	0.01	0.01	0.02	81.02	0.01	5.15
R4/stream	1.348	0.00	0.00	15.86	0.00	0.01	0.01	57.36	0.01	3.64

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

* PECsw values were calculated for slightly higher dose (details in dRR Part B8)

For the intended uses (use no. 19, 26, 27, 34, 36, 38, 40, 44, 45, 46), calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive groups of aquatic organisms (*Daphnia magna* and *Chironomus riparius*) in most of FOCUS Steps 1-3 scenarios. Therefore, additional risk with RAC based on mesocosm studies has been performed where some PEC/RAC values were below 1 indicating no unacceptable risk. However, for scenarios D3 ditch, D4 stream, D5 stream, R1 stream, R2 stream, R3 stream and R4 stream further risk assessment with Step 4 PECsw was performed.

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Table 9.5-24: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for acetamiprid based on FOCUS Step 4 calculations and toxicity data for mesocosm with mitigation of spray drift and run-off for the use of Acetamipryd 200 SL in orchards, early application (2 x 22 g as/ha, BBCH 51-73) (use no. 19, 26, 27, 34, 36, 38, 40, 44, 45, 46)*

Intended use		orchards						
Active substance		acetamiprid						
Application rate (g as/ha)		2 × 25						
Nozzle reduction	Vegetated filter strip (m)	None	None	None	None	None	10 (VFS)	20 (VFS)
	No-spray buffer (m)	1/3	5	10	15	20	10	20
None	D3/ditch	1.678	1.294	0.7642	0.4195	0.1979	0.7642	0.1979
50 %		-	0.6468	0.3821	0.2098	-	-	-
75 %		-	0.3235	0.1911	0.1049	-	-	-
90 %		-	0.1294	0.07645	0.04197	-	-	-
None	D4/stream	1.763	1.497	0.8840	0.4854	0.2289	0.8840	0.2289
50 %		-	0.7482	0.4420	0.2427	-	-	-
75 %		-	0.3741	0.2210	0.1213	-	-	-
90 %		-	0.1497	0.08840	0.04854	-	-	-
None	D5/stream	1.904	1.616	0.9547	0.5242	0.2472	0.9547	0.2472
50 %		-	0.8080	0.4774	0.2621	-	-	-
75 %		-	0.4040	0.2387	0.1310	-	-	-
90 %		-	0.1616	0.09547	0.05242	-	-	-
None	R1/stream	1.351	1.147	0.6774	0.3720	0.1754	0.6774	0.1754
50 %		-	0.5733	0.3387	0.1860	-	-	-
75 %		-	0.2867	0.1694	0.1157	-	-	-
90 %		-	0.1157	0.1157	0.1157	-	-	-
None	R2/stream	1.807	1.534	0.9063	0.4976	0.2346	0.9063	0.2346
50 %		-	0.7670	0.4531	0.2488	-	-	-
75 %		-	0.3835	0.2266	0.1244	-	-	-
90 %		-	0.1534	0.09104	0.09104	-	-	-
None	R3/stream	1.904	1.617	0.9548	0.5243	0.2472	0.9548	0.2472
50 %		-	0.8081	0.4774	0.2621	-	-	-
75 %		-	0.4040	0.2387	0.1310	-	-	-
90 %		-	0.1617	0.09548	0.05243	-	-	-

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None	R4/stream	1.348	1.145	0.6761	0.3712	0.1751	0.6761	0.1751
50 %		-	0.5722	0.3381	0.1856	-	-	-
75 %		-	0.2861	0.1691	0.1540	-	-	-
90 %		-	0.1540	0.1540	0.1540	-	-	-
RAC (µg/L)								
0.37		PEC/RAC ratio						
None	D3/ditch	4.54	3.5	2.07	1.13	0.53	2.07	0.53
50 %		-	1.75	1.03	0.57	-	-	-
75 %		-	0.87	0.52	0.28	-	-	-
90 %		-	0.35	0.21	0.11	-	-	-
None	D4/stream	4.76	4.05	2.39	1.31	0.62	2.39	0.62
50 %		-	2.02	1.19	0.66	-	-	-
75 %		-	1.01	0.6	0.33	-	-	-
90 %		-	0.4	0.24	0.13	-	-	-
None	D5/stream	5.15	4.37	2.58	1.42	0.67	2.58	0.67
50 %		-	2.18	1.29	0.71	-	-	-
75 %		-	1.09	0.65	0.35	-	-	-
90 %		-	0.44	0.26	0.14	-	-	-
None	R1/stream	3.65	3.1	1.83	1.01	0.47	1.83	0.47
50 %		-	1.55	0.92	0.5	-	-	-
75 %		-	0.77	0.46	0.31	-	-	-
90 %		-	0.31	0.31	0.31	-	-	-
None	R2/stream	4.88	4.15	2.45	1.34	0.63	2.45	0.63
50 %		-	2.07	1.22	0.67	-	-	-
75 %		-	1.04	0.61	0.34	-	-	-
90 %		-	0.41	0.25	0.25	-	-	-
None	R3/stream	5.15	4.37	2.58	1.42	0.67	2.58	0.67
50 %		-	2.18	1.29	0.71	-	-	-
75 %		-	1.09	0.65	0.35	-	-	-
90 %		-	0.44	0.26	0.14	-	-	-
None	R4/stream	3.64	3.09	1.83	1	0.47	1.83	0.47
50 %		-	1.55	0.91	0.5	-	-	-
75 %		-	0.77	0.46	0.42	-	-	-
90 %		-	0.42	0.42	0.42	-	-	-

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

* PECsw values were calculated for slightly higher dose (details in dRR Part B8)

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For the intended uses (use no. 19, 27, 34, 36, 40, 44, 45, 46), calculated Step 4 PEC/RAC ratios for scenarios D3 ditch, D4 stream, D5 stream, R1 stream, R2 stream, R3 stream and R4 stream were below 1 indicating no unacceptable risk provided appropriate risk mitigation measures are applied.

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Table 9.5-25: 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 Acetamipryd 200 SL to orchards, late application (2 x 25 g as/ha, BBCH 71-84) (use no. 5, 6, 16, 22, 23, 24, 25, 29, 32)*

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. pro- longed	Algae	Higher plants	Sed. dwell. prolonged	Amphibians	Mesocosm
Test species		<i>Cyprinodon variegatus</i>	<i>Pimephales promelas</i>	Geomean.	<i>Daphnia magna</i>	<i>Anabaena flos-aquae</i>	<i>Lemna gibba</i>	<i>Chironomus riparius</i>	<i>Xenopus laevis</i>	-
Endpoint (µg/L)		LC ₅₀ 100 000	NOEC 9 400	EC ₅₀ 8.5	NOEC 2 960	EC ₅₀ 1 300	EC ₅₀ 1 000	NOEC 0.235	NOEC 2 600	NOEC/NOEAEC 1.1
AF		100	10	100	10	10	10	10	10	3
RAC (µg/L)		1000	940	0.085	296	130	100	0.0235	260	0.37
FOCUS Scenario	PEC ^{gl-} max (µg/L)									
Step 1										
-	18.6756	0.02	0.02	219.71	0.06	0.14	0.19	794.71	0.07	50.47
Step 2										
N-Europe	1.9383	0.00	0.00	22.80	0.01	0.01	0.02	82.48	0.01	5.24
S-Europe	1.9383	0.00	0.00	22.80	0.01	0.01	0.02	82.48	0.01	5.24
Step 3										
D3/ditch	0.7879	0.00	0.00	9.27	0.00	0.01	0.01	33.53	0.00	2.13
D4/pond	0.06386	0.00	0.00	0.75	0.00	0.00	0.00	2.72	0.00	0.17
D4/stream	0.7789	0.00	0.00	9.16	0.00	0.01	0.01	33.14	0.00	2.11
D5/pond	0.05183	0.00	0.00	0.61	0.00	0.00	0.00	2.21	0.00	0.14
D5/stream	0.8607	0.00	0.00	10.13	0.00	0.01	0.01	36.63	0.00	2.33

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Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. pro- longed	Algae	Higher plants	Sed. dwell. prolonged	Amphibians	Mesocosm
R1/pond	0.05941	0.00	0.00	0.70	0.00	0.00	0.00	2.53	0.00	0.16
R1/stream	0.5981	0.00	0.00	7.04	0.00	0.00	0.01	25.45	0.00	1.62
R2/stream	0.8180	0.00	0.00	9.62	0.00	0.01	0.01	34.81	0.00	2.21
R3/stream	0.8602	0.00	0.00	10.12	0.00	0.01	0.01	36.60	0.00	2.32
R4/stream	0.6102	0.00	0.00	7.18	0.00	0.00	0.01	25.97	0.00	1.65

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

* PEC_{sw} values were calculated for slightly higher dose (details in dRR Part B8)

For the intended uses (use no. 5, 6, 16, 22, 23, 24, 25, 29, 32), calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive groups of aquatic organisms (*Daphnia magna* and *Chironomus riparius*) in most of FOCUS Steps 1-3 scenarios. Therefore, additional risk with RAC based on mesocosm studies has been performed where some PEC/RAC values were below 1 indicating no unacceptable risk. However, for scenarios D3 ditch, D4 stream, D5 stream, R1 stream, R2 stream, R3 stream and R4 stream further risk assessment with Step 4 PEC_{sw} was performed.

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Table 9.5-26: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for acetamiprid based on FOCUS Step 4 calculations and toxicity data for mesocosm with mitigation of spray drift and run-off for the use of Acetamipryd 200 SL in orchards, late application (2 x 25 g as/ha, BBCH 71-84) (use no. 5, 6, 16, 22, 23, 24, 25, 29, 32)*

Intended use		orchards						
Active substance		acetamiprid						
Application rate (g as/ha)		2 × 25						
Nozzle reduction	Vegetated filter strip (m)	None	None	None	None	None	10 (VFS)	20 (VFS)
	No-spray buffer (m)	1/3	5	10	15	20	10	20
None	D3/ditch	0.7879	0.5481	0.2632	0.1289	0.07474	0.2632	0.07474
50 %		-	0.2740	0.1316	-	-	-	-
75 %		-	0.1370	0.06580	-	-	-	-
90 %		-	0.05482	0.02632	-	-	-	-
None	D4/stream	0.7789	0.6198	0.2976	0.1457	0.08453	0.2976	0.08453
50 %		-	0.3099	0.1488	-	-	-	-
75 %		-	0.1550	0.07443	-	-	-	-
90 %		-	0.06198	0.02976	-	-	-	-
None	D5/stream	0.8607	0.6848	0.3289	0.1610	0.09340	0.3289	0.09340
50 %		-	0.3424	0.1644	-	-	-	-
75 %		-	0.1712	0.08224	-	-	-	-
90 %		-	0.06848	0.03289	-	-	-	-
None	R1/stream	0.5981	0.4759	0.2285	0.1119	0.06491	0.2285	0.06491
50 %		-	0.2379	0.1143	-	-	-	-
75 %		-	0.1190	0.05715	-	-	-	-
90 %		-	0.04759	0.02285	-	-	-	-
None	R2/stream	0.8180	0.6509	0.3126	0.1530	0.08877	0.3126	0.08877
50 %		-	0.3254	0.1563	-	-	-	-
75 %		-	0.1627	0.07816	-	-	-	-
90 %		-	0.06509	0.03126	-	-	-	-
None	R3/stream	0.8602	0.6844	0.3287	0.1609	0.09335	0.3287	0.09335
50 %		-	0.3422	0.1643	-	-	-	-
75 %		-	0.1711	0.08219	-	-	-	-
90 %		-	0.06844	0.03287	-	-	-	-

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None	R4/stream	0.6102	0.4856	0.2332	0.1834	0.09335	0.2332	0.09335
50 %		-	0.2428	0.1834	-	-	-	-
75 %		-	0.1834	0.1834	-	-	-	-
90 %		-	0.1834	0.1834	-	-	-	-
RAC (µg/L)								
0.37		PEC/RAC ratio						
None	D3/ditch	2.13	1.48	0.71	0.35	0.2	0.71	0.2
50 %		-	0.74	0.36	-	-	-	-
75 %		-	0.37	0.18	-	-	-	-
90 %		-	0.15	0.07	-	-	-	-
None	D4/stream	2.11	1.68	0.8	0.39	0.23	0.8	0.23
50 %		-	0.84	0.4	-	-	-	-
75 %		-	0.42	0.2	-	-	-	-
90 %		-	0.17	0.08	-	-	-	-
None	D5/stream	2.33	1.85	0.89	0.44	0.25	0.89	0.25
50 %		-	0.93	0.44	-	-	-	-
75 %		-	0.46	0.22	-	-	-	-
90 %		-	0.19	0.09	-	-	-	-
None	R1/stream	1.62	1.29	0.62	0.3	0.18	0.62	0.18
50 %		-	0.64	0.31	-	-	-	-
75 %		-	0.32	0.15	-	-	-	-
90 %		-	0.13	0.06	-	-	-	-
None	R2/stream	2.21	1.76	0.84	0.41	0.24	0.84	0.24
50 %		-	0.88	0.42	-	-	-	-
75 %		-	0.44	0.21	-	-	-	-
90 %		-	0.18	0.08	-	-	-	-
None	R3/stream	2.32	1.85	0.89	0.43	0.25	0.89	0.25
50 %		-	0.92	0.44	-	-	-	-
75 %		-	0.46	0.22	-	-	-	-
90 %		-	0.18	0.09	-	-	-	-
None	R4/stream	1.65	1.31	0.63	0.5	0.25	0.63	0.25
50 %		-	0.66	0.5	-	-	-	-
75 %		-	0.5	0.5	-	-	-	-
90 %		-	0.5	0.5	-	-	-	-

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

* PECsw values were calculated for slightly higher dose (details in dRR Part B8)

For the intended uses (use no. 5, 6, 16, 22, 23, 25, 29, 32), calculated Step 4 PEC/RAC ratios for scenarios

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D3 ditch, D4 stream, D5 stream, R1 stream, R2 stream, R3 stream and R4 stream were below 1 indicating no unacceptable risk provided appropriate risk mitigation measures are applied.

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Table 9.5-27: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for acetamiprid for each organism group based on FOCUS Steps 1 and 2 calculations for the use of Acetamipryd 200 SL in greenhouses (1 x 0.06 g as/ha - 0.01% of application rate 60 g a.s./ha, BBCH 20-89) (use no. 41, 42, 43)

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. pro-longed	Algae	Higher plants	Sed. dwell. prolonged	Amphibians	Mesocosm
Test species		<i>Cyprinodon variegatus</i>	<i>Pimephales promelas</i>	Geomean.	<i>Daphnia magna</i>	<i>Anabaena flos-aquae</i>	<i>Lemna gibba</i>	<i>Chironomus riparius</i>	<i>Xenopus laevis</i>	.
Endpoint (µg/L)		LC ₅₀ 100 000	NOEC 9 400	EC ₅₀ 8.5	NOEC 2 960	EC ₅₀ 1 300	EC ₅₀ 1 000	NOEC 0.235	NOEC 2 600	NOEC/NOEAEC 1.1
AF		100	10	100	10	10	10	10	10	3
RAC (µg/L)		1000	940	0.085	296	130	100	0.0235	260	0.37
FOCUS Scenario	PEC _{gl-max} (µg/L)									
Step 1										
.	0.0182	0.00	0.00	0.21	0.00	0.00	0.00	0.77	0.00	0.05
Step 2										
N-Europe	0.0006	0.00	0.00	0.01	0.00	0.00	0.00	0.03	0.00	0.00
S-Europe	0.0008	0.00	0.00	0.01	0.00	0.00	0.00	0.03	0.00	0.00

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

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Table 9.5-28: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolites for each organism group based on FOCUS Step 1 calculations for the use of Acetamipryd 200 SL

Group		Fish acute	Inverteb. acute		Inverteb. acute		Inverteb. acute	Inverteb. prolonged		Inverteb. acute	Inverteb. acute
Metabo- lite		IM-1-4	IM-1-4		IM-1-2		IM-1-5	IM-1-5			IC-0
Test spe- cies		<i>Oncorhyn- chus mykiss</i>	<i>Mysidopsis bahia</i>		<i>Chironomus riparius</i>		<i>Daphnia magna</i>	<i>Daphnia magna</i>		<i>Daphnia magna</i>	<i>Daphnia magna</i>
Endpoint (µg/L)		LC ₅₀ 98 100	EC ₅₀ 19 000		EC ₅₀ 15 000		EC ₅₀ 25 000	NOEC 26 000		EC ₅₀ 95 100	EC ₅₀ 100 000
AF		100	100		100		100	10		100	100
RAC (µg/L)		981	190		150		250	2600		951	1000
FOCUS Scenario	IM-1-4 PEC _{gl-max} (µg/L)			IM-1-2 PEC _{gl-max} (µg/L)		IM-1-5 PEC _{gl-max} (µg/L)			IC-0 PEC _{gl-max} (µg/L)		
Step 1 - winter rape (1 x 50 g as/ha, BBCH 30-50) (use no. 1)											
-	14.9795	0.02	0.08	11.7352	0.08	2.0975	0.01	0.00	4.3113	0.00	0.00
Step 1 - winter rape (1 × 24 g as/ha, BBCH 50-69) (use no. 2, 3)											
-	7.1902	0.01	0.04	5.6329	0.04	1.0068	0.00	0.00	2.0694	0.00	0.00
Step 1 - winter rape (1 × 60 g as/ha, BBCH 30-61) (use no. 13, 14)											
-	17.9754	0.02	0.09	14.0822	0.09	2.5169	0.01	0.00	5.1736	0.01	0.01
Step 1 - spring rape (1 × 24 g as/ha, BBCH 50-69) (use no. 10)											
-	7.1902	0.01	0.04	5.6329	0.04	1.0068	0.00	0.00	2.0694	0.00	0.00
Step 1 - spring rape (1 × 50 g/ha, BBCH 30-50) (use no. 11)											
-	14.9795	0.02	0.08	11.7352	0.08	2.0975	0.01	0.00	4.3113	0.00	0.00

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Step 1 - spring rape (1 × 60 g/ha, BBCH 59-71) (use no. 12)											
-	17.9754	0.02	0.09	14.0822	0.09	2.5169	0.01	0.00	5.1736	0.01	0.01
Step 1 - potato (1 x 24 g as/ha, BBCH 35-75) (use no. 4)											
-	7.1902	0.01	0.04	5.6329	0.04	1.0068	0.00	0.00	2.0694	0.00	0.00
Step 1 - orchards, early application (1 × 22 g as/ha, BBCH 56-84) (use no. 7, 8, 15, 17, 18, 20, 21, 28, 30, 31, 33, 35, 37, 39)											
-	7.7023	0.01	0.04	5.4443	0.04	0.9229	0.00	0.00	2.3016	0.00	0.00
Step 1 - orchards, late application (1 × 22 g as/ha, BBCH 56-84) (use no. 7, 8, 15, 17, 18, 20, 21, 28, 30, 31, 33, 35, 37, 39)											
-	7.136	0.01	0.04	5.3012	0.04	0.9229	0.00	0.00	2.0954	0.00	0.00
Step 1 - orchards, early application (1 × 36 g as/ha, BBCH 56-84) (use no. 9)											
-	12.6037	0.01	0.07	8.9088	0.06	1.5102	0.01	0.00	3.7663	0.00	0.00
Step 1 - orchards, late application (1 × 36 g as/ha, BBCH 56-84) (use no. 9)											
-	11.6771	0.01	0.06	8.6747	0.06	1.5102	0.01	0.00	3.4289	0.00	0.00
Step 1 - orchards, early application (1 × 38 g as/ha, BBCH 11-69) (use no. 47)*											
-	14.0041	0.01	0.07	9.8987	0.07	1.678	0.01	0.00	4.1848	0.00	0.00
Step 1 - orchards, early application (2 x 22 g as/ha, BBCH 51-73) (use no. 19, 26, 27, 34, 36, 38, 40, 44, 45, 46)*											
-	17.5051	0.02	0.09	12.3734	0.08	2.0975	0.01	0.00	5.231	0.01	0.01
Step 1 - orchards, late application (2 x 25 g as/ha, BBCH 71-84) (use no. 5, 6, 16, 22, 23, 24, 25, 29, 32)*											
-	17.5156	0.02	0.09	13.012	0.09	2.2652	0.01	0.00	5.1434	0.01	0.01
Step 1 - greenhouses (1 x 0.06 g as/ha - 0.01% of application rate 60 g a.s./ha, BBCH 20-89) (use no. 41, 42, 43)											
1	0.0180	0.00	0.00	0.0141	0.00	0.0025	0.00	0.00	0.0052	0.00	0.00

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

* PECsw values were calculated for slightly higher doses (details in dRR Part B8)

For the intended uses (use no. 1-47), calculated PEC/RAC ratios indicate an acceptable risk for the most sensitive group of aquatic organisms. Therefore, no further assessment is necessary.

9.5.3 Overall conclusions

PEC/RAC values were calculated on the basis of PEC_{sw} calculations as well as worst case toxicity endpoints from studies for active substance and metabolites. On the basis of PEC/RAC values it was concluded that the application of Acetamipryd 200 SL does not pose unacceptable risk for aquatic organisms under condition that appropriate risk mitigations are applied.

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Table 9.5-29: Acetamipryd 200 SL – overview on appropriate mitigation measures for winter rape, spring rape and potato scenarios

	winter rape 1 × 50 g as/ha BBCH 30-50	winter rape 1 × 24 g as/ha BBCH 50-69	winter rape 1 × 60 g as/ha BBCH 30-61	spring rape 1 × 24 g as/ha BBCH 50-65	spring rape 1 × 50 g as/ha BBCH 30-50	spring rape 1 × 60 g as/ha BBCH 59-71	potato 1 × 24 g as/ha BBCH 35-75
Use no	1	2, 3	13, 14	10	11	12	4
D1/ditch	NR	NR	NR	-	-	5mBZ	NR
D1/stream	NR	NR	NR	-	-	-	NR
D2/ditch	-	-	5mBZ	NR	NR	NR	NR
D2/stream	-	-	-	NR	NR	NR	NR
D3/ditch	-	-	5mBZ	-	-	5mBZ	-
D4/pond	-	-	-	-	-	-	-
D4/stream	-	-	-	-	-	-	-
D5/pond	-	-	-	-	-	-	NR
D5/stream	-	-	-	-	-	-	NR
D6/ditch	NR	NR	NR	NR	NR	NR	-
R1/pond	-	-	-	-	-	-	-
R1/stream	-	-	-	-	10mVBZ	10mVBZ	-
R2/stream	NR	NR	NR	NR	NR	NR	-
R3/stream	-	-	10mVBZ	NR	NR	NR	-

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Table 9.5-30: Acetamipryd 200 SL – overview on appropriate mitigation measures for orchards early application and late application scenarios

	orchards, early appl. 1 × 22 g as/ha BBCH 56-84	orchards, late appl. 1 × 22 g as/ha BBCH 56-84	orchards, early appl. 1 × 36 g as/ha BBCH 56-84	orchards, late appl. 1 × 36 g as/ha BBCH 56-84	orchards, early appl. 1 × 38 g as/ha BBCH 11-69	orchards, early appl. 2 x 22 g as/ha BBCH 51-73	orchards, late appl. 2 x 25 g as/ha BBCH 71-84
Use no	7, 8, 15, 17, 18, 20, 21, 28, 30, 31, 33, 35, 37, 39	7, 8, 15, 17, 18, 20, 21, 28, 30, 31, 33, 35, 37, 39	9	9	47	19, 26, 27, 34, 36, 38, 40, 44, 45, 46	5, 6, 16, 22, 23, 24, 25, 29, 32
D3/ditch	5mBZ+75%DRN or 15mBZ+50% DRN or 20mBZ	5mBZ+50%DRN or 10mBZ	5mBZ+90% DRN or 10mBZ+75% DRN or 15mBZ+50% DRN or 20mBZ	5mBZ+75%DRN or 10mBZ+50%DRN or 15mBZ	5mBZ+90% DRN or 15mBZ+50% DRN or 20mBZ	5mBZ+75%DRN or 15mBZ+50% DRN or 20mBZ	5mBZ+50%DRN or 10mBZ
D4/pond	-	-	-	-	-	-	-
D4/stream	5mBZ+90%DRN or 10mBZ+75%DRN or 15mBZ+50%DRN or 20mBZ	5mBZ+50%DRN or 10mBZ	5mBZ+90%DRN or 15mBZ+50%DRN or 20mBZ	5mBZ+75%DRN or 10mBZ+50%DRN or 15mBZ	5mBZ+90% DRN or 15mBZ+75% DRN	5mBZ+90% DRN or 10mBZ+75% DRN or 15mBZ+50% DRN or 20mBZ	5mBZ+50%DRN or 10mBZ
D5/pond	-	-	-	-	-	-	-
D5/stream	5mBZ + 90%DRN or 10mBZ+75%DRN or 15mBZ+50%DRN or 20mBZ	5mBZ+50%DRN or 10mBZ	5mBZ+90%DRN or 15mBZ+50%DRN or 20mBZ	5mBZ+75%DRN or 10mBZ+50%DRN or 15mBZ	5mBZ+90% DRN or 15mBZ+50% DRN	5mBZ+90% DRN or 10mBZ+75% DRN or 15mBZ+50% DRN or 20mBZ	5mBZ+50%DRN or 10mBZ
R1/pond	-	-	-	-	-	-	-
R1/stream	5mBZ+75%DRN or 10mBZ+50%DRN or 15mBZ	5mBZ+50%DRN or 10mBZ	5mBZ+90%DRN or 10mBZ+75%DRN or 15mBZ+50%DRN or 20mBZ	5mBZ+75%DRN or 10mBZ	5mBZ+90% DRN or 10mBZ+75% DRN or 15mBZ+50% DRN or 20mBZ	5mBZ+75%DRN or 10mBZ+50% DRN or 20mBZ	5mBZ+50%DRN or 10mBZ
R2/stream	5mBZ + 90%DRN or 10mBZ+75%DRN or 15mBZ+50%DRN or 20mBZ	5mBZ+50%DRN or 10mBZ	5mBZ + 90%DRN or 15mBZ+50%DRN	5mBZ+75%DRN or 10mBZ+50%DRN or 15mBZ	5mBZ+90% DRN or 15mBZ+75% DRN	5mBZ+90% DRN or 10mBZ+75% DRN or 15mBZ+50% DRN or 20mBZ	5mBZ+50%DRN or 10mBZ
R3/stream	5mBZ + 90%DRN or 10mBZ+75%DRN or 15mBZ+50%DRN or 20mBZ	5mBZ+50%DRN or 10mBZ	5m + 90%DRN or 15mBZ+75%DRN	5mBZ+75%DRN or 10mBZ+50%DRN or 15mBZ	5mBZ+90% DRN or 15mBZ+75% DRN	5mBZ+90% DRN or 10mBZ+75% DRN or 15mBZ+50% DRN or 20mBZ	5mBZ+50%DRN or 10mBZ
R4/stream	5mBZ+75%DRN or 10mBZ+50%DRN or 15mBZ	5mBZ+50%DRN or 10mBZ	5mBZ + 90%DRN or 10mBZ + 75%DRN or 15mBZ+50%DRN or 20mBZ	5mBZ+75%DRN or 10mBZ	5mBZ+90% DRN or 10mBZ+75% DRN or 15mBZ+50% DRN or 20mBZ	5mBZ+75%DRN or 10mBZ+50% DRN or 20mBZ	5mBZ+50%DRN or 10mBZ

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zRMS comments: The evaluation of the risk for aquatic 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” (EFSA Journal 2013;11(7):3290).

The PEC_{sw} calculations for acetamiprid have been approved for applications proposed in GAP. PEC_{sw} and PEC_{sed} calculations were carried out according to the FOCUS recommendations.

The relevant predicted environmental concentrations in water (PEC_{sw}) for risk assessments covering the proposed use pattern are taken from Part B Section 8 (Environmental Fate). Details on PEC_{sw} calculations for acetamiprid and formulation **PIORUN 200 SL** are included in Section B8.

Since not all relevant to the central zone scenarios are defined for the evaluated crops, the surrogate crops were considered by the Applicant in simulations.

Step 4 simulations were performed according to recommendations of the FOCUS work group on landscape and mitigation, FOCUS TOXSWA v5.5.3, ECPA SWAN v5.0.1, VFSmod.

The acceptability of proposed risk mitigation measures should be taken at MSs level.

PL

For Poland D3, D4 and R1 scenarios are relevant so it can be concluded that **PIORUN 200 SL** in accordance with GAP does not pose unacceptable risk to aquatic organisms under condition following risk mitigations measures are applied:

To protect aquatic organisms respect 10m unsprayed vegetated buffer zone to surface water bodies in case of spring oilseed rape and turnip rape sprayed with 0.25-0.3 L/ha.	Use no: 11, 12
To protect aquatic organisms respect 5m unsprayed buffer zone to surface water bodies in case of flax-fiber production and common hemp fiber production sprayed with 0.3 L/ha.	Use no: 13, 14
To protect aquatic organisms respect 5m unsprayed buffer zone to surface water bodies + 90% drift reduction nozzles or 15m unsprayed buffer zone to surface water bodies + 50% drift reduction nozzles or 20m unsprayed buffer zone to surface water bodies in case of orchards, walnuts, hazelnuts, common osier and purple willow sprayed with 0.11-0.18 L/ha.	Use no: 7-9, 15, 17-21, 26-28, 30, 31, 33-40, 44-46
To protect aquatic organisms respect 5m unsprayed buffer zone to surface water bodies + 90% drift reduction nozzles or 15m unsprayed buffer zone to surface water bodies + 75% drift reduction nozzles bodies in case of forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations, Christmas trees grown on plantations sprayed with 0.19 L/ha.	Use no: 47
To protect aquatic organisms respect 5m unsprayed buffer zone to surface water bodies + 50% drift reduction nozzles or 10m unsprayed buffer zone to surface water bodies in case of orchards sprayed with 2 x 0.125 L/ha.	Use no: 5, 6, 16, 22-25, 29, 32

In case of winter oilseed rape (uses no. 1-3), spring oilseed rape and turnip rape (uses no. 10) as well as potato (use no. 4) no risk mitigations measures are required.

A product PIORUN 200 SL in ecotoxicology section approved for uses 41-43 only in greenhouses with a durable structure, isolated from the ground.

The application of **PIORUN 200 SL** to tomatoes, aubergine and paprika (uses. 41-43) is limited to greenhouses, risk assessment is not required.

Final risk mitigation measures should be considered at MSs level.

New data was accepted.

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

Effects on bees of Acetamipryd 200 SL were not evaluated as part of the EU assessment of acetamiprid. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

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

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

Species	Substance	Exposure System	Results	Reference
<i>Apis mellifera</i>	acetamiprid	Chronic, oral, 10 days	LDD ₅₀ = 11.7 µg as/bee/day	EFSA Journal 2016;14(11):4610
<i>Apis mellifera</i>	acetamiprid	Chronic larvae	EC ₁₀ = 1.3 µg/larvae/ developmental period	EFSA Journal 2016;14(11):4610
<i>Apis mellifera</i>	Acetamipryd 200 SL	Oral, acute	48 h LD₅₀ = 26.31 µg/bee (4.59 µg as/bee)	Mautino G/ 2023/ Study code: 1148.I.SAG23/r KCP 10.3.1.1.1/01
<i>Bombus spp</i>	Acetamipryd 200 SL	Oral, acute	48 h LD ₅₀ = 191.8 µg/bee (33.06 µg as/bee)	Fulczyk A/ 2022/ Study code: B-105-22 KCP 10.3.1.1.1/02
<i>Bombus spp</i>	Acetamipryd 200 SL	Contact, acute	48 h LD ₅₀ > 100 µg/bee (19.7 µg as/bee)	Fulczyk A/ 2022/ Study code: B-107-22 KCP 10.3.1.1.2/01
<i>Apis mellifera</i>	Acetamipryd 200 SL	Contact, acute	48 h LD₅₀ = 62.92 µg/bee (11.06 µg as/bee)	Mautino G/ 2024/ Study code: 3053.1I.SAGIT24 KCP 10.3.1.1.2/02
<i>Apis mellifera</i>	Acetamipryd 200 SL	Chronic, oral, 10 days	LDD ₅₀ = 0.017 µL/bee/day (3.27 µg as/bee/day)	Mautino G/ 2024/ Study code: 1032.I.SAG23/r KCP 10.3.1.2/01
<i>Apis mellifera</i>	Acetamipryd 200 SL	Chronic exposure, larvae	ED50= 0.019 µL/larva (3.84 µg as/larva) NOED = 0.0014 µL/larva (0.27 µg as/larva)	Mautino G/ 2024/ Study code: 1033.I.SAG23/r KCP 10.3.1.4/01
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 as/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				

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not be used to draw any conclusion, and in particular to exclude potential chronic effects and effects on the brood development.

9.6.1.1 Justification for new endpoints

New endpoints are provided for the formulated product Acetamipryd 200 SL. Details of studies and results are included in Table 9.6-1. Summary of the studies is included in Appendix II. Additional studies are required according to Regulation (EC) No. 284/2013.

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

The acute risk to honeybees from use of Acetamipryd 200 SL was assessed using the maximum single application rate and the oral and contact LD₅₀ values. A Hazard Quotient (HQ) of less than 50 indicates a low risk to bees.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use no. 12 (oilseed rape) also covers the risk for bees from all other intended uses (see 9.1.2).

Table 9.6-2: First-tier acute assessment of the risk for bees due to the use of Acetamipryd 200 SL in oilseed rape (use no. 12)

Intended use	oilseed rape (use no. 12)		
Product	Acetamipryd 200 SL		
Application rate (g/ha)	1 × 60		
Test design	LD₅₀ (lab.) (µg/bee)	Single application rate (g/ha)	Trigger HQ ≤ 50
Oral toxicity	4.59	60	13.1
Contact toxicity	11.06	60	5.4

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

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

Not relevant.

9.6.3 Effects on bumble bees

Not relevant.

9.6.4 Effects on solitary bees

Not relevant.

9.6.5 Overall conclusions

The acute risk of Acetamipryd 200 SL to honeybees was assessed from HQ between toxicity endpoints, estimated from acute oral and contact studies with formulated product as well as the maximum single application rate. The HQ values were considerably less than 50 that means product Acetamipryd 200 SL does not pose unacceptable acute oral and contact risk to honeybees. It can be concluded that Acetamipryd 200 SL used in accordance with GAP does not pose unacceptable risk to bees. No risk management measures are required.

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.

Considering that the chronic RA for honey bee adults and larvae has not been addressed, a concern regarding to the risks in bees has been identified (acetamiprid is an insecticide with the specific mode of action). Thus, zRMS agrees that a new security phrase should be included in the conclusions:

SPe 8: To protect bees and other pollinating insects do not apply to crop plants when in flower./Do not use where bees are actively foraging./ Do not apply when flowering weeds are present.

Final risk mitigation measures should be considered at MSs level.

9.7 Effects on arthropods other than bees (KCP 10.3.2)

9.7.1 Toxicity data

Studies on the toxicity to non-target arthropods have been carried out with representative formulation and metabolites. Full details of these studies are provided in the respective EU RAR and related documents.

Effects on non-target arthropods of Acetamipryd 200 SL were not evaluated as part of the EU assessment of acetamiprid. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

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

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

Species	Substance	Exposure System	Results	Reference
Aged residue tests				
<i>Aphidius rhopalosiphi</i>	Acetamipryd 200 SL	Extended laboratory Aged residues	<u>Mortality:</u> 0 DAA 300 ml/ha 57.14% 7 DAA 300 ml/ha 53.33% 14 DAA 300 ml/ha 10.34% 21 DAA 300 ml/ha 7.14% 28 DAA 300 ml/ha 3.45% 35 DAA 300 ml/ha 0.0% <u>Reproduction:</u> 14 DAA 300 ml/ha 35.12% 21 DAA 300 ml/ha 29.06% 28 DAA 300 ml/ha 11.49% 35 DAA 300 ml/ha -1.21%	Mautino G / 2023/Study code: 1036.I.SAG23/r KCP 10.3.2.2/01
<i>Typhlodromus pyri</i>	Acetamipryd 200 SL	Extended laboratory Aged residues	<u>Mortality:</u> 0 DAA 300 ml/ha 4.49% 7 DAA 300 ml/ha 1.08% 14 DAA 300 ml/ha -1.09% <u>Fecundity:</u> 0 DAA 300 ml/ha -0.42% 7 DAA 300 ml/ha -0.10% 14 DAA 300 ml/ha -1.37%	Mautino G / 2023/Study code: 1037.I.SAG23/r KCP 10.3.2.2/02
<i>Coccinella septempunctata</i>	Acetamipryd 200 SL	Extended laboratory Aged residues	<u>Mortality:</u> 0 DAA 300 ml/ha 77.14% 7 DAA 300 ml/ha 60.61% 14 DAA 300 ml/ha 42.42% 21 DAA 300 ml/ha 33.33% 28 DAA 300 ml/ha 13.89% 35 DAA 300 ml/ha 2.94% <u>Reproduction:</u> 14 DAA 300 ml/ha 92.20% 21 DAA 300 ml/ha 93.39% 28 DAA 300 ml/ha 92.77% 35 DAA 300 ml/ha 93.01%	Mautino G / 2023/Study code: 1035.I.SAG23/r KCP 10.3.2.2/03
<i>Chrysoperla carnea</i>	Acetamipryd 200 SL	Extended laboratory Aged residues	<u>Mortality:</u> 0 DAA 300 ml/ha 26.92% 7 DAA 300 ml/ha 3.70% 14 DAA 300 ml/ha 0.00% <u>Reproduction:</u> 0 DAA 300 ml/ha 85.29% 7 DAA 300 ml/ha 80.15% 14 DAA 300 ml/ha 86.53%	Mautino G / 2023/Study code: 1038.I.SAG23/r KCP 10.3.2.2/04
Field or semi-field tests				
-				

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9.7.1.1 Justification for new endpoints

New endpoints are provided for the formulated product Acetamipryd 200 SL. Details of studies and results are included in Table 9.7-1. Summary of the studies is included in Appendix II. Additional studies are required according to Regulation (EC) No. 284/2013.

9.7.2 Risk assessment

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

9.7.2.1 Risk assessment for in-field exposure

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use no. 12 (oilseed rape) also covers the in-field risk for arthropods from all other intended uses (see 9.1.2).

Table 9.7-2: First- and higher-tier assessment of the in-field risk for non-target arthropods due to the use of Acetamipryd 200 SL in oilseed rape (use no 12)

Intended use	oilseed rape (use no. 12)		
Product	Acetamipryd 200 SL		
Application rate (g/ha)	1 × 0.3 L/ha		
MAF	1		
Test species Higher-tier	Rate with ≤ 50 % effect (L/ha)	PER_{in-field} (L/ha)	PER_{in-field} below rate with ≤ 50 % effect?
<i>Typhlodromus pyri</i>	0 DAA 0.3 L/ha 4.49%	0.3	yes
<i>Aphidius rhopalosiphi</i>	14 DAA 0.3 L/ha 10.34%		yes
<i>Coccinella septempunctata</i>	14 DAA 0.3 L/ha 42.42%		yes
<i>Chrysoperla carnea</i>	0 DAA 0.3 L/ha 26.92%		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.

9.7.2.2 Risk assessment for off-field exposure

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use no. 5 (orchards) also covers the in-field risk for arthropods from all other intended uses (see 9.1.2).

Table 9.7-3: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of Acetamipryd 200 SL in orchards (use no. 5)

Intended use	orchards (use no. 5)
Product	Acetamipryd 200 SL
Application rate (g/ha)	2 × 0.125 L/ha
MAF	1.7

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VDF		5			
Test species Higher-tier	Rate with ≤ 50 % effect (L/ha)	Drift rate (%)	PER _{off-field} (L/ha)	CF	PER _{off-field} below rate with ≤ 50 % ef- fect?
<i>Typhlodromus pyri</i>	0 DAA 0.3 L/ha 4.49%	25.63	0.0545	10	yes
<i>Aphidius rhopalosiphi</i>	14 DAA 0.3 L/ha 10.34%				yes
<i>Coccinella septempunctata</i>	14 DAA 0.3 L/ha 42.42%				yes
<i>Chrysoperla carnea</i>	0 DAA 0.3 L/ha 26.92%				yes

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.

9.7.2.3 Additional higher-tier risk assessment

Not relevant.

9.7.2.4 Risk mitigation measures

No risk mitigation needed.

9.7.3 Overall conclusions

The in-field and off-field risk of Acetamipryd 200 SL to non-target arthropods was assessed by comparison of no-effect application rate derived from extended laboratory aged residue tests and appropriate predicted environmental rate in-field and off-field. No risk was determined for *Typhlodromus pyri* and *Chrysoperla carnea* after application of Acetamipryd 200 SL at rate of 300 ml/ha which is higher than maximum application rate in GAP. In case of in case of *Aphidius rhopalosiphi* and *Coccinella septempunctata* effects below 50% mortality was observed on 14 DAA what confirms rapid recolonisation at area treated with the product. It can be concluded that there is no unacceptable risk to non-target arthropods following application of Acetamipryd 200 SL in accordance with GAP. No risk management measures are required.

zRMS comments:

zRMS agrees with calculations presented above.

As a worst case the VDF of 5 has been considered, since available investigations indicate that VDF of 10 recommended by ESCORT 2 guidance document is not appropriate and may lead to underestimation of the exposure. It should be, however, noted that according to EFSA Supporting publication 2019:EN-1673, VDF of 5 should be considered as the interim solution that will be reflected in the SANCO/10329/2002 rev 2 final with its implementation considered further. Since use of VDF of 5 was not reflected in the current SANCO terrestrial guidance, its use is not yet mandatory. Nevertheless, the risk assessment performed with VDF of 5 is more protective and is thus agreed by the zRMS.

No unacceptable risk to non-target arthropods following application of Acetamipryd 200 SL in accordance with GAP. No risk management measures are required.

Final risk mitigation measures should be considered at MSs level.

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 metabolite of acetamiprid. Full details of these studies are provided in the respective EU RAR and related documents.

Effects on earthworms and other non-target soil organisms (meso- and macrofauna) of Acetamipryd 200 SL were not evaluated as part of the EU assessment of acetamiprid. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

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

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

Species	Substance	Exposure System	Results	Reference
<i>Eisenia fetida</i>	IM-1-5	Homogenous mixing, chronic	NOEC = 62.5 mg/kg d.w. soil (growth, reproduction, behaviour)	EFSA Journal 2016;14(11):4610
<i>Folsomia candida</i>	IM-1-5	Homogenous mixing, chronic	NOECmortality = 62.7 mg/kg soil d.w. No EC values could be calculated as there were no effects below the highest tested value. NOECreproduction = 12.5 mg/kg soil d.w. No EC values were calculated as the data were not appropriate for modelling.	EFSA Journal 2016;14(11):4610
<i>Eisenia fetida</i>	Acetamipryd 200 SL	Mixed into substrate 56 d, chronic 10 % peat content	Reproduction: EC ₅₀ = 9.54 mg/kg dw (1.80 mg as/kg dw) NOEC = 1.8 mg/kg dw (0.34 mg as/kg dw) Survival: LC ₅₀ = 22.49 mg/kg dw (4.25 mg as/kg dw) NOEC = 5.6 mg/kg dw (1.06 mg as/kg dw)	Wróbel A / 2022/ Study code: G-93-21 KCP 10.4.1.1/01
<i>Hypoaspis aculeifer</i>	Acetamipryd 200 SL	Mixed into substrate 14 d, chronic 5 % peat content	Mortality: LC ₅₀ >1500 mg/kg dw (262.24 mg as/kg dw) NOEC ≥ 1500 mg/kg dw (262.24 mg as/kg dw) Reproduction:	Mautino G /2023/ Study code: 1039.I.SAG23/r KCP 10.4.2.1/01

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Species	Substance	Exposure System	Results	Reference
			LC ₅₀ = 1281.8 mg/kg dw (224.09 mg as/kg dw) NOEC = 24.5 mg/kg dw (4.28 mg as/kg dw)	
<i>Folsomia candida</i>	Acetamipryd 200 SL	Mixed into substrate 28 d, chronic 5 % peat content	Mortality: LC ₅₀ = 3.98 mg/kg dw (0.66 mg as/kg dw) NOEC = 0.59 mg/kg dw (0.10 mg as/kg dw) Reproduction: EC ₅₀ = 2.02 mg/kg dw (0.33 mg as/kg dw) NOEC = 0.59 mg/kg dw (0.10 mg as/kg dw)	
Field studies				
Not relevant.				
Litter bag test				
Not relevant.				

* Corrected value derived by dividing the endpoint by a factor of 2 in accordance with the EPPO earthworm scheme 2002.

9.8.1.1 Justification for new endpoints

New endpoints are provided for the formulated product Acetamipryd 200 SL. Details of studies and results are included in Table 9.8-1. Summary of the studies is included in Appendix II. Additional studies are required according to Regulation (EC) No. 284/2013.

9.8.2 Risk assessment

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

9.8.2.1 First-tier risk assessment

The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use no. 5 (orchards) also covers the risk for earthworms and other non-target soil organisms (meso- and macrofauna) from all other intended uses (see 9.1.2).

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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 Acetamipryd 200 SL in orchards (use no. 5)

Intended use	orchards (use no. 5)		
Chronic effects on earthworms			
Active substance/metabolite	NOEC (mg/kg dw)	PEC _{soil} (mg/kg dw)	TER _{lt} (criterion TER ≥ 5)
IM-1-5	62.5	0.018	3472.2
acetamipryd (Acetamipryd 200 SL)	0.34	0.02	17
Chronic effects on <i>Folsomia candida</i>			
Active substance/metabolite	NOEC (mg/kg dw)	PEC _{soil} (mg/kg dw)	TER _{lt} (criterion TER ≥ 5)
IM-1-5	12.5	0.018	694.4
acetamipryd (Acetamipryd 200 SL)	0.1	0.02	5
Chronic effects on <i>Hypoaspis aculeifer</i>			
Active substance	NOEC (mg/kg dw)	PEC _{soil} (mg/kg dw)	TER _{lt} (criterion TER ≥ 5)
acetamipryd (Acetamipryd 200 SL)	4.28	0.02	214

TER values shown in bold fall below the relevant trigger.

9.8.2.2 Higher-tier risk assessment

Not relevant.

9.8.3 Overall conclusions

The risk of Acetamipryd 200 SL to earthworms and *Hypoaspis aculeifer* was assessed from toxicity exposure ratio (TER) between the selected toxicity endpoints for metabolite IM-1-5 and the formulated product Acetamipryd 200 SL as well as the maximum soil PECs. The chronic TER values were greater than the trigger of 5, indicating an acceptable risk to earthworms and *Hypoaspis aculeifer* following application of Acetamipryd 200 SL in accordance with GAP. No risk management measures are required.

zRMS comments:

zRMS agrees with calculations presented above.

The long-term risks of **PIORUN 200 SL** 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 **PIORUN 200 SL** were confirmed based on TER_{LT} calculations for active substances, their metabolites and for formulation.

Final risk mitigation measures should be considered at MSs level.

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 representative formulation. Full details of these studies are provided in the respective EU RAR.

Effects on soil microorganisms of Acetamipryd 200 SL were not evaluated as part of the EU assessment of acetamiprid. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

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

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

Endpoint	Substance	Exposure System	Results	Reference
N-mineralisation	Acetamipryd 200 SL	28 d, aerobic	<25% effect at day 28 at: 0.17 mg/kg dw (0.03 mg as/kg dw) 0.85 mg/kg dw (0.15 mg as/kg dw)	Wróbel A/ 2022/ Study code: G-94-21 KCP 10.5/01

9.9.1.1 Justification for new endpoints

New endpoints are provided for the formulated product Acetamipryd 200 SL. Details of studies and results are included in Table 9.5-4. Summary of the studies is included in Appendix II. Additional studies are required according to Regulation (EC) No. 284/2013.

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 and were already used in the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna) (see 9.8).

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use no. 5 (orchards) also covers the risk for soil microorganisms from all other intended uses (see 9.1.2).

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Table 9.9-2: Assessment of the risk for effects on soil micro-organisms due to the use of Acetamipryd 200 SL in orchards (use no. 5)

Intended use	orchards (use no. 5)		
N-mineralisation			
Active substance/metabolite	Max. conc. with effects ≤ 25 % (mg/kg dw)	PEC _{soil} (mg/kg dw)	Risk acceptable?
acetamipryd (Acetamipryd 200 SL)	0.15 (at 28 d)	0.02	yes

No toxicity data for metabolites IM-1-2, IM-1-4, IM-1-5 and IC-0 since the risk to soil micro-organisms from those metabolites is covered by evaluation performed for formulation Acetamipryd 200 SL.

9.9.3 Overall conclusions

The risk of Acetamipryd 200 SL to soil micro-organisms was evaluated by comparison of no-effect concentration in soil, derived from laboratory tests and appropriate predicted environmental concentrations in soil (PECs). According to the performed risk assessment it was concluded that Acetamipryd 200 SL does not pose unacceptable risk to soil micro-organisms following application in accordance with GAP. No risk management measures are required.

zRMS comments:

zRMS agrees with calculations presented above. **PIORUN 200 SL** has no significant effect on soil micro-organisms at 0.15 mg a.s./kg dry soil.

Based on it, can be concluded that **PIORUN 200 SL** under field conditions, use at the proposed rates poses no unacceptable risk to non-target soil micro-organisms.

Final risk mitigation measures should be considered at MSs level.

9.10 Effects on non-target terrestrial plants (KCP 10.6)

9.10.1 Toxicity data

Studies on the toxicity to non-target terrestrial plants have been carried out with the reference formulation. Full details of these studies are provided in the respective EU RAR.

Effects on non-target terrestrial plants of Acetamipryd 200 SL 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 is in line with the results of the EU review process.

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

Species	Substance	Exposure System	Results	Reference
Sunflower Pea Cabbage Onion Perennial ryegrass Oats	Acetamipryd 200 SL	21 d Seedling emergence	Plant number at the end of the experiment ER ₅₀ > 1500 ml/ha (>295.8 g as/ha) Shoot length ER ₅₀ > 1500 ml/ha (>295.8 g as/ha) Plant dry weight ER ₅₀ > 1500 ml/ha (>295.8 g as/ha) Plant damage ER ₅₀ > 1500 ml/ha (>295.8 g as/ha)	Wróbel A/ 2022/ Study code: G-96-21 KCP 10.6/01
Sunflower Pea Cabbage Onion Perennial ryegrass Oats	Acetamipryd 200 SL	21 d Vegetative vigour	Plant number at the end of the experiment ER ₅₀ > 1500 ml/ha (>295.8 g as/ha) Shoot length ER ₅₀ > 1500 ml/ha (>295.8 g as/ha) Plant dry weight ER ₅₀ > 1500 ml/ha (>295.8 g as/ha) Plant damage ER ₅₀ > 1500 ml/ha (>295.8 g as/ha)	Wróbel A/ 2022/ Study code: G-95-21 KCP 10.6/02

9.10.1.1 Justification for new endpoints

New endpoints are provided for the formulated product Acetamipryd 200 SL. Details of studies and results are included in Table 9.10-1. Summary of the studies is included in Appendix II. Additional studies are required according to Regulation (EC) No. 284/2013.

9.10.2 Risk assessment

9.10.2.1 Tier-1 risk assessment (based screening data)

Not relevant.

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

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

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use no. 5 (orchards) also covers the off-field risk for non-target terrestrial plants from all other intended uses (see 9.1.2).

Table 9.10-2: Assessment of the risk for non-target plants due to the use of Acetamipryd 200 SL in orchards (use no. 5)

Intended use	orchards (use no. 5)
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Product	Acetamipryd 200 SL			
Application rate (ml/ha)	2 × 0.125 L/ha			
MAF	1.7			
Test species	ER₅₀ (ml/ha)	Drift rate (%)	PER_{off-field} (ml/ha)	TER criterion: TER ≥ 5
NR	> 1500 ml/ha	25.63	54.46	27.54

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

¹MAF and drift rate from ESCORT 2 Guidance Document on Regulatory Testing and Risk Assessment Procedures for Plant Protection Products with Non-Target Arthropods

9.10.2.3 Higher-tier risk assessment

Not relevant.

9.10.2.4 Risk mitigation measures

No risk mitigation needed.

9.10.3 Overall conclusions

The risk of Acetamipryd 200 SL to non-target plants was assessed from toxicity exposure ratios between toxicity endpoints for the formulation Acetamipryd 200 SL and off-field predicted environmental rate. The TER values were greater than the trigger of 5, indicating an acceptable risk to non-target terrestrial plants following application of Acetamipryd 200 SL in accordance with GAP. No risk management measures are required.

zRMS comments: zRMS agrees with calculations presented above. 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. No risk management measures are required.
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9.11 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)

Not relevant.

9.12 Monitoring data (KCP 10.8)

Not relevant.

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9.13 Classification and Labelling

Justified proposals for classification and labelling

According to the criteria given in Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008, the following classification and labelling with regard to ecotoxicological data is proposed for the formulation:

Table 9.13-1: Justified proposals for classification and labelling for Acetamipryd 200 SL according to Regulation (EC) No 1272/2008


Hazard class(es), categories:	Aquatic Chronic 1, H410
Hazard pictograms or Code(s) for hazard pictogram(s):	 GHS09
Signal word:	Warning
Hazard statement(s):	Very toxic to aquatic life with long lasting effects. [H410]
Precautionary statement(s):	-
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401] Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farm-yards and roads). [SP 1] Collect spillage [P391]

Table 9.13-2: Summary of evaluation of the ecotoxicological studies for Acetamipryd 200 SL

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
Acute toxicity to aquatic organisms (lowest value)	$E_rC_{50} = 151.3 \text{ mg/L}_{\text{nom}}$ $E_yC_{50} = 25.1 \text{ mg/L}_{\text{nom}}$	A	no classification	Czarnecka M./ 2022/ Study code: W-12-22 KCP 10.2.1.3/01
Chronic toxicity to aquatic organisms	no data, extrapolation from active substance data	A	Aquatic Chronic 1, H410	dRR Part C

zRMS comments: Accepted.

