FINAL REGISTRATION REPORT

Part B

Section 9

Ecotoxicology

Detailed summary of the risk assessment

Product code: CLOROL 200 SC

Product name(s): Catanga 200 SC, Boland 200 SC

Chemical active substance:

Chlorantraniliprole, 200 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Innvigo Sp. z o.o.

Submission date: September 2024

zRMS Assessment: 12 September 2025

Following commenting period/Verification List of References: 18 November 2025

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Table of Contents

9 Ecotoxicology (KCP 10) 7

9.1 Critical GAP and overall conclusions 8
9.1.1 Overall conclusions 22
9.1.1.1 Effects on birds (KCP 10.1.1), Effects on terrestrial vertebrates other than birds (KCP 10.1.2), Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3) 22
9.1.1.2 Effects on aquatic organisms (KCP 10.2) 22
9.1.1.3 Effects on bees (KCP 10.3.1) 24
9.1.1.4 Effects on arthropods other than bees (KCP 10.3.2) 25
9.1.1.5 Effects on non-target soil meso- and macrofauna (KCP 10.4), Effects on soil microbial activity (KCP 10.5) 27
9.1.1.6 Effects on non-target terrestrial plants (KCP 10.6) 28
9.1.1.7 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7) 28
9.1.2 Grouping of intended uses for risk assessment 28
9.1.3 Consideration of metabolites 30
9.2 Effects on birds (KCP 10.1.1) 31
9.2.1 Toxicity data 31
9.2.1.1 Justification for new endpoints 32
9.2.2 Risk assessment for spray applications 32
9.2.2.1 First-tier assessment (screening/generic focal species) 32
9.2.2.2 Higher-tier risk assessment 42
9.2.2.3 Drinking water exposure 42
9.2.2.4 Effects of secondary poisoning 43
9.2.2.5 Biomagnification in terrestrial food chains 45
9.2.3 Risk assessment for baits, pellets, granules, prills or treated seed 45
9.2.4 Overall conclusions 45
9.3 Effects on terrestrial vertebrates other than birds (KCP 10.1.2) 46
9.3.1 Toxicity data 46
9.3.1.1 Justification for new endpoints 47
9.3.2 Risk assessment for spray applications 47
9.3.2.1 First-tier assessment (screening/generic focal species) 47
9.3.2.2 Higher-tier risk assessment 54
9.3.2.3 Drinking water exposure 54
9.3.2.4 Effects of secondary poisoning 54
9.3.2.5 Biomagnification in terrestrial food chains 56
9.3.3 Risk assessment for baits, pellets, granules, prills or treated seed 56
9.3.4 Overall conclusions 56
9.4 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3) 56
9.5 Effects on aquatic organisms (KCP 10.2) 57
9.5.1 Toxicity data 57
9.5.1.1 Justification for new endpoints 60
9.5.2 Risk assessment 60
9.5.3 Overall conclusions 235
9.6 Effects on bees (KCP 10.3.1) 238
9.6.1 Toxicity data 238
9.6.1.1 Justification for new endpoints 242

9.6.2 Risk assessment ... 242
9.6.2.1 Hazard quotients for bees ... 242
9.6.2.2 Higher-tier risk assessment for bees (tunnel test, field studies) ... 268
9.6.3 Effects on bumble bees ... 268
9.6.4 Effects on solitary bees ... 269
9.6.5 Overall conclusions ... 269
9.7 Effects on arthropods other than bees (KCP 10.3.2) ... 269
9.7.1 Toxicity data ... 271
9.7.1.1 Justification for new endpoints ... 272
9.7.2 Risk assessment ... 272
9.7.2.1 Risk assessment for in-field exposure ... 272
9.7.2.2 Risk assessment for off-field exposure ... 272
9.7.2.3 Additional higher-tier risk assessment ... 274
9.7.2.4 Risk mitigation measures ... 278
9.7.3 Overall conclusions ... 280
9.8 Effects on non-target soil meso- and macrofauna (KCP 10.4) ... 280
9.8.1 Toxicity data ... 282
9.8.1.1 Justification for new endpoints ... 285
9.8.2 Risk assessment ... 285
9.8.2.1 First-tier risk assessment ... 285
9.8.2.2 Higher-tier risk assessment ... 291
9.8.3 Overall conclusions ... 292
9.9 Effects on soil microbial activity (KCP 10.5) ... 293
9.9.1 Toxicity data ... 293
9.9.1.1 Justification for new endpoints ... 294
9.9.2 Risk assessment ... 294
9.9.3 Overall conclusions ... 295
9.10 Effects on non-target terrestrial plants (KCP 10.6) ... 296
9.10.1 Toxicity data ... 296
9.10.1.1 Justification for new endpoints ... 296
9.10.2 Risk assessment ... 296
9.10.2.1 Tier-1 risk assessment (based screening data) ... 296
9.10.2.2 Tier-2 risk assessment (based on dose-response data) ... 296
9.10.2.3 Higher-tier risk assessment ... 298
9.10.2.4 Risk mitigation measures ... 298
9.10.3 Overall conclusions ... 298
9.11 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7) ... 300
9.12 Monitoring data (KCP 10.8) ... 300
9.13 Classification and Labelling ... 300

Appendix 1 Lists of data considered in support of the evaluation ... 301

Appendix 2 Detailed evaluation of the new studies ... 316

A 2.1 KCP 10.1 Effects on birds and other terrestrial vertebrates ... 316
A 2.1.1 KCP 10.1.1 Effects on birds ... 316
A 2.1.2 KCP 10.1.2 Effects on terrestrial vertebrates other than birds ... 316
A 2.1.3 KCP 10.1.3 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) ... 316
A 2.2 KCP 10.2 Effects on aquatic organisms ... 316

A 2.2.1 KCP 10.2.1 Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes 316
A 2.2.2 KCP 10.2.2 Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms..... 333
A 2.2.3 KCP 10.2.3 Further testing on aquatic organisms 342
A 2.3 KCP 10.3 Effects on arthropods 342
A 2.3.1 KCP 10.3.1 Effects on bees 342
A 2.4 KCP 10.4 Effects on non-target soil meso- and macrofauna..... 349
A 2.4.1 KCP 10.4.1 Earthworms 349
A 2.4.2 KCP 10.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms) 354
A 2.5 KCP 10.5 Effects on soil nitrogen transformation..... 364
A 2.6 KCP 10.6 Effects on terrestrial non-target higher plants..... 364
A 2.6.1 KCP 10.6.1 Summary of screening data..... 364
A 2.6.2 KCP 10.6.2 Testing on non-target plants..... 364
A 2.6.3 KCP 10.6.3 Extended laboratory studies on non-target plants 364
A 2.7 KCP 10.7 Effects on other terrestrial organisms (flora and fauna)..... 364
A 2.8 KCP 10.8 Monitoring data..... 364

No comments during commenting period.

9 Ecotoxicology (KCP 10)

Studies for chlorantraniliprole and Coragen 200 SC have been evaluated during inclusion of it on Annex 1 and approved in 02.08.2007. Also First registration on Coragen 200 SC in Poland was in 2011 (Authorization number: R-65/2011). According to reg. 1107/2009 data protection is expiring after 10 years since first registration, so data for chlorantraniliprole and Coragen 200 SC is already not longer protect. Additionaly Clorol 200 SC and Coragen 200 SC have the same compostion of formulation.
Therefore, to sup-port the authorization of Clorol 200 SC (Catanga 200 SC, Boland 200 SC) INNVIGO is allowed to refer to EU and Coragen 200 SC approved reports.

The changes involve deleting newly added information on aquatic organisms for Chironomus riparius in sediment [DuPont-36097: Thomas et al 2014; *^{14}C Chlorantraniliprole (DPX-E2Y45) technical: A prolonged sediment toxicity test with Chironomus riparius using spiked natural sediment*], which is now considered non-protected data. This is because the study was not used in the assessment of the reference product. It was neither used for the extension granted by the Kingdom of the Netherlands nor for its mutual recognition in Poland for Coragen 200 SL. Therefore, the data protection period never started and could not have expired.

9.1 Critical GAP and overall conclusions

Table 9.1-1: Table of critical GAPs

GAP rev. , date: 29.05.2024

PPP (product name/code):	CLOROL	Formulation type:	SC [a, b]
Active substance 1:	Chlorantraniliprole	Conc. of as 1:	200 [c]
Safener:	-	Conc. of safener:	- [c]
Synergist:	-	Conc. of synergist:	- [c]
Applicant:	Innvigo	Professional use:	☐
Zone(s):	Central zone [d]	Non professional use:	☐
Verified by MS:	yes		

Field of use: insecticide

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15						
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]	**Conclusion**						
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			Birds	Mammals	Aquatic organisms	Bees	Non-target arthropods	Soil organisms	Non-target plants
Zonal uses (field or outdoor uses, certain types of protected crops)																				
1	PL	Potato *Solanum tuberosum* SOLTU	F	*Leptinotarsa decemlineata* LPTNDE	Spray, medium sprayer	after the pest occurrence, BBCH 31-60	a) 1 b) 2	10	a) 0.050-0.0625 L/ha b) 0.125 L/ha	a) 10.0-12.5 g as/ha b) 25 g as/ha	150-400	14	-							
2	PL	Maize *Zea mays* ZEAMX	F	*Ostrinia nubilalis* PYRUNU	Spray, medium sprayer	BBCH 53-69	a) 1 b) 1	n/a	a) 0.125 L/ha b) 0.125 L/ha	a) 25 g as/ha b) 25 g as/ha	300-400	7	-							
3	PL	Winter oilseed rape *Brassica napus var. napus* BRSNW	F	*Ceutorhynchus assimilis* CEUTPL, *Dasyneura brassicae* DASYBR	Spray, medium sprayer	BBCH 61-71	a) 1 b) 1	n/a	a) 0.10-0.175 L/ha b) 0.10-0.175 L/ha	a) 20-35 g as/ha b) 20-35 g as/ha	200-300	7								

4	PL	Winter oilseed rape *Brassica napus var. napus* BRSNW	F	*Ceutorhynchus assimilis* CEUTPL, *Dasyneura brassicae* DASYBR, *Ceutorhynchus quadridens, syn. C. pallidactylus* CEUTQU, *Ceu-torhynchus napi* CEUTNA, *Brassico-gethes aeneus syn. Meli-gethes aeneus* MELIAE	Spray, medium sprayer	A: BBCH 30-50 B: BBCH 61-71	a) 2 b) 2	14	a) 0.10-0.175 L/ha b) 0.350 L/ha	a) 20-35 g as/ha b) 70 g as/ha	200-300	7									
5	PL	Apple *Malus domestica* MABSD	F	*Cydia pomonella* CARPPO	Spray, medium sprayer	BBCH 70-87*	a) 2 b) 2	14	a) 0.125-0.175 L/ha b) 0.350 L/ha	a) 25-35 g as/ha b) 70 g as/ha	500-750	14								in every 2nd year	
6	PL	Apple *Malus domestica* MABSD	F	*Tortricidae* 1TORTF	Spray, medium sprayer	BBCH 56 or BBCH 7087*	a) 2 b) 2	14	a) 0.125-0.175 L/ha b) 0.350 L/ha	a) 25-35 g as/ha b) 70 g as/ha	500-750	14								in every 2nd year	

Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)																				
Minor uses according to Article 51 (zonal uses)																				
7	PL	Sugar beet *Beta vulgaris* subsp. *vulgaris* var. *altissima* BEAVA	F	*Asproparthenis punctiventris* CLEOPU, *Scrobipalpa ocellatella* PHTOOC	Spray, medium sprayer	BBCH 31-49	a) 1 b) 1	n/a	a) 0.10 L/ha + 0.1 L/ha adjuvant Asystent+ b) 0.10 L/ha+ 0.1 L/ha adjuvant Asystent+	a) 20 g as/ha + 0.1 L/ha adjuvant Asystent+ b) 20 g as/ha + 0.1 L/ha adjuvant Asystent+	150-200	28									
8	PL	Sweet Potato *Ipomoea batatas* IPOBA	F	*Autographa gamma* PYTOGA, *Delia florilega* HYLEFG	Spray, medium sprayer	after the pest occurrence, BBCH 31-60	a) 1 b) 2	10	a) 0.050-0.0625 L/ha b) 0.125 L/ha	a) 10.0-12.5 g as/ha b) 25 g as/ha	150-400	14									
9	PL	Yams *Dioscorea* L. 1DIUG	F	*Trialeurodes vaporariorum* TRIAVA, *Thysanoptera* 1THYSO, *Tetranychus* 1TETRG	Spray, medium sprayer	after the pest occurrence, BBCH 31-60	a) 1 b) 2	10	a) 0.050-0.0625 L/ha b) 0.125 L/ha	a) 10.0-12.5 g as/ha b) 25 g as/ha	150-400	14									
10	PL	Carrot *Daucus carota* subsp. *sativus* DAUCS	F	*Chamaepsila rosae* PSILRO, *Autographa gamma* PYTOGA	Spray, medium sprayer	BBCH 12-49	a) 1 b) 1	n/a	a) 0.175 L/ha b) 0.175 L/ha	a) 35 g as/ha b) 35 g as/ha	300-800	21									
11	PL	Beetroot *Beta vulgaris s*subsp. *vulgaris* var. *conditiva* BEAVD	F	*Athalia rosae* ATALCO, *Barathra brassicae* BARABR, *Pieris brassicae* PIERBR, *Plutella maculipennis* PLUTMA, *Delia radicum* HYLERA, *Artogeia rapae* PIERRA,	Spray, medium sprayer	BBCH 12-49	a) 1 b) 1	n/a	a) 0.175 L/ha b) 0.175 L/ha	a) 35 g as/ha b) 35 g as/ha	300-800	21									
12	PL	Horseradish *Armoracia rusticana* ARWLA	F	*Athalia rosae* ATALCO, *Barathra brassicae* BARABR, *Pieris brassicae* PIERBR, *Plutella maculipennis* PLUTMA, *Delia radicum* HYLERA, *Artogeia rapae* PIERRA,	Spray, medium sprayer	BBCH 12-49	a) 1 b) 1	n/a	a) 0.175 L/ha b) 0.175 L/ha	a) 35 g as/ha b) 35 g as/ha	300-800	21									
13	PL	Radish *Raphanus sativus* RAPSR	F	*Athalia rosae* ATALCO, *Barathra brassicae* BARABR, *Pieris brassicae* PIERBR, *Plutella maculipennis* PLUTMA, *Delia radicum* HYLERA, *Artogeia rapae* PIERRA,	Spray, medium sprayer	BBCH 12-49	a) 1 b) 1	n/a	a) 0.175 L/ha b) 0.175 L/ha	a) 35 g as/ha b) 35 g as/ha	300-800	21									
14	PL	Celery *Apium graveolens* APUGV	F	*Chamaepsila rosae* PSILRO, *Autographa gamma* PYTOGA	Spray, medium sprayer	BBCH 12-49	a) 1 b) 1	n/a	a) 0.175 L/ha b) 0.175 L/ha	a) 35 g as/ha b) 35 g as/ha	300-800	21									

15	PL	Jerusalem artichoke *Helianthus tuberosus* HELTU	F	*Autographa gamma* PYTOGA, *Homoeosoma nebulellum* HMOENE	Spray, medium sprayer	BBCH 12-49	a) 1 b) 1	n/a	a) 0.175 L/ha b) 0.175 L/ha	a) 35 g as/ha b) 35 g as/ha	300-800	21								
16	PL	Parsley *Petroselinum crispum* PARCR	F	*Chamaepsila rosae* PSILRO, *Autographa gamma* PYTOGA	Spray, medium sprayer	BBCH 12-49	a) 1 b) 1	n/a	a) 0.175 L/ha b) 0.175 L/ha	a) 35 g as/ha b) 35 g as/ha	300-800	21								
17	PL	Parsnip *Pastinaca sativa* PAVSA	F	*Chamaepsila rosae* PSILRO, *Autographa gamma* PYTOGA	Spray, medium sprayer	BBCH 12-49	a) 1 b) 1	n/a	a) 0.175 L/ha b) 0.175 L/ha	a) 35 g as/ha b) 35 g as/ha	300-800	21								
18	PL	Salsify *Tragopogon porrifolius* TROPS	F	*Chamaepsila rosae* PSILRO, *Autographa gamma* PYTOGA	Spray, medium sprayer	BBCH 12-49	a) 1 b) 1	n/a	a) 0.175 L/ha b) 0.175 L/ha	a) 35 g as/ha b) 35 g as/ha	300-800	21								
19	PL	Rutabaga *Brassica napus* subsp. *rapifera* BRSNA	F	*Athalia rosae* ATALCO, Brevicoryne brassicae BRVCBR, *Barathra brassicae* BARABR, *Pieris brassicae* PIERBR, *Plutella maculipennis* PLUTMA, *Delia radicum* HYLERA, *Artogeia rapae* PIERRA,	Spray, medium sprayer	BBCH 12-49	a) 1 b) 1	n/a	a) 0.175 L/ha b) 0.175 L/ha	a) 35 g as/ha b) 35 g as/ha	300-800	21								
20	PL	Turnip *Brassica rapa* BRSRR	F	*Athalia rosae* ATALCO, *Barathra brassicae* BARABR, *Pieris brassicae* PIERBR, *Plutella maculipennis* PLUTMA, *Delia radicum* HYLERA, *Artogeia rapae* PIERRA,	Spray, medium sprayer	BBCH 12-49	a) 1 b) 1	n/a	a) 0.175 L/ha b) 0.175 L/ha	a) 35 g as/ha b) 35 g as/ha	300-800	21								
21	PL	Scorzonera *Scorzonera hispanica* SCVHI	F	*Chamaepsila rosae* PSILRO, *Autographa gamma* PYTOGA	Spray, medium sprayer	BBCH 12-49	a) 1 b) 1	n/a	a) 0.175 L/ha b) 0.175 L/ha	a) 35 g as/ha b) 35 g as/ha	300-800	21								
22	PL	Sweet Corn *Zea mays* subsp. *saccharata* ZEAMS	F	*Ostrinia nubilalis* PYRUNU	Spray, medium sprayer	BBCH 53-69	a) 1 b) 1	n/a	a) 0.125 L/ha b) 0.125 L/ha	a) 25 g as/ha b) 25 g as/ha	300-400	7								
23	PL	Sweet cane *Saccharum officinarum* SACOF	F	*Ostrinia nubilalis* PYRUNU	Spray, medium sprayer	BBCH 53-69	a) 1 b) 1	n/a	a) 0.125 L/ha b) 0.125 L/ha	a) 25 g as/ha b) 25 g as/ha	300-400	7								
24	PL	Sorghum *Sorghum bicolor* SORVU	F	*Ostrinia nubilalis* PYRUNU	Spray, medium sprayer	BBCH 53-69	a) 1 b) 1	n/a	a) 0.125 L/ha b) 0.125 L/ha	a) 25 g as/ha b) 25 g as/ha	300-400	7								
25	PL	Millet *Panicum miliaceum*	F	*Ostrinia nubilalis* PYRUNU	Spray, medium	BBCH 53-69	a) 1 b) 1	n/a	a) 0.125 L/ha b) 0.125 L/ha	a) 25 g as/ha b) 25 g as/ha	300-400	7								

		PANMI			sprayer															
26	PL	Spring oilseed rape *Brassica napus var. napus* BRSNS	F	*Ceutorhynchus assimilis* CEUTPL, *Dasyneura brassicae* DASYBR, *Ceutorhynchus quadridens, syn. C. pallidactylus* CEUTQU, *Ceu-torhynchus napi* CEUTNA, *Brassico-gethes aeneus syn. Meli-gethes aeneus* MELIAE, *Plutella xylostella* PLUT-MA, *Athalia rosae* ATALCO	Spray, medium sprayer	BBCH 61-71	a) 1 b) 1	n/a	a) 0.10-0.175 L/ha b) 0.10-0.175 L/ha	a) 20-35 g as/ha b) 20-35 g as/ha	200-300	7								
27	PL	Flax *Linum usitatissimum* LIUUT	F	*Cochylis epilinana* PHA-OEP, *Aphthona euphorbi-ae* APHTEU	Spray, medium sprayer	BBCH 61-71	a) 1 b) 1	n/a	a) 0.10-0.175 L/ha b) 0.10-0.175 L/ha	a) 20-35 g as/ha b) 20-35 g as/ha	200-300	7	Only for seeds							
28	PL	Opium poppy *Papaver som-niferum* PAPSO	F	*Neoglocianus maculaalba* CEUTMA	Spray, medium sprayer	BBCH 61-65	a) 1 b) 1	n/a	a) 0.10-0.175 L/ha b) 0.10-0.175 L/ha	a) 20-35 g as/ha b) 20-35 g as/ha	200-300	7	Only for seeds							
29	PL	White mustard *Sinapis alba* SINAL	F	*Ceutorhynchus assimilis* CEUTPL, *Dasyneura brassicae* DASYBR, *Ceutorhynchus quadridens, syn. C. pallidactylus* CEUTQU, *Ceu-torhynchus napi* CEUTNA, *Brassico-gethes aeneus syn. Meli-gethes aeneus* MELIAE, *Plutella xylostella* PLUT-MA, *Athalia rosae* ATALCO	Spray, medium sprayer	BBCH 61-65	a) 1 b) 1	n/a	a) 0.10-0.175 L/ha b) 0.10-0.175 L/ha	a) 20-35 g as/ha b) 20-35 g as/ha	200-300	7	Only for seeds							
30	PL	Winter Turnip rape *Brassica rapa* subsp. *oleifera* BRSRO	F	*Ceutorhynchus assimilis* CEUTPL, *Dasyneura brassicae* DASYBR, *Ceutorhynchus quadridens, syn. C. pallidactylus* CEUTQU, *Ceu-torhynchus napi* CEUTNA, *Brassico-gethes aeneus syn. Meli-gethes aeneus* MELIAE, *Plutella xylostella* PLUT-MA, *Athalia rosae* ATALCO,	Spray, medium sprayer	BBCH 61-65	a) 1 b) 1	n/a	a) 0.10-0.175 L/ha b) 0.10-0.175 L/ha	a) 20-35 g as/ha b) 20-35 g as/ha	200-300	7	Only for seeds							
31	PL	Sunflower *Helianthus annuus* HELAN	F	*Autographa gamma* PYTOGA, *Homoeosoma nebulellum* HMOENE	Spray, medium sprayer	BBCH 61-65	a) 1 b) 1	n/a	a) 0.10-0.175 L/ha b) 0.10-0.175 L/ha	a) 20-35 g as/ha b) 20-35 g as/ha	200-300	7								

32	PL	Soybean *Glycine max* GLXMA	F	*Delia florilega* HYLEFG, *Ostrinia nubilalis* PY-RUNU	Spray, medium sprayer	BBCH 61-65	a) 1 b) 1	n/a	a) 0.10-0.175 L/ha b) 0.10-0.175 L/ha	a) 20-35 g as/ha b) 20-35 g as/ha	200-300	7	Only for seeds							
33	PL	Pumpkin *Cucurbita pepo* CUUPE	F	*Delia florilega* HYLEFG	Spray, medium sprayer	BBCH 61-65	a) 1 b) 1	n/a	a) 0.10-0.175 L/ha b) 0.10-0.175 L/ha	a) 20-35 g as/ha b) 20-35 g as/ha	200-300	7	Only for seeds							
34	PL	Hemp *Cannabis sativa* CNISA	F	*Ostrinia nubilalis* PY-RUNU	Spray, medium sprayer	BBCH 61-65	a) 1 b) 1	n/a	a) 0.10-0.175 L/ha b) 0.10-0.175 L/ha	a) 20-35 g as/ha b) 20-35 g as/ha	200-300	7	Only for seeds							
35	PL	White cabbage *Brassica oleracea* var. *capitata* f. *alba* BRSOH	F	*Ceutorhynchus quadridens, syn. C. pallidactylus* CEUTQU, *Ceu-torhynchus napi* CEUTNA, *Brassicogethes aeneus syn. Meligethes aeneus* MELIAE, *Delia radicum* HYLERA, *Athalia rosae* ATALCO, *Plutella xylostella* PLUTMA, *Phyllotreta* sp. PHYESP, *Pieris rapae* PIERRA, *Mamestra brassicae* BARABR	Spray, medium sprayer	BBCH ~~20~~-49	a) 1 ~~b) 2~~	~~14~~	a) 0.125 L/ha ~~b) 0.250 L/ha~~	a) 25 g as/ha ~~b) 50 g as/ha~~	200-~~600~~	1									
36	PL	Red cabbage *Brassica oleracea* var. *capitata* f. *rubra* BRSOR	F	*Ceutorhynchus quadridens, syn. C. pallidactylus* CEUTQU, *Ceu-torhynchus napi* CEUTNA, *Brassicogethes aeneus syn. Meligethes aeneus* MELIAE, *Delia radicum* HYLERA, *Athalia rosae* ATALCO, *Plutella xylostella* PLUTMA, *Phyllotreta* sp. PHYESP, *Pieris rapae* PIERRA, *Mamestra brassicae* BARABR	Spray, medium sprayer	BBCH ~~20~~-49	a) 1 ~~b) 2~~	~~14~~	a) 0.125 L/ha ~~b) 0.250 L/ha~~	a) 25 g as/ha ~~b) 50 g as/ha~~	200-~~600~~	1									
37	PL	Kale *Brassica oleracea* var. *viridis* BRSOA	F	*Ceutorhynchus quadridens, syn. C. pallidactylus* CEUTQU, *Ceu-torhynchus napi* CEUTNA, *Brassicogethes aeneus syn. Meligethes aeneus* MELIAE, *Delia radicum* HYLERA, *Athalia rosae* ATALCO, *Plutella xylostella* PLUTMA, *Phyllotreta* sp. PHYESP	Spray, medium sprayer	BBCH ~~20~~-49	a) 1 ~~b) 2~~	~~14~~	a) 0.125 L/ha ~~b) 0.250 L/ha~~	a) 25 g as/ha ~~b) 50 g as/ha~~	200-~~600~~	1									
38	PL	Chinese cabbage/pe-tsai	F	*Ceutorhynchus quadridens, syn. C. pallidactylus*	Spray, medium sprayer	BBCH ~~20~~-49	a) 1 ~~b) 2~~	~~14~~	a) 0.125 L/ha ~~b) 0.250 L/ha~~	a) 25 g as/ha ~~b) 50 g as/ha~~	200-~~600~~	1									