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Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

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

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.2.1.2/01	Czarnecka M	2022	Acetamipryd 200 SL Daphnia magna, Acute immobilisation test Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland Study code: W-11-22 GLP: Y Published: N	N	Pestila* ProAgri*
	Czarnecka M	2022	AMENDMENT NO. 1 TO THE FINAL REPORT Acetamipryd 200 SL Daphnia magna, Acute immobilisation test Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland Study code: W-11-22 GLP: Y Published: N	N	Pestila* ProAgri*
KCP 10.2.1.3/01	Czarnecka M	2022	Acetamipryd 200 SL <i>Raphidocelis subcapitata</i> SAG 61.81 (formerly <i>Pseudokirchneriella subcapitata</i>), Growth inhibition test Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland Study code: W-12-22 GLP: Y Published: N	N	Pestila* ProAgri*
	Czarnecka M	2023	AMENDMENT NO. 1 TO THE FINAL REPORT	N	Pestila*

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			Acetamipryd 200 SL <i>Raphidocelis subcapitata</i> SAG 61.81 (formerly <i>Pseudokirchneriella subcapitata</i>), Growth inhibition test Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland Study code: W-12-22 GLP: Y Published: N		ProAgri*
KCP 10.3.1.1.1/01	Mautino G	2023	Effects of Acetamipryd 200 SL on Honeybees (<i>Apis mellifera</i> L.) in the laboratory – Acute Oral Toxicity Test SAGEA Centro di Saggio s.r.l., Italy Study code: 1148.I.SAG23/r GLP: Y Published: N	N	Pestila* ProAgri*
KCP 10.3.1.1.1/02	Fulczyk A	2022	Acetamipryd 200 SL Bumblebees (<i>Bombus</i> spp.), Acute Oral Toxicity Test Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland Study Code: B-105-22 GLP: Y Published: N	N	Pestila* ProAgri*
KCP 10.3.1.1.2/01	Fulczyk A	2022	Acetamipryd 200 SL Bumblebees (<i>Bombus</i> spp.), Acute Contact Toxicity Test Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland Study code: B-107-22 GLP: Y Published: N	N	Pestila* ProAgri*
KCP 10.3.1.1.2/02	Mautino G	2024	Effects of Acetamipryd 200 SL on Honeybees (<i>Apis mellifera</i> L.) in the laboratory – Acute Contact Toxicity Test SAGEA Centro di Saggio s.r.l., Italy Study code: 3053.1I.SAGIT24 GLP: Y Published: N	N	Pestila* ProAgri*
KCP 10.3.1.2/01	Mautino G	2024	Effects of Acetamipryd 200 SL on Honeybees (<i>Apis mellifera</i> L.) in the laboratory – Chronic Oral Toxicity Test SAGEA Centro di Saggio s.r.l., Italy Study code: 1032.I.SAG23/r GLP: Y	N	Pestila* ProAgri*

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			Published: N		
KCP 10.3.1.4/01	Mautino G	2024	Effects of Acetamipryd 200 SL on Honeybees (<i>Apis mellifera</i> L.) in the laboratory – Larval Toxicity Test Following Repeated Exposure SAGEA Centro di Saggio s.r.l., Italy Study code: 1033.I.SAG23/r; GLP: Y Published: N	N	Pestila* ProAgri*
KCP 10.3.2.2/01	Mautino G	2023	Effects of Acetamipryd 200 SL on <i>Aphidius rhopalosiphi</i> – Extended laboratory aged residue test SAGEA Centro di Saggio s.r.l., Italy Study Code: 1036.I.SAG23/r GLP: Y Published: N	N	Pestila* ProAgri*
KCP 10.3.2.2/02	Mautino G	2023	Effects of Acetamipryd 200 SL on <i>Typhlodromus pyri</i> – Extended laboratory aged residue test SAGEA Centro di Saggio s.r.l., Italy Study Code: 1037.I.SAG23/r GLP: Y Published: N	N	Pestila* ProAgri*
KCP 10.3.2.2/03	Mautino G	2024	Effects of Acetamipryd 200 SL on <i>Coccinella Septempunctata</i> – Extended laboratory aged residue test SAGEA Centro di Saggio s.r.l., Italy Study code: 1035.I.SAG23/r GLP: Y Published: N	N	Pestila* ProAgri*
KCP 10.3.2.2/04	Mautino G	2023	Effects of Acetamipryd 200 SL on <i>Chrysoperla carnea</i> – Extended laboratory aged residue test SAGEA Centro di Saggio s.r.l., Italy Study code: 1038.I.SAG23/r GLP: Y Published: N	N	Pestila* ProAgri*
KCP 10.4.1.1/01	Wróbel A	2022	Acetamipryd 200 SL Earthworm reproduction test (<i>Eisenia andrei</i>) Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland Study code: G-93-21 GLP: Y Published: N	N	Pestila* ProAgri*

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KCP 10.4.2.1/01	Mautino G	2023	Predatory mites <i>Hypoaspis (Geolaelaps) aculeifer</i> reproduction test in soil with Acetamipryd 200 SL SAGEA Centro di Saggio s.r.l., Italy Study code: 1039.I.SAG23/r GLP: Y Published: N	N	Pestila* ProAgri*
KCP 10.4.2.1/02	Szlauer S	2024	Collembolan (<i>Folsomia candida</i>) Reproduction Test in soil EcoTox Alliance Sp. z o. o., Poland Study code: ETOX-2024-2 GLP: Y Published: N	N	Pestila* ProAgri*
KCP 10.5/01	Wróbel A	2022	Acetamipryd 200 SL Soil Microorganisms: Nitrogen Transformation Test Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland Study code: G-94-21 GLP: Y Published: N	N	Pestila* ProAgri*
KCP 10.6.2/01	Wróbel A	2022	Acetamipryd 200 SL Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland Study code: G-96-21 GLP: Y Published: N	N	Pestila* ProAgri*
KCP 10.6.2/02	Wróbel A	2022	Acetamipryd 200 SL Terrestrial Plant Test: Vegetative Vigour Test Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland Study code: G-95-21 GLP: Y Published: N	N	Pestila* ProAgri*
		2022	AMENDMENT NO. 1 TO THE FINAL REPORT Acetamipryd 200 SL Terrestrial Plant Test: Vegetative Vigour Test Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland Study code: G-95-21 GLP: Y Published: N	N	Pestila* ProAgri*

*Pestila Spółka z ograniczoną odpowiedzialnością (short name: Pestila Sp. z o.o.)

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**ProAgri Spółka z ograniczoną odpowiedzialnością or ProAgri International Spółka z ograniczoną odpowiedzialnością (short name: ProAgri Sp. z o.o. or ProAgri International Sp. z o.o.)

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

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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

Not relevant. No studies submitted. It is possible to extrapolate data from the active substance.

A 2.1.2 KCP 10.1.2 Effects on terrestrial vertebrates other than birds

Not relevant. No studies submitted. It is possible to extrapolate data from the active substance.

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

Not relevant. No studies 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

A 2.2.1.1 KCP 10.2.1.1 Acute toxicity to fish

Not relevant. No studies submitted. It is possible to extrapolate data from the active substance.

A 2.2.1.2 KCP 10.2.1.2 Acute toxicity to aquatic invertebrates

Comments of zRMS:	The study was accepted by zRMS.
	The validity criteria was met:
	In the definitive test, the validity criteria were met according to the OECD Guideline No. 202 (2004) and EU Method C.2.:
	<ul style="list-style-type: none"> - the percentage of immobilisation of <i>Daphnia magna</i> in the control was 0% (criterion: not more than 10%), - the dissolved oxygen concentrations in the test vessels at the end of the test were within the range of 6.5 – 8.5 mg/L (criterion: not less than 3 mg/L).
	Deviation of the study: none
	Results of chemical determinations:
	At exposure initiation, the determined concentrations of acetamiprid were in the range of 95.5 – 97.9% of the nominal concentration. The results confirm that the

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test item concentrations were prepared correctly. At exposure termination, the determined concentrations of acetamiprid were in the range of 97.0 – 98.1% of the nominal concentration. Therefore, the concentrations of acetamiprid were stable under test conditions.	The agreed toxicity endpoints:																						
	<table><tr><th rowspan="2">Endpoint value [mg/L]</th><th colspan="2">Time of exposure</th></tr><tr><th>24 h</th><th>48 h</th></tr><tr><td>EC₅₀</td><td>>1000</td><td>951.7 (789.8 - >1000)</td></tr><tr><td>EC₂₀</td><td>>1000</td><td>686.0 (466.7 - 824.6)</td></tr><tr><td>EC₁₀</td><td>>1000</td><td>578.1 (321.7 - 710.2)</td></tr><tr><td>LOEC</td><td>>1000</td><td>1000</td></tr><tr><td>NOEC</td><td>≥1000</td><td>500</td></tr></table>			Endpoint value [mg/L]	Time of exposure		24 h	48 h	EC ₅₀	>1000	951.7 (789.8 - >1000)	EC ₂₀	>1000	686.0 (466.7 - 824.6)	EC ₁₀	>1000	578.1 (321.7 - 710.2)	LOEC	>1000	1000	NOEC	≥1000	500
	Endpoint value [mg/L]	Time of exposure																					
		24 h	48 h																				
	EC ₅₀	>1000	951.7 (789.8 - >1000)																				
	EC ₂₀	>1000	686.0 (466.7 - 824.6)																				
	EC ₁₀	>1000	578.1 (321.7 - 710.2)																				
	LOEC	>1000	1000																				
	NOEC	≥1000	500																				
	Calculations were made according to [7], [SOP/W/68] (-) - 95% confidence interval																						
<u>The endpoint values based on the nominal test item concentrations:</u>																							
The EC ₅₀ /48 h value is 951.7 mg/L (95% confidence limits: 789.8 - >1000).																							
The LOEC/48 h value is 1000 mg/L.																							
The NOEC/48 h value is 500 mg/L.																							
<u>The endpoint values based on the nominal concentrations of acetamiprid:</u>																							
The EC ₅₀ /48 h value is 164.1 mg/L (95% confidence limits: 136.2 - >1000).																							
The LOEC/48 h value is 172.4 mg/L.																							
The NOEC/48 h value is 86.2 mg/L.																							

Reference:	KCP 10.2.1.2/01
Report	Acetamipryd 200 SL <i>Daphnia magna</i> , Acute immobilisation test, Czarnecka M; 2022; Study code: W-11-22
	AMENDMENT NO. 1 TO THE FINAL REPORT Acetamipryd 200 SL <i>Daphnia magna</i> , Acute immobilisation test, Czarnecka M; 2022; Study code: W-11-22
Guideline(s):	Yes, OECD 202
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

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MATERIALS AND METHODS

1. Test material

Test item (chemical/other name):	Acetamipryd 200 SL
Formulation:	SL (soluble liquid), acetamiprid: specification 200.0 g/L
Description (physical state):	light brown liquid
Batch no.:	1/ACE/2022
Production date:	01.2022
Expiration date:	01.2024

2. Vehicle and/or positive control:

vehicle control: Elendt M7 medium,
positive control: potassium dichromate

3. Test organism

Species:	<i>Daphnia magna</i> Straus
Source:	Łukasiewicz Research Network - Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland
Age:	< 24 h old at exposure initiation, not first brood progeny
Feeding:	during the test daphnia were not fed
Test units:	glass beakers of volume 150 mL

4. Environmental conditions:

Medium:	Elendt M7 medium recommended by the OECD Guideline No. 202 prepared on the basis of deionized water by adding stock solutions of reagent-grade chemicals
pH in control:	7.77 – 7.93
Dissolved oxygen in control:	8.4 – 8.6 mg/L
Temperature:	20.5 – 21.8°C
Lighting:	daily cycle 16 h light : 8 h dark; fluorescent light source

STUDY DESIGN AND METHOD

Immobilisation of *Daphnia magna* exposed to the test item, Acetamipryd 200 SL was investigated during a 48-hour static test. The test was performed in glass beakers of 150 mL capacity, containing 100 mL of either the test item concentration or the control per replicate. The definitive test was performed in the following test item concentrations: 1000, 500, 250, 125, 62.5 mg/L plus the control (Elendt M7 medium). The *Daphnia magna* were observed for immobilisation after 24 and 48 h of exposure. The *Daphnia magna* were considered immobile if they showed no ability to swim within 15 seconds after gentle swirling of the test vessel. In the control and in the test item concentrations of 62.5, 125, and 250 mg/L no immobilisation of *Daphnia magna* were observed during the exposure. In the test item concentrations of 500 and 1000 mg/L after 48 h of exposure immobilisation of 5 and 55% was observed, respectively. The concentrations of acetamiprid in the test item concentrations, were determined using a validated high performance liquid chromatographic (HPLC) with Diode Array Detection. Samples for chemical determination were collected from all the test item concentrations and the control at exposure initiation and at exposure termination. The endpoint values were determined based on the nominal test item concentration.

Test design:	4 replicates per each test item concentration and the control; 5 <i>Daphnia magna</i> in each replicate
Type of the exposure:	static
Exposure time:	48 hours
Tested concentrations, definitive test:	1000, 500, 250, 125, 62.5 mg/L plus the control
Stability of test compound:	The concentrations of acetamiprid in the test item concentrations, were determined using a validated high performance liquid chromatographic (HPLC) with Diode Array Detection. Samples for chemical determination were collected from all the test item concentrations and the control at exposure initiation and at exposure termination. At exposure initiation, the determined concentrations of acetamiprid were in the range of 95.5 – 97.9% of the nominal concentration. The results confirm that the test item concentrations were prepared correctly. At exposure termination, the determined concentrations of acetamiprid were in the range of 97.0 – 98.1% of the nominal concentration. Therefore, the concentrations of acetamiprid were stable under test conditions.
Dates:	start of the study 04.04.2022 start of the experimental part: 11.04.2022 end of the experimental part: 14.04.2022 end of the study: 09.06.2022
Statistic:	Probit analysis using linear max. likelihood regression, Tarone's Test Procedure, Step-down Cochran-Armitage Test Procedure
Validity of the test:	In the definitive test, the validity criteria were met according to the OECD Guideline No. 202 (2004) and EU Method C.2.: <ul style="list-style-type: none">- the percentage of immobilisation of <i>Daphnia magna</i> in the control was 0% (criterion: not more than 10%),- the dissolved oxygen concentrations in the test vessels were within the range of 6.5 – 8.5 mg/L (criterion: not less than 3 mg/L).

RESULTS

The effect of the test item on immobilisation of *Daphnia magna* was assessed. The test item concentration used in the definitive test were determined on the basis of the preliminary test results. The *Daphnia magna* were considered immobile if they showed no ability to swim within 15 seconds after gentle swirling of the test vessel (visual check). At exposure initiation, the determined concentrations of acetamiprid were in the range of 95.5 – 97.9% of the nominal concentration. The results confirm that the test item concentrations were prepared correctly. At exposure termination, the determined concentrations of acetamiprid were in the range of 97.0 – 98.1% of the nominal concentration. Therefore, the concentrations of acetamiprid were stable under test conditions.

In the definitive test, the recorded temperature during exposure was in the range of 20.5 – 21.8°C and constant within 1.3°C. The pH values measured in all test item concentrations and the control were in the ranges 7.82 – 7.93 at exposure initiation and 7.30 – 7.77 at exposure termination. The dissolved oxygen

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concentrations measured in all test item concentrations and the control were in the ranges of 8.6 – 8.7 mg/L at exposure initiation and 6.5 – 8.5 mg/L at exposure termination. In the control and the test item concentrations of 62.5, 125 and 250 mg/L no immobilisation of *Daphnia magna* was observed during the exposure. In the test item concentrations of 500 and 1000 mg/L after 48 h of exposure immobilisation of 5 and 55% was observed, respectively. Additionally, in the test item concentration of 1000 mg/L, some daphnids were covered with particles of the test item. The immobilisation of *Daphnia magna* after 24 h and 48 h of exposure is given below.

Table KCP 10.2.1.2-1: Immobilisation of *Daphnia magna*, definitive test

Nominal test item concentration [mg/L]	Number of <i>Daphnia magna</i>	Number of immobilised <i>Daphnia magna</i>								Total of immobilised <i>Daphnia magna</i> [%]	
		24 h				48 h					
		Replicates									
		A	B	C	D	A	B	C	D	24 h	48 h
Control	20	0	0	0	0	0	0	0	0	0	0
62.5	20	0	0	0	0	0	0	0	0	0	0
125	20	0	0	0	0	0	0	0	0	0	0
250	20	0	0	0	0	0	0	0	0	0	0
500	20	0	0	0	0	0	0	0	1	0	5
1000	20	0	0	0	0	2	4	2	3	0	55

CONCLUSION

The endpoint values were estimated based on the nominal test item concentrations. The ECx values were calculated with a probit method. The lowest observed effect concentration (LOEC) and the no observed effect concentration (NOEC) were determined on the basis of statistical analyses. To make calculations and to conduct statistical analyses, the ToxRat Professional commercial software was used. The median concentration causing 50% immobilisation of *Daphnia magna* after 24 h of exposure, i.e. the EC50/24 h value as well as the EC20/24 h and the EC10/24 h values are higher than the highest nominal test item concentration, i.e., 1000 mg/L. The median concentration causing 50% immobilisation of *Daphnia magna* after 48 h of exposure, i.e. the EC50/48 h value is 951.7 mg/L (95% confidence interval 789.8 – >1000). The EC20/48 h value is 686.0 mg/L (95% confidence interval 466.7 – 824.6). The EC10/48 h value is 578.1 mg/L (95% confidence interval 321.7 – 710.2). The data on immobilisation of the *Daphnia magna* at exposure termination were analysed using Step-down Cochran-Armitage Test Procedure, which showed significant difference between nominal test item concentration of 1000 mg/L and the control. Therefore, the LOEC/48 h value is 1000 mg/L and the NOEC/48 h value 500 mg/L.

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Table KCP 10.2.1.2-1: Endpoint values based on the nominal test item concentrations of acetamiprid, definitive test

Endpoint value [mg/L]	Time of exposure	
	24 h	48 h
EC ₅₀	>172.4	164.1 (136.2 – >172.4)
EC ₂₀	>172.4	118.3 (80.5 – 142.2)
EC ₁₀	>172.4	99.7 (55.5 – 122.4)
LOEC	>172.4	172.4
NOEC	≥172.4	86.2

Table KCP 10.2.1.2-1: Endpoint values based on the nominal test item concentration, definitive test

Endpoint value [mg/L]	Time of exposure	
	24 h	48 h
EC ₅₀	>1000	951.7 (789.8 – >1000)
EC ₂₀	>1000	686.0 (466.7 – 824.6)
EC ₁₀	>1000	578.1 (321.7 – 710.2)
LOEC	>1000	1000
NOEC	≥1000	500

A 2.2.1.3 KCP 10.2.1.3 Effects on aquatic algae

Comments of zRMS:	The study was accepted by zRMS.
	<p>The validity criteria was met:</p> <p>In the definitive test, the following validity criteria specified in the OECD Guideline No. 201 (2006) and EU Method C.3 were met:</p> <ul style="list-style-type: none"> - the biomass in the control increased by a factor of 156.4 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 1.1% (criterion: it must not exceed 7%), - the mean coefficient of variation for the section-by-section growth rate in the control culture was 28.9% (criterion: it must not exceed 35%).

Deviation of the study: none

Results of chemical determinations:

At exposure initiation, the determined concentrations of acetamiprid were in the range of 97.4 – 99.3% of the nominal concentration. The results confirm that the test item concentrations were prepared correctly. At exposure termination, the determined concentrations of acetamiprid were in the range of 96.7 – 98.4% of the nominal concentration. Therefore, the concentrations of acetamiprid were stable under test conditions. The endpoint values were determined based on the nominal test item concentrations.

The agreed toxicity endpoints:

The endpoint values based on the nominal test item concentrations:

The ErC₅₀/72 h value is 151.3 mg/L (95% confidence interval: 116.4 – 197.9).

The EyC₅₀/72 h value is 25.1 mg/L (95% confidence interval: 20.7 – 29.5).

The LOEC/72 h values for growth rate and yield are 30.5 mg/L.

The NOEC/72 h values for growth rate and yield are 9.5 mg/L.

The endpoint values based on the nominal concentrations of acetamiprid:

The ErC₅₀/72 h value is 26.1 mg/L (95% confidence interval 20.1 – 34.0).

The EyC₅₀/72 h value is 4.4 mg/L (95% confidence interval 3.6 – 5.1).

The LOEC/72 h values for growth rate and yield are 5.3 mg/L.

The NOEC/72 h values for growth rate and yield are 1.6 mg/L.

Growth rate endpoint values based on the nominal concentrations of acetamiprid (definitive test)

Endpoint value [mg/L]	Time of exposure:		
	24 h	48 h	72 h
ErC ₅₀	> 172.4	28.5 (19.2 – 43.2)	26.1 (20.1 – 34.0)
ErC ₂₀	26.6 (6.3 – 48.4)	5.2 (2.2 – 8.6)	5.4 (3.2 – 7.7)
ErC ₁₀	10.0 (0.8 – 22.9)	2.1 (0.6 – 4.2)	2.3 (1.2 – 3.8)
LOEC	16.8	5.3	5.3
NOEC	5.3	1.6	1.6

(-) – 95% confidence interval

Calculations were made according to [8], [SOP/W/68]

Yield endpoint values based on the nominal concentrations of acetamiprid (definitive test)

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Endpoint value [mg/L]	Time of exposure:		
	24 h	48 h	72 h
EyC50	80.6 (43.3 – >172.4)	6.1 (4.8 – 7.7)	4.4 (3.6 – 5.1)
EyC20	14.0 (2.3 – 28.0)	2.6 (1.6 – 3.5)	2.4 (1.5 – 3.1)
EyC10	5.6 (0.3 – 14.2)	1.7 (0.8 – 2.4)	1.8 (1.0 – 2.4)
LOEC	16.8	5.3	5.3
NOEC	5.3	1.6	1.6

(–) – 95% confidence interval
 Calculations were made according to [8], [SOP/W/68]

Reference: KCP 10.2.1.3/01

Report Acetamipryd 200 SL *Raphidocelis subcapitata* SAG 61.81 (formerly *Pseudokirchneriella subcapitata*), Growth inhibition test;
 Czarnecka M; 2022; Study code: W-12-22

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 Acetamipryd 200 SL *Raphidocelis subcapitata* SAG 61.81 (formerly *Pseudokirchneriella subcapitata*), Growth inhibition test;
 Czarnecka M; 2023; Study code: W-12-22

Guideline(s): Yes, OECD 201

Deviations: No

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study) No

MATERIALS AND METHODS

1. Test material

Test item (chemical/other name): Acetamipryd 200 SL

Formulation: SL (soluble liquid), acetamiprid: specification 200.0 g/L

Description (physical state): light brown liquid

Batch no.: 1/ACE/2022

Production date: 01.2022

Expiration date: 01.2024

2. Vehicle and/or positive control: vehicle control: APP medium,
 positive control: 3,5-dichlorophenol

3. Test organism

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Species:	unicellular freshwater green algae, <i>Raphidocelis subcapitata</i> (formerly <i>Pseudokirchneriella subcapitata</i> (Korshikov) Hindák, <i>Selenastrum capricornutum</i> Prinz) SAG 61.81
Source:	Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna, Department of Ecotoxicological Studies, Laboratory of Aquatic Toxicology, Poland; the algae were obtained from the Algae Collection, University Göttingen, Germany
Age:	72 hours
Test units:	flasks with a capacity of 250 mL containing 100 mL of either test item concentration or the control plugged with air permeable stoppers

4. Environmental conditions:

Medium:	APP
Medium temperature:	21.6 – 22.4°C
pH of the control:	7.41 – 8.01
Lighting:	mean light intensity: 7575 – 7868 lux; constant illumination

STUDY DESIGN AND METHOD

The growth of the green algae *Raphidocelis subcapitata* SAG 61.81 (formerly *Pseudokirchneriella subcapitata*) exposed to the test item, Acetamipryd 200 SL was investigated during a 72-hour test. The test was performed in glass flasks with a capacity of 250 mL containing 100 mL of either the test item concentration, or the control, per replicate. The initial density of the algae was 1×10^4 cells/mL. The definitive test was performed with the following test item concentrations: 1000, 312.5, 97.7, 30.5, 9.5 mg/L plus the control. The number of algal cells was determined with indirect method, which involves a spectrophotometric measurement of the absorbance of algal suspension at 670 nm and converting its value into the number of cells using a standard curve. The absorbance for each replicate of each test item concentration and the control were measured after 24, 48, and 72 h of exposure. Morphology observations of the algae cells were performed at exposure termination. The concentrations of acetamiprid were chemically determined using the validated high performance liquid chromatographic method (HPLC) with Diode Array Detection (DAD). Samples of all test item concentrations and the control collected at exposure initiation and at exposure termination were chemically determined. The endpoint values were determined based on the nominal test item concentrations.

Test design:	three replicates per each test item concentration; six replicates per control; a background for each treatment
Type of the exposure:	static
Exposure time:	72 hours
Inoculum:	10^4 cells/mL
Tested concentrations, definitive test:	1000, 312.5, 97.7, 30.5, 9.5 mg/L plus the control

Stability of the test compound:

The concentrations of acetamiprid were chemically determined using the validated high performance liquid chromatographic method (HPLC) with Diode Array Detection (DAD). Samples of all test item concentrations and the control collected at exposure initiation and at exposure termination were chemically determined. At exposure initiation, the determined concentrations of acetamiprid were in the range of 97.4 – 99.3% of the nominal concentration. The results confirm that the test item concentrations were prepared correctly. At exposure termination, the determined concentrations of acetamiprid were in the range of 96.7 – 98.4% of the nominal concentration. Therefore, the concentrations of dicamba were stable under test conditions.

Dates:

start of the study 25.02.2022
start of the experimental part: 26.10.2022
end of the experimental part: 29.04.2022
end of the study: 15.06.2022

Statistic:

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

Validity of the test:

In the definitive test, the following validity criteria specified in the OECD Guideline No. 201 (2006) and EU Method C.3 were met:

- the biomass in the control increased by a factor of 156.4 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 1.1% (criterion: it must not exceed 7%),
- the mean coefficient of variation for the section-by-section growth rate in the control culture was 28.9% (criterion: it must not exceed 35%).

RESULTS

The recorded temperature was in the range of 21.6 – 22.4°C and constant within 0.8°C. The mean light intensity was in the range of 7575 – 7868 lux. The pH values measured at exposure initiation were in the range of 7.39 – 7.46 and at exposure termination were in the range of 7.41 – 8.01. In the test item concentrations of 9.5, 30.5 and 97.7 mg/L no differences in shape, size and colour of algal cells were reported as compared to the algae cells in the control. In the test item concentration of 312.5 mg/L deformed cells were reported as compared to the algae cells in the control. In the test item concentration of 1000 mg/L deformed bigger cells were reported as compared to the algae cells in the control.

Table KCP 10.2.1.3-1: Observations of algal cell morphology at exposure termination, definitive test

Nominal test item concentration [mg/L]	Observations
Control	Normal colour, shape and size of the algal cells
9.5	No changes
30.5	No changes
97.7	No changes
312.5	Deformed cells
1000	Deformed bigger cells

The transmittance was measured at 670 nm in replicates without the algae at exposure initiation and at exposure termination. The average transmittance values were in the range of 99.3 – 99.8 at exposure initiation and in the range of 94.5 – 99.3% at exposure termination when compared with the control.

Table KCP 10.2.1.3-2: Transmittance of a background for spectrophotometric measurements, definitive test

Nominal test item concentration [mg/L]	Transmittance at exposure initiation [%]	Transmittance at exposure termination [%]
Control	100.0	100.0
9.5	99.7	99.3
30.5	99.3	98.4
97.7	99.7	98.0
312.5	99.8	99.3
1000	99.5	94.5

Hence, the indirect method was adequate to determine the number of algal cells. The average specific growth rates and yield for the whole exposure were calculated using algal cells densities determined after 24, 48, and 72 h of exposure. The cell density, the specific growth rate, and the yield increase during exposure are provided below.

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Table KCP 10.2.1.3-3: Average absorbance values converted into the algal cell density, definitive test

Nominal test item concentration [mg/L]	Average absorbance* obtained for each replicate at each time			Algal cell density [10 ⁶ cells per mL] calculated according to the standard curve formula*		
	24 h	48 h	72 h	24 h	48 h	72 h
Control	0.014	0.125	0.648	0.035	0.308	1.599
	0.013	0.122	0.634	0.032	0.301	1.564
	0.012	0.124	0.658	0.030	0.306	1.623
	0.016	0.126	0.665	0.039	0.311	1.641
	0.016	0.135	0.631	0.039	0.333	1.557
	0.013	0.120	0.567	0.032	0.296	1.399
mean	0.014	0.125	0.634	0.035	0.309	1.564
<i>standard deviation</i>	<i>0.002</i>	<i>0.005</i>	<i>0.035</i>	<i>0.004</i>	<i>0.013</i>	<i>0.087</i>
9.5	0.014	0.132	0.568	0.035	0.326	1.401
	0.014	0.140	0.660	0.035	0.345	1.628
	0.012	0.145	0.666	0.030	0.358	1.643
mean	0.013	0.139	0.631	0.033	0.343	1.557
<i>standard deviation</i>	<i>0.001</i>	<i>0.007</i>	<i>0.055</i>	<i>0.003</i>	<i>0.016</i>	<i>0.136</i>
30.5	0.015	0.050	0.152	0.037	0.123	0.375
	0.015	0.076	0.312	0.037	0.188	0.770
	0.015	0.062	0.225	0.037	0.153	0.555
mean	0.015	0.063	0.230	0.037	0.155	0.567
<i>standard deviation</i>	<i>0.000</i>	<i>0.013</i>	<i>0.080</i>	<i>0.000</i>	<i>0.033</i>	<i>0.198</i>
97.7	0.013	0.025	0.070	0.032	0.062	0.173
	0.010	0.031	0.081	0.025	0.076	0.200
	0.009	0.029	0.093	0.022	0.072	0.229
mean	0.011	0.028	0.081	0.026	0.070	0.201
<i>standard deviation</i>	<i>0.002</i>	<i>0.003</i>	<i>0.012</i>	<i>0.005</i>	<i>0.007</i>	<i>0.028</i>
312.5	0.012	0.018	0.024	0.030	0.044	0.059
	0.011	0.017	0.017	0.027	0.042	0.042
	0.008	0.007	0.012	0.020	0.017	0.030
mean	0.010	0.014	0.018	0.026	0.034	0.044
<i>standard deviation</i>	<i>0.002</i>	<i>0.006</i>	<i>0.006</i>	<i>0.005</i>	<i>0.015</i>	<i>0.015</i>
1000	0.008	0.008	0.012	0.020	0.020	0.030
	0.008	0.017	0.018	0.020	0.042	0.044
	0.006	0.007	0.011	0.015	0.017	0.027
mean	0.007	0.011	0.014	0.018	0.026	0.034
<i>standard deviation</i>	<i>0.001</i>	<i>0.006</i>	<i>0.004</i>	<i>0.003</i>	<i>0.014</i>	<i>0.009</i>

Time of exposure: 26.04.2022 – 29.04.2022

*- Average absorbance read at λ 670 nm in a glass cuvette with a length of 5 cm was calculated according to the following standard curve formula: $\Delta A_{670} = 0.4053 \times [10^6 \text{ cells per mL}]$, $R^2 = 0.9927$

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Table KCP 10.2.1.3-4: Growth rate and yield, definitive test

Nominal test item concentration [mg/L]	Growth rate* [10 ⁶ cells/mL]				Yield** [10 ⁶ cells/mL]
	0-24 h	24-48 h	48-72 h	0-72 h	72 h
Control	1.253	2.175	1.647	1.692	1.589
	1.163	2.241	1.648	1.684	1.554
	1.099	2.322	1.668	1.696	1.613
	1.361	2.076	1.663	1.700	1.631
	1.361	2.145	1.542	1.683	1.547
	1.163	2.225	1.553	1.647	1.389
mean	1.233	2.197	1.620	1.684	1.554
standard deviation	0.110	0.085	0.057	0.019	0.087
9.5	1.253	2.232	1.458	1.647	1.391
	1.253	2.288	1.552	1.698	1.618
	1.099	2.479	1.524	1.701	1.633
mean	1.201	2.333	1.511	1.682	1.547
standard deviation	0.089	0.130	0.048	0.030	0.136
30.5	1.308	1.201	1.115	1.208	0.365
	1.308	1.626	1.410	1.448	0.760
	1.308	1.420	1.289	1.339	0.545
mean	1.308	1.415	1.271	1.332	0.557
standard deviation	0.000	0.212	0.148	0.120	0.198
97.7	1.163	0.661	1.026	0.950	0.163
	0.916	1.112	0.968	0.999	0.190
	0.788	1.186	1.157	1.044	0.219
mean	0.956	0.986	1.050	0.998	0.191
standard deviation	0.190	0.284	0.097	0.047	0.028
312.5	1.099	0.383	0.293	0.592	0.049
	0.993	0.442	0.000	0.478	0.032
	0.693	n.d.	0.568	0.366	0.020
mean	0.928	n.d.	0.287	0.479	0.034
standard deviation	0.210	n.d.	0.284	0.113	0.015
1000	0.693	0.000	0.405	0.366	0.020
	0.693	0.742	0.047	0.494	0.034
	0.405	0.125	0.463	0.331	0.017
mean	0.597	0.289	0.305	0.397	0.024
standard deviation	0.166	0.397	0.226	0.086	0.009

* - Growth rate [10⁶ cells/mL] was calculated according to the following formula:

The relationship between the inhibition of growth rate and the nominal test item concentrations at 72 h and the relationship between the inhibition of yield and the nominal test item concentrations at 72 h is provided below.

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Table KCP 10.2.1.3-5: Growth rate and yield inhibition, definitive test

Nominal test item concentration [mg/L]	[%] inhibition after 72 h of exposure	
	growth rate	yield
Control	0.0	0.0
9.5	0.1	0.4
30.5	20.9	64.2
97.7	40.8	87.7
312.5	71.6	97.8
1000	76.4	98.5

CONCLUSION

The endpoint values based on the nominal test item concentration:

Table KCP 10.2.1.3-6: Growth rate endpoint values based on the nominal concentrations of test item, definitive test

Endpoint value [mg/L]	Time of exposure:		
	24 h	48 h	72 h
E _r C ₅₀	> 1000	165.3 (111.3 – 251.3)	151.3 (116.4 – 197.9)
E _r C ₂₀	154.0 (36.5 – 280.3)	30.0 (12.9 – 50.0)	31.2 (18.8 – 44.5)
E _r C ₁₀	57.8 (4.6 – 132.7)	12.3 (3.7 – 24.2)	13.6 (6.8 – 21.9)
LOEC	97.7	30.5	30.5
NOEC	30.5	9.5	9.5

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Table KCP 10.2.1.3-7: Yield endpoint values based on the nominal concentrations of test item, definitive test

Endpoint value [mg/L]	Time of exposure:		
	24 h	48 h	72 h
E _y C ₅₀	467.0 (251.2 – >1000)	35.3 (27.7 – 45.0)	25.1 (20.7 – 29.5)
E _y C ₂₀	80.9 (13.4 – 162.1)	15.2 (9.2 – 20.4)	14.4 (9.0 – 18.0)
E _y C ₁₀	32.4 (1.9 – 82.1)	9.8 (4.9 – 14.3)	10.7 (5.6 – 14.5)
LOEC	97.7	30.5	30.5
NOEC	30.5	9.5	9.5

The endpoint values based on the nominal concentrations of acetamiprid

Table KCP 10.2.1.3-8: Growth rate endpoint values based on the nominal concentrations of acetamiprid, definitive test

Endpoint value [mg/L]	Time of exposure:		
	24 h	48 h	72 h
E _r C ₅₀	> 172.4	28.5 (19.2 – 43.2)	26.1 (20.1 – 34.0)
E _r C ₂₀	26.6 (6.3 – 48.4)	5.2 (2.2 – 8.6)	5.4 (3.2 – 7.7)
E _r C ₁₀	10.0 (0.8 – 22.9)	2.1 (0.6 – 4.2)	2.3 (1.2 – 3.8)
LOEC	16.8	5.3	5.3
NOEC	5.3	1.6	1.6

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Table KCP 10.2.1.3-9: Yield endpoint values based on the nominal concentrations of acetamiprid, definitive test

Endpoint value [mg/L]	Time of exposure:		
	24 h	48 h	72 h
E_yC₅₀	80.6 (43.3 – >172.4)	6.1 (4.8 – 7.7)	4.4 (3.6 – 5.1)
E_yC₂₀	14.0 (2.3 – 28.0)	2.6 (1.6 – 3.5)	2.4 (1.5 – 3.1)
E_yC₁₀	5.6 (0.3 – 14.2)	1.7 (0.8 – 2.4)	1.8 (1.0 – 2.4)
LOEC	16.8	5.3	5.3
NOEC	5.3	1.6	1.6

A 2.2.1.4 KCP 10.2.1.4 Effects on aquatic macrophytes

Not relevant. No studies submitted. It is possible to extrapolate data from the active substance.

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

Not relevant. No studies submitted. It is possible to extrapolate data from the active substance.

A 2.2.3 KCP 10.2.3 Further testing on aquatic organisms

Not relevant. No studies 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 was accepted by zRMS. The validity criteria was met:
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Mortality in the control group

In the control units, the mean value of dead bees was 3.33%, so the validity criterion was met.

The 24-HAA LD₅₀ value for reference group

The 24-HAA LD₅₀ for the acute oral test was 0.11 µg a.i./bee therefore, the validity criterion was met, because in the range 0.10-0.35 µg a.i./bee.

Deviations of the study: none

Agreed toxicity endpoints:

Table 1a. Mortality at 4 HAA, 24 HAA and 48 HAA – Acute Oral Toxicity test

Treatment number	Treatment	Test Item (Nominal intake)	Test Item (Calculated intake*)	Mortality 4 HAA (%)	p*	Mortality 24 HAA (%)	p*	Mortality 48 HAA (%)	p*
T1	Control	-	-	0.00	-	3.33	-	3.33	-
T2	Acetamipryd 200 SL	0.0049 µL f.p./bee (0.97 µg a.i./bee)	0.0041 µL f.p./bee (0.81 µg a.i./bee)	0.00	n.s.	3.33	n.s.	3.33	n.s.
T3	Acetamipryd 200 SL	0.011 µL f.p./bee (2.13 µg a.i./bee)	0.0075 µL f.p./bee (1.50 µg a.i./bee)	0.00	n.s.	3.33	n.s.	6.67	n.s.
T4	Acetamipryd 200 SL	0.023 µL f.p./bee (4.70 µg a.i./bee)	0.012 µL f.p./bee (2.31 µg a.i./bee)	0.00	n.s.	43.33	***	43.33	***
T5	Acetamipryd 200 SL	0.052 µL f.p./bee (10.33 µg a.i./bee)	0.034 µL f.p./bee (6.76 µg a.i./bee)	10.00	**	50.00	***	50.00	***
T6	Acetamipryd 200 SL	0.11 µL f.p./bee (22.73 µg a.i./bee)	0.064 µL f.p./bee (12.81 µg a.i./bee)	10.00	**	90.00	***	93.33	***
T7	Acetamipryd 200 SL	0.25 µL f.p./bee (50 µg a.i./bee)	0.14 µL f.p./bee (27.26 µg a.i./bee)	26.67	***	96.67	***	100.00	***
T8	ROGOR L 40 ST	0.00023 µL f.p./bee (0.090 µg a.i./bee)	0.00023 µL f.p./bee (0.091 µg a.i./bee)	3.33	n.s.	40.00	***	40.00	***
T9	ROGOR L 40 ST	0.00045 µL f.p./bee (0.18 µg a.i./bee)	0.00043 µL f.p./bee (0.17 µg a.i./bee)	23.33	***	73.33	***	73.33	***
T10	ROGOR L 40 ST	0.00088 µL f.p./bee (0.35 µg a.i./bee)	0.00083 µL f.p./bee (0.33 µg a.i./bee)	36.67	***	90.00	***	90.00	***

Note: Nominal intake according to the Study Plan

HAA = Hours After Application

* intake of µL f.p./µg a.i. calculated on the feeding consumption data obtained over the 6 hrs exposure

*, Cochran-Armitage test, α<0.001 ***, 0.01 **, 0.05 *

f.p.: formulated product

a.i.: active ingredient acetamipryd

n.s., not significantly different compared to the control

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	Table 1b. Mortality' endpoints at 4 HAA, 24 HAA and 48 HAA – Acute Oral Toxicity test			
	Endpoints	µL test item/bee	µg a.i./bee	µg test item /bee
	4-HAA LD ₅₀	>0.14 [95%-CLs n.d.]	>27.26 [95%-CLs n.d.]	>160.16 [95%-CLs n.d.]
	4-HAA NOED	0.012	2.31	13.73
	4-HAA LOED	0.034	6.76	38.90
	24-HAA LD ₅₀	0.025 [0.012 – 0.060]	5.04 [2.32 – 12.04]	28.60 [13.73 – 68.64]
	24-HAA NOED	0.0075	1.50	8.58
	24-HAA LOED	0.012	2.31	13.73
	48-HAA LD ₅₀	0.023 [0.011 – 0.052]	4.59 [2.19 – 10.37]	26.31 [12.58 – 59.49]
	48-HAA NOED	0.0075	1.50	8.58
	48-HAA LOED	0.012	2.31	13.73
	HAA = Hours After Application f.p.: formulated product a.i.: active ingredient acetamiprid 95%-CLs n.d., Confidence Limits not determined due to mathematical reasons			

Reference: KCP 10.3.1.1.1/01

Report Effects of Acetamipryd 200 SL on Honeybees (*Apis mellifera* L.) in the laboratory – Acute Oral Toxicity Test
 Mautino G.; 2023; Study Code: 1148.I.SAG23/r

Guideline(s): Yes, OECD 213

Deviations: No

GLP: Yes

Acceptability: Yes

Duplication No
 (if vertebrate study)

MATERIALS AND METHODS

1. Test material

Test item (chemical/other name): Acetamipryd 200 SL

Formulation: SL, 200 g/L (nominal content)

Description (physical state): liquid

Batch no.: 1/ACE/2022

Production date: 01.2022

Expiration date: 01.2024

2. Vehicle and/or positive control: vehicle: 50% sucrose solution
 positive control: ROGOR L40 ST (nominally dimethoate 400g/L)

3. Test organism

Species:	honeybee <i>Apis mellifera</i>
Source:	Beekeeper Marco Messa, via della colla 1, Pocapaglia (CN), 12060. Three commercial beehives, queen-right, healthy (disease free) and adequately fed, with normal population of young adult worker individuals (approx. 2 weeks old)
Age:	adults (female workers)
Acclimation period:	the test units were placed into a climatic chamber and kept under darkness at the environmental conditions of the test (25 ± 2 °C and 50-70% RH) for 6 hours, until the beginning of the test. No food or water was supplied during acclimatisation
Maintenance:	no chemical substances were applied to the hive for at least 1 month prior to the start of the study
Collection:	on the morning of use, from the outer honeycombs (away from the brood) without the use of smoke and without anaesthetics. By means of a proper brush, the bees were collected in plastic containers with holes for oxygenation and immediately transported to SAGEA's laboratory
Diet:	sucrose solution in water with a final concentration of 500 g/L (50% w/v) was used as food ad libitum. The syrup was administered using 2 mL syringe (deprived of the tip). One syringe was placed in each cage via an opening in the top of the test unit. If necessary, feeding solution was re-filled during the test course
Test units:	ventilated stainless steel cages 8.5 cm x 6.5 cm x 4.5 cm (length x height x width) with removable glass panel and perforated with 50 ventilation holes; Ø 2 mm
4. Environmental conditions:	
Temperature:	24.63 ± 0.011 °C (24.62 – 24.64 °C)
Relative humidity:	$64.7\pm 0.2\%$ (64.6 – 64.9%) RH
Photoperiod:	dark room

STUDY DESIGN AND METHOD

Aim of this study was to determine the acute oral toxicity of Acetamipryd 200 SL (acetamiprid 200 g/L) to honeybees. Mortality of the bees was used as the toxic endpoint. Sublethal effects, such as changes in behaviour, were also assessed. The study comprised 10 treatments (6 concentrations of the test item with a spacing factor of 2.2, 1 control group, 3 concentrations of the reference item with a spacing factor of 2) with 3 replicates; each test unit (stainless-steel cage) contained 10 individuals. Each cage was provided with a feeder containing 2 mL of tested doses dispersed in 50% w/v sucrose solution for maximum 6 hours. The amount of treated diet consumed per group was monitored. Then, feeders were replaced with ones

containing sucrose solution only ad libitum. Mortality was recorded after 4, 24 and 48 hours after application and compared with that of control group. Since There was no significant increase in mortality between 24 and 48 HAA (< 10%) among the different treatments, the test was stopped at 48 HAA in accordance with OECD 213.

Test design:	number of replicates: 3 replicates, number of bees: 10 bees/replicate
Exposure time:	acute test, 48 h
Tested concentrations, definitive test:	0.0049 µL test item/bee (0.97 µg as/bee) – T2 0.011 µL test item/bee (2.13 µg as/bee) – T3 0.023 µL test item/bee (4.70 µg as/bee) – T4 0.052 µL test item/bee (10.33 µg as/bee) – T5 0.11 µL test item/bee (22.73 µg as/bee) – T6 0.25 µL test item/bee (50 µg as/bee) – T7 0.00023 µL reference item/bee (0.090 µg as/bee) – T8 0.00045 µL reference item/bee (0.18 µg as/bee) – T9 0.00088 µL reference item/bee (0.35 µg as/bee) – T10
Stability of the test compound:	-
Dates:	start of the study 24.05.2023 start of the experimental part: 07.06.2023 end of the experimental part: 09.06.2023 end of the study: 29.09.2023
Statistic:	Software used for statistical analysis was “ToxRatPro” Solutions GmbH, version 3.3.0. Mortality data were processed using the Cochran-Armitage test ($\alpha \leq 0.05$). Correction for control mortality was carried out using the Schneider-Orelli's formula. The LD50 values at different timing (4, 24 and 48-HAA) were calculated for the test item with 95% confidence interval, using a Probit distribution linear regression. The No Observed Effect Concentration (NOEC) and Lowest Observed Effect Concentration (LOEC) values for mortality and reproduction were determined, where possible.
Validity of the test:	The following criteria should be satisfied for a test result to be considered valid: - Average mortality for the total number of control groups $\leq 10\%$ at the end of the test (in the control units, the mean value of dead bees was 3.33%, so the validity criterion was met) - LD50 value of the reference item meets the specified range (the 24-HAA LD50 for the acute oral test was 0.11 µg a.i./bee therefore, the validity criterion was met, because in the range 0.10-0.35 µg a.i./bee)

RESULTS

All study validity criteria were met. The results are summarized in the following table.

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Table KCP 10.3.1.1.1-1: Mortality at 4 HAA, 24 HAA and 48 HAA – Acute Oral Toxicity test

Treatment number	Treatment	Test Item (Nominal intake)	Test Item (Calculated intake [#])	Mortality 4 HAA (%)	<i>p</i> ^a	Mortality 24 HAA (%)	<i>p</i> ^a	Mortality 48 HAA (%)	<i>p</i> ^a
T1	Control	-	-	0.00	-	3.33	-	3.33	-
T2	Acetamipryd 200 SL	0.0049 µL f.p./bee (0.97 µg a.i./bee)	0.0041 µL f.p./bee (0.81 µg a.i./bee)	0.00	n.s.	3.33	n.s.	3.33	n.s.
T3	Acetamipryd 200 SL	0.011 µL f.p./bee (2.13 µg a.i./bee)	0.0075 µL f.p./bee (1.50 µg a.i./bee)	0.00	n.s.	3.33	n.s.	6.67	n.s.
T4	Acetamipryd 200 SL	0.023 µL f.p./bee (4.70 µg a.i./bee)	0.012 µL f.p./bee (2.31 µg a.i./bee)	0.00	n.s.	43.33	***	43.33	***
T5	Acetamipryd 200 SL	0.052 µL f.p./bee (10.33 µg a.i./bee)	0.034 µL f.p./bee (6.76 µg a.i./bee)	10.00	**	50.00	***	50.00	***
T6	Acetamipryd 200 SL	0.11 µL f.p./bee (22.73 µg a.i./bee)	0.064 µL f.p./bee (12.81 µg a.i./bee)	10.00	**	90.00	***	93.33	***
T7	Acetamipryd 200 SL	0.25 µL f.p./bee (50 µg a.i./bee)	0.14 µL f.p./bee (27.26 µg a.i./bee)	26.67	***	96.67	***	100.00	***
T8	ROGOR L 40 ST	0.00023 µL f.p./bee (0.090 µg a.i./bee)	0.00023 µL f.p./bee (0.091 µg a.i./bee)	3.33	n.s.	40.00	***	40.00	***
T9	ROGOR L 40 ST	0.00045 µL f.p./bee (0.18 µg a.i./bee)	0.00043 µL f.p./bee (0.17 µg a.i./bee)	23.33	***	73.33	***	73.33	***
T10	ROGOR L 40 ST	0.00088 µL f.p./bee (0.35 µg a.i./bee)	0.00083 µL f.p./bee (0.33 µg a.i./bee)	36.67	***	90.00	***	90.00	***

Note: Nominal intake according to the Study Plan

HAA = Hours After Application

[#] intake of µL f.p./µg a.i. calculated on the feeding consumption data obtained over the 6 hrs exposure

^a, Cochran-Armitage test, α≤0.001 ***, 0.01 **, 0.05 *

f.p.: formulated product

a.i.: active ingredient acetamiprid

n.s., not significantly different compared to the control

CONCLUSION

Calculated endpoint values based on the nominal test item and active ingredient concentration for mortality are given in table below.

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Table KCP 10.3.1.1.1-2: Mortality endpoints at 4 HAA, 24 HAA and 48 HAA – Acute Oral Toxicity test

Endpoints	µL test item/bee	µg a.i./bee	µg test item /bee
4-HAA LD ₅₀	>0.14 [95%-CLs n.d.]	>27.26 [95%-CLs n.d.]	>160.16 [95%-CLs n.d.]
4-HAA NOED	0.012	2.31	13.73
4-HAA LOED	0.034	6.76	38.90
24-HAA LD ₅₀	0.025 [0.012 – 0.060]	5.04 [2.32 – 12.04]	28.60 [13.73 – 68.64]
24-HAA NOED	0.0075	1.50	8.58
24-HAA LOED	0.012	2.31	13.73
48-HAA LD ₅₀	0.023 [0.011 – 0.052]	4.59 [2.19 – 10.37]	26.31 [12.58 – 59.49]
48-HAA NOED	0.0075	1.50	8.58
48-HAA LOED	0.012	2.31	13.73

HAA = Hours After Application

f.p.: formulated product

a.i.: active ingredient acetamiprid

95%-CLs n.d., Confidence Limits not determined due to mathematical reasons

Comments of zRMS:

The study was accepted by zRMS.

The validity criteria was met:

The following validity criteria were met:

– Mortality of the control groups was 0.0% at the end of the test (criterion: ≤ 10%).

– Mortality in the toxic reference item group (dimethoate) at the end of the test was 100% (criterion: ≥ 50%).

Agreed toxicity endpoints:

Test item dose [µg test item/ bumblebee]	Acetamiprid concentration [µg of acetamiprid/ bumblebee]	Number of tested bumble- bees [no.]	Mortality after 48 h		LD ₅₀	
			[no.]	[%]	[µg test item/ bumblebee]	[µg acetamiprid/ bumblebee]
Control	–	30	0	0.0	191.8* (n.d. - n.d.)	33.06
12.5	2.15	30	0	0.0		
25.0	4.31	30	1	3.3		
50.0	8.62	30	0	0.0		
100.0 ⁺	17.24	30	5	16.7		
200.0 ⁺	34.48	30	17	56.7		
NOED					50.0	8.62
Reference item: dimethoate						
Dose [4.0 µg/ bumblebee]		30	30	100.0	–	

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Reference: KCP 10.3.1.1.1/02
Report Acetamipryd 200 SL Bumblebees (*Bombus* spp.), Acute Oral Toxicity Test; Fulczyk A; 2022; Study Code: B-105-22
Guideline(s): Yes, OECD 247
Deviations: According to the OECD Guideline No. 247 it is recommended to use plastic syringes for the test item administration. However, in the experiment they were replaced by calibrated glass pipettes. This deviation had no impact on the quality, integrity and final results of the study.
GLP: Yes
Acceptability: Yes
Duplication (if vertebrate study) No

MATERIALS AND METHODS

1. Test material

Test item (chemical/other name): Acetamipryd 200 SL
Formulation: SL (soluble liquid), acetamiprid: specification 200.0 g/L
Description (physical state): light brown liquid
Batch no.: 1/ACE/2022
Production date: 01.2022
Expiration date: 01.2024

2. Vehicle and/or positive control: vehicle: 50% sucrose solution
positive control: dimethoat

3. Test organism

Species: bumblebee (*Bombus* spp.)
Source: commercial supplier: Koppert Polska sp. z o.o.
Age: adult worker bumblebees
Acclimation period: acclimatized to the test conditions for about 24 hours before starting the experiment
Diet: 50% sucrose solution
Test units: a dark climate room

4. Environmental conditions:

Temperature: 25-26.5°C
Relative humidity: 64 – 66%
Photoperiod: darkness

STUDY DESIGN AND METHOD

The study was conducted to determine the acute oral toxicity of Acetamipryd 200 SL to bumblebees (*Bombus* spp.) with a laboratory method and to calculate the median lethal doses, i.e. the LD50 and NOED. Five doses of the test item, i.e. 200, 100, 50, 25 and 12.5 µg/bumblebee plus the control and the reference item were used. The design of the definitive test was selected on the basis of the GLP definitive test – limit test results. The bumblebees were exposed to the test item distributed in a 50% aqueous sucrose solution. The insects were selected for the exposure in terms of their sizes. The treated diet was provided in calibrated pipettes. Each pipette contained 40 µL of the sucrose solution with the test item at the tested dose. The insects were kept individually in isolators. The sensitivity of the test bumblebees was verified using a reference item, i.e. dimethoate at the dose of 4.0 µg/bumblebee. The insects were observed for mortality and other signs of toxicity 4, 24 and 48 hours after the test/ reference item administration. The acute oral toxicity test finished after the 48- hour observation.

Test design:	<ul style="list-style-type: none">- a control (50% sucrose solution w/v): number of replicates: 30; number of insects: 1 insect/replicate;- test item: number of replicates: 30; number of insects: 1 insect/replicate;- the reference item: number of replicates: 30; number of insects: 1 insect/replicate
Exposure time:	acute test, 48 h
Tested concentrations, definitive test:	200, 100, 50, 25, 12.5 µg test item/bumblebee and a control (0.0 µg/bumblebee)
Stability of the test compound:	The aim of the analytical part of the definitive full range test was to determine the concentrations of acetamiprid using a validated high performance liquid chromatographic method with DAD detection. At exposure initiation, in the fresh test item samples, the concentration of acetamiprid at the test item concentrations 5.0 g/L (i.e. 200 µg/40 µL) and 0.3125 g/L (i.e. 12.5 µg/40 µL) were 101.4 and 108.9%, respectively. The results confirm that the test item concentration was prepared correctly.
Dates:	start of the study 12.04.2022 start of the experimental part: 07.06.2022 end of the experimental part: 10.06.2022 end of the study: 29.07.2022
Statistic:	Regression analysis using the log-probit method, Step-down Cochran-Armitage Test Procedure
Validity of the test:	The following validity criteria were met: <ul style="list-style-type: none">– Mortality of the control group was 0.0% at the end of the test (criterion: ≤ 10%).– Mortality in the toxic reference item group (dimethoate) at the end of the test was 100.0% (criterion: ≥ 50%).

RESULTS

After 4 hours of exposure there were no dead bumblebees in the control group. The percentage of mortality in the groups exposed to the test item at the doses of 12.5, 25.0, 50.0, 100.0 and 200.0 µg /bumblebee were

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0.0, 3.3, 0.0, 13.3 and 46.7%, respectively. There were statistically significant differences in mortality between groups treated with the test item at the doses of 100.0 and 200.0 µg /bumblebee and the control group (Step-down Cochran-Armitage Test Procedure, $p(\text{trend}) < \alpha$). After 24 hours, the percentage of mortality in the control group was 0.0%. The percentage of mortality in the groups exposed to the test item at the doses of 12.5, 25.0, 50.0, 100.0 and 200.0 µg /bumblebee were 0.0, 3.3, 0.0, 13.3 and 56.7%, respectively. There were statistically significant differences in mortality between groups treated with the test item at the doses of 100.0 and 200.0 µg /bumblebee and the control group (Step-down Cochran-Armitage Test Procedure, $p(\text{trend}) < \alpha$). After 48 hours, the percentage of mortality in the control group was 0.0%. The percentage of mortality in the groups exposed to the test item at the doses of 12.5, 25.0, 50.0, 100.0 and 200.0 µg /bumblebee were 0.0, 3.3, 0.0, 16.7 and 56.7%, respectively. There were statistically significant differences in mortality between groups treated with the test item at the doses of 100.0 and 200.0 µg /bumblebee and the control group (Step-down Cochran-Armitage Test Procedure, $p(\text{trend}) < \alpha$). During the experiment no sub-lethal effects (toxic symptoms) were observed. The median lethal dose LD50/24 h is 196.8 µg/bumblebee (95% confidence). The median lethal dose LD50/48 h is 191.8 µg/bumblebee (95% confidence). The NOED value after 24 and 48 hours of exposure is 50.0 µg/bumblebee. The percentage of mortality after 4 and 24 h hours of exposure to the reference item at the dose of 4.0 µg/bumblebee was 30.0 and 100.0%, respectively. The mean weight of the bumblebees in the control group at test initiation was: 0.240 g. The mean weights of the bumblebees in the groups exposed to the test item at doses of 12.5, 25.0, 50.0, 100.0 and 200.0 µg /bumblebee were: 0.262, 0.264, 0.261, 0.254 and 0.250 g, respectively. The mean weight of the bumblebees in the group treated with the reference item was: 0.252 g.

Table KCP 10.3.1.1.1-3: *Bombus* spp. mortality after 24 hours of exposure and LD50/24 h

Dose [µg/bumblebee]	Number of tested bumble- bees [no.]	Mortality		LD ₅₀ [µg/bumblebee]	NOED [µg/bumblebee]
		Number of dead bumble- bees [no.]	[%]		
Control	30	0	0.0	196.8*	50.0
12.5	30	0	0.0		
25.0	30	1	3.3		
50.0	30	0	0.0		
100.0 ⁺	30	4	13.3		
200.0 ⁺	30	17	56.7		
Reference item: dimethoate					
4.0	30	30	100	–	

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Table KCP 10.3.1.1.1-4: *Bombus* spp. mortality after 48 hours of exposure and LD50/48 h

Dose [µg/bumblebee]	Number of tested bumble- bees [no.]	Mortality		LD ₅₀ [µg/bumblebee]	NOED [µg/bumblebee]
		Number of dead bumble- bees [no.]	[%]		
Control	30	0	0.0	191.8*	50.0
12.5	30	0	0.0		
25.0	30	1	3.3		
50.0	30	0	0.0		
100.0 ⁺	30	5	16.7		
200.0 ⁺	30	17	56.7		

Table KCP 10.3.1.1.1-5: Sublethal effects – definitive test

Dose [µg/bumblebee]	Time of exposure [h]		
	4	24	48
	Number of bumblebees showing signs of toxicity * / number of living bumblebees		
Control	0/30	0/30	0/30
12.5	0/30	0/30	0/30
25.0	0/29	0/29	0/29
50.0	0/30	0/30	0/30
100.0	0/26	0/26	0/25
200.0	0/16	0/13	0/13
reference item: dimethoate	0/21	0/0	0/0

* bumblebees showing signs of toxicity were classified according to the following criteria:

- a – affected
- b – moribund

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CONCLUSION

The median lethal doses are the following: LD50/24 h is 196.8 µg test item/bumblebee, LD50/48 h is 191.8 µg test item/bumblebee. The NOED value after 24 and 48 hours is 50.0 µg test item/bumblebee.

Table KCP 10.3.1.1.1-6: *Bombus* spp. acute oral toxicity test -final results

Test item dose [µg test item/ bumblebee]	<u>Acetamiprid concentration</u> [µg of acetamiprid/ bumblebee]	Number of tested bumble- bees [no.]	Mortality after 48 h		LD ₅₀	
			[no.]	[%]	[µg test item/ bumblebee]	[µg acetamiprid/ bumblebee]
Control	–	30	0	0.0	191.8* (<i>n.d.</i> - <i>n.d.</i>)	<u>33.06</u>
12.5	<u>2.15</u>	30	0	0.0		
25.0	<u>4.31</u>	30	1	3.3		
50.0	<u>8.62</u>	30	0	0.0		
100.0 ⁺	<u>17.24</u>	30	5	16.7		
200.0 ⁺	<u>34.48</u>	30	17	56.7		
NOED					50.0	<u>8.62</u>
Reference item: dimethoate						
Dose [4.0 µg/ bumblebee]		30	30	100.0	–	

A 2.3.1.1.2 KCP 10.3.1.1.2 Acute contact toxicity to bees

Comments of zRMS:	The study was accepted by zRMS.
	The validity criteria was met:
	<ul style="list-style-type: none"> – Mortality of the control groups (with surfactant and without surfactant) was 0.0% at the end of the test (criterion: ≤ 10%). – Mortality in the toxic reference item group (dimethoate) at the end of the test was 100% (criterion: ≥ 50%).
Agreed toxicity endpoints:	

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Dose		Number of tested bumblebees [no.]	Mortality after 48 h		LD ₅₀ /48 h	
test item [µg/ bumblebee]	acetamiprid [µg a.i. / bumblebee]		[no.]	[%]	[µg/ bumblebee]	acetamiprid [µg a.i. / bumblebee]
Control (water)		50	0	0.0	> 100.0	> 19.7
Control + 1% surfactant		50	0	0.0		
100.0	19.7	50	0	0.0		
Reference item: dimethoate						
Dose [µg/ bumblebee]	10.0	30	30	100	-	

Reference: KCP 10.3.1.1.2/01

Report Acetamipryd 200 SL Bumblebees (*Bombus* spp.), Acute Contact Toxicity Test; Fulczyk A; 2022; Study Code: B-107-22

Guideline(s): Yes, OECD 246

Deviations: According to the OECD Guideline No. 246 the bumblebees may be anesthetized with carbon dioxide or chilled for the application of the test item. Anesthesia with carbon dioxide or chilling was replaced with mechanical immobilisation [8]. This deviation had no impact on the quality, integrity and final results of the study. A deviation from the Study Plan concerning study completion date occurred. According to the Study Plan the study should be completed in May 2022. However, it will complete in June 2022.

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study) No

MATERIALS AND METHODS

1. Test material

Test item (chemical/other name): Acetamipryd 200 SL

Formulation: SL (soluble liquid), acetamiprid: specification 200.0 g/L

Description (physical state): light brown liquid

Batch no.: 1/ACE/2022

Production date: 01.2022

Expiration date: 01.2024

2. Vehicle and/or positive control: vehicle water + control with surfactant (distilled water with 1% of Triton(R)X-100)
 positive control: dimethoate

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3. Test organism

Species:	bumblebee (<i>Bombus</i> spp.)
Source:	commercial supplier: Koppert Polska sp. z o.o.
Age:	adult worker bumblebees
Acclimation period:	acclimatized to the test conditions for about 24 hours before starting the experiment
Diet:	50% sucrose solution
Test units:	a dark climate room

4. Environmental conditions:

Temperature:	24 – 25.5°C
Relative humidity:	65 – 67%
Photoperiod:	darkness

STUDY DESIGN AND METHOD

The study was conducted to determine the acute contact toxicity of Acetamipryd 200 SL to bumblebees (*Bombus* spp.) with a laboratory method and to demonstrate, that the median lethal dose, i.e. the LD50 at the end of exposure, is higher than the dose used in the test (limit test). One dose of the test item, i.e. 100.0 µg test item/bumblebee, plus the controls and one dose of the reference item were used. The design of the definitive test was selected on the basis of the non-GLP preliminary range finding test results. The bumblebees were exposed to the test item diluted in distilled water with surfactant Triton(R) X-100 and applied to the dorsal part of the thorax, using a microapplicator. The volume was 2 µL/bumblebee. The insects were selected for the exposure in terms of their sizes. After that, the insects were kept individually in isolators. The sensitivity of the test bumblebees was verified using a reference item, i.e. dimethoate at the dose of 10.0 µg/bumblebee. The insects were observed for mortality and other signs of toxicity 4, 24 and 48 hours after the test/ reference item administration. The acute contact toxicity test finished after the 48-hour observation.

Test design:	<ul style="list-style-type: none">- a control (distilled water): number of replicates: 50; number of insects: 1 insect/replicate;- control with surfactant: (distilled water with 1% of Triton(R) X-100) number of replicates: 50; number of insects: 1 insect/replicate;- test item: number of replicates: 50; number of insects: 1 insect/replicate;- the reference item: number of replicates: 30; number of insects: 1 insect/replicate
Exposure time:	acute test, 48 h
Tested concentrations, definitive test:	100.0 µg test item/bumblebee

Stability of the test compound:	the aim of the analytical part of the definitive test was to determine the concentrations of acetamiprid using a validated liquid chromatographic method with DAD detector. At exposure initiation, in the fresh test item sample, the concentration of acetamiprid was 89.9% of the nominal concentration. The results confirm that the test item concentration was prepared correctly.
Dates:	start of the study 29.03.2022 start of the experimental part: 05.04.2022 end of the experimental part: 08.04.2022 end of the study: 15.06.2022
Statistic:	statistical analysis was not needed due to the lack of mortality
Validity of the test:	The following validity criteria were met: - Mortality of the control groups was 0.0% at the end of the test (criterion: $\leq 10\%$). - Mortality in the toxic reference item group (dimethoate) at the end of the test was 100.0% (criterion: $\geq 50\%$).

RESULTS

Mortality in both control groups (with surfactant and without surfactant) was 0.0% after 48 hours of exposure. The percentage of mortality after 48 h hours of exposure to the test item at the dose of 100.0 µg test item/bumblebee with 1% surfactant was 0.0%. During the experiment sublethal effects (toxic symptoms) in the group treated with the test item were not observed. The median lethal doses for the test item (LD50/24 h, LD50/48 h) are higher than the dose used in the test, i.e. > 100.0 µg test item/bumblebee, i.e. > 19.7 µg acetamiprid/bumblebee. Dose-effect curves showing the influence of the test item on mortality after 24 and 48 hours of exposure are not given due to the lack of mortality. The percentage of mortality after 48 h hours of exposure to the reference item at the dose of 10.0 µg/bumblebee with 1% surfactant was 100% (Table 9). In the reference item group no sublethal effects (toxic symptoms) were observed. The mean weights of the bumblebees in each group were: 0.247 g for the water control group, 0.250 g for the control with 1% surfactant, 0.244 g for the group treated with the test item and 0.246 g for the group treated with the reference item.

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Table KCP 10.3.1.1.2-1: *Bombus* spp. mortality after 24 hours of exposure and LD50/24 h

Dose [µg/bumblebee]	Number of tested bumble- bees [no.]	Mortality		LD50	
		Number of dead bumblebees [no.]	[%]	[µg test item/ bumblebee]	acetamiprid [µg a.i. / bumblebee]
Control (water)	50	0	0.0	> 100.0	> 19.7
Control + 1% surfactant	50	0	0.0		
100.0 + 1 % surfactant	50	0	0.0		
Reference item: dimethoate					
10.0 + 1% surfactant	30	30	100	–	–

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Table KCP 10.3.1.1.2-2: *Bombus* spp. mortality after 48 hours of exposure and LD50/48 h

Dose [µg/bumblebee]	Number of tested bumble- bees [no.]	Mortality		LD ₅₀	
		Number of dead bumblebees [no.]	[%]	[µg test item/ bumblebee]	acetamiprid [µg a.i. / bumblebee]
Control (water)	50	0	0.0	> 100.0	> 19.7
Control + 1% surfactant	50	0	0.0		
100.0 + 1 % surfactant	50	0	0.0		
Reference item: dimethoate					
10.0 + 1% surfactant	30	30	100	–	–

Table KCP 10.3.1.1.2-3: Sublethal effects – definitive test

Dose [µg/bumblebee]	Time of exposure [h]		
	4	24	48
	Number of bumblebees showing signs of toxicity * / number of living bumblebees		
Control (water)	0/50	0/50	0/50
Control + 1 % surfactant	0/50	0/50	0/50
100.0 + 1% surfactant	0/50	0/50	0/50
reference item: dimethoate + 1% surfactant	0/30	0/0	0/0

CONCLUSION

The median lethal doses (LD50/24 h, LD50/48 h) are higher than the dose used in the test, i.e. > 100.0 µg test item/bumblebee, i.e. > 19.7 µg acetamiprid/ bumblebee.

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Table KCP 10.3.1.1.2-4: *Bombuss* spp. acute contact toxicity test - final results

Dose		Number of tested bumblebees [no.]	Mortality after 48 h		LD ₅₀ /48 h	
test item [µg/ bumblebee]	acetamiprid [µg a.i. / bumblebee]		[no.]	[%]	[µg/ bumblebee]	acetamiprid [µg a.i. / bumblebee]
Control (water)		50	0	0.0	> 100.0	> 19.7
Control + 1% surfactant		50	0	0.0		
100.0	19.7	50	0	0.0		
Reference item: dimethoate						
Dose [µg/ bumblebee]	10.0	30	30	100	–	

Comments of zRMS:	<p>The study was accepted by zRMS.</p> <p>The validity criteria was met:</p> <p>The following criteria should be satisfied for a test result to be considered valid:</p> <ul style="list-style-type: none"> - average mortality for the total number of control groups ≤ 10% at the end of the test. - LD₅₀ value of the reference item meets the specified range. <p>Agreed toxicity endpoints:</p>
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Endpoints	µL test item/bee	µg test item/bee	µg a.i./bee
4-HAA LD ₁₀	0.023 [0.012 – 0.034]	26.31 [13.73 – 38.90]	4.62 [2.43 – 6.87]
4-HAA LD ₅₀	0.14 [0.097 – 0.25]	160.16 [110.97 – 286.00]	28.17 [19.45 – 49.84]
4-HAA NOED	0.0085	9.72	1.71
4-HAA LOED	0.019	21.74	3.76
24-HAA LD ₁₀	0.023 [0.004 – 0.041]	26.31 [4.58 – 46.90]	4.51 [0.82 – 8.22]
24-HAA LD ₅₀	0.085 [0.049 – 0.20]	97.24 [56.06 – 228.80]	17.01 [9.66 – 40.95]
24-HAA NOED	0.0085	9.72	1.71
24-HAA LOED	0.019	21.74	3.76
48-HAA LD ₁₀	0.012 [0.007 – 0.017]	13.73 [8.01 – 19.45]	2.32 [1.33 – 3.36]
48-HAA LD ₅₀	0.055 [0.042 – 0.075]	62.92 [48.05 – 85.80]	11.06 [8.38 – 15.09]
48-HAA NOED	0.0085	9.72	1.71
48-HAA LOED	0.019	21.74	3.76
72-HAA LD ₁₀	0.012 [0.007 – 0.017]	13.73 [8.01 – 19.45]	2.32 [1.33 – 3.36]
72-HAA LD ₅₀	0.055 [0.042 – 0.075]	62.92 [48.05 – 85.80]	11.06 [8.38 – 15.09]
72-HAA NOED	0.0085	9.72	1.71
72-HAA LOED	0.019	21.74	3.76

HAA = Hours After Application
 f.p.: formulated product
 a.i.: active ingredient acetamiprid

Reference: KCP 10.3.1.1.2/02

Report Acetamipryd 200 SL Honeybees (*Apis mellifera* L.), Acute Contact Toxicity Test; Mautino G; 2024; Study Code:3053.1L.SAGIT24

Guideline(s): Yes, OECD 214, 1998

Deviations: No

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study) No

MATERIALS AND METHODS

1. Test material

Test item (chemical/other name): Acetamipryd 200 SL

Formulation: SL (soluble liquid), acetamiprid: specification 200.0 g/L

Description (physical state): liquid

Batch no.: 1/ACE/2022

Production date: 01.2024

Expiration date: 01.2026

2. Vehicle and/or positive control: Deionized water + Wetting agent
 positive control: -

3. Test organism

Species:	Honeybee <i>Apis mellifera</i>
Source:	Beekeeper Marco Messa, via della colla 1, Pocapaglia (CN), 12060. Three commercial beehives, queen-right, healthy(disease free) and adequately fed, with normal population of young adult worker individuals (approx. 2 weeks old).
Age:	adults (female workers)
Acclimation period:	The test units were placed into an incubator and kept under environmental controlled conditions (24.19 °C and 68.0% RH; darkness) until the test' beginning. No food or water was supplied during acclimatisation. Acclimation duration: 7,5 hours.
Maintenance:	No chemical substances were applied to the hive for at least 1 month prior to the start of the study
Collection:	On the morning of use, from the outer honeycombs (away from the brood) without the use of smoke and without anaesthetics. By means of a proper brush, the bees were collected in plastic containers with holes for oxygenation and immediately transported to the SAGEA's laboratory.
Allocation to test units	Once in the laboratory, the bees were randomly allocated to the test units (cages) without anaesthetisation. Bees were gently transferred to the test units by means of a plastic tweezers.
Diet:	Sucrose solution in water with a final concentration of 500 g/L (50% w/v) was used as food ad libitum. The syrup was administered using 2 mL syringe (deprived of the tip). One syringe was placed in each cage via an opening in the top of the test unit. If necessary, feeding solution was re-filled during the test course
Test units:	Ventilated stainless steel cages 8.5 cm x 6.5 cm x 4.5 cm (length x height x width) with removable glass panel and perforated with 50 ventilation holes; Ø 2 mm

4. Environmental conditions:

Temperature:	24.34 °C± 0.06 °C (24.30 – 24.44 °C)
Relative humidity:	68.0 % ± 2.0 % (65.8 – 70.7%) RH
Photoperiod:	Darkness
Ventilation:	Ventilation to avoid possible accumulation of pesticide vapour

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Part B – Section 9 - Core Assessment
Applicant version

STUDY DESIGN AND METHOD

Aim of this study was to determine the acute contact toxicity of Acetamipryd 200 SL (acetamiprid nominally 200 g/L) to honeybees. Mortality of the bees was used as the toxic endpoint. The study comprised 10 treatments (6 concentrations of the test item with a spacing factor of 2.2, 1 control group, 3 concentrations of the reference item with a spacing factor of 2 with 3 replicates); each test unit (stainless-steel cage) contained 10 individuals. The tested doses were dispersed in deionized water with a Wetting agent and applied once to the thorax dorsal side of the bees. The bees were then fed ad libitum with 50% sucrose solution until the end of the test. Mortality was recorded after 4, 24, 48 and 72 hours after application and compared with that of control group. Since There was no significant increase in mortality between 24 and 48 HAA (< 10%) among the different treatments, the test was stopped at 48 HAA in accordance with OECD 214.

Test design: Number of replicates: 3 replicates, number of bees: 10 bees/replicate

Exposure time: Acute test ,72h

Tested concentrations, definitive test: Control group with Wetting agent (Triton TM X-100 BioXtra) – T1
0.0039 µL test item/bee (0.78 µg a.i.*/bee) – T2**
0.0085 µL test item/bee (1.71 µg a.i.*/bee) – T3**
0.019 µL test item/bee (3.76 µg a.i.*/bee) – T4**
0.041 µL test item/bee (8.26 µg a.i.*/bee) – T5**
0.091 µL test item/bee (18.18 µg a.i.*/bee) – T6**
0.20 µL test item/bee (40 µg a.i.*/bee) – T7**
0.00019 µL reference item/bee (0.075 µg a.i.*/bee) – T8
0.00038 µL reference item/bee (0.15 µg a.i.*/bee) – T9
0.00075 µL reference item/bee (0.30 µg a.i.*/bee) – T10
***Wetting agent Trion TM X-100 was added to each treatment group at 0.1%*

Stability of the test compound: -

Dates: Study Director Study Plan Approval 05 Apr 2024
Start of the experimental Phase: 13 May 2024
End of the experimental phase: 16 May 2024
Final Report of the study: 26 August 2024

Statistic:

- Software used for statistical analysis was “ToxRatPro” Solutions GmbH, version 3.3.0.

- Mortality data were processed using the Rao-Scott-Cochran-Armitage and Cochran-Armitage tests ($\alpha \leq 0.05$). Correction for control mortality was carried out using the Schneider-Orelli's formula.

- The LD50 values at different timing (4, 24, 48 and 72-HAA) were calculated determined for the test item with 95% confidence interval, using a Probit distribution linear regression.

- The No Observed Effect Concentration (NOEC) and Lowest Observed Effect Concentration (LOEC) values for mortality and reproduction were determined, where possible.

Validity of the test:

The following criteria should be satisfied for a test result to be considered valid:

- average mortality for the total number of control groups $\leq 10\%$ at the end of the test.

- LD₅₀ value of the reference item meets the specified range.

RESULTS

All study validity were met. The results are summarized in the following tables

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Table KCP 10.3.1.1.2-5: Mortality at 4 HAA and 24 HAA- Acute Contact Toxicity test

Treatment number	Treatment	Test item f.p./bee	Test item a.i./bee	Mortality 4 HAA (%)	<i>p</i> ^a	Mortality 24 HAA (%)	<i>p</i> ^a
T1	TRITON X-100	0.1%	0.1% #	3.33	-	3.33	-
T2	Acetamipryd 200 SL	0.0039 µL f.p./ bee	0.78 µg a.i./bee	0.00	n.s.	3.33	n.s.
T3	Acetamipryd 200 SL	0.0085 µL f.p./ bee	1.71 µg a.i./bee	3.33	n.s.	6.67	n.s.
T4	Acetamipryd 200 SL	0.019 µL f.p./ bee	3.76 µg a.i./bee	16.67	*	16.67	*
T5	Acetamipryd 200 SL	0.041 µL f.p./ bee	8.26 µg a.i./bee	20.00	***	13.33	*
T6	Acetamipryd 200 SL	0.091 µL f.p./ bee	18.18 µg a.i./bee	40.00	***	46.67	***
T7	Acetamipryd 200 SL	0.20 µL f.p./ bee	40.00 µg a.i./bee	60.00	***	90.00	***
T8	ROGOR L 40 ST	0.00019 µL f.p./ bee	0.075 µg a.i./bee	13.33	n.s.	13.33	n.s.
T9	ROGOR L 40 ST	0.00038 µL f.p./ bee	0.15 µg a.i./bee	60.00	***	60.00	***
T10	ROGOR L 40 ST	0.00075 µL f.p./ bee	0.30 µg a.i./bee	90.00	***	90.00	***

HAA = Hours After Application

^a, Rao-Scott-Cochran-Armitage and Cochran-Armitage tests, $\alpha \leq 0.001$ ***, 0.01 **, 0.05 *

Wetting agent Triton™ X-100 was added to each treatment (0.1% of the final volume)

f.p.: formulated product

a.i.: active ingredient acetamiprid

n.s., not significantly different compared to the control

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Table KCP 10.3.1.1.2-6: Mortality at 48 HAA and 72 HAA -Acute Contact Toxicity test

Treatment number	Treatment	Test item f.p./bee	Test item a.i./bee	Mortality 48 HAA (%)	<i>p</i> ^a	Mortality 72 HAA (%)	<i>p</i> ^a
T1	TRITON X-100	0.1%	0.1% [#]	3.33	-	3.33	-
T2	Acetamipryd 200 SL	0.0039 µL f.p./ bee	0.78 µg a.i./bee	3.33	n.s.	3.33	n.s.
T3	Acetamipryd 200 SL	0.0085 µL f.p./ bee	1.71 µg a.i./bee	13.33	n.s.	13.33	n.s.
T4	Acetamipryd 200 SL	0.019 µL f.p./ bee	3.76 µg a.i./bee	23.33	**	23.33	**
T5	Acetamipryd 200 SL	0.041 µL f.p./ bee	8.26 µg a.i./bee	36.67	***	36.67	***
T6	Acetamipryd 200 SL	0.091 µL f.p./ bee	18.18 µg a.i./bee	63.33	***	63.33	***
T7	Acetamipryd 200 SL	0.20 µL f.p./ bee	40.00 µg a.i./bee	90.00	***	90.00	***
T8	ROGOR L 40 ST	0.00019 µL f.p./ bee	0.075 µg a.i./bee	16.67	*	16.67	*
T9	ROGOR L 40 ST	0.00038 µL f.p./ bee	0.15 µg a.i./bee	63.33	***	63.33	***
T10	ROGOR L 40 ST	0.00075 µL f.p./ bee	0.30 µg a.i./bee	100.00	***	100.00	***

HAA = Hours After Application

^a Cochran-Armitage test, α≤0.001 ***, 0.01 **, 0.05 *

[#] Wetting agent TritonTM X-100 was added to each treatment (0.1% of the final volume)

f.p.: formulated product

a.i.: active ingredient acetamiprid

n.s., not significantly different compared to the control

CONCLUSION

Calculated endpoint values based on the nominal test item and active ingredient concentration for mortality are given in table below.

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Table KCP 10.3.1.1.2-7: Mortality endpoints at 4 HAA, 24 HAA at 48 HAA and 72 HAA

Endpoints	µL test item/bee	µg test item/bee	µg a.i./bee
4-HAA LD ₁₀	0.023 [0.012 – 0.034]	26.31 [13.73 – 38.90]	4.62 [2.43 – 6.87]
4-HAA LD ₅₀	0.14 [0.097 – 0.25]	160.16 [110.97 – 286.00]	28.17 [19.45 – 49.84]
4-HAA NOED	0.0085	9.72	1.71
4-HAA LOED	0.019	21.74	3.76
24-HAA LD ₁₀	0.023 [0.004 – 0.041]	26.31 [4.58 – 46.90]	4.51 [0.82 – 8.22]
24-HAA LD ₅₀	0.085 [0.049 – 0.20]	97.24 [56.06 – 228.80]	17.01 [9.66 – 40.95]
24-HAA NOED	0.0085	9.72	1.71
24-HAA LOED	0.019	21.74	3.76
48-HAA LD ₁₀	0.012 [0.007 – 0.017]	13.73 [8.01 – 19.45]	2.32 [1.33 – 3.36]
48-HAA LD ₅₀	0.055 [0.042 – 0.075]	62.92 [48.05 – 85.80]	11.06 [8.38 – 15.09]
48-HAA NOED	0.0085	9.72	1.71
48-HAA LOED	0.019	21.74	3.76
72-HAA LD ₁₀	0.012 [0.007 – 0.017]	13.73 [8.01 – 19.45]	2.32 [1.33 – 3.36]
72-HAA LD ₅₀	0.055 [0.042 – 0.075]	62.92 [48.05 – 85.80]	11.06 [8.38 – 15.09]
72-HAA NOED	0.0085	9.72	1.71
72-HAA LOED	0.019	21.74	3.76

HAA = Hours After Application
 f.p.: formulated product
 a.i.: active ingredient acetamiprid

A 2.3.1.2 KCP 10.3.1.2 Chronic toxicity to bees

Comments of zRMS:	The study was accepted by zRMS.	
	The validity criteria was met:	
	Mortality in the control group	Average mortality across replicates for the control (50% w/v sucrose solution only) ≤ 15% at the end of the test (actual value was 6.67%), therefore, the validity criterion was met).
	Mortality in the reference group	Mortality rate at the end of the test period of 100% (actual value was 100.00%), therefore, the validity criterion was met).
Agreed toxicity endpoints:		

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Table 1a. Mortality of young adult bees after 10 days (dosages on µL f.p./bee – mL f.p./Kg)

Treatment number	Treatment	Application rate (f.p. nominal intake)	Concentration (mL f.p./kg feeding solution)	Concentration (µL f.p./bee/day)	Mortality (%)	p ^a	Survivors' correction (%) ^b
T1	Control	Sucrose solution 50% w/v	---	---	6.67	-	-
T2	Acetamipryd 200 SL	0.030 µL f.p./bee	0.22 mL f.p./Kg	0.0045 µL f.p./bee/day	10.00	n.s.	3.57
T3	Acetamipryd 200 SL	0.044 µL f.p./bee	0.34 mL f.p./Kg	0.0068 µL f.p./bee/day	10.00	n.s.	3.57
T4	Acetamipryd 200 SL	0.067 µL f.p./bee	0.55 mL f.p./Kg	0.011 µL f.p./bee/day	23.33	*	17.86
T5	Acetamipryd 200 SL	0.10 µL f.p./bee	0.94 mL f.p./Kg	0.019 µL f.p./bee/day	76.67	***	75.00
T6	Acetamipryd 200 SL	0.15 µL f.p./bee	1.46 mL f.p./Kg	0.029 µL f.p./bee/day	86.67	***	85.71
T7	Acetamipryd 200 SL	0.23 µL f.p./bee	3.19 mL f.p./Kg	0.065 µL f.p./bee/day	93.33	***	92.86
T8	ROGOR L 40 ST	1 mg dimethoate/Kg feeding solution		0.04 µg dimethoate /bee/day	100.00	***	100.00
Endpoints			mL test item/Kg feeding solution				
LC ₁₀ [95% confidence intervals]			0.36 [0.11 – 0.55]				
LC ₂₀ [95% confidence intervals]			0.48 [0.21 – 0.69]				
LC ₅₀ [95% confidence intervals]			0.82 [0.54 – 1.34]				
NOEC			0.34 mL				
LOEC			0.55 mL				
Endpoints			µL test item/bee/day				
LDD ₁₀			0.0072 [0.0022 – 0.011]				
LDD ₂₀			0.0096 [0.0040 – 0.014]				
LDD ₅₀			0.017 [0.027 – 0.011]				
NOEDD			0.0068				
LOEDD			0.011				

^a, Rao-Scott-Cochran-Armitage and Chi² 2x2 Table tests (reference item ROGOR L40 ST), α≤0.001 ***, 0.01 **, 0.05 *

^b, mean survivors corrected by Abbott's formula

f.p., formulated product; n.s., not significantly different compared to the control

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Table 1b. Mortality of young adult bees after 10 days (dosages on µg a.i./bee – mg a.i./Kg)							
Treatment number	Treatment	Application rate (a.i. nominal intake)	Concentration (mg a.i./kg feeding solution)	Concentration (µg a.i./bee/day)	Mortality (%)	P ^a	Survivors' correction (%) ^b
T1	Control	Sucrose solution 50% w/v	-	-	6.67	-	-
T2	Acetamipryd 200 SL	5.93 µg a.i./bee	44.87 mg a.i./kg	0.90 µg a.i./bee/day	10.00	n.s.	3.57
T3	Acetamipryd 200 SL	8.89 µg a.i./bee	67.69 mg a.i./kg	1.35 µg a.i./bee/day	10.00	n.s.	3.57
T4	Acetamipryd 200 SL	13.33 µg a.i./bee	109.44 mg a.i./kg	2.19 µg a.i./bee/day	23.33	*	17.86
T5	Acetamipryd 200 SL	20.00 µg a.i./bee	187.65 mg a.i./kg	3.75 µg a.i./bee/day	76.67	***	75.00
T6	Acetamipryd 200 SL	30.00 µg a.i./bee	291.08 mg a.i./kg	5.73 µg a.i./bee/day	86.67	***	85.71
T7	Acetamipryd 200 SL	45 µg a.i./bee	637.49 mg a.i./kg	12.95 µg a.i./bee/day	93.33	***	92.86
T8	ROGOR L 40 ST	1 mg dimethoate/kg feeding solution		0.04 µg dimethoate /bee/day	100.00	***	100.00
Endpoints			mg a.i./Kg feeding solution				
LC ₁₀ [95% confidence intervals]			71.81 [22.56 – 108.89]				
LC ₂₀ [95% confidence intervals]			95.35 [41.37 – 138.43]				
LC ₅₀ [95% confidence intervals]			164.01 [107.90 – 267.85]				
NOEC			67.69				
LOEC			109.44				
Endpoints			µg a.i./bee/day				
LDD ₁₀			1.43 [0.41 – 2.19]				
LDD ₂₀			1.90 [0.78 – 2.79]				
LDD ₅₀			3.27 [2.12 – 5.49]				
NOEDD			1.35				
LOEDD			2.19				

^a, Rao-Scott-Cochran-Armitage and Chi² 2x2 Table tests (reference item ROGOR L40 ST), α≤0.001 ***, 0.01 **, 0.05 *
^b, mean survivors corrected by Abbott's formula
a.i., active ingredient
n.s., not significantly different compared to the control

Reference: KCP 10.3.1.2/01

Report Effects of Acetamipryd 200 SL on Honeybees (*Apis mellifera* L.) in the laboratory – Chronic Oral Toxicity Test; Mautino G.; 2024; Study Code: 1032.ISAG23/r

Guideline(s): Yes, OECD 245

Deviations: To add the Analytical Phase plan, To add the Dosages of the Definitive test

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study) No

MATERIALS AND METHODS

1. Test material

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Test item (chemical/other name):	Acetamipryd 200 SL
Formulation:	SL (soluble liquid), acetamiprid: specification 200.0 g/L
Description (physical state):	light brown liquid
Batch no.:	1/ACE/2022
Production date:	01.2022
Expiration date:	01.2024
2. Vehicle and/or positive control:	vehicle: 50% sucrose solution positive control: ROGOR L 40 ST (nominally dimethoate 400 g/L)
3. Test organism	
Species:	<i>Apis mellifera</i> x Ligustica
Source:	Beekeeper Paolo Farinetti, Via Montà Castino 25, 12074 Cortemilia (CN), Italy. Three commercial beehives, queen-right, healthy (disease free) and adequately fed, with normal population of young adult worker individuals
Maintenance:	no chemical substances had been applied to the hive for at least 1 month prior to the start of the study
Bees collection:	one day before test start, bees were collected from brood combs without the use of smoke and without anaesthetics, by means of a proper brush, the bees were collected in plastic containers with holes for oxygenation and immediately transported to SAGEA's laboratory
Age:	young adults (max 2 days old)
Acclimation period:	the test units were placed into an incubator and kept under darkness at the mean 34.33 °C, 65.2% RH for 1 day, until the beginning of the test. Bees were fed ad libitum with sucrose solution only
Diet:	sucrose solution in water with a final concentration of 500 g/L (50% w/v) was used as food ad libitum, the syrup was administered using a 2.5 mL syringe, the syringes were inserted into the cage via an opening in the top of the test unit, food was daily replaced by changing the feeders until the end of test. Food consumption was adjusted for the test solutions evaporation from the feeders
Test units:	ventilated stainless steel cages 8.5 cm x 6.5 cm x 4.5 cm (length x height x width) with removable glass panel and perforated with 50 ventilation holes; Ø 2 mm, lined with filter paper
4. Environmental conditions:	

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Temperature: 34.27± 0.039 °C (34.33 – 34.22 °C)
Relative humidity: 67.5.8± 1.9% (69.3 – 62.3%);
Photoperiod: 0 h light: 24 h dark

STUDY DESIGN AND METHOD

Aim of this study was to determine the potential effects of test item Acetamipryd 200 SL (acetamiprid 200 g/L) to young adult bees to treated food (sucrose solution) over a period of 10 days. Mortality of the bees was used as the toxic endpoint. Sublethal effects, such as changes in behaviour, was also assessed. For this purpose, a not-GLP Range Finding test was initially performed followed by the Definitive Test. The Definitive Test rates were established taking into consideration the Range finding test results. The study consisted of 8 treatments (6 rates of the test item, 1 control group, 1 reference item) with 3 replicates, each containing 10 bees per cage. Dosages of the test and reference items were dispersed in a 50% sucrose solution in water and offered ad libitum. Feeding solutions were replaced daily by changing the feeders. Mortality was recorded daily for 10 days.

Test design: 8 treatments (6 rates of the test item, 1 control group, 1 reference item) with 3 replicates, each containing 10 bees per cage

Exposure time: chronic test, 10 days

Tested concentrations, definitive test: 0.030 µL/bee (5.93 µg as/bee) – T2
0.044 µL/bee (8.89 µg as/bee) – T3
0.067 µL/bee (13.33 µg as/bee) – T4
0.10 µL/bee (20.00 µg as/bee) – T5
0.15 µL/bee (30.00 µg as/bee) – T6
0.23 µL/bee (45.00 µg as/bee) – T7

Stability of the test compound: the content of acetamiprid active ingredient was determined in the feeding solutions of honeybees' newborn workers of the biological phase of the study

Dates: start of the study: 12.06.2023
start of the experimental part: 19.09.2023
end of the experimental part: 29.07.2023

Statistic: Software used for statistical analysis was “ToxRatPro” Solutions GmbH, version 3.3.0. Mortality data were processed using Rao-Scott-Cochran-Armitage and Chi2 2x2 Table tests ($\alpha \leq 0.05$). Correction for control mortality was carried out using the Abbott's formula. At least the 10-d LD50 and LDD50 values were determined for the test item with 95% confidence interval, where possible. The No Observed Effect Dietary Dose (NOEDD), the No Observed Effect Concentration (NOEC), the Lowest Observed Effect Dietary Dose (LOEDD) and the Lowest Observed Effect Concentration (LOEC) values for mortality were calculated.

Validity of the test:

The following criteria should be satisfied in the control 10 days following start of exposure for a test result to be considered valid:

- average mortality across replicates for the control (50% w/v sucrose solution only) $\leq 15\%$ at the end of the test;
- mortality in the reference group $\geq 50\%$ at the end of the test period.

RESULTS

All study validity criteria were met. The results are summarized in the following table.

At the end of the exposure period the cumulative mortality in the control group (sucrose solution in water 50% w/v) was 6.67% and Acetamipryd 200 SL values ranged from 10.00% in treatments T2 (44.87 mg a.i./Kg feeding solution) and T3 (67.69 mg a.i./Kg feeding solution) to 93.33% in treatment T7 (637.49 mg a.i./Kg feeding solution). Reference item ROGOR L40 ST showed a mortality value of 100.00%.

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Table KCP 10.3.1.2-1: Average percentage of young adult bee's mortality at day 10

Treatment number	Treatment	Application rate (nominal intake)	Concentration (mg/kg feeding solution)	Day 10		
				Mortality	P ^a	Corrected survivor ^b (%)
				(%)		
T1	Control	Sucrose solution 50% w/v	-	6.67	-	-
T2	Acetamipryd 200 SL	0.030 µL f.p./bee (5.93 µg a.i./bee)	44.87 mg a.i./kg	10.00	n.s.	3.57
T3	Acetamipryd 200 SL	0.044 µL f.p./bee (8.89 µg a.i./bee)	67.69 mg a.i./kg	10.00	n.s.	3.57
T4	Acetamipryd 200 SL	0.067 µL f.p./bee (13.33 µg a.i./bee)	109.44 mg a.i./kg	23.33	*	17.86
T5	Acetamipryd 200 SL	0.10 µL f.p./bee (20.00 µg a.i./bee)	187.65 mg a.i./kg	76.67	***	75.00
T6	Acetamipryd 200 SL	0.15 µL f.p./bee (30.00 µg a.i./bee)	291.08 mg a.i./kg	86.67	***	85.71
T7	Acetamipryd 200 SL	0.23 µL f.p./bee (45 µg a.i./bee)	637.49 mg a.i./kg	93.33	***	92.86
T8	ROGOR L 40 ST	0.0025 mg f.p./kg feeding solution (1 mg a.i./kg)		100.00	***	100.00

^a, Rao-Scott-Cochran-Armitage and Chi2 2x2 Table tests (reference item ROGOR L40 ST), $\alpha \leq 0.001$ ***, 0.01 **, 0.05 *

^b, mean survivor corrected by Abbott's formula

-, not applicable

f.p.: formulated product

a.i.: active ingredient acetamiprid

n.s., not significantly different compared to the control

At each assessment, before and after feeding the syringes were weighed to determine the total amount ingested for each cage. The mean uptake µg a.i./bee/day and the mean mg a.i./Kg feeding solution over the test period were calculated taking into account the number of alive bees, as well as the feeders' solution evaporation. After 10 days, bees exposed to test item Acetamipryd 200 SL showed a sum uptake of mg a.i./bee/day feeding solution (expressed as sum of the mean values) ranging from 44.87 mg (treatment T2, lowest test item' dosage) to 637.49 mg a.i./bee/day feeding solution (treatment T7, highest test item' dosage). When bees were exposed to reference item ROGOR L40 ST (treatment T8) showed a value of 0.93 mg a.i./bee/day.

After 10 days of exposure period, the mean uptake µg of a.i./bee/day (expressed as sum of the mean values) ranged from 8.97 µg (treatment T2, lowest test item' dosage) to 127.50 µg a.i./bee/day (treatment T7, highest test item' dosage). Reference item ROGOR L40 ST (treatment T8) showed a value of 0.19 µg a.i./bee/day.

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Test item Acetamipryd 200 SL mean values (expressed as mean of the mean values) ranged from 0.90 to 12.95 µg a.i./bee/day on treatments T2 (lowest test item' dosage) and T7 (highest test item' dosage), respectively. Reference item ROGOR L40 ST showed a mean value of 0.04 µg a.i./bee/day.

CONCLUSION

The endpoints are summarized in the following table.

Table KCP 10.3.1.2-2: Mortality endpoints (dosages on µL f.p./bee – mL f.p./Kg)

Endpoints	mL test item/Kg feeding solution
LC ₁₀ [95% confidence intervals]	0.36 [0.11 – 0.55]
LC ₂₀ [95% confidence intervals]	0.48 [0.21 – 0.69]
LC ₅₀ [95% confidence intervals]	0.82 [0.54 – 1.34]
NOEC	0.34 mL
LOEC	0.55 mL
Endpoints	µL test item/bee/day
LDD ₁₀	0.0072 [0.0022 – 0.011]
LDD ₂₀	0.0096 [0.0040 – 0.014]
LDD ₅₀	0.017 [0.027 – 0.011]
NOEDD	0.0068
LOEDD	0.011

Table KCP 10.3.1.2-2: Mortality endpoints (dosages on µg a.i./bee – mg a.i./Kg)

Endpoints	mg a.i./Kg feeding solution
LC ₁₀ [95% confidence intervals]	71.81 [22.56 – 108.89]
LC ₂₀ [95% confidence intervals]	95.35 [41.37 – 138.43]
LC ₅₀ [95% confidence intervals]	164.01 [107.90 – 267.85]
NOEC	67.69
LOEC	109.44
Endpoints	µg a.i./bee/day
LDD ₁₀	1.43 [0.41 – 2.19]
LDD ₂₀	1.90 [0.78 – 2.79]
LDD ₅₀	3.27 [2.12 – 5.49]
NOEDD	1.35
LOEDD	2.19

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

Not relevant.

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A 2.3.1.4 KCP 10.3.1.4 Sub-lethal effects

Comments of zRMS:	The study was accepted by zRMS.	
	The validity criteria was met:	
	Mortality in the control group	Cumulative larval mortality from day 3 (D3) to day 8 (D8) was 8.33%, therefore the validity criterion was met. Adult emergence at day 22 (D22) was 87.50%, therefore the validity criterion was met.
	Mortality in the reference group at day 8 (D8)	Larval mortality was 100%.
	Agreed toxicity endpoints:	

Endpoints	µg a.i./larva	µL test item/larva
ED ₅₀ [95% confidence intervals]	3.84 [6.36 – 2.52]	0.019 [0.032 – 0.013]
NOED	0.27	0.0014
LOED	0.81	0.0041

Endpoints	mg a.i./Kg of diet	µL test item/Kg of diet
EC ₅₀ [95% confidence intervals]	24.98 [41.33 – 16.42]	124.93 [206.86 – 82.05]
NOEC	1.76	8.82
LOEC	5.29	26.46

Reference:	KCP 10.3.1.4/01
Report	Effects of Acetamipryd 200 SL on Honeybees (<i>Apis mellifera</i> L.) in the laboratory – Larval Toxicity Test Following Repeated Exposure; Mautino G.; 2024; Study Code: 1033.I.SAG23/r;
Guideline(s):	Yes, OECD GD 239
Deviations:	To add the Definitive test dosages; To change the Specimens' code of the highest dosage rate; To add the Analytical Phase plan
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

MATERIALS AND METHODS

1. Test material

Test item (chemical/other name):	Acetamipryd 200 SL
Formulation:	200 g/L (nominal content)
Description (physical state):	liquid
Batch no.:	1/ACE/2022
Production date:	01.2022

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Expiration date:	01.2024
2. Vehicle and/or positive control:	vehicle: sucrose solution positive control: dimethoate
3. Test organism	
Species:	Insecta, Hymenoptera (<i>Apis mellifera</i> L.)
Source:	Beekeeper Marco Messa, via della colla 1, Pocapaglia (CN), 12060. Three commercial beehives, queen-right, healthy (disease free) and adequately fed, with normal population of young adult worker individuals (approx. 2 weeks old)
Maintenance:	no chemical substances had been applied to the hive for at least 1 month prior to the start of the study
Bees collection:	at day-1, the combs containing first instar larvae were carried from the hive and immediately transported to SAGEA's laboratory in an insulated container in order to avoid temperature variation then, maintained at ambient temperature; newly hatched larvae were allocated randomly to the plates for each colony
Stage at test start:	first instar larvae
Acclimation period:	-

Diet:

The larval food was composed of the three following diets, adapted to the needs of the larvae at different stages of development:

- Diet A (14 Aug 2023) for all theses: 50% weight of fresh royal jelly (12.100 g) + 50% weight of an aqueous solution containing 2% weight of yeast extract (0.242 g), 12% weight of glucose (1.452 g), 12% weight of fructose (1.452 g) and 8.954 g of deionized water.

- Diet B (16 Aug 2023) for thesis T1 (untreated): 50% weight of fresh royal jelly (3.300 g) + 50% weight of an aqueous solution containing 3% weight of yeast extract (0.099 g), 15% weight of glucose (0.495 g), 15% weight of fructose (0.495 g) and 2.211 g of deionized water.

- Diet B (16 Aug 2023) for treated theses: 50% weight of fresh royal jelly (8.800 g) + 50% weight of an aqueous solution containing 3% weight of yeast extract (0.264 g), 15% weight of glucose (1.320 g), 15% weight of fructose (1.320 g) and 4.196 g of deionized water.

- Diet C (17 Aug 2023) for thesis T1 (untreated): 50% weight of fresh royal jelly (6.600 g) + 50% weight of an aqueous solution containing 4% weight of yeast extract (0.264 g), 18% weight of glucose (1.188 g), 18% weight of fructose (1.188 g) and 3.960 g of deionized water.

- Diet C (17 Aug 2023) for treated thesis: 50% weight of fresh royal jelly (33.000 g) + 50% weight of an aqueous solution containing 4% weight of yeast extract (1.320 g), 18% weight of glucose (5.940 g), 18% weight of fructose (5.940 g) and 13.250 g of deionized water.

After preparation, both containers of diet C has been preserved in fridge well covered with parafilm at 4 °C for two days.

Test units:

Larvae were reared in crystal polystyrene grafting cells having an internal diameter of 9 mm and a depth of 8 mm. Each cell was placed into a well of a 48 multi-well plate. The top of the grafting cell was maintained at the level of the plate by placing a piece of dental roll. The plates have been sterilized before being used.

The well-plates were placed into a hermetic Plexiglas desiccator and kept at a relative humidity of $93.9 \pm 2.2\%$ RH adequate for larvae from D1 to D8. The desiccator was placed into an incubator equipped with a forced air circulation system at $34.64 \pm 0.09^\circ\text{C}$ to equilibrate temperature around the desiccator for the duration of the test.

On D8 (pre-pupae stage), the well-plates were transferred into a hermetic Plexiglas desiccator at a relative humidity of $83.2 \pm 0.5\%$ RH adequate for pupae. The container was then placed into an incubator equipped with a forced air circulation system at $34.84 \pm 0.17^\circ\text{C}$.

On D15 (pupae stage), each plate was transferred into an emergence box (290 x 230 x 130 mm) with a cover aerated. Emerging bees were fed with syrup/sucrose solution dispensed ad libitum, using feeder. The boxes were transferred into an incubator at $34.16 \pm 0.18^\circ\text{C}$ and at relative humidity of $70.6 \pm 0.1\%$ RH.

4. Environmental conditions:

Temperature:

D1 – D8: $34.64 \pm 0.089^\circ\text{C}$ (34.50 – 34.75 $^\circ\text{C}$)

D8 – D15: $34.84 \pm 0.17^\circ\text{C}$ (34.57 – 35.18 $^\circ\text{C}$)

D15 – D22: $34.16 \pm 0.18^\circ\text{C}$ (34.01 – 34.57 $^\circ\text{C}$)

Relative humidity:

D1 – D8: $93.9 \pm 2.2\%$ RH (91.4 – 96.5%) RH

D8 – D15: $83.2 \pm 0.5\%$ RH (82.6 – 83.8%) RH

D15 – D22: $70.6 \pm 0.1\%$ RH (70.5 – 70.7%) RH

Photoperiod:

darkness (except during observation and food replacement)

STUDY DESIGN AND METHOD

Aim of this study was to determine the chronic oral toxicity of the Acetamipryd 200 SL (acetamiprid 200 g/L) on honeybee larvae (*Apis mellifera* L.) consequently to a repeated exposure under laboratory conditions, providing larvae with food added with the test item. Adults' emergence at day-22 was used as the toxic endpoint. A not-GLP Range finding test was initially performed followed by the Definitive Test. The Definitive Test rates were established taking into consideration the Range finding test results. The study was performed using 7 dosages of the test item in a geometric series, with a spacing factor of 3.0 and covering the range for ED/EC50 values. Larvae were collected from three different colonies, each one representing a replicate. No. 16 larvae per replicate were collected, overall no. 48 per treatment. Test item was compared with a control group and a reference item as recommended in the guideline for an ED/EC50 approach. Reference item was ROGOR L 40 ST (nominally dimethoate 400 g/L) to achieve a mortality $\geq 50\%$ on day-8 (D8) across all replicates. From day-3 to day-6, test and reference items were dispersed in the diet, following the guideline OECD 239 scheme (see Section 9.5), at the suitable concentrations. Larval mortality was recorded at the time of feeding from day-4 to day-8, moreover from day-8 to day-22 pupal mortality was evaluated and on day-22, the number of emerged adults was counted.

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Test design:	16 larvae X 3 colonies = 48 larvae
Exposure time:	22 days
Tested concentrations, definitive test:	0.00015 µL test item/larva (0.030 µg as/larva) – T2 0.00045 µL test item/larva (0.091 µg as/larva) – T3 0.0014 µL test item/larva (0.27 µg as/larva) – T4 0.0041 µL test item/larva (0.81 µg as/larva) – T5 0.012 µL test item/larva (2.44 µg as/larva) – T6 0.037 µL test item/larva (7.33 µg as/larva) – T7 0.11 µL test item/larva (22 µg as/larva) – T8
Stability of the test compound:	The content of acetamiprid active ingredient was determined in the lowest concentration and in the highest concentration of the water stock solutions prepared in the biological phase of the study. The content of test item' active ingredient was determined in the lowest concentration and in the highest concentration of the water stock solutions prepared in the biological phase of the study.
Dates:	start of the study 20.07.2023 start of the experimental part: 14.08.2023 end of the experimental part: 04.09.2023 end of the study: 20.02.2023
Statistic:	Software used for statistical analysis was “ToxRatPro” Solutions GmbH, version 3.3.0. Mortality data were processed using Cochran-Armitage and Chi2 2x2 Table tests ($\alpha \leq 0.05$). At least the ED50/EC50 values were determined for the test item with 95% confidence interval, where possible. The No Observed Effect Dose (NOED) and Lowest Observed Effect Dose (LOED) values for adults' emergence rate were calculated, where possible.
Validity of the test:	The following criteria should be satisfied in the control and reference item for a test result to be considered valid: - in the control plate(s), cumulative larval mortality from day-3 to day-8 $\leq 15\%$ across all replicates; - in the control plate(s), the adult emergence rate on day-22 $\geq 70\%$ across all replicates; - Reference item: larval mortality $\geq 50\%$ on day-8 across all replicates.

RESULTS

All study validity criteria were met. The results are summarized in the following table.

From day-3 to day-8, larvae were exposed to the control and treated groups. The diet volume and composition were adapted on a daily basis.