		Brassica rapa subsp. *pekinensis* BRSPK		CEUTQU, *Ceu-torhynchus napi* CEUTNA, *Brassico-gethes aeneus syn. Meli-gethes aeneus* MELIAE, *Delia radicum* HYLERA, *Athalia rosae* ATALCO, *Plutella xylostella* PLUT-MA, *Phyllotreta* sp. PHYESP																	
39	PL	Brussels sprout *Brassica oleracea* var. *gemmifera* BRSOF	F	*Ceutorhynchus quadridens, syn. C. pallidactylus* CEUTQU, *Ceu-torhynchus napi* CEUTNA, *Brassico-gethes aeneus syn. Meli-gethes aeneus* MELIAE, *Delia radicum* HYLERA, *Athalia rosae* ATALCO, *Plutella xylostella* PLUT-MA, *Phyllotreta* sp. PHYESP	Spray, medium sprayer	BBCH ~~20~~-49	a) 1 ~~b) 2~~	~~14~~	a) 0.125 L/ha ~~b) 0.250 L/ha~~	a) 25 g as/ha ~~b) 50 g as/ha~~	200-~~600~~	1										
40	PL	Cauliflower *Brassica oleracea* var. *botrytis* BRSOB	F	*Ceutorhynchus quadridens, syn. C. pallidactylus* CEUTQU, *Ceu-torhynchus napi* CEUTNA, *Brassico-gethes aeneus syn. Meli-gethes aeneus* MELIAE, *Delia radicum* HYLERA, *Athalia rosae* ATALCO, *Plutella xylostella* PLUT-MA, *Phyllotreta* sp. PHYESP	Spray, medium sprayer	BBCH ~~20~~-49	a) 1 ~~b) 2~~	~~14~~	a) 0.125 L/ha ~~b) 0.250 L/ha~~	a) 25 g as/ha ~~b) 50 g as/ha~~	200-~~600~~	1										
41	PL	Broccoli *Brassica oleracea var. italica* BRSOK	F	*Ceutorhynchus quadridens, syn. C. pallidactylus* CEUTQU, *Ceu-torhynchus napi* CEUTNA, *Brassico-gethes aeneus syn. Meli-gethes aeneus* MELIAE, *Delia radicum* HYLERA, *Athalia rosae* ATALCO, *Plutella xylostella* PLUT-MA, *Phyllotreta* sp. PHYESP	Spray, medium sprayer	BBCH ~~20~~-49	a) 1 ~~b) 2~~	~~14~~	a) 0.125 L/ha ~~b) 0.250 L/ha~~	a) 25 g as/ha ~~b) 50 g as/ha~~	200-~~600~~	1										
42	PL	Pear *Pyrus communis* PYUCO	F	*Cydia pomonella* CARP-PO, *Dasineura pyri* DASYPY, *Contarinia pyrivora* CONTPY, *Tortricidae* 1TORTF	Spray, medium sprayer	BBCH 56-7087*	a) 2 b) 2	14	a) 0.125-0.175 L/ha b) 0.350 L/ha	a) 25-35 g as/ha b) 70 g as/ha	500-750	14							in every 2nd year		
43	PL	Plum *Prunus domestic*a PRN-	F	*Rhagoletis cerasi* RHAGCE, *Furcipus*	Spray, medium	BBCH 56-7087*	a) 2 b) 2	14	a) 0.125-0.175 L/ha b) 0.350 L/ha	a) 25-35 g as/ha b) 70 g as/ha	500-750	14							in every		

		DO		*rectirostris* ANTHRE, *Grapholita funebrana* LASPFU	sprayer															2nd year	
44	PL	Common quince *Cydonia oblonga* CYDOB	F	*Cydia pomonella* CARPPO, *Dasineura pyri* DASYPY, *Contarinia pyrivora* CONTPY, *Tortricidae* 1TORTF	Spray, medium sprayer	BBCH 56-7087*	a) 2 b) 2	14	a) 0.125-0.175 L/ha b) 0.350 L/ha	a) 25-35 g as/ha b) 70 g as/ha	500-750	14									in every 2nd year	
45	PL	Wild Apple *Malus sylvestris* MABSY	F	*Cydia pomonella* CARPPO *Tortricidae* 1TORTF	Spray, medium sprayer	BBCH 56-7087*	a) 2 b) 2	14	a) 0.125-0.175 L/ha b) 0.350 L/ha	a) 25-35 g as/ha b) 70 g as/ha	500-750	14									in every 2nd year	
46	PL	Chinese Pear *Pyrus pyrifolia* PYUPY	F	*Cydia pomonella* CARPPO, *Dasineura pyri* DASYPY, *Contarinia pyrivora* CONTPY, *Tortricidae* 1TORTF	Spray, medium sprayer	BBCH 56-7087*	a) 2 b) 2	14	a) 0.125-0.175 L/ha b) 0.350 L/ha	a) 25-35 g as/ha b) 70 g as/ha	500-750	14									in every 2nd year	
47	PL	Common medlar *Mespilus germanica* MSPGE	F	*Rhagoletis cerasi* RHAGCE, *Furcipus rectirostris* ANTHRE, *Grapholita funebrana* LASPFU	Spray, medium sprayer	BBCH 56-7087*	a) 2 b) 2	14	a) 0.125-0.175 L/ha b) 0.350 L/ha	a) 25-35 g as/ha b) 70 g as/ha	500-750	14									in every 2nd year	
48	PL	Loquats/Japanese medlars *Eriobotrya japonica* EIOJA	F	*Rhagoletis cerasi* RHAGCE, *Furcipus rectirostris* ANTHRE, *Grapholita funebrana* LASPFU	Spray, medium sprayer	BBCH 56-7087*	a) 2 b) 2	14	a) 0.125-0.175 L/ha b) 0.350 L/ha	a) 25-35 g as/ha b) 70 g as/ha	500-750	14									in every 2nd year	
49	PL	Peach *Prunus persica* PRNPS	F	*Rhagoletis cerasi* RHAGCE, *Furcipus rectirostris* ANTHRE, *Grapholita funebrana* LASPFU	Spray, medium sprayer	BBCH 56-7087*	a) 2 b) 2	14	a) 0.125-0.175 L/ha b) 0.350 L/ha	a) 25-35 g as/ha b) 70 g as/ha	500-750	14									in every 2nd year	
50	PL	Apricot *Prunus armeniaca* PRNAR	F	*Rhagoletis cerasi* RHAGCE, *Furcipus rectirostris* ANTHRE, *Grapholita funebrana* LASPFU	Spray, medium sprayer	BBCH 56-7087*	a) 2 b) 2	14	a) 0.125-0.175 L/ha b) 0.350 L/ha	a) 25-35 g as/ha b) 70 g as/ha	500-750	14									in every 2nd year	
51	PL	Sour Cherry *Prunus cerasus* PRNCE	F	*Rhagoletis cerasi* RHAGCE, *Furcipus rectirostris* ANTHRE, *Grapholita funebrana* LASPFU	Spray, medium sprayer	BBCH 56-7087*	a) 2 b) 2	14	a) 0.125-0.175 L/ha b) 0.350 L/ha	a) 25-35 g as/ha b) 70 g as/ha	500-750	14									in every 2nd year	
52	PL	Sweet cherry *Prunus avium* PRNAV	F	*Rhagoletis cerasi* RHAGCE, *Furcipus rectirostris* ANTHRE,	Spray, medium sprayer	BBCH 56-7087*	a) 2 b) 2	14	a) 0.125-0.175 L/ha b) 0.350 L/ha	a) 25-35 g as/ha b) 70 g as/ha	500-750	14									in every 2nd	

																				year	
53	PL	Hazelnuts/cobnuts *Corylus avellana* CYLAV	F	*Rhagoletis cerasi* RHAGCE, *Furcipus rectirostris* ANTHRE, *Grapholita funebrana* LASPFU	Spray, medium sprayer	BBCH 56-7087*	a) 2 b) 2	14	a) 0.125-0.175 L/ha b) 0.350 L/ha	a) 25-35 g as/ha b) 70 g as/ha	500-750	14								in every 2nd year	
54	PL	Walnuts *Juglans regia* IUGRE	F	*Rhagoletis cerasi* RHAGCE, *Furcipus rectirostris* ANTHRE, *Grapholita funebrana* LASPFU	Spray, medium sprayer	BBCH 56-7087*	a) 2 b) 2	14	a) 0.125-0.175 L/ha b) 0.350 L/ha	a) 25-35 g as/ha b) 70 g as/ha	500-750	14								in every 2nd year	
55	PL	Chestnuts *Castanea sativa* CSNSA	F	*Rhagoletis cerasi* RHAGCE, *Furcipus rectirostris* ANTHRE, *Grapholita funebrana* LASPFU	Spray, medium sprayer	BBCH 56-7087*	a) 2 b) 2	14	a) 0.125-0.175 L/ha b) 0.350 L/ha	a) 25-35 g as/ha b) 70 g as/ha	500-750	14								in every 2nd year	
56	PL	Table grape *Vitis vinifera* VITVI	F	*Tetranychus urticae* TETRUR, *Lobesia botrana* POLYBO, *Eupoecilia ambiguella* CLYSAM	Spray, medium sprayer	BBCH 57-BBCH 83	a)1 b)1	-	a) 0.270 L/ha b) 0.270 L/ha	a) 54 g as/ha b) 54 g as/ha	700-1500	30									
57	PL	Grapevine *Vitis vinifera* VITVI	F	*Lobesia botrana* POLYBO, *Eupoecilia ambiguella* CLYSAM	Spray, medium sprayer	BBCH 57-BBCH 83	a)1 b)1	-	a) 0.270 L/ha b) 0.270 L/ha	a) 54 g as/ha b) 54 g as/ha	700-1500	30									
~~58~~	~~PL~~	~~Tobacco *Nicotiana tabacum* NIOTA~~	~~F~~	~~*Mamestra brassicae* BARABR~~	~~Spray, medium sprayer~~	~~BBCH 20-85~~	~~a)1 b)2~~	~~7~~	~~a) 0.265-0.550 L/ha b) 0.530-1.100 L/ha~~	~~a) 53-110 g as/ha b) 106-220 g as/ha~~	~~600-1000~~	~~1~~	not accepted in Part B8								
59	PL	Grass	F	*Oulema* sp.OULESP	Spray, medium sprayer	BBCH 53-69	a) 1 b) 1	-	a) 0.175 L/ha b) 0.175 L/ha	a) 35 g as/ha b) 35 g as/ha	200-400	n/a	Only for seeds								
60	PL	Christmas tree *Picea abies* PIEAB	F	*Collembola* 1COLLO, *Coleophora laricella* COLELA	Spray, medium sprayer	~~BBCH 11-69~~ BBCH 56-69	a) 1 b) 1	-	a) 0.175 L/ha b) 0.175 L/ha	a) 35 g as/ha b) 35 g as/ha	200-400	n/a								in every 2nd year	
61	PL	Forestry tree	F	*Collembola* 1COLLO, *Coleophora laricella* COLELA	Spray, medium sprayer	~~BBCH 11-69~~ BBCH 56-69	a) 1 b) 1	-	a) 0.175 L/ha b) 0.175 L/ha	a) 35 g as/ha b) 35 g as/ha	200-400	n/a								in every 2nd year	
62	PL	Ornamentals	F	*Collembola* 1COLLO, *Coleophora laricella* COLELA	Spray, medium sprayer	BBCH ~~11~~ 50-69	a) 1 b) 1	-	a) 0.175 L/ha b) 0.175 L/ha	a) 35 g as/ha b) 35 g as/ha	200-400	n/a								in every 2nd year	

63	PL	Willow *Salix* sp. SAXSS	F	*Chrysomela populi* CHRSPO, *Phratora vulgatissima* PHRRVU, *Phyllodecta vitellinae* PHRRVI, *Earias clorana* EARICH, *Cecidomyiidae* 1CECIF	Spray, medium sprayer	>BBCH 69	a) 1 b) 1	-	a) 0.175 L/ha b) 0.175 L/ha	a) 35 g as/ha b) 35 g as/ha	200-750	n/a							In every 2nd years		
64	PL	Energetic tree	F	*Chrysomela populi* CHRSPO, *Phratora vulgatissima* PHRRVU, *Phyllodecta vitellinae* PHRRVI, *Earias clorana* EARICH, *Cecidomyiidae* 1CECIF *Cecidomyiidae*	Spray, medium sprayer	>BBCH 69	a) 1 b) 1	-	a) 0.175 L/ha b) 0.175 L/ha	a) 35 g as/ha b) 35 g as/ha	200-750	n/a							In every 2nd years		
Minor uses according to Article 51 (interzonal uses)																						
65	PL	Cucumber *Cucumis sativus* CUMSA	G	*Delia florilega* HYLEFG	Spray, medium sprayer	BBCH 15-89	a) 1 b) 2	7	a) 0.14-0.25 L/ha b) 0.28-0.50 L/ha	a) 28-50 g as/ha b) 56-100 g as/ha	500-1200	1										
66	PL	Pepper *Capsicum annuum* CPSAN	G	*Autographa gamma* PYTOGA, *Tuta absoluta* GNORAB	Spray, medium sprayer	BBCH 15-89	a) 1 b) 2	7	a) 0.14-0.215 L/ha b) 0.28-0.43 L/ha	a) 28-43 g as/ha b) 56-86 g as/ha	300-1250	1										
67	PL	Tomato *Solanum lycopersicum* LYPES	G	*Autographa gamma* PYTOGA, *Tuta absoluta* GNORAB	Spray, medium sprayer	BBCH 15-89	a) 1 b) 2	7	a) 0.14-0.315 L/ha b) 0.28-0.63 L/ha	a) 28-63 g as/ha b) 56-126 g as/ha	500-1500	1										
68	PL	Lettuce *Lactuca sativa* LACSA	G	*Delia florilega* HYLEFG	Spray, medium sprayer	~~BBCH 12-49~~ BBCH ~~20~~-49	a) 1 ~~b) 2~~	7	a) 0.155-0.210 L/ha ~~b) 0.310-0.420 L/ha~~	a) 31-42 g as/ha ~~b) 62-84 g as/ha~~	500-~~1000~~	1										
69	PL	Corn salad *Valerianella locusta* VLLLO	G	*Delia florilega* HYLEFG	Spray, medium sprayer	~~BBCH 12-49~~ BBCH ~~20~~-49	a) 1 ~~b) 2~~	7	a) 0.155-0.210 L/ha ~~b) 0.310-0.420 L/ha~~	a) 31-42 g as/ha b) 62-84 g as/ha	500-~~1000~~	1										
70	PL	Endive *Cichorium endivia* CICEN	G	*Delia florilega* HYLEFG	Spray, medium sprayer	~~BBCH 12-49~~ BBCH ~~20~~-49	a) 1 ~~b) 2~~	7	a) 0.155-0.210 L/ha ~~b) 0.310-0.420 L/ha~~	a) 31-42 g as/ha ~~b) 62-84 g as/ha~~	500-~~1000~~	1										
71	PL	Garden cress *Lepidium sativum* LEPSA	G	*Delia florilega* HYLEFG	Spray, medium sprayer	~~BBCH 12-49~~ BBCH ~~20~~-49	a) 1 ~~b) 2~~	7	a) 0.155-0.210 L/ha ~~b) 0.310-0.420 L/ha~~	a) 31-42 g as/ha ~~b) 62-84 g as/ha~~	500-~~1000~~	1										
72	PL	Arugula *Eruca vesicaria subsp. sativa* ERUVE	G	*Delia florilega* HYLEFG	Spray, medium sprayer	~~BBCH 12-49~~ BBCH ~~20~~-49	a) 1 ~~b) 2~~	~~7~~	a) 0.155-0.210 L/ha ~~b) 0.310-0.420 L/ha~~	a) 31-42 g as/ha ~~b) 62-84 g as/ha~~	500-~~1000~~	1										
73	PL	Escaroles Cichorium endivia var. latifolia	G	*Delia florilega* HYLEFG	Spray, medium sprayer	~~BBCH 12-49~~ BBCH ~~20~~-49	a) 1 b) 2	~~7~~	a) 0.155-0.210 L/ha ~~b) 0.310-0.420 L/ha~~	a) 31-42 g as/ha ~~b) 62-84 g as/ha~~	500-~~1000~~	1										

74	PL	Cresses and other sprouts and shoots	G	*Delia florilega* HYLEFG	Spray, medium sprayer	~~BBCH 12-49~~ BBCH ~~20-~~49	a) 1 ~~b) 2~~	~~7~~	a) 0.155-0.210 L/ha ~~b) 0.310-0.420 L/ha~~	a) 31-42 g as/ha ~~b) 62-84 g as/ha~~	500-~~1000~~	1										
75	PL	Land creses *Barbarea verna* BARVE	G	*Delia florilega* HYLEFG	Spray, medium sprayer	~~BBCH 12-49~~ BBCH ~~20-~~49	a) 1 ~~b) 2~~	~~7~~	a) 0.155-0.210 L/ha ~~b) 0.310-0.420 L/ha~~	a) 31-42 g as/ha ~~b) 62-84 g as/ha~~	500-~~1000~~	1										
76	PL	Roman rock-et/rucola *Eruca vesicaria* subsp. *sativa* ERUVE	G	*Delia florilega* HYLEFG	Spray, medium sprayer	~~BBCH 12-49~~ BBCH ~~20-~~49	a) 1 ~~b) 2~~	~~7~~	a) 0.155-0.210 L/ha ~~b) 0.310-0.420 L/ha~~	a) 31-42 g as/ha ~~b) 62-84 g as/ha~~	500-~~1000~~	1										
77	PL	Red Mustard *Brassica juncea* BRSJU	G	*Delia florilega* HYLEFG	Spray, medium sprayer	~~BBCH 12-49~~ BBCH ~~20-~~49	a) 1 ~~b) 2~~	~~7~~	a) 0.155-0.210 L/ha ~~b) 0.310-0.420 L/ha~~	a) 31-42 g as/ha ~~b) 62-84 g as/ha~~	500-~~1000~~	1										
78	PL	Baby leaf crops	G	*Delia florilega* HYLEFG	Spray, medium sprayer	~~BBCH 12-49~~ BBCH ~~20-~~49	a) 1 ~~b) 2~~	~~7~~	a) 0.155-0.210 L/ha ~~b) 0.310-0.420 L/ha~~	a) 31-42 g as/ha ~~b) 62-84 g as/ha~~	500-~~1000~~	1										
79	PL	Spinach *Spinacia oleracea* SPQOL	G	*Delia florilega* HYLEFG	Spray, medium sprayer	~~BBCH 12-49~~ BBCH ~~20-~~49	a) 1 ~~b) 2~~	~~7~~	a) 0.155-0.210 L/ha b) 0.310-0.420 ~~L/ha~~	a) 31-42 g as/ha ~~b) 62-84 g as/ha~~	500-~~1000~~	1										
80	PL	Swiss Chard *Beta vulgaris subsp. vulgaris var. flavescens* BEAVF	G	*Delia florilega* HYLEFG	Spray, medium sprayer	~~BBCH 12-49~~ BBCH ~~20-~~49	a) 1 b) 2	~~7~~	a) 0.155-0.210 L/ha ~~b) 0.310-0.420 L/ha~~	a) 31-42 g as/ha ~~b) 62-84 g as/ha~~	500-~~1000~~	1										
81	PL	Chards/beet leaves	G	*Delia florilega* HYLEFG	Spray, medium sprayer	~~BBCH 12-49~~ BBCH ~~20-~~49	a) 1 ~~b) 2~~	~~7~~	a) 0.155-0.210 L/ha ~~b) 0.310-0.420 L/ha~~	a) 31-42 g as/ha ~~b) 62-84 g as/ha~~	500-~~1000~~	1										
82	PL	Purslane *Portu-laca oleracea* POROL	G	*Delia florilega* HYLEFG	Spray, medium sprayer	~~BBCH 12-49~~ BBCH ~~20-~~49	a) 1 ~~b) 2~~	~~7~~	a) 0.155-0.210 L/ha ~~b) 0.310-0.420 L/ha~~	a) 31-42 g as/ha ~~b) 62-84 g as/ha~~	500-~~1000~~	1										
83	PL	Melon *Cucumis melo* CUMME	G	*Delia florilega* HYLEFG	Spray, medium sprayer	BBCH 15-89	a) 1 b) 2	7	a) 0.14-0.25 L/ha b) 0.28-0.50 L/ha	a) 28-50 g as/ha b) 56-100 g as/ha	200-1000	1										
84	PL	Aubergine *Solanum melongena* SOLME	G	*Delia florilega* HYLEFG	Spray, medium sprayer	BBCH 15-89	a) 1 b) 2	7	a) 0.14-0.25 L/ha b) 0.28-0.50 L/ha	a) 28-50 g as/ha b) 56-100 g as/ha	200-1000	1										
85	PL	Okra/Lady's fingers Abelmoschus esculentus	G	*Delia florilega* HYLEFG	Spray, medium sprayer	BBCH 15-89	a) 1 b) 2	7	a) 0.14-0.215 L/ha b) 0.28-0.43 L/ha	a) 28-43 g as/ha b) 56-86 g as/ha	300-1250	1										
86	PL	Watermelon	G	*Delia florilega* HYLEFG	Spray,	BBCH 15-89	a) 1	7	a) 0.14-0.25 L/ha	a) 28-50 g as/ha	200-	1										

		Citrullus lanatus CITLA			medium sprayer		b) 2		b) 0.28-0.50 L/ha	b) 56-100 g as/ha	1000									
87	PL	Zucchini *Cucurbita pepo var. giromontiina* CUUPG	G	*Delia florilega* HYLEFG	Spray, medium sprayer	BBCH 15-89	a) 1 b) 2	7	a) 0.14-0.25 L/ha b) 0.28-0.50 L/ha	a) 28-50 g as/ha b) 56-100 g as/ha	200-1000	1								
88	PL	Gherkins *Cucumis sativus* CUMSA	G	*Delia florilega* HYLEFG	Spray, medium sprayer	BBCH 15-89	a) 1 b) 2	7	a) 0.14-0.25 L/ha b) 0.28-0.50 L/ha	a) 28-50 g as/ha b) 56-100 g as/ha	200-1000	1								
89	PL	Curgettes *Cucurbita pepo* CUUPE	G	*Delia florilega* HYLEFG	Spray, medium sprayer	BBCH 15-89	a) 1 b) 2	7	a) 0.14-0.25 L/ha b) 0.28-0.50 L/ha	a) 28-50 g as/ha b) 56-100 g as/ha	200-1000	1								
90	PL	Spaghetti squash *Cucurbita pepo* subsp. *pepo* CUUPE	G	*Delia florilega* HYLEFG	Spray, medium sprayer	BBCH 15-89	a) 1 b) 2	7	a) 0.14-0.25 L/ha b) 0.28-0.50 L/ha	a) 28-50 g as/ha b) 56-100 g as/ha	200-1000	1								
91	PL	Giant pumpkin *Cucurbita maxima* CUUMA	G	*Delia florilega* HYLEFG	Spray, medium sprayer	~~BBCH 15-89~~ ~~BBCH 20–89~~	a) 1 b) 2	7	a) 0.14-0.25 L/ha b) 0.28-0.50 L/ha	a) 28-50 g as/ha b) 56-100 g as/ha	200-1000	1								
92	PL	Canada crookneck *Cucurbita moschata* CUUMO	G	*Delia florilega* HYLEFG	Spray, medium sprayer	BBCH 15-89	a) 1 b) 2	7	a) 0.14-0.25 L/ha b) 0.28-0.50 L/ha	a) 28-50 g as/ha b) 56-100 g as/ha	200-1000	1								
93	PL	Pumpkin *Cucurbita pepo* CUUPE	G	*Delia florilega* HYLEFG	Spray, medium sprayer	BBCH 15-89	a) 1 b) 2	7	a) 0.14-0.25 L/ha b) 0.28-0.50 L/ha	a) 28-50 g as/ha b) 56-100 g as/ha	200-1000	1								
94	PL	Cucumber *Cucumis sativus* CUMSA	G	*Delia florilega* HYLEFG	Spray, medium sprayer	BBCH 15-89	a) 1 b) 2	7	a) 0.14-0.25 L/ha b) 0.28-0.50 L/ha	a) 28-50 g as/ha b) 56-100 g as/ha	200-1000	1								
95	PL	Bush squash *Cucurbita melopepo* CUUPM	G	*Delia florilega* HYLEFG	Spray, medium sprayer	BBCH 15-89	a) 1 b) 2	7	a) 0.14-0.25 L/ha b) 0.28-0.50 L/ha	a) 28-50 g as/ha b) 56-100 g as/ha	200-1000	1								
96	PL	Watercresses *Nasturtium officinale* NAAOF	G	*Delia florilega* HYLEFG	Spray, medium sprayer	~~BBCH 15-89~~ ~~BBCH 20–89~~	a) 1 ~~b) 2~~	7	a) 0.155-0.210 L/ha ~~b) 0.310-0.420 L/ha~~	a) 31-42 g as/ha ~~b) 62-84 g as/ha~~	500-~~1000~~	1								

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l

(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

1 Numeration necessary to allow references 2 Use official codes/nomenclatures of EU Member States 3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure) 4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application 5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named. 6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.		7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application 8 The maximum number of application possible under practical conditions of use must be provided. 9 Minimum interval (in days) between applications of the same product 10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products. 11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha). 12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”. 13 PHI - minimum pre-harvest interval 14 Remarks may include: Extent of use/economic importance/restrictions	

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

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

Explanation for column 15 – 21 “Conclusion”

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

Remarks table:

(1) Numeration necessary to allow references
(2) Use official codes/nomenclatures of EU
(3) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(4) F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
(5) Scientific names and EPPO-Codes of target pests/diseases/ weeds or when relevant the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named
(6) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(7) Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(8) The maximum number of application possible under practical conditions of use must be provided
(9) Minimum interval (in days) between applications of the same product.
(10) For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products
(11) The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
(12) If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
(13) PHI - minimum pre-harvest interval
(14) Remarks may include: Extent of use/economic importance/restrictions

9.1.1 Overall conclusions

9.1.1.1 Effects on birds (KCP 10.1.1), Effects on terrestrial vertebrates other than birds (KCP 10.1.2), The acute, short term and long term risk on birds from the proposed uses of chlorantraniliprole was found acceptable. CLOROL 200 SC do not pose unacceptable risk to birds with according to Gap Table for all crops without any changes and Tobbaco with reduction dose ~~to two application of 110 g as/ha.~~ to one application of 54 g as/ha.