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Table KCP 10.3.1.4-1: Number of bee's larvae alive from day-2 to day-8

Treatment no.	Treatment	Application rate (Nominal intake)	Test item concentration in the larval diet	Bee's larvae alive						
				D2	D3	D4	D5	D6	D7	D8
T1	Control	---	---	48	48	47	46	44	44	44
T2	Acetamipryd 200 SL	0.00015 µL f.p./larva (0.030 µg a.i./larva)	0.98 µL f.p./Kg of diet (0.20 mg a.i./Kg of diet)	48	48	46	44	44	44	44
T3	Acetamipryd 200 SL	0.00045 µL f.p./larva (0.091 µg a.i./larva)	2.94 µL f.p./Kg of diet (0.59 mg a.i./Kg of diet)	48	48	47	46	44	44	44
T4	Acetamipryd 200 SL	0.0014 µL f.p./larva (0.27 µg a.i./larva)	8.82 µL f.p./Kg of diet (1.76 mg a.i./Kg of diet)	48	48	45	43	40	40	40
T5	Acetamipryd 200 SL	0.0041 µL f.p./larva (0.81 µg a.i./larva)	26.46 µL f.p./Kg of diet (5.29 mg a.i./Kg of diet)	48	48	44	42	37	36	36
T6	Acetamipryd 200 SL	0.012 µL f.p./larva (2.44 µg a.i./larva)	79.37 µL f.p./Kg of diet (15.87 mg a.i./Kg of diet)	48	48	44	42	40	37	36
T7	Acetamipryd 200 SL	0.037 µL f.p./larva (7.33 µg a.i./larva)	238.097 µL f.p./Kg of diet (47.62 mg a.i./Kg of diet)	48	48	41	32	29	26	21
T8	Acetamipryd 200 SL	0.11 µL f.p./larva (22 µg a.i./larva)	714.29 µL f.p./Kg of diet (142.86 mg a.i./Kg of diet)	48	48	42	33	27	25	19
T9	ROGOR L 40 ST	0.018 µL f.p./larva (7.39 µg a.i./larva)	120 µL f.p./Kg of diet (48 mg a.i./Kg of diet)	48	48	35	22	5	0	0

D = day
f.p.: formulated product
a.i.: active ingredient

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Table KCP 10.3.1.4-2: Cumulative mortality of bee's larvae from day-3 to day-8

Treatment		Application rate (Nominal intake)	Test item concentration in the larval diet	Cumulative %mortality					<i>p</i> ^a
				D4	D5	D6	D7	D8	
T1	Control	---	---	2.08	4.17	8.33	8.33	8.33	-
T2	Acetamipryd 200 SL	0.00015 µL f.p./larva (0.030 µg a.i./larva)	0.98 µL f.p./Kg of diet (0.20 mg a.i./Kg of diet)	4.17	8.33	8.33	8.33	8.33	n.s.
T3	Acetamipryd 200 SL	0.00045 µL f.p./larva (0.091 µg a.i./larva)	2.94 µL f.p./Kg of diet (0.59 mg a.i./Kg of diet)	2.08	4.17	8.33	8.33	8.33	n.s.
T4	Acetamipryd 200 SL	0.0014 µL f.p./larva (0.27 µg a.i./larva)	8.82 µL f.p./Kg of diet (1.76 mg a.i./Kg of diet)	6.25	10.42	16.67	16.67	16.67	n.s.
T5	Acetamipryd 200 SL	0.0041 µL f.p./larva (0.81 µg a.i./larva)	26.46 µL f.p./Kg of diet (5.29 mg a.i./Kg of diet)	8.33	12.50	22.92	25.00	25.00	*
T6	Acetamipryd 200 SL	0.012 µL f.p./larva (2.44 µg a.i./larva)	79.37 µL f.p./Kg of diet (15.87 mg a.i./Kg of diet)	8.33	12.50	16.67	22.92	25.00	**
T7	Acetamipryd 200 SL	0.037 µL f.p./larva (7.33 µg a.i./larva)	238.097 µL f.p./Kg of diet (47.62 mg a.i./Kg of diet)	14.58	33.33	39.58	45.83	56.25	***
T8	Acetamipryd 200 SL	0.11 µL f.p./larva (22 µg a.i./larva)	714.29 µL f.p./Kg of diet (142.86 mg a.i./Kg of diet)	12.50	31.25	43.75	47.92	60.42	***
T9	ROGOR L 40 ST	0.018 µL f.p./larva (7.39 µg a.i./larva)	120 µL f.p./Kg of diet (48 mg a.i./Kg of diet)	27.08	54.17	89.58	100	100	***

D = day

^a, Cochran-Armitage and Chi² 2x2 Table tests (reference item ROGOR L 40 ST), α≤0.001 ***, 0.01 **, 0.05 *

-, not applicable

f.p.: formulated product

a.i.: active ingredient

n.s., not significantly different compared to the control

At day-8 (D8), the cumulative mortality ranged from 8.33% to 60.42% on treatments T2, T3 and T8, respectively. Reference item ROGOR L 40 ST and the control group showed a cumulative mortality of 100% and 8.33%, respectively.

Larval mortality was evaluated from day-3 to day-8 after an exposure period of 3 days (from day-3 to day-6). Pupal mortality was calculated in percentage from D8 to D22.

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Table KCP 10.3.1.4-3: Adults' emergence at day-22

Treatment		Application rate (Nominal intake)	Test item concentration in the larval diet	% pupae mortality at D15	Corrected mortality at D15	% pupal mortality at D22	p ^a	Corrected mortality at D22 ^b
T1	Control	---	---	4.44	-	0.00	-	-
T2	Acetamipryd 200 SL	0.00015 µL f.p./larva (0.030 µg a.i./larva)	0.98 µL f.p./Kg of diet (0.20 mg a.i./Kg of diet)	4.44	0.00	4.76	n.s.	4.76
T3	Acetamipryd 200 SL	0.00045 µL f.p./larva (0.091 µg a.i./larva)	2.94 µL f.p./Kg of diet (0.59 mg a.i./Kg of diet)	9.21	4.98	0.00	n.s.	0.00
T4	Acetamipryd 200 SL	0.0014 µL f.p./larva (0.27 µg a.i./larva)	8.82 µL f.p./Kg of diet (1.76 mg a.i./Kg of diet)	7.54	3.24	2.56	n.s.	2.56
T5	Acetamipryd 200 SL	0.0041 µL f.p./larva (0.81 µg a.i./larva)	26.46 µL f.p./Kg of diet (5.29 mg a.i./Kg of diet)	5.59	1.20	16.67	n.s.	16.67
T6	Acetamipryd 200 SL	0.012 µL f.p./larva (2.44 µg a.i./larva)	79.37 µL f.p./Kg of diet (15.87 mg a.i./Kg of diet)	11.11	6.28	21.52	n.s.	21.52
T7	Acetamipryd 200 SL	0.037 µL f.p./larva (7.33 µg a.i./larva)	238.097 µL f.p./Kg of diet (47.62 mg a.i./Kg of diet)	8.33	4.07	0.00	n.s.	0.00
T8	Acetamipryd 200 SL	0.11 µL f.p./larva (22 µg a.i./larva)	714.29 µL f.p./Kg of diet (142.86 mg a.i./Kg of diet)	13.89	9.88	44.44	***	44.44

D = day

^a, Cochran-Armitage test, $\alpha \leq 0.001$ ***, 0.01 **, 0.05 *

^b, mean mortality corrected by Schneider-Orelli's formula

-, not applicable

*f.p.: formulated product

**a.i.: active ingredient

n.s., not significantly different compared to the control

At day-15 (D15), mortality ranged from 4.44% (corrected value: 0.00%) in treatment T2 to 13.89% (corrected value: 9.88%) in treatment T8. Mortality in the control group was equal to 4.44%. At day-22 (D22), pupal mortality ranged from 0.00% in treatment T3 to 44.44 in treatment T8 and in the control group corresponded to 0.00%.

Adults' emergence and percent reduction in the adults' emergence were evaluated at day-22.

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Table KCP 10.3.1.4-4: Adults' emergence at day-22

Treatment number	Treatment	Application rate (Nominal intake)	Test item concentration in the larval diet	Adults' emergence rate (%)	<i>p</i> ^a	Er (%) ^b
T1	Control	---	---	87.50	-	-
T2	Acetamipryd 200 SL	0.00015 µL f.p./larva (0.030 µg a.i./larva)	0.98 µL f.p./Kg of diet (0.20 mg a.i./Kg of diet)	83.33	n.s.	4.76
T3	Acetamipryd 200 SL	0.00045 µL f.p./larva (0.091 µg a.i./larva)	2.94 µL f.p./Kg of diet (0.59 mg a.i./Kg of diet)	83.33	n.s.	4.76
T4	Acetamipryd 200 SL	0.0014 µL f.p./larva (0.27 µg a.i./larva)	8.82 µL f.p./Kg of diet (1.76 mg a.i./Kg of diet)	75.00	n.s.	14.29
T5	Acetamipryd 200 SL	0.0041 µL f.p./larva (0.81 µg a.i./larva)	26.46 µL f.p./Kg of diet (5.29 mg a.i./Kg of diet)	58.33	***	33.33
T6	Acetamipryd 200 SL	0.012 µL f.p./larva (2.44 µg a.i./larva)	79.37 µL f.p./Kg of diet (15.87 mg a.i./Kg of diet)	52.08	***	40.48
T7	Acetamipryd 200 SL	0.037 µL f.p./larva (7.33 µg a.i./larva)	238.097 µL f.p./Kg of diet (47.62 mg a.i./Kg of diet)	39.58	***	54.76
T8	Acetamipryd 200 SL	0.11 µL f.p./larva (22 µg a.i./larva)	714.29 µL f.p./Kg of diet (142.86 mg a.i./Kg of diet)	18.75	***	78.57
T9	ROGOR L 40 ST	0.018 µL f.p./larva (7.39 µg a.i./larva)	120µL f.p./Kg diet (48 mg a.i./Kg of diet)	0.00	***	100.00

^a, Cochran-Armitage and Chi² 2x2 Table tests (reference item ROGOR L 40 ST), $\alpha \leq 0.001$ ***, 0.01 **, 0.05 *

^b, Er = emergence % reduction in comparison to the control

-, not applicable

f.p.: formulated product

a.i.: active ingredient

n.s., not significantly different compared to the control

Emergence rate ranged from 18.75% on treatment T8 to 83.33% with treatments T2 and T3. Control group showed a value of 87.50%. Percent reduction in emergence (Er%) ranged from 4.76% to 78.57% for treatments T2, T3 and T8, respectively.

CONCLUSION

The effects of ACETAMIPRYD 200 SL on mortality of honey bee larvae are summarized below:

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Table KCP 10.3.1.4-5: Endpoints for the adults' emergence at day-22

Endpoints	µg a.i./larva	µL test item/larva
ED ₅₀ [95% confidence intervals]	3.84 [6.36 – 2.52]	0.019 [0.032 – 0.013]
NOED	0.27	0.0014
LOED	0.81	0.0041
Endpoints	mg a.i./Kg of diet	µL test item/Kg of diet
EC ₅₀ [95% confidence intervals]	24.98 [41.33 – 16.42]	124.93 [206.86 – 82.05]
NOEC	1.76	8.82
LOEC	5.29	26.46

A 2.3.1.5 KCP 10.3.1.5 Cage and tunnel tests

Not relevant. No studies submitted.

A 2.3.1.6 KCP 10.3.1.6 Field tests with honeybees

Not relevant. No studies submitted.

A 2.3.2 KCP 10.3.2 Effects on non-target arthropods

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

No new studies provided.

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

Comments of zRMS:	The study was accepted by zRMS.		
	The validity criteria was met:		
	Mortality in the control groups after 48 hours	Bioassay 1 at 0 DAA	Actual value was 6.67%, therefore, the validity criterion was met.
	Reproduction in the control groups	Bioassay 1 at 0 DAA	The mean number of parasitized aphids per female was 32.07 and none female produced zero mummies, so this validity criteria were met.
	Mortality in the reference item after 48 hours	Bioassay 1 at 0 DAA	Actual value was 93.33% (corrected value 92.86%), so the validity criterion was met.
Agreed toxicity endpoints:			

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Endpoints	mL test item/ha	g a.i./ha*
0-DAA Bioassay: fresh residues		
LR ₅₀ (Mortality)	<300 [95%-CLs: n.d.]	<60 [95%-CLs: n.d.]
NOER (Mortality)	<300	<60
LOER (Mortality)	≤300	≤60
ER ₅₀ (Reproduction)	Not determined*	Not determined*
NOER (Reproduction)	Not determined*	Not determined*
LOER (Reproduction)	Not determined*	Not determined*
7-DAA Bioassay: 7-day aged residues		
LR ₅₀ (Mortality)	<300 [95%-CLs: n.d.]	<60 [95%-CLs: n.d.]
NOER (Mortality)	<300	<60
LOER (Mortality)	≤300	≤60
ER ₅₀ (Reproduction)	Not determined*	Not determined*
NOER (Reproduction)	Not determined*	Not determined*
LOER (Reproduction)	Not determined*	Not determined*
14-DAA Bioassay: 14-day aged residues		
LR ₅₀ (Mortality)	>500 [95%-CLs: 384.89 – U.L. n.d.]	>100 [95%-CLs: 76.98 – U.L. n.d.]
NOER (Mortality)	300	60
LOER (Mortality)	400	80
ER ₅₀ (Reproduction)	>400 [95%-CLs: n.d.]	>80 [95%-CLs: n.d.]
NOER (Reproduction)	<300	<60
LOER (Reproduction)	≤300	≤60
21-DAA Bioassay: 21-day aged residues		
LR ₅₀ (Mortality)	>500 [95%-CLs: n.d.]	>100 [95%-CLs: n.d.]
NOER (Mortality)	≥500	≥100
LOER (Mortality)	>500	>100
ER ₁₀ (Reproduction)	<300 [95%-CLs: n.d.]	<60 [95%-CLs: n.d.]
ER ₂₀ (Reproduction)	<300 [95%-CLs: n.d.]	<60 [95%-CLs: n.d.]
ER ₃₀ (Reproduction)	>500 [95%-CLs: n.d.]	>100 [95%-CLs: n.d.]
NOER (Reproduction)	<300	<60
LOER (Reproduction)	≤300	≤60

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Endpoints	mL test item/ha	g a.i./ha*
28-DAA Bioassay: 28-day aged residues		
LR ₅₀ (Mortality)	>500 [95%-CLs: n.d.]	>100 [95%-CLs: n.d.]
NOER (Mortality)	≥500	≥100
LOER (Mortality)	>500	>100
ER ₁₀ (Reproduction)	<300 [95%-CLs: n.d.]	<60 [95%-CLs: n.d.]
ER ₂₀ (Reproduction)	453.12 [95%-CLs: 326.14 – U.L. n.d.]	90.62 [95%-CLs: 65.23 – U.L. n.d.]
ER ₅₀ (Reproduction)	>500 [95%-CLs: n.d.]	>100 [95%-CLs: n.d.]
NOER (Reproduction)	≥500	≥100
LOER (Reproduction)	>500	>100
35-DAA Bioassay: 35-day aged residues		
LR ₅₀ (Mortality)	>500 [95%-CLs: n.d.]	>100 [95%-CLs: n.d.]
NOER (Mortality)	≥500	≥100
LOER (Mortality)	>500	>100
ER ₁₀ (Reproduction)	>400 [95%-CLs: n.d.]	>80 [95%-CLs: n.d.]
ER ₂₀ (Reproduction)	>500 [95%-CLs: n.d.]	>100 [95%-CLs: n.d.]
ER ₅₀ (Reproduction)	>500 [95%-CLs: n.d.]	>100 [95%-CLs: n.d.]
NOER (Reproduction)	≥500	≥100
LOER (Reproduction)	>500	>100

Note: the LR₅₀ and EC₅₀ values were estimated, therefore no confidence limits were provided (95%-CL n.d. = not determined)
 *The NOEC, LOEC and ER₅₀ could not be determined, because there were not responses
 #The active ingredient content was calculate based on the nominal test item content of 200 g/L
 95%-CLs, Confidence Limits
 n.d.: not determined due to mathematical reasons
 95%- U.L., Upper Limit

Reference: KCP 10.3.2.2/01

Report Effects of Acetamipryd 200 SL on *Aphidius rhopalosiphi* – Extended laboratory aged residue test;
Mautino G.; 2023; Study Code: 1036.I.SAG23/r

Guideline(s): Yes, SETAC; ESCORT; IOBC/BART/EPPO

Deviations: No

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study) No

MATERIALS AND METHODS

1. Test material

Test item (chemical/other name): Acetamipryd 200 SL

Formulation: 200 g/L (nominal content)

Description (physical state): liquid

Batch no.: 1/ACE/2022

Production date: 01.2022

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Expiration date:	01.2024
2. Vehicle and/or positive control:	vehicle: deionised water positive control: ROGOR L 40 ST (nominally 400 g dimetho- ate/L)
3. Test organism	
Species:	Parasitoids, <i>Aphidius rhopalosiphi</i>
Source:	Katz Biotech AG, Baruth, Germany
Age:	adults less than 48-hour old
Acclimation period:	1 days under test conditions in climatic chamber
Diet:	During the acclimation period a 1:3 v/v solution of honey and water was provided ad libitum to the insects. Before the application (0 DAA) and before the test unit settle- ment (7, 14, 21, 28 and 35 DAA), barley plants were lightly sprayed with a 10% w/w solution of sugar in water to provide both food and a foraging stimulus for the wasps; for the reproduction assessment a 1:3 v/v solution of honey and water was put on a cotton wool and provided for 24 hours.
Test units:	Mortality assessment: The test unit consisted of one pot (15.0 cm Ø) with barley seedlings (<i>Hordeum vulgare</i> ; 10 seeds per pot), confined within a clear polyacrylic and transparent cylinder (22 cm high and 10 cm Ø). The cyl- inder had a ventilated cap with a waspproof netting (0.1 x 0.5 mm mesh size) and a ventilated hole (2 cm Ø) used for wasp introduction. After the introduction of the in- sects, this hole was plugged up with cotton wool. Reproduction assessment: Untreated pots (15.0 cm Ø) with barley seedlings (<i>Hordeum vulgare</i> ; 30 seeds per pot) infested with ≥ 100 host aphids of all development stages (<i>Rhopalosiphum padi</i> ; number of aphids was esti- mated) were enclosed within a clear polyacrylic cylinder (22 cm high and 10 cm Ø). The cylinder had a ventilated cap with a wasp-proof netting (0.1 x 0.5 mm mesh size) and a ventilated hole (2 cm Ø) used for wasp introduction. After the introduction of the insects, this hole was plugged up with a cotton wool. After the adult wasps were re- moved, the polyacrylic cylinders were left on the pots.

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Plants: Taxonomic group: Poaceae
 Common name: barley
 Species: *Hordeum vulgare* L.
 Variety: Cometa
 Stage at delivery: seed
 Source: Agricola Albese (Alba, CN)
 Cultivation substrate: artificial soil
 Grown site: open field under a rain cover (N44° 44' 48.88"; E08° 04' 09.00).
 Length: 39 m; width: 6 m; height: 2.10 m)
 Stage for test start: BBCH 12
 Maintenance: automatic drip irrigation 3 times a day (3 minutes each) with a water volume of 3L/ha
 Agrochemicals and/or fertilizers: none

4. Environmental conditions:

Temperature: 19.27 ± 0.393 °C (18.70 – 20.28 °C)
Relative humidity: 73.2% ± 2.3% (67.9 – 79.2% RH)
Light Intensity: 850 to 950 (mortality), 19500 to 20000 (reproduction)
Light regime: 16 h light:8 h dark

STUDY DESIGN AND METHOD

Aim of the study was to determine the product persistence, intended as the decline rate of residues (fresh and aged) on barley plants treated once with the test item Acetamipryd 200 SL (acetamipryd 200 g/L), under rain-protected field conditions. Insects were exposed to fresh and aged residue of the test item at different timings (bioassay) after application (DAA).

The study consisted of 5 treatments (3 concentrations of the test item, 1 control group, 1 reference item), with 6 replicates, each containing 5 insects. Insects were exposed to fresh or aged residues on barley plants at six different times: 0, 7, 14, 21, 28 and 35 days after application (DAA). For each time (bioassay), repellency evaluation (location of the parasitoids, i.e. on plants, cylinder and sand) was performed after 30, 60, 90, 120 and 150 minutes during the initial 3 hours after their release in the treated test units. Then parasitoids' survival assessed after 2, 24 and 48 hours of exposure. After 48 hours of exposure, no. 15 surviving females from the control and test item groups were removed and evaluated for their reproductive capacity by confining them individually over untreated barley plants infested with the host cereal aphids *Rhopalosiphum padi*. The adult females were then removed after 24 hours and the aphid-infested plants left for a further 12 days before the assessment of the number of developed aphids' mummies. For each bioassay, at the end of the mortality assessments (48 hours of exposure), the surviving females were evaluated for reproduction after 12 days by comparing the test item treatment groups parasitisation with that of the control group.

Test design: 6 replicates per treatment for the mortality assessment; 15 replicates (females) per treatment for the reproduction assessment
 5 females per replicate for the mortality assessment and
 1 female per replicate for the reproduction assessment

Exposure time: mortality phase: 48 hours + fecundity phase: 12 days

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Tested concentrations, definitive test: 300 mL test item/ha (60 g acetamiprid/ha) – T2
400 mL test item/ha (80 g acetamiprid/ha) – T3
500 mL test item/ha (100 g acetamiprid/ha) – T4
400 L water/ha

Stability of test compound:

Dates: start of the study: 20.04.2023
start of the experimental part: 01.05.2023
end of the experimental part: 20.06.2023
end of the study: 21.12.2023

Statistic: Software used for statistical analysis were “ToxRatPro” Solutions GmbH, version 3.3.0. Mortality data were processed using the Cochran-Armitage Test and Chi² 2×2 Table test with Bonferroni Correction or without (reference item), $\alpha \leq 0.05$. Correction for control mortality was processed using the Schneider-Orelli formula. Reproduction data were analysed by Jonckheere-Terpstra Test, $\alpha \leq 0.05$, Williams and Dunnett's t-tests, $\alpha = 0.05$. For all bioassays, at least the LR50 (mortality) and ER50 (reproduction) values were determined, where possible. The No Observed Effect Rate (NOER) and Lowest Observed Effect Rate (LOER) values for mortality and reproduction were determined, where possible.

Validity of the test: The following criteria should be satisfied in the control for a test result to be considered valid:
- mortality in the control treatment $\leq 10\%$ after 48 hours;
- mean number of parasitized aphids per female in the control treatment ≥ 5 ;
- no more than two surviving wasps producing zero values in the control treatment;
- corrected mortality $> 50\%$ in the reference item treatment.

RESULTS

Bioassay 1 – repellence (0 DAA)

The mean percentage of wasps settled on the treated plants ranged from 43.61% in treatment T4 (500 mL f.p./ha) to 48.44% on T2 (300 mL f.p./ha). Control group and reference item ROGOR L40 ST showed a percentage of 44.67% and 45.89%, respectively. Concerning the mean percentage of wasps settled on cylinder, values ranged from 38.17% in treatment T3 (400 mL f.p./ha) to 42.33% in T4 (500 mL f.p./ha). Control group and reference item showed a percentage of 41.33% and 39.33%, respectively. Wasps settled on sand ranged from 11.17% in treatment T2 (300 mL f.p./ha) to 15.50% in treatment T3 (400 mL f.p./ha). Control group and reference item showed a percentage of 14.00% and 14.78%, respectively.

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Table KCP 10.3.2.2-1: Summary of results from the repellence assessment (bioassay 1 – 0 DAA)

Treatment number	Treatment rate		Mean % of wasps on treated plants	Mean % of wasps on cylinder	Mean % of wasps on sand
	mL test item/ha	g a.i./ha			
T1	0 (Control)	0	44.67	41.33	14.00
T2	300	60	48.44	40.39	11.17
T3	400	80	46.33	38.17	15.50
T4	500	100	43.61	42.33	14.06
T5	ROGOR L40 ST at 20	8 dimethoate/ha	45.89	39.33	14.78

a.i. = acetamiprid nominal content 200 g/L

Bioassay 2 – repellence (7 DAA)

The mean percentage of wasps settled on the treated plants ranged from 45.00% in treatment T2 (300 mL f.p./ha) to 51.67% on T3 (400 mL f.p./ha). Control group and reference item ROGOR L40 ST showed a percentage of 45.33% and 48.00%, respectively. Concerning the mean percentage of wasps settled on cylinder, values ranged from 36.67% in treatment T3 (400 mL f.p./ha) to 42.67% in T2 (300 mL f.p./ha). Control group and reference item showed a percentage of 40.00% and 39.11%, respectively. Wasps settled on sand ranged from 11.17% in treatment T3 (400 mL f.p./ha) to 14.33% in treatment T4 (500 mL f.p./ha). Control group and reference item showed a percentage of 14.67% and 12.89%, respectively.

Table KCP 10.3.2.2-2: Summary of results from the repellence assessment (bioassay 2 – 7 DAA)

Treatment number	Treatment rate		Mean % of wasps on treated plants	Mean % of wasps on cylinder	Mean % of wasps on sand
	mL test item/ha	g a.i./ha			
T1	0 (Control)	0	45.33	40.00	14.67
T2	300	60	45.00	42.67	12.33
T3	400	80	51.67	36.67	11.67
T4	500	100	46.33	39.33	14.33
T5	ROGOR L40 ST at 20	8 dimethoate/ha	48.00	39.11	12.89

a.i. = acetamiprid nominal content 200 g/L

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Bioassay 3 – repellence (14 DAA)

The mean percentage of wasps settled on the treated plants ranged from 49.33% in treatment T2 (300 mL f.p./ha) to 55.67% on T4 (500 mL f.p./ha). Control group and reference item ROGOR L40 ST showed a percentage of 56.00% and 53.22%, respectively. Concerning the mean percentage of wasps settled on cylinder, values ranged from 32.83% in treatment T4 (500 mL f.p./ha) to 36.00% in T2 (300 mL f.p./ha). Control group and reference item showed a percentage of 31.33% and 34.11%, respectively. Wasps settled on sand ranged from 11.50% in treatment T4 (500 mL f.p./ha) to 14.67% in treatment T2 (300 mL f.p./ha). Control group and reference item showed a percentage of 12.67% and 12.67%, respectively.

Table KCP 10.3.2.2-3: Summary of results from the repellence assessment (bioassay 3 – 14 DAA)

Treatment number	Treatment rate		Mean % of wasps on treated plants	Mean % of wasps on cylinder	Mean % of wasps on sand
	mL test item/ha	g a.i./ha			
T1	0 (Control)	0	56.00	31.33	12.67
T2	300	60	49.33	36.00	14.67
T3	400	80	52.67	35.33	12.00
T4	500	100	55.67	32.83	11.50
T5	ROGOR L40 ST at 20	8 dimethoate/ha	53.22	34.11	12.67

a.i. = acetamiprid nominal content 200 g/L

Bioassay 4 – repellence (21 DAA)

The mean percentage of wasps settled on the treated plants ranged from 55.33% in treatment T2 (300 mL f.p./ha) to 58.00% on T3 (400 mL f.p./ha). Control group and reference item ROGOR L40 ST showed a percentage of 57.33% and 56.72%, respectively. Concerning the mean percentage of wasps settled on cylinder, values ranged from 30.00% in treatment T2 (300 mL f.p./ha) to 32.67% in T4 (500 mL f.p./ha). Control group and reference item showed a percentage of 32.00% and 32.00%, respectively. Wasps settled on sand ranged from 10.67% in treatment T4 (500 mL f.p./ha) to 14.67% in treatment T2 (300 mL f.p./ha). Control group and reference item showed a percentage of 10.67% and 11.28%, respectively.

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Table KCP 10.3.2.2-4: Summary of results from the repellence assessment (bioassay 4 – 21 DAA)

Treatment number	Treatment rate		Mean % of wasps on treated plants	Mean % of wasps on cylinder	Mean % of wasps on sand
	mL test item/ha	g a.i./ha			
T1	0 (Control)	0	57.33	32.00	10.67
T2	300	60	55.33	30.00	14.67
T3	400	80	58.00	30.67	11.33
T4	500	100	56.67	32.67	10.67
T5	ROGOR L40 ST at 20	8 dimethoate/ha	56.72	32.00	11.28

a.i. = acetamiprid nominal content 200 g/L

Bioassay 5 – repellence (28 DAA)

The mean percentage of wasps settled on the treated plants ranged from 54.67% in treatment T2 (300 mL f.p./ha) to 57.33% on T4 (500 mL f.p./ha). Control group and reference item ROGOR L40 ST showed a percentage of 58.67% and 57.44%, respectively. Concerning the mean percentage of wasps settled on cylinder, values ranged from 31.33% in treatment T4 (500 mL f.p./ha) to 34.67% in T2 (300 mL f.p./ha). Control group and reference item showed a percentage of 32.00% and 31.56%, respectively. Wasps settled on sand ranged from 9.33% in treatment T3 (400 mL f.p./ha) to 11.33% in treatment T4 (500 mL f.p./ha). Control group and reference item showed a percentage of 9.33% and 11.00%, respectively.

Table KCP 10.3.2.2-5: Summary of results from the repellence assessment (bioassay 5 – 28 DAA)

Treatment number	Treatment rate		Mean % of wasps on treated plants	Mean % of wasps on cylinder	Mean % of wasps on sand
	mL test item/ha	g a.i./ha			
T1	0 (Control)	0	58.67	32.00	9.33
T2	300	60	54.67	34.67	10.67
T3	400	80	56.67	34.00	9.33
T4	500	100	57.33	31.33	11.33
T5	ROGOR L40 ST at 20	8 dimethoate/ha	57.44	31.56	11.00

a.i. = acetamiprid nominal content 200 g/L

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Bioassay 6 – repellence (35 DAA)

The mean percentage of wasps settled on the treated plants ranged from 58.00% in treatment T2 (300 mL f.p./ha) to 60.67% on T3 (400 mL f.p./ha). Control group and reference item ROGOR L40 ST showed a percentage of 59.33% and 59.50%, respectively. Concerning the mean percentage of wasps settled on cylinder, values ranged from 30.00% in treatment T3 (400 mL f.p./ha) to 34.67% in T2 (300 mL f.p./ha). Control group and reference item showed a percentage of 30.67% and 31.67%, respectively. Wasps settled on sand ranged from 7.33% in treatment T2 (300 mL f.p./ha) to 9.33% in treatment T3 (400 mL f.p./ha). Control group and reference item showed a percentage of 10.00% and 8.83%, respectively.

Table KCP 10.3.2.2-6: Summary of results from the repellence assessment (bioassay 6 – 35 DAA)

Treatment number	Treatment rate		Mean % of wasps on treated plants	Mean % of wasps on cylinder	Mean % of wasps on sand
	mL test item/ha	g a.i./ha			
T1	0 (Control)	0	59.33	30.67	10.00
T2	300	60	58.00	34.67	7.33
T3	400	80	60.67	30.00	9.33
T4	500	100	58.67	33.33	8.00
T5	ROGOR L40 ST at 20	8 dimethoate/ha	59.50	31.67	8.83

a.i. = acetamiprid nominal content 200 g/L

Bioassay 1 – mortality (0 DAA)

For test item Acetamipryd 200 SL, mean mortality at 2 hours ranged from 16.67% in treatment T2 (300 mL test item/ha) to 36.67% in treatment T4 (500 mL test item/ha). The control group and reference item showed a mortality of 0.00% and 66.67%, respectively. Mean mortality at 24 hours ranged from 40.00% in treatment T2 (300 mL test item/ha) to 63.33% in treatment T4 (500 mL test item/ha). The control group and reference item showed a mortality value of 3.33% and 76.67%, respectively. After 48 hours of exposure, mortality ranged from 60.00% in treatment T2 (300 mL test item/ha, corrected value: 57.14%) to 90.00% in treatments T4 (500 mL test item/ha, corrected value: 89.29%). Significant differences (93.33% mortality, corrected 92.86%) were observed when reference item ROGOR L 40 ST was applied. Control group showed a mortality value of 6.67%.

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Table KCP 10.3.2.2-7: Summary of results from the mortality assessment (bioassay 1 – 0 DAA)

Treatment number	Treatment rate		Check at 2 hours	Check at 24 hours	Check at 48 hours			
	mL test item/ha	g a.i./ha	Mortality (%)	Mortality (%)	Mortality (%)	SE ^a	p ^b	Corrected mortality ^c (%)
T1	0 (Control)	0	0.00	3.33	6.67	±0.21	-	-
T2	300	60	16.67	40.00	60.00	±0.52	***	57.14
T3	400	80	26.67	50.00	83.33	±0.31	***	82.14
T4	500	100	36.67	63.33	90.00	±0.34	***	89.29
T5	ROGOR L40 ST at 20	8 dimethoate/ha	66.67	76.67	93.33	±0.21	***	92.86

a.i. = acetamiprid nominal content 200 g/L

a, standard error on the number of dead insects of 6 replicates

b, Cochran-Armitage Test for test item and Chi² 2×2 Table test for reference item, α≤0.001 ***, 0.01 **, 0.05 *

c, mean mortality corrected by Schneider-Orelli's formula

-, not applicable

Bioassay 2 – mortality (7 DAA)

For test item Acetamipryd 200 SL, mean mortality at 2 hours ranged from 16.67% in treatment T2 (300 mL test item/ha) to 30.00% in treatment T4 (500 mL test item/ha). The control group and reference item showed a mortality of 0.00% and 60.00%, respectively. Mean mortality at 24 hours ranged from 30.00% in treatment T2 (300 mL test item/ha) to 56.67% in treatment T4 (500 mL test item/ha). The control group and reference item showed a mortality value of 0.00% and 70.00%, respectively. After 48 hours of exposure, mortality ranged from 53.33% in treatment T2 (300 mL test item/ha, corrected value: 53.33%) to 86.67% in treatments T4 (500 mL test item/ha, corrected value: 86.67%). Significant differences (76.67% mortality, corrected 76.67%) were observed when reference item ROGOR L 40 ST was applied. Control group showed a mortality value of 0.00%.

Table KCP 10.3.2.2-8: Summary of results from the mortality assessment (bioassay 2 – 7 DAA)

Treatment number	Treatment rate		Check at 2 hours	Check at 24 hours	Check at 48 hours			
	mL test item/ha	g a.i./ha	Mortality (%)	Mortality (%)	Mortality (%)	SE ^a	p ^b	Corrected mortality ^c (%)
T1	0 (Control)	0	0.00	0.00	0.00	±0.00	-	-
T2	300	60	16.67	30.00	53.33	±0.33	***	53.33
T3	400	80	23.33	46.67	80.00	±0.26	***	80.00
T4	500	100	30.00	56.67	86.67	±0.33	***	86.67
T5	ROGOR L40 ST at 20	8 dimethoate/ha	60.00	70.00	76.67	±0.31	***	76.67

a.i. = acetamiprid nominal content 200 g/L

a, standard error on the number of dead insects of 6 replicates

b, Cochran-Armitage Test for test item and Chi² 2×2 Table test for reference item, α≤0.001 ***, 0.01 **, 0.05 *

c, mean mortality corrected by Schneider-Orelli's formula

-, not applicable

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Bioassay 3 – mortality (14 DAA)

For test item Acetamipryd 200 SL, mean mortality at 2 hours ranged from 6.67% in treatment T2 (300 mL test item/ha) and T3 (400 mL test item/ha) to 13.33% in treatment T4 (500 mL test item/ha). The control group and reference item showed a mortality of 0.00% and 53.33%, respectively. Mean mortality at 24 hours ranged from 10.00% in treatment T2 (300 mL test item/ha) to 26.67% in treatment T4 (500 mL test item/ha). The control group and reference item showed a mortality value of 0.00% and 60.00%, respectively. After 48 hours of exposure, mortality ranged from 13.33% in treatment T2 (300 mL test item/ha, corrected value: 10.34%) to 53.33% in treatments T4 (500 mL test item/ha, corrected value: 51.72%). Significant differences (63.33% mortality, corrected 62.07%) were observed when reference item ROGOR L 40 ST was applied. Control group showed a mortality value of 3.33%.

Table KCP 10.3.2.2-9: Summary of results from the mortality assessment (bioassay 3 – 14 DAA)

Treatment number	Treatment rate		Check at 2 hours	Check at 24 hours	Check at 48 hours			
	mL test item/ha	g a.i./ha	Mortality (%)	Mortality (%)	Mortality (%)	SE ^a	p ^b	Corrected mortality ^c (%)
T1	0 (Control)	0	0.00	0.00	3.33	±0.17	-	-
T2	300	60	6.67	10.00	13.33	±0.33	n.s.	10.34
T3	400	80	6.67	13.33	20.00	±0.26	*	17.24
T4	500	100	13.33	26.67	53.33	±0.21	***	51.72
T5	ROGOR L40 ST at 20	8 dimethoate/ha	53.33	60.00	63.33	±0.31	***	62.07

a.i. = acetamiprid nominal content 200 g/L

a, standard error on the number of dead insects of 6 replicates

b, Cochran-Armitage Test for test item and Chi² 2×2 Table test for reference item, α≤0.001 ***, 0.01 **, 0.05 *

c, mean mortality corrected by Schneider-Orelli's formula

-, not applicable

n.s., not significantly different compared to the control

Bioassay 4 – mortality (21 DAA)

For test item Acetamipryd 200 SL, mean mortality at 2 hours was 3.33% for all treatments T2 (300 mL test item/ha), T3 (400 mL test item/ha) and T4 (500 mL test item/ha). The control group and reference item showed a mortality of 0.00% and 36.67%, respectively. Mean mortality at 24 hours ranged from 6.67% in treatment T3 (400 mL test item/ha) to 10.00% in treatment T2 (300 mL test item/ha) and T4 (500 mL test item/ha). The control group and reference item showed a mortality value of 3.33% and 46.67%, respectively. After 48 hours of exposure, mortality ranged from 13.33% in treatment T2 (300 mL test item/ha, corrected value: 7.14%) and T3 (400 mL test item/ha, corrected value: 7.14%) to 20.00% in treatments T4 (500 mL test item/ha, corrected value: 14.29%). Significant differences (53.33% mortality, corrected 50.00%) were observed when reference item ROGOR L 40 ST was applied. Control group showed a mortality value of 6.67%.

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Table KCP 10.3.2.2-10: Summary of results from the mortality assessment (bioassay 4 – 21 DAA)

Treatment number	Treatment rate		Check at 2 hours	Check at 24 hours	Check at 48 hours			
	mL test item/ha	g a.i./ha	Mortality (%)	Mortality (%)	Mortality (%)	SE ^a	p ^b	Corrected mortality ^c (%)
T1	0 (Control)	0	0.00	3.33	6.67	±0.21	-	-
T2	300	60	3.33	10.00	13.33	±0.21	n.s.	7.14
T3	400	80	3.33	6.67	13.33	±0.33	n.s.	7.14
T4	500	100	3.33	10.00	20.00	±0.26	n.s.	14.29
T5	ROGOR L40 ST at 20	8 dimethoate/ha	36.67	46.67	53.33	±0.33	***	50.00

a.i. = acetamiprid nominal content 200 g/L

a, standard error on the number of dead insects of 6 replicates

b, Chi² 2×2 Table test with or without (reference item) Bonferroni correction, α≤0.001 ***, 0.01 **, 0.05 *

c, mean mortality corrected by Schneider-Orelli's formula

-, not applicable

n.s., not significantly different compared to the control

Bioassay 5 – mortality (28 DAA)

For test item Acetamipryd 200 SL, mean mortality at 2 hours was 0.00% for all treatments T2 (300 mL test item/ha), T3 (400 mL test item/ha) and T4 (500 mL test item/ha). The control group and reference item showed a mortality of 0.00% and 30.00%, respectively. Mean mortality at 24 hours ranged from 0.00% in treatment T2 (300 mL test item/ha) to 6.67% in treatment T4 (500 mL test item/ha). The control group and reference item showed a mortality value of 0.00% and 36.67%, respectively. After 48 hours of exposure, mortality ranged from 6.67% in treatment T2 (300 mL test item/ha, corrected value: 3.45%) and T3 (400 mL test item/ha, corrected value: 3.45%) to 13.33% in treatments T4 (500 mL test item/ha, corrected value: 10.34%). Significant differences (40.00% mortality, corrected 37.93%) were observed when reference item ROGOR L 40 ST was applied. Control group showed a mortality value of 3.33%.

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Table KCP 10.3.2.2-11: Summary of results from the mortality assessment (bioassay 5 – 28 DAA)

Treatment number	Treatment rate		Check at 2 hours	Check at 24 hours	Check at 48 hours			
	mL test item/ha	g a.i./ha	Mortality (%)	Mortality (%)	Mortality (%)	SE ^a	p ^b	Corrected mortality ^c (%)
T1	0 (Control)	0	0.00	0.00	3.33	±0.17	-	-
T2	300	60	0.00	0.00	6.67	±0.21	n.s.	3.45
T3	400	80	0.00	3.33	6.67	±0.21	n.s.	3.45
T4	500	100	0.00	6.67	13.33	±0.33	n.s.	10.34
T5	ROGOR L40 ST at 20	8 dimethoate/ha	30.00	36.67	40.00	±0.26	***	37.93

a.i. = acetamiprid nominal content 200 g/L

a, standard error on the number of dead insects of 6 replicates

b, Chi² 2×2 Table test with or without (reference item) Bonferroni correction, α≤0.001 ***, 0.01 **, 0.05 *

c, mean mortality corrected by Schneider-Orelli's formula

-, not applicable

n.s., not significantly different compared to the control

Bioassay 6 – mortality (35 DAA)

For test item Acetamipryd 200 SL, mean mortality at 2 hours was 0.00% for all treatments T2 (300 mL test item/ha), T3 (400 mL test item/ha) and T4 (500 mL test item/ha). The control group and reference item showed a mortality of 0.00% and 13.33%, respectively. Mean mortality at 24 hours was 3.33% for all treatments T2 (300 mL test item/ha), T3 (400 mL test item/ha) and T4 (500 mL test item/ha). The control group and reference item showed a mortality of 0.00% and 23.33%, respectively. After 48 hours of exposure, mortality ranged from 6.67% in treatment T2 (300 mL test item/ha, corrected value: 0.00%) and T3 (400 mL test item/ha, corrected value: 0.00%) to 10.00% in treatments T4 (500 mL test item/ha, corrected value: 3.57%). Significant differences (30.00% mortality, corrected 25.00%) were observed when reference item ROGOR L 40 ST was applied. Control group showed a mortality value of 6.67%.

Table KCP 10.3.2.2-12: Summary of results from the mortality assessment (bioassay 6 – 35 DAA)

Treatment number	Treatment rate		Check at 2 hours	Check at 24 hours	Check at 48 hours			
	mL test item/ha	g a.i./ha	Mortality (%)	Mortality (%)	Mortality (%)	SE ^a	p ^b	Corrected mortality ^c (%)
T1	0 (Control)	0	0.00	0.00	6.67	±0.21	-	-
T2	300	60	0.00	3.33	6.67	±0.21	n.s.	0.00
T3	400	80	0.00	3.33	6.67	±0.21	n.s.	0.00
T4	500	100	0.00	3.33	10.00	±0.34	n.s.	3.57
T5	ROGOR L40 ST at 20	8 dimethoate/ha	13.33	23.33	30.00	±0.22	*	25.00

a.i. = acetamiprid nominal content 200 g/L

a, standard error on the number of dead insects of 6 replicates

b, Chi² 2×2 Table test with or without (reference item) Bonferroni correction, α≤0.001 ***, 0.01 **, 0.05 *

c, mean mortality corrected by Schneider-Orelli's formula

-, not applicable

n.s., not significantly different compared to the control

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Bioassay 1 – reproduction (0 DAA)

The mean number of mummies was 32.07 in the control group, in the other treatments the minimum number of survived insects (i.e., 15 females) has not been achieved.

Table KCP 10.3.2.2-13: Summary of results from the reproduction assessment (bioassay 1 – 0 DAA)

Treatment number	Treatment rate		Reproduction (fecundity)		
	mL test item/ha	g a.i./ha	Mean no. of mummies per female	Standard error	Reduction in reproduction (% R)
T1	0 (Control)	0	32.07	±4.16	n.a.
T2	300	60	n.a.	n.a.	n.a.
T3	400	80	n.a.	n.a.	n.a.
T4	500	100	n.a.	n.a.	n.a.

a.i. = acetamiprid nominal content 200 g/L

n.a., not applicable due to absence of the minimum number of survived insects (i.e., 15 females)

Bioassay 2 – reproduction (7 DAA)

The mean number of mummies was 29.13 in the control group, in the other treatments the minimum number of survived insects (i.e., 15 females) has not been achieved.

Table KCP 10.3.2.2-14: Summary of results from the reproduction assessment (bioassay 2 – 7 DAA)

Treatment number	Treatment rate		Reproduction (fecundity)		
	mL test item/ha	g a.i./ha	Mean no. of mummies per female	Standard error	Reduction in reproduction (% R)
T1	0 (Control)	0	29.13	±3.31	n.a.
T2	300	60	n.a.	n.a.	n.a.
T3	400	80	n.a.	n.a.	n.a.
T4	500	100	n.a.	n.a.	n.a.

a.i. = acetamiprid nominal content 200 g/L

n.a., not applicable due to absence of the minimum number of survived insects (i.e., 15 females)

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Bioassay 3 – reproduction (14 DAA)

The mean number of mummies ranged from 16.73 in treatment T3 (400 mL test item/ha) to 20.20 in treatment T2 (300 mL test item/ha). Given that only two test item treatment rates were tested, the 12-d ER50 (reproduction) value could not be determined but was estimated to be >400 mL test item/ha (95% confidence limits not determined), corresponding to >80 g a.i./ha (95% confidence limits not determined). Significant differences were observed, in terms of reproduction, for treatments T2 (300 mL f.p./ha), T3 (400 mL f.p./ha) in comparison to the control group (mean of 31.13 mummies). The 12-d NOER (reproduction) value was estimated to be <300 mL test item/ha (<60 g a.i./ha) and the 12-d LOER (reproduction) value was estimated to be ≤300 mL test item/ha (≤60 g a.i./ha).

Table KCP 10.3.2.2-15: Summary of results from the reproduction assessment (bioassay 3 – 14 DAA)

Treatment number	Treatment rate		Reproduction (fecundity)			
	mL test item/ha	g a.i./ha	Mean no. of mummies per female	Standard error	Reduction in reproduction (% R)	P ^a
T1	0 (Control)	0	31.13	±4.25	-	-
T2	300	60	20.20	±3.76	35.12	*
T3	400	80	16.73	±3.21	46.25	**
T4	500	100	n.a.	n.a.	n.a.	n.a.

a.i. = acetamiprid nominal content 200 g/L

a, Jonckheere-Terpstra Test, $\alpha \leq 0.001$ ***, 0.01 **, 0.05 *

-, not applicable

n.a., not applicable due to absence of the minimum number of survived insects (i.e., 15 females)

Bioassay 4 – reproduction (21 DAA)

The mean number of mummies ranged from 18.00 in treatment T4 (500 mL test item/ha) to 19.20 in treatment T2 (300 mL test item/ha). Significant differences were observed, in terms of reproduction, for treatments T2 (300 mL f.p./ha), T3 (400 mL f.p./ha) and T4 (500 mL f.p./ha) in comparison to the control group (mean of 27.07 mummies). The 12-d NOER (reproduction) value was estimated to be <300 mL test item/ha (<60 g a.i./ha) and the 12-d LOER (reproduction) value was estimated to be ≤300 mL test item/ha (≤60 g a.i./ha). The 12-d ER10 (reproduction) value was estimated to be <300 mL test item/ha (95% confidence limits not determined), corresponding to <60 g a.i./ha (95% confidence limits not determined). The 12-d ER20 (reproduction) value was estimated to be <300 mL test item/ha (95% confidence limits not determined), corresponding to <60 g a.i./ha (95% confidence limits not determined). The 12-d ER50 (reproduction) value was estimated to be >500 mL test item/ha (95% confidence limits not determined), corresponding to >100 g a.i./ha (95% confidence limits not determined).

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Table KCP 10.3.2.2-16: Summary of results from the reproduction assessment (bioassay 4 – 21 DAA)

Treatment number	Treatment rate		Reproduction (fecundity)			
	mL test item/ha	g a.i./ha	Mean no. of mummies per female	Standard error	Reduction in reproduction (% R)	P ^a
T1	0 (Control)	0	27.07	±3.20	-	-
T2	300	60	19.20	±2.43	29.06	*
T3	400	80	18.33	±3.25	32.27	*
T4	500	100	18.00	±2.65	33.50	*

a.i. = acetamiprid nominal content 200 g/L

a, Williams' t- test, α=0.05 *

-, not applicable

Bioassay 5 – reproduction (28 DAA)

The mean number of mummies ranged from 22.73 in treatment T4 (500 mL test item/ha) to 26.20 in treatment T2 (300 mL test item/ha). Nonsignificant differences were observed relative to the control group (mean of 29.60 mummies). The 12-d NOER (reproduction) value was estimated to be ≥500 mL test item/ha (≥100 g a.i./ha) and the 12-d LOER (reproduction) value was estimated to be >500 mL test item/ha (>100 g a.i./ha). The 12-d ER10 (reproduction) value was estimated to be <300 mL test item/ha (95% confidence limits not determined), corresponding to <60 g a.i./ha (95% confidence limits not determined). The 12-d ER20 (reproduction) value was 453.12 mL test item/ha (95% confidence limits: 326.14 – Upper Limit not determined), corresponding to 90.62 g a.i./ha (95% confidence limits: 65.23 – Upper Limit not determined). The 12-d ER50 (reproduction) value was estimated to be >500 mL test item/ha (95% confidence limits not determined), corresponding to >100 g a.i./ha (95% confidence limits not determined).

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Table KCP 10.3.2.2-17: Summary of results from the reproduction assessment (bioassay 5 – 28 DAA)

Treatment number	Treatment rate		Reproduction (fecundity)			
	mL test item/ha	g a.i./ha	Mean no. of mummies per female	Standard error	Reduction in reproduction (% R)	P ^a
T1	0 (Control)	0	29.60	±2.96	-	-
T2	300	60	26.20	±3.23	11.49	n.s.
T3	400	80	24.80	±2.50	16.22	n.s.
T4	500	100	22.73	±2.66	23.20	n.s.

a.i. = acetamiprid nominal content 200 g/L

a, Williams' t- test, α=0.05 *

-, not applicable

n.s., not significantly different compared to the control

Bioassay 6 – reproduction (35 DAA)

The mean number of mummies ranged from 22.93 in treatment T4 (500 mL test item/ha) to 27.87 in treatment T2 (300 mL test item/ha). Nonsignificant differences were observed relative to the control group (mean of 27.53 mummies). The 12-d NOER (reproduction) value was estimated to be ≥500 mL test item/ha (≥100 g a.i./ha) and the 12-d LOER (reproduction) value was estimated to be >500 mL test item/ha (>100 g a.i./ha). The 12-d ER10 value was estimated to be >400 mL test item/ha (>80.00 g a.i./ha), the 12-d ER20 and 12-d ER50 (reproduction) values were estimated to be >500 mL test item/ha (95% confidence limits not determined), corresponding to >100 g a.i./ha (95% confidence limits not determined).

Table KCP 10.3.2.2-18: Summary of results from the reproduction assessment (bioassay 6 – 35 DAA)

Treatment number	Treatment rate		Reproduction (fecundity)			
	mL test item/ha	g a.i./ha	Mean no. of mummies per female	Standard error	Reduction in reproduction (% R)	P ^a
T1	0 (Control)	0	27.53	±3.08	-	-
T2	300	60	27.87	±2.91	-1.21	n.s.
T3	400	80	26.40	±3.29	4.12	n.s.
T4	500	100	22.93	±2.65	16.71	n.s.

a.i. = acetamiprid nominal content 200 g/L

a, Dunnett' t- test, α=0.05 *

-, not applicable

n.s., not significantly different compared to the control

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CONCLUSION

The obtained endpoints have been summarised below.

Table KCP 10.3.2.2-19: Endpoints for the 0-DAA, 7-DAA, 14-DAA, 21-DAA, 28-DAA and 35-DAA bioassay

Endpoints	mL test item/ha	g a.i./ha [#]
0-DAA Bioassay: fresh residues		
LR ₅₀ (Mortality)	<300 [95%-CLs: n.d.]	<60 [95%-CLs: n.d.]
NOER (Mortality)	<300	<60
LOER (Mortality)	≤300	≤60
ER ₅₀ (Reproduction)	Not determined*	Not determined*
NOER (Reproduction)	Not determined*	Not determined*
LOER (Reproduction)	Not determined*	Not determined*
7-DAA Bioassay: 7-day aged residues		
LR ₅₀ (Mortality)	<300 [95%-CLs: n.d.]	<60 [95%-CLs: n.d.]
NOER (Mortality)	<300	<60
LOER (Mortality)	≤300	≤60
ER ₅₀ (Reproduction)	Not determined*	Not determined*
NOER (Reproduction)	Not determined*	Not determined*
LOER (Reproduction)	Not determined*	Not determined*
14-DAA Bioassay: 14-day aged residues		
LR ₅₀ (Mortality)	>500 [95%-CLs: 384.89 – U.L. n.d.]	>100 [95%-CLs: 76.98 – U.L. n.d.]
NOER (Mortality)	300	60
LOER (Mortality)	400	80
ER ₅₀ (Reproduction)	>400 [95%-CLs: n.d.]	>80 [95%-CLs: n.d.]
NOER (Reproduction)	<300	<60
LOER (Reproduction)	≤300	≤60
21-DAA Bioassay: 21-day aged residues		
LR ₅₀ (Mortality)	>500 [95%-CLs: n.d.]	>100 [95%-CLs: n.d.]
NOER (Mortality)	≥500	≥100
LOER (Mortality)	>500	>100
ER ₁₀ (Reproduction)	<300 [95%-CLs: n.d.]	<60 [95%-CLs: n.d.]
ER ₂₀ (Reproduction)	<300 [95%-CLs: n.d.]	<60 [95%-CLs: n.d.]
ER ₅₀ (Reproduction)	>500 [95%-CLs: n.d.]	>100 [95%-CLs: n.d.]
NOER (Reproduction)	<300	<60
LOER (Reproduction)	≤300	≤60

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28-DAA Bioassay: 28-day aged residues		
LR ₅₀ (Mortality)	>500 [95%-CLs: n.d.]	>100 [95%-CLs: n.d.]
NOER (Mortality)	≥500	≥100
LOER (Mortality)	>500	>100
ER ₁₀ (Reproduction)	<300 [95%-CLs: n.d.]	<60 [95%-CLs: n.d.]
ER ₂₀ (Reproduction)	453.12 [95%-CLs: 326.14 – U.L n.d.]	90.62 [95%-CLs: 65.23 – U.L n.d.]
ER ₅₀ (Reproduction)	>500 [95%-CLs: n.d.]	>100 [95%-CLs: n.d.]
NOER (Reproduction)	≥500	≥100
LOER (Reproduction)	>500	>100
35-DAA Bioassay: 35-day aged residues		
LR ₅₀ (Mortality)	>500 [95%-CLs: n.d.]	>100 [95%-CLs: n.d.]
NOER (Mortality)	≥500	≥100
LOER (Mortality)	>500	>100
ER ₁₀ (Reproduction)	>400 [95%-CLs: n.d.]	>80 [95%-CLs: n.d.]
ER ₂₀ (Reproduction)	>500 [95%-CLs: n.d.]	>100 [95%-CLs: n.d.]
ER ₅₀ (Reproduction)	>500 [95%-CLs: n.d.]	>100 [95%-CLs: n.d.]
NOER (Reproduction)	≥500	≥100
LOER (Reproduction)	>500	>100

Note: the LR₅₀ and EC₅₀ values were estimated, therefore no confidence limits were provided (95%-CL n.d. = not determined)

*The NOEC, LOEC and ER₅₀ could not be determined, because there were not responses

#The active ingredient content was calculate based on the nominal test item content of 200 g/L

95%-CLs, Confidence Limits

n.d.: not determined due to mathematical reasons

95%- U.L., Upper Limit

Comments of zRMS:	The study was accepted by zRMS. The validity criteria was met:
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	Mortality in the control groups on day 7	Bioassay 1 at 0 DAA	Actual value was 11.00%, therefore, the validity criterion was met.
		Bioassay 2 at 7 DAA	Actual value was 7.00%, therefore, the validity criterion was met.
		Bioassay 3 at 14 DAA	Actual value was 8.00%, therefore, the validity criterion was met.
	Reproduction in the control groups	Bioassay 1 at 0 DAA	The mean cumulative number of eggs per female was 7.76, so this validity criterion was met.
		Bioassay 2 at 7 DAA	The mean cumulative number of eggs per female was 7.11, so this validity criterion was met.
		Bioassay 3 at 14 DAA	The mean cumulative number of eggs per female was 6.85, so this validity criterion was met.
	Mortality in the reference group on day 7	Bioassay 1 at 0 DAA	Actual value was 79.00% (corrected value 76.40%), so the validity criterion was met.
		Bioassay 2 at 7 DAA	Actual value was 66.00% (corrected value 63.44%), so the validity criterion was met.
		Bioassay 3 at 14 DAA	Actual value was 59.00% (corrected value 55.43%), so the validity criterion was met.
	Agreed toxicity endpoints:		
	Endpoints	mL test item/ha	g a.i./ha*
	0-DAA Bioassay: fresh residues		
	LR ₅₀ (Mortality)	>500 [95%-CLs n.d.]	>100 [95%-CLs n.d.]
	NOER (Mortality)	400	80
	LOER (Mortality)	500	100
	ER ₅₀ (Reproduction)	>500 [95%-CLs n.d.]	>100 [95%-CLs n.d.]
	NOER (Reproduction)	≥500	≥100
	LOER (Reproduction)	>500	>100
	7-DAA Bioassay: 7-day aged residues		
	LR ₁₀ (Mortality)	>500 [442.58 – U.L. n.d.]	>100 [88.52 – U.L. n.d.]
	LR ₂₀ (Mortality)	>500 [95%-CLs n.d.]	>100 [95%-CLs n.d.]
	LR ₅₀ (Mortality)	>500 [95%-CLs n.d.]	>100 [95%-CLs n.d.]
	NOER (Mortality)	≥500	≥100
	LOER (Mortality)	>500	>100
	ER ₅₀ (Reproduction)	>500 [95%-CLs n.d.]	>100 [95%-CLs n.d.]
	NOER (Reproduction)	≥500	≥100
	LOER (Reproduction)	>500	>100
	14-DAA Bioassay: 14-day aged residues		
	LR ₅₀ (Mortality)	>500 [95%-CLs n.d.]	>100 [95%-CLs n.d.]
	NOER (Mortality)	≥500	≥100
	LOER (Mortality)	>500	>100
	ER ₅₀ (Reproduction)	>500 [95%-CLs n.d.]	>100 [95%-CLs n.d.]
	NOER (Reproduction)	≥500	≥100
	LOER (Reproduction)	>500	>100

*The active ingredient content was calculate based on the nominal test item content of 200 g/L
95%- U.L., Upper Limit
95%-CLs, Confidence Limits
n.d.: not determined due to mathematical reasons

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Reference:	KCP 10.3.2.2/02
Report	Effects of Acetamipryd 200 SL on on <i>Typhlodromus pyri</i> – Extended laboratory aged residue test; Mautino G.; 2023; Study Code: 1037.I.SAG23/r
Guideline(s):	Yes, SETAC; ESCORT; IOBC/BART/EPPO
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

MATERIALS AND METHODS

1. Test material

Test item (chemical/other name):	Acetamipryd 200 SL
Formulation:	200 g/L (nominal content)
Description (physical state):	liquid
Batch no.:	1/ACE/2022
Production date:	01.2022
Expiration date:	01.2024

2. Vehicle and/or positive control:

vehicle: distilled water
positive control: ROGOR L 40 ST (nominally 400 g dimetho-
ate/L)

3. Test organism

Species:	Acari, Phytoseiidae (<i>Typhlodromus pyri</i>)
Source:	Katz Biotech AG, Baruth, Germany
Age:	protonymphs ≤24 hours old
Acclimation period:	1 day under test conditions in an incubator
Diet:	apple (<i>Malus domestica</i>) pollen, added at the day of the test start and at each assessment day, except for the last one
Test units:	one leaf disc (44-mm Ø) placed in a glass petri dish lid (54-mm Ø), with a central hole (6-mm Ø), located on a grid immersed in water, all systems were contained within a plastic container (250 × 250 × 80 mm)

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Plants: Taxonomic group: Fabaceae
Common name: Bean
Species: *Phaseolus vulgaris* L.
Variety: Bingo
Source: Agricola Albese (Alba, CN)
Cultivation substrate: artificial soil
Sowing date: 27 Mar 2023
Emergence date: 01 Apr 2023
Grown site: open field under a rain cover (N44° 44' 48.88"; E08° 04' 09.00). Length: 39 m; width: 6 m; height: 2.10 m)
Stage at test start: BBCH 18-19
Maintenance: automatic drip irrigation 3 times a day (3 minutes each) with a water volume of 2L/ha
Agrochemical and fertilizer: none

4. Environmental conditions:

Temperature: 24.52 ± 0.178 °C (24.32 – 24.95 °C)
Relative humidity: $79.0 \pm 3.0\%$ (70.7 – 82.7% RH)
Photoperiod: 16 h light : 8 h dark

STUDY DESIGN AND METHOD

The aim of the study was to determine the product persistence, intended as the decline rate of residues (fresh and aged) on bean plants treated once with the test item Acetamipryd 200 SL (acetamiprid 200 g/L), growing under rain-protected field conditions. Mites were exposed to fresh and aged residue of the test item at different timings (bioassay) after application (DAA). Three bioassays were investigated: bioassay 1, where mites were introduced immediately after the application on dried discs (0 DAA); bioassay 2, where mites were introduced 7 days after the application (7 DAA) and bioassay 3, where mites were introduced 14 days after the application (14 DAA). At each bioassay, residual toxicity was evaluated by assessing *Typhlodromus pyri* mortality after 3 and 7 days of exposure to the test item, using bean leaf discs cut out from treated bean plants. Mite reproduction was also assessed; the test units were maintained for 7 additional days, during which the number of juveniles and eggs were counted (i.e., 9, 11, and 14 days after the application). The effects of the test item were compared with a control group and a reference item.

The study consisted of 5 treatments (3 concentrations of the test item, 1 control group, 1 reference item), with 5 replicates, each containing 20 mites. Mites were exposed to fresh or aged residues on bean leaf discs at three different times: 0, 7, and 14 days after application (DAA). For each time (bioassay), mortality was assessed after 3 and 7 days of exposure. Then at day 7, surviving mites from the control and test-item groups were evaluated for reproduction; the number of eggs and juveniles per female was counted 9, 11, and 14 days after the application.

Test design: tested concentrations, reference item and control in 5 replications, number of mites: 20 mites/replicate

Exposure time: 14 days (7 days of mortality phase + 7 days of fecundity test)

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Tested concentrations, definitive test:	300 mL test item/ha (60 g acetamiprid/ha) – T2 400 mL test item/ha (80 g acetamiprid/ha) – T3 500 mL test item/ha (100 g acetamiprid/ha) – T4 400 L water/ha
Stability of test compound:	-
Dates:	start of the study: 20.04.2023 start of the experimental part: 24.04.2023 end of the experimental part: 22.05.2023 end of the study: 15.11.2023
Statistic:	Software used for statistical analysis were “ToxRatPro” Solutions GmbH, version 3.3.0. Mortality data were processed using the Cochran-Armitage test and Chi ² 2×2 Table test with or without (reference item) Bonferroni Correction, $\alpha \leq 0.05$. Correction for control mortality was processed using the Schneider-Orelli formula. Reproduction data were analysed with Dunnett's t-test, $\alpha \leq 0.05$. For all bioassays, the LR50 (mortality) and ER50 (reproduction) values could not be calculated, because data were not appropriate for the computation, the number of responses was less than three. The No Observed Effect Rate (NOER) and Lowest Observed Effect Rate (LOER) values for mortality and reproduction were determined, where possible.
Validity of the test:	The following criteria for each bioassay should be satisfied for a test result to be considered valid: - mortality in the control group $\leq 20\%$ on day 7; - mean cumulative number of eggs per female in the control group ≥ 4 ; - corrected mortality between 50% and 100% in the reference item on day 7.

RESULTS

Bioassay 1 – mortality (0 DAA)

Mean mortality at 3 days of exposure ranged from 12.00% in treatment T2 (Acetamipryd 200 SL at 300 mL f.p./ha) to 19.00% in treatment T4 (Acetamipryd 200 SL at 500 mL f.p./ha). The control and reference item groups showed a mortality of 9.00% and 71.00%, respectively. Mean mortality at day 7 ranged from 15.00% in treatment T2 (Acetamipryd 200 SL at 300 mL f.p./ha, corrected mortality: 4.49%) to 32.00% in treatment T4 (Acetamipryd 200 SL at 500 mL f.p./ha, corrected mortality: 23.60%). The control and reference item groups showed a mortality of 11.00% and 79.00% (corrected value: 76.40%), respectively. Significant differences were noticed for all the test item dosages, except T4 (Acetamipryd 200 SL at 500 mL f.p./ha) in comparison to the control group. The calculated NOER (mortality) value was 400 mL test item/ha (80 g a.i./ha), while calculated LOER (mortality) value was 500 mL test item/ha (100 g a.i./ha).

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Table KCP 10.3.2.2-20: Summary of results from the mortality assessment (bioassay 1 – 0 DAA)

	Treatment	Rate (g a.i./ha)	Check at 3 days Mortality (%)	Check at 7 days			
				Mortality (%)	SE ^a	p ^b	Corrected mortality ^c (%)
T1	Control	0	9.00	11.00	±0.37	-	-
T2	Acetamipryd 200 SL at 300 mL f.p./ha	60	12.00	15.00	±0.55	n.s.	4.49
T3	Acetamipryd 200 SL at 400 mL f.p./ha	80	13.00	19.00	±0.58	n.s.	8.99
T4	Acetamipryd 200 SL at 500 mL f.p./ha	100	19.00	32.00	±0.93	***	23.60
T5	ROGOR L 40 ST 18 mL f.p./ha	7.20	71.00	79.00	±0.37	***	76.40

a.i., acetamiprid

^a, standard error from 5 replicates

^b, Chi² 2×2 Table test without Bonferroni Correction (reference item ROGOR L 40 ST), α≤0.001 ***, 0.01 **, 0.05 *

^c, mean mortality corrected by Schneider-Orelli's formula

-, not applicable

Bioassay 2 – mortality (7 DAA)

Mean mortality at 3 days of exposure ranged from 7.00% in treatment T3 (Acetamipryd 200 SL at 400 mL f.p./ha) to 9.00% in treatment T4 (Acetamipryd 200 SL at 500 mL f.p./ha). The control and reference item groups showed a mortality of 3.00% and 63.00%, respectively. Mean mortality at day 7 ranged from 8.00% in treatment T2 (Acetamipryd 200 SL at 300 mL f.p./ha, corrected mortality: 1.08%) to 16.00% in treatment T4 (Acetamipryd 200 SL at 500 mL f.p./ha, corrected mortality: 9.68%). The control and reference item groups showed a mortality of 7.00% and 66.00% (corrected mortality: 63.44%), respectively. No significant differences were noticed for test item dosages in comparison to the control group.

Table KCP 10.3.2.2-21: Summary of results from the mortality assessment (bioassay 2 – 7 DAA)

	Treatment	Rate (g a.i./ha)	Check at 3 days Mortality (%)	Check at 7 days			
				Mortality (%)	SE ^a	p ^b	Corrected mortality ^c (%)
T1	Control	0	3.00	7.00	±0.40	-	-
T2	Acetamipryd 200 SL at 300 mL f.p./ha	60	8.00	8.00	±0.40	n.s.	1.08
T3	Acetamipryd 200 SL at 400 mL f.p./ha	80	7.00	11.00	±0.37	n.s.	4.30
T4	Acetamipryd 200 SL at 500 mL f.p./ha	100	9.00	16.00	±0.58	n.s.	9.68
T5	ROGOR L 40 ST 18 mL f.p./ha	7.20	63.00	66.00	±0.86	***	63.44

a.i., acetamiprid

^a, standard error from 5 replicates

^b, Chi² 2×2 Table test without Bonferroni Correction (reference item ROGOR L 40 ST), α≤0.001 ***, 0.01 **, 0.05 *

^c, mean mortality corrected by Schneider-Orelli's formula

-, not applicable

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Bioassay 3 – mortality (14 DAA)

Mean mortality at 3 days of exposure ranged from 7.00% in treatment T2 (Acetamipryd 200 SL at 300 mL f.p./ha) to 12.00% in treatment T3 (Acetamipryd 200 SL at 400 mL f.p./ha) and T4 (Acetamipryd 200 SL at 500 mL f.p./ha). The control and reference item groups showed a mortality of 8.00% and 53.00%, respectively. Mean mortality at day 7 ranged from 7.00% in treatment T2 (Acetamipryd 200 SL at 1000 mL f.p./ha, corrected mortality: -1.09%) to 12.00% in both treatments T3 (Acetamipryd 200 SL at 400 mL f.p./ha) and T4 (Acetamipryd 200 SL at 500 mL f.p./ha, corrected mortality: 4.35%). The control and reference item groups showed a mortality of 8.00% and 59.00% (corrected mortality: 55.43%), respectively. No significant differences were noticed for test item dosages in comparison to the control group.

Table KCP 10.3.2.2-22: Summary of results from the mortality assessment (bioassay 3 – 14 DAA)

	Treatment	Rate (g a.i./ha)	Check at 3 days Mortality (%)	Check at 7 days			
				Mortality (%)	SE ^a	p ^b	Corrected mortality ^c (%)
T1	Control	0	8.00	8.00	±0.40	-	-
T2	Acetamipryd 200 SL at 300 mL f.p./ha	60	7.00	7.00	±0.51	n.s.	-1.09
T3	Acetamipryd 200 SL at 400 mL f.p./ha	80	12.00	12.00	±0.24	n.s.	4.35
T4	Acetamipryd 200 SL at 500 mL f.p./ha	100	12.00	12.00	±0.75	n.s.	4.35
T5	ROGOR L 40 ST 18 mL f.p./ha	7.20	53.00	59.00	±0.66	***	55.43

a.i., acetamiprid

^a, standard error from 5 replicates

^b, Chi² 2×2 Table test without Bonferroni Correction (reference item ROGOR L 40 ST), α≤0.001 ***, 0.01 **, 0.05 *

^c, mean mortality corrected by Schneider-Orelli's formula

-, not applicable

Bioassay 1 – reproduction (0 DAA)

The mean number of eggs was 7.22 in treatment T4 (Acetamipryd 200 SL at 500 mL f.p./ha) and 7.79 in treatment T2 (Acetamipryd 200 SL at 300 mL f.p./ha). None significantly effect was observed for the treatments in comparison to the control group, which showed a mean cumulative number of eggs of 7.76. The 14-day NOER (reproduction) value was determined to be ≥ 500 mL test item/ha (≥ 100 g a.i./ha) and the calculated 14-d LOER (reproduction) value was > 500 mL test item/ha (> 100 g a.i./ha).

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Table KCP 10.3.2.2-23: Summary of results from the reproduction assessment (bioassay 1 – 0 DAA)

	Treatment	Rate (g a.i./ha)	Mean cumulative number of eggs per female	Standard error ^a	Effect on reproduction (R%)	<i>p</i> ^b
T1	Control	0	7.76	±0.27	-	-
T2	Acetamipryd 200 SL at 300 mL f.p./ha	60	7.79	±0.30	-0.42	n.s.
T3	Acetamipryd 200 SL at 400 mL f.p./ha	80	7.72	±0.67	0.49	n.s.
T4	Acetamipryd 200 SL at 500 mL f.p./ha	100	7.22	±0.85	6.88	n.s.

a.i., acetamiprid

^a, standard error from 5 replicates

^b, Dunnett's t-test, α=0.05 *

-, not applicable

n.s., not significantly different compared to the control

Bioassay 2 – reproduction (7 DAA)

The mean number of eggs was 6.80 in treatment T4 (Acetamipryd 200 SL at 500 mL f.p./ha) and 7.12 in treatment T2 (Acetamipryd 200 SL at 300 mL f.p./ha). None significantly effect was observed for the treatments in comparison to the control group, which showed a mean cumulative number of eggs of 7.11. The calculated 14-day NOER (reproduction) value was ≥ 500 mL test item/ha (≥ 100 g a.i./ha) and the 14-d LOER (reproduction) value was determined to be > 500 mL test item/ha (> 100 g a.i./ha).

Table KCP 10.3.2.2-24: Summary of results from the reproduction assessment (bioassay 2 – 14 DAA)

	Treatment	Rate (g a.i./ha)	Mean cumulative number of eggs per female	Standard error ^a	Effect on reproduction (R%)	<i>p</i> ^b
T1	Control	0	7.11	±0.62	-	-
T2	Acetamipryd 200 SL at 300 mL f.p./ha	60	7.12	±0.66	-0.10	n.s.
T3	Acetamipryd 200 SL at 400 mL f.p./ha	80	7.13	±0.59	-0.23	n.s.
T4	Acetamipryd 200 SL at 500 mL f.p./ha	100	6.80	±0.91	4.32	n.s.

a.i., acetamiprid

^a, standard error from 5 replicates

^b, Dunnett's t-test, α=0.05 *

-, not applicable

n.s., not significantly different compared to the control

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Bioassay 3 – reproduction (14 DAA)

The mean number of eggs was 6.72 in treatment T4 (Acetamipryd 200 SL at 500 mL f.p./ha) and 6.95 in treatment T2 (Acetamipryd 200 SL at 300 mL f.p./ha). None significantly effect was observed for the treatments in comparison to the control group, which showed a mean cumulative number of eggs of 6.85. The 14-day NOER (reproduction) value was determined to be ≥ 500 mL test item/ha (≥ 100 g a.i./ha) and the calculated 14-d LOER (reproduction) value was > 500 mL test item/ha (> 100 g a.i./ha).

Table KCP 10.3.2.2-25: Summary of results from the reproduction assessment (bioassay 3 – 21 DAA)

	Treatment	Rate (g a.i./ha)	Mean cumulative number of eggs per female	Standard error ^a	Effect on reproduction (R%)	<i>p</i> ^b
T1	Control	0	6.85	±0.49	-	-
T2	Acetamipryd 200 SL at 300 mL f.p./ha	60	6.95	±0.31	-1.37	n.s.
T3	Acetamipryd 200 SL at 400 mL f.p./ha	80	6.82	±0.38	0.45	n.s.
T4	Acetamipryd 200 SL at 500 mL f.p./ha	100	6.72	±0.45	2.01	n.s.

a.i., acetamipryd

^a, standard error from 5 replicates

^b, Dunnett's t-test, $\alpha=0.05$ *

-, not applicable

n.s., not significantly different compared to the control

CONCLUSION

The obtained endpoints have been summarised below.

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Table KCP 10.3.2.2-26: Endpoints for mortality and reproduction (Bioassay 1 at 0 DAA, 2 at 7 DAA and 3 at 14 DAA)

Endpoints	mL test item/ha	g a.i./ha*
0-DAA Bioassay: fresh residues		
LR ₅₀ (Mortality)	>500 [95%-CLs n.d.]	>100 [95%-CLs n.d.]
NOER (Mortality)	400	80
LOER (Mortality)	500	100
ER ₅₀ (Reproduction)	>500 [95%-CLs n.d.]	>100 [95%-CLs n.d.]
NOER (Reproduction)	≥500	≥100
LOER (Reproduction)	>500	>100
7-DAA Bioassay: 7-day aged residues		
LR ₁₀ (Mortality)	>500 [442.58 – U.L. n.d.]	>100 [88.52 – U.L. n.d.]
LR ₂₀ (Mortality)	>500 [95%-CLs n.d.]	>100 [95%-CLs n.d.]
LR ₅₀ (Mortality)	>500 [95%-CLs n.d.]	>100 [95%-CLs n.d.]
NOER (Mortality)	≥500	≥100
LOER (Mortality)	>500	>100
ER ₅₀ (Reproduction)	>500 [95%-CLs n.d.]	>100 [95%-CLs n.d.]
NOER (Reproduction)	≥500	≥100
LOER (Reproduction)	>500	>100
14-DAA Bioassay: 14-day aged residues		
LR ₅₀ (Mortality)	>500 [95%-CLs n.d.]	>100 [95%-CLs n.d.]
NOER (Mortality)	≥500	≥100
LOER (Mortality)	>500	>100
ER ₅₀ (Reproduction)	>500 [95%-CLs n.d.]	>100 [95%-CLs n.d.]
NOER (Reproduction)	≥500	≥100
LOER (Reproduction)	>500	>100

*The active ingredient content was calculate based on the nominal test item content of 200 g/L
95%- U.L., Upper Limit
95%-CLs, Confidence Limits
n.d.: not determined due to mathematical reasons

Comments of zRMS:	The study was accepted by zRMS. The validity criteria was met:
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Mean mortality of larvae in the water treated control should not exceed 30% Mean mortality of larvae in the toxic reference treatment should be higher than 40% No. 2 fertile eggs per viable female per day		
Mortality in control check	Bioassay 1 at 0 DAA	Mortality was 12.50%, therefore, the validity criterion was met.
	Bioassay 2 at 7 DAA	Mortality was 17.50%, therefore, the validity criterion was met.
	Bioassay 3 at 14 DAA	Mortality was 17.50%, therefore, the validity criterion was met.
	Bioassay 4 at 21 DAA	Mortality was 25.00%, therefore, the validity criterion was met.
	Bioassay 5 at 28 DAA	Mortality was 10.00%, therefore, the validity criterion was met.
	Bioassay 6 at 35 DAA	Mortality was 15.00%, therefore, the validity criterion was met.
Reproduction in control check	Bioassay 3 at 14 DAA	The mean number of eggs per female per day was 14.19, so this validity criterion was met.
	Bioassay 4 at 21 DAA	The mean number of eggs per female per day was 14.32, so this validity criterion was met.
	Bioassay 5 at 28 DAA	The mean number of eggs per female per day was 13.24, so this validity criterion was met.
	Bioassay 6 at 35 DAA	The mean number of eggs per female per day was 11.96, so this validity criterion was met.
Mortality in reference	Bioassay 1 at 0 DAA	Mortality was 92.50% (corrected value 91.43%) in the toxic reference treatment and so the validity criterion was met.
	Bioassay 2 at 7 DAA	Mortality was 82.50% (corrected value 78.79%) in the toxic reference treatment and so the validity criterion was met.
	Bioassay 3 at 14 DAA	Mortality was 65.00% (corrected value 57.58%) in the toxic reference treatment and so the validity criterion was met.
	Bioassay 4 at 21 DAA	Mortality was 65.00% (corrected value 53.33%) in the toxic reference treatment and so the validity criterion was met.
	Bioassay 5 at 28 DAA	Mortality was 45.00% (corrected value 38.89%) in the toxic reference treatment and so the validity criterion was met.
	Bioassay 6 at 35 DAA	Mortality was 35.00% (corrected value 23.53%) in the toxic reference treatment and so the validity criterion was met.
Agreed toxicity endpoints:		

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Table 2a. Endpoints for the 0 DAA, 7 DAA and 14 DAA bioassay		
Endpoints	mL test item/ha	g a.i./ha*
0-DAA Bioassay: fresh residues		
LR ₁₀	<300	<60
LR ₅₀	<300 [95%-CLs n.d.]	<60 [95%-CLs n.d.]
NOER (Mortality)	<300	<60
LOER (Mortality)	300	60
7-DAA Bioassay: 7-day aged residues		
LR ₁₀	<300	<60
LR ₅₀	<300 [95%-CLs n.d.]	<60 [95%-CLs n.d.]
NOER (Mortality)	<300	<60
LOER (Mortality)	300	60
14-DAA Bioassay: 14-day aged residues		
LR ₁₀	<300	<60
LR ₅₀	<400 [95%-CLs n.d.]	<80 [95%-CLs n.d.]
NOER (Mortality)	<300	<60
LOER (Mortality)	300	60
*The active ingredient content was calculate based on the nominal test item content of 200 g/L acetamiprid Note: the LR ₅₀ value were estimated, therefore no confidence limits were provided (95%-CLs n.d. = not determined)		

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Table 2b. Endpoints for the 21 DAA, 28 DAA and 35 DAA bioassay		
Endpoints	mL test item/ha	g a.i./ha*
21-DAA Bioassay: 21-day aged residues		
LR ₁₀	<300	<60
LR ₅₀	437.34 [300 – 500]	87.47 [60 – 100]
NOER (Mortality)	<300	<60
LOER (Mortality)	300	60
28-DAA Bioassay: 7-day aged residues		
LR ₁₀	<300	<60
LR ₅₀	>500 [95%-CLs n.d.]	>100 [95%-CLs n.d.]
NOER (Mortality)	300	60
LOER (Mortality)	400	80
35-DAA Bioassay: 14-day aged residues		
LR ₁₀	<300	<60
LR ₂₀	>300	>60
LR ₅₀	>500 [95%-CLs n.d.]	>100 [95%-CLs n.d.]
NOER (Mortality)	≥500	≥100
LOER (Mortality)	>500	>100
*The active ingredient content was calculate based on the nominal test item content of 200 g/L acetamiprid Note: where the LR ₅₀ value were estimated, no confidence limits were provided (95%-CLs n.d. = not determined)		

Reference: KCP 10.3.2.2/03

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Mautino G.; 2024; Study Code: 1035.I.SAG23/r

Guideline(s): Yes, SETAC; ESCORT; IOBC/BART/EPPO

Deviations: No

GLP: Yes

Acceptability: Yes

Duplication No
(if vertebrate study)

MATERIALS AND METHODS

1. Test material

Test item (chemical/other name): Acetamipryd 200 SL

Formulation: 200 g/L (nominal content)

Description (physical state): liquid

Batch no.: 1/ACE/2022

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Production date:	01.2022
Expiration date:	01.2024
2. Vehicle and/or positive control:	vehicle: deionised water positive control: ROGOR L 40 ST (nominally 400 g dimetho- ate/L)
3. Test organism	
Species:	Coleoptera, Coccinellidae, <i>Coccinella septempunctata</i> L.
Source:	Katz Biotech AG, Baruth, Germany
Age:	first instar larvae, 3-day old
Acclimation period:	3 days before test start
Diet:	During the mortality assessments larvae were fed ad libi- tum with aphids (<i>Acyrtosiphon pisum</i> Mordv.) of mixed stages. During the fecundity evaluation, ladybirds were fed daily with honey and 3-4 aphid infested (<i>Acyrtosi- phon pisum</i>) broad bean stems. Plastic tubes filled with water and closed with a cotton wool were also provided for water supply. Water was provided permanently in a reservoir and replaced at least once a week.
Test units:	Mortality assessment: Cylinder (45.8 mm Ø x 50 mm) of transparent plastic provided with PTFE (politetrafluoro- etilene), a perforated lid (28 mm Ø) and with an insect proof net. The cylinder was inserted into a plate provided with a leaf disc of bean (50 mm Ø) leaning on two filter paper layers and blocked to it by rubbers, arranged in a cross design. Fecundity assessment Transparent plastic boxes (145 × 135 × 85 mm) with a perforated lid provided with an in- sect proof net for aeration. At the box bottom one layer of filter paper, while inside, three pieces of bubble wrap (PE) and a dark plastic cylinder, as oviposition substrate. Egg clutches were stored in individually labelled plastic containers (60 mL in volume) until larval hatch, over a wet layer of filter paper.

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Plants: Taxonomic group: Fabaceae
Common name: bean
Species: *Phaseolus vulgaris* L.
Variety: Bingo
Source: Agricola Albese (Alba, CN)
Cultivation substrate: natural soil
Sowing date: 30 Mar 2023
Emergence date: 04 Apr 2023
Grown site: open field under a rain cover (N44° 44' 48.88"; E08° 04' 09.00). Length: 39 m; width: 6 m; height: 2.10 m)
Stage for test start: BBCH 18-19
Maintenance: automatic drip irrigation, three irrigation events per day
Agrochemicals and/or fertilizers: none

4. Environmental conditions:

Temperature: 24.22 ± 0.240 °C (23.74 – 24.81 °C)
Relative humidity: $80.0 \pm 2.6\%$ (74.5 – 85.7%)
Photoperiod: 16 hours light : 8 hours dark, light intensity 1850-2200 lx

STUDY DESIGN AND METHOD

The aim of the study was to determine the product persistence, intended as the rate of decline of residues (fresh and aged) on bean leaves of plants growing under rain-protected field conditions treated with test item Acetamipryd 200 SL. Residual toxicity was evaluated observing the effects on *Coccinella septempunctata* mortality over time and to evaluate the sub-lethal effects on insect fecundity subsequent to their exposure to the test item at different timings (bioassay) after application (DAA). Three bioassays were investigated: bioassay 1, where insects were introduced immediately after the application on dried leaf discs (0 DAA); bioassay 2, where insects were introduced 7 days after the application (7 DAA); bioassay 3, where insects were introduced 14 days after the application (14 DAA); bioassay 4, where insects were introduced 21 days after the application (21 DAA); bioassay 5, where insects were introduced 28 days after the application (28 DAA) and bioassay 6, where insects were introduced 35 days after the application (35 DAA). The effects of the test item were compared with a control group and a reference item.

The test item was applied once on bean plants. The study encompassed 4 treatments (3 rates of the test item, 1 control group, 1 reference item) with 40 replicates each containing 1 larva. The larvae were exposed to fresh and aged residue on bean leaf discs at three different times: 0, 7, 14, 21, 28 and 35 days after application (DAA). At the end of this period, the observations consisted in recording percent mortality; when the survived pupae were hatch in the control, females and males (adults) were sexed, assessed for their reproductive performance and transferred to the mass-rearing units. The reproduction test started one week after the first egg laying observation. Insects' oviposition was checked daily for up to 14 days. The eggs-hatching was assessed. Alive beetles were recorded. Reproductive performance was evaluated only qualitatively due to the very high species-inherent variability in egg-laying performance. The mean number of eggs laid per female per day and the egg hatching rate were assessed.

Test design: 40 replicates per group, 1 larva per replicate

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Tested concentrations, definitive test: 300 mL test item/ha (60 g acetamiprid/ha) – T2
400 mL test item/ha (80 g acetamiprid/ha) – T3
500 mL test item/ha (100 g acetamiprid/ha) – T4
400 L water/ha

Stability of test compound:

Dates: start of the study: 07.06.2023
start of the experimental part: 21.06.2023
end of the experimental part: 22.09.2023
end of the study: 10.01.2024

Statistic: Software used for statistical analysis were “ToxRatPro” Solutions GmbH, version 3.3.0. Mortality data were processed using the Cochran-Armitage and χ^2 2x2 Table tests, $\alpha \leq 0.05$. Correction for control mortality was processed using the Schneider-Orelli formula. Reproductive performance was evaluated only qualitatively due to the very high species-inherent variability in egg-laying performance. For all bioassays, at least the LR50 (mortality) value was determined, where possible. The No Observed Effect Rate (NOER) and Lowest Observed Effect Rate (LOER) values for mortality were determined, where possible.

Validity of the test: The following criteria should be satisfied in the control for a test result to be considered valid:
- mean mortality of larvae in the water treated control should not exceed 30%;
- mean mortality of larvae in the toxic reference treatment should be higher than 40%;
- no. 2 fertile eggs per viable female per day.

RESULTS

Bioassay 1 – mortality (0 DAA)

For test item Acetamipryd 200 SL, mean mortality ranged from 80.00% (corrected value: 77.14%) to 100.00% in treatments T2 (60 mL test item/ha) and T4 (500 mL test item/ha), respectively. The control group and reference item showed a mortality of 12.50% and 92.50% (corrected value: 91.43%), respectively.

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Table KCP 10.3.2.2-27: Average percentage of *Coccinella septempunctata* mortality (Bioassay 1 – 0 DAA)

Treatment number	Treatment rate		Mortality (%) \pm SE ^a		P ^b	Corrected mortality ^c (%)
	mL f.p./ha	g a.i./ha				
T1	0 (Control)	0	12.50	\pm 0.05	-	-
T2	300	60	80.00	\pm 0.06	***	77.14
T3	400	80	85.00	\pm 0.06	***	82.86
T4	500	100	100.00	\pm 0.00	***	100.00
T5	ROGOR L40 ST at 18 mL/ha	7.2 g dimethoate/ha	92.50	\pm 0.04	***	91.43

f.p. = formulated product

a.i. = acetamiprid 200 g/L

^a, standard error from 40 replicates

^b, Cochran-Armitage test and Chi² 2x2 Table test (reference item ROGOR L40 ST), $\alpha \leq 0.001$ ***, 0.01 **, 0.05 *

^c, mean mortality corrected by Schneider-Orelli's formula

-, not applicable

Bioassay 2 – mortality (7 DAA)

For test item Acetamipryd 200 SL, mean mortality ranged from 67.50% (corrected value: 60.61%) to 100.00% in treatments T2 (60 mL test item/ha) and T4 (500 mL test item/ha), respectively. The control group and reference item showed a mortality of 17.50% and 82.50% (corrected value: 78.79%), respectively.

Table KCP 10.3.2.2-28: Average percentage of *Coccinella septempunctata* mortality (Bioassay 2 – 7 DAA)

Treatment number	Treatment rate		Mortality (%) \pm SE ^a		P ^b	Corrected mortality ^c (%)
	mL f.p./ha	g a.i./ha				
T1	0 (Control)	0	17.50	\pm 0.06	-	-
T2	300	60	67.50	\pm 0.08	***	60.61
T3	400	80	82.50	\pm 0.06	***	78.79
T4	500	100	100.00	\pm 0.00	***	100.00
T5	ROGOR L40 ST at 18 mL/ha	7.2 g dimethoate/ha	82.50	\pm 0.06	***	78.79

f.p. = formulated product

a.i. = acetamiprid 200 g/L

^a, standard error from 40 replicates

^b, Cochran-Armitage test and Chi² 2x2 Table test (reference item ROGOR L40 ST), $\alpha \leq 0.001$ ***, 0.01 **, 0.05 *

^c, mean mortality corrected by Schneider-Orelli's formula

-, not applicable

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Bioassay 3 – mortality (14 DAA)

For test item Acetamipryd 200 SL, mean mortality ranged from 52.50% (corrected value: 42.42%) to 90.00% (corrected value: 87.88%) in treatments T2 (60 mL test item/ha) and T4 (500 mL test item/ha), respectively. The control group and reference item showed a mortality of 17.50% and 65.00% (corrected value: 57.58%), respectively.

Table KCP 10.3.2.2-29: Average percentage of *Coccinella septempunctata* mortality (Bioassay 3 – 14 DAA)

Treatment number	Treatment rate		Mortality (%) \pm SE ^a		P ^b	Corrected mortality ^c (%)
	mL f.p./ha	g a.i./ha				
T1	0 (Control)	0	17.50	\pm 0.06	-	-
T2	300	60	52.50	\pm 0.08	***	42.42
T3	400	80	70.00	\pm 0.07	***	63.64
T4	500	100	90.00	\pm 0.05	***	87.88
T5	ROGOR L40 ST at 18 mL/ha	7.2 g dimethoate/ha	65.00	\pm 0.08	***	57.58

f.p. = formulated product

a.i. = acetamiprid 200 g/L

^a, standard error from 40 replicates

^b, Cochran-Armitage test and Chi² 2x2 Table test (reference item ROGOR L40 ST), $\alpha \leq 0.001$ ***, 0.01 **, 0.05 *

^c, mean mortality corrected by Schneider-Orelli's formula

-, not applicable

Bioassay 4 – mortality (21 DAA)

For test item Acetamipryd 200 SL, mean mortality ranged from 50.00% (corrected value: 33.33%) to 70.00% (corrected value: 60.00%) in treatments T2 (60 mL test item/ha) and T4 (500 mL test item/ha), respectively. The control group and reference item showed a mortality of 25.00% and 65.00% (corrected value: 53.33%), respectively.

Table KCP 10.3.2.2-30: Average percentage of *Coccinella septempunctata* mortality (Bioassay 4 – 21 DAA)

Treatment number	Treatment rate		Mortality (%) \pm SE ^a		P ^b	Corrected mortality ^c (%)
	mL f.p./ha	g a.i./ha				
T1	0 (Control)	0	25.00	\pm 0.07	-	-
T2	300	60	50.00	\pm 0.08	**	33.33
T3	400	80	57.50	\pm 0.08	**	43.33

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T4	500	100	70.00	±0.07	***	60.00
T5	ROGOR L40 ST at 18 mL/ha	7.2 g dimethoate/ha	65.00	±0.08	***	53.33

f.p. = formulated product

a.i. = acetamiprid 200 g/L

^a, standard error from 40 replicates

^b, Cochran-Armitage test and Chi² 2x2 Table test (reference item ROGOR L40 ST), $\alpha \leq 0.001$ ***, 0.01 **, 0.05 *

^c, mean mortality corrected by Schneider-Orelli's formula

-, not applicable

Bioassay 5 – mortality (28 DAA)

For test item Acetamipryd 200 SL, mean mortality ranged from 22.50% (corrected value: 13.89%) to 37.50% (corrected value: 30.56%) in treatments T2 (60 mL test item/ha) and T4 (500 mL test item/ha), respectively. The control group and reference item showed a mortality of 10.00% and 45.00% (corrected value: 38.89%), respectively.

Table KCP 10.3.2.2-31: Average percentage of *Coccinella septempunctata* mortality (Bioassay 5 – 28 DAA)

Treatment number	Treatment rate		Mortality (%) ±SE ^a		P ^b	Corrected mortality ^c (%)
	mL f.p./ha	g a.i./ha				
T1	0 (Control)	0	10.00	±0.05	-	-
T2	300	60	22.50	±0.07	n.s.	13.89
T3	400	80	32.50	±0.08	**	25.00
T4	500	100	37.50	±0.08	***	30.56
T5	ROGOR L40 ST at 18 mL/ha	7.2 g dimethoate/ha	45.00	±0.08	***	38.89

f.p. = formulated product

a.i. = acetamiprid 200 g/L

^a, standard error from 40 replicates

^b, Cochran-Armitage test and Chi² 2x2 Table test (reference item ROGOR L40 ST), $\alpha \leq 0.001$ ***, 0.01 **, 0.05 *

^c, mean mortality corrected by Schneider-Orelli's formula

-, not applicable

n.s., not significantly different compared to the control

Bioassay 6 – mortality (35 DAA)

For test item Acetamipryd 200 SL, mean mortality ranged from 17.50% (corrected value: 2.94%) to 25.00% (corrected value: 11.76%) in treatments T2 (60 mL test item/ha) and T3 (400 mL test item/ha), respectively. The control group and reference item showed a mortality of 15.00% and 35.00% (corrected value: 23.53%), respectively.

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Table KCP 10.3.2.2-32: Average percentage of *Coccinella septempunctata* mortality (Bioassay 6 – 35 DAA)

Treatment number	Treatment rate		Mortality (%) \pm SE ^a		P ^b	Corrected mortality ^c (%)
	mL f.p./ha	g a.i./ha				
T1	0 (Control)	0	15.00	± 0.06	-	-
T2	300	60	17.50	± 0.06	n.s.	2.94
T3	400	80	25.00	± 0.07	n.s.	11.76
T4	500	100	22.50	± 0.07	n.s.	8.82
T5	ROGOR L40 ST at 18 mL/ha	7.2 g dimethoate/ha	35.00	± 0.08	**	23.53

f.p. = formulated product

a.i. = acetamiprid 200 g/L

^a, standard error from 40 replicates

^b, Chi² 2x2 Table test with or without (reference item ROGOR L40 ST) Bonferroni Correction, $\alpha \leq 0.001$ ***, 0.01 **, 0.05 *

^c, mean mortality corrected by Schneider-Orelli's formula

-, not applicable

n.s., not significantly different compared to the control

Bioassay 3 – mortality (14 DAA)

The mean number of eggs per female per day was 14.19 in the control group and 9.00 in T2 (300 mL test item/ha). The hatching rate was 92.20% in treatment T2 (300 mL test item/ha) and 94.30% in the control group. For treatments T3 (400 mL test item/ha) and T4 (500 mL test item/ha) the reproductive part was not conducted, because the mean mortality exceeded 50% (corrected for control).

Table KCP 10.3.2.2-33: Mean number of eggs per female per day (bioassay 3 – 14 DAA)

Treatment number	Treatment		Mean number of females	Mean no. of eggs	Mean no. of hatched eggs	Mean number of eggs per female per day (RrX)	SE ^a	Egg-hatching (%) ^b
	mL f.p./ha	g a.i./ha						
T1	0 (Control)	0	4.21	891.67	841.00	14.19	± 0.17	94.30
T2	300	60	3.75	539.00	496.50	9.00	± 0.75	92.20

f.p. = formulated product

a.i. = acetamiprid 200 g/L

^a, standard error (SE) from the number of breeding boxes.

^b, mean values from four breeding boxes.

Bioassay 4 – mortality (21 DAA)

The mean number of eggs per female per day was 11.06 in T2 (300 mL test item/ha) and 11.37 in T3 (400 mL test item/ha). The control group showed a mean number of 14.32 eggs per female per day. The hatching

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rate was 93.39% in treatment T2 (300 mL test item/ha) and 92.15% in treatment T3 (400 mL test item/ha), while in the control it was equal to 94.38%.

Table KCP 10.3.2.2-34: Mean number of eggs per female per day (bioassay 4 – 21 DAA)

Treatment number	Treatment		Mean number of females	Mean no. of eggs	Mean no. of hatched eggs	Mean number of eggs per female per day (RrX)	SE ^a	Egg-hatching (%) ^b
	mL f.p./ha	g a.i./ha						
T1	0 (Control)	0	4.10	816.33	770.33	14.32	±1.37	94.38
T2	300	60	3.86	623.50	582.50	11.06	±1.05	93.39
T3	400	80	3.46	593.50	547.00	11.37	±0.83	92.15

f.p. = formulated product

a.i. = acetamiprid 200 g/L

^a, standard error (SE) from the number of breeding boxes.

^b, mean values from four breeding boxes.

Bioassay 5 – mortality (28 DAA)

The mean number of eggs per female per day ranged from 12.65 in T4 (500 mL test item/ha) to 15.13 in T3 (400 mL test item/ha). The control group showed a mean number of 13.24 eggs per female per day. The hatching rate ranged from 92.94% in treatment T4 (500 mL test item/ha) to 91.41% in treatment T3 (400 mL test item/ha), while in the control it was equal to 92.62%.

Table KCP 10.3.2.2-35: Mean number of eggs per female per day (bioassay 5 – 28 DAA)

Treatment number	Treatment		Mean number of females	Mean no. of eggs	Mean no. of hatched eggs	Mean number of eggs per female per day (RrX)	SE ^a	Egg-hatching (%) ^b
	mL f.p./ha	g a.i./ha						
T1	0 (Control)	0	4.33	779.00	721.33	13.24	±1.59	92.62
T2	300	60	3.50	746.00	692.67	14.09	±0.20	92.77
T3	400	80	3.33	713.67	652.00	15.13	±1.25	91.41
T4	500	100	3.33	607.00	564.67	12.65	±0.22	92.94

f.p. = formulated product

a.i. = acetamiprid 200 g/L

^a, standard error (SE) from the number of breeding boxes.

^b, mean values from four breeding boxes.

Bioassay 6 – mortality (35 DAA)

The mean number of eggs per female per day ranged from 12.88 in T4 (500 mL test item/ha) to 13.43 in T3 (400 mL test item/ha). The control group showed a mean number of 11.96 eggs per female per day. The hatching rate ranged from 92.80% in treatment T4 (500 mL test item/ha) to 93.01% in treatment T2 (300 mL test item/ha), while in the control it was equal to 92.16%.

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Table KCP 10.3.2.2-36: Mean number of eggs per female per day (bioassay 6 – 35 DAA)

Treatment number	Treatment		Mean number of females	Mean no. of eggs	Mean no. of hatched eggs	Mean number of eggs per female per day (RrX)	SE ^a	Egg-hatching (%) ^b
	mL f.p./ha	g a.i./ha						
T1	0 (Control)	0	4.55	796.00	733.67	11.96	±0.44	92.16
T2	300	60	4.21	813.67	756.67	13.04	±0.33	93.01
T3	400	80	4.07	791.00	734.67	13.43	±1.18	92.89
T4	500	100	3.81	745.67	692.00	12.88	±1.34	92.80

f.p. = formulated product

a.i. = acetamiprid 200 g/L

^a, standard error (SE) from the number of breeding boxes.

^b, mean values from four breeding boxes.

CONCLUSION

The obtained endpoints have been summarised below.

Table KCP 10.3.2.2-37: Endpoints for the 0 DAA, 7 DAA and 14 DAA bioassay

Endpoints	mL test item/ha	g a.i./ha*
0-DAA Bioassay: fresh residues		
LR ₁₀	<300	<60
LR ₅₀	<300 [95%-CLs n.d.]	<60 [95%-CLs n.d.]
NOER (Mortality)	<300	<60
LOER (Mortality)	300	60
7-DAA Bioassay: 7-day aged residues		
LR ₁₀	<300	<60
LR ₅₀	<300 [95%-CLs n.d.]	<60 [95%-CLs n.d.]
NOER (Mortality)	<300	<60
LOER (Mortality)	300	60
14-DAA Bioassay: 14-day aged residues		
LR ₁₀	<300	<60
LR ₅₀	<400 [95%-CLs n.d.]	<80 [95%-CLs n.d.]
NOER (Mortality)	<300	<60
LOER (Mortality)	300	60

*The active ingredient content was calculate based on the nominal test item content of 200 g/L acetamiprid

Note: the LR₅₀ value were estimated, therefore no confidence limits were provided (95%-CLs n.d. = not determined)

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Table KCP 10.3.2.2-38: Endpoints for the 21 DAA, 28 DAA and 35 DAA bioassay

Endpoints	mL test item/ha	g a.i./ha*
21-DAA Bioassay: 21-day aged residues		
LR ₁₀	<300	<60
LR ₅₀	437.34 [300 – 500]	87.47 [60 – 100]
NOER (Mortality)	<300	<60
LOER (Mortality)	300	60
28-DAA Bioassay: 7-day aged residues		
LR ₁₀	<300	<60
LR ₅₀	>500 [95%-CLs n.d.]	>100 [95%-CLs n.d.]
NOER (Mortality)	300	60
LOER (Mortality)	400	80
35-DAA Bioassay: 14-day aged residues		
LR ₁₀	<300	<60
LR ₂₀	>300	>60
LR ₅₀	>500 [95%-CLs n.d.]	>100 [95%-CLs n.d.]
NOER (Mortality)	≥500	≥100
LOER (Mortality)	>500	>100

*The active ingredient content was calculate based on the nominal test item content of 200 g/L acetamiprid
 Note: where the LR₅₀ value were estimated, no confidence limits were provided (95%-CLs n.d. = not determined)

Comments of zRMS:	The study was accepted by zRMS. The validity criteria was met:
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	Mortality in control check	Bioassay 1 at 0 DAA	Mortality was 13.33%, therefore, the validity criterion was met.
		Bioassay 2 at 7 DAA	Mortality was 10.00%, therefore, the validity criterion was met.
		Bioassay 3 at 14 DAA	Mortality was 10.00%, therefore, the validity criterion was met.
	Reproduction in control check	Bioassay 1 at 0 DAA	The mean number of eggs per female per day was 40.09, so this validity criterion was met.
		Bioassay 2 at 7 DAA	The mean number of eggs per female per day was 40.60, so this validity criterion was met.
		Bioassay 3 at 14 DAA	The mean number of eggs per female per day was 41.05, so this validity criterion was met.
	Hatching rate in control check	Bioassay 1 at 0 DAA	The hatching rate was 87.28% and so the validity criterion was met.
		Bioassay 2 at 7 DAA	The hatching rate was 81.87% and so the validity criterion was met.
		Bioassay 3 at 14 DAA	The hatching rate was 86.70% and so the validity criterion was met.
	Mortality in reference	Bioassay 1 at 0 DAA	Actual value was 83.33% (corrected value 80.77%), so the validity criterion was met.
		Bioassay 2 at 7 DAA	Actual value was 73.33% (corrected value 70.37%), so the validity criterion was met.
		Bioassay 3 at 14 DAA	Actual value was 66.67% (corrected value 62.96%), so the validity criterion was met.
Agreed toxicity endpoints:			

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Table 1a. *Chrysoperla carnea* mortality (Bioassay 1 at 0 DAA, 2 at 7 DAA and 3 at 14 DAA)

	T1 Control	T2 Acetamipryd 200 SL at 300 mL test item/ha	T3 Acetamipryd 200 SL at 400 mL test item/ha	T4 Acetamipryd 200 SL at 500 mL test item/ha	T5 ROGOR L 40 ST at 60 mL f.p./ha
	Deionized water	60 g a.i./ha	80 g a.i./ha	100 g a.i./ha	24 g a.i./ha
Mortality (bioassay 1 – 0 DAA) [mean %]	13.33	36.67	40.00	40.00	83.33
Significance ^a	-	**	**	**	***
Corrected mortality ^b (bioassay 1 – 0 DAA) [%]	-	26.92	30.77	30.77	80.77
Mortality (bioassay 2 – 7 DAA) [mean %]	10.00	13.33	16.67	20.00	73.33
Significance ^a	-	n.s.	n.s.	n.s.	***
Corrected mortality ^b (bioassay 2 – 7 DAA) [%]	-	3.70	7.41	11.11	70.37
Mortality (bioassay 3 – 14 DAA) [mean %]	10.00	10.00	13.33	13.33	66.67
Significance ^a	-	n.s.	n.s.	n.s.	***
Corrected mortality ^b (bioassay 3 – 14 DAA) [%]	-	0.00	3.70	3.70	62.96

-, not applicable

n.s., not significantly different compared to the control

a, Cochran-Armitage test and Fisher's Exact test (reference item), $\alpha \leq 0.001$ ***, 0.01 **, 0.05 *

b, Schneider-Orelli's formula

Table 1b. *Chrysoperla carnea* reproduction (Bioassay 1 at 0 DAA, 2 at 7 DAA and 3 at 14 DAA)

	T1 Control	T2 Acetamipryd 200 SL at 300 mL test item/ha	T3 Acetamipryd 200 SL at 400 mL test item/ha	T4 Acetamipryd 200 SL at 500 mL test item/ha
	Deionized water	60 g a.i./ha	80 g a.i./ha	100 g a.i./ha
Reproduction (bioassay 1 – 0 DAA) [mean no. eggs/female/day]	40.09	41.82	39.83	38.56
% egg-hatching (bioassay 1 – 0 DAA)	87.28	85.29	86.53	63.20
Reproduction (bioassay 2 – 7 DAA) [mean no. eggs/female/day]	40.60	40.27	40.03	38.63
% egg-hatching (bioassay 2 – 7 DAA)	81.87	80.15	80.21	69.92
Reproduction (bioassay 3 – 14 DAA) [mean no. eggs/female/day]	41.05	40.90	40.52	39.50
% egg-hatching (bioassay 3 – 14 DAA)	86.70	86.53	85.95	84.09

a.i., active ingredient acetamiprid 200 g/L.