Comments of zRMS:

The risk assessment to mammals was performed in accordance with the recommendation of Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA (EFSA Journal 2009; 7(12):1438).
The results of the 'screening phase' acute dietary risk assessment and Tier-1 long term dietary risk assessment - Toxicity Exposure Ratios (TERA and TERLT) were calculated taking into account the EU agreed and accepted in core assessment endpoints for most sensitive species for the active substance and using the EFSA Bird and Mammal risk assessment calculator exceeding the trigger set by Commission regulation (EU) 546/2011 for acceptability of effects. Revealed that there is no potential of risk for mammals resulting from acute and long-term exposure to active substance following use of CLOROL 200 SC in compliance with modified GAP.
A quantitative drinking water risk assessment is not triggered for the proposed use pattern of CLOROL 200 SC according to EFSA/2009/1438 criteria and therefore the risk to mammals via drinking water is acceptable.
No unacceptable effects to fish-eating and earthworm-eating mammals are expected following application of CLOROL 200 SC according to the proposed use pattern.

No risk mitigation measures are required.

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

CLOROL 200 SC pose no unacceptable risk to birds and mammals used according to the label.

9.1.1.3 Effects on aquatic organisms (KCP 10.2)

CLOROL 200 SC pose no unacceptable risk to ~~bees~~ aquatic organisms according to the label with applying appropriate buffer zone.

~~1) on field and no fully-closed glass house:~~

~~A) Poland:~~
~~- 5 meters buffer zone - potatoes, sugar beet, vegetables root,soyabean, maize, sunflower, grass, spring oilseed rape, ornamentals <50 cm,~~
~~- 10 meters zone - fruting vegetables with redcution dose to one application of 50 g as/ha,~~

~~- 20 meters buffer zone – vegetable leafy with reduction fose to one application of 42 g as/ha or 2 appliac-tion of dose 25 g as/ha;~~
~~- 25 meters buffer zone for vines~~
~~- 40 meters buffer zone for apple~~

~~b) Central Zone:~~
~~- 5 meters buffer zone – potatoes, sugar beet, soyabean, maize, sunflower, grass~~
~~- 10 meters buffer zone – fruting vegetables with recution dose to one applicationof 50 g as/ha; root vege-tables; ornamentals <50cm, winter oilseed rape~~
~~- 20 meters buffer zone – vegetable leafy with reduction fose to one application of 42 g as/ha or 2 appliac-tion of dose 25 g as/ha;~~
~~- 25 meters buffer zone for vines~~
~~- 40 meters buffer zone for apple~~

~~Tobbaco pose unaaceptable risk to aquatic organisms.~~

~~2) fully closed greenhouse (only 1% of dose is taking into account for environmental exposure):~~

~~A) Poland:~~
~~- without buffer zone – leafy vegetable, fruiting vegetables~~

~~b) Central Zone:~~
~~- without buffer zone – vegetables leafy, fruiting vegetables~~

zRMS comment:

Acceptability of refinements for invertebrates, sediment dwelling organisms, proposed by Applicant, and risk mitigation measures should be considered on the MSs level.

For Poland the risk assessment was based on the refined HC5 for invertebrates and refined endpoint for sediment-dwelling organisms considering exposure via sediment. A detailed analysis of risk mitigation measures for individual crops is presented in Part A for Poland.

1 Pome/stone fruits
For BBCH 87 risk is not accepted based for D4 pond and D4 stream scenarios
For pome/stone fruits the risk is acceptable at 2 x 35 g a.s./ha, BBCH 56 - 70 when 40 m buffer zone containing 20 meters vegetative buffer zone is applied.
2. Potatoes
For potatoes the risk is acceptable at BBCH 31-60 when 5 meters buffer zone is applied.
3. Fruiting vegetables
For fruiting vegetables the risk is acceptable at BBCH 15 when 10 m VFS + 10 m buffer zone is applied. However, taking into account the risk to soil macroorrganism the BBCH was changed from 15-89 to 20-89.
For BBCH 20, PEC/RAC calculations were not performed.
For BBCH 89 the risk is unresolved due to D4 pond scenario (with 10 m vegetative strip and 10 meters buffer zone).
For fruiting vegetables the risk is not acceptable.
4. Sugar beet
For Sugar beet the risk is acceptable at BBCH 31-49 with 5 meters buffer zone.
5. Roots vegetable

For Roots vegetable the risk is acceptable at BBCH 12-49 with 5 meters buffer zone.

6. Vegetable leafy

For vegetable leafy the risk is acceptable at 1 x 42 g as/ha, BBCH 49, when 20 m vegetative filter strip and 20 meters buffer zone is applied,

7. Soyaben

For soyabean the risk is acceptable at BBCH 61-65 with 5 meters buffer zone.

8. Maize

For maize the risk is acceptable at BBCH 53-69 with 5 meters buffer zone.

9. Sunflower

For sunflower the risk is acceptable at BBCH 61-65 with 5 meters buffer zone.

10. Tobacco

The use in tobacco was not accepted in Part B8.

11. Grass

For grass the risk is acceptable at BBCH 53-69 when 5 meters buffer zone is applied.

12. Spring oilseed rape

For spring oilseed rape the risk is acceptable at BBCH 61-71 when 5 meters buffer zone is applied.

13. Winter oilseed rape

For winter oilseed rape the risk is acceptable at BBCH 30-50 and BBCH 61-71 when 10 m vegetative filter strip and 10 m buffer zone is applied.

14. Vine

For vine the risk is acceptable at BBCH 57-83 when 40 m buffer zone containing 20 m vegetative filter strip is applied.

15. Ornamentals

For ornamentals the risk is acceptable at BBCH 11-69 when 6 m buffer zone is applied.

The uses in Pumpkin, Cucumber, Pepper, Tomato, Melon, Aubergine, Okra/Lady's fingers, Watermelon, Zucchini, Gherkins, Curgettes, Spaghetti squash, Giant pumpkin, Canada crook-neck, Cucumber, Bush squash were not accepted.

9.1.1.4 Effects on bees (KCP 10.3.1)

CLOROL 200 SC pose no unacceptable risk to bees according to the label.

zRMS comment:

An acceptable risk to bees of the formulation CLOROL 200 SC can be concluded, based on the risk assessment scheme of the Guidance Document on Terrestrial Eco-toxicology (SANCO/10329/2002 rev 2).

The final decision on this issue and its impact on the registration process will be made by the Concerned Member State (cMS) during national product authorization. The cMS will consider the EFSA (2013) recommendations at a national level, as the current zonal risk assessment is only indicative until the guidance is formally adopted at the EU level.

Acceptability of refinements proposed by Applicant, and risk mitigation measures should be considered on the MSs level.

9.1.1.5 **On the basis of the available extensive data set generated for honeybees (acute oral and contact laboratory studies and 10 semi-field tunnel tests with Phacelia and wheat) exposed to chlorantraniliprole and the formulated products Coragen 200 SC, it can be concluded that the insecticide chlorantraniliprole generally demonstrated low intrinsic toxicity for honey bees and should be safe to honey bees for the proposed practical use conditions. Therefore, CLOROL 200 SC pose no unacceptable risk to bees at maximum dose for melliferous crops – 2 application of 63 grams chlorantraniliprole/ha which also covering flowering weeds scenario for unmelliforous crops Tobbaco (it can be assume that 55 grams per application drop on growing weeds under tobacco (worst dose for all crops weed scenario).**

zRMS Comments:

The submitted risk assessment is based on the recommendations of the Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 rev 2) and new EU guidance (2013).

The EU agreed endpoints for active substance were used in risk assessment.

In addition to that, the Applicant submitted studies on chronic toxicity of formulation CLOROL 200 SC to adult bees and larvae. New studies were accepted. Therefore, the requirements set out in Regulation 284/2013 are fulfilled.

The acute risk assessment performed in accordance with the SANCO guidance presented by the Applicant was accepted.

There is currently no EU agreed chronic risk assessment scheme for bees. However, as agreed in the Central Zone a risk assessment based on the EFSA bee GD is presented below for illustrative purposes.

Chronic risk assessment to bees:

All steps for the chronic risk assessment, i.e. the screening step, 1st and 2nd oral tier calculations were performed using the corresponding EFSA Bee calculator Tool (Bee-Tool v.3) provided by EFSA.

The acute and chronic risks to adult honey bees and honey bee larvae bees from the use of CLOROL 200 SC were assessed using the maximum single application rates and the respective 'hazard quotients' (HQs) and 'exposure toxicity ratios' (ETRs).

Considering the proposed uses of at a maximum application rate a potential risk of formulation is indicated following the chronic exposure of adults and for honey bee larvae at this stage of testing. Therefore, 1st tier oral risk assessments were carried out by applicant.

The ETR values are less than the Tier 1 trigger values for downward sprays indicating that the chronic risk to honeybee bees is acceptable following use of CLOROL 200 SC according to the proposed uses.

For all intended uses, the Tier 1 assessment shows a ETR above the trigger, indicating a potential risk for the bee brood development. Therefore, further refinements are necessary.

Higher-tier studies, compliant with EPPO 170 and OECD 75 guidelines, were conducted with the comparable EU representative formulation and evaluated during the EU peer review (*DAR (2008)*).

In most of the tunnel tests, which all cover the maximum application rate of 54 g a.s./ha (tobacco), no

adverse effects on adult honeybees and honeybee larvae were observed. *All the studies concluded to the absence of effects of Chlorantraniliprole on either the survival and behaviour of foragers or the colony condition (brood development), up to 28 days after application.*

The OECD 75 brood feeding study conducted at 2 x 60 or 1 x 120 Chlorantraniliprole 200 g /ha during full flowering of Phacelia tanacetifolia found no unacceptable effects on the condition of colonies and brood development relative to the water treated control. Therefore, the application of CLOROL 200 SC, according to the GAP, should not pose any problem to bee brood development.
In some studies at application rates of 60 g a.s./ha a slight increase in mortality and decrease in flight intensity was observed at the first days of exposure.
The review concluded that, based on available data, the risk to honeybees is acceptable. However, the suitability of semi-field studies for assessing chronic risk to honeybee larvae remains under discussion due to methodological limitations in their design.

When the new guidance EFSA Journal 2023;21(5):7989 will be applied, the semi-field studies will no longer be considered relevant to refine chronic Tier 1 assessment. This was already questioned in EFSA Journal 2013;11(7):3295. This topic was also discussed in the Ecotox harmonization meeting in 2023, but no final agreement was reached. It was decided to continue to use these studies case by case.

The final decision on this issue and its impact on the registration process will be made by the Concerned Member State (cMS) during national product authorization. The cMS will consider the EFSA (2013) recommendations at a national level, as the current zonal risk assessment is only indicative until the guidance is formally adopted at the EU level.

An acceptable risk to bees of the formulation CLOROL 200 SC can be concluded, based on the risk assessment scheme of the Guidance Document on Terrestrial Eco-toxicology (SANCO/10329/2002 rev 2).

Hence, MSs should consider appropriate risk mitigation measures to address the identified risk.

9.1.1.6 Effects on arthropods other than bees (KCP 10.3.2)

~~CLOROL 200 SC pose no unacceptable risk to NTA according to the label~~

For the intended uses of CLOROL 200 SC outlined in the modified GAP, the risk to in-field and off-field non-target arthropod populations is acceptable according to the label with applying appropriate buffer zone with the exception of the uses in tomatoes (2 x 64 g as/ha) and tobacco (2 x 110 g as/ha) where the risk is unacceptable.

zRMS comment:

Acceptability of refinements proposed by Applicant, and risk mitigation measures should be considered on the MSs level.

~~9.1.1.7~~ CLOROL 200 SC pose no unacceptable risk to nontarget arthropods than ~~bees if maximum application is lower or equival to 2 application of 0.3 L/ha (60 g as/ha) in -field scenario.~~

~~For protection non-target arthropods than bees in off-field scenario, buffer zones presented below has to be take into account:~~

~~Field crops and vegetables h <50cm:~~
- ~~5 meters buffer zone or~~
- ~~1 meters and 50% nozzle reduction~~

~~Vines and ornamentals and vegetables h > 50 cm:~~

~~a) Late application:~~
- ~~10 meters buffer zone~~
- ~~5 meters buffer zone and 75 nozzle reduction~~
- ~~1 meter buffer zone and 90% nozzle reduction~~

~~b) Early application:~~
- ~~5 meter buffer zone~~
- ~~1 meters and 75% nozzle reduction~~

~~Fruit crops:~~

~~c) Late application:~~
- ~~10 meters buffer zone~~
- ~~5 meters buffer zone and 50% nozzle reduction~~
- ~~1 meter buffer zone and 75% nozzle reduction~~

~~d) Early application:~~
- ~~20 meter buffer zone~~
- ~~15 meters buffer zone and 50% nozzle reduction~~
- ~~10 meters buffer zone and 75% nozzle reduction~~
- ~~1 meters and 90% nozzle reduction~~

zRMS Comments:
The submitted risk assessment based on the "Guidance Document on Terrestrial Ecotoxicology" (2002) was accepted.

For the intended uses of CLOROL 200 SC outlined in the modified GAP, the risk to in-field and off-field non-target arthropod populations is acceptable with the exception of the use in tomatoes. No further refinement is proposed because this use has not been demonstrated to be safe for aquatic organisms.

To demonstrate acceptable risks for the intended uses in orchards, the following risk management measures should be applied:
- 50% drift reduction, or
- 5m buffer zone.

Conclusion
The risk to arthropods other than bees is acceptable if CLOROL 200 SC is applied in accordance with the proposed use pattern, taking into account the recommended risk management measures, with the exception of proposed use in tomatoes.

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

CLOROL 200 SC pose no unacceptable risk to non-target soil meso- and macrofauna and microbial activity according to the label for:

- All field crops, field vegetables, orchards, vegetable leafy and fruiting vegetables in closed greenhouse
- Tobbaco after changing start BBCH from 20 – to 30-
- Cabbage in greenhouse (different than fully closed) after changing start BBCH from 12- to 20-
- Tomato in greenhouse (different than fully closed) after changing start BBCH from 15- to 20-

zRMS comment:

For pome/stone fruit the use in every 2nd year is required.

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

CLOROL 200 SC pose no unacceptable risk to non-target terrestrial plants according to label.

9.1.1.10 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).

Table 9.1-2: Critical use pattern of CLOROL 200 SC grouped according to organisms

Grouping according to organisms			
Group	**Intended uses number**	**relevant use parameters for grouping**	**relevant parameter or value for sorting**
Birds and mammals	~~1, 11-12~~ 1;8,9	Potatoes	
	~~59-60~~ 56-57	Vine	
	~~7-9,83-95~~ 33, 65-67, 83-95	Fruiting vegetable	
	~~2, 25-27~~ 2, 22-25; 58	Maize	
	~~38-44; 68 - 82; 96~~ 35-41,68-82, 96	Leafy vegetable	
	~~62~~ 59	Grassland	
	~~3-4; 29-33; 36-37~~	Oilseeds	

Grouping according to organisms			
Group	**Intended uses number**	**relevant use parameters for grouping**	**relevant parameter or value for sorting**
	3-4; 26-30;34		
	~~5-6; 45-58; 63-64;66-67~~ 5-6, 42-55; 60-64	Orchards	
	~~35~~ 32	Pulses	
	~~61;65~~ 58, 60-62	Ornamentals	
	~~10~~ 7	Sugarbeet	
	~~34~~ 31	Sunflower	
	~~13-24~~ 10-21	Roots and steam vegetables	
Aquatic species	For more details please see Section B8 > Prediction Enviroment Concentration in Surface Water.		
Bees	All intended uses are coverd by worst case scenario – 2x 110 g as/ha		
NTA	All intended uses are coverd by worst case scenario – 2x 110 g as/ha and calculated with different drift reduction.		
Soils organisms	All intended uses are coverd by worst case scenario – 2x 110 g as/ha. More details please see Section B8.		
NTP	All intended uses are coverd by worst case scenario – 2x 110 g as/ha and calculated with different drift reduction.		

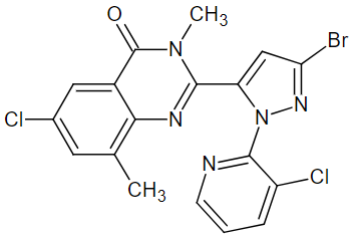
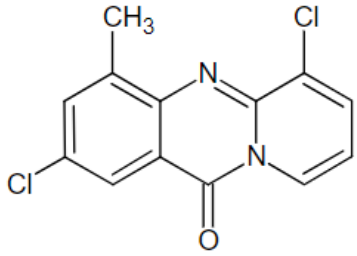
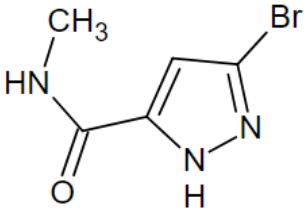
Grouping according to organisms			
Group	**Intended uses number**	**relevant use parameters for grouping**	**relevant parameter or value for sorting**
Birds and mammals	1, 11-12	Potatoes	
	59-60	Vine	
	7-9,83-95	Fruiting vegetable	
	2, 25-27	Maize	
	38-44; 68 – 82; 96	Leafy vegetable	
	62	Grassland	
	3-4; 29-33; 36-37	Oilseeds	
	5-6; 45-58; 63-64;66-67	Orchards	
	35	Pulses	
	61;65	Ornamentals	
	10	Sugarbeet	
	34	Sunflower	
	13-24	Roots and steam vegetables	
Aquatic species	For more details please see Section B8 > Prediction Enviroment Concentration in Surface Water.		

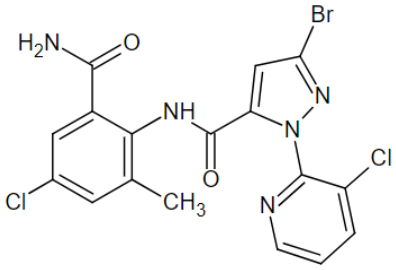
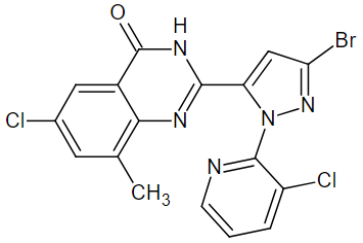
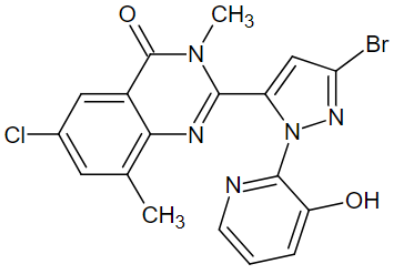
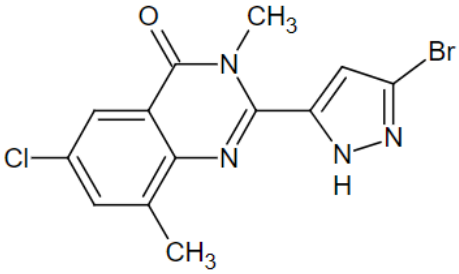
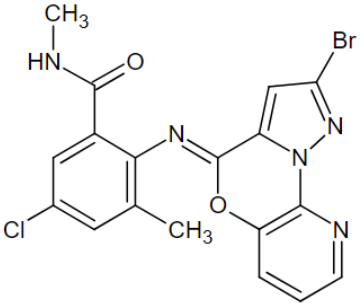
Grouping according to organisms			
Group	**Intended uses number**	**relevant use parameters for grouping**	**relevant parameter or value for sorting**
Bees	All intended uses are coverd by worst case scenario – 2x 110 g as/ha		
NTA	All intended uses are coverd by worst case scenario – 2x 110 g as/ha and calculated with different drift reduction.		
Soils organisms	All intended uses are coverd by worst case scenario – 2x 110 g as/ha. More details please see Section B8.		
NTP	All intended uses are coverd by worst case scenario – 2x 110 g as/ha and calculated with different drift reduction.		

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 CLOROL 200 SC is indicated in the table.

Table 9.1-3 Metabolites of Chlorantraniliprole

Metabolite	Molar mass	Chemical structure	Maximum occurrence in compartments	Risk assessment required?
IN-EQW78	465.14 g/mol		Maximum occurrence observed (% of applied):Water/sediment: 41.0 (irradiated system, worst case)Soil: 31.7 (field)	Aquatic species, soils organisms
IN-ECD73	279.13 g/mol		Maximum occurrence observed (% of applied):Water/sediment: 4.7Soil: 11.3 (field)	Aquatic species, soils organisms
IN-F6L99	204.03 g/mol		Maximum occurrence observed (% of applied):Water/sediment: 4.2Soil: 2.2 (lab 25□C)	Aquatic species, soils organisms

Metabolite	Molar mass	Chemical structure	Maximum occurrence in compartments	Risk assessment required?
IN-F9N04	469.12 g/mol		Maximum occurrence observed (% of applied):Water/sediment: 2.7Soil: 4.8 (lab 25□C)	Aquatic species, soils organisms
IN-GAZ70	451.11 g/mol		Maximum occurrence observed (% of applied):Water/sediment: 3.1Soil: 4.4 (lab 25□C	Aquatic species, soils organisms
IN-LBA23	446.69 g/mol		Maximum occurrence observed (% of applied):Water/sediment: 51.4 (aq. photolysis Study)Soil: not present	Aquatic species
IN-LBA24	353.61 g/mol		Maximum occurrence observed (% of applied):Water/sediment: 94.4 (aq. photolysis study)Soil: not present	Aquatic species
IN-LBA22	446.69 g/mol		Maximum occurrence observed (% of applied):Water/sediment: 52.8 (aq. photolysis Study)Soil: not present	Aquatic species

9.2 Effects on birds (KCP 10.1.1)

9.2.1 Toxicity data

Avian toxicity studies have been carried out with chlorantraniliprole and its relevant metabolites. Full

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

Comments of zRMS:

Effects on birds of CLOROL 200 SC were not evaluated as part of the EU assessment of chlorantraniliprole. Further data on the CLOROL 200 SC is not considered essential, because data on toxicity of chlorantraniliprole to birds are used in this assessment. An acute oral toxicity study with a similar formulation, Chlorantraniliprole 200 g/L SC was previously reviewed and accepted. Therefore, additional formulation data are not required.

zRMS agrees with the EU agreed endpoints.

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

Species	Substance	Exposure System	Results	Reference
Northern bobwhite quail	Chlorantraniliprole	Acute	LD_{50} > 2250 mg/kg bw	EFSA Journal 2013;11(6):3143
Northern bobwhite quail	IN-EQW78	Acute	LD_{50} > 2250 mg/kg bw/d	EFSA Journal 2013;11(6):3143
Northern bobwhite quail	Chlorantraniliprole	Short-term	LDD50 > 1729 mg/kg bw/d	EFSA Journal 2013;11(6):3143
Northern bobwhite quail	Chlorantraniliprole	Long term	NOEL = 10.1 mg/kg bw/d	EFSA Journal 2013;11(6):3143

9.2.1.1 Justification for new endpoints

No new endpoints were presented by applicant

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. Calculations for IN-EQW78 metabolite are covered by calculation for chlorantraniliprole, because IN-EQW78 shows similar toxicity and occurs mostly in soil, water, sediment and unlikely to be in plant and animal matrices.