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Table 2. Endpoints for mortality (Bioassay 1 at 0 DAA, 2 at 7 DAA and 3 at 14 DAA)		
Endpoints	mL test item/ha	g a.i./ha*
0-DAA Bioassay: fresh residues		
LR ₅₀	>500 [95%-CLs n.d.]	>100 [95%-CLs n.d.]
NOER (Mortality)	≤300	≤60
LOER (Mortality)	300	60
7-DAA Bioassay: 7-day aged residues		
LR ₅₀	>500 [95%-CLs n.d.]	>100 [95%-CLs n.d.]
NOER (Mortality)	≥500	≥100
LOER (Mortality)	>500	>100
14-DAA Bioassay: 14-day aged residues		
LR ₅₀	>500 [95%-CLs n.d.]	>100 [95%-CLs n.d.]
NOER (Mortality)	≥500	≥100
LOER (Mortality)	>500	>100

*The active ingredient content was calculate based on the nominal test item content of 200 g/L
95%-CLs n.d., Confidence Limits not determined due to mathematical reasons

Reference: KCP 10.3.2.2/04

Report Effects of Acetamipryd 200 SL on *Chrysoperla carnea* – Extended laboratory aged residue test;
Mautino G.; 2023; Study Code: 1038.I.SAG23/r

Guideline(s): Yes, SETAC; ESCORT; IOBC/BART/EPPO

Deviations: No

GLP: Yes

Acceptability: Yes

Duplication No

(if vertebrate study)

MATERIALS AND METHODS

1. Test material

Test item (chemical/other name): Acetamipryd 200 SL

Formulation: 200 g/L (nominal content)

Description (physical state): liquid

Batch no.: 1/ACE/2022

Production date: 01.2022

Expiration date: 01.2024

2. Vehicle and/or positive control: vehicle: deionised water

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positive control: ROGOR L 40 ST (nominally 400 g dimetho-
ate/L)

3. Test organism

Species:

Chrysoperla carnea

Source:

Katz Biotech AG, Baruth, Germany

Age:

first instar larvae, 2-day old

Acclimation period:

2 days under test conditions (same feeding)

Diet:

During mortality evaluation, *Sitotroga* sp.'s eggs were put into the test units the same day of test units setting after the application and then, replaced 3 times a week. During the fecundity evaluation, the adult diet consisted of mixture of 15 mL condensed milk, 1 egg, 1 egg yolk, 30 g honey, 20 g fructose, 30 g dried brewer's yeast, 50 g wheatgerm and 45 mL drinking water. This food was available continuously and replaced at least twice, preferably three times per week. Water was provided permanently in a reservoir and replaced at least once a week.

Test units:

Mortality assessment: Cylinder (45.8 mm Ø x 50 mm) of transparent plastic provided with PTFE (politetrafluoro-
etylene), a perforated lid (28 mm Ø) and with an insect proof net. The cylinder was inserted into a plate provided with a leaf disc of bean (50 mm Ø) leaning on two filter paper layers and blocked to it by rubbers, arranged in a cross design.

Fecundity assessment Glass cylinder (5000 cc, 16 cm Ø, 29 cm) provided with an insect proof net, blocked to it by rubbers.

Plants:

Taxonomic group: Fabaceae

Common name: bean

Species: *Phaseolus vulgaris* L.

Variety: Bingo

Source: Agricola Albese (Alba, CN)

Cultivation substrate: natural soil

Sowing date: 23 Mar 2023

Emergence date: 29 Apr 2023

Grown site: open field under a rain cover (N44° 44' 48.88"; E08° 04' 09.00). Length: 39 m; width: 6 m; height: 2.10 m)

Stage for test start: BBCH 18-19

Maintenance: automatic drip irrigation

Agrochemicals and/or fertilizers: none

4. Environmental conditions:

Temperature:

24.58 ± 0.281 °C (24.23 – 25.34 °C)

Relative humidity:

78.6±2.7% (70.7 – 82.7% RH)

Photoperiod:

16 hours light : 8 hours dark, light intensity 1800-2000 lx

STUDY DESIGN AND METHOD

The aim of the study was to determine the product persistence, intended as the decline rate of residues (fresh and aged) on bean plants treated once with the test item Acetamipryd 200 SL (acetamiprid 200 g/L), growing under rain-protected field conditions. Insects (2-3 days old) were exposed to fresh and aged residue of the test item at different timings (bioassay) after application (DAA) and observed three times per week. Three bioassays were investigated: bioassay 1, where insects were introduced immediately after the application on dried discs (0 DAA); bioassay 2, where insects were introduced 7 days after the application (7 DAA), and bioassay 3, where insects were introduced 14 days after the application (14 DAA). At each bioassay, residual toxicity was evaluated by assessing *Chrysoperla carnea* mortality over the time and by evaluating the sub-lethal effects on the insect's reproduction subsequently to their exposure to the test item's residue (fresh and aged). The effects of the test item were compared with a control group and a reference item.

The study encompassed 5 treatments (3 rates of the test item, control, reference item) with 30 replicates each containing 1 larva. The larvae were exposed to fresh and aged residue on bean leaf discs at three different times: 0, 7, and 14 days after application (DAA). At the end of this period, the observations consisted in giving percent mortality; $\geq 50\%$ of larvae exposed to the test item survived and successfully completed their metamorphosis, females and males (adults) were sexed, assessed for their reproductive performance and transferred to the mass-rearing units. The reproduction test started one week after the first egg laying observation. Samples of two laid eggs, covering an oviposition period of 24 hours, were taken in one week. Larvae hatching and lacewings survival were assessed.

Test design:	30 replicates per group, 1 larva per replicate
Tested concentrations, definitive test:	300 mL test item/ha (60 g acetamiprid/ha) – T2 400 mL test item/ha (80 g acetamiprid/ha) – T3 500 mL test item/ha (100 g acetamiprid/ha) – T4 400 L water/ha
Stability of test compound:	-
Dates:	start of the study: 20.04.2023 start of the experimental part: 20.04.2023 end of the experimental part: 12.06.2023 end of the study: 10.11.2023
Statistic:	Software used for statistical analysis were “ToxRatPro” Solutions GmbH, version 3.3.0. Mortality data were processed using the Cochran-Armitage and Fisher's test test (reference item), $\alpha \leq 0.05$. Correction for control mortality was processed using the Schneider-Orelli formula. Reproductive performance was evaluated only qualitatively due to the very high species-inherent variability in egg-laying performance. For all bioassays, at least the LR50 (mortality) value was determined, where possible. The No Observed Effect Rate (NOER) and Lowest Observed Effect Rate (LOER) values for mortality and reproduction were determined, where possible.

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Validity of the test:

The following criteria should be satisfied in the control for a test result to be considered valid:

- mortality in the water control $\leq 20\%$ (dead larvae, pupae and adults during emergence);
- mean number of eggs per female per day in the water control ≥ 15 ;
- mean hatching rate ≥ 70 ;
- mortality in the reference group $\geq 50 \%$.

RESULTS

Bioassay 1 – mortality (0 DAA)

Mean mortality for test item Acetamipryd 200 SL was 36.67% in treatment T2 (300 mL f.p./ha, corrected mortality: 26.92%), 40.00 in treatment T3 (400 mL f.p./ha, corrected mortality: 30.77%) and 40.00% in treatment T4 (500 mL f.p./ha, corrected mortality: 30.77%). The control and reference item groups showed a mortality of 13.33% and 83.33% (corrected value: 80.77%), respectively.

Table KCP 10.3.2.2-39: Average percentage of *Chrysoperla carnea* mortality (Bioassay 1 – 0 DAA)

Treatment number	Treatment rate		Mortality (%) \pm SE ^a		P ^b	Corrected mortality ^c (%)
	mL f.p./ha	g a.i./ha				
T1	0 (Control)	0	13.33	± 0.06	-	-
T2	300	60	36.67	± 0.09	**	26.92
T3	400	80	40.00	± 0.09	**	30.77
T4	500	100	40.00	± 0.09	**	30.77
T5	ROGOR L40 ST at 60 mL/ha	24 g dimethoate/ha	83.33	± 0.07	***	80.77

a.i., acetamiprid

^a, standard error from 30 replicates

^b, Cochran-Armitage test and Fisher's Exact test (reference item ROGOR L 40 ST), $\alpha \leq 0.001$ ***, 0.01 **, 0.05 *

^c, mean mortality corrected by Schneider-Orelli's formula

-, not applicable

Bioassay 2 – mortality (7 DAA)

Mean mortality for test item Acetamipryd 200 SL was 13.33% in treatment T2 (300 mL f.p./ha, corrected mortality: 3.70%), 16.67% in treatment T3 (400 mL f.p./ha, corrected mortality: 7.41%) and 20.00% in treatment T4 (500 mL f.p./ha, corrected mortality: 11.11%). The control and reference item groups showed a mortality of 10.00% and 73.33% (corrected value: 70.37%), respectively.

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Table KCP 10.3.2.2-40: Average percentage of *Chrysoperla carnea* mortality (Bioassay 2 – 7 DAA)

Treatment number	Treatment rate		Mortality (%) \pm SE ^a		P ^b	Corrected mortality ^c (%)
	mL f.p./ha	g a.i./ha				
T1	0 (Control)	0	10.00	± 0.06	-	-
T2	300	60	13.33	± 0.06	n.s.	3.70
T3	400	80	16.67	± 0.07	n.s.	7.41
T4	500	100	20.00	± 0.07	n.s.	11.11
T5	ROGOR L40 ST at 60 mL/ha	24 g dimethoate/ha	73.33	± 0.08	***	70.37

a.i. = acetamiprid

^a, standard error from 30 replicates

^b, Cochran-Armitage test and Fisher's Exact test (reference item ROGOR L 40 ST), $\alpha \leq 0.001$ ***, 0.01 **, 0.05 *

^c, mean mortality corrected by Schneider-Orelli's formula

-, not applicable

n.s., not significantly different compared to the control

Bioassay 3 – mortality (14 DAA)

Mean mortality for the test item Acetamipryd 200 SL was 10.00% in treatment T2 (300 mL f.p./ha, corrected mortality: 0.00%), 13.33 in treatment T3 (400 mL f.p./ha, corrected mortality: 3.70%) and 13.33% in treatment T4 (500 mL f.p./ha, corrected mortality: 3.70%). The control and reference item groups showed a mortality of 10.00% and 66.67% (corrected value: 62.96%), respectively.

Table KCP 10.3.2.2-41: Average percentage of *Chrysoperla carnea* mortality (Bioassay 3 – 14 DAA)

Treatment number	Treatment rate		Mortality (%) \pm SE ^a		P ^b	Corrected mortality ^d (%)
	mL f.p./ha	g a.i./ha				
T1	0 (Control)	0	10.00	± 0.06	-	-
T2	300	60	10.00	± 0.06	n.s.	0.00
T3	400	80	13.33	± 0.06	n.s.	3.70
T	500	100	13.33	± 0.06	n.s.	3.70
T5	ROGOR L40 ST at 60 mL/ha	24 g dimethoate/ha	66.67	± 0.09	***c	62.96

a.i. = acetamiprid

^a, standard error from 30 replicates

^b, Cochran-Armitage test and Fisher's Exact test (reference item ROGOR L 40 ST), $\alpha \leq 0.001$ ***, 0.01 **, 0.05 *

^c, mean mortality corrected by Schneider-Orelli's formula

-, not applicable

n.s., not significantly different compared to the control

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Bioassay 1 – fecundity (0 DAA)

The mean number of eggs per female per day was 41.82 in treatment T2 (300 mL test item/ha), 39.83 in treatment T3 (400 mL test item/ha) and 38.56 in treatment T4 (500 mL test item/ha). The control group showed a mean number of eggs per female / day of 40.09. The hatching rate was 85.29% in treatment T2 (300 mL test item/ha), 86.53% in treatment T3 (400 mL test item/ha) and 63.20% in treatment T4 (500 mL test item/ha), while in the control it was equal to 87.28%.

Table KCP 10.3.2.2-42: Mean number of eggs per female per day

Treatment number	Treatment		Replicate	First oviposition			Second oviposition			Mean number of eggs per female per day	±SE
	mL f.p./ha	g a.i./ha		Female start	Female end	Eggs	Female start	Female end	Eggs		
T1	0 Control	0	I	7	6	247	6	6	267	40.09	±1.16
			II	8	8	305	8	7	298		
T2	300	60	I	6	6	234	6	5	182	41.82	±5.78
			II	5	5	256	5	5	220		
T3	400	80	I	4	4	182	4	4	170	39.83	±4.17
			II	5	4	186	4	4	120		
T4	500	100	I	4	4	190	4	3	131	38.556	±3.90
			II	4	4	155	4	3	107		

SE, Standard error

Table KCP 10.3.2.2-43: Average percentage of egg-hatching

Treatment number	Treatment		Treatment	First oviposition		Second oviposition		% egg-hatching
	mL f.p./ha	mL f.p./ha		Eggs	Larvae	Eggs	Larvae	
T1	0 Control	0	I	247	212	267	236	87.28
			II	305	279	298	248	
T2	300	60	I	234	208	182	152	85.29
			II	256	205	220	195	
T3	400	80	I	182	153	170	149	86.53
			II	186	164	120	103	
T4	500	100	I	190	102	131	93	63.20
			II	155	85	107	87	

Bioassay 2 – fecundity (7 DAA)

The mean number of eggs per female per day was 40.27 in treatment T2 (300 mL test item/ha), 40.03 in treatment T3 (400 mL test item/ha) and 38.63 in treatment T4 (500 mL test item/ha). The control group showed a mean number of eggs per female / day of 40.60. The hatching rate was 80.15% in treatment T2 (300 mL test item/ha), 80.21% in treatment T3 (400 mL test item/ha) and 69.92% in treatment T4 (500 mL test item/ha), while in the control it was equal to 81.87%.

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Table KCP 10.3.2.2-44: Mean number of eggs per female per day

Treatment number	Treatment		Replicate	First oviposition			Second oviposition			Mean number of eggs per female per day	±SE
	mL f.p./ha	g a.i./ha		Female start	Female end	Eggs	Female start	Female end	Eggs		
T1	0 Control	0	I	7	6	288	6	6	239	40.60	±1.47
			II	6	6	296	6	5	159		
T2	300	60	I	7	7	290	7	6	275	40.27	±1.60
			II	8	8	269	8	6	306		
T3	400	80	I	5	5	264	5	5	170	40.03	±3.37
			II	6	5	121	5	4	231		
T4	500	100	I	5	5	218	5	4	157	38.63	±0.61
			II	6	6	167	6	4	241		

SE, Standard error

Table KCP 10.3.2.2-45: Average percentage of egg-hatching

Treatment number	Treatment		Treatment	First oviposition		Second oviposition		% egg-hatching
	mL f.p./ha	mL f.p./ha		Eggs	Larvae	Eggs	Larvae	
T1	0 Control	0	I	288	232	239	207	81.87
			II	296	241	159	125	
T2	300	60	I	290	224	275	210	80.15
			II	269	201	306	279	
T3	400	80	I	264	204	170	110	80.21
			II	121	101	231	209	
T3	500	100	I	218	181	157	98	69.92
			II	167	101	241	166	

Bioassay 3 – fecundity (14 DAA)

The mean number of eggs per female per day was 40.90 in treatment T2 (300 mL test item/ha), 40.52 in treatment T3 (400 mL test item/ha) and 39.50 in treatment T3 (1500 mL test item/ha). The control group showed a mean number of eggs per female / day of 41.05. The hatching rate was 86.53% in treatment T2 (300 mL test item/ha), 85.95% in treatment T3 (400 mL test item/ha) and 84.09% in treatment T4 (500 mL test item/ha), while in the control it was equal to 86.70%.

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Table KCP 10.3.2.2-46: Mean number of eggs per female per day

Treatment number	Treatment		Replicate	First oviposition			Second oviposition			Mean number of eggs per female per day	±SE
	mL f.p./ha	g a.i./ha		Female start	Female end	Eggs	Female start	Female end	Eggs		
T1	0 Control	0	I	6	6	260	6	5	236	41.05	±2.07
			II	6	5	223	5	5	187		
T2	300	60	I	8	7	313	6	6	279	40.90	±2.97
			II	7	7	286	7	7	245		
T3	400	80	I	7	7	168	7	5	304	40.52	±3.19
			II	7	7	277	7	6	311		
T4	500	100	I	6	5	190	5	4	194	39.50	±0.67
			II	6	6	246	6	6	236		

SE, Standard error

Table KCP 10.3.2.2-47: Average percentage of egg-hatching

Treatment number	Treatment		Treatment	First oviposition		Second oviposition		% egg-hatching
	mL f.p./ha	mL f.p./ha		Eggs	Larvae	Eggs	Larvae	
T1	0 Control	0	I	260	238	236	189	86.70
			II	223	210	187	148	
T2	300	60	I	313	272	276	226	86.53
			II	286	251	245	219	
T3	400	80	I	168	144	304	250	85.95
			II	277	226	311	294	
T4	500	100	I	190	169	194	139	84.09
			II	246	218	236	206	

CONCLUSION

The obtained endpoints have been summarised below.

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Table KCP 10.3.2.2-48: Endpoints for mortality (Bioassay 1 at 0 DAA, 2 at 7 DAA and 3 at 14 DAA)

Endpoints	mL test item/ha	g a.i./ha*
0-DAA Bioassay: fresh residues		
LR ₅₀	>500 [95%-CLs n.d.]	>100 [95%-CLs n.d.]
NOER (Mortality)	≤300	≤60
LOER (Mortality)	300	60
7-DAA Bioassay: 7-day aged residues		
LR ₅₀	>500 [95%-CLs n.d.]	>100 [95%-CLs n.d.]
NOER (Mortality)	≥500	≥100
LOER (Mortality)	>500	>100
14-DAA Bioassay: 14-day aged residues		
LR ₅₀	>500 [95%-CLs n.d.]	>100 [95%-CLs n.d.]
NOER (Mortality)	≥500	≥100
LOER (Mortality)	>500	>100

*The active ingredient content was calculate based on the nominal test item content of 200 g/L
 95%-CLs n.d., Confidence Limits not determined due to mathematical reasons

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 was accepted by zRMS.
	The validity criteria was met:
	<p>The results are considered valid because the following criteria were satisfied in the controls:</p> <ul style="list-style-type: none"> • each replicate produced from 215 to 319 juveniles (250.9 mean) at the end of the exposure period (criterion: ≥ 30 juveniles by the end of the experiment), • the coefficient of variation of reproduction was 12.9% (criterion: ≤ 30%), • adult mortality over the initial 4 weeks of the experiment was 1.3% (criterion: ≤ 10%).
The agreed toxicity endpoints:	

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Parameter	Value [mg test item/kg dry weight of artificial soil]	Value [mg of acetamiprid/kg dry weight of artificial soil]
EC ₁₀	2.81 (2.11 – 3.48)	0.53 (0.40 – 0.66)
EC ₂₀	4.28 (3.46 – 5.03)	0.81 (0.65 – 0.95)
EC ₅₀	9.54 (8.46 – 10.75)	1.80 (1.60 – 2.03)
NOEC (reproduction)	1.80	0.34
LOEC (reproduction)	3.20	0.60
LC ₅₀	22.49 (16.21 – 29.57)	4.25 (3.06 – 5.59)
NOEC (survival)	5.60	1.06
LOEC (survival)	10.0	1.89

Reference: KCP 10.4.1.1/01
 Report Acetamipryd 200 SL Earthworm reproduction test (*Eisenia andrei*);
 Wróbel A.; 2022; Study Code: G-93-21
 Guideline(s): Yes, OECD 222
 Deviations: No
 GLP: Yes
 Acceptability: Yes
 Duplication (if vertebrate study) No

MATERIALS AND METHODS

1. Test material

Test item (chemical/other name): Acetamipryd 200 SL
Formulation: SL (soluble liquid), acetamiprid: specification 200.0 g/L
Description (physical state): light brown liquid
Batch no.: 1/ACE/2022
Production date: 01.2022
Expiration date: 01.2024

2. Vehicle and/or positive control: vehicle: deionized water

positive control: carbendazim

3. Test organism

Species:	earthworm <i>Eisenia andrei</i>
Source:	cultivated at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna, Ecotoxicology Research Group, Laboratory of Soil Organisms Toxicology, Poland
Age:	about 10 months old
Acclimation period:	24 hours acclimatization
Diet:	during the experiment, the earthworms were fed on air-dried finely ground cow manure; one day after the beginning of the experiment, it was spread on the soil surface (5 g food/ container) and moistened; the food prepared in this way was provided once a week during the four-week period (5 g food/container); after 4 weeks (when the adult earthworms were removed from the soil), the juvenile earthworms were fed only once (5 g food/container)
Test units:	plastic containers (204 cm ²) with a capacity of about 1.4L, containers were covered with perforated transparent foil in order to prevent the earthworms from escaping, to allow gaseous exchange, and to provide access to light

4. Environmental conditions:

Temperature:	19.8 – 22.0°C
Soil:	artificial soil 10% sphagnum peat, 20% kaolin clay, 69.945% air-dried industrial sand, 0.055% calcium carbonate
pH:	pH at the beginning of the experiment: 6.33 – 6.38; pH at the end of the experiment: 6.28 – 6.33;
Soil moisture content:	soil moisture content at the beginning of the experiment: 24.9 – 28.4% (50.9 – 58.1% of the maximum water holding capacity) soil moisture content at the end of the experiment: 26.8 – 29.2% (54.8 – 59.7% of the maximum water holding capacity)
Photoperiod:	light-dark cycle: 16h : 8h light intensity at the beginning of the experiment: 532.7 – 573.5 lux light intensity at the end of the experiment: 534.3 – 659.7 lux

STUDY DESIGN AND METHOD

The aims of the study were to assess the impact of Acetamipryd 200 SL on reproduction of the earthworm, *Eisenia andrei* and to determine EC10, EC20, EC50 and NOEC. The test item in the form of an aqueous

solution was mixed with a suitable amount of the artificial soil. The concentrations of the test item were: 0.56, 1.0, 1.8, 3.2, 5.6, 10.0, 18.0, 32.0, 56.0 and 100.0 mg/kg dry weight of the artificial soil. Each of them was divided into four replicates. There was also one untreated control group with the deionised water only. Control group was divided into eight replicates. The experiment lasted 8 weeks. After 4 weeks, all of adult earthworms were removed from the test containers and observed. All changes in their behaviour and morphology were recorded. The number of earthworms and their body weights were also determined. The impact of the test item on reproduction was evaluated after the additional 4 week period on the basis of the number of juveniles hatched from cocoons during the experiment.

Test design:	number of replicates: 4 replicates/concentration + 8 replicates/control; number of earthworms: 10 earthworms /replicate
Exposure time:	8 weeks
Tested concentrations, definitive test:	0.56, 1.0, 1.8, 3.2, 5.6, 10.0, 18.0, 32.0, 56.0 and 100.0 mg/kg dry weight of the artificial soil
Stability of the test compound:	In order to verify the nominal soil concentration of the test item, the analytical measurements of the artificial soil treated with the test item at the highest concentration (i.e. 100.0 mg of the test item/kg dry weight of the artificial soil) were performed at the beginning, during (after 4 weeks) and at the end of the test.
Dates:	start of the study: 23.03.2022 start of the experimental part: 06.04.2022 end of the experimental part: 03.06.2022 end of the study: 20.07.2022
Statistic:	EC10, EC20, EC50 – probit analysis using linear max. likelihood regression; LC50 – Weibull analysis using linear max. likelihood regression; NOEC (reproduction): - Shapiro-Wilk's Test on Normal Distribution, - Bartlett's Test Procedure on Variance Homogeneity, - Williams Multiple Sequential t-test Procedure. NOEC (survival): - Fisher's Exact Binomial Test with Bonferroni Correction LOEC: a values suggested by the ToxRat Professional 2.10 statistical computer software
Validity of the test:	The results are considered valid because the following criteria were satisfied in the controls: - each replicate produced from 215 to 319 juveniles (250.9 mean) at the end of the exposure period (criterion: ≥ 30 juveniles by the end of the experiment), - the coefficient of variation of reproduction was 12.9% (criterion: $\leq 30\%$), - adult mortality over the initial 4 weeks of the experiment was 1.3% (criterion: $\leq 10\%$).

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RESULTS

After 4 weeks of exposure to the test item At concentrations ranging from 0.56 to 18.0 mg /kg dry weight of artificial soil, mortality of the adult earthworms was between 0.0 and 20.0%. At concentrations ranging from 32.0 to 100.0 mg of the test item/kg dry weight of artificial soil, mortality of the adult earthworms was between 87.5 and 100.0%. As for the control group, mortality of the adult earthworms was equal to 1.3%.

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Table KCP 10.4.1.1-1: Mortality of the adult earthworms (*Eisenia andrei*) after 4 weeks of the experiment

Concentration of the test item [mg/kg dry weight of the artificial soil]	Replicate	Number of tested earthworms [no.]	Number of alive earthworms [no.]	Total mortality	
				[no.]	[%]
0.0 (control)	1	10	10	1	1.3
	2	10	10		
	3	10	10		
	4	10	10		
	5	10	10		
	6	10	9		
	7	10	10		
	8	10	10		
0.56	1	10	10	1	2.5
	2	10	10		
	3	10	9		
	4	10	10		
1.0	1	10	10	0	0.0
	2	10	10		
	3	10	10		
	4	10	10		
1.8	1	10	10	1	2.5
	2	10	10		
	3	10	9		
	4	10	10		
3.2	1	10	10	0	0.0
	2	10	10		
	3	10	10		
	4	10	10		
5.6	1	10	10	3	7.5
	2	10	9		
	3	10	10		
	4	10	8		
10.0	1	10	7	6+	15.0
	2	10	9		
	3	10	9		
	4	10	9		
18.0	1	10	8	8+	20.0
	2	10	10		
	3	10	7		
	4	10	7		
32.0	1	10	0	35+	87.5
	2	10	1		
	3	10	2		
	4	10	2		
56.0	1	10	0	39+	97.5
	2	10	1		
	3	10	0		
	4	10	0		
100.0	1	10	0	40+	100.0
	2	10	0		
	3	10	0		
	4	10	0		

After 4 weeks of the experiment, at the concentrations between 0.56 and 100.0 mg of the test item/kg dry weight of the artificial soil, the changes in appearance and behaviour of the adult living earthworms were not observed.

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Table KCP 10.4.1.1-2: Results of the observations of the adult earthworms (*Eisenia andrei*) for changes in behaviour and in morphology.

Concentration of the test item [mg/kg dry weight of the artificial soil]	Replicate	Number of tested earthworms [no.]	Changes in behaviour and in morphology
0.0 (control)	1	10	10 nc
	2	10	10 nc
	3	10	10 nc
	4	10	10 nc
	5	10	10 nc
	6	10	9 nc, 1 d
	7	10	10 nc
	8	10	10 nc
0.56	1	10	10 nc
	2	10	10 nc
	3	10	9 nc, 1 d
	4	10	10 nc
1.0	1	10	10 nc
	2	10	10 nc
	3	10	10 nc
	4	10	10 nc
1.8	1	10	10 nc
	2	10	10 nc
	3	10	9 nc, 1 d
	4	10	10 nc
3.2	1	10	10 nc
	2	10	10 nc
	3	10	10 nc
	4	10	10 nc
5.6	1	10	10 nc
	2	10	9 nc, 1 d
	3	10	10 nc
	4	10	8 nc, 2 d
10.0	1	10	7 nc, 3 d
	2	10	9 nc, 1 d
	3	10	9 nc, 1 d
	4	10	9 nc, 1 d
18.0	1	10	8 nc, 2 d
	2	10	10 nc
	3	10	7 nc, 3 d
	4	10	7 nc, 3 d
32.0	1	10	10 d
	2	10	1 nc, 9 d
	3	10	2 nc, 8 d
	4	10	2 nc, 8 d
56.0	1	10	10 d
	2	10	1 nc, 9 d
	3	10	10 d
	4	10	10 d
100.0	1	10	10 d
	2	10	10 d
	3	10	10 d
	4	10	10 d

nc – no changes, d – dead earthworm

After 4 weeks of the exposure period of the test item at the concentrations ranging from 0.56 to 32.0 mg/kg dry weight of artificial soil, the body weight increase was between 20.7 and 45.6%. As for the control group, the body weight increase was equal to 43.4%.

After the application of the test item at the concentrations ranging from 0.56 to 32.0 mg/kg dry weight of the artificial soil, the mean number of juveniles was between 7.3 and 253.0 per replicate. No juveniles earthworms after application of the test item at the concentrations 56.0 and 100.0 mg/kg dry weight were observed. The mean number of juveniles in the control group was equal to 250.9 per replicate. After 8 weeks of the experiment, it was concluded that Acetamipryd 200 SL had a statistically significant impact on reproduction of the earthworms at the concentrations ranging from 3.2 to 100.0 mg/kg dry weight of artificial soil.

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Table KCP 10.4.1.1-3: Number of juvenile earthworms (*Eisenia andrei*) after 8 weeks of the experiment

Concentration of the test item [mg/kg dry weight of the artificial soil]	Replicate	Number of juveniles [no.]	Mean ±SD	Comparison to the control [%]	CV* [%]
0.0 (control)	1	319	250.9 ± 32.4	-	12.9
	2	221			
	3	250			
	4	247			
	5	263			
	6	215			
	7	259			
	8	233			
0.56	1	286	253.0 ± 41.8	100.8	16.5
	2	292			
	3	212			
	4	222			
1.0	1	241	251.3 ± 25.0	100.1	10.0
	2	284			
	3	225			
	4	255			
1.8	1	246	239.3 ± 10.1	95.4	4.2
	2	235			
	3	227			
	4	249			
3.2	1	209	211.0 ⁺ ± 16.6	84.1	7.9
	2	235			
	3	199			
	4	201			
5.6	1	181	175.3 ⁺ ± 13.2	69.9	7.5
	2	162			
	3	191			
	4	167			
10.0	1	136	128.5 ⁺ ± 17.8	51.2	13.8
	2	150			
	3	116			
	4	112			
18.0	1	42	74.5 ⁺ ± 26.4	29.7	35.5
	2	95			
	3	97			
	4	64			
32.0	1	0	7.3 ⁺ ± 6.1	2.9	83.8
	2	5			
	3	10			
	4	14			
56.0	1	0	0.0 ⁺	0.0	-
	2	0			
	3	0			
	4	0			
100.0	1	0	0.0 ⁺	0,0	-
	2	0			
	3	0			
	4	0			

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Table KCP 10.4.1.1-4: Results of the observations for changes in behaviour and in morphology of the juveniles earthworms (*Eisenia andrei*)

Concentration of the test item [mg/kg dry weight of the artificial soil]	Replicate	Number of juveniles after 8 weeks of the exposure [no.]	Changes in behaviour and in morphology
0.0 (control)	1	319	nc
	2	221	nc
	3	250	nc
	4	247	nc
	5	263	nc
	6	215	nc
	7	259	nc
	8	233	nc
0.56	1	286	nc
	2	292	nc
	3	212	nc
	4	222	nc
1.0	1	241	nc
	2	284	nc
	3	225	nc
	4	255	nc
1.8	1	246	nc
	2	235	nc
	3	227	nc
	4	249	nc
3.2	1	209	nc
	2	235	nc
	3	199	nc
	4	201	nc
5.6	1	181	nc
	2	162	nc
	3	191	nc
	4	167	nc
10.0	1	136	nc
	2	150	nc
	3	116	nc
	4	112	nc
18.0	1	42	nc
	2	95	nc
	3	97	nc
	4	64	nc
32.0	1	0	-
	2	5	nc
	3	10	nc
	4	14	nc
56.0	1	0	-
	2	0	-
	3	0	-
	4	0	-
100.0	1	0	-
	2	0	-
	3	0	-
	4	0	-

After 8 weeks of the experiment, the juveniles of earthworms did not exhibit any changes in appearance and behaviour.

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CONCLUSION

The concentration of the test item causing 50% mortality of the adult earthworms (LC₅₀) is equal to 22.49 mg/kg dry weight of the artificial soil (i.e. 4.25 mg of acetamiprid /kg dry weight of the artificial soil).

Table KCP 10.4.1.1-5: Earthworm reproduction test – final results

Parameter	Value [mg test item/kg dry weight of artificial soil]	Value [mg of acetamiprid/kg dry weight of artificial soil]
EC ₁₀	2.81 (2.11 – 3.48)	0.53 (0.40 – 0.66)
EC ₂₀	4.28 (3.46 – 5.03)	0.81 (0.65 – 0.95)
EC ₅₀	9.54 (8.46 – 10.75)	1.80 (1.60 – 2.03)
NOEC (reproduction)	1.80	0.34
LOEC (reproduction)	3.20	0.60
LC ₅₀	22.49 (16.21 – 29.57)	4.25 (3.06 – 5.59)
NOEC (survival)	5.60	1.06
LOEC (survival)	10.0	1.89

A 2.4.1.2 KCP 10.4.1.2 Earthworms - field studies

Not relevant. No studies submitted.

A 2.4.2 KCP 10.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms)

A 2.4.2.1 KCP 10.4.2.1 Species level testing

Comments of zRMS:	The study was accepted by zRMS. The validity criteria was met:
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The agreed toxicity endpoints:

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Table 1b. Reproduction of soil mite <i>Hypoaspis (Geolaelaps) aculeifer</i>											
Acetamipryd 200 SL											
	T1 Control	T2 7.56 mg test item/kg soil d.w.	T3 13.61 mg test item/kg soil d.w.	T4 24.50 mg test item/kg soil d.w.	T5 44.10 mg test item/kg soil d.w.	T6 79.38 mg test item/kg soil d.w.	T7 142.89 mg test item/kg soil d.w.	T8 257.20 mg test item/kg soil d.w.	T9 462.96 mg test item/kg soil d.w.	T10 833.33 mg test item/kg soil d.w.	T11 1500 mg test item/kg soil d.w.
	Deionised water	1.32 mg a.i./kg soil d.w.	2.38 mg a.i./kg soil d.w.	4.28 mg a.i./kg soil d.w.	7.71 mg a.i./kg soil d.w.	13.88 mg a.i./kg soil d.w.	24.98 mg a.i./kg soil d.w.	44.97 mg a.i./kg soil d.w.	80.94 mg a.i./kg soil d.w.	145.69 mg a.i./kg soil d.w.	262.24 mg a.i./kg soil d.w.
Reproduction [mean juveniles]	172.75	162.00	158.75	158.25	148.25	147.75	133.75	130.75	124.25	101.00	66.50
Effect on reproduction [%R]	-	6.2	8.1	8.4	14.2	14.5	22.6	24.3	28.1	41.5	61.5
Significance ^a	-	n.s.	n.s.	n.s.	*	*	*	*	*	*	*
Endpoint					mg test item/kg soil d.w.			mg a.i./kg soil d.w. [#]			
EC ₁₀ [95% confidence intervals] (Reproduction)					65.95 [24.88 – 174.85]			11.53 [4.35 – 30.57]			
EC ₂₀ [95% confidence intervals] (Reproduction)					182.63 [66.61 – 497.65]			31.93 [11.65 – 87.00]			
EC ₅₀ [95% confidence intervals] (Reproduction)					1281.80 [317.83 – U.L. n.d.]			224.09 [55.56 – U.L. n.d.]			
NOEC (Reproduction)					24.50			4.28			
LOEC (Reproduction)					44.10			7.71			

[#] The active ingredient content was calculated based on the nominal test item content of 200 g/L and actual density of 1.144 g/mL.
d.w. = dry weight soil
a.i. = acetamiprid
-, not applicable
a, Williams' t-test, α=0.05 *
n.s., not significantly different compared to the control
95%-U.L. Upper Limit
n.d.: not determined due to mathematical reasons

Reference: KCP 10.4.2.1/01

Report: Predatory mites *Hypoaspis (Geolaelaps) aculeifer* reproduction test in soil with Acetamipryd 200 SL;
Mautino G.; 2023; Study Code: 1039.I.SAG23/r

Guideline(s): Yes, OECD 226

Deviations: To add the Dosages of the Definitive test, To add the Analytical Phase Plan deadlines, To add Sampling Specimen codes for dosages T10 and T11, To add the Analytical Phase plan code, To add the Analytical Phase plan amendment 1

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study): No

MATERIALS AND METHODS

1. Test material

Test item (chemical/other name): Acetamipryd 200 SL

Formulation: SL (soluble liquid), acetamiprid: specification 200.0 g/L

Description (physical state): liquid

Batch no.: 1/ACE/2022

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Production date:	01.2022
Expiration date:	01.2024
2. Vehicle and/or positive control:	vehicle: deionized water positive control: ROGOR L 40 ST (nominally 400 g/L dime- thoate)
3. Test organism	
Species:	Predatory mite (Acari, Laelapidae), <i>Hypoaspis (Geo- laelaps) aculeifer</i> Canestrini
Source:	Katz Biotech AG, Baruth, Germany
Age:	28-35 days after the start of the egg-laying period
Sex:	females
Diet:	after the introduction of the test organisms (day 0) and 3 times a week, a small amount of <i>Tyrophagus putres- centiae</i> (Schränk) was provided to the mites ad libitum. T. putrescentia was provided by Katz Biotech AG, Baruth, Germany
Test units:	inert plastic (non-toxic) box (diameter: 4.6 cm), partly transparent, with a cross-sectional area that allows the ac- tual soil depth within it of 1.5 cm with polyethylene lid as a locking system
4. Environmental conditions:	
Temperature:	19.24 ± 0.238 °C (18.95 – 19.90 °C)
Humidity:	$73.2 \pm 2.0\%$ (69.6 – 77.9%)
Soil:	artificial soil: 5% sphagnum peat, 20% kaolin clay, 88% quartz sand
Stability of test compound:	the content of Acetamiprid 200 SL (nominally acetam- iprid 200 g/L) active ingredient was determined in soil samples collected during the trial at the beginning, during and at the end of the test,
WHC:	38.39%
pH:	6.08
Photoperiod:	light-dark cycle: 16 h light and 8 h dark, 650 lux

STUDY DESIGN AND METHOD

The aim of the study was to determine the effect of Acetamipryd 200 SL (acetamiprid 200 g/L) on the vitality and reproduction of predatory mite under laboratory conditions in an artificial soil substrate. All the experimental procedures were designed by following the OECD Guidelines for testing of chemicals no. 226 (2016). For this reason, *Hypoaspis (Geolaelaps) aculeifer* has been selected to investigate the effect of the test item applied alone on this non-target organism following its application into the soil. For this purpose, a not-GLP Range finding test was initially performed, followed by a Definitive test.

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The Definitive test rates were established taking into consideration the Range finding test results. A 14-day test in treated artificial soil prepared according to the OECD 226 (2016) test guideline; different concentrations of the test item were mixed into the soil. There were 11 treatment groups (10 concentrations of the test item; 1 control), consisting of 4 replicates for the test item treatments and for the reference item and 8 replicates for the control group. Each replicate contained 10 adult female mites. Assessment of adult mortality, behavioural effects and reproduction rate (mean number of juveniles produced per vessel over the test period) was performed after 14-day exposure in treated artificial soil.

Test design:	8 for the control; 4 per test item, 4 additional containers per treatment to check the pH and water content of the test substrate; 10 females per replicate. The synchronous mites were impartially selected
Exposure time:	14 days
Tested concentrations, definitive test:	7.56 mg/kg soil d.w. (1.32 mg as/ kg soil d.w.) – T2 13.61 mg/kg soil d.w. (2.38 mg as / kg soil d.w.) – T3 24.50 mg/kg soil d.w. (4.28 mg as/ kg soil d.w.) – T4 44.10 mg/kg soil d.w. (7.71 mg as /kg soil d.w.) – T5 79.38 mg/kg soil d.w. (13.88 mg as/kg soil d.w.) – T6 142.89 mg/ kg soil d.w. (24.98 mg as /kg soil d.w.) – T7 257.20 mg/ kg soil d.w. (44.97 mg as /kg soil d.w.) – T8 462.96 mg/ kg soil d.w. (80.94 mg as /kg soil d.w.) – T9 833.33 mg/ kg soil d.w. (145.69 mg as /kg soil d.w.)T10 1500 mg/ kg soil d.w. (262.24 mg as /kg soil d.w.)–T11
Dates:	start of the study: 07.02.2023 start of the experimental part: 21.04.2023 end of the experimental part: 09.03.2023 end of the study: 19.09.2023
Statistic:	Software used for statistical analysis was “ToxRatPro” Solutions GmbH, version 3.3.0. Mortality data were processed using the Fisher's Exact Test after Bonferroni Correction, $\alpha \leq 0.05$ and at least the LC50 calculated where possible. Reproduction data were analysed with a Williams' t-test $\alpha = 0.05$ and at least the EC50 calculated where possible. The No Observed Effect Concentration (NOEC) and Lowest Observed Effect Concentration (LOEC) values for mortality, and fecundity were obtained where possible.
Validity of the test:	The following criteria should be satisfied in the control group for a test result to be considered valid: - mean adult mortality $\leq 20\%$ at the end of the test; - mean number of juveniles per replicate at least 50 at the end of the test; - coefficient of variation calculated for the number of juvenile mites per replicate $\leq 30\%$ at the end of the Definitive test.

RESULTS

Mean adult mortality after 14 days was ranged between 2.50% in T7 (142.89 mg test item/kg soil d.w.) to 7.50% in T11 (1500 mg test item/kg soil d.w.); compared to 0.00% in the control group. No significant difference in terms of survival was observed in comparison to the control group. The NOEC and LOEC (mortality) values were estimated to be ≥ 1500 mg test item/kg soil d.w. (≥ 262.24 mg a.i./kg soil d.w.) and >1500 mg test item/kg soil d.w. (>262.24 mg a.i./kg soil d.w.) respectively. The LC10 value could not be determined, but was estimated to be >1500 mg test item/kg soil d.w. (95% confidence limits not determined) corresponding to >262.24 mg a.i./kg soil d.w. The LC20 value could not be determined, but was estimated to be >1500 mg test item/kg soil d.w. (95% confidence limits not determined) corresponding to >262.24 mg a.i./kg soil d.w. The LC50 value could not be determined, but was estimated to be >1500 mg test item/kg soil d.w. (95% confidence limits not determined) corresponding to >262.24 mg a.i./kg soil d.w.

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Concerning morphological alterations, no effects were noticed as consequence of the treatment.

Table KCP 10.4.2.1-1: Summary of results from the mortality assessment

Treatment name	Treatment number	Concentration (mg a.i./kg soil d.w.)	Check 14 days		
			Mortality		
			Mean (%)	±SE ^a	p ^b
Control	T1	-	0.00	0.00	-
Acetamipryd 200 SL at 7.56 mg test item/kg soil d.w.	T2	1.32	0.00	0.00	n.s.
Acetamipryd 200 SL at 13.61 mg test item/kg soil d.w.	T3	2.38	0.00	0.00	n.s.
Acetamipryd 200 SL at 24.50 mg test item/kg soil d.w.	T4	4.28	0.00	0.00	n.s.
Acetamipryd 200 SL at 44.10 mg test item/kg soil d.w.	T5	7.71	0.00	0.00	n.s.
Acetamipryd 200 SL at 79.38 mg test item/kg soil d.w.	T6	13.88	0.00	0.00	n.s.
Acetamipryd 200 SL at 142.89 mg test item/kg soil d.w.	T7	24.98	2.50	0.25	n.s.
Acetamipryd 200 SL at 257.20 mg test item/kg soil d.w.	T8	44.97	2.50	0.25	n.s.
Acetamipryd 200 SL at 462.96 mg test item/kg soil d.w.	T9	80.94	2.50	0.25	n.s.
Acetamipryd 200 SL at 833.33 mg test item/kg soil d.w.	T10	145.69	5.00	0.29	n.s.
Acetamipryd 200 SL at 1500 mg test item/kg soil d.w.	T11	262.24	7.50	0.25	n.s.

a.i. = acetamiprid

d.w.= dry weight soil

a, standard error from 8 replicates (control group) and from 4 replicates (treated groups)

b, Chi² Table test with Bonferroni correction, α≤0.001 ***, 0.01 **, 0.05 *

-, not applicable

n.s., not significantly different compared to the control

In the control group, the number of juvenile mites per replicate ranged from 148 to 211, with a CV of 11.69%. The mean number of juvenile worms was 172.75 in the control group and in the treated group ranged between 66.50 in T11 (1500 mg test item/kg soil d.w.) to 162.00 in T2 (7.56 mg test item /kg soil d.w.). The effect on fecundity ranged between 6.2% in T2 (7.56 mg test item /kg soil d.w.) to 61.5% in T11 (1500 mg test item/kg soil d.w.). Significant differences were observed in terms of fecundity reduction for the treatments T5 (44.10 mg test item/kg soil d.w.), T6 (79.38 mg test item/kg soil d.w.), T7 (142.89 mg test item/kg soil d.w.), T8 (257.20 mg test item/kg soil d.w.), T9 (462.96 mg test item/kg soil d.w.), T10

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(833.33 mg test item/kg soil d.w.) and T11 (1500 mg test item/kg soil d.w.), in comparison to the control. The NOEC (fecundity) and LOEC (fecundity) values were 24.50 mg test item/kg soil d.w. (4.28 mg a.i./kg soil d.w.) and 44.10 mg test item/kg soil d.w. (7.71 mg a.i./kg soil d.w.) respectively. The EC10 value observed was of 65.95 mg test item/kg soil d.w. (95%-CL: 24.88 – 174.85) corresponding to 11.53 mg a.i./kg soil d.w. (95%-CL: 4.35 – 30.57), active ingredient. The EC20 value observed was of 182.63 mg test item/kg soil d.w. (95%-CL: 66.61 – 497.65) corresponding to 31.93 mg a.i./kg soil d.w. (95%-CL: 11.65 – 87.00). The EC50 value observed was of 1281.80 mg test item/kg soil d.w. (95%-CL: 317.83 – Upper Limit not determined) corresponding to 224.09 mg a.i./kg soil d.w. (95%-CL: 55.56 – Upper Limit not determined) in terms of active ingredient.

Table KCP 10.4.2.1-2: Summary of results from the fecundity assessment

Treatment name	Treatment number	Concentration (mg a.i./kg soil d.w.)	Extraction check			Fecundity inhibition (% control)
			Mean number of juvenile mites (%±SE ^a)		<i>p</i> ^b	
Control	T1	-	172.75	7.14	-	-
Acetamipryd 200 SL at 7.56 mg test item/kg soil d.w.	T2	1.32	162.00	9.94	n.s.	6.2
Acetamipryd 200 SL at 13.61 mg test item/kg soil d.w.	T3	2.38	158.75	9.53	n.s.	8.1
Acetamipryd 200 SL at 24.50 mg test item/kg soil d.w.	T4	4.28	158.25	8.66	n.s.	8.4
Acetamipryd 200 SL at 44.10 mg test item/kg soil d.w.	T5	7.71	148.25	7.19	*	14.2
Acetamipryd 200 SL at 79.38 mg test item/kg soil d.w.	T6	13.88	147.75	10.95	*	14.5
Acetamipryd 200 SL at 142.89 mg test item/kg soil d.w.	T7	24.98	133.75	8.37	*	22.6
Acetamipryd 200 SL at 257.20 mg test item/kg soil d.w.	T8	44.97	130.75	8.66	*	24.3
Acetamipryd 200 SL at 462.96 mg test item/kg soil d.w.	T9	80.94	124.25	8.50	*	28.1
Acetamipryd 200 SL at 833.33 mg test item/kg soil d.w.	T10	145.69	101.00	7.18	*	41.5
Acetamipryd 200 SL at 1500 mg test item/kg soil d.w.	T11	262.24	66.50	5.61	*	61.5

a.i. = acetamipryd

d.w. = dry weight soil

a, standard error from 8 replicates (control group) and from 4 replicates (treated groups)

b, Williams' t-test, α= 0.05 *

-, not applicable

n.s., not significantly different compared to the control

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CONCLUSION

The endpoints values are presented in tables below.

Table KCP 10.4.2.1-3: Mortality of soil mite *Hypoaspis (Geolaelaps) aculeifer*

Acetamipryd 200 SL											
	T1 Control	T2 7.56 mg test item/kg soil d.w.	T3 13.61 mg test item/kg soil d.w.	T4 24.50 mg test item/kg soil d.w.	T5 44.10 mg test item/kg soil d.w.	T6 79.38 mg test item/kg soil d.w.	T7 142.89 mg test item/kg soil d.w.	T8 257.20 mg test item/kg soil d.w.	T9 462.96 mg test item/kg soil d.w.	T10 833.33 mg test item/kg soil d.w.	T11 1500 mg test item/kg soil d.w.
	Deionised water	1.32 mg a.i./kg soil d.w.	2.38 mg a.i./kg soil d.w.	4.28 mg a.i./kg soil d.w.	7.71 mg a.i./kg soil d.w.	13.88 mg a.i./kg soil d.w.	24.98 mg a.i./kg soil d.w.	44.97 mg a.i./kg soil d.w.	80.94 mg a.i./kg soil d.w.	145.69 mg a.i./kg soil d.w.	262.24 mg a.i./kg soil d.w.
Mortality [mean %]	0.00	0.00	0.00	0.00	0.00	0.00	2.50	2.50	2.50	5.00	7.50
Significance ^a	-	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
Endpoint					mg test item/kg soil d.w.			mg a.i./kg soil d.w. [#]			
LC ₁₀ [95% confidence intervals] (Mortality)					>1500 [95%-CLs n.d.]			>262.24 [95%-CLs n.d.]			
LC ₂₀ [95% confidence intervals] (Mortality)					>1500 [95%-CLs n.d.]			>262.24 [95%-CLs n.d.]			
LC ₅₀ [95% confidence intervals] (Mortality)					>1500 [95%-CLs n.d.]			>262.24 [95%-CLs n.d.]			
NOEC (Mortality)					≥1500			≥262.24			
LOEC (Mortality)					>1500			>262.24			

[#] The active ingredient content was calculate based on the nominal test item content of 200 g/L and actual density of 1.144 g/mL

d.w.= dry weight soil

a.i. = acetamiprid

-, not applicable

a, Fisher's Exact Test after Bonferroni Correction, $\alpha \leq 0.001$ ***, 0.01 **, 0.05 *

n.s., not significantly different compared to the control

95%-CLs, Confidence Limits

n.d.: not determined due to mathematical reasons

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Table KCP 10.4.2.1-4: Reproduction of soil mite *Hypoaspis (Geolaelaps) aculeifer*

Acetamipryd 200 SL											
	T1 Control	T2 7.56 mg test item/kg soil d.w.	T3 13.61 mg test item/kg soil d.w.	T4 24.50 mg test item/kg soil d.w.	T5 44.10 mg test item/kg soil d.w.	T6 79.38 mg test item/kg soil d.w.	T7 142.89 mg test item/kg soil d.w.	T8 257.20 mg test item/kg soil d.w.	T9 462.96 mg test item/kg soil d.w.	T10 833.33 mg test item/kg soil d.w.	T11 1500 mg test item/kg soil d.w.
	Deionised water	1.32 mg a.i./kg soil d.w.	2.38 mg a.i./kg soil d.w.	4.28 mg a.i./kg soil d.w.	7.71 mg a.i./kg soil d.w.	13.88 mg a.i./kg soil d.w.	24.98 mg a.i./kg soil d.w.	44.97 mg a.i./kg soil d.w.	80.94 mg a.i./kg soil d.w.	145.69 mg a.i./kg soil d.w.	262.24 mg a.i./kg soil d.w.
Reproduction [mean juveniles]	172.75	162.00	158.75	158.25	148.25	147.75	133.75	130.75	124.25	101.00	66.50
Effect on reproduction [%R]	-	6.2	8.1	8.4	14.2	14.5	22.6	24.3	28.1	41.5	61.5
Significance ^a	-	n.s.	n.s.	n.s.	*	*	*	*	*	*	*
Endpoint					mg test item/kg soil d.w.			mg a.i./kg soil d.w. [#]			
EC ₁₀ [95% confidence intervals] (Reproduction)					65.95 [24.88 – 174.85]			11.53 [4.35 – 30.57]			
EC ₂₀ [95% confidence intervals] (Reproduction)					182.63 [66.61 – 497.65]			31.93 [11.65 – 87.00]			
EC ₅₀ [95% confidence intervals] (Reproduction)					1281.80 [317.83 – U.L. n.d.]			224.09 [55.56 – U.L. n.d.]			
NOEC (Reproduction)					24.50			4.28			
LOEC (Reproduction)					44.10			7.71			

[#] The active ingredient content was calculated based on the nominal test item content of 200 g/L and actual density of 1.144 g/mL

d.w. = dry weight soil

a.i. = acetamiprid

-, not applicable

a, Williams' t-test, α=0.05 *

n.s., not significantly different compared to the control

95%-U.L. Upper Limit

n.d.: not determined due to mathematical reasons

Comments of zRMS:	The study was accepted by zRMS.
	The validity criteria was met:
	<p>The following validity criteria were met during the experiment [1]:</p> <ul style="list-style-type: none"> – mean adult mortality of the control group was 13.8% at the end of the test (criterion: not exceed 20%), – mean number of juveniles per vessel in the control was 483.8 at the end of the test (criterion: a minimum of 100 number of offspring), – the coefficient of variation calculated for the number of juveniles in the control was 8.7% (criterion: less than 30%) at the end of the test.
Deviation of the study:	

Two deviations from OECD Guideline No. 232 (2016) were introduced to the Study Plan:

- in order to maintain proper moisture content, the vessels with the artificial soil was weighed at the beginning and after 2 weeks of the exposure. According to OECD Guideline No. 232 the vessels should also be weighed at the end of the test. Instead, the soil moisture content was determined by drying a small sample (about 10 g) at 105°C and re-weighing at the end of the test.
- at the test termination, collembolans was humanely euthanized by freezing at about – 20°C, instead of – 80°C, as it is stated in OECD 232 Guideline.

Above deviations did not affect the study results, since validity criteria were met.

The agreed toxicity endpoints:

Concentration [mg test item/kg dry weight of artificial soil]		Number of tested collembolans	Total mortality		Reproduction	
			No.	[%]	Mean number of juveniles [no.]	Reduction [%]
Control (0.0)		80	11	13.75	483.75	–
R1	0.33	40	7	17.50	483.75	0.000
R2	0.59	40	6	15.00	459.00	5.116
R3	1.06 ⁺	40	18	45.00	389.75	19.432
R4	1.91 ⁺	40	17	42.50	295.25	38.966
R5	3.43 ⁺	40	22	55.00	100.75	79.173
R6	6.17 ⁺	40	24	60.00	2.75	99.432
R7	11.11 ⁺	40	31	77.50	0.00	100.000
R8	20.00 ⁺	40	35	87.50	0.00	100.000

+ : statistically significant difference in mortality and mean number of juveniles

Endpoints calculated for test item concentrations [mg test item/kg dry weight of artificial soil]			
Mortality		Reproduction	
LC ₁₀	0.53 (0.17 – 0.96)*	EC ₁₀	0.81 (0.56 – 1.02)*
LC ₂₀	1.06 (0.48 – 1.70)*	EC ₂₀	1.11 (0.84 – 1.32)*
LC ₅₀	3.98 (2.58 – 6.57)*	EC ₅₀	2.02 (1.76 – 2.33)*
LOEC	1.06	LOEC	1.06
NOEC	0.59	NOEC	0.59

Endpoints calculated for acetamiprid concentrations [mg/kg dry weight of artificial soil]			
Mortality		Reproduction	
LC ₁₀	0.09 (0.03 – 0.16)*	EC ₁₀	0.13 (0.09 – 0.17)*
LC ₂₀	0.17 (0.08 – 0.28)*	EC ₂₀	0.18 (0.14 – 0.22)*
LC ₅₀	0.66 (0.43 – 1.08)*	EC ₅₀	0.33 (0.29 – 0.38)*
LOEC	0.17	LOEC	0.17
NOEC	0.10	NOEC	0.10

* LCx, ECx values (with 95% - confidence limits)

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Reference: KCP 10.4.2.1/02

Report Collembolan (*Folsomia candida*) Reproduction Test in soil;
Szlaue S.; 2024; Study Code: ETOX-2024-2

Guideline(s): Yes, OECD 232

Deviations: Two deviations from OECD Guideline No. 232 (2016) were introduced to the Study Plan:
- in order to maintain proper moisture content, the vessels with the artificial soil was weighed at the beginning and after 2 weeks of the exposure. According to OECD Guideline No. 232 the vessels should also be weighed at the end of the test. Instead, the soil moisture content was determined by drying a small sample (about 10 g) at 105°C and re-weighing at the end of the test,
- at the test termination, collembolans was humanely euthanized by freezing at about – 20°C, instead of – 80°C, as it is stated in OECD 232 Guideline.