Comments of zRMS:

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for potatoes (2 × 12.5 g a.s./ha at BBCH 31-60), grapes (1 × 54 g a.s./ha at BBCH 57-83), fruiting vegetables (2 × 63 g a.s./ha at BBCH 20-89, 7 days application interval), maize (1 × 25 g a.s./ha at BBCH 53-69), leafy vegetables (2 × 42 g a.s./ha at BBCH 12-49, 14 days application interval), grassland (1 × 35 g a.s./ha at BBCH 53-69), oilseeds (2 × 35 g a.s./ha at BBCH 30-71, 14 days application interval), orchards (2 × 35 g a.s./ha at BBCH 56-87, 14 days application interval), pulses (1 × 35 g a.s./ha at BBCH 61-65), ornamentals (1 × 35 g a.s./ha at BBCH 11-69), sugarbeet (1 × 20 g a.s./ha at BBCH 31-49, for tobacco 1 x 110 g a.s./ha at BBCH 30-85), sunflower (1 × 35 g a.s./ha at BBCH 61-65) and root and tuber vegetables (1 × 35 g a.s./ha at BBCH 12-65) also covers the risk for birds from all other intended uses.

Table 9.2-2: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of CLOROL 200 SC in potatoes

Intended use					
Active substance/product	Chlorantraniliprole				
Application rate (g/ha)	2 × 12.5				
Acute toxicity (mg/kg bw)	≥ 2250				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening step	Small omnivorous bird	158.8	1.3	2.58	≥871.9
Reprod. toxicity (mg/kg bw/d)	10.1				
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 step	Small omnivorous bird	64.8	0.795	0.64	15.7

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 CLOROL 200 SC in vine

Intended use					
Active substance/product	Chlorantraniliprole				
Application rate (g/ha)	1 × 54				
Acute toxicity (mg/kg bw)	≥ 2250				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening step	Small omnivorous bird	158.8	1	5.15	≥437.2
Reprod. toxicity (mg/kg bw/d)	10.1				
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 step	Small omnivorous bird	38.9	0.53	1.11	9.1

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

Table 9.2-4: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of CLOROL 200 SC in fruiting vegetables

Intended use					
Active substance/product	Chlorantraniliprole				
Application rate (g/ha)	2 × 63				
Acute toxicity (mg/kg bw)	>2250				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening step	Small omnivorous bird	158.8	1.4	14.01	> 160.6
Reprod. toxicity (mg/kg bw/d)	10.1				
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 step	Small omnivorous bird	64.8	0.848	3.46	2.9
Fruiting vegetables BBCH 10 - 19	Small insectivorous bird “wagtail” ground invertebrates without interception 50% ground arthropods, 50% foliar arthropods	11.3	-	-	16.7
Fruiting vegetables BBCH 10 - 49	Small granivorous bird “finch” Small seeds 100% weed seeds	11.4	-	-	16.6
Fruiting vegetables BBCH 10 - 49	Small omnivorous bird “lark” Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	10.9	-		17.3
Fruiting vegetables BBCH ≥ 20	Small insectivorous bird “wagtail” ground invertebrates with interception 50% ground arthropods, 50% foliar arthropods	9.7	-	-	19.5
Fruiting vegetables BBCH ≥ 50	Small granivorous bird “finch” Small seeds 100% weed seeds	3.4	-	-	55.6
Fruiting vegetables BBCH ≥ 50	Small omnivorous bird “lark” Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	3.3	-	-	57.3
Fruiting vegetables Fruit stage BBCH 71-89	Frugivorous bird "crow Gourds 100% fruit	32.0	-	-	5.9

Fruiting vegetables Fruit stage BBCH 71-89	Frugivorous bird "Starling" Tomato 100% fruit	20.7	-	-	9.1

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

Table 9.2-5: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of CLOROL 200 SC in maize

Intended use					
Active substance/product		**Chlorantraniliprole**			
Application rate (g/ha)		**2 x 110 g**			
Acute toxicity (mg/kg bw)		**2250**			
TER criterion		**10**			
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening step	Small omnivorous bird	158.8	1.4	24.46	92.0
Reprod. toxicity (mg/kg bw/d)	10.1				
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 step	Small omnivorous bird	64.8	0.848	6.04	1.7
Maize BBCH ≥ 20	Small insectivorous bird "wagtail" ground invertebrates with interception 50% ground arthropods, 50% foliar arthropods	4.8			22.6
Maize BBCH ≥ 40	Medium granivorous bird "gamebird" Small seeds 100% seed	0.8			135.3
Maize BBCH ≥ 40	medium herbivorous/granivorous bird "pigeon" Non-grass herbs 100% leaves	5.7			19.0
Maize BBCH ≥ 40	Small omnivorous bird "lark" Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	2.7			40.1
Maize BBCH 10 - 19	Small insectivorous bird "wagtail" ground invertebrates without interception 50% ground arthropods, 50% foliar arthropods	11.3			9.6
Maize BBCH 10 - 29	Medium granivorous bird "gamebird" Small seeds 100% seed	3.0			36.1
Maize BBCH 10 - 29	medium herbivorous/granivorous bird "pigeon" Non-grass herbs 100% leaves	22.7			4.8
Maize BBCH 10 - 29	Small omnivorous bird "lark" Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	10.9			9.9
Maize BBCH 30 - 39	Medium granivorous bird "game-	1.5			72.2

	bird" Small seeds 100% seed				
Maize BBCH 30 - 39	medium herbivorous/granivorous bird "pigeon" Non-grass herbs 100% leaves	11.4			9.5
Maize BBCH 30 - 39	Small omnivorous bird "lark" Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	5.4			20.1
Maize Leaf development BBCH 10 to 19	Small insectivorous/worm feeding species "thrush" ground invertebrates without interception 100% soil dwelling invertebrates	5.7			19.0

The risk exposure for medium herbivorous/granivorous bird "pigeon" Non-grass herbs 100% leaves is lower than trigger value for reproduction. Therefore, calculation for two application of dose 100g as/ha is presented:

Active substance/product	**Chlorantraniliprole**
Application rate (g/ha)	**2 x 100 g**
Acute toxicity (mg/kg bw)	**2250**
TER criterion	**10**

Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening step	Small omnivorous bird	158.8	1.4	22.23	101.2

Reprod. toxicity (mg/kg bw/d)	10.1
TER criterion	5

Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**$MAF_m \times TWA$**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Screening step	Small omnivorous bird	64.8	0.848	5.50	1.8
Maize BBCH ≥ 20	Small insectivorous bird "wagtail" ground invertebrates with interception 50% ground arthropods, 50% foliar arthropods	4.8			24.8
Maize BBCH ≥ 40	Medium granivorous bird "gamebird" Small seeds 100% seed	0.8			148.9
Maize BBCH ≥ 40	medium herbivorous/granivorous bird "pigeon" Non-grass herbs 100% leaves	5.7			20.9
Maize BBCH ≥ 40	Small omnivorous bird "lark" Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	2.7			44.1
Maize BBCH 10 - 19	Small insectivorous bird "wagtail" ground invertebrates without interception 50% ground arthropods, 50% foliar arthropods	11.3			10.5
Maize BBCH 10 - 29	Medium granivorous bird "gamebird" Small seeds 100% seed	3.0			39.7
Maize BBCH 10 - 29	medium herbivorous/granivorous bird "pigeon" Non-grass herbs 100% leaves	22.7			5.2

~~Maize BBCH 10 - 29~~	~~Small omnivorous bird "lark" Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods~~	~~10.9~~			~~10.9~~
~~Maize BBCH 30 - 39~~	~~Medium granivorous bird "gamebird" Small seeds 100% seed~~	~~1.5~~			~~79.4~~
~~Maize BBCH 30 - 39~~	~~medium herbivorous/granivorous bird "pigeon" Non-grass herbs 100% leaves~~	~~11.4~~			~~10.4~~
~~Maize BBCH 30 - 39~~	~~Small omnivorous bird "lark" Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods~~	~~5.4~~			~~22.1~~
~~Maize Leaf development BBCH 10 to 19~~	~~Small insectivorous/worm feeding species "thrush" ground invertebrates without interception 100% soil dwelling invertebrates~~	~~5.7~~			~~20.9~~

Intended use	
Active substance/product	Chlorantraniliprole
Application rate (g/ha)	1 × 25
Acute toxicity (mg/kg bw)	≥2250
TER criterion	10

Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening step	Small omnivorous bird	158.8	1	3.97	≥566.8

Reprod. toxicity (mg/kg bw/d)	10.1
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 step	Small omnivorous bird	64.8	0.53	0.86	11.8

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

Table 9.2-6: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of CLOROL 200 SC in leafy vegetable

Intended use	
Active substance/product	Chlorantraniliprole
Application rate (g/ha)	2 x 42
Acute toxicity (mg/kg bw)	≥2250
TER criterion	10

Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening step	Small omnivorous bird	158.8	1.2	8	≥281.1

Reprod. toxicity (mg/kg bw/d)	10.1
TER criterion	5

Crop scenario	**Indicator/generic focal species**	**SV_m**	**MAF_m ×**	**DDD_m**	**TER_{lt}**

Growth stage			**TWA**	**(mg/kg bw/d)**	
Screening step	Small omnivorous bird	64.8	0.795	2.02	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.

Table 9.2-7: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of CLOROL 200 SC in grassland

Intended use					
Active substance/product	Chlorantraniliprole				
Application rate (g/ha)	1 x 35				
Acute toxicity (mg/kg bw)	>2250				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening step	Large herbivorous vird	30.5	1	1.07	>2107.7
Reprod. toxicity (mg/kg bw/d)	10.1				
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 step	Large herbivorous bird	16.2	0.53	0.3	33.6

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 9.2-8: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of CLOROL 200 SC in oilseeds

Intended use					
Active substance/product	Chlorantraniliprole				
Application rate (g/ha)	2 x 35				
Acute toxicity (mg/kg bw)	>2250				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening step	Small omnivorous bird	158.8	1.2	6.67	>337.4
Reprod. toxicity (mg/kg bw/d)	10.1				
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 step	Small omnivorous bird	64.8	0.795	1.68	6

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 9.2-9: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of CLOROL 200 SC in orchards

Intended use					
Active substance/product	Chlorantraniliprole				
Application rate (g/ha)	2 x 35				
Acute toxicity (mg/kg bw)	≥2250				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening step	Small insectivorous bird	46.8	1.2	1.97	≥1144.7
Reprod. toxicity (mg/kg bw/d)	10.1				
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 step	Small insectivorous bird	18.2	0.795	0.47	21.4

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

Table 9.2-10: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of CLOROL 200 SC in ornamentals

Intended use					
Active substance/product	Chlorantraniliprole				
Application rate (g/ha)	1 x 35 ~~2 x 110~~				
Acute toxicity (mg/kg bw)	≥ 2250				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening step	Small insectivorous bird	46.8	1.40	~~7.21~~ 1.64	> 1373.6 ~~312.2~~
Reprod. toxicity (mg/kg bw/d)	10.1				
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 step	Small insectivorous bird	18.2	~~0.848~~ 0.53	~~1.7~~ 0.34	~~5.9~~ 29.9

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

Table 9.2-11: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of CLOROL 200 SC in pulses

Intended use	
Active substance/product	Chlorantraniliprole
Application rate (g/ha)	1 x 35

Acute toxicity (mg/kg bw)	≥ 2250				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening step	Small omnivorous bird	158.8	1	5.56	≥ 404.8
Reprod. toxicity (mg/kg bw/d)	10.1				
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 step	Small omnivorous bird	64.8	0.53	1.2	8.4

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

Table 9.2-12: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of CLOROL 200 SC in sugar beet

Intended use					
Active substance/product	Chlorantraniliprole				
Application rate (g/ha)	1 x 20				
Acute toxicity (mg/kg bw)	≥2250				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening step	Small omnivorous bird	158.8	1	3.18	≥708.4
Reprod. toxicity (mg/kg bw/d)	10.1				
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 step	Small omnivorous bird	64.8	0.53	0.69	14.7

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 9.2-13: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of CLOROL 200 SC in sugar beet (tobacco)

Intended use					
Active substance/product	Chlorantraniliprole				
Application rate (g/ha)	1 x 110				
Acute toxicity (mg/kg bw)	>2250				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening step	Small omnivorous bird	158.8	1	17.47	>128.8
Reprod. toxicity (mg/kg bw/d)	10.1				

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 step	Small omnivorous bird	64.8	0.53	3.78	**2.7**

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.

No refinement was proposed and evaluated because use in tobacco was unacceptable in par B8 (fate).

Intended use					
Active substance/product	Chlorantraniliprole				
Application rate (g/ha)	1 x 54				
Acute toxicity (mg/kg bw)	>2250				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening step	Small omnivorous bird	158.8	1	8.58	>262.4
Reprod. toxicity (mg/kg bw/d)	10.1				
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 step	Small omnivorous bird	64.8	0.53	1.85	5.4

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

Table 9.2-14: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of CLOROL 200 SC in sunflower

Intended use					
Active substance/product	Chlorantraniliprole				
Application rate (g/ha)	1 x 35				
Acute toxicity (mg/kg bw)	≥2250				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening step	Small omnivorous bird	158.8	1	5.56	≥404.8
Reprod. toxicity (mg/kg bw/d)	10.1				
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 step	Small omnivorous bird	64.8	0.53	1.2	8.4

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER:

toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-15: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of CLOROL 200 SC in roots and stem vegetables

Intended use					
Active substance/product	Chlorantraniliprole				
Application rate (g/ha)	1 x 35				
Acute toxicity (mg/kg bw)	≥2250				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening step	Small omnivorous bird	158.8	1	5.56	≥404.8
Reprod. toxicity (mg/kg bw/d)	10.1				
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 step	Small omnivorous bird	64.8	0.53	1.2	8.4

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

9.2.2.2 Higher-tier risk assessment

Not necessary

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 CLOROL 200 SC is 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 must be considered.
To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the worst case scenario for whole intended uses from GAP table – two application of 110 g as/ha solved in 200 L water/ha.

Table 9.2-16: Assessment of the acute risk for birds due to exposure to chlorantraniliprole via contaminated drinking water in leaf whorls

Intended use	
Active substance	chlorantraniliprole
Application rate (g/ha)	2 x 110
Acute toxicity (mg/kg bw)	≥ 2250

TER criterion		10				
(Single) applic. rate (g/ha)	**Water applic. rate (L/ha)**	**$C_{spray-sol.}$ (g/L)**	**$PEC_{leaf-whorl}$ = $C_{spray-sol.}$/5 (mg/L)**	**DW uptake (L/kg bw/d)**	**Daily dose (mg/kg bw/d)**	**TER_a**
110	200	0.55	110	0.46	50.6	≥ 44.47

$C_{spray-sol}$: concentration in spray solution; $PEC_{leaf-whorl}$: concentration in pools in leaf whorls; DW: drinking water; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Puddle scenario

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

With a K(f)oc of 301, chlorantraniliprole 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 worst case scenario for whole intended uses from GAP table – two application of 110 g as/ha

Effective application rate (g/ha)	=	220	(conservative approach)		
Acute toxicity (mg/kg bw)	=	> 2250	quotient	=	< 0.097
Reprod. toxicity (mg/kg bw/d)	=	10.1	quotient	=	21.78

9.2.2.4 Effects of secondary poisoning

The log P_{ow} of chlorantraniliprole does not exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is not required.

The log P_{ow} of IN-EQW78 does exceed the trigger value of 3 (log Pow = 3.9). A risk assessment for effects due to secondary poisoning is presented below.

The log P_{ow} of IN-ECD73 does exceed the trigger value of 3 (log Pow = 5.1). A risk assessment for effects due to secondary poisoning is presented below.

The log P_{ow} of IN-GAZ70 does exceed the trigger value of 3 (log Pow = 3.8). A risk assessment for effects due to secondary poisoning is presented below.

The water metabolites – IN-LBA22, IN-LBA23, IN-LBA24- were assessed only in fish-eating scenario.

Risk assessment for earthworm-eating birds ~~mammals~~ via secondary poisoning

~~According to EFSA/2009/1438, the risk for vermivorous mammals is assessed for a small mammal of 10 g body weight with a daily food consumption of 12.8 g. Bioaccumulation in earthworms is estimated based on measured/predicted concentrations in soil/porewater / is based on experimental data.~~
According to EFSA/2009/1438, the risk for vermivorous birds is assessed for a bird of 100 g body weight with a daily food consumption of 104.6 g. Bioaccumulation in earthworms is estimated based on predicted concentrations in soil.

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

Table 9.2-17: Assessment of the risk for earthworm-eating birds ~~mammals~~ due to exposure to IN-EQW78, IN-ECD73 and IN-GAZ70 via bioaccumulation in earthworms (secondary poisoning) for the intended use in all crop presented in GAP Table (calculation covered all uses)

Parameter	IN-EWQ78	IN-ECD73	IN-GAZ70	comments
PEC_{soil} (twa = 21 d) (mg/kg soil) PECsoil accumulation	~~0.0099~~ 0.3648	~~0.0021~~ 0.2665	~~0.0022~~ 0.3573	Worst case scenario for PECsoil before changing BBCH
log P_{ow} / P_{ow}	3.9/7943	5.1/125893	3.8/6310	
Koc	~~10787~~ 14851	~~29849~~ 44073	~~23581~~ 23165	Mean
foc	0.02	0.02	0.02	Default
BCF_{worm}	~~0.45~~ 0.33	~~2.53~~ 1.72	~~0.16~~ 0.17	$BCF_{worm/soil}$ = ($PEC_{worm,ww}$/$PEC_{soil,dw}$) = (0.84 + 0.012 × P_{ow}) / foc × Koc
PEC_{worm}	~~0.0045~~ 0.118	~~0.0053~~ 0.457	~~0.0004~~ 0.05904	PEC_{worm} = PEC_{soil} × $BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	~~0.0058~~ 0.15117	~~0.0068~~ 0.585	~~0.0005~~ 0.07558	DDD = PEC_{worm} × ~~1.28~~ 1.05
NOEL (mg/kg bw/d)	10.1	10.1	10.1	
TER_{lt}	~~1 741~~ 66.81	~~1 485~~ 17.27	~~20 200~~ 133.64	

TER values shown in bold fall below the relevant trigger.

Risk assessment for fish-eating ~~mammals~~ birds via secondary poisoning

~~According to EFSA/2009/1438, the risk for piscivorous mammals is assessed for a mammal of 3000 g body weight with a daily food consumption of 425 g.~~ According to EFSA/2009/1438, the risk for piscivorous birds is assessed for a bird of 1000 g body weight with a daily food consumption of 159 g. Bioaccumulation in fish is estimated based on predicted concentrations in surface water / is based on the regulatory acceptable concentration for aquatic organisms as a limit value for admissible concentrations of IN-EQW78, IN-ECD73 and IN-GAZ70 in water.

Table 9.2-18: Assessment of the risk for fish-eating ~~mammals~~ birds due to exposure to IN-EQW78, IN-ECD73 and IN-GAZ70 via bioaccumulation in fish (secondary poisoning) for the intended use in all crop presented in GAP Table (calculation below covered all uses)

Parameter	IN-EQW78	IN-ECD73	IN-GAZ70	IN-LBA22	IN-LBA 23	IN-LBA 24	comments
PEC_{sw} (twa = 21 d) (mg/L)	0.00338	0.00017	0.00016	0,00005	0,00003	0.01547	Worst case scenario - STEP 1 for Tobbaco.
BCF_{fish}	15	15	15	15	15	15	Extrapolated from parent
BMF	-	-	-	-	-	-	biomagnification

							factor (relevant for BCF ≥ 2000)
PEC_{fish}	0.0507	0.00255	0.0024	0.00075	0.00045	0.23	$PEC_{fish} = PEC_{water} \times BCF_{fish}$
Daily dietary dose (mg/kg bw/d)	0.0072	0.00036	0.00034	0.0001	0.00006	0.033	DDD = PEC_{fish} × ~~0.142~~ 0.159
NOEL (mg/kg bw/d)	10.1	10.1	10.1	10.1	10.1	10.1	
TER_{lt}	1402	28 056	29 706	101 000	1683 33	306	

9.2.2.5 Biomagnification in terrestrial food chains

Not relevant.

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

Not relevant.

9.2.4 Overall conclusions

The acute, short term and long term risk on birds from the proposed uses of chlorantraniliprole was found acceptable. CLOROL 200 SC do not pose unacceptable risk to birds with according to Gap Table for all crops without any changes and Tobbaco with reduction dose ~~to two application of 110 g as/ha.~~ to one application of 54 g as/ha.

Comments of zRMS:

The risk assessment to birds was performed in accordance with the recommendation of Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA (EFSA Journal 2009; 7(12):1438).
The results of the 'screening phase' acute dietary risk assessment and Tier-1 long term dietary risk assessment - Toxicity Exposure Ratios (TER_A and TER_{LT}) were calculated taking into account the EU agreed and accepted in core assessment endpoints for most sensitive species for the active substance and using the EFSA Bird and Mammal risk assessment calculator exceeding the trigger set by Commission regulation (EU) 546/2011 for acceptability of effects. Revealed that there is no potential of risk for birds resulting from acute and long-term exposure to active substance following use of CLOROL 200 SC in compliance with modified GAP.
A quantitative drinking water risk assessment is not triggered for the proposed use pattern of CLOROL 200 SC according to EFSA/2009/1438 criteria and therefore the risk to birds via drinking water is acceptable.
No unacceptable effects to fish-eating and earthworm-eating birds are expected following application of CLOROL 200 SC according to the proposed use pattern.

No risk mitigation measures are 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 chlorantraniliprole. Full details of these studies are provided in the respective EU DAR and related documents.

Comments of zRMS:

Effects on mammals of CLOROL 200 SC were not evaluated as part of the EU assessment of chlorantraniliprole. Further data on the CLOROL 200 SC is not considered essential, because data on toxicity of chlorantraniliprole to mammals are used in this assessment. An acute oral toxicity study with a similar formulation, Chlorantraniliprole 200 g/L SC was previously reviewed and accepted. Therefore, additional formulation data are not required.

zRMS agrees with the EU agreed endpoints.

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

Species	Substance	Exposure System	Results	Reference
Rat	chlorantraniliprole	Acute	LD_{50} > 5000 mg/kg bw	EFSA Journal 2013;11(6):3143
Rat	IN-EQW78	Acute	LD_{50} > 2000 mg/kg bw	EFSA Journal 2013;11(6):3143
Mouse	IN-ECD73	Acute	LD_{50} > 2000 mg/kg bw	EFSA Journal 2013;11(6):3143
Mouse	IN-F6L99	Acute	LD_{50} > 2000 mg/kg bw	EFSA Journal 2013;11(6):3143

Species	Substance	Exposure System	Results	Reference
Rat	IN-LBA24	Acute	LD_{50} > 2000 mg/kg bw	EFSA Journal 2013;11(6):3143
Rat	chlorantraniliprole	Long term	NOAEL = 1199 mg/kg bw/d	EFSA Journal 2013;11(6):3143
Rat	IN-EQW78 IN-ECD73 IN-F6L99 IN-LBA24	Long term	NOAEL = 119.9 mg/kg bw/d – extrapolated from parent with assessment factor 10 to present worst case scenario.	

9.3.1.1 Justification for new endpoints

No new endpoint were presented by applicant.

9.3.2 Risk assessment for spray applications

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

Comments of zRMS:
To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for potatoes (2 × 12.5 g a.s./ha at BBCH 31-60, 10 days application interval), grapes (1 × 54 g a.s./ha at BBCH 57-83), fruiting vegetables (2 × 63 g a.s./ha at BBCH 20-89, 7 days application interval), maize (1 × 25 g a.s./ha at BBCH 53-69), leafy vegetables (2 × 42 g a.s./ha at BBCH 12-49, 14 days application interval), grassland (1 × 35 g a.s./ha at BBCH 53-69), oilseeds (2 × 35 g a.s./ha at BBCH 30-71, 14 days application interval), orchards (2 × 35 g a.s./ha at BBCH 56-87, 14 days application interval), pulses (1 × 35 g a.s./ha at BBCH 61-65), ornamentals (1 × 35 g a.s./ha at BBCH 11-69), sugarbeet (1 × 20 g a.s./ha at BBCH 31-49, for tobacco 1 x 54 g a.s./ha at BBCH 30-85), sunflower (1 × 35 g a.s./ha at BBCH 61-65) and root and tuber vegetables (1 × 35 g a.s./ha at BBCH 12-65) also covers the risk for mammals from all other intended uses.

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

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

Table 9.3-2: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of CLOROL 200 SC in potaotes

Intended use	
Active substance/product	chlorantraniliprole
Application rate (g/ha)	2 x 12.5
Acute toxicity (mg/kg bw)	5000

TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening step	Small herbivorous mammal	118.4	1.3	1.92	2598.8
Reprod. toxicity (mg/kg bw/d)	1199				
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 step	Small herbivorous mammal	48.3	0.795	0.48	2498.01

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 CLOROL 200 SC in vine

Intended use					
Active substance/product	chlorantraniliprole				
Application rate (g/ha)	1 x 54				
Acute toxicity (mg/kg bw)	5000				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening step	Small herbivorous mammal	136.4	1	7.37	678.8
Reprod. toxicity (mg/kg bw/d)	1199				
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 step	Small herbivorous mammal	72.3	0.53	2.07	579.44

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 CLOROL 200 SC in fruiting vegetable

Intended use					
Active substance/product	chlorantraniliprole				
Application rate (g/ha)	2 x 63				
Acute toxicity (mg/kg bw)	5000				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening step	Small herbivorous mammal	136.4	1.4	12.03	415.6
Reprod. toxicity (mg/kg bw/d)	1199				
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 step	Small herbivorous mammal	72.3	0.848	3.86	310.42

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 9.3-5: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of CLOROL 200 SC in maize

~~Intended use~~					
~~Active substance/product~~	~~chlorantraniliprole~~				
~~Application rate (g/ha)~~	~~2 x 110 g~~				
~~Acute toxicity (mg/kg bw)~~	~~5000~~				
~~TER criterion~~	~~10~~				
~~Crop scenario Growth stage~~	~~Indicator/generic focal species~~	~~SV_{90}~~	~~MAF_{90}~~	~~DDD_{90} (mg/kg bw/d)~~	~~TER_a~~
~~Screening step~~	~~Small herbivorous mammal~~	~~136.4~~	~~1.4~~	~~21.01~~	~~238~~
~~Reprod. toxicity (mg/kg bw/d)~~	~~1199~~				
~~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 step~~	~~Small herbivorous mammal~~	~~72.3~~	~~0.848~~	~~6.74~~	~~177.78~~
Intended use					
Active substance/product	chlorantraniliprole				
Application rate (g/ha)	1 x 25				
Acute toxicity (mg/kg bw)	5000				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening step	Small herbivorous mammal	136.4	1	3.41	1466.3
Reprod. toxicity (mg/kg bw/d)	1199				
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 step	Small herbivorous mammal	72.3	0.53	0.96	1251.6

Table 9.3-6: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of CLOROL 200 SC in leafy vegetable)

Intended use	
Active substance/product	chlorantraniliprole
Application rate (g/ha)	2 x 42
Acute toxicity (mg/kg bw)	5000
TER criterion	10

Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening step	Small herbivorous mammal	136.4	1.2	6.87	727.3
Reprod. toxicity (mg/kg bw/d)	1199				
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 step	Small herbivorous mammal	72.3	0.742	2.25	532.14

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

Table 9.3-7: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of CLOROL 200 SC in grassland

Intended use					
Active substance/product	chlorantraniliprole				
Application rate (g/ha)	1 x 35				
Acute toxicity (mg/kg bw)	5000				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening step	Small herbivorous mammal	136.4	1	4.77	1047.3
Reprod. toxicity (mg/kg bw/d)	1199				
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 step	Small herbivorous mammal	72.3	0.53	1.34	894.0

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 9.3-8: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of CLOROL 200 SC in oilseed

Intended use					
Active substance/product	chlorantraniliprole				
Application rate (g/ha)	2 x 35				
Acute toxicity (mg/kg bw)	5000				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening step	Small herbivorous mammal	118.4	1.2	4.97	1005.5
Reprod. toxicity (mg/kg bw/d)	1199				
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 step	Small herbivorous mammal	48.3	0.748	1.25	955.87

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 9.3-9: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of CLOROL 200 SC in orchards

Intended use					
Active substance/product	chlorantraniliprole				
Application rate (g/ha)	2 x 35				
Acute toxicity (mg/kg bw)	5000				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening step	Small herbivorous mammal	136.4	1.2	5.73	872.8
Reprod. toxicity (mg/kg bw/d)	1199				
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 step	Small herbivorous mammal	72.3	0.748	1.88	638.57

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 9.3-10: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of CLOROL 200 SC in ornamentals

Intended use					
Active substance/product	chlorantraniliprole				
Application rate (g/ha)	1 x 35 ~~2 x 110~~				
Acute toxicity (mg/kg bw)	5000				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening step	Small herbivorous mammal	136.4	~~1.4~~ 1.0	~~21.01~~ 4.77	~~238~~ 1047.3
Reprod. toxicity (mg/kg bw/d)	1199				
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 step	Small herbivorous mammal	72.3	~~0.848~~ 0.53	~~6.74~~ 1.34	~~177.78~~ 894

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 9.3-11: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of CLOROL 200 SC in pulses

Intended use	

Active substance/product	chlorantraniliprole				
Application rate (g/ha)	1 x 35				
Acute toxicity (mg/kg bw)	5000				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening step	Small herbivorous mammal	136.4	1	4.77	1047.3
Reprod. toxicity (mg/kg bw/d)	1199				
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 step	Small herbivorous mammal	72.3	0.53	1.34	894

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 9.3-12: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of CLOROL 200 SC in sugar beet

Intended use					
Active substance/product	chlorantraniliprole				
Application rate (g/ha)	1 x 20				
Acute toxicity (mg/kg bw)	5000				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening step	Small herbivorous mammal	118.4	1	2.37	2111.5
Reprod. toxicity (mg/kg bw/d)	1199				
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 step	Small herbivorous mammal	48.3	0.53	0.51	2341.89

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 9.3-13: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of CLOROL 200 SC in sunflower

Intended use					
Active substance/product	chlorantraniliprole				
Application rate (g/ha)	1 x 35				
Acute toxicity (mg/kg bw)	5000				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening step	Small herbivorous mammal	118.4	1	4.14	1206.6

Reprod. toxicity (mg/kg bw/d)	1199				
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 step	Small herbivorous mammal	48.3	0.53	0.90	1338.22

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 9.3-14: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of CLOROL 200 SC in roots and stem vegetable

Intended use					
Active substance/product	chlorantraniliprole				
Application rate (g/ha)	1 x 35				
Acute toxicity (mg/kg bw)	5000				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening step	Small herbivorous mammal	118.4	1	4.14	1206.6
Reprod. toxicity (mg/kg bw/d)	1199				
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 step	Small herbivorous mammal	48.3	0.53	0.90	1338.22

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.

Calculations for IN-EQW78, IN-ECD73, IN-F6L99 and IN-LBA24 metabolites are covered by calculation performed below for worst case application rate – 2 x 110 g as/ha (worst case max. occurrence – 100% from parent), because they shows similar toxicity:

Table 9.3-15: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of CLOROL 200 SC ~~in ornamentals~~ in sugar beet (tobacco)

Intended use					
Active substance/product	chlorantraniliprole				
Application rate (g/ha)	~~2 x 110 (conservative approach)~~ 1 x 54				
Acute toxicity (mg/kg bw)	~~2000~~ 5000				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening step	Small herbivorous mammal	~~136.4~~ 118.4	~~1.4~~ 1.0	~~21.01~~ 6.39	~~95.2~~ 782
Reprod. toxicity (mg/kg bw/d)	119.9				
TER criterion	5				
Crop scenario	**Indicator/generic focal species**	**SV_m**	**MAF_m ×**	**DDD_m**	**TER_{lt}**

Growth stage			**TWA**	**(mg/kg bw/d)**	
Screening step	Small herbivorous mammal	~~72.3~~ 48.3	0.53	~~6.74~~ 1.38	~~17.78~~ 867.37

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

9.3.2.2 Higher-tier risk assessment

Not relevant.

9.3.2.3 Drinking water exposure

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

Puddle scenario

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

With a K(f)oc of 301, chlorantraniliprole 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 worst case scenario for whole intended uses from GAP table – two application of 110 g as/ha.

Effective application rate (g/ha) = 220
Acute toxicity (mg/kg bw) = 5000 quotient = 0.044
Reprod. toxicity (mg/kg bw/d) =1199 quotient = 0.18

PEC_{puddle}: concentration in puddles; DW: drinking water; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Additionally puddle scenario calculations for IN-EQW78, IN-ECD73, IN-F6L99 and IN-LBA24 metabolites are covered by calculation performed below for worst case application rate – 2 x 110 g as/ha (worst case max. occurrence – 100% from parent), because they shows similar toxicity:

Effective application rate (g/ha) = 220
Acute toxicity (mg/kg bw) = 2000 quotient = 0.1
Reprod. toxicity (mg/kg bw/d) =119.9 quotient = 1.83

PEC_{puddle}: concentration in puddles; DW: drinking water; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

9.3.2.4 Effects of secondary poisoning

The log P_{ow} of chlorantraniliprole does not exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is not required.

The log P_{ow} of IN-EQW78 does exceed the trigger value of 3 (log Pow = 3.9). A risk assessment for effects due to secondary poisoning is presented below.

The log P_{ow} of IN-ECD73 does exceed the trigger value of 3 (log Pow = 5.1). A risk assessment for effects due to secondary poisoning is presented below.

The log P_{ow} of IN-GAZ70 does exceed the trigger value of 3 (log Pow = 3.8). A risk assessment for effects due to secondary poisoning is presented below.

The water metabolites – IN-LBA22, IN-LBA23, IN-LBA24- were assessed only in fish-eating scenario.

Risk assessment for earthworm-eating mammals via secondary poisoning

According to EFSA/2009/1438, the risk for vermivorous mammals is assessed for a small mammal of 10 g body weight with a daily food consumption of 12.8 g. Bioaccumulation in earthworms is estimated based on measured/predicted concentrations in soil/porewater / is based on experimental data.
To achieve a concise risk assessment, the risk envelope approach is applied. (see 9.1.2).

Table 9.3-16: Assessment of the risk for earthworm-eating mammals due to exposure to IN-EQW78, IN-ECD73 and IN-GAZ70 via bioaccumulation in earthworms (secondary poisoning) for the intended use in all crop in presented GAP Table (calculation below covered all uses)

Parameter	IN-EQW78	IN-ECD73	IN-GAZ70	comments
~~PECsoil (twa = 21 d) (mg/kg soil)~~	~~0.0099~~	~~0.0021~~	~~0.0022~~	Worst case scenario for PECsoil before changing BBCH
~~PEC_{soil} (twa = 21 d) (mg/kg soil)~~ **PECsoil accumulation**	~~0.0099~~ **0.3648**	~~0.0021~~ **0.2665**	~~0.0022~~ **0.3573**	Worst case scenario for PECsoil before changing BBCH
log P_{ow} / P_{ow}	3.9/7943	5.1/125893	3.8/6310	
Koc	~~10787~~ 14851	~~29849~~ 44073	~~23581~~ 23165	Mean
foc	0.02	0.02	0.02	Default
BCF_{worm}	~~0.45~~ 0.33	~~2.53~~ 1.72	~~0.16~~ 0.17	$BCF_{worm/soil}$ = ($PEC_{worm,ww}/PEC_{soil,dw}$) = (0.84 + 0.012 × P_{ow}) / foc × Koc
PEC_{worm}	~~0.0045~~ 0.118	~~0.0053~~ 0.457	~~0.0004~~ 0.05904	PEC_{worm} = PEC_{soil} × $BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	~~0.0058~~ 0.151	~~0.0068~~ 0.585	~~0.0005~~ 0.0756	DDD = PEC_{worm} × 1.28
NOEL (mg/kg bw/d)	119.9	119.9	119.9	
TER_{lt}	~~20 672~~ 794	~~17 632~~ 205	~~239 800~~ 163	

TER values shown in bold fall below the relevant trigger.

Risk assessment for fish-eating mammals via secondary poisoning

According to EFSA/2009/1438, the risk for piscivorous mammals is assessed for a mammal of 3000 g body weight with a daily food consumption of 425 g. Bioaccumulation in fish is estimated based on predicted concentrations in surface water / is based on the regulatory acceptable concentration for aquatic organisms as a limit value for admissible concentrations of soil metabolites IN-EQW78, IN-ECD73 and IN-GAZ70 in water.

Table 9.3-17: Assessment of the risk for fish-eating mammals due to exposure to IN-EQW78, IN-ECD73 and IN-GAZ70 via bioaccumulation in fish (secondary poisoning) for the intended use in all crop in presented GAP Table (calculation below covered all uses)

Parameter	IN-EQW78	IN-ECD73	IN-GAZ70	IN-LBA22	IN-LBA 23	IN-LBA 24	comments
PEC_{sw} (twa = 21 d) (mg/L)	0.00338	0.00017	0.00016	0.00005	0,00003	0.01547	Worst case scenario - STEP 1 for Tobbaco.
BCF_{fish}	15	15	15	15	15	15	Extrapolated from parent
BMF	-	-	-	-	-	-	biomagnification factor (relevant for BCF ≥ 2000)
PEC_{fish}	0.0507	0.00255	0.0024	0.00075	0.00045	0.23	$PEC_{fish} = PEC_{water} \times BCF_{fish}$
Daily dietary dose (mg/kg bw/d)	0.0072	0.00036	0.00034	0.0001	0.00006	0.033	DDD = $PEC_{fish} \times 0.142$
NOEL (mg/kg bw/d)	119.9	119.9	119.9	119.9	119.9	119.9	
TER_{lt}	16 653	333 056	352 647	1 199 000	1 998 333	3 633	

9.3.2.5 Biomagnification in terrestrial food chains

Not relevant.

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

Not relevant.

9.3.4 Overall conclusions

The acute, short term and long term risk on birds from the proposed uses of chlorantraniliprole was found acceptable. CLOROL 200 SC do not pose unacceptable risk to birds with according to Gap Table for all crops without any changes and Tobbaco with reduction dose ~~to two application of 110 g as/ha.~~ to one

application of 54 g as/ha.

Comments of zRMS:

The risk assessment to mammals was performed in accordance with the recommendation of Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA (EFSA Journal 2009; 7(12):1438).
The results of the 'screening phase' acute dietary risk assessment and Tier-1 long term dietary risk assessment - Toxicity Exposure Ratios (TER_A and TER_{LT}) were calculated taking into account the EU agreed and accepted in core assessment endpoints for most sensitive species for the active substance and using the EFSA Bird and Mammal risk assessment calculator exceeding the trigger set by Commission regulation (EU) 546/2011 for acceptability of effects. Revealed that there is no potential of risk for mammals resulting from acute and long-term exposure to active substance following use of CLOROL 200 SC in compliance with modified GAP.
A quantitative drinking water risk assessment is not triggered for the proposed use pattern of CLOROL 200 SC according to EFSA/2009/1438 criteria and therefore the risk to mammals via drinking water is acceptable.
No unacceptable effects to fish-eating and earthworm-eating mammals are expected following application of CLOROL 200 SC according to the proposed use pattern.

No risk mitigation measures are required.

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

Not relevant.

9.5 Effects on aquatic organisms (KCP 10.2)

9.5.1 Toxicity data

Studies on the toxicity to aquatic organisms have been carried out with chlorantraniliprole and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on aquatic organisms of Coragen 200 SC were evaluated as part of the EU assessment of chlorantraniliprole.

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

Species	Substance	Exposure System	Results	Reference
Sheepshead minnow	chlorantranilipole	96 h, s	LC_{50} = 12 mg a.s./L $_{mm}$	EFSA Journal 2013;11(6):3143
Rainbow trout	chlorantranilipole	90 d early life stage (flow-through)	NOEC = 0.11 mg a.s./L $_{mm}$	EFSA Journal 2013;11(6):3143
Daphnia magna	chlorantranilipole	48 h, s	EC_{50} = 0.0116 mg a.s./L $_{mm}$	EFSA Journal 2013;11(6):3143
Centroptilum	chlorantranilipole	48 h, s	EC_{50} = 0.0116	EFSA Journal

Species	Substance	Exposure System	Results	Reference
triangulifer			mg a.s./L mm	2013;11(6):3143
Chimarra atterima	chlorantranilipole	48 h, s	LC_{50} = 0.0117 mg a.s./L mm	EFSA Journal 2013;11(6):3143
Gammarus pseudolimnaeus	chlorantranilipole	48 h, s	LC_{50} = 0.0351 mg a.s./L mm	EFSA Journal 2013;11(6):3143
Crassostrea virginica	chlorantranilipole	96 h, s	EC_{50} = 0.0399 mg a.s./L mm	EFSA Journal 2013;11(6):3143
Hyallella azteca	chlorantranilipole	48 h, s	LC_{50} = 0.389 mg a.s./L mm	EFSA Journal 2013;11(6):3143
Hyallella azteca	chlorantranilipole	48 h, s	LC_{50} = 0.260 mg a.s./L mm	Coragen 200 SC
Procambarus clarkii	chlorantraniliprole	96h, s	LC_{50} = 0.951 mg a.s./L mm	EFSA Journal 2013;11(6):3143
Soyedina carolinensis	chlorantranilipole	48 h, s	LC_{50} = 0.258 mg a.s./L mm	EFSA Journal 2013;11(6):3143
Americamysis bahia	chlorantranilipole	96 h, s	LC_{50} = 1.15 mg a.s./L mm	EFSA Journal 2013;11(6):3143
Oronectes virilis	chlorantranilipole	48 h, s	LC_{50} = 1.42 mg a.s./L mm	EFSA Journal 2013;11(6):3143
Ceriodaphnia dubia	chlorantranilipole	48 h, s	LC_{50} = 0.0062 mg a.s./L mm	Coragen 200 SC
Daphnia pulex	chlorantranilipole	48 h, s	LC_{50} = 0.0121 mg a.s./L mm	Coragen 200 sC
Daphnia magna	chlorantranilipole	21, ss	NOEC = 0.00447 mg a.s./L mm	EFSA Journal 2013;11(6):3143
Daphnia magna	IN-EQW78	48 h, s	LC_{50} = 0.138 mg met./L mm	EFSA Journal 2013;11(6):3143
Daphnia magna	IN-ECD73	48 h, s	LC_{50} = 0.0138 mg met./L mm	EFSA Journal 2013;11(6):3143
Daphnia magna	IN-GAZ70	48 h, s	LC_{50} = 0.00987 mg met./L mm	EFSA Journal 2013;11(6):3143
Daphnia magna	IN-F6L99	48 h, s	LC_{50} = 46.8 mg met/L mm	EFSA Journal 2013;11(6):3143
Daphnia magna	IN-F9N04	48 h, s	LC_{50} = 0.03 mg met/L mm	EFSA Journal 2013;11(6):3143
~~Daphnia magna~~	~~IN-LBA22~~	~~48 h, s~~	~~LC_{50} = 0.24 mg met./L mm~~	~~Coragen 200 SC~~
Daphnia magna	IN-LBA22	48 h, ss	EC_{50} > 0.85 mg/L mm	Ireland, 2016a. Addendum to the assessment report on chlorantraniliprole, confirmatory data, April 2016, updated September 2016. Brougher et al. (2014)

Species	Substance	Exposure System	Results	Reference
				(DuPont-39689) see Section 9.5.1.1
~~Daphnia magna~~	~~IN-LBA23~~	~~48 h, s~~	~~LC_{50} = 0.1 mg met./L mm~~	~~Coragen 200 SC~~
Daphnia magna	IN-LBA23	48 h, s	EC_{50} > 1.1 mg/L mm	Ireland, 2016b. Addendum to the assessment report on chlorantraniliprole, confirmatory data, April 2016, updated September 2016. Brougher et al. (2014) (DuPont-38899) see Section 9.5.1.1
~~Daphnia magna~~	~~IN-LBA24~~	~~48 h, s~~	~~LC_{50} = 10 mg met./L mm~~	~~Coragen 200 SC~~
Daphnia magna	IN-LBA24	48 h, s	**EC_{50} = 0.54 mg/L mm**	Ireland, 2016c. Addendum to the assessment report on chlorantraniliprole, confirmatory data, April 2016, updated September 2016. Brougher et al. (2014) (DuPont-38207) see Section 9.5.1.1
Chironomus riparius	chlorantranilipole	48h, s	LC_{50} = 0.0859 mg a.s./L mm	EFSA Journal 2013;11(6):3143
Lumbriculus variegatus	Chlorantraniliprole	48 h, s	LC_{50} > 1.49 mg/L mm	EFSA Conclusion (2013) Samel, A. (2005) (DuPont-15873)
~~Pseudokirchneriella subcapitata~~ Chironomus riparius	~~chlorantranilipole~~	~~72 h, s~~	~~LC_{50} = 0.0859 mg a.s./L mm~~	~~EFSA Journal 2013;11(6):3143~~
Chironomus riparius	chlorantranilipole	28d, s,	NOEC = 0.0025 mg/L (water spike)	EFSA Journal 2013;11(6):3143
Chironomus riparius	chlorantranilipole	28 d, s	NOEC = 0.005 mg/kg sediment(sediment natural spiked)	EFSA Journal 2013;11(6):3143
~~Chironomus riparius~~	~~chlorantranilipole~~	~~28 d~~	~~NOEC = 0.025 mg/kg sediment (sediment natural spiked)~~	~~Coragen 200 SC~~
Pseudokirchneriella subcapitata	chlorantranilipole	120h, s	EC_{50} = 2 mg a.s./L mm (biomass and	EFSA Journal 2013;11(6):3143

Species	Substance	Exposure System	Results	Reference
			growth rate)	
Lemna gibba	chlorantranilipole	14d, s	EC_{50} = 2 mg a.s./L $_{mm}$ (frond number and biomass)	EFSA Journal 2013;11(6):3143
Higher-tier studies (micro- or mesocosm studies)				
Based on SSD using ETX 2.0 for 9 species median HC5 value is 2.91 mg a.s./L, with AF of 5 regulatory acceptable concentration (RAC) = 0.58 mg a.s./L Including new studies median HC5 value is 2.61 mg a.s./L with an assessment factor of 3; RAC = 0.87 mg a.s./L(explanation provided below)				

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 – formulation

Species	Substance	Exposure System	Results [mg/L]	Reference
Bluegill sunfish	Coragen 200 SC	96 h, ~~s~~ f	LC_{50} = >9.9 n formul.n ≡ >1.84 m a.s	EFSA Journal 2013;11(6):3143
Daphnia magna	Coragen 200 SC	48 h, s	EC_{50} = 0.035 n formul.n ≡ 0.0071 m a.s.	EFSA Journal 2013;11(6):3143
Pseudokirchneriella subcapitata	Coragen 200 SC	120h, s	EC_{50} =>20 n formul.n ≡ >4.0 n a.s.	EFSA Journal 2013;11(6):3143
~~**Higher-tier studies (micro- or mesocosm studies)**~~				
~~Based on SSD using ETX 2.0 for 9 species median HC5 value is 2.91 mg a.s./L, with AF of 5 regulatory acceptable concentration (RAC) = 0.58 mg a.s./L~~ ~~Including new studies median HC5 value is 2.61 mg a.s./L with an assessment factor of 3; RAC = 0.87 mg a.s./L~~				

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

9.5.1.1 Justification for new endpoints

No new endpoints for chlorantraniliprole were established.

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.
Also toxicity for Corgaen 200 SC (Clorol 200 SC) is lower than toxicity of active substance, so risk assessment for formulation is covered by active substance except for acute toxicity to fish.

In risk assessment presented below, two risk refinements are used :

1) Refinement of exposure level protective of 95% of species (HC5 evaluation)

Chlorantraniliprole acts as a highly selective antagonistic ryanodine receptor modulator by activating the uncontrolled release of calcium stores from the sarcoplasmic reticulum in sensitive organisms. This causes loss of muscle function leading to paralysis and ultimately death3. EFSA:3143 (2013) concluded that a species sensitivity distribution of acute toxicity endpoints with 9 species of aquatic invertebrates resulted in a median HC5 = 2.91 mg a.s./L, an assessment factor of 5 and a Tier 2 regulatory acceptable concentration (RAC) of 0.58 mg a.s./L. EFSA (2013) also concluded that the Tier 2 RAC was applicable to acute and chronic exposures via water to aquatic invertebrates and sediment dwelling organisms living in water or sediment. To further evaluate interspecies variability in detail, the effect endpoints of 13 invertebrate species tested on the active substance chlorantraniliprole were re-evaluated to construct a refined species sensitivity distribution from which an HC5 was obtained:

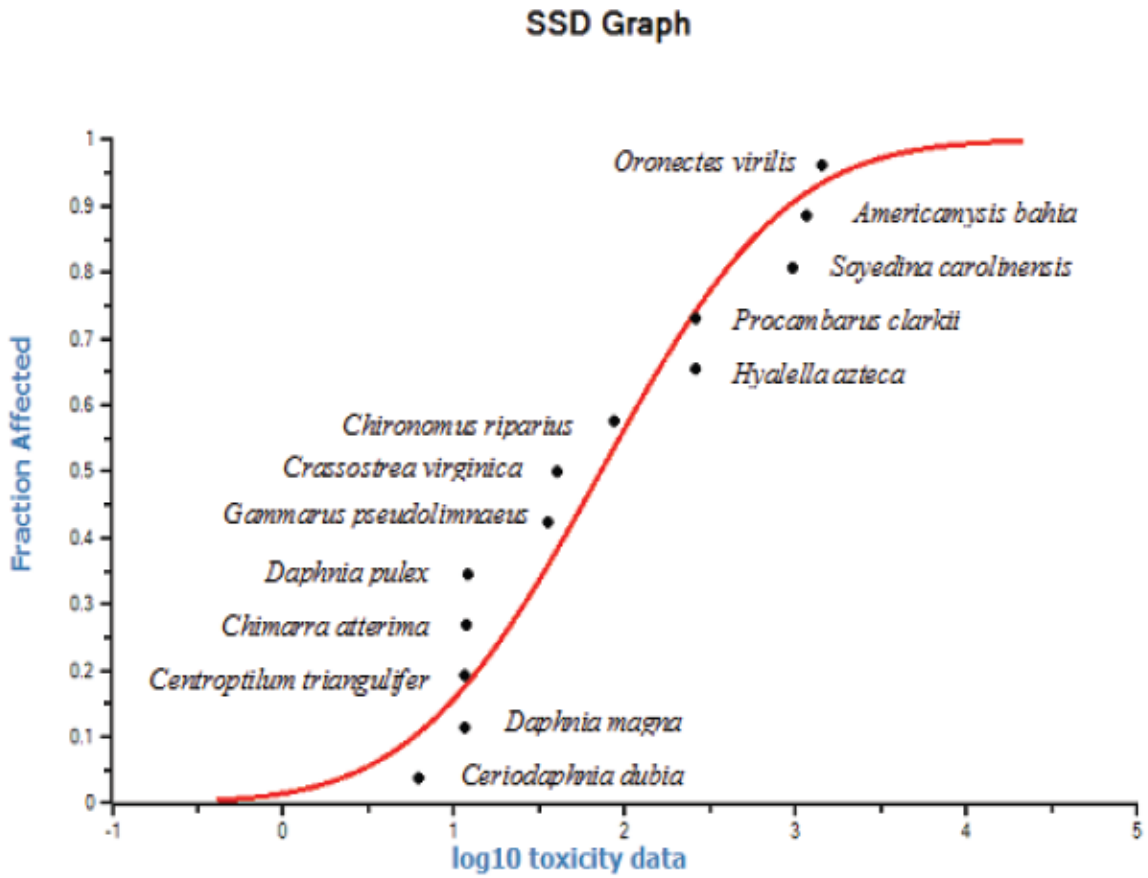
Test organism	Taxonomic group	48 h EC/LC_{50} (µg a.s./L)
Ceriodaphnia dubia	Cladocera	6.2
Daphnia magna	Cladocera	11.6
Centroptilum triangulifer	Ephemeroptera	11.6
Chimarra atterima	Trichoptera	11.7
Daphnia pulex	Cladocera	12.1
Gammarus pseudolimnaeus	Amphipoda	35.1
Crassostrea virginica	Bivalvia (class)	39.9 [a]
Chironomus riparius	Diptera	85.9
Hyalella azteca	Amphipoda	260
Procambarus clarkii	Decapoda	951
Soyedina carolinensis	Plecoptera	258
Brachionus calyciflorus	Rotifera (phylum)	>1000
Copepods (Cyclopoidea)	Cyclopoida (subphylum crustacea)	>1000
Americamysis bahia	Mysida (subphylum crustacea)	1150 [a]
Oronectes virilis	Decapoda	>1420 [b]
Lumbriculus variegatus	Oligochaeta (subclass)	>1490
Chironomus tentans	Diptera	>7500
Geometric mean (unbound data only)		**72.3**
Median HC_5 (lower limit - upper limit)		**2.61 (0.38-8.59)**
Adjusted St.dev. $LogEC_{50}$		**0.80**
Mean $LogEC_{50}$		**1.86**

[a] 96 h EC_{50}

[b] EFSA LoEP endpoint selected for use in higher tier assessment

In total, acute toxicity of chlorantraniliprole technical was assessed with 17 aquatic invertebrate species. However, to add statistical robustness, 4 unbound, i.e. 'greater than' values were excluded from the evaluation. One non-definitive value for Oronectes virilis was included in the calculation of HC5 because it was an agreed EFSA:3143 (2013 LoEP endpoint. The HC5 was calculated based on the recommendations of EUFRAM (EUFRAM, 2006 4) using the software package ETX 2.0, developed by the RIVM, The Netherlands, based on Aldenberg and Jaworska (2000)5 and Aldenberg and Luttik (2002)6.
Figure 1 is a graphical representation of the species distribution and the fit to those data using this approach. Based on this methodology, the HC5 is 2.61 µg a.s./L with a lower confidence bound of 0.38 mg a.s./L and an upper confidence bound of 8.59 mg a.s./L.

Figure 1
Species sensitivity distribution for the HC_5 estimation of aquatic invertebrates exposed to chlorantraniliprole technical; Log distribution of EC_{50} values



Due to the statistical robustness of data, a comparative calculation using a non-parametric tool such as BurrliOZ was omitted. Goodness-of-fit was checked using three different tests for normality:
· Anderson-Darling test
· Kolmogorov-Smirnov test
· Cramer von-Mises test
Normal distribution of data following log-transformation was confirmed for all levels of significance tested (p = 0.1 through p = 0.01) for all three tests except for the Anderson-Darling test at a significance level of 0.1

Results of goodness-of-fit tests for aquatic invertebrates

P-values	Critical values for test statistic	Calculated test statistic	Normal distribution accepted or rejected
Anderson-Darling test for normality			
0.05	0.752	0.637	Accepted
Kolmogorov-Smirnov test for normality			
0.05	0.895	0.776	Accepted
Cramer von Mises test for normality			
0.05	0.126	0.086	Accepted

With regard to the evaluation of uncertainty, besides the tier 1 assessment, the level of protection is not specified in the current Guidance Document on Aquatic Ecotoxicology in the frame of Directive 91/414/EEC Commission document Sanco/3268/2001 rev. 4 (2002). However, for the probabilistic assessment of risk using species sensitivity distributions the EFSA:3290 (2013)7 guidance provides the following criteria to derive an assessment factor. Furthermore, EFSA:3290 (2013)8 provides the following criteria to be considered for the selection of the assessment factor:

· *The quality of the acute toxicity data used to construct the SSD.*

If the toxicity data used to construct the SSD comprise several different genera/families/orders of the potential sensitive taxonomic group, including EPT taxa (Ephemeroptera/Plecoptera/Trichoptera), a lower AF in the proposed range may be selected. However, if another valid SSD can be constructed with a more limited dataset containing the most sensitive species, and the HC5 derived from this SSD curve is lower than that of the SSD curve using toxicity data for a wider array of taxa, a higher AF in the proposed range may be selected to be applied to the SSD from the wider set.

The SSD comprises data derived from studies on a wide range of different taxa, including Ephemeroptera, Plecoptera and Trichoptera, which are known to be particularly sensitive to insecticides (see Table above). An HC5 calculated out of the data provided for the 8 most sensitive species (HC5 = 4.11 µg/L) is higher than the – statistically more robust – 13 species HC5 of 2.61 µg/L. Therefore, a lower assessment factor (AF) is warranted.

· *The lower limit value of the HC5.*

If the lower limit HC5 derived from the curve is less than one-third of the median HC5, a higher AF in the proposed range may be warranted.

This criterion relates to the level of uncertainty at the lower bound of the SSD. Four of the 5 most sensitive species are “stacked” in a vertical line across the low end of the curve, which artificially increases the span of the lower limit beyond the acceptable range of 1/3 the median HC5. This can therefore be considered as an artefact as this distribution is protective of the lower bound values. Therefore, a higher assessment factor (AF) is not warranted in this specific case.

· *The lower tier RACs on the basis of standard toxicity data (tier 1), standard and additional toxicity data (Geomean approach) and tier 3 data*

The size of the AF should ideally not result in an SSD-RACsw;ac higher than the tier 3 RAC derived from effect class 1 and 2 of micro-/mesocosms studies nor lower than the tier 1RACsw;ac on the basis of standard test species and/or the Geomean-RACsw;ac and/or method 3 to 5 (EFSA, 2006a) on the basis of the same toxicity data that were used to construct the SSD. The Geomean approach aims to achieve the same average level of protection as in the tier 1 effect assessment but can be predicted more accurately because of the availability of additional toxicity data for the relevant taxonomic groups.

No micro- or mesocosm studies have been conducted; none of the assessment factors proposed in Error! Reference source not found. result in lower values than the tier 1 RACsw;ac on the basis of the tandard test species (0.116 µg/L) and/or the geomean-RACsw;ac (0.723 µg/L). In addition, the ATS (Adjusted Toxicity Statistic) value (2.51 µg/L) is within the same range as the HC5 of 2.61 µg/L. Therefore, a lower assessment factor (AF) is warranted.

· *The position of the toxicity data in the lower tail of the SSD (around the HC5).*

If in the lower tail the toxicity data overall are positioned on the right side of the SSD curve, the derived HC5 estimate may be considered relatively conservative for the most sensitive species. This may be a reason to adopt a lower AF from the proposed range. In contrast, if in the lower tail, the toxicity data

overall are positioned on the left side of the SSD curve, this may be a reason to adopt a higher AF from the proposed range.

Data are distributed to the right of the curve, therefore the SSD can be considered as conservative and a lower assessment factor (AF) is warranted.

· *The steepness of the SSD curve.*
In the case of a relatively steep SSD curve (e.g. less than a factor of 100 between lowest and highest L(E)C50 value used to construct the SSD curve) a higher AF from the proposed range is recommended since exposure concentrations that exceed the RACsw;ac may have ecotoxicological consequences for a larger number of taxa.

The SSD already contains a large number of taxa delivering a high intrinsic level of protection. Additional taxa were tested but not considered for the SSD (i.e. unbound data, showing no effect at the highest concentration tested). In addition, the factor between lowest and highest EC50 value is substantially higher than 100 in any case, irrespectively of whether bound or unbound data only are considered. Therefore, a lower assessment factor (AF) is warranted.

· *Read-across information for compounds with a similar toxic mode of action.*
For a PPP with a well-known mode of action sufficient higher tier information on related compounds (e.g. organophosphates) may be available that allow the evaluation of the predictive value of the median HC5 and/or lower limit HC5 for possible effects in micro-/mesocosms. This information may be used to select an appropriate AF within the proposed range.

Very few diamides with a similar mode of action (Ryanodine receptor modulators) are currently registered as plant protection products (cyantraniliprole and flubendiamide). Cyantraniliprole, provides a comparable ecotoxicological profile (see Cyantraniliprole DAR, Volume 3, B9, June 2014). For flubendiamide, insufficient data for a read-across are available.

· *Considering information on chronic effects.*
If the acute to chronic ratio (acute EC50/chronic EC10) is larger than 10, then an AF in the higher range may be warranted. The acute to chronic ratios for Daphnia magna (being amongst the most sensitive species) and Americamysis bahia are both <10. Therefore, a lower assessment factor (AF) is warranted.

It can be concluded that, for the current evaluation and based on the criteria listed above, an assessment factor of 3 is considered as protective for acute risk assessment considering median acute HC5s based on EC50 data for a wide taxonomic range of aquatic invertebrates. This results in a refined Tier 2 Regulatory Acceptable Concentration (RAC) of 0.87 mg a.s./L (HC5 of 2.61 mg a.s./L).

~~**2) Refinement of endpoint for sediment exposure of Chironomus riparius**~~

~~The exposure route in the water-spiked sediment study was considered to be by water. The aquatic risk assessments were split between the water phase and the sediment phase. For water phase species, the acute effects drive the chronic risk assessment. This is the case for the C. riparius water-spike study. The NOEC was 2.5 mg a.s./L because there was only 11% reduction in emergence at 2.5 mg a.s./L and 74% reduction of emergence at 5 mg a.s./L. The Pesticides Peer Review Meeting 99 took into consideration the following: (1) the acute/chronic ratios, (2) the acute effects seen in chronic studies and (3) the tier 1 chronic risk assessments, the assessment ends up to a similar level of protection (RAC). For these reasons the experts agreed that chronic risk (for water phase species) can be considered addressed by the acute SSD; however exposures must be PECmax. A data gap was concluded after Pesticide Peer Review meeting 99 (Chlorantraniliprole Expert Meeting Reports (05-06-2013)) to address the chronic risk to sediment dwellers by considering PECsed. The water route is the most relevant exposure pathway for risk assessment of sediment-dwelling organisms such as Chironomus potentially exposed to chlorantraniliprole. Upon reaching water, chlorantraniliprole may degrade abiotically at higher pH and could be degraded~~

~~rapidly via aqueous photolysis. Upon reaching sediment, chlorantraniliprole binds weakly to moderately to organic matter because of the low Kfom value (average Kfom = 174 mL g-1). Chlorantraniliprole is not expected to accumulate in sediment; therefore, increased exposure via this route over the longer term is not anticipated. In the laboratory sediment toxicity studies, there was limited retention of chlorantraniliprole in sediment in the sediment-spiked study and no movement of chlorantraniliprole into sediment in the water-spiked study. Thus, the NOECs reflect water exposures and the relevant risk assessment for sediment organisms potentially exposed to chlorantraniliprole should be based only on the water-spiked sediment study with Chironomus.~~

~~To provide a more realistic endpoint for sediment dwelling invertebrates, a study was conducted using spiked natural sediment with C. riparius instead of artificial substrate. As there were treatment related effects observed for development time between the negative control group and the 37 mg/kg treatment group, the 28-day LOEC was 37 mg/kg and the 28-day NOEC was 25 mg/kg~~

The average K_{fom} value of 174 mL/g indicates low to moderate organic matter sorption, suggesting limited partitioning of chlorantraniliprole into the sediment and a preference for remaining in the aqueous phase. With a K_{oc} value of 301 mL/kg, the substance is classified within the lower sorption group (K_{oc} < 500 mL/kg). The 1/n exponent of 0.95 indicates near-linear and reversible sorption behavior, without strong, irreversible binding to the sediment matrix. According to FOCUS guidance (EFSA Journal 2017; 15(10):4982), significant accumulation in sediment is primarily expected for substances characterized by both high sorption and high persistence criteria which chlorantraniliprole does not meet.
Available anaerobic metabolism data [*Anaerobic soil metabolism of ^{14}C-DPX-E2Y45*; DuPont-14568, 2006] demonstrate that chlorantraniliprole undergoes biochemical degradation in sediment into safe metabolites, such as IN-EQW78 and IN-F9N04. This evidence confirms that the presence of the substance in the sediment is transient rather than cumulative. The lack of potential for long-term accumulation is further supported by the "aged sorption" phenomenon, which progressively binds residues within the sediment matrix, rendering them biologically inactive. Degradation occurs predominantly in the water phase, while it remains limited within the sediment itself. Consequently, the dissipation of chlorantraniliprole in sediment is primarily driven by back-transfer to the water column, and the overall half-life is mainly dependent on aqueous degradation processes.
With reference to toxicity studies on living organisms (*^{14}C-DPX-EY245: A prolonged sediment toxicity test with Chironomus riparius using spiked sediment*; DuPont-14396, 2005; and *^{14}C-DPX-E2Y45: A prolonged sediment toxicity test with Chironomus riparius using spiked water;* DuPont-14395, 2006)), analytical recoveries of ^{14}C-chlorantraniliprole equivalents in sediment, overlying water, and pore water on days 0, 7, and 28 showed that the test material leached from the sediment back into the water. This result is consistent with the moderate K_d and K_{oc} values calculated for sandy soils, where adsorbed chlorantraniliprole readily undergoes desorption and may return to the aqueous phase (e.g., groundwater or flowing surface water).
Furthermore, in column and batch studies, chlorantraniliprole concentrations in sediment over 28 days remained below the Limit of Quantification LOQ = 1.88 µg/kg at all sampling points (days 0, 7, 14, 21, and 28), while the majority of the total radioactive residue was detected in the overlying and pore water. These findings indicate that chlorantraniliprole does not undergo significant accumulation in sediment during short-term exposure. Although the study duration was 28 days, the data strongly suggest that under natural conditions, sediment does not serve as a primary sink or retention site for this substance.
Under the presented conditions, all relevant exposure scenarios are effectively covered by exposure in the water phase, which represents a conservative worst-case assessment. In the case of Catanga 200 SC, the risk characterization is further refined through a higher-tier assessment based on a Species Sensitivity Distribution (SSD) approach for *Chironomus riparius* (using ETX 2.0 for 9 species), as well as new studies in which the median HC5 value is 2.61 mg a.s./L. These include representatives of different taxonomic groups, including bluegill, *Daphnia magna*, and *Pseudokirchneriella subcapitata*. This approach provides a realistic and ecologically relevant evaluation of the potential risk of chlorantraniliprole to aquatic organisms, as it accounts for interspecies variability and reflects the sensitivity of a broad range of taxa under environmentally relevant exposure conditions.

zRMS comments:
The studies with the metabolites IN-LBA22, IN-LBA23 and IN-LBA24 have already been evaluated and discussed as confirmatory data and have been added in Table 9.5 1 by zRMS. The risk assessment for these metabolite should be based on confirmatory data.

For acute risk to fish the endpoint from study with the formulation, expressed in terms of active substance, as the worst case, was used for the risk assessment for active substance by Applicant.
Following the recommendations of the EFSA "Outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology" (EFSA Supporting publication 2019: EN-1673), it is necessary to consider whether the formulation is more or less toxic than the parent compound. When the endpoint of the formulation expressed in terms of active substance is at least three times lower than the equivalent endpoint for the active substance, it should be considered more toxic.
The measured toxicity data available for the given endpoints are shown in the table below for the formulation and the active substance.

Test species	Measured toxicity of formulation	Measured toxicity of a.s.	Formulation endpoint recalculated for a.s.	Ratio a.s. endpoint/recalculated formulation endpoint
Fish	9.9 mg/L	12 mg/L	1.84 mg/L	6.5
Invertebrates	0.035 mg/L	0.0116 mg/L	0.0071 mg/L	1.63
Algae	>20 mg/L	> 2.0 mg/L	>4.0 mg/L	0.5

The formulation endpoint expressed in terms of active substance is more than three times lower for fish. Therefore, the formulation endpoint, expressed in terms of active substance, need to be used in the risk assessment for the active substance.

In the EFSA Conclusion (2013); 11(6):3143, it was concluded that the available SSD (HC5 at 2.91 with AF of 5) was suitable to address both the acute and chronic risk to aquatic invertebrates given the toxicological profile of chlorantraniliprole to aquatic invertebrates. Therefore the PEC/RAC calculations with tier 1 data for aquatic invertebrates (acute and chronic) were not assessed by zRMS.

Based on the art. 34 of regulation (EC) No 1107/2009, the additional HC_5 at 2.61µg/L, including new studies, accepted in Core dossier for Coragen 200 SC (CHLORANTRANILIPROLE 200 G/L SC, zRMS Ireland, APPLICANT: E. I. DU PONT de NEMOURS AND COMPANY, Part B Section 6 , 25 July 2014), was provided by Applicant.

New studies accepted in the Core dossier of Coragen 200 SC:

- DuPont-36901: Brougher *et al* 2013; Chlorantraniliprole (DPX-E2Y45) technical: A 48-hour static acute toxicity test with *Hyalella azteca*

- DuPont-36902: Brougher *et al* 2013; Chlorantraniliprole (DPX-E2Y45) technical: A 48-hour static acute toxicity test with the Cladoceran (*Daphnia pulex*)

- DuPont-36903: Brougher *et al* 2013; Chlorantraniliprole (DPX-E2Y45) technical: A 48-hour static acute toxicity test with the Cladoceran (*Ceriodaphnia dubia*)

Summary of these studies were provided in Appendix 2.

In the Core dossier (2014) new studies were assessed and accepted by zRMS for updated Species Sensitivity Distribution (SSD). The conclusion of zRMS on the use of updated SSD presented in Core dossier (2014) was copied below:

"The applicant has submitted an updated Species Sensitivity Distribution (SSD) in order to address the apparent and outstanding unresolved risk to aquatic invertebrates. Three new studies have been submit-

ted, evaluated (see summaries in IIIA 10.10.1below) and accepted by the Reviewer for the purpose of inclusion in the SSD. The studies on Ceriodaphnia dubis and Daphnia pulex are considered appropriate for inclusion considering the sensitivity of Cladocerans to chlorantraniliprole. The endpoint from the study on Hyalella azteca has replaced an older unbounded endpoint for this invertebrate with a definitive endpoint.
EFSA:3143 (2013) concluded that a species sensitivity distribution of acute toxicity endpoints with 9 species of aquatic invertebrates resulted in a median HC5 = 2.91 µg a.s./L, an assessment factor of 5. EFSA:3143 (2013) also concluded that the SSD was suitable to address both the acute and chronic risk to aquatic invertebrates given the toxicological profile of chlorantraniliprole to aquatic invertebrates. The updated SSD applied 13 definitive acute toxicity endpoints, thereby allowing for further clarification of the effects of chlorantraniliprole on aquatic invertebrates. The Reviewer accepts the a species sensitivity distribution of acute toxicity endpoints with 13 species of aquatic invertebrates which results in a median HC5 = 2.61 µg a.s./L.
The applicant has proposed a reduction in the Assessment Factor from 5 to 3 based on the consideration of a number of of the options presented by EFSA:3290 (2013). The Reviewer is in agreement that on the basis of an improved robust SSD and the supporting weight of evidence as presented allows for a reduction of the AF from 5 to 3. This AF is considered to be appropriately protective of aquatic invertebrates and this AF is applied to both the acute and long-term risk assessment presented below. Therefore, the SSD with the median HC5 of 2.61 and the AF of 3 results in the Regulatory Acceptable Concentration (RAC) of 0.87 µg a.s./L for risk assessment."

This new HC_5 was also accepted in National Addendum, NL for CHLORANTRANILIPROLE 200 G/L SC (27 October 2014).

The *Guidance document on the evaluation of new active substance data post (renewal of) approval* (SANCO/10328/2004– rev 9 21.10.2021) describes which new active substance data may be taken into consideration after its (renewal of) approval. Following point 4.3.1 of this guidance, new active substance data necessary for authorisation may be evaluated and taken into consideration in cases where a safe use can only be demonstrated by using this refined endpoint. Furthermore, although the data are active substance data, they should be handled as product data.

The zRMS evaluated, whether the conditions to take the new endpoints into consideration are fulfilled:

The calculated PEC/RAC ratios with the EFSA agreed endpoint of HC5 2.91 µg a.s./L resulting in a RAC of 0.582 µg a.s./L (AF = 5) does not results in acceptable risk for all requested GAPs when RMM are applied (see risk assessment below). However, not all possible RMM options were considered, therefore, the conditions were partially fulfilled.

The acceptability new HC_5 should be considered on the MSs level. Nevertheless PEC/RAC calculations with new HC_5 of 2.61 and the AF of 3 were also assessed by zRMS below.

Refinement of the risk assessment for invertebrates, proposed by Applicant, should be considered on the MSs level.

For *Chironomus riparius* the EU agreed endpoints for sediment (5 µg/kg) and water (2.5 µg/L) spiked tests are available. During the peer-review of the active substance it was agreed that the risk to sediment-dwelling invertebrates is covered by the refined risk assessment for aquatic invertebrates. However, risk to sediment-dwelling invertebrates considering exposure via sediment has to be assessed to address potential bioaccumulation of the active substance in the sediment. Hence, in the following a risk assessment taking into account the endpoint derived from the sediment-spiked study was considered (NOEC = 5 µg a.s./kg sediment).
The calculated PEC/RAC ratios with the EFSA agreed endpoint of NOEC = 5 µg a.s./ kg sediment does not results in acceptable risk for all requested GAPs when RMM are applied (see risk assessment below).

~~Based on the art. 34 of regulation (EC) No 1107/2009, a more realistic endpoint for sediment dwelling~~

~~invertebrates (28 day NOEC was 25 mg/ kg sediment) form study conducted using spiked natural sediment with *C. riparius* instead of artificial substrate, accepted in Core dossier for Coragen 200 SC (CHLORANTRANILIPROLE 200 G/L SC, zRMS Ireland, APPLICANT: E. I. DU PONT de NEMOURS AND COMPANY, Part B Section 6 , 25 July 2014),was provided by Applicant.~~

~~New study accepted in the Core dossier of Coragen 200 SC:~~

~~DuPont 36097: Thomas *et al* 2014; ^{14}C Chlorantraniliprole (DPX-E2Y45) technical: A prolonged sediment toxicity test with *Chironomus riparius* using spiked natural sediment~~

~~Summary of this study was provided in Appendix 2.~~

~~The use of a new endpoint for the risk assessment for *Chironomus riparius* is necessary to demonstrate acceptable risk to aquatic organisms when using RRMs~~

The Applicant submitted the statement regarding the most relevant exposure rout for sediment-dwelling organisms and the risk assessment based on the weight of evidence.

zRMS agrees that the water route is the most relevant exposure pathway for risk assessment of sediment-dwelling organisms such as Chironomus potentially exposed to chlorantraniliprole. Upon reaching water, chlorantraniliprole may degrade abiotically at higher pH and could be degraded rapidly via aqueous photolysis. Upon reaching sediment, chlorantraniliprole binds weakly to moderately to organic matter because of the low K_{fom} value (average K_{fom}= 174 mL g-1).
Chlorantraniliprole is not expected to accumulate in sediment; therefore, increased exposure via this route over the longer-term is not anticipated. In the laboratory sediment toxicity studies, there was limited retention of chlorantraniliprole in sediment in the sediment-spiked study and no movement of chlorantraniliprole into sediment in the water-spiked study. Thus, the relevant risk assessment for sediment organisms potentially exposed to chlorantraniliprole should be based only on the water-spiked sediment study with Chironomus.

In the risk assessment presented above available SSD was suitable to address both the acute and chronic risk to aquatic invertebrates given the toxicological profile of chlorantraniliprole to aquatic invertebrates. Since the SSD for HC_5 estimation covers the effect endpoints of 13 invertebrate species data, including *Chironomus riparius*, the risk assessment based on Tier 2 RAC covers the risk assessment for sediment-dwelling organisms.

Refinement of the risk assessment for sediment-dwelling organisms, proposed by Applicant, should be considered on the MSs level.

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.