GLP: Yes

Acceptability: Yes

Duplication No
(if vertebrate study)

MATERIALS AND METHODS

1. Test material

Test item (chemical/other name): Acetamipryd 200 SL

Formulation: SL (soluble liquid), acetamiprid: specification 200.0 g/L

Description (physical state): -

Batch no.: 1/ACE/2024

Production date: 01.2024

Expiration date: 01.2026

2. Vehicle and/or positive control: vehicle: water
positive control: boric acid

3. Test organism

Species: collembolan *Folsomia candida*

Source: laboratory culture at Test Facility, obtained from commercial supplier: Bias Labs Ltd.

Age: synchronised 9 –12 days old; hatched from eggs laid from 21.05 – 31.05.2024

Sex: females

Diet: During the experiment, the collembolans were fed with granulated dried baker's yeast. The amount of food was about 10 mg/container. The collembolans were fed at the beginning of the experiment and after 2 weeks of incubation. Food was introduced into each test vessel using a small spatula.

Test units: Glass bottles with a capacity of 100 mL were used to allow light transmission. The actual soil depth within the test vessels was 2 – 4 cm. The vessel's lids were made from polyethylene to reduce water evaporation.

4. Environmental conditions:

Temperature: 18.3 – 20.9°C

Soil: The artificial soil was prepared before the study. It consisted of the following components: 5% sphagnum peat (a particle size of 2 ± 1 mm), 20% kaolin clay, 75% air-dried industrial sand with more than 50% of the particles between 50 and 200 μ m.

Stability of test compound: In order to verify the nominal active substance concentrations in soil, the analytical measurements of the artificial soil treated with the test item at the concentrations of: 0.33, 3.45 and 20.00 mg of the test item/kg soil dry weight and the control were performed at the beginning, after 14 days of the experiment and at the end of the test. The concentrations of acetamiprid were determined using a validated own analytical method.

WHC: 24.15%

pH: 6 ± 0.5

Photoperiod: 16-hour light and 8-hour dark

STUDY DESIGN AND METHOD

The aims of the study were to assess the impact of ACETAMIPRYD 200 SL on mortality and reproduction of the collembolans, *Folsomia candida* and to determine the LC10, LC20, LC50 and NOEC/LOEC values for mortality as well as EC10, EC20, EC50, and NOEC/LOEC values for reproduction. Eight concentrations of the test item were used. These were 0.33, 0.59, 1.06, 1.91, 3.43, 6.17, 11.11 and 20.00 mg of the test item/kg of dry weight of the artificial soil. Each concentration was divided into four replicates. There was also an untreated control group divided into eight replicates. The test item in form of aqueous solution was mixed with the artificial soil. The control artificial soil was mixed with ultrapure water alone. The experiment lasted 28 days. After that, the collembolans were extracted from the artificial soil. The numbers of adults and juveniles were determined separately. The sensitivity of the biological test system was verified using a reference item, i.e. boric acid at the doses of 15.0, 22.0, 32.0, 46.0, 68.0, 100.0, 150.0, 220.0, 320.0, 460.0, 680.0 and 1000.0 mg/kg dry weight of artificial soil.

Test design: 8 concentrations in 4 replicates + untreated control in 8 replicates; 10 females in each vessel

Exposure time: 28 days

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Tested concentrations, definitive test: 0.33, 0.59, 1.06, 1.91, 3.43, 6.17, 11.11 and 20.00 mg of the test item/kg of dry weight of the artificial soil

Dates: start of the experimental part: 14 June, 2024
 end of the experimental part: 17 July, 2024

Statistic: Statistical analysis was performed using ToxRat Professional software, version 3.3.0. LCx and ECx values were calculated with Probit analysis using linear max likelihood regression. Significance of differences in mortality was checked Step-down Cochran-Armitage test procedure, statistical differences at $p(\text{trend}) < \text{Alpha } 0.05$ were considered significant. Significance of differences in reproduction assessment was checked using Williams Multiple Sequential t-test Procedure, statistical differences at $|t| > |t^*|$ were considered significant. Normal distribution and variance homogeneity of offspring number data were checked using Shapiro-Wilk's and Levene's Tests.

Validity of the test: The following validity criteria were met during the experiment:
 –mean adult mortality of the control group was 13.8% at the end of the test (criterion: not exceed 20%),
 –mean number of juveniles per vessel in the control was 483.8 at the end of the test (criterion: a minimum of 100 number of offspring),
 –the coefficient of variation calculated for the number of juveniles in the control was 8.7% (criterion: less than 30%) at the end of the test.

RESULTS

Mortality after 28 days of the experiment is presented in Table 5, whereas the endpoint values, showing the impact of the test item on mortality are shown in table below.

Table KCP 10.4.2.1-5: Mortality of adult collembolans (*Folsomia candida*) after 28 days of exposure

Concentration [mg/kg of dry weight of the ar- tificial soil]	Replicate	Number of liv- ing collembolans after 28 days [no.]	Observations	Total mortality	
				[no.]	[%]
0.0 (Control)	1	8	bz	11	13.75
	2	9	bz		
	3	6	bz		
	4	9	bz		
	5	9	bz		
	6	9	bz		
	7	10	bz		
	8	9	bz		

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R1	0.33	1 2 3 4	7 8 10 8	bz bz bz bz	7	17.50
R2	0.59	1 2 3 4	8 8 9 9	bz bz bz bz	6	15.00
R3	1.06⁺	1 2 3 4	8 2 7 5	bz bz bz bz	18	45.00
R4	1.91⁺	1 2 3 4	8 7 4 4	bz bz bz bz	17	42.50
R5	3.43⁺	1 2 3 4	6 6 3 3	bz bz bz bz	22	55.00
R6	6.17⁺	1 2 3 4	3 5 3 5	en en en en	24	60.00
R7	11.11⁺	1 2 3 4	1 1 3 4	en en en en	31	77.50
R8	20.00⁺	1 2 3 4	3 0 2 0	en - en -	35	87.50

+ : statistically significant difference between the control and the treatment group
 bz: no change; en: negative effect

After 28 days, the percentage of mortality of *Folsomia candida* in the control group was equal to 13.75%. After 28 days of exposure to the test item at the concentrations of 0.33, 0.59, 1.06, 1.91, 3.43, 6.17, 11.11 and 20.00 mg/kg dry weight of the artificial soil, mortality of *Folsomia candida* was 17.50, 15.00, 45.00, 42.50, 55.00, 60.00, 77.50, 87.50%, respectively. There were statistically significant differences in mortality between groups treated with the test item at the concentrations from 1.06 to 20.00 mg/kg dry weight of the artificial soil, in comparison to the control group.

The concentrations of the test item causing 10, 20 and 50% mortality of adults after the exposure period are

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equal to:

- LC₁₀: 0.53 mg/kg dry weight of the artificial soil (95% confidence limits: 0.17 – 0.96).
- LC₂₀: 1.06 mg/kg dry weight of the artificial soil (95% confidence limits: 0.48 – 1.70).
- LC₅₀: 3.98 mg/kg dry weight of the artificial soil (95% confidence limits: 2.58 – 6.57).

The LOEC value for mortality is 1.06 mg/kg dry weight of the artificial soil.

The NOEC value for mortality is 0.59 mg/kg dry weight of the artificial soil.

Reproduction results are presented in table below.

Table KCP 10.4.2.1-6: Number of juvenile collembolans (*Folsomia candida*) and reproduction reduction after 28 days of exposure

Concentration [mg/kg of dry weight of the ar- tificial soil]		Replicate	Number of ju- veniles	Mean ± SD	Reduction [%]	CV* [%]
0.0 (Control)		1	491	483.750 ± 42.1519	–	8.714
		2	470			
		3	485			
		4	391			
		5	491			
		6	502			
		7	537			
		8	503			
R1	0.33	1	436	483.750 ± 76.3779	0.000	15.789
		2	497			
		3	586			
		4	416			
R2	0.59	1	492	459.000 ± 35.9166	5.116	7.825
		2	416			
		3	443			
		4	485			
R3	1.06⁺	1	452	389.750 ± 160.8195	19.432	41.262
		2	198			
		3	574			
		4	335			
R4	1.91⁺	1	338	295.250 ± 31.8891	38.966	10.801
		2	298			
		3	282			
		4	263			
R5	3.43⁺	1	103	100.750 ± 53.6182	79.173	53.219
		2	32			
		3	105			
		4	163			
R6	6.17⁺	1	6	2.750 ± 2.5000	99.432	90.909
		2	0			
		3	2			
		4	3			
R7	11.11⁺	1	0	0.000 ± 0.0000	100.000	–
		2	0			

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		3	0			
		4	0			
R8	20.00⁺	1	0	0.00 ± 0.0000	100.000	–
		2	0			
		3	0			
		4	0			

*CV: coefficient of variation

+: statistically significant difference between the control and the treatment group

After 28 days, the mean number of juveniles in the control group was equal to 483.75. After 28 days of the exposure of collembolans to the test item at the concentrations of 0.33, 0.59, 1.06, 1.91, 3.43, 6.17, 11.11 and 20.00 mg/kg dry weight of the artificial soil, the mean number of juveniles was 483.75, 459.00, 389.75, 295.25, 100.75, 2.75, 0.00 and 0.00 respectively. There were statistically significant differences in reproduction between the groups treated with the test item at the concentrations 1.06, 1.91, 3.43, 6.17, 11.11 and 20.00 mg/kg dry weight of the artificial soil and the control group. The reproduction reduction in the groups treated with the test item at the concentrations of 0.33, 0.59, 1.06, 1.91, 3.43, 6.17, 11.11 and 20.00 mg/kg dry weight of the artificial soil, was: 0.000, 5.116, 19.432, 38.966, 79.173, 99.432, 100.000 and 100.000% in comparison to the control group.

The concentrations of the test item causing 10, 20 and 50% reduction in the number of juvenile after the exposure period are equal to:

- EC10: 0.81 mg/kg dry weight of the artificial soil (95% confidence limits: 0.56 – 1.02)
- EC20: 1.11 mg/kg dry weight of the artificial soil (95% confidence limits: 0.84 – 1.32)
- EC50: 2.02 mg/kg dry weight of the artificial soil (95% confidence limits: 1.76 – 2.33)

The LOEC value for mean number of offspring is 1.06 mg/kg dry weight of the artificial soil.

The NOEC value for mean number of offspring is 0.59 mg/kg dry weight of the artificial soil.

CONCLUSION

The endpoints values are presented below.

Table KCP 10.4.2.1-7: Endpoint values - the impact of the test item on the mortality and the reproduction of collembolans (*Folsomia candida*)

Endpoints calculated for test item concentrations [mg test item/kg dry weight of artificial soil]			
Mortality		Reproduction	
LC₁₀	0.53 (0.17 – 0.96)*	EC₁₀	0.81 (0.56 – 1.02)*
LC₂₀	1.06 (0.48 – 1.70)*	EC₂₀	1.11 (0.84 – 1.32)*
LC₅₀	3.98 (2.58 – 6.57)*	EC₅₀	2.02 (1.76 – 2.33)*
LOEC	1.06	LOEC	1.06
NOEC	0.59	NOEC	0.59

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Endpoints calculated for acetamiprid nominal concentrations [mg/kg dry weight of artificial soil]			
Mortality		Reproduction	
LC ₁₀	0.09 (0.03 – 0.16)*	EC ₁₀	0.13 (0.09 – 0.17)*
LC ₂₀	0.17 (0.08 – 0.28)*	EC ₂₀	0.18 (0.14 – 0.22)*
LC ₅₀	0.66 (0.43 – 1.08)*	EC ₅₀	0.33 (0.29 – 0.38)*
LOEC	0.17	LOEC	0.17
NOEC	0.10	NOEC	0.10

* LCx, ECx values (with 95% - confidence limits)

A 2.4.2.2 KCP 10.4.2.2 Higher tier testing

Not relevant. No studies submitted.

A 2.5 KCP 10.5 Effects on soil nitrogen transformation

Comments of zRMS:	The study was accepted by zRMS.
	The validity criteria was met:
	The coefficients of variation (CV) in the control group were 3.2, 1.6, 7.4 and 5.6%, after 0, 7, 14 and 28 days of incubation. The validity criterion was met, because the variation between replicate control samples is less than 15%.
	Deviation in the study:
	<u>Deviation from the OECD Guideline No. 216 (2000), the EU Method C.21:</u> According the Guideline, the soil extraction should be conducted at 150 rpm for 60 min. However, in this study, the extraction was performed at 90 rpm and time duration between 18 to 24 hours. The modification resulted from the optimization of the nitrate extraction which showed that the extraction was more effective when the shaking rate was lower and the extraction lasted longer (point 3.4.4.4.). These deviation did not affect the results of the study.
	The agreed toxicity endpoints:
	Nitrate formation rate* [mg nitrate/kg dry weight of soil/day] for selected time intervals.

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Time interval [d]	Control					PEC				5xPEC				
	Replicate			Mean ± SD	Replicate			Mean ± SD	Replicate			Mean ± SD		
	I	II	III		I	II	III		I	II	III			
0 – 7	13.266	10.623	17.552	13.814 ± 3.50	-4.425	-11.425	-0.496	-5.448* ± 5.54	7.647	10.933	9.718	9.433* ± 1.66		
0 – 14	6.429	15.286	24.357	15.357 ± 8.96	12.012	14.476	13.798	13.429 ± 1.27	22.191	20.762	20.905	21.286 ± 0.79		
0 – 28	11.230	16.016	18.855	15.367 ± 3.85	14.754	14.093	15.718	14.855 ± 0.82	19.129	17.468	19.218	18.605 ± 0.99		

* - Rate of nitrate ions formation per a day = [(mg nitrate / kg of soil dry weight on sampling day 'a') - (mg nitrate / kg of soil dry weight on day 0)]/ 'a' day; 'a' = 7, 14 and 28 day

* - statistically significant difference between the control and the treatment group (Williams Multiple Sequential t-test Procedure, significance level = 0.05, two-sided)

Reference: KCP 10.5/01

Report Acetamipryd 200 SL Soil Microorganisms: Nitrogen Transformation Test; Wróbel A.; 2022; Study Code: G-94-21

Guideline(s): Yes, OECD 216

Deviations: According to the Guideline, the soil extraction should be conducted at 150 rpm for 60 min. However, in this study, the extraction was performed at 90 rpm and time duration between 18 to 24 hours. The modification resulted from the optimization of the nitrate extraction which showed that the extraction was more effective when the shaking rate was lower and the extraction lasted longer. These deviations did not affect the results of the study.

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study) No

MATERIALS AND METHODS

1. Test material

Test item (chemical/other name): Acetamipryd 200 SL

Formulation: SL (soluble liquid), acetamidrid: specification 200.0 g/L

Description (physical state): light brown liquid

Batch no.: 1/ACE/2022

Production date: 01.2022

Expiration date: 01.2024

2. Vehicle and/or positive control: vehicle: deionized water
positive control: not relevant

3. Test organism

Soil:	the site chosen for soil collection was covered with grass, it had not been treated with any plant protection products or organic and inorganic fertilizers for at least 5 years, soil samples were taken from a depth of 20 cm, they were collected from different parts of the field to obtain a common laboratory sample
Source:	collected from a place belonging to the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna
Soil preparation:	the collected soil was manually cleared of large objects, sieved to a particle size equal to 2 mm and thus the laboratory soil sample was obtained, the soil, prepared in that way, was thoroughly mixed and divided into three equal portions, the test item at two concentrations: PEC and 5 x PEC was added into two portions of the soil, the test item in the form of aqueous suspensions was introduced to the soil, the control artificial soil was mixed with deionized water alone, at the beginning of the experiment, the soil moisture content was adjusted with deionized water to obtain value between 40 – 60% (about 50%) of the maximum water holding capacity
Test units:	test container
4. Environmental conditions:	
Temperature:	20.2 – 22.0°C
Soil moisture:	44.2 – 48.9% of the maximum water holding capacity
Photoperiod:	darkness

STUDY DESIGN AND METHOD

The aim of the study was to detect long-term adverse effects of Acetamipryd 200 SL on the processes of nitrogen transformation in aerobic surface soils. The freshly collected agricultural soil was used in the experiment. It was manually cleared of large objects and sieved to a particle size of 2 mm.

Two concentrations of the test item were used, i.e.:

- PEC: 0.17 mg test item/kg dry weight of soil
- 5 x PEC: 0.85 mg test item/kg dry weight of soil.

The treated and the control soils were divided into three replicates.

On days 0, 7, 14 and 28 of incubation, soil samples were collected to determine the quantities of nitrate. The method involves a measurement of the nitrates ions concentration in a soil extract obtained by using deionised water. The pH/ION 7320 digital meter and the NO 800 nitrate electrode were used. The nitrate formation rate in each treated group was compared with that in the control, and the percent deviation of the treated from the control was calculated.

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Test design:	three portions of soil (3 x 1500 g), i.e. one control group and two treated groups. Every portion was divided into three replicates (3 x 500 g); the soil was enriched with the organic substrate, i.e. lucerne at dose of 5 g/kg dry weight of soil.
Exposure time:	28 days
Tested concentrations, definitive test:	PEC: 0.17 mg of the test item / kg dry weight of soil (0.03 mg of as / kg dry weight of soil) and 5 x PEC: 0.85 mg of the test item / kg dry weight of soil (0.15 mg of as / kg dry weight of soil)
Stability of the test compound:	-
Dates:	start of the study 30.03.2022 start of the experimental part: 12.04.2022 end of the experimental part: 11.05.2022 end of the study: 20.07.2022
Statistic:	Shapiro-Wilk's test on Normal Distribution Levene's Test on Variance Homogeneity (with Residuals) Williams Multiple Sequential t-test Procedure
Validity of the test:	The coefficients of variation (CV) in the control group were 3.2, 1.6, 7.4 and 5.6%, after 0, 7, 14 and 28 days of incubation. The validity criterion was met, because the variation between replicate control samples is less than 15%.

RESULTS

The difference in the nitrate formation rate between the control soil and the ones treated with the test item at the concentrations corresponding to the PEC: 0.17 mg test item/kg dry weight of soil and 5 x PEC: 0.85 mg test item/kg dry weight of soil did not exceed 25% on 28 day of analysis.

Table KCP 10.5.-1: Nitrate formation rate [mg nitrate/kg dry weight of soil/day] for selected time intervals

Time interval [d]	Control				PEC				5xPEC			
	Replicate			Mean ± SD	Replicate			Mean ± SD	Replicate			Mean ± SD
	I	II	III		I	II	III		I	II	III	
0 – 7	13.266	10.623	17.552	13.814 ± 3.50	-4.425	-11.425	-0.496	-5.448 ⁺ ± 5.54	7.647	10.933	9.718	9.433 ⁺ ± 1.66
0 – 14	6.429	15.286	24.357	15.357 ± 8.96	12.012	14.476	13.798	13.429 ± 1.27	22.191	20.762	20.905	21.286 ± 0.79
0 – 28	11.230	16.016	18.855	15.367 ± 3.85	14.754	14.093	15.718	14.855 ± 0.82	19.129	17.468	19.218	18.605 ± 0.99

* - Rate of nitrate ions formation per a day = [(mg nitrate / kg of soil dry weight on sampling day 'a') - (mg nitrate / kg of soil dry weight on day 0)] / 'a' day; 'a' = 7, 14 and 28 day

* - statistically significant difference between the control and the treatment group (Williams Multiple Sequential t-test Procedure, significance level = 0.05, two-sided)

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Table KCP 10.5.-2: Deviations from the control based on nitrate formation rate for selected time intervals [%]

Time interval [d]	PEC	5 x PEC
0 – 7	139.4	31.7
0 – 14	12.6	-38.6
0 – 28	3.3	-21.1

CONCLUSION

On the basis of the results, it was concluded that Acetamiprid 200 SL at the concentrations corresponding to the PEC: 0.17 mg test item/kg dry weight of soil and 5 x PEC: 0.85 mg test item/kg dry weight of soil did not have any long-term adverse effects on the process of nitrogen transformation in aerobic surface soils.

A 2.6 KCP 10.6 Effects on terrestrial non-target higher plants

A 2.6.1 KCP 10.6.1 Summary of screening data

A 2.6.2 KCP 10.6.2 Testing on non-target plants

Comments of zRMS:	The study was accepted by zRMS.
	The validity criteria was met:
	<p>On the basis of the obtained results, it was stated that the following validity criteria of the study aimed at evaluating the impact of Acetamipryd 200 SL on seedling emergence and seedling growth of terrestrial plants were met:</p> <ul style="list-style-type: none"> - the seedling emergence in the control (validity criterion: at least 70%) was as follows: <ul style="list-style-type: none"> 100% – sunflower, 100% – pea, 85.7% – cabbage, 100% – onion, 100% – perennial ryegrass, 100% – oats, - the mean survival of the emerged control seedlings was 100% for each tested plant species (validity criterion: 90%); - the control seedlings did not exhibit any visible phytotoxic effects; - environmental conditions for all plants of the same species were identical.
	Deviation in the study:

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	<p><u>Deviation from OECD Guideline No. 208:</u></p> <p>According to OECD Guideline No. 208 (2006), the light intensity should be $350 \pm 50 \mu\text{E}/\text{m}^2/\text{s}$. However, these values are recommended for tests conducted in greenhouses. The experiment was conducted in a test room, where only artificial lighting was used. The light intensity was between 106.8 and 259.2 $\mu\text{E}/\text{m}^2/\text{s}$. Good control plant vigour was observed. Therefore, it was concluded that the light intensity was suitable for plant growing.</p>					
	The agreed toxicity endpoints:					
		Sunflower <i>Helianthus annuus</i>	Pea <i>Pisum sativum</i>	Cabbage <i>Brassica oleracea var. capitata</i>	Onion <i>Allium cepa</i>	Perennial ryegrass <i>Lolium perenne</i>
						Oats <i>Avena sativa</i>
	Plant number at the end of the experiment					
	ER ₅₀	>1500.0	>1500.0	>1500.0	>1500.0	>1500.0
	NOER	>1500.0*	> 1500.0*	≥1500.0	≥1500.0	≥1500.0
	Shoot length					
	ER ₅₀	>1500.0	>1500.0	>1500.0	>1500.0	>1500.0
	NOER	750.0	≥1500.0	≥1500.0	≥1500.0	375.0
	Plant dry weight					
	ER ₅₀	>1500.0	>1500.0	>1500.0	>1500.0	>1500.0
	NOER	≥1500.0	≥1500.0	≥1500.0	≥1500.0	≥1500.0
	Plant Damage					
	ER ₅₀	>1500.0	>1500.0	>1500.0	>1500.0	>1500.0
	<p>*the value could not be determined, it can be probably higher than the highest rate of the test item used in the experiment, i.e. 1500 mL/ha</p>					

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	Sunflower <i>Helianthus annuus</i>	Pea <i>Pisum sativum</i>	Cabbage <i>Brassica oleracea var. capitata</i>	Onion <i>Allium cepa</i>	Perennial ryegrass <i>Lolium perenne</i>	Oats <i>Avena sativa</i>
Plant number at the end of the experiment						
ER ₅₀	>295.8	>295.8	>295.8	>295.8	>295.8	>295.8
NOER	>295.8*	> 295.8*	≥295.8	≥295.8	≥295.8	≥295.8
Shoot length						
ER ₅₀	>295.8	>295.8	>295.8	>295.8	>295.8	>295.8
NOER	147.9	≥295.8	≥295.8	≥295.8	74.0	≥295.8
Plant dry weight						
ER ₅₀	>295.8	>295.8	>295.8	>295.8	>295.8	>295.8
NOER	≥295.8	≥295.8	≥295.8	≥295.8	≥295.8	≥295.8
Plant Damage						
ER ₅₀	>295.8	>295.8	>295.8	>295.8	>295.8	>295.8
*the value could not be determined, it can be probably higher than the highest rate of the test item used in the experiment, i.e. 295.8 g a.s./ha						

Reference: KCP 10.6.2/01

Report Acetamipryd 200 SL Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test;
 Wróbel A.; 2022; Study Code: G-96-21

Guideline(s): Yes, OECD 208

Deviations: According to OECD Guideline No. 208 (2006), the light intensity should be $350 \pm 50 \mu\text{E}/\text{m}^2/\text{s}$. However, these values are recommended for tests conducted in greenhouses. The experiment was conducted in a test room, where only artificial lighting was used. The light intensity was between 106.8 and $259.2 \mu\text{E}/\text{m}^2/\text{s}$. Good control plant vigour was observed. Therefore, it was concluded that the light intensity was suitable for plant growing. The deviation did not affect the results of the study.
 Deviation from the Study Plan: The study finished in August 2022, not in July 2022 as it had been planned. These deviations did not affect results of the experiment.

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study) No

MATERIALS AND METHODS

1. Test material

Test item (chemical/other name): Acetamipryd 200 SL

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Formulation:	SL (soluble liquid), acetamiprid: specification 200.0 g/L
Description (physical state):	light brown liquid
Batch no.:	1/ACE/2022
Production date:	01.2022
Expiration date:	01.2024
2. Vehicle and/or positive control:	vehicle control: water positive control: not relevant
3. Test plants:	sunflower (<i>Helianthus annuus</i>), pea (<i>Pisum sativum</i>), cabbage (<i>Brassica oleracea</i> var. <i>capitata</i>), onion (<i>Allium cepa</i>), perennial ryegrass (<i>Lolium perenne</i>), oats (<i>Avena sativa</i>)
Seed sowing:	There were the following number of seeds in each pot: - sunflower: 3 seeds/pot – 21 seeds/application rate (7 pots/application rate); - pea: 3 seeds/pot – 21 seeds/application rate (7 pots/application rate); - cabbage: 3 seeds/pot – 21 seeds/application rate (7 pots/application rate); - onion: 5 seeds/pot – 20 seeds/ application rate (4 pots/ application rate); - perennial ryegrass: 5 seeds/pot – 20 seeds/ application rate (4 pots/ application rate); - oats: 5 seeds/pot – 20 seeds/ application rate (4 pots/ application rate).
Soil:	sandy loam, collected from the place belonging to the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna, (49° 59', 780 N; 18°55', 190 E) where no plant protection products or organic and inorganic fertilizers had been used; the soil was collected from a depth of 20 cm, it was manually cleared of large objects, e.g. plant residuals or stones, and sieved to 2 mm particle size
Test containers:	plastic pots (diameter: 15 cm; 177 cm ²)
4. Environmental conditions:	
Temperature:	16.0 – 22.7 °C
Relative humidity:	50.1 – 79.7 %
Photoperiod:	lighting: 16 h light : 8 h dark; light intensity: 106.8 – 259.2 µE/m ² /s
CO₂ concentration:	337 – 381 ppm

STUDY DESIGN AND METHODS

The study, aimed at evaluating the effect Acetamipryd 200 SL on seedling emergence and seedling growth of 6 terrestrial plants, was conducted on 3 dicotyledonous and 3 monocotyledonous species. The test item

was sprayed onto the soil surface. There was also a concurrent control group. Seeds of the test plant species were sown in plastic pots. There were 5 (onion, perennial ryegrass and oats) or 3 (sunflower, pea, cabbage) seeds/pot. The experiment was conducted in a special room. Suitable environmental conditions for each test species were provided. During the experiment, the plants were observed for emergence (every day to the emergence of 50% of the control seedlings and after then every 1 – 3 days) and visual phytotoxicity (after 7 and 14 days after the emergence of 50% of the control seedlings). The exposure period finished 14 days after the emergence of 50% of the control seedlings. At the end of the exposure, the number of surviving plants was determined. Next, the plants were cut down, measured, dried to a constant weight at 60°C, and weighed. The results concerning the emergence, the shoot length, and the dry weight were statistically analyzed in order to determine the ER10, ER25, ER50, and NOER. Additionally, the ER50 was determined for visual phytotoxicity effects, basis on the results obtained at the end exposure period.

Test design:	number of replicates/rate: 7 (sunflower, pea, cabbage), 4 (onion, perennial ryegrass and oats). The total number of seeds per application rate: 21 (sunflower, pea, cabbage) and 20 (onion, perennial ryegrass and oats)
Exposure time:	14 days since emergence of 50% seeds in control
Tested concentrations, definitive test:	- 23.4 mL of the test item /ha (4.61 g of as/ha) - 46.9 mL of the test item /ha (9.25 g of as/ha) - 93.8 mL of the test item /ha (18.50 g of as/ha) - 187.5 mL of the test item /ha (39.98 g of as/ha) - 375.0 mL of the test item /ha (73.95 g of as/ha) - 750.0 mL of the test item /ha (147.90 g of as/ha) - 1500.0 mL of the test item /ha (295.80 g of as/ha) volume of deionized water used to prepare the highest rate corresponded to 500 L spraying liquid/ha
Stability of test compound:	The concentration of acetamiprid in water was determined with a validated analytical method. The highest test solution (application rate) i.e. 1500.0 mL/ha as well as the control sample were subjected to chemical analysis in order to confirm the correct preparation of the tested aqueous solutions. Basis on the results of the analytical measurements it was proved, that the test aqueous solution was prepared correctly.
Dates:	start of the study 23.03.2022 start of the experimental part: 25.04.2022 end of the experimental part: 16.05.2022 end of the study: 02.08.2022

Statistic:

ER10, ER25, ER50 (plant emergence, shoot length and dry weight): probit or logit analysis using linear max likelihood regression. ER50 (phytotoxic symptoms) probit analysis using linear max likelihood regression.

NOER:

The final number of plants: Fisher's Exact Binomial Test with Bonferroni Correction or Chi2 2x2 Table with Bonferroni Correction. The shoot length: Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Trend analysis by Contrasts (Monotonicity of Rate/Response), Williams Multiple Sequential t-test Procedure or Dunnett's Multiple t-test Procedure. The plant dry weight: Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Trend analysis by Contrasts (Monotonicity of Rate/Response), Williams Multiple Sequential t-test Procedure or Dunnett's Multiple t-test Procedure.

Validity of the test:

On the basis of the obtained results, it was stated that the following validity criteria of the study aimed at evaluating the impact of Acetamipryd 200 SL on seedling emergence and seedling growth of terrestrial plants were met:

- the seedling emergence in the control (validity criterion: at least 70%) was as follows:
 - 100% – sunflower,
 - 100% – pea,
 - 85.7% – cabbage,
 - 100% – onion,
 - 100% – perennial ryegrass,
 - 100% – oats,
- the mean survival of the emerged control seedlings was 100% for each tested plant species (validity criterion: 90%);
- the control seedlings did not exhibit any visible phytotoxic effects;
- environmental conditions for all plants of the same species were identical.

RESULTS

Sunflower (*Helianthus annuus*)

After the application of the test item at the rates between 23.4 and 1500.0 mL/ha, seedling emergence of sunflower was not delayed compared with the control. At the control group, 100.0% of plants emerged. At the rates ranging from 23.4 to 1500.0 mL/ha, total number of plants at the end of the experiment was 100.0% in comparison to the control group. After the application of the test item at the ranging from 23.4 to 1500.0 mL/ha, the sunflower shoot length was between 92.7 and 104.5% of the control shoot length. After the application of the test item at the rates ranging from 23.4 to 1500.0 mL/ha, the sunflower shoot weight was between 94.1 and 111.4% of the control shoot weight. At the end of the exposure period the plant damages were not observed.

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Table KCP 10.6.2-1: Sunflower (*Helianthus annuus*) – plant number at the end of the experiment

Application rate [mL/ha]	Total number of seeds	Number of plants in particular replicates							Total number of plants [no.]	Total number of plants [%]	Number of plants in comparison to the control [%]
		1	2	3	4	5	6	7			
control	21	3	3	3	3	3	3	3	21	100.0	-
23.4	21	3	3	3	3	3	3	3	21	100.0	100.0
46.9	21	3	3	3	3	3	3	3	21	100.0	100.0
93.8	21	3	3	3	3	3	3	3	21	100.0	100.0
187.5	21	3	3	3	3	3	3	3	21	100.0	100.0
375.0	21	3	3	3	3	3	3	3	21	100.0	100.0
750.0	21	3	3	3	3	3	3	3	21	100.0	100.0
1500.0	21	3	3	3	3	3	3	3	21	100.0	100.0

Table KCP 10.6.2-2: Sunflower (*Helianthus annuus*) – shoot length

Application rate [mL/ha]	Mean shoot length in particular replicates [mm]							Mean shoot length [mm]	SD	Shoot length in comparison to the control [%]
	1	2	3	4	5	6	7			
control	175.0	180.7	185.7	202.0	181.7	155.3	175.7	179.4	14.0	-
23.4	170.0	173.3	161.7	166.0	177.3	196.0	153.3	171.1	13.5	95.4
46.9	164.0	185.3	199.0	183.7	181.0	185.7	170.0	181.2	11.4	101.0
93.8	183.0	203.3	181.3	172.7	196.3	186.0	190.3	187.6	10.1	104.5
187.5	152.3	151.7	162.3	163.7	160.7	170.3	151.7	159.0	7.3	88.6
375.0	177.0	177.7	184.0	167.7	188.3	184.3	174.7	179.1	7.0	99.8
750.0	175.0	185.3	175.7	171.7	184.0	189.0	190.3	181.6	7.4	101.2
1500.0	151.7	189.0	176.7	170.7	156.3	170.7	149.3	166.3 ⁺	14.5	92.7

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Table KCP 10.6.2-3: Sunflower (*Helianthus annuus*) – plant weight

Application rate [mL/ha]	Mean shoot weight in particular replicates [mg]							Mean shoot weight [mg]	SD	Shoot weight in comparison to the control [%]
	1	2	3	4	5	6	7			
control	182.3	195.0	139.3	174.3	153.0	179.7	190.7	173.5	20.3	-
23.4	183.3	163.0	182.3	192.3	209.3	170.0	149.7	178.6	19.7	102.9
46.9	179.0	160.0	172.0	169.0	199.3	235.3	152.3	181.0	28.2	104.3
93.8	196.3	192.3	171.0	194.3	190.3	172.0	174.0	184.3	11.4	106.3
187.5	173.3	186.0	195.3	194.7	194.3	210.0	199.7	193.3	11.4	111.4
375.0	212.7	171.3	172.0	148.0	176.3	186.3	169.7	176.6	19.6	101.8
750.0	186.7	209.7	197.3	180.0	195.3	169.7	183.3	188.9	13.1	108.9
1500.0	131.7	159.0	217.7	185.0	143.3	149.7	156.3	163.2	29.1	94.1

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Table KCP 10.6.2-4: Sunflower (*Helianthus annuus*) – plant damage

Application rate [mL/ha]	Replicate	Plant damage					
		Day 7			Day 14		
		Mean effects/ replicate [%]	Mean effects/ application rate [%]	Plant damage	Mean effects/ replicate [%]	Mean effects/ application rate [%]	Plant damage
control	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
	5	0			0		
	6	0			0		
	7	0			0		
23.4	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
	5	0			0		
	6	0			0		
	7	0			0		
46.9	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
	5	0			0		
	6	0			0		
	7	0			0		
93.8	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
	5	0			0		
	6	0			0		
	7	0			0		
187.5	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
	5	0			0		
	6	0			0		
	7	0			0		

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Application rate [mL/ha]	Replicate	Plant damage					
		Day 7			Day 14		
		Mean effects/ replicate [%]	Mean effects/ application rate [%]	Plant damage	Mean effects/ replicate [%]	Mean effects/ application rate [%]	Plant damage
375.0	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
	5	0			0		
	6	0			0		
	7	0			0		
750.0	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
	5	0			0		
	6	0			0		
	7	0			0		
1500.0	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
	5	0			0		
	6	0			0		
	7	0			0		

Pea (*Pisum sativum*)

After the application of the test item at the rates between 23.4 and 1500.0 mL/ha, seedling emergence of plants was not delayed when compared with the control. The death of plants was not observed. At the control group 100.0% of plants emerged. At the rates ranging from 23.4 to 1500.0 mL/ha, total number of plants at the end of the experiment was 100.0% in comparison to the control group. After the application of the test item at the rates ranging from 23.4 to 1500.0 mL/ha, the pea shoot length was between 94.3 and 102.7% of the control shoot length. After the application of the test item at the rates ranging from 23.4 to 1500.0 mL/ha, the pea shoot weight was between 92.9 and 111.8% of the control shoot weight. At the end of the exposure period the plant damages were not observed.

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Table KCP 10.6.2-5: Pea (*Pisum sativum*) – plant number at the end of the experiment

Application rate [mL/ha]	Total number of seeds	Number of plants in particular replicates							Total number of plants [no.]	Total number of plants [%]	Number of plants in comparison to the control [%]
		1	2	3	4	5	6	7			
control	21	3	3	3	3	3	3	3	21	100.0	-
23.4	21	3	3	3	3	3	3	3	21	100.0	100.0
46.9	21	3	3	3	3	3	3	3	21	100.0	100.0
93.8	21	3	3	3	3	3	3	3	21	100.0	100.0
187.5	21	3	3	3	3	3	3	3	21	100.0	100.0
375.0	21	3	3	3	3	3	3	3	21	100.0	100.0
750.0	21	3	3	3	3	3	3	3	21	100.0	100.0
1500.0	21	3	3	3	3	3	3	3	21	100.0	100.0

Table KCP 10.6.2-6: Pea (*Pisum sativum*) – shoot length

Application rate [mL/ha]	Mean shoot length in particular replicates [mm]							Mean shoot length [mm]	SD	Shoot length in comparison to the control [%]
	1	2	3	4	5	6	7			
control	373.3	344.0	341.0	332.0	417.7	408.3	395.7	373.1	34.9	-
23.4	333.0	407.7	371.0	315.0	351.7	326.0	358.3	351.8	31.4	94.3
46.9	420.0	349.7	393.3	345.3	334.7	388.0	339.0	367.1	33.0	98.4
93.8	384.7	375.7	379.3	397.7	319.3	378.3	279.3	359.2	43.1	96.3
187.5	372.3	390.7	336.7	376.7	369.3	334.3	334.7	359.2	23.4	96.3
375.0	383.3	385.0	400.7	367.3	366.0	343.3	315.3	365.9	28.7	98.0
750.0	405.0	382.3	393.7	378.0	370.0	374.0	380.7	383.4	12.1	102.7
1500.0	327.0	370.3	360.7	361.7	393.0	317.0	354.3	354.9	25.8	95.1

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Table KCP 10.6.2-7: Pea (*Pisum sativum*) – plant weight

Application rate [mL/ha]	Mean shoot weight in particular replicates [mg]							Mean shoot weight [mg]	SD	Shoot weight in comparison to the control [%]
	1	2	3	4	5	6	7			
control	240.3	261.0	249.0	242.3	322.7	319.3	331.3	280.9	41.5	-
23.4	305.7	272.7	250.3	262.3	266.7	288.7	266.3	273.2	18.4	97.3
46.9	268.3	278.7	329.3	278.0	276.7	250.3	288.7	281.4	24.2	100.2
93.8	265.7	282.3	229.7	341.0	251.0	323.0	231.0	274.8	43.5	97.8
187.5	253.3	297.0	250.3	266.0	249.3	258.3	253.0	261.0	16.8	92.9
375.0	281.7	269.3	288.7	244.3	318.0	273.3	258.3	276.2	23.5	98.4
750.0	323.3	285.0	342.7	351.7	302.7	306.0	287.3	314.1	26.1	111.8
1500.0	269.7	366.3	304.7	276.7	306.7	222.3	284.0	290.0	43.8	103.3

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Table KCP 10.6.2-8: Pea (*Pisum sativum*) – plant damage

Application rate [mL/ha]	Replicate	Plant damage					
		Day 7			Day 14		
		Mean effects/ replicate [%]	Mean effects/ application rate [%]	Plant damage	Mean effects/ replicate [%]	Mean effects/ application rate [%]	Plant damage
control	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
	5	0			0		
	6	0			0		
	7	0			0		
23.4	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
	5	0			0		
	6	0			0		
	7	0			0		
46.9	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
	5	0			0		
	6	0			0		
	7	0			0		
93.8	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
	5	0			0		
	6	0			0		
	7	0			0		
187.5	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
	5	0			0		
	6	0			0		
	7	0			0		

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Application rate [mL/ha]	Replicate	Plant damage					
		Day 7			Day 14		
		Mean effects/ replicate [%]	Mean effects/ application rate [%]	Plant damage	Mean effects/ replicate [%]	Mean effects/ application rate [%]	Plant damage
375.0	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
	5	0			0		
	6	0			0		
	7	0			0		
750.0	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
	5	0			0		
	6	0			0		
	7	0			0		
1500.0	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
	5	0			0		
	6	0			0		
	7	0			0		

Cabbage (*Brassica oleracea* ver. *capitata*)

After the application of the test item at the rates between 23.4 and 1500.0 mL/ha, seedling emergence of cabbage was not delayed when compared with the control. The death of plants was not observed. At the control group 85.7% of plants emerged. At the rates ranging from 23.4 to 1500.0 mL/ha, total number of plants at the end of the experiment was between 94.4 and 116.7% in comparison to the control group. After the application of the test item at the rates ranging from 23.4 to 1500.0 mL/ha, the cabbage shoot length was between 90.8 and 96.9% of the control shoot length. After the application of the test item at the rates ranging from 23.4 to 1500.0 mL/ha, the cabbage shoot weight was between 91.2 and 108.0% of the control shoot weight. At the end of the exposure period the plant damages were not observed.

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Table KCP 10.6.2-9: Cabbage (*Brassica oleracea ver. capitata*) – plant number at the end of the experiment

Application rate [mL/ha]	Total number of seeds	Number of plants in particular replicates							Total number of plants [no.]	Total number of plants [%]	Number of plants in comparison to the control [%]
		1	2	3	4	5	6	7			
control	21	3	3	2	3	3	2	2	18	85.7	-
23.4	21	2	2	3	3	3	3	3	19	90.5	105.6
46.9	21	3	3	3	3	3	3	3	21	100.0	116.7
93.8	21	3	3	3	3	3	3	3	21	100.0	116.7
187.5	21	3	3	3	3	3	3	3	21	100.0	116.7
375.0	21	3	3	3	3	3	3	3	21	100.0	116.7
750.0	21	3	2	3	2	2	3	2	17	81.0	94.4
1500.0	21	3	3	3	3	2	3	2	19	90.5	105.6

Table KCP 10.6.2-10: Cabbage (*Brassica oleracea ver. capitata*) – shoot length

Application rate [mL/ha]	Mean shoot length in particular replicates [mm]							Mean shoot length [mm]	SD	Shoot length in comparison to the control [%]
	1	2	3	4	5	6	7			
control	92.7	76.7	84.0	82.0	86.3	89.5	71.5	83.2	7.3	-
23.4	78.0	91.5	74.3	79.7	82.0	79.3	80.0	80.7	5.3	96.9
46.9	89.7	76.7	80.3	69.0	82.7	82.3	62.3	77.6	9.2	93.2
93.8	83.3	88.3	68.3	79.0	71.0	79.0	69.3	76.9	7.6	92.4
187.5	75.0	71.7	71.0	80.7	87.7	69.0	74.3	75.6	6.5	90.8
375.0	71.0	83.3	68.3	82.0	82.7	83.3	67.0	76.8	7.6	92.3
750.0	70.3	86.5	78.7	71.0	76.0	75.7	95.5	79.1	9.0	95.0
1500.0	84.3	70.0	78.7	84.7	79.5	77.7	57.0	76.0	9.7	91.3

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Table KCP 10.6.2-11: Cabbage (*Brassica oleracea ver. capitata*) – plant weight

Application rate [mL/ha]	Mean shoot weight in particular replicates [mg]							Mean shoot weight [mg]	SD	Shoot weight in comparison to the control [%]
	1	2	3	4	5	6	7			
control	65.3	47.3	69.5	49.7	55.0	60.0	41.0	55.4	10.2	-
23.4	56.5	70.0	52.7	65.0	52.3	50.7	60.0	58.2	7.2	105.0
46.9	63.7	58.3	52.3	46.0	45.3	38.0	58.3	51.7	9.1	93.3
93.8	64.3	58.7	48.0	44.0	40.3	45.7	52.7	50.5	8.5	91.2
187.5	50.0	40.0	48.0	50.0	73.0	37.0	56.3	50.6	11.8	91.4
375.0	65.7	51.3	43.3	54.0	55.0	49.3	50.0	52.7	6.9	95.1
750.0	42.0	55.5	43.0	52.5	63.0	53.3	52.5	51.7	7.3	93.3
1500.0	61.3	60.3	58.0	66.0	72.0	56.7	44.5	59.8	8.5	108.0

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Table KCP 10.6.2-12: Cabbage (*Brassica oleracea ver. capitata*) – plant damage

Application rate [mL/ha]	Replicate	Plant damage					
		Day 7			Day 14		
		Mean effects/ replicate [%]	Mean effects/ application rate [%]	Plant damage	Mean effects/ replicate [%]	Mean effects/ application rate [%]	Plant damage
control	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
	5	0			0		
	6	0			0		
	7	0			0		
23.4	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
	5	0			0		
	6	0			0		
	7	0			0		
46.9	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
	5	0			0		
	6	0			0		
	7	0			0		
93.8	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
	5	0			0		
	6	0			0		
	7	0			0		

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Application rate [mL/ha]	Replicate	Plant damage					
		Day 7			Day 14		
		Mean effects/ replicate [%]	Mean effects/ application rate [%]	Plant damage	Mean effects/ replicate [%]	Mean effects/ application rate [%]	Plant damage
187.5	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
	5	0			0		
	6	0			0		
	7	0			0		
375.0	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
	5	0			0		
	6	0			0		
	7	0			0		
750.0	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
	5	0			0		
	6	0			0		
	7	0			0		
1500.0	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
	5	0			0		
	6	0			0		
	7	0			0		

Onion (*Allium cepa*)

After the application of the test item at the rates between 23.4 and 1500.0 mL/ha seedling emergence of onion was not delayed when compared with the control. At the control group 100.0% of plants emerged. At the rates ranging from 23.4 to 1500.0 mL/ha, total number of plants at the end of the experiment was between 95.0 to 100.0% in comparison to the control group. After the application of the test item at the rates ranging from 23.4 to 1500.0 mL/ha, the onion shoot length was between 89.2 and 102.0% of the control shoot length. After the application of the test item at the rates ranging from 23.4 to 1500.0 mL/ha, the onion shoot weight was between 86.5 and 101.0% of the control shoot weight. At the end of the exposure period the plant damages were not observed.

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Table KCP 10.6.2-13: Onion (*Allium cepa*) – plant number at the end of the experiment

Application rate [mL/ha]	Total number of seeds	Number of plants in particular replicates				Total number of plants [no.]	Total number of plants [%]	Number of plants in comparison to the control [%]
		1	2	3	4			
control	20	5	5	5	5	20	100.0	-
23.4	20	5	5	5	5	20	100.0	100.0
46.9	20	5	5	5	5	20	100.0	100.0
93.8	20	5	5	5	5	20	100.0	100.0
187.5	20	5	5	5	5	20	100.0	100.0
375.0	20	5	4	5	5	19	95.0	95.0
750.0	20	5	5	5	5	20	100.0	100.0
1500.0	20	4	5	5	5	19	95.0	95.0

Table KCP 10.6.2-14: Onion (*Allium cepa*) – shoot length

Application rate [mL/ha]	Mean shoot length in particular replicates [mm]				Mean shoot length [mm]	SD	Shoot length in comparison to the control [%]
	1	2	3	4			
control	103.0	100.4	80.6	87.0	92.8	10.7	-
23.4	106.2	92.4	86.2	93.2	94.5	8.4	101.9
46.9	101.2	93.8	88.0	95.6	94.7	5.4	102.0
93.8	93.2	84.6	80.8	74.6	83.3	7.8	89.8
187.5	75.6	73.0	87.8	99.4	84.0	12.2	90.5
375.0	75.8	92.8	63.4	98.8	82.7	16.1	89.2
750.0	94.6	88.2	92.6	89.8	91.3	2.9	98.4
1500.0	89.5	96.8	94.4	82.0	90.7	6.5	97.8

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Table KCP 10.6.2-15: Onion (*Allium cepa*) – plant weight

Application rate [mL/ha]	Mean shoot weight in particular replicates [mg]				Mean shoot weight [mg]	SD	Shoot weight in comparison to the control [%]
	1	2	3	4			
control	5.0	6.2	3.4	4.6	4.8	1.2	-
23.4	6.4	4.4	3.4	5.2	4.9	1.3	101.0
46.9	5.2	4.4	3.4	4.6	4.4	0.7	91.7
93.8	4.6	4.0	4.2	4.6	4.4	0.3	90.6
187.5	4.4	3.6	4.4	4.2	4.2	0.4	86.5
375.0	4.4	4.3	3.6	4.6	4.2	0.4	87.8
750.0	4.6	4.2	4.0	3.8	4.2	0.3	86.5
1500.0	4.3	4.0	4.4	4.4	4.3	0.2	88.8

Table KCP 10.6.2-16: Onion (*Allium cepa*) – plant damage

Application rate [mL/ha]	Replicate	Phytotoxic effects					
		Day 7			Day 14		
		Mean effects/replicate [%]	Mean effects/application rate [%]	Symptoms	Mean effects/replicate [%]	Mean effects/application rate [%]	Symptoms
control	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
23.4	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
46.9	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
93.8	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		

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Application rate [mL/ha]	Replicate	Phytotoxic effects					
		Day 7			Day 14		
		Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms	Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms
187.5	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
375.0	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
750.0	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
1500.0	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		

Perennial ryegrass (*Lolium perenne*)

After the application of the test item at the rates between 23.4 and 1500.0 mL/ha seedling emergence of plants was not delayed when compared with the control group. The death of plants was not observed. At the control group 100% of plants emerged. At the rates ranging from 23.4 to 1500.0 mL/ha, total number of plants at the end of the experiment was between 90.0 and 100.0% in comparison to the control group. After the application of the test item at the rates ranging from 23.4 to 1500.0 mL/ha, the perennial ryegrass shoot length was between 86.4 and 96.4% of the control shoot length. After the application of the test item at the rates ranging from 23.4 to 1500.0 mL/ha, the perennial ryegrass shoot weight was between 94.5 and 120.2% of the control shoot weight. At the end of the exposure period the plant damages were not observed.

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Table KCP 10.6.2-17: Perennial ryegrass (*Lolium perenne*) – plant number at the end of the experiment

Application rate [mL/ha]	Total number of seeds	Number of plants in particular replicates				Total number of plants [no.]	Total number of plants [%]	Number of plants in comparison to the control [%]
		1	2	3	4			
control	20	5	5	5	5	20	100.0	-
23.4	20	5	5	5	5	20	100.0	100.0
46.9	20	5	5	4	4	18	90.0	90.0
93.8	20	5	4	5	4	18	90.0	90.0
187.5	20	4	5	5	5	19	95.0	95.0
375.0	20	5	5	5	5	20	100.0	100.0
750.0	20	5	5	5	5	20	100.0	100.0
1500.0	20	5	5	5	5	20	100.0	100.0

Table KCP 10.6.2-18: Perennial ryegrass (*Lolium perenne*) – shoot length

Application rate [mL/ha]	Mean shoot length in particular replicates [mm]				Mean shoot length [mm]	SD	Shoot length in comparison to the control [%]
	1	2	3	4			
control	236.8	254.0	246.0	257.0	248.5	9.0	-
23.4	244.6	235.6	239.0	238.8	239.5	3.7	96.4
46.9	220.0	232.4	237.8	249.3	234.9	12.1	94.5
93.8	223.8	229.8	232.2	259.3	236.3	15.7	95.1
187.5	226.8	243.4	235.2	219.0	231.1	10.5	93.0
375.0	241.4	232.4	228.6	247.0	237.4	8.4	95.5
750.0	218.6	217.2	217.6	205.6	214.8 ⁺	6.1	86.4
1500.0	205.4	206.4	242.6	225.0	219.9 ⁺	17.6	88.5

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Table KCP 10.6.2-19: Perennial ryegrass (*Lolium perenne*) – plant weight

Application rate [mL/ha]	Mean shoot weight in particular replicates [mg]				Mean shoot weight [mg]	SD	Shoot weight in comparison to the control [%]
	1	2	3	4			
control	14.0	16.0	16.6	14.8	15.4	1.2	-
23.4	18.6	20.8	17.0	17.4	18.5	1.7	120.2
46.9	13.8	11.2	19.0	15.8	14.9	3.3	97.3
93.8	14.0	17.3	11.0	16.0	14.6	2.7	94.9
187.5	15.0	14.4	13.8	14.8	14.5	0.5	94.5
375.0	16.4	15.6	12.8	17.2	15.5	1.9	101.0
750.0	15.8	15.0	15.4	13.2	14.9	1.1	96.7
1500.0	14.8	14.2	15.6	15.0	14.9	0.6	97.1

Table KCP 10.6.2-20: Perennial ryegrass (*Lolium perenne*) – plant damage

Application rate [mL/ha]	Replicate	Phytotoxic effects					
		Day 7			Day 14		
		Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms	Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms
control	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
23.4	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
46.9	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
93.8	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		

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Application rate [mL/ha]	Replicate	Phytotoxic effects					
		Day 7			Day 14		
		Mean effects/replicate [%]	Mean effects/application rate [%]	Symptoms	Mean effects/replicate [%]	Mean effects/application rate [%]	Symptoms
187.5	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
375.0	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
750.0	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
1500.0	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		

Oats (*Avena sativa*)

After the application of the test item at the rates between 23.4 and 1500.0 mL/ha, seedling emergence of oats was not delayed when compared with the control. The death of plants was not observed. At the control group 100% of plants emerged. At the rates ranging from 23.4 to 1500.0 mL/ha, total number of plants at the end of the experiment was between 90.0 and 100.0% in comparison to the control group. After the application of the test item at the rates ranging from 23.4 to 1500.0 mL/ha, the oats shoot length was between 94.5 and 110.8% of the control shoot length. After the application of the test item at the rates ranging from 23.4 to 1500.0 mL/ha, the oats shoot weight was between 106.0 and 128.3% of the control shoot weight. At the end of the exposure period the plant damages were not observed.