Pome/stone fruit, use no.:

5, Apple, 2 x 35 g a.s./ha BBCH 70-87,
6, Apple, 2 x 35 g as/ha, BBCH 56 or BBCH 70-87,
42, Pear, 2 x 35 g a.s./ha BBCH 56-87,
43, Plum, 2 x 35 g a.s./ha BBCH 56-87,
44, Common quince, 2 x 35 g a.s./ha BBCH 56-87,
45, Wild Apple, 2 x 35 g a.s./ha BBCH 56-87,
46, Chinese Pear, 2 x 35 g a.s./ha BBCH 56-87,
47, Common medlar, 2 x 35 g a.s./ha BBCH 56-87,
48, Loquats/Japanese medlars, 2 x 35 g a.s./ha BBCH 56-87,
49, Peach, 2 x 35 g a.s./ha BBCH 56-87,
50, Apricot, 2 x 35 g a.s./ha BBCH 56-87,
51, Sour Cherry, 2 x 35 g a.s./ha BBCH 56-87,
52, Sweet cherry, 2 x 35 g a.s./ha BBCH 56-87,
53, Hazelnuts/cobnuts, 2 x 35 g a.s./ha BBCH 56-87,
54, Walnuts, 2 x 35 g a.s./ha BBCH 56-87,
55, Chestnuts, 2 x 35 g a.s./ha BBCH 56-87,
60, Christmas tree, 1 x 35 g a.s./ha BBCH 56-69,
61, Forestry tree, 1 x 35 g as/ha, BBCH 56-69,
63, Willow, 1 x 35 g as/ha, BBCH >69,
64, Energetic tree, 1 x 35 g as/ha, BBCH >69

~~**Table 9.5-3: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for chlorantraniliprole for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CLOROL 200 SC in apple**~~

~~Group~~		~~Fish acute~~	~~Fish prolonged~~	~~Inverteb. acute~~	~~Inverteb. prolonged~~	~~Algae~~	~~Higher-tier information~~	~~Higher-tier information~~	~~Aquatic plants~~		~~Sed. dwell. prolonged~~

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged
Test species		*Cyprinodon variegatus/ Bluegill sunfish*	*Oncorhynchus mykiss*	*Daphnia magna*	*Daphnia magna*	*Pseudokirchn. subcapitata*	*Invertebrate*	*Invertebrate* [redacted]	*Lemna Gibba*		*Chironomus riparius*
Endpoint (µg/L)		LC_{50} 1840[redacted]	NOEC 110	EC_{50} 6.2	NOEC 4.47	EC_{50} [redacted]	HC5 2.61	HC5 2.91	EC50 2000		NOEC [redacted]
AF		100	10	100	10	10	3	5	10		10
RAC (µg/L)		18.4	11	0.062	0.447	[redacted]	0.87	0.58	200		[redacted]
FOCUS Scenario	$PEC_{gl\ max}$ (µg/L)									$PEC_{gl\ max}$ (µg/kg)	
Step 1											
-	20.36	1.1065	1.8509	328.3871	45.5481	2.3702	23.4023	35.1034	0.1018	57.88	23.1520
Step 2											
N-Europe	4.18	0.2272	0.3800	67.4194	9.3512	0.4866	4.8046	7.2069	0.0209	11.93	4.7720
Step 3											
D3/ditch	2.347	0.1276	0.2134	37.8548	5.2506	0.2732	2.6977	4.0466	0.0117	1.292	0.5168
D4/pond	0.4762	0.0259	0.0433	7.6806	1.0653	0.0554	0.5474	0.8210	0.0024	2.116	0.8464
D4/stream	2.472	0.1343	0.2247	39.8710	5.5302	0.2878	2.8414	4.2621	0.0124	0.5650	0.2260
D5/pond	0.3903	0.0212	0.0355	6.2952	0.8732	0.0454	0.4486	0.6729	0.0020	2.083	0.8332
D5/stream	2.665	0.1448	0.2423	42.9839	5.9620	0.3102	3.0632	4.5948	0.0133	0.6550	0.2620
R1/pond	0.2656	0.0144	0.0241	4.2839	0.5942	0.0309	0.3053	0.4579	0.0013	0.8595	0.3438
R1/stream	1.891	0.1028	0.1719	30.5000	4.2304	0.2201	2.1736	3.2603	0.0095	0.2831	0.1132

~~Group~~		~~Fish acute~~	~~Fish prolonged~~	~~Inverteb. acute~~	~~Inverteb. prolonged~~	~~Algae~~	~~Higher-tier information~~	~~Higher-tier information~~	~~Aquatic plants~~		~~Sed. dwell. prolonged~~
~~R3/stream~~	~~2.665~~	~~0.1448~~	~~0.2423~~	~~42.9839~~	~~5.9620~~	~~0.3102~~	~~3.0632~~	~~4.5948~~	~~0.0133~~	~~0.5352~~	~~0.2141~~
~~R4/stream~~	~~1.848~~	~~0.1004~~	~~0.1680~~	~~29.8065~~	~~4.1342~~	~~0.2151~~	~~2.1241~~	~~3.1862~~	~~0.0092~~	~~0.1920~~	~~0.0768~~
~~D3/ditch~~	~~0.2767~~	~~0.0150~~	~~0.0252~~	~~4.4629~~	~~0.6190~~	~~0.0322~~	~~0.3180~~	~~0.4771~~	~~0.0014~~	~~0.1602~~	~~0.0641~~
~~D4/stream~~	~~0.4340~~	~~0.0236~~	~~0.0395~~	~~7.0000~~	~~0.9709~~	~~0.0505~~	~~0.4989~~	~~0.7483~~	~~0.0022~~	~~0.5437~~	~~0.2175~~
~~D5/stream~~	~~0.3476~~	~~0.0189~~	~~0.0316~~	~~5.6065~~	~~0.7776~~	~~0.0405~~	~~0.3995~~	~~0.5993~~	~~0.0017~~	~~0.2850~~	~~0.1140~~
~~R1/stream~~	~~0.2455~~	~~0.0133~~	~~0.0223~~	~~3.9597~~	~~0.5492~~	~~0.0286~~	~~0.2822~~	~~0.4233~~	~~0.0012~~	~~0.04867~~	~~0.0195~~
~~R3/stream~~	~~0.3461~~	~~0.0188~~	~~0.0315~~	~~5.5823~~	~~0.7743~~	~~0.0403~~	~~0.3978~~	~~0.5967~~	~~0.0017~~	~~0.07162~~	~~0.0286~~
~~R4/stream~~	~~0.2400~~	~~0.0130~~	~~0.0218~~	~~3.8710~~	~~0.5369~~	~~0.0279~~	~~0.2759~~	~~0.4138~~	~~0.0012~~	~~0.03299~~	~~0.0132~~

Risk assessment was updates by Applicant as follows:

Group		**Fish acute**	**Fish pro-longed**	Inverteb. acute	Inverteb. prolonged	**Algae**	**Sed. Dwell. prolonged (aquatic phase)**	**Higher-tier information**	**Higher-tier information**	**Aquatic plants**		**Sed. dwell. prolonged**	~~**Higher Tier information for Sed. dwell. pro-longed**~~
Test spe-cies		***Bluegill sunfish***	***Oncorhynchus mykiss***	*Daphnia magna*	*Daphnia magna*	***Pseudokirchn. subcapitata***	***Chironomus riparius***	***Invertebrate***	***Invertebrate***	***Lemna Gibba***		***Chironomus riparius***	~~***Chironomus riparius***~~
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	NOEC	HC5	HC5	EC50		NOEC	~~NOEC~~
(µg/L)		1840	110	6.2	4.47	85.9	0.25 2.5	2.61	2.91	2000		5	~~25~~
AF		100	10	100	10	10	10	3	5	10		10	~~10~~
RAC (µg/L)		18.4	11	0.062	0.447	8.59	0.025 0.25	0.87	0.58	200		0.5	~~2.5~~

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. Dwell. prolonged (aquatic phase)	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged	~~Higher-Tier information for Sed. dwell. pro-longed~~
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**										**PEC $_{gl-max}$ (µg/kg)**		
Step 1													
	20.36	1.1065	1.8509	328.3871	45.5481	2.3702	814.4	23.4023	35.1034	0.1018	57.88	115.760	~~23.1520~~
Step 2													
N-Europe	4.18	0.2272	0.3800	67.4194	9.3512	0.4866	167.2	4.8046	7.2069	0.0209	11.93	23.860	~~4.7720~~
Step 3 (application at BBCH 56)													
D3/ditch	2.347	0.1276	0.2134	37.8548	5.2506	0.2732	93.88	2.6977	4.0466	0.0117	1.292	2.584	~~0.5168~~
D4/pond	0.4762	0.0259	0.0433	7.6806	1.0653	0.0554	19.05	0.5474	0.8210	0.0024	2.116	4.232	~~0.8464~~
D4/stream	2.472	0.1343	0.2247	39.8710	5.5302	0.2878	98.88	2.8414	4.2621	0.0124	0.5650	1.130	~~0.2260~~
D5/pond	0.3903	0.0212	0.0355	6.2952	0.8732	0.0454	15.61	0.4486	0.6729	0.0020	2.083	4.166	~~0.8332~~
D5/stream	2.665	0.1448	0.2423	42.9839	5.9620	0.3102	106.60	3.0632	4.5948	0.0133	0.6550	1.310	~~0.2620~~
R1/pond	0.2656	0.0144	0.0241	4.2839	0.5942	0.0309	10.62	0.3053	0.4579	0.0013	0.8595	1.719	~~0.3438~~
R1/stream	1.891	0.1028	0.1719	30.5000	4.2304	0.2201	75.64	2.1736	3.2603	0.0095	0.2831	0.566	~~0.1132~~
R3/stream	2.665	0.1448	0.2423	42.9839	5.9620	0.3102	106.60	3.0632	4.5948	0.0133	0.5352	1.070	~~0.2141~~
R4/stream	1.848	0.1004	0.1680	29.8065	4.1342	0.2151	73.92	2.1241	3.1862	0.0092	0.1920	0.384	~~0.0768~~
		Step 3 (application at BBCH 70)											
D3/ditch	1.021	0.0555	0.0928	16.4677	2.2841	0.1189	40.84	1.1736	1.7603	0.0051	~~1.292~~ 0.6224	~~2.584~~ 1.2448	~~0.5168~~ ~~0.249~~
D4/pond	0.5251	0.0285	0.0477	8.4694	1.1747	0.0611	21.00	0.6036	0.9053	0.0026	~~2.116~~ 2.016	~~4.232~~ 4.032	~~0.8464~~ ~~0.8064~~

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. Dwell. prolonged (aquatic phase)	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged	~~Higher-Tier information for Sed. dwell. pro-longed~~
D4/stream	1.034	0.0562	0.0940	16.6774	2.3132	0.1204	41.36	1.1885	1.7828	0.0052	~~0.5650~~ 0.6861	~~1.130~~ 1.3722	~~0.2260~~ ~~0.2744~~
D5/pond	0.3041	0.0165	0.0276	4.9048	0.6803	0.0354	12.16	0.3495	0.5243	0.0015	~~2.083~~ 1.828	~~4.166~~ 3.656	~~0.8332~~ ~~0.7312~~
D5/stream	1.115	0.0606	0.1014	17.9839	2.4944	0.1298	44.60	1.2816	1.9224	0.0056	~~0.6550~~ 0.3668	~~1.310~~ 0.7336	~~0.2620~~ ~~0.1467~~
R1/pond	0.08812	0.0048	0.0080	1.4213	0.1971	0.0103	3.52	0.1013	0.1519	0.0004	~~0.8595~~ 0.2740	~~1.719~~ 0.548	~~0.3438~~ ~~0.1096~~
R1/stream	0.7750	0.0421	0.0705	12.5000	1.7338	0.0902	31.00	0.8908	1.3362	0.0039	~~0.2831~~ 0.07736	~~0.566~~ 0.15472	~~0.1132~~ ~~0.0309~~
R3/stream	1.476	0.0802	0.1342	23.8065	3.3020	0.1718	59.04	1.6966	2.5448	0.0074	~~0.5352~~ 0.3103	~~1.070~~ 0.6206	~~0.2141~~ ~~0.1241~~
R4/stream	0.7910	0.0430	0.0719	12.7581	1.7696	0.0921	31.64	0.9092	1.3638	0.0040	~~0.1920~~ 0.3259	~~0.384~~ 0.6518	~~0.0768~~ ~~0.1304~~
		Step 3 (application at BBCH 87)											
D3/ditch	1.020	~~1.02~~ 0.0554	~~0.0554~~ 0.0927	0.0927	16.4516	~~2.2819~~ 0.0119	40.80	~~0.1187~~ **1.1724**	~~1.1724~~ **1.7586**	~~1.7586~~ 0.0051	0.5158	1.032	~~0.2063~~
D4/pond	0.8206	~~0.8206~~ 0.0445	~~0.0446~~ 0.0746	0.0746	13.2355	~~1.8358~~ 0.0096	32.82	~~0.0955~~ 0.9432	~~0.9432~~ **1.4148**	~~1.4148~~ 0.0043	2.928	5.856	~~1.1712~~
D4/stream	1.008	~~1.008~~ 0.0548	~~0.0548~~ 0.0916	0.0916	16.2581	~~2.2550~~ 0.0117	40.32	~~0.1173~~ **1.1586**	~~1.1586~~ **1.7379**	~~1.7379~~ 0.0050	1.081	2.162	~~0.4324~~
D5/pond	0.3984	~~0.3984~~ 0.0217	~~0.0217~~ 0.0362	0.0362	6.4258	~~0.8913~~ 0.0046	15.94	~~0.0464~~ 0.4579	~~0.4579~~ 0.6869	~~0.6869~~ 0.0020	2.567	5.134	~~1.0268~~
D5/stream	1.115	~~1.115~~ 0.0606	~~0.0606~~ 0.1013	0.1014	17.9839	~~2.4944~~ 0.0130	44.60	~~0.1298~~ **1.2817**	~~1.2816~~ **1.9224**	~~1.9224~~ 0.0056	0.4580	0.916	~~0.1832~~

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. Dwell. prolonged (aquatic phase)	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged	Higher-Tier information for Sed. dwell. pro-longed
R1/pond	0.08302	~~0.08302~~ 0.0045	~~0.0045~~ 0.0075	0.0075	1.3390	~~0.1857~~ 0.001	3.32	~~0.0097~~ 0.0954	~~0.0954~~ 0.1431	~~0.1431~~ 0,0004	0.2784	0.557	~~0.1114~~
R1/stream	0.7908	~~0.7908~~ 0.0430	~~0.0430~~ 0.0719	0.0719	12.7548	~~1.7691~~ 0.0092	31.63	~~0.0921~~ 0.90896	~~0.9090~~ **1.3634**	~~1.3634~~ 0.0040	0.1054	0.211	~~0.0422~~
R3/stream	1.115	~~1.115~~ 0.0606	~~0.0606~~ 0.1014	0.1014	17.9839	~~2.4944~~ 0.0130	44.60	~~0.1298~~ **1.2816**	~~1.2816~~ **1.9224**	~~1.9224~~ 0.0056	0.2047	0.409	~~0.0819~~
R4/stream	0.7907	~~0.7907~~ 0.0430	~~0.0430~~ 0.0719	0.0719	12.7532	~~1.7689~~ 0.0092	31.63	~~0.0920~~ 0.9088	~~0.9089~~ **1.3632**	~~1.3633~~ 0.0040	0.3018	0.604	~~0.1207~~
		Step 4 – 20 meters vegetative and no spray buffer zone (application at BBCH 56)											
D3/ditch	0.2767	0.0150	0.0252	4.4629	0.6190	0.0322	11.07	0.3180	0.4771	0.0014	0.1602	0.320	~~0.0641~~
D4/stream	0.4340	0.0236	0.0395	7.0000	0.9709	0.0505	17.36	0.4989	0.7483	0.0022	0.5437	1.087	~~0.2175~~
D5/stream	0.3476	0.0189	0.0316	5.6065	0.7776	0.0405	13.90	0.3995	0.5993	0.0017	0.2850	0.570	~~0.1140~~
R1/stream	0.2455	0.0133	0.0223	3.9597	0.5492	0.0286	9.82	0.2822	0.4233	0.0012	0.04867	0.097	~~0.0195~~
R3/stream	0.3461	0.0188	0.0315	5.5823	0.7743	0.0403	13.84	0.3978	0.5967	0.0017	0.07162	0.143	~~0.0286~~
R4/stream	0.2400	0.0130	0.0218	3.8710	0.5369	0.0279	9.60	0.2759	0.4138	0.0012	0.03299	0.066	~~0.0132~~
		Step 4 – 20 meters buffer zone (application at BBCH 70)											
D3/ditch	0.09697	0.0053	0.0088	1.5640	0.2169	0.0113	3.88	0.1115	0.1672	0.0005	0.06259	0.125	~~0.0250~~
D4/pond	0.5040	0.0274	0.0458	8.1290	1.1275	0.0587	20.16	0.5793	0.8690	0.0025	1.847	3.694	~~0.7388~~
D4/stream	0.5486	0.0298	0.0499	8.8484	1.2273	0.0639	21.94	0.6306	0.9459	0.0027	0.6763	1.353	~~0.2705~~
D5/pond	0.2888	0.0157	0.0263	4.6581	0.6461	0.0336	11.55	0.3320	0.4979	0.0014	1.632	3.264	~~0.6528~~
D5/stream	0.2270	0.0123	0.0206	3.6613	0.5078	0.0264	9.08	0.2609	0.3914	0.0011	0.3400	0.680	~~0.1360~~
R1/pond	0.02273	0.0012	0.0021	0.3666	0.0509	0.0026	0.91	0.0261	0.0392	0.0001	0.07283	0.146	~~0.0291~~
R1/stream	0.08404	0.0046	0.0076	1.3555	0.1880	0.0098	3.36	0.0966	0.1449	0.0004	0.01146	0.023	~~0.0046~~

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. Dwell. prolonged (aquatic phase)	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged	~~Higher-Tier information for Sed. dwell. pro-longed~~
R3/stream	0.2530	0.0138	0.0230	4.0806	0.5660	0.0295	10.12	0.2908	0.4362	0.0013	0.07207	0.144	~~0.0288~~
R4/stream	0.1603	0.0087	0.0146	2.5855	0.3586	0.0187	6.41	0.1843	0.2764	0.0008	0.07189	0.144	~~0.0288~~
		Step 4 – 20 meters buffer zone (application at BBCH 87)											
D3/ditch	0.09683	0.0053	0.0088	1.5618	0.2166	0.0113	3.87	0.1113	0.1669	0.0005	0.05178	0.104	~~0.0207~~
D4/pond	0.7845	0.0426	0.0713	12.6532	1.7550	0.0913	31.38	0.9017	1.3526	0.0039	2.779	5.558	~~1.1116~~
D4/stream	0.9034	0.0491	0.0821	14.5710	2.0210	0.1052	36.14	1.0384	1.5576	0.0045	1.072	2.144	~~0.4288~~
D5/stream	0.5822	0.0316	0.0529	9.3903	1.3025	0.0678	23.29	0.6692	1.0038	0.0029	0.4548	0.910	~~0.1819~~
R1/stream	0.08575	0.0047	0.0078	1.3831	0.1918	0.0100	3.43	0.0986	0.1478	0.0004	0.01168	0.023	~~0.0047~~
R3/stream	0.1209	0.0066	0.0110	1.9500	0.2705	0.0141	4.84	0.1390	0.2084	0.0006	0.03108	0.062	~~0.0124~~
R4/stream	0.1439	0.0078	0.0131	2.3210	0.3219	0.0168	5.76	0.1654	0.2481	0.0007	0.06909	0.138	~~0.0276~~

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

zRMS comments:

For algae the EU agreed endpoint - ErC50 >2000 µg/L should be used. For the PEC/RAC calculations for algae the lover value at 85.9 µg/L (worse case) was used by Applicant. This was not corrected because it had no impact on the assessment result.

The acute and chronic risk to invertebrates and chronic risk to sediment-dwelling invertebrates considering exposure via water, based on Tier 1 EU agreed endpoints is covered by the refined risk assessment for aquatic invertebrates. Therefore PEC/RAC calculations with Tier 1 EU agreed endpoints were not assessed by zRMS.

Refinement of the risk assessment for invertebrates ~~and sediment-dwelling invertebrates considering exposure via sediment,~~ proposed by Applicant, should be considered on the MSs level.

Result of risk assessment with EU HC_5 for invertebrates ~~and refined endpoint for sediment-dwelling organisms considering exposure via sediment.~~

PEC/RAC based on refinement endpoints		
Scenario	**Surrogate crop**	**Acceptable -A Not acceptable - N**
Step 3, BBCH 56, 2 x 35 g as/ha		
D3 ditch		**N**
D4 pond		A
D4 stream		**N**
D5 pond		A
D5 stream		**N**
R1 pond		A
R1 stream		**N**
R3 stream		**N**
R4 stream		**N**
Step 4, BBCH 56, 2 x 35 g as/ha, 20 meters vegetative and no spray buffer zone		
D3 ditch		A
D4 pond		Accepted at Step 3
D4 stream		A
D5 pond		Accepted at Step 3
D5 stream		A
R1 pond		Accepted at Step 3
R1 stream		A
R3 stream		A
R4 stream		A
Step 3, BBCH 70, 2 x 35 g as/ha		
D3 ditch		**N**
D4 pond		A
D4 stream		**N**
D5 pond		A
D5 stream		**N**

R1 pond		A
R1 stream		A
R3 stream		**N**
R4 stream		A
Step 4, BBCH 70, 2 x 35 g as/ha, 20 meters buffer zone		
D3 ditch		A
D4 pond		Accepted at Step 3
D4 stream		A
D5 pond		Accepted at Step 3
D5 stream		A
R1 pond		Accepted at Step 3
R1 stream		Accepted at Step 3
R3 stream		A
R4 stream		Accepted at Step 3
Step 3, BBCH 87, 2 x 35 g as/ha		
D3 ditch		**N**
D4 pond		**N**
D4 stream		**N**
D5 pond		**N**
D5 stream		**N**
R1 pond		A
R1 stream		**N**
R3 stream		**N**
R4 stream		**N**
Step 4, BBCH 87, 2 x 35 g as/ha, 20 meters buffer zone		
D3 ditch		A
D4 pond		**N**
D4 stream		**N**
D5 pond		**Not calculated**
D5 stream		**N**
R1 pond		Accepted at Step 3

R1 stream		A
R3 stream		A
R4 stream		A

In summary:

For BBCH 56 at 2 x 35 g as/L
Step 3 risk is acceptable for:
- D4 pond, D5 pond, R1 pond scenarios;

Step 4 with 20 m VFS + 20 m buffer zone risk is acceptable for
- D3 ditch, D4 stream, D5 stream, R1 stream, R3 stream, R4 stream scenarios.

For BBCH 70 at 2 x 35 g as/L
Step 3 risk is acceptable for:
- D4 pond, D5 pond, R1 pond, R1 stream,R4 stream scenarios;

Step 4 with 20 m buffer zone risk is acceptable for:
- D3 ditch, D4 stream, D5 Stream, R3 stream scenarios;

For BBCH 87 at 2 x 35 g as/L
Step 3 risk is acceptable for:
- R1 pond scenario;

Step 4 with 20 m buffer zone risk is acceptable for:
- D3 ditch, R1 stream, R3 stream, R4 stream scenarios;
- **the risk for D4 pond, D4 stream, D5 stream scenarios (BBCH 87) is unresolved;**
- **the PEC/RAC for D5 pond scenario (BBCH 87) is not provided.**

Individual scenarios should be considered in accordance with the requirements of each Member State.

Result of risk assessment with refined HC5 for invertebrates ~~and refined endpoint for sediment-dwelling organisms considering exposure via sediment~~

PEC/RAC based on refinement endpoints		
Scenario	**Surrogate crop**	**Acceptable -A**

		Not acceptable - N
Step 3, BBCH 56, 2 x 35 g as/ha		
D3 ditch		N
D4 pond		A
D4 stream		N
D5 pond		A
D5 stream		N
R1 pond		A
R1 stream		N
R3 stream		N
R4 stream		N
Step 4, BBCH 56, 2 x 35 g as/ha,20 meters vegetative and no spray buffer zone		
D3 ditch		A
D4 pond		Accepted at Step 3
D4 stream		A
D5 pond		Accepted at Step 3
D5 stream		A
R1 pond		Accepted at Step 3
R1 stream		A
R3 stream		A
R4 stream		A
Step 3, BBCH 70, 2 x 35 g as/ha		
D3 ditch		N
D4 pond		A
D4 stream		N
D5 pond		A
D5 stream		N
R1 pond		A
R1 stream		A
R3 stream		N
R4 stream		A

Step 4, BBCH 70, 2 x 35 g as/ha, 20 meters buffer zone		
D3 ditch		A
D4 pond		Accepted at Step 3
D4 stream		A
D5 pond		Accepted at Step 3
D5 stream		A
R1 pond		Accepted at Step 3
R1 stream		Accepted at Step 3
R3 stream		A
R4 stream		Accepted at Step 3
Step 3, BBCH 87, 2 x 35 g as/ha		
D3 ditch		N
D4 pond		N
D4 stream		N
D5 pond		N
D5 stream		N
R1 pond		A
R1 stream		A
R3 stream		N
R4 stream		A
Step 4, BBCH 87, 2 x 35 g as/ha, 20 meters buffer zone		
D3 ditch		A
D4 pond		**N**
D4 stream		**N**
D5 pond		**Not calculated**
D5 stream		A
R1 pond		Accepted at Step 3
R1 stream		Accepted at Step 3
R3 stream		A
R4 stream		Accepted at Step 3

In summary:

For BBCH 56 at 2 x 35 g as/L
Step 3 risk is acceptable for:
- D4 pond, D5 pond, R1 pond scenarios

Step 4 with 20 meters vegetative and no spray buffer zone risk is acceptable for
- D3 ditch, D4 stream, D5 stream, R1 stream, R3 stream, R4 stream scenarios

For BBCH 70 at 2 x 35 g as/L
Step 3 risk is acceptable for:
- D4 pond, D5 pond, R1 pond, R1 stream,R4 stream scenarios;

Step 4 with 20 m buffer zone risk is acceptable for:
- D3 ditch, D4 stream, D5 Stream, R3 stream scenarios;

For BBCH 87 at 2 x 35 g as/L
Step 3 risk is acceptable for:
- R1 pond, R1 stream, R4 stream scenarios;

Step 4 with 20 m buffer zone risk is acceptable for:
- D3 ditch, D5 stream, R3 stream scenarios;
- **the risk for D4 pond, D4 stream scenarios (BBCH 87) is unresolved.**
- **the PEC/RAC for D5 pond scenario (BBCH 87) is not provided.**

Individual scenarios should be considered in accordance with the requirements of each Member State.

Potatoes, use no.:

1, Potatoes, BBCH 31-60, 2 x 12.5 g a.s./ha
8, Sweet Potato, BBCH 31-60, 2 x 12.5 g a.s./ha

9, Yams, BBCH 31-60, 2 x 12.5 g a.s./ha

Table 9.5-4: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for chlorantraniliprole for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CLOROL 200 SC in potatoes

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged
Test species		*Bluegill sunfish*	*Oncorhynchus mykiss*	*Daphnia magna*	*Daphnia magna*	*Pseudokirchn. subcapitata*	*Invertebrate*	*Invertebrate* acute and chronic SSD	*Lemna Gibba*		*Chironomus riparius*
Endpoint (µg/L)		LC_{50} 1840	NOEC 110	EC_{50} 6.2	NOEC 4.47	EC_{50} 85.9 > 2.000	HC5 2.61	HC5 2.91	EC50 2000		NOEC 25 5
AF		100	10	100	10	10	3	5	10		10
RAC (µg/L)		18.4	11	0.062	0.447	8.59 >200	0.87	0.58	200		2.5 0.5
FOCUS Scenario	$PEC_{gl\ max}$ (µg/L)									$PEC_{gl\ max}$ (µg/kg)	
Step 1											
-	6.18	0.3359	0.5618	99.6774	13.8255	0.7194	7.1034	10.6552	0.0309	18.36	7.3440
Step 2											
N-Europe	1.18	0.0641	0.1073	19.0323	2.6398	0.1374	1.3563	2.0345	0.0059	3.44	1.3760
Step 3											
D3/ditch	0.05717	0.0031	0.0052	0.9221	0.1279	0.0067	0.0657	0.0986	0.0003	0.02658	0.0106
D4/pond	0.2409	0.0131	0.0219	3.8855	0.5389	0.0280	0.2769	0.4153	0.0012	1.015	0.4060
D4/stream	0.2287	0.0124	0.0208	3.6887	0.5116	0.0266	0.2629	0.3943	0.0011	0.3648	0.1459
R1/pond	0.04992	0.0027	0.0045	0.8052	0.1117	0.0058	0.0574	0.0861	0.0002	0.1713	0.0685
R1/stream	0.3552	0.0193	0.0323	5.7290	0.7946	0.0414	0.4083	0.6124	0.0018	0.1831	0.0732

~~Group~~		~~Fish acute~~	~~Fish prolonged~~	~~Inverteb. acute~~	~~Inverteb. prolonged~~	~~Algae~~	~~Higher-tier information~~	~~Higher-tier information~~	~~Aquatic plants~~		~~Sed. dwell. prolonged~~
~~R3/stream~~	~~0.2494~~	~~0.0136~~	~~0.0227~~	~~4.0226~~	~~0.5579~~	~~0.0290~~	~~0.2867~~	~~0.4300~~	~~0.0012~~	~~0.1196~~	~~0.0478~~

Risk assessment was updates (with Legumes as surrogate crops for D5 and R4 scenarios) by Applicant as follows:

Group		**Fish acute**	**Fish pro-longed**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. Dwell. prolonged (aquatic phase)**	**Higher-tier information**	**Higher-tier information**	**Aquatic plants**		**Sed. dwell. prolonged**	**~~Higher Tier information for Sed. dwell. pro-longed~~**
Test species		***Bluegill sunfish***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchn. subcapitata***	***Chironomus riparius***	***Invertebrate***	***Invertebrate***	***Lemna Gibba***		***Chironomus riparius***	***~~Chironomus riparius~~***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	NOEC	HC5	HC5	EC50		NOEC	~~NOEC~~
(µg/L)		1840	110	6.2	4.47	85.9	0.25	2.61	2.91	2000		5	~~25~~
AF		100	10	100	10	10	10	3	5	10		10	~~10~~
RAC (µg/L)		18.4	11	0.062	0.447	8.59	0.025	0.87	0.58	200		0.5	~~2.5~~
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**										**PEC $_{gl-max}$ (µg/kg)**		
Step 1													
	6.18	0.3359	0.5618	99.6774	13.8255	0.7194	247.2	7.1034	10.6552	0.0309	18.36	36.720	~~7.3440~~
Step 2													
N-Europe	~~1.18~~ 1.16	~~0.0641~~ 0.0630	~~0.1073~~ 0.0105	19.0323	2.6398	~~0.1374~~ 0.1350	47.2	~~1.3563~~ 1.3333	~~2.0345~~ 2.0000	~~0.0059~~ 0.0058	3.44	~~8.880~~ 6.88	~~1.3760~~
Step 3 (application at BBCH 31)													
D3/ditch	0.05717	0.0031	0.0052	0.9221	0.1279	0.0067	2.29	0.0657	0.0986	0.0003	0.02658	0.053	~~0.0106~~
D4/pond	0.2409	0.0131	0.0219	3.8855	0.5389	0.0280	9.64	0.2769	0.4153	0.0012	1.015	2.030	~~0.4060~~

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. Dwell, prolonged (aquatic phase)	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell, prolonged	~~Higher-Tier information for Sed. dwell, pro-longed~~
D4/stream	0.2287	0.0124	0.0208	3.6887	0.5116	0.0266	9.15	0.2629	0.3943	0.0011	0.3648	0.730	~~0.1459~~
R1/pond	~~0.04992~~ 0.04922	0.0027	0.0045	0.8052	0.1117	0.0058	2.00	0.0574	0.0861	0.0002	0.1713	0.343	~~0.0685~~
R1/stream	0.3552	0.0193	0.0323	5.7290	0.7946	0.0414	14.21	0.4083	0.6124	0.0018	0.1831	0.366	~~0.0732~~
R3/stream	0.2494	0.0136	0.0227	4.0226	0.5579	0.0290	9.98	0.2867	0.4300	0.0012	0.1196	0.239	~~0.0478~~
		Legumes as a surrogate crops for potato for D5 and R4 scenario											
D5/pond	0.1118	0.0061	0.0102	1.8032	0.2501	0.0130	4.47	0.1285	0.1928	0.0006	0.6050	1.210	~~0.2420~~
D5/stream	0.08324	0.0045	0.0076	1.3426	0.1862	0.0097	3.33	0.0957	0.1435	0.0004	0.1339	0.268	~~0.0536~~
R4/stream	0.2504	0.0136	0.0228	4.0387	0.5602	0.0292	10.02	0.2878	0.4317	0.0013	0.09231	0.185	~~0.0369~~
		Step 3 (application at BBCH 60)											
D3/ditch	0.05711	0.0031	0.0052	0.9211	0.1278	0.0066	2.28	0.0656	0.0985	0.0003	0.02756	0.055	~~0.0110~~
D4/pond	0.1927	0.0105	0.0175	3.1081	0.4311	0.0224	7.71	0.2215	0.3322	0.0010	0.7838	1.568	~~0.3135~~
D4/stream	0.1856	0.0101	0.0169	2.9935	0.4152	0.0216	7.42	0.2133	0.3200	0.0009	0.2883	0.577	~~0.1153~~
R1/pond	0.04234	0.0023	0.0038	0.6829	0.0947	0.0049	1.69	0.0487	0.0730	0.0002	0.1361	0.272	~~0.0544~~
R1/stream	0.2592	0.0141	0.0236	4.1806	0.5799	0.0302	10.37	0.2979	0.4469	0.0013	0.1261	0.252	~~0.0504~~
R3/stream	0.3623	0.0197	0.0329	5.8435	0.8105	0.0422	14.49	0.4164	0.6247	0.0018	0.1705	0.341	~~0.0682~~
		Legumes as a surrogate crops for potato for D5 and R4 scenario											
D5/pond	0.07830	0.0043	0.0071	1.2629	0.1752	0.0091	12.40	0.0900	0.1350	0.0004	0.4673	0.935	~~0.1869~~
D5/stream	0.05648	0.0031	0.0051	0.9110	0.1264	0.0066	9.20	0.0649	0.0974	0.0003	0.1022	0.204	~~0.0409~~
R4/stream	0.3474	0.0189	0.0316	5.6032	0.7772	0.0404	55.60	0.3993	0.5990	0.0017	0.1441	0.288	~~0.0576~~

zRMS comments:

For algae the EU agreed endpoint - ErC50 >2000 µg/L should be used. For the PEC/RAC calculations for algae the lover value at 85.9 µg/L (worse case) was used by Applicant. This was not corrected because it had no impact on the assessment result.

The acute and chronic risk to invertebrates and chronic risk to sediment-dwelling invertebrates considering exposure via water, based on Tier 1 EU agreed endpoints is covered by the refined risk assessment for aquatic invertebrates. Therefore PEC/RAC calculations with Tier 1 EU agreed endpoints were not assessed by zRMS.

Refinement of the risk assessment for invertebrates ~~and sediment-dwelling invertebrates considering exposure via sediment~~, proposed by Applicant, should be considered on the MSs level.

Result of risk assessment with EU HC_5 for invertebrates ~~and refined endpoint for sediment-dwelling organisms considering exposure via sediment.~~

PEC/RAC based on refinement endpoints		
Scenario	**Surrogate crop**	**Acceptable -A Not acceptable - N**
Step 3, BBCH 31, 2 x 12.5 g as/ha		
D3 ditch		A
D4 pond		A
D4 stream		A
D5 pond	Legumes	A
D5 stream	Legumes	A
R1 pond		A
R1 stream		A
R3 stream		A
R4 stream	Legumes	A
Step 3, BBCH 60, 2 x 12.5 g as/ha		
D3 ditch		A
D4 pond		A
D4 stream		A
D5 pond	Legumes	A
D5 stream	Legumes	A
R1 pond		A
R1 stream		A
R3 stream		A

R4 stream	Legumes	A

In summary:

For BBCH 31 at 2 x 12.5 g as/L
At Step 3 risk is acceptable for all scenarios.

For BBCH 60 at 2 x 12.5 g as/L
At Step 3 risk is acceptable for all scenarios.

Individual scenarios should be considered in accordance with the requirements of each Member State.

Result of risk assessment with refined HC5 for invertebrates ~~and refined endpoint for sediment-dwelling organisms considering exposure via sediment~~

PEC/RAC based on refinement endpoints		
Scenario	**Surrogate crop**	**Acceptable -A Not acceptable - N**
Step 3, BBCH 31, 2 x 12.5 g as/ha		
D3 ditch		A
D4 pond		A
D4 stream		A
D5 pond	Legumes	A
D5 stream	Legumes	A
R1 pond		A
R1 stream		A
R3 stream		A
R4 stream	Legumes	A
Step 3, BBCH 60, 2 x 12.5 g as/ha		
D3 ditch		A
D4 pond		A
D4 stream		A

D5 pond	Legumes	A
D5 stream	Legumes	A
R1 pond		A
R1 stream		A
R3 stream		A
R4 stream	Legumes	A

In summary:

For BBCH 31 at 2 x 12.5 g as/L
At Step 3 risk is acceptable for all scenarios.

For BBCH 60 at 2 x 12.5 g as/L
At Step 3 risk is acceptable for all scenarios.

Individual scenarios should be considered in accordance with the requirements of each Member State.

Fruiting vegetables, use no:
33, Pumpkin, 1 x 35 g as/ha, BBCH 61-65, F
65 Cucumber 2 x 50 g as/ha, BBCH 15-49 G,
66 Pepper, 2 x 43 g as/ha, BBCH 15-49, G
67, Tomato, 2 x 63 g/ha, BBCH 15-49
83, Melon, 2 x 50 g as/ha, BBCH 15-89, G
84, Aubergine, 2 x 50 g as/ha, BBCH 15-89, G
85, Okra, 2 x 43 g as/ha, BBCH 15-89, G
86, Watermelon, 2 x 50 g as/ha, BBCH 15-89, G
87, Zucchini, 2x50 g as/ha, BBCH 15-89, G
88, Gherkins, 2 x 50 g as/ha, BBCH 15-89, G
89, Curgettes, 2 x 50 g as/ha, BBCH 15-89, G
90, Spaghetti squash, 2 x 50 g as/ha, BBCH 15-89, G
91, Giant pumpkin, 2 x 50 g as/ha, BBCH 15-89, G
92, Canada crookneck, 2 x 50 g/ha, BBCH 15-89, G

93, Pumpkin, 2 x 50 g as/ha, BBCH 15-89, G
33, Pumpkin, 1 x 35 g as/ha, BBCH 61-65, F
94, Cucumber, 2 x 50 g as/ha, BBCH 15-89, G
95, Bush squash, 2 x 50 g as/ha, BBCH 15-89, G

Table 9.5-5: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for chlorantraniliprole for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CLOROL 200 SC in fruiting vegetables

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged
Test species		*Bluegill sunfish*	*Oncorhynchus mykiss*	*Daphnia magna*	*Daphnia magna*	*Pseudokirchn. subcapitata*	*Invertebrate*	*Invertebrate*	*Lemna Gibba*		*Chironomus riparius*
Endpoint (µg/L)		LC_{50} 1840	NOEC 110	EC_{50} 6.2	NOEC 4.47	EC_{50} 85.9	HC5 2.61	HC5 2.91	EC50 2000		NOEC 25
AF		100	10	100	10	10	3	5	10		10
RAC (µg/L)		18.4	11	0.062	0.447	8.59	0.87	0.58	200		2.5
FOCUS Scenario	$PEC_{gl\ max}$ (µg/L)									$PEC_{gl\ max}$ (µg/kg)	
Step 1											
-	31.13	1.6918	2.8300	502.0968	69.6421	3.6240	35.7816	53.6724	0.1557	92.52	37.0080
Step 2											
N-Europe	4.18	0.2272	0.3800	67.4194	9.3512	0.4866	4.8046	7.2069	0.0209	15.57	6.2280
Step 3											
R3/stream	1.953	0.1061	0.1775	31.5000	4.3691	0.2274	2.2448	3.3672	0.0098	0.8446	0.3378
R4/stream	2.584	0.1404	0.2349	41.6774	5.7808	0.3008	2.9701	4.4552	0.0129	0.9254	0.3702
Step 4 – 20 meters buffer zone											

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged
R3/stream	0.4670	0.0254	0.0425	7.5323	1.0447	0.0544	0.5368	0.8052	0.0023	0.1786	0.0714
R4/stream	0.6050	0.0329	0.0550	9.7581	1.3535	0.0704	0.6954	1.0431	0.0030	0.2114	0.0846
Step 3											
D3/ditch	0.2901	0.0158	0.0264	4.6790	0.6490	0.0338	0.3334	0.5002	0.0015	0.1385	0.0554
D4/pond	1.047	0.0569	0.0952	16.8871	2.3423	0.1219	1.2034	1.8052	0.0052	4.581	1.8324
D4/stream	0.9535	0.0518	0.0867	15.3790	2.1331	0.1110	1.0960	1.6440	0.0048	1.580	0.6320
D6/ditch	0.4220	0.0229	0.0384	6.8065	0.9441	0.0491	0.4851	0.7276	0.0021	0.7963	0.3185
R1/pond	0.1561	0.0085	0.0142	2.5177	0.3492	0.0182	0.1794	0.2691	0.0008	0.5295	0.2118
R1/stream	1.257	0.0683	0.1143	20.2742	2.8121	0.1463	1.4448	2.1672	0.0063	0.5068	0.2027
R2/stream	0.8724	0.0474	0.0793	14.0710	1.9517	0.1016	1.0028	1.5041	0.0044	0.3178	0.1271
R3/stream	1.650	0.0897	0.1500	26.6129	3.6913	0.1921	1.8966	2.8448	0.0083	0.5087	0.2035
Step 4 – 20 meters buffer zone											
D3/ditch	0.02766	0.0015	0.0025	0.4461	0.0619	0.0032	0.0318	0.0477	0.0001	0.07239	0.0290
D4/stream	1.045	0.0568	0.0950	16.8548	2.3378	0.1217	1.2011	1.8017	0.0052	4.561	1.8244
D4/stream	0.9535	0.0518	0.0867	15.3790	2.1331	0.1110	1.0960	1.6440	0.0048	1.580	0.6320
D6/ditch	0.4220	0.0229	0.0384	6.8065	0.9441	0.0491	0.4851	0.7276	0.0021	0.7950	0.3180
R1/pond	0.03504	0.0019	0.0032	0.5652	0.0784	0.0041	0.0403	0.0604	0.0002	0.1256	0.0502
R1/stream	0.2977	0.0162	0.0271	4.8016	0.6660	0.0347	0.3422	0.5133	0.0015	0.1134	0.0454
R2/stream	0.2026	0.0110	0.0184	3.2677	0.4532	0.0236	0.2329	0.3493	0.0010	0.06631	0.0265
R4/stream	0.3918	0.0213	0.0356	6.3194	0.8765	0.0456	0.4503	0.6755	0.0020	0.1185	0.0474
Step 3 – Step 3 for potatoes as surrogate crop according to polish national requirements – for dose 2x 50 g as/ha											

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged
D3/ditch	0.2901	0.0158	0.0264	4.6790	0.6490	0.0338	0.3334	0.5002	0.0015	0.1086	0.0434
D4/pond	1.047	0.0569	0.0952	16.8871	2.3423	0.1219	1.2034	1.8052	0.0052	3.621	1.4484
D4/stream	0.9535	0.0518	0.0867	15.3790	2.1331	0.1110	1.0960	1.6440	0.0048	1.252	0.5008
D6/ditch	0.4220	0.0229	0.0384	6.8065	0.9441	0.0491	0.4851	0.7276	0.0021	0.6243	0.2497
R1/pond	0.1561	0.0085	0.0142	2.5177	0.3492	0.0182	0.1794	0.2691	0.0008	0.4227	0.1691
R1/stream	1.257	0.0683	0.1143	20.2742	2.8121	0.1463	1.4448	2.1672	0.0063	0.4044	0.1618
R2/stream	0.8724	0.0474	0.0793	14.0710	1.9517	0.1016	1.0028	1.5041	0.0044	0.2518	0.1007
R3/stream	1.650	0.0897	0.1500	26.6129	3.6913	0.1921	1.8966	2.8448	0.0083	0.4041	0.1616
Step 4 – Step 4 for potatoes as surrogate crop according to polish national requirements for dose 2x 50 g as/ha – 20 meters buffer zone											
D3/ditch	0.02766	0.0015	0.0025	0.4461	0.0619	0.0032	0.0318	0.0477	0.0001	0.05230	0.0209
D4/stream	1.045	0.0568	0.0950	16.8548	2.3378	0.1217	1.2011	1.8017	0.0052	3.604	1.4416
D4/stream	0.9535	0.0518	0.0867	15.3790	2.1331	0.1110	1.0960	1.6440	0.0048	1.252	0.5008
D6/ditch	0.4220	0.0229	0.0384	6.8065	0.9441	0.0491	0.4851	0.7276	0.0021	0.6232	0.2493
R1/pond	0.03504	0.0019	0.0032	0.5652	0.0784	0.0041	0.0403	0.0604	0.0002	0.1004	0.0402
R1/stream	0.2977	0.0162	0.0271	4.8016	0.6660	0.0347	0.3422	0.5133	0.0015	0.09032	0.0361
R2/stream	0.2026	0.0110	0.0184	3.2677	0.4532	0.0236	0.2329	0.3493	0.0010	0.05243	0.0210
R4/stream	0.3918	0.0213	0.0356	6.3194	0.8765	0.0456	0.4503	0.6755	0.0020	0.09412	0.0376

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

Risk assessment was updates (with Legumes as surrogate crops for D5 scenario and with potatoes as surrogate crop for D3, D4, D6, R1, R2 and R3 scenarios and with reduced doses) by Applicant as follows:

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. Dwell, prolonged (aquatic phase)**	**Higher-tier information**	**Higher-tier information**	**Aquatic plants**		**Sed. dwell. prolonged**	~~**Higher Tier information for Sed. dwell. prolonged**~~
Test species		***Bluegill sunfish***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchn. subcapitata***	***Chironomus riparius***	***Invertebrate* acute and chronic SSD**	***Invertebrate* acute and chronic SSD**	***Lemna Gibba***		***Chironomus riparius***	~~***Chironomus riparius***~~
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	NOEC	HC5	HC5	EC50		NOEC	~~NOEC~~
(µg/L)		1840*	110	6.2	4.47	85.9**	0.25	2.61	2.91	2000		5	~~25~~
AF		100	10	100	10	10	10	3	5	10		10	~~10~~
RAC (µg/L)		18.4	11	0.062	0.447	8.59	0.025	0.87	0.58	200		0.5	~~2.5~~
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**										**PEC $_{gl-max}$ (µg/kg)**		
Step 1													
	31.13	1.6918	2.8300	502.0968	69.6421	3.6240	1252	35.7816	53.6724	0.1557	92.52	185.040	~~37.0080~~
Step 2													
N-Europe	~~4.18~~ 5.26	0.2272	0.3800	67.4194	9.3512	0.4866	167.2	4.8046	7.2069	0.0209	15.57	31.140	~~6.2280~~
	Step 3 (application at BBCH 15) for doses 2 x 63 g/ha												
R3/stream	1.953	0.1061	0.1775	31.5000	4.3691	0.2274	78.12	2.2448	3.3672	0.0098	0.8446	1.689	~~0.3378~~
R4/stream	2.584	0.1404	0.2349	41.6774	5.7808	0.3008	103.36	2.9701	4.4552	0.0129	0.9254	1.851	~~0.3702~~
	Step 3 - for legumes as surrogate crop for vegetables fruiting for D5 scenario (application at BBCH 15) for doses 2 x 63 g/ha												

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. Dwell, prolonged (aquatic phase)	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell, prolonged	~~Higher-Tier information for Sed. dwell, pro-longed~~
D5/pond	0.6086	0.0331	0.0553	9.8161	1.3615	0.0708	24.34	0.6995	1.0493	0.0030	3.187	6.374	~~1.2748~~
D5/stream	0.4551	0.0247	0.0414	7.3403	1.0181	0.0530	18.20	0.5231	0.7847	0.0023	0.7040	1.408	~~0.2816~~
	Step 3 - for potatoes as surrogate crop according to polish national requirements (application at BBCH 15) for doses 2 x 63 g/ha												
D3/ditch	0.2901	0.0158	0.0264	4.6790	0.6490	0.0338	11.60	0.3334	0.5002	0.0015	0.1385	0.277	~~0.0554~~
D4/pond	1.047	0.0569	0.0952	16.8871	2.3423	0.1219	41.88	1.2034	1.8052	0.0052	4.581	9.162	~~1.8324~~
D4/stream	0.9535	0.0518	0.0867	15.3790	2.1331	0.1110	38.14	1.0960	1.6440	0.0048	1.580	3.160	~~0.6320~~
D6/ditch	0.4220	0.0229	0.0384	6.8065	0.9441	0.0491	16.88	0.4851	0.7276	0.0021	0.7963	1.593	~~0.3185~~
R1/pond	0.1561	0.0085	0.0142	2.5177	0.3492	0.0182	6.24	0.1794	0.2691	0.0008	0.5295	1.059	~~0.2118~~
R1/stream	1.257	0.0683	0.1143	20.2742	2.8121	0.1463	50.28	1.4448	2.1672	0.0063	0.5068	1.014	~~0.2027~~
R2/stream	0.8724	0.0474	0.0793	14.0710	1.9517	0.1016	34.90	1.0028	1.5041	0.0044	0.3178	0.636	~~0.1271~~
~~R3/stream~~	~~1.650~~	~~0.0897~~	~~0.1500~~			~~0.1921~~		~~1.8966~~	~~2.8448~~	~~0.0083~~	~~0.5087~~	~~1.017~~	~~0.2035~~
	Step 4 – 20 meters buffer zone (application at BBCH 15) for doses 2 x 63 g/ha												
R3/stream	0.4670	0.0254	0.0425	7.5323	1.0447	0.0544	18.68	0.5368	0.8052	0.0023	0.1786	0.357	~~0.0714~~
R4/stream	0.6050	0.0329	0.0550	9.7581	1.3535	0.0704	24.20	0.6954	1.0431	0.0030	0.2114	0.423	~~0.0846~~
	Step 4 - for potatoes as surrogate