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Table KCP 10.6.2-21: Oats (*Avena sativa*) – plant number at the end of the experiment

Application rate [mL/ha]	Total number of seeds	Number of plants in particular replicates				Total number of plants [no.]	Total number of plants [%]	Number of plants in comparison to the control [%]
		1	2	3	4			
control	20	5	5	5	5	20	100.0	-
23.4	20	5	5	4	5	19	95.0	95.0
46.9	20	5	4	5	5	19	95.0	95.0
93.8	20	5	5	5	5	20	100.0	100.0
187.5	20	5	4	5	5	19	95.0	95.0
375.0	20	4	4	5	5	18	90.0	90.0
750.0	20	5	5	5	5	20	100.0	100.0
1500.0	20	5	5	5	5	20	100.0	100.0

Table KCP 10.6.2-22: Oats (*Avena sativa*) – shoot length

Application rate [mL/ha]	Mean shoot length in particular replicates [mm]				Mean shoot length [mm]	SD	Shoot length in comparison to the control [%]
	1	2	3	4			
control	312.6	340.2	324.0	316.8	323.4	12.1	-
23.4	320.0	330.2	290.8	281.8	305.7	23.1	94.5
46.9	332.6	339.8	312.8	308.8	323.5	15.0	100.0
93.8	322.8	295.8	307.0	349.0	318.7	23.1	98.5
187.5	387.0	355.3	353.4	337.4	358.3	20.8	110.8
375.0	324.5	354.3	337.4	337.0	338.3	12.2	104.6
750.0	363.2	348.4	335.2	355.0	350.5	11.8	108.4
1500.0	309.8	312.0	296.6	312.0	307.6	7.4	95.1

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Table KCP 10.6.2-23: Oats (*Avena sativa*) – plant weight

Application rate [mL/ha]	Mean shoot weight in particular replicates [mg]				Mean shoot weight [mg]	SD	Shoot weight in comparison to the control [%]
	1	2	3	4			
control	75.2	85.4	67.4	76.2	76.1	7.4	-
23.4	96.0	92.2	78.3	62.0	82.1	15.4	108.0
46.9	85.6	97.0	80.2	75.8	84.7	9.2	111.3
93.8	82.0	71.4	85.4	83.6	80.6	6.3	106.0
187.5	91.8	116.3	90.6	91.6	97.6	12.5	128.3
375.0	83.5	96.5	91.6	76.2	87.0	8.9	114.3
750.0	112.6	95.6	84.0	86.6	94.7	12.9	124.5
1500.0	82.8	84.4	73.6	88.0	82.2	6.1	108.1

Table KCP 10.6.2-24: Oats (*Avena sativa*) – plant damage

Application rate [mL/ha]	Replicate	Phytotoxic effects					
		Day 7			Day 14		
		Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms	Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms
control	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
23.4	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
46.9	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
93.8	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		

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Application rate [mL/ha]	Replicate	Phytotoxic effects					
		Day 7			Day 14		
		Mean effects/replicate [%]	Mean effects/application rate [%]	Symptoms	Mean effects/replicate [%]	Mean effects/application rate [%]	Symptoms
187.5	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
375.0	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
750.0	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		
1500.0	1	0	0.0	nc	0	0.0	nc
	2	0			0		
	3	0			0		
	4	0			0		

CONCLUSION

On the basis of the obtained results it was proved that the test item i.e. Acetamipryd 200 SL had no impact on seedling emergence and seedling growth of the tested plant species.

Mortality of plants was not observed.

The ER₅₀ and NOER values determined on the basis of plants number at the end of the experiment, shoot length and shoot dry weight measurements and ER50 values for plant damages at the end of the exposure period expressed as mL of the test item/ha for all test species are given below.

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Table KCP 10.6.2-25: Seedling emergence and seedling growth test – final results (g of test item/ha)

	Sunflower <i>Helianthus annuus</i>	Pea <i>Pisum sativum</i>	Cabbage <i>Brassica oleracea</i> var. <i>capitata</i>	Onion <i>Allium cepa</i>	Perennial ryegrass <i>Lolium perenne</i>	Oats <i>Avena sativa</i>
Plant number at the end of the experiment						
ER₅₀	>1500.0	>1500.0	>1500.0	>1500.0	>1500.0	>1500.0
NOER	>1500.0*	> 1500.0*	≥1500.0	≥1500.0	≥1500.0	≥1500.0
Shoot length						
ER₅₀	>1500.0	>1500.0	>1500.0	>1500.0	>1500.0	>1500.0
NOER	750.0	≥1500.0	≥1500.0	≥1500.0	375.0	≥1500.0
Plant dry weight						
ER₅₀	>1500.0	>1500.0	>1500.0	>1500.0	>1500.0	>1500.0
NOER	≥1500.0	≥1500.0	≥1500.0	≥1500.0	≥1500.0	≥1500.0
Plant Damage						
ER₅₀	>1500.0	>1500.0	>1500.0	>1500.0	>1500.0	>1500.0

The ER₅₀ and NOER values determined on the basis of plants number at the end of the experiment, shoot length and shoot dry weight measurements expressed as g of active substance / ha for all test species are given below.

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Table KCP 10.6.2-26: Seedling emergence and seedling growth test – final results (g of as/ha)

	Sunflower <i>Helianthus annuus</i>	Pea <i>Pisum sativum</i>	Cabbage <i>Brassica oleracea var. capitata</i>	Onion <i>Allium cepa</i>	Perennial ryegrass <i>Lolium perenne</i>	Oats <i>Avena sativa</i>
Plant number at the end of the experiment						
ER₅₀	>295.8	>295.8	>295.8	>295.8	>295.8	>295.8
NOER	>295.8*	> 295.8*	≥295.8	≥295.8	≥295.8	≥295.8
Shoot length						
ER₅₀	>295.8	>295.8	>295.8	>295.8	>295.8	>295.8
NOER	147.9	≥295.8	≥295.8	≥295.8	74.0	≥295.8
Plant dry weight						
ER₅₀	>295.8	>295.8	>295.8	>295.8	>295.8	>295.8
NOER	≥295.8	≥295.8	≥295.8	≥295.8	≥295.8	≥295.8
Plant Damage						
ER₅₀	>295.8	>295.8	>295.8	>295.8	>295.8	>295.8

On the basis of the obtained results it was proved that the test item i.e. Acetamipryd 200 SL had no impact on seedling emergence and seedling growth of the tested plant species.

Mortality of plants was not observed.

On the basis of NOER, ER10, ER25 and ER50 values determined from the plant number it was proved that the test item did not inhibit seedling emergence of all test species.

On the basis of NOER, ER10, ER25 and ER50 values determined from the shoot length it was proved that the test item slightly inhibited the process of growth of sunflower and perennial ryegrass. Process of the growth of pea, cabbage, onion and oats was not inhibited.

On the basis of NOER, ER10, ER25 and ER50 values determined from the dry shoot weight it was proved that the test item did not inhibit the process of growth of all test species.

During the experiment no phytotoxic symptoms were observed.

Comments of zRMS:	The study was accepted by zRMS. The validity criteria was met:
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	<p>On the basis of the obtained results, it was stated that the following validity criteria of the study aimed at evaluating the impact of Acetamipryd 200 SL on vegetative vigour of terrestrial plants were met:</p> <ul style="list-style-type: none"> - the seedling emergence of plants (validity criterion: at least 70%) was as follows: <ul style="list-style-type: none"> 88.1 – 95.2% – sunflower, 81.0 – 88.1% – pea,
	<ul style="list-style-type: none"> 81.0 – 90.5% –cabbage, 87.5 – 100.0% – onion, 92.5 – 95.0% – perennial ryegrass, 80.0 – 92.5% – oats. <ul style="list-style-type: none"> - the mean plant survival of the control was 100% for all tested species (validity criterion: at least 90%), - the control plants did not exhibit any visible phytotoxic symptoms, - environmental conditions for all plants belonging to the same species were identical.
	<p>Deviation in the study:</p> <p><u>Deviation from OECD Guideline No. 227:</u></p> <p>According to OECD Guideline No. 227 (2006), the light intensity should be $350 \pm 50 \mu\text{E}/\text{m}^2/\text{s}$. However, these values are recommended for tests conducted in greenhouses. The experiment was conducted in a test room, where only artificial lighting was used. The light intensity was between $82.4 - 270.6 \mu\text{E}/\text{m}^2/\text{s}$. Good control plant vigour was observed. Therefore, it was concluded that the light intensity was suitable for plant growing. The deviation did not affect the results of the experiment.</p>
	<p>The agreed toxicity endpoints:</p>

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	Sunflower <i>Helianthus annuus</i>	Pea <i>Pisum sativum</i>	Cabbage <i>Brassica oleracea</i> var. <i>capitata</i>	Onion <i>Allium cepa</i>	Perennial ryegrass <i>Lolium perenne</i>	Oats <i>Avena sativa</i>
Plant number at the end of the experiment						
ER ₅₀	> 1500.0	> 1500.0	> 1500.0	> 1500.0	> 1500.0	> 1500.0
NOER	> 1500.0*	> 1500.0*	> 1500.0*	> 1500.0*	> 1500.0*	> 1500.0*
Shoot length						
ER ₅₀	> 1500.0	> 1500.0	> 1500.0	> 1500.0	> 1500.0	> 1500.0
NOER	≥ 1500.0	≥ 1500.0	≥ 1500.0	≥ 1500.0	≥ 1500.0	≥ 1500.0
Plant dry weight						
ER ₅₀	> 1500.0	> 1500.0	> 1500.0	> 1500.0	> 1500.0	> 1500.0
NOER	≥ 1500.0	≥ 1500.0	≥ 1500.0	≥ 1500.0	93.8	375.0
Plant Damage						
ER ₅₀	> 1500.0	> 1500.0	> 1500.0	> 1500.0	> 1500.0	> 1500.0
*the value could not be determined, it can be probably higher than the highest rate of the test item used in the experiment, i.e. 1500 mL/ha						
	Sunflower <i>Helianthus annuus</i>	Pea <i>Pisum sativum</i>	Cabbage <i>Brassica oleracea</i> var. <i>capitata</i>	Onion <i>Allium cepa</i>	Perennial ryegrass <i>Lolium perenne</i>	Oats <i>Avena sativa</i>
Plant number at the end of the experiment						
ER ₅₀	> 295.8	> 295.8	> 295.8	> 295.8	> 295.8	> 295.8
NOER	> 295.8*	> 295.8*	> 295.8*	> 295.8*	> 295.8*	> 295.8*
Shoot length						
ER ₅₀	> 295.8	> 295.8	> 295.8	> 295.8	> 295.8	> 295.8
NOER	≥ 295.8	≥ 295.8	≥ 295.8	≥ 295.8	≥ 295.8	≥ 295.8
Plant dry weight						
ER ₅₀	> 295.8	> 295.8	> 295.8	> 295.8	> 295.8	> 295.8
NOER	≥ 295.8	≥ 295.8	≥ 295.8	≥ 295.8	18.5	74.0
Plant Damage						
ER ₅₀	> 295.8	> 295.8	> 295.8	> 295.8	> 295.8	> 295.8
*the value could not be determined, it can be probably higher than the highest rate of the test item used in the experiment, i.e. 295.8 g a.s./ha						

Reference:

KCP 10.6.2/02

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Wróbel A.; 2022; Study Code: G-95-21

AMENDMENT NO. 1 TO THE FINAL REPORT
Acetamipryd 200 SL Terrestrial Plant Test: Vegetative Vigour Test;
Wróbel A.; 2022; Study Code: G-95-21

Guideline(s): Yes, OECD 227

Deviations: According to OECD Guideline No. 227 (2006), the light intensity should be $350 \pm 50 \mu\text{E}/\text{m}^2/\text{s}$. However, these values are recommended for tests conducted in greenhouses. The experiment was conducted in a test room, where only artificial lighting was used. The light intensity was between $82.4 - 270.6 \mu\text{E}/\text{m}^2/\text{s}$. Good control plant vigour was observed. Therefore, it was concluded that the light intensity was suitable for plant growing.

GLP: Yes

Acceptability: Yes

Duplication No
(if vertebrate study)

MATERIALS AND METHODS

1. Test material

Test item (chemical/other name): Acetamipryd 200 SL

Formulation: SL (soluble liquid), acetamiprid: specification 200.0 g/L

Description (physical state): light brown liquid

Batch no.: 1/ACE/2022

Production date: 01.2022

Expiration date: 01.2024

2. Vehicle and/or positive control: vehicle control: water
positive control: not relevant

3. Test plants: sunflower (*Helianthus annuus*), pea (*Pisum sativum*), cabbage (*Brassica oleracea* var. *capitata*), onion (*Allium cepa*), perennial ryegrass (*Lolium perenne*), oats (*Avena sativa*)

Seed sowing:	The number of plants per pot as well as the total number of plants per application rate was: - sunflower: 3 plants/pot – 21 plants/application rate (7 pots/application rate); - pea: 3 plants/pot – 21 plants/application rate (7 pots/application rate); - cabbage: 3 plants/pot – 21 plants/application rate (7 pots/application rate); - onion: 5 plants/pot – 20 plants/ application rate (4 pots/ application rate); - perennial ryegrass: 5 plants/pot – 20 plants/ application rate (4 pots/ application rate); - oats: 5 plants/pot – 20 plants/ application rate (4 pots/ application rate).
Soil:	sandy loam taken from a place belonging to the Łukasiewicz Research Network - Institute of Industrial Organic Chemistry, Branch Pszczyna (49° 59', 780 N; 18°55', 190 E); the site chosen for soil collection had not been treated with any plant protection products or organic and inorganic fertilisers; the soil was collected from a depth of 20 cm. It was sieved to 2 mm particle size to homogenize it and remove coarse particles
Test containers:	plastic pots (pot's diameter – 15 cm, pot's surface area – about 177 cm ²)
4. Environmental conditions:	
Temperature:	18.0 – 26.9°C
Relative humidity:	48.1 – 75.7%
Photoperiod:	16h light and 8h dark, light intensity: 82.4 – 270.6 µE/m ² /s
CO₂ concentration:	336 – 379 ppm

STUDY DESIGN AND METHODS

The study, aimed at evaluating the effect of Acetamipryd 200 SL on vegetative vigour of 6 terrestrial plants, was conducted on 3 dicotyledonous and 3 monocotyledonous species. Seeds of the test plant species were sown in plastic pots (6 seeds/pot for sunflower, pea, and cabbage; 10 seeds/pot for onion, perennial ryegrass and oats). The plants were grown to the 2- to 4- true leaf stage. Then, some of them were removed. As a result, the number of plants per pot as well as the total number of plants per rate were:

- sunflower, pea and cabbage: 3 plants/pot – 21 plants/application rate (7 pots/application rate);
- onion, perennial ryegrass and oats: 5 plants/pot – 20 plants/ application rate (4 pots/ application rate).

The pot is defined as a replicate. The test item was sprayed onto the plants. For each species, seven application rates were used. Untreated control group was conducted simultaneously. The experiment was conducted in a plant growth room where suitable environmental conditions for each test species were provided. During the experiment, the plants were observed for visual phytotoxicity (7, 14 and 21 days after the test item application). The exposure period finished 21 days after the spraying. At the end of the exposure, the number of surviving plants was counted. Next, the plants were cut down, and the lengths of their shoots were determined. Finally, they were dried at 60°C to a constant weight and weighed.

The results concerning the shoot length, the dry weight, and the number of plants at the end of the experiment were statistically analyzed to determine the ER10, ER25, ER50 and NOER. Additionally, the ER50 was determined for visual phytotoxicity effects, basis on the results after 21 days of the exposure period.

Test design:	number of replicates/rate: 7 (sunflower, pea, cabbage), 4 (onion, perennial ryegrass and oats). The total number of plants per application rate: 21 (sunflower, pea, cabbage) or 20 (onion, perennial ryegrass and oats)
Exposure time:	21 days after the spraying
Tested concentrations, definitive test:	<ul style="list-style-type: none">- 23.4 mL of the test item /ha (4.61 g of as/ha),- 46.9 mL of the test item /ha (9.25 g of as/ha),- 93.8 mL of the test item /ha (18.50 g of as/ha),- 187.5 mL of the test item /ha (73.95 g of as/ha),- 375.0 mL of the test item /ha (78.88 g of as/ha),- 750.0 mL of the test item /ha (147.9 g of as/ha),- 1500.0 mL of the test item /ha (295.8 g of as/ha), Volume of deionized water used to prepare the highest rate corresponded to 500 L spraying liquid/ha.
Stability of test compound:	The concentration of acetamiprid in water was determined with a validated analytical method. The highest test solution (application rate) i.e. 1500.0 mL/ha as well as the control sample were subjected to chemical analysis in order to confirm the correct preparation of the tested aqueous solutions.
Dates:	start of the study 23.03.2022 start of the experimental part: 25.4. 2022 end of the experimental part: 18.05.2022 end of the study: 21.07.2022
Statistic:	Due to the lack of mortality of plants during the exposure period, no computations have been performed for the plant number at the end of the experiment. ER10, ER25, ER50 (shoot length, shoot dry weight) – probit analysis using linear max. likelihood regression; ER50 (plant damages) - probit analysis using linear max. likelihood regression; NOER: In order to determine the NOER values, the following tests were used: - for the shoot length and shoot dry weight: Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Williams Multiple Sequential t-test Procedure or Welch-t test for Inhomogeneous Variances with Bonferroni-Holm Adjustment.

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Validity of the test:

On the basis of the obtained results, it was stated that the following validity criteria of the study aimed at evaluating the impact of Acetamipryd 200 SL on vegetative vigour of terrestrial plants were met:

- the seedling emergence of plants (validity criterion: at least 70%) was as follows:
88.1 – 95.2% – sunflower,
81.0 – 88.1% – pea,
81.0 – 90.5% –cabbage,
87.5 – 100.0% – onion,
92.5 – 95.0% – perennial ryegrass,
80.0 – 92.5% – oats.
- the mean plant survival of the control was 100% for all tested species (validity criterion: at least 90%),
- the control plants did not exhibit any visible phytotoxic symptoms,
- environmental conditions for all plants belonging to the same species were identical.

RESULTS

Sunflower (*Helianthus annuus*)

After the application of the test item at the rates ranging from 23.4 to 1500.0 mL/ha the mortality of sunflower plants was not observed. After the application of the test item at the rates ranging from 23.4 to 500.0 mL/ha, the sunflower shoot length was between 88.5 and 108.7% of the control shoot length. After the application of the test item at the rates ranging from 23.4 to 1500.0 mL/ha, the sunflower shoot dry weight was between 91.6 and 126.9% of the control shoot dry weight. At the end of the exposure period the plant damages were not observed.

Table KCP 10.6.2-27: Sunflower (*Helianthus annuus*) – plant number at the end of the experiment

Application rate [mL/ha]	Total number of plants [no.]	Number of plants in particular replicates							Number of plants [no.]	Number of plants [%]	Number of plants in comparison to the control [%]
		1	2	3	4	5	6	7			
control	21	3	3	3	3	3	3	3	21	100.0	-
23.4	21	3	3	3	3	3	3	3	21	100.0	100.0
46.9	21	3	3	3	3	3	3	3	21	100.0	100.0
93.8	21	3	3	3	3	3	3	3	21	100.0	100.0
187.5	21	3	3	3	3	3	3	3	21	100.0	100.0
375.0	21	3	3	3	3	3	3	3	21	100.0	100.0
750.0	21	3	3	3	3	3	3	3	21	100.0	100.0
1500.0	21	3	3	3	3	3	3	3	21	100.0	100.0

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Table KCP 10.6.2-28: Sunflower (*Helianthus annuus*) – shoot length

Application rate [mL/ha]	Mean shoot length in particular replicates [mm]							Mean shoot length [mm]	SD [mm]	Shoot length in comparison to the control [%]
	1	2	3	4	5	6	7			
control	361.0	394.3	371.7	368.3	329.7	376.7	312.3	359.1	28.4	-
23.4	347.3	298.3	331.7	352.3	289.7	333.3	437.3	341.4	48.4	95.1
46.9	324.0	406.7	400.7	378.7	374.0	329.0	296.0	358.4	42.3	99.8
93.8	285.0	389.0	361.0	335.0	366.3	370.0	408.3	359.2	39.9	100.0
187.5	322.7	337.0	346.0	289.3	290.7	321.0	319.0	318.0	21.4	88.5
375.0	298.7	318.0	346.3	410.0	362.7	390.0	337.7	351.9	39.1	98.0
750.0	312.0	339.0	392.7	407.7	386.3	356.0	381.3	367.9	33.7	102.4
1500.0	375.7	402.7	339.3	378.3	407.7	407.0	422.7	390.5	28.1	108.7

Table KCP 10.6.2-29: Sunflower (*Helianthus annuus*) – plant weight

Application rate [mL/ha]	Mean shoot dry weight in particular replicates [mg]							Mean shoot dry weight [mg]	SD [mg]	Shoot dry weight in comparison to the control [%]
	1	2	3	4	5	6	7			
control	925.7	799.3	591.7	854.7	753.3	696.7	775.0	770.9	107.8	-
23.4	913.7	708.7	946.0	910.0	966.3	728.3	965.7	877.0	110.7	113.8
46.9	921.3	978.3	826.0	1235.0	1040.7	1003.3	845.0	978.5	138.2	126.9
93.8	633.0	722.7	593.3	629.0	744.0	771.0	873.7	709.5	98.3	92.0
187.5	721.7	875.0	881.0	730.0	620.7	706.7	774.3	758.5	93.7	98.4
375.0	791.7	733.0	646.0	610.3	847.3	661.7	732.7	717.5	84.2	93.1
750.0	601.0	798.3	666.0	603.7	720.0	631.3	921.7	706.0	118.3	91.6
1500.0	977.3	917.7	843.3	912.3	930.7	684.7	881.7	878.2	94.9	113.9

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Table KCP 10.6.2-30: Sunflower (*Helianthus annuus*) – plant damage

Application rate [mL/ha]	Replicate	Phytotoxic effects								
		Day 7			Day 14			Day 21		
		Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms	Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms	Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms
control	1	0			0			0		
	2	0			0			0		
	3	0			0			0		
	4	0	0.0	nc	0	0.0	nc	0	0.0	nc
	5	0			0			0		
	6	0			0			0		
	7	0			0			0		
23.4	1	0			0			0		
	2	0			0			0		
	3	0			0			0		
	4	0	0.0	nc	0	0.0	nc	0	0.0	nc
	5	0			0			0		
	6	0			0			0		
	7	0			0			0		
46.9	1	0			0			0		
	2	0			0			0		
	3	0			0			0		
	4	0	0.0	nc	0	0.0	nc	0	0.0	nc
	5	0			0			0		
	6	0			0			0		
	7	0			0			0		
93.8	1	0			0			0		
	2	0			0			0		
	3	0			0			0		
	4	0	0.0	nc	0	0.0	nc	0	0.0	nc
	5	0			0			0		
	6	0			0			0		
	7	0			0			0		
187.5	1	0			0			0		
	2	0			0			0		
	3	0			0			0		
	4	0	0.0	nc	0	0.0	nc	0	0.0	nc
	5	0			0			0		
	6	0			0			0		
	7	0			0			0		
375.0	1	0			0			0		
	2	0			0			0		
	3	0			0			0		
	4	0	0.0	nc	0	0.0	nc	0	0.0	nc
	5	0			0			0		
	6	0			0			0		
	7	0			0			0		

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750.0	1	0	0.0	nc	0	0.0	nc	0	0.0	nc
	2	0			0			0		
	3	0			0			0		
	4	0			0			0		
	5	0			0			0		
	6	0			0			0		
	7	0			0			0		
1500.0	1	0	0.0	nc	0	0.0	nc	0	0.0	nc
	2	0			0			0		
	3	0			0			0		
	4	0			0			0		
	5	0			0			0		
	6	0			0			0		
	7	0			0			0		

Pea (*Pisum sativum*)

After the application of the test item at the rates ranging from 23.4 to 1500.0 mL/ha the mortality of pea plants was not observed. After the application of the test item at the rates ranging from 23.4 to 1500.0 mL/ha, the pea shoot length was between 86.4 and 103.0% of the control shoot length. After the application of the test item at the rates ranging from 23.4 to 1500.0 mL/ha, the pea shoot dry weight was between 91.3 and 121.5% of the control shoot dry weight. At the end of the exposure period the plant damages were not observed.

Table KCP 10.6.2-31: Pea (*Pisum sativum*) – plant number at the end of the experiment

Application rate [mL/ha]	Total number of plants [no.]	Number of plants in particular replicates							Number of plants [no.]	Number of plants [%]	Number of plants in comparison to the control [%]
		1	2	3	4	5	6	7			
control	21	3	3	3	3	3	3	3	21	100.0	-
23.4	21	3	3	3	3	3	3	3	21	100.0	100.0
46.9	21	3	3	3	3	3	3	3	21	100.0	100.0
93.8	21	3	3	3	3	3	3	3	21	100.0	100.0
187.5	21	3	3	3	3	3	3	3	21	100.0	100.0
375.0	21	3	3	3	3	3	3	3	21	100.0	100.0
750.0	21	3	3	3	3	3	3	3	21	100.0	100.0
1500.0	21	3	3	3	3	3	3	3	21	100.0	100.0

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Table KCP 10.6.2-32: Pea (*Pisum sativum*) – shoot length

Application rate [mL/ha]	Mean shoot length in particular replicates [mm]							Mean shoot length [mm]	SD [mm]	Shoot length in comparison to the control [%]
	1	2	3	4	5	6	7			
control	827.3	837.7	830.0	798.0	897.7	809.7	872.7	839.0	35.0	-
23.4	805.7	766.0	926.7	605.3	707.3	764.7	819.7	770.8	99.5	91.9
46.9	873.3	696.7	905.7	841.7	776.0	499.7	748.7	763.1	137.1	91.0
93.8	837.3	802.0	642.0	892.3	878.7	1025.0	850.3	846.8	114.7	100.9
187.5	727.7	805.7	721.3	786.3	775.7	641.7	616.3	725.0	72.6	86.4
375.0	830.0	706.0	779.3	785.3	958.7	773.0	659.7	784.6	95.1	93.5
750.0	812.3	860.7	1002.7	817.7	905.0	904.0	749.3	864.5	82.1	103.0
1500.0	964.3	767.3	885.3	648.3	828.3	737.0	776.3	801.0	103.0	95.5

Table KCP 10.6.2-33: Pea (*Pisum sativum*) – plant weight

Application rate [mL/ha]	Mean shoot dry weight in particular replicates [mg]							Mean shoot dry weight [mg]	SD [mg]	Shoot dry weight in comparison to the control [%]
	1	2	3	4	5	6	7			
control	570.0	687.0	748.0	780.7	605.0	558.3	866.0	687.9	116.5	-
23.4	751.0	927.0	1091.7	366.0	688.0	909.7	890.0	803.3	232.6	116.8
46.9	906.7	766.3	972.0	772.3	873.7	769.3	790.7	835.9	82.0	121.5
93.8	591.0	835.0	690.0	906.7	665.0	761.3	583.3	718.9	121.8	104.5
187.5	555.3	431.7	721.7	590.7	677.0	556.3	861.7	627.8	139.1	91.3
375.0	794.7	747.0	549.0	569.3	728.0	764.7	532.3	669.3	113.7	97.3
750.0	478.3	696.7	903.3	859.3	841.7	753.7	788.3	760.2	142.2	110.5
1500.0	794.0	596.0	785.3	608.3	626.7	519.0	716.0	663.6	103.7	96.5

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Table KCP 10.6.2-34 **Pea (*Pisum sativum*) – plant damage**

Application rate [mL/ha]	Replicate	Phytotoxic effects								
		Day 7			Day 14			Day 21		
		Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms	Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms	Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms
control	1	0			0			0		
	2	0			0			0		
	3	0			0			0		
	4	0	0.0	nc	0	0.0	nc	0	0.0	nc
	5	0			0			0		
	6	0			0			0		
	7	0			0			0		
23.4	1	0			0			0		
	2	0			0			0		
	3	0			0			0		
	4	0	0.0	nc	0	0.0	nc	0	0.0	nc
	5	0			0			0		
	6	0			0			0		
	7	0			0			0		
46.9	1	0			0			0		
	2	0			0			0		
	3	0			0			0		
	4	0	0.0	nc	0	0.0	nc	0	0.0	nc
	5	0			0			0		
	6	0			0			0		
	7	0			0			0		
93.8	1	0			0			0		
	2	0			0			0		
	3	0			0			0		
	4	0	0.0	nc	0	0.0	nc	0	0.0	nc
	5	0			0			0		
	6	0			0			0		
	7	0			0			0		
187.5	1	0			0			0		
	2	0			0			0		
	3	0			0			0		
	4	0	0.0	nc	0	0.0	nc	0	0.0	nc
	5	0			0			0		
	6	0			0			0		
	7	0			0			0		
375.0	1	0			0			0		
	2	0			0			0		
	3	0			0			0		
	4	0	0.0	nc	0	0.0	nc	0	0.0	nc
	5	0			0			0		
	6	0			0			0		
	7	0			0			0		

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750.0	1	0	0.0	nc	0	0.0	nc	0	0.0	nc
	2	0			0			0		
	3	0			0			0		
	4	0			0			0		
	5	0			0			0		
	6	0			0			0		
	7	0			0			0		
1500.0	1	0	0.0	nc	0	0.0	nc	0	0.0	nc
	2	0			0			0		
	3	0			0			0		
	4	0			0			0		
	5	0			0			0		
	6	0			0			0		
	7	0			0			0		

Cabbage (*Brassica oleracea* var. *capitata*)

After the application of the test item at the rates ranging from 23.4 to 1500.0 mL/ha the mortality of cabbage plants was not observed. After the application of the test item at the rates ranging from 23.4 to 1500.0 mL/ha, the cabbage shoot length was between 91.8 and 104.9% of the control shoot length. After the application of the test item at the rates ranging from 23.4 to 1500.0 mL/ha, the cabbage shoot dry weight was between 89.1 and 117.4% of the control shoot dry weight. At the end of the exposure period the plant damages were not observed.

Table KCP 10.6.2-35: Cabbage (*Brassica oleracea* var. *capitata*) – plant number at the end of the experiment

Application rate [mL/ha]	Total number of plants [no.]	Number of plants in particular replicates							Number of plants [no.]	Number of plants [%]	Number of plants in comparison to the control [%]
		1	2	3	4	5	6	7			
control	21	3	3	3	3	3	3	3	21	100.0	-
23.4	21	3	3	3	3	3	3	3	21	100.0	100.0
46.9	21	3	3	3	3	3	3	3	21	100.0	100.0
93.8	21	3	3	3	3	3	3	3	21	100.0	100.0
187.5	21	3	3	3	3	3	3	3	21	100.0	100.0
375.0	21	3	3	3	3	3	3	3	21	100.0	100.0
750.0	21	3	3	3	3	3	3	3	21	100.0	100.0
1500.0	21	3	3	3	3	3	3	3	21	100.0	100.0

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Table KCP 10.6.2-36: Cabbage (*Brassica oleracea* var. *capitata*) – shoot length

Application rate [mL/ha]	Mean shoot length in particular replicates [mm]							Mean shoot length [mm]	SD [mm]	Shoot length in comparison to the control [%]
	1	2	3	4	5	6	7			
control	169.7	142.3	144.7	160.0	149.0	139.3	171.0	153.7	13.1	-
23.4	155.0	144.7	137.7	162.0	137.0	148.7	161.3	149.5	10.4	97.2
46.9	146.3	156.0	174.7	160.0	151.7	158.7	134.3	154.5	12.5	100.5
93.8	155.7	147.3	159.3	130.0	130.0	144.3	144.3	144.4	11.4	94.0
187.5	153.3	136.3	130.3	140.0	147.7	140.7	139.0	141.0	7.5	91.8
375.0	142.7	144.3	134.7	138.7	155.0	138.0	136.7	141.4	6.9	92.0
750.0	151.7	151.3	161.7	154.0	172.7	170.7	167.0	161.3	9.1	104.9
1500.0	139.0	154.7	156.7	135.0	149.0	143.0	147.0	146.3	7.9	95.2

Table KCP 10.6.2-37: Cabbage (*Brassica oleracea* var. *capitata*) – plant weight

Application rate [mL/ha]	Mean shoot dry weight in particular replicates [mg]							Mean shoot dry weight [mg]	SD [mg]	Shoot dry weight in comparison to the control [%]
	1	2	3	4	5	6	7			
control	565.0	589.0	663.3	665.0	625.3	555.7	653.3	616.7	46.7	-
23.4	672.7	624.7	758.0	718.7	890.0	703.3	698.3	723.7	84.0	117.4
46.9	767.3	714.7	593.3	741.7	692.3	703.3	764.0	711.0	59.4	115.3
93.8	626.7	679.0	687.7	681.3	628.3	657.7	677.3	662.6	25.7	107.4
187.5	573.3	571.0	614.0	741.7	602.0	501.7	394.3	571.1	106.4	92.6
375.0	573.3	493.3	536.3	600.3	857.7	654.3	578.7	613.4	118.8	99.5
750.0	560.3	554.3	608.7	549.0	591.7	569.0	455.7	555.5	48.9	90.1
1500.0	601.0	533.0	650.0	524.7	448.0	454.0	633.3	549.1	81.7	89.1

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Table KCP 10.6.2-38: Cabbage (*Brassica oleracea* var. *capitata*) – plant damage

Application rate [mL/ha]	Replicate	Phytotoxic effects								
		Day 7			Day 14			Day 21		
		Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms	Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms	Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms
control	1	0			0			0		
	2	0			0			0		
	3	0			0			0		
	4	0	0.0	nc	0	0.0	nc	0	0.0	nc
	5	0			0			0		
	6	0			0			0		
	7	0			0			0		
23.4	1	0			0			0		
	2	0			0			0		
	3	0			0			0		
	4	0	0.0	nc	0	0.0	nc	0	0.0	nc
	5	0			0			0		
	6	0			0			0		
	7	0			0			0		
46.9	1	0			0			0		
	2	0			0			0		
	3	0			0			0		
	4	0	0.0	nc	0	0.0	nc	0	0.0	nc
	5	0			0			0		
	6	0			0			0		
	7	0			0			0		
93.8	1	0			0			0		
	2	0			0			0		
	3	0			0			0		
	4	0	0.0	nc	0	0.0	nc	0	0.0	nc
	5	0			0			0		
	6	0			0			0		
	7	0			0			0		
187.5	1	0			0			0		
	2	0			0			0		
	3	0			0			0		
	4	0	0.0	nc	0	0.0	nc	0	0.0	nc
	5	0			0			0		
	6	0			0			0		
	7	0			0			0		
375.0	1	0			0			0		
	2	0			0			0		
	3	0			0			0		
	4	0	0.0	nc	0	0.0	nc	0	0.0	nc
	5	0			0			0		
	6	0			0			0		
	7	0			0			0		

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Application rate [mL/ha]	Replicate	Phytotoxic effects								
		Day 7			Day 14			Day 21		
		Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms	Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms	Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms
750.0	1	0			0			0		
	2	0			0			0		
	3	0			0			0		
	4	0	0.0	nc	0	0.0	nc	0	0.0	nc
	5	0			0			0		
	6	0			0			0		
	7	0			0			0		
1500.0	1	0			0			0		
	2	0			0			0		
	3	0			0			0		
	4	0	0.0	nc	0	0.0	nc	0	0.0	nc
	5	0			0			0		
	6	0			0			0		
	7	0			0			0		

Onion (*Allium cepa*)

After the application of the test item at the rates ranging from 23.4 to 1500.0 mL/ha the mortality of onion plants was not observed. After the application of the test item at the rates ranging from 23.4 to 1500.0 mL/ha, the onion shoot length was between 91.8 and 108.6% of the control shoot length. After the application of the test item at the rates ranging from 23.4 to 1500.0 mL/ha, the onion shoot dry weight was between 97.8 and 119.9% of the control shoot dry weight. At the end of the exposure period the plant damages were not observed.

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Table KCP 10.6.2-39: Onion (*Allium cepa*) – plant number at the end of the experiment

Application rate [mL/ha]	Total number of plants [no.]	Number of plants in particular replicates				Number of plants [no.]	Number of plants [%]	Number of plants in comparison to the control [%]
		1	2	3	4			
control	20	5	5	5	5	20	100.0	-
23.4	20	5	5	5	5	20	100.0	100.0
46.9	20	5	5	5	5	20	100.0	100.0
93.8	20	5	5	5	5	20	100.0	100.0
187.5	20	5	5	5	5	20	100.0	100.0
375.0	20	5	5	5	5	20	100.0	100.0
750.0	20	5	5	5	5	20	100.0	100.0
1500.0	20	5	5	5	5	20	100.0	100.0

Table KCP 10.6.2-40: Onion (*Allium cepa*) – shoot length

Application rate [mL/ha]	Mean shoot length in particular replicates [mm]				Mean shoot length [mm]	SD [mm]	Shoot length in comparison to the control [%]
	1	2	3	4			
control	225.6	220.2	198.6	189.8	208.6	17.1	-
23.4	205.6	249.2	213.8	216.4	221.3	19.2	106.1
46.9	232.6	228.4	239.0	159.6	214.9	37.1	103.0
93.8	174.8	211.4	184.4	195.6	191.6	15.7	91.8
187.5	191.2	198.4	211.0	193.4	198.5	8.9	95.2
375.0	197.6	216.8	241.4	192.4	212.1	22.2	101.7
750.0	205.2	234.4	228.0	238.6	226.6	14.9	108.6
1500.0	219.2	233.6	185.0	221.0	214.7	20.8	102.9

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Table KCP 10.6.2-41: Onion (*Allium cepa*) – plant weight

Application rate [mL/ha]	Mean shoot dry weight in particular replicates [mg]				Mean shoot dry weight [mg]	SD [mg]	Shoot dry weight in comparison to the control [%]
	1	2	3	4			
control	20.0	28.6	18.2	15.6	20.6	5.6	-
23.4	25.6	23.8	23.0	26.4	24.7	1.6	119.9
46.9	26.6	24.8	23.4	22.4	24.3	1.8	118.0
93.8	25.0	21.8	17.6	18.8	20.8	3.3	101.0
187.5	22.4	21.6	22.8	18.6	21.4	1.9	103.6
375.0	19.6	18.8	23.0	19.2	20.2	1.9	97.8
750.0	14.6	23.4	25.4	18.0	20.4	4.9	98.8
1500.0	18.2	25.2	20.0	24.0	21.9	3.3	106.1

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Table KCP 10.6.2-42: Onion (*Allium cepa*)– plant damage

Application rate [mL/ha]	Replicate	Phytotoxic effects								
		Day 7			Day 14			Day 21		
		Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms	Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms	Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms
control	1	0			0			0		
	2	0			0			0		
	3	0	0.0	nc	0	0.0	nc	0	0.0	nc
	4	0			0			0		
23.4	1	0			0			0		
	2	0			0			0		
	3	0	0.0	nc	0	0.0	nc	0	0.0	nc
	4	0			0			0		
46.9	1	0			0			0		
	2	0			0			0		
	3	0	0.0	nc	0	0.0	nc	0	0.0	nc
	4	0			0			0		
93.8	1	0			0			0		
	2	0			0			0		
	3	0	0.0	nc	0	0.0	nc	0	0.0	nc
	4	0			0			0		
187.5	1	0			0			0		
	2	0			0			0		
	3	0	0.0	nc	0	0.0	nc	0	0.0	nc
	4	0			0			0		
375.0	1	0			0			0		
	2	0			0			0		
	3	0	0.0	nc	0	0.0	nc	0	0.0	nc
	4	0			0			0		
750.0	1	0			0			0		
	2	0			0			0		
	3	0	0.0	nc	0	0.0	nc	0	0.0	nc
	4	0			0			0		
1500.0	1	0			0			0		
	2	0			0			0		
	3	0	0.0	nc	0	0.0	nc	0	0.0	nc
	4	0			0			0		

Perennial ryegrass (*Lolium perenne*)

After the application of the test item at the rates ranging from 23.4 to 1500.0 mL/ha the mortality of perennial ryegrass plants was not observed. After the application of the test item at the rates ranging from 23.4 to 1500.0 mL/ha, the perennial ryegrass shoot length was between 94.2 and 115.5% of the control shoot length. After the application of the test item at the rates ranging from 23.4 to 1500.0 mL/ha, the perennial ryegrass shoot dry weight was between 74.4 and 125.5% of the control shoot dry weight. At the end of the exposure period the plant damages were not observed.

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Table KCP 10.6.2-43: Perennial ryegrass (*Lolium perenne*) – plant number at the end of the experiment

Application rate [mL/ha]	Total number of plants [no.]	Number of plants in particular replicates				Number of plants [no.]	Number of plants [%]	Number of plants in comparison to the control [%]
		1	2	3	4			
control	20	5	5	5	5	20	100.0	-
23.4	20	5	5	5	5	20	100.0	100.0
46.9	20	5	5	5	5	20	100.0	100.0
93.8	20	5	5	5	5	20	100.0	100.0
187.5	20	5	5	5	5	20	100.0	100.0
375.0	20	5	5	5	5	20	100.0	100.0
750.0	20	5	5	5	5	20	100.0	100.0
1500.0	20	5	5	5	5	20	100.0	100.0

Table KCP 10.6.2-44: Perennial ryegrass (*Lolium perenne*) – shoot length

Application rate [mL/ha]	Mean shoot length in particular replicates [mm]				Mean shoot length [mm]	SD [mm]	Shoot length in comparison to the control [%]
	1	2	3	4			
control	412.0	407.6	424.0	430.4	418.5	10.5	-
23.4	419.2	457.2	442.0	444.2	440.7	15.8	105.3
46.9	462.0	499.4	473.0	497.0	482.9	18.3	115.4
93.8	403.0	383.4	419.6	371.2	394.3	21.4	94.2
187.5	398.6	374.8	440.0	492.0	426.4	51.4	101.9
375.0	432.6	396.8	396.0	447.0	418.1	25.7	99.9
750.0	503.6	473.6	458.4	497.4	483.3	21.0	115.5
1500.0	456.0	477.6	475.0	475.0	470.9	10.0	112.5

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Table KCP 10.6.2-45: Perennial ryegrass (*Lolium perenne*) – plant weight

Application rate [mL/ha]	Mean shoot dry weight in particular replicates [mg]				Mean shoot dry weight [mg]	SD [mg]	Shoot dry weight in comparison to the control [%]
	1	2	3	4			
control	224.6	215.6	179.8	202.4	205.6	19.5	-
23.4	255.2	245.6	273.0	258.4	258.1	11.4	125.5
46.9	214.0	219.2	264.8	251.6	237.4	24.7	115.5
93.8	210.0	180.8	177.4	193.4	190.4	14.8	92.6
187.5	162.0	156.4	184.8	204.0	176.8 ⁺	21.9	86.0
375.0	159.2	174.4	168.4	173.2	168.8 ⁺	6.9	82.1
750.0	139.0	158.4	150.8	199.4	161.9 ⁺	26.2	78.7
1500.0	167.0	152.0	148.8	144.0	153.0 ⁺	9.9	74.4

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Table KCP 10.6.2-46: Perennial ryegrass (*Lolium perenne*) – plant damage

Application rate [mL/ha]	Replicate	Phytotoxic effects								
		Day 7			Day 14			Day 21		
		Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms	Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms	Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms
0.00 (control)	1	0			0			0		
	2	0			0			0		
	3	0	0.0	nc	0	0.0	nc	0	0.0	nc
	4	0			0			0		
23.4	1	0			0			0		
	2	0			0			0		
	3	0	0.0	nc	0	0.0	nc	0	0.0	nc
	4	0			0			0		
46.9	1	0			0			0		
	2	0			0			0		
	3	0	0.0	nc	0	0.0	nc	0	0.0	nc
	4	0			0			0		
93.8	1	0			0			0		
	2	0			0			0		
	3	0	0.0	nc	0	0.0	nc	0	0.0	nc
	4	0			0			0		
187.5	1	0			0			0		
	2	0			0			0		
	3	0	0.0	nc	0	0.0	nc	0	0.0	nc
	4	0			0			0		
375.0	1	0			0			0		
	2	0			0			0		
	3	0	0.0	nc	0	0.0	nc	0	0.0	nc
	4	0			0			0		
750.0	1	0			0			0		
	2	0			0			0		
	3	0	0.0	nc	0	0.0	nc	0	0.0	nc
	4	0			0			0		
1500.0	1	0			0			0		
	2	0			0			0		
	3	0	0.0	nc	0	0.0	nc	0	0.0	nc
	4	0			0			0		

Oats (*Avena sativa*)

After the application of the test item at the rates ranging from 23.4 to 1500.0 mL/ha the mortality of oats plants was not observed. After the application of the test item at the rates ranging from 23.4 to 1500.0 mL/ha, the oats shoot length was between 91.8 and 116.8% of the control shoot length. After the application of the test item at the rates ranging from 23.4 to 1500.0 mL/ha, the oats shoot dry weight was between 83.2 and 107.6% of the control shoot dry weight. At the end of the exposure period the plant damages were not observed.

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Table KCP 10.6.2-47: Oats (*Avena sativa*) – plant number at the end of the experiment

Application rate [mL/ha]	Total number of plants [no.]	Number of plants in particular replicates				Number of plants [no.]	Number of plants [%]	Number of plants in comparison to the control [%]
		1	2	3	4			
control	20	5	5	5	5	20	100.0	-
23.4	20	5	5	5	5	20	100.0	100.0
46.9	20	5	5	5	5	20	100.0	100.0
93.8	20	5	5	5	5	20	100.0	100.0
187.5	20	5	5	5	5	20	100.0	100.0
375.0	20	5	5	5	5	20	100.0	100.0
750.0	20	5	5	5	5	20	100.0	100.0
1500.0	20	5	5	5	5	20	100.0	100.0

Table KCP 10.6.2-48: Oats (*Avena sativa*) – shoot length

Application rate [mL/ha]	Mean shoot length in particular replicates [mm]				Mean shoot length [mm]	SD [mm]	Shoot length in comparison to the control [%]
	1	2	3	4			
control	471.2	400.2	384.4	411.6	416.9	37.9	-
23.4	411.6	406.4	398.0	491.4	426.9	43.4	102.4
46.9	492.2	524.6	441.6	324.6	445.8	87.7	106.9
93.8	506.8	473.8	498.4	468.6	486.9	18.6	116.8
187.5	499.0	471.6	502.6	243.8	429.3	124.4	103.0
375.0	396.2	418.8	358.2	387.2	390.1	25.1	93.6
750.0	375.8	456.6	402.6	372.0	401.8	39.0	96.4
1500.0	403.2	410.4	408.6	308.6	382.7	49.5	91.8

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Table KCP 10.6.2-49: Oats (*Avena sativa*) – plant weight

Application rate [mL/ha]	Mean shoot dry weight in particular replicates [mg]				Mean shoot dry weight [mg]	SD [mg]	Shoot dry weight in comparison to the control [%]
	1	2	3	4			
control	246.4	259.6	256.0	247.0	252.3	6.6	-
23.4	283.2	269.0	276.0	257.0	271.3	11.2	107.6
46.9	214.2	225.2	278.0	244.0	240.4	28.0	95.3
93.8	173.2	247.8	315.0	229.4	241.4	58.5	95.7
187.5	226.6	233.4	275.0	190.6	231.4	34.6	91.7
375.0	246.0	233.0	188.4	214.4	220.5	25.0	87.4
750.0	212.6	233.2	208.0	187.4	210.3 ⁺	18.8	83.4
1500.0	204.0	256.0	185.2	194.4	209.9 ⁺	31.7	83.2

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Table KCP 10.6.2-50: Oats (*Avena sativa*) – plant damage

Application rate [mL/ha]	Replicate	Phytotoxic effects								
		Day 7			Day 14			Day 21		
		Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms	Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms	Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms
control	1	0			0			0		
	2	0			0			0		
	3	0	0.0	nc	0	0.0	nc	0	0.0	nc
	4	0			0			0		
23.4	1	0			0			0		
	2	0			0			0		
	3	0	0.0	nc	0	0.0	nc	0	0.0	nc
	4	0			0			0		
46.9	1	0			0			0		
	2	0			0			0		
	3	0	0.0	nc	0	0.0	nc	0	0.0	nc
	4	0			0			0		
93.8	1	0			0			0		
	2	0			0			0		
	3	0	0.0	nc	0	0.0	nc	0	0.0	nc
	4	0			0			0		
187.5	1	0			0			0		
	2	0			0			0		
	3	0	0.0	nc	0	0.0	nc	0	0.0	nc
	4	0			0			0		
375.0	1	0			0			0		
	2	0			0			0		
	3	0	0.0	nc	0	0.0	nc	0	0.0	nc
	4	0			0			0		
750.0	1	0			0			0		
	2	0			0			0		
	3	0	0.0	nc	0	0.0	nc	0	0.0	nc
	4	0			0			0		
1500.0	1	0			0			0		
	2	0			0			0		
	3	0	0.0	nc	0	0.0	nc	0	0.0	nc
	4	0			0			0		

CONCLUSION

The mortality of plants was not observed in cultivation of all tested plant species.

On the basis of NOER, ER10, ER25 and ER50 values determined from the shoot length it was proved that the test item did not inhibit the process of growth of all test species.

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On the basis of NOER, ER10, ER25 and ER50 values determined from the dry shoot weight it was proved that the test item moderately inhibited the process of growth of perennial ryegrass and oats. No influence was observed in cultivation of sunflower, pea, cabbage and onion.

During the experiment the phytotoxic symptoms were not observed.

The ER₅₀ and NOER values determined on the basis of plants number at the end of the experiment, shoot length and shoot dry weight measurements expressed as g of the test item/ ha for all test species are given below.

Table KCP 10.6.2-51: Vegetative Vigour Test – final results (g of test item/ha)

	Sunflower <i>Helianthus annuus</i>	Pea <i>Pisum sativum</i>	Cabbage <i>Brassica oleracea var. capitata</i>	Onion <i>Allium cepa</i>	Perennial ryegrass <i>Lolium perenne</i>	Oats <i>Avena sativa</i>
Plant number at the end of the experiment						
ER₅₀	> 1500.0	> 1500.0	> 1500.0	> 1500.0	> 1500.0	> 1500.0
NOER	> 1500.0*	> 1500.0*	> 1500.0*	> 1500.0*	> 1500.0*	> 1500.0*
Shoot length						
ER₅₀	> 1500.0	> 1500.0	> 1500.0	> 1500.0	> 1500.0	> 1500.0
NOER	≥ 1500.0	≥ 1500.0	≥ 1500.0	≥ 1500.0	≥ 1500.0	≥ 1500.0
Plant dry weight						
ER₅₀	> 1500.0	> 1500.0	> 1500.0	> 1500.0	> 1500.0	> 1500.0
NOER	≥ 1500.0	≥ 1500.0	≥ 1500.0	≥ 1500.0	93.8	375.0
Plant Damage						
ER₅₀	> 1500.0	> 1500.0	> 1500.0	> 1500.0	> 1500.0	> 1500.0

The ER₅₀ and NOER values determined on the basis of plants number at the end of the experiment, shoot length and shoot dry weight measurements expressed as g of active substance/ha for all test species are given below.

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Table KCP 10.6.2-52: Vegetative Vigour Test – final results (g of as/ha)

	Sunflower <i>Helianthus annuus</i>	Pea <i>Pisum sativum</i>	Cabbage <i>Brassica oleracea var. capitata</i>	Onion <i>Allium cepa</i>	Perennial ryegrass <i>Lolium perenne</i>	Oats <i>Avena sativa</i>
Plant number at the end of the experiment						
ER₅₀	> 295.8	> 295.8	> 295.8	> 295.8	> 295.8	> 295.8
NOER	> 295.8*	> 295.8*	> 295.8*	> 295.8*	> 295.8*	> 295.8*
Shoot length						
ER₅₀	> 295.8	> 295.8	> 295.8	> 295.8	> 295.8	> 295.8
NOER	≥ 295.8	≥ 295.8	≥ 295.8	≥ 295.8	≥ 295.8	≥ 295.8
Plant dry weight						
ER₅₀	> 295.8	> 295.8	> 295.8	> 295.8	> 295.8	> 295.8
NOER	≥ 295.8	≥ 295.8	≥ 295.8	≥ 295.8	18.5	74.0
Plant Damage						
ER₅₀	> 295.8	> 295.8	> 295.8	> 295.8	> 295.8	> 295.8

The mortality of plants was not observed in cultivation of all tested plant species.

On the basis of NOER, ER10, ER25 and ER50 values determined from the shoot length it was proved that the test item did not inhibit the process of growth of all test species.

On the basis of NOER, ER10, ER25 and ER50 values determined from the dry shoot weight it was proved that the test item moderately inhibited the process of growth of perennial ryegrass and oats. No influence was observed in cultivation of sunflower, pea, cabbage and onion.

During the experiment the phytotoxic symptoms were not observed.

A 2.6.3 KCP 10.6.3 Extended laboratory studies on non-target plants

Not relevant. No studies submitted.

A 2.7 KCP 10.7 Effects on other terrestrial organisms (flora and fauna)

Not relevant. No studies submitted.

A 2.8 KCP 10.8 Monitoring data

Not relevant. No studies submitted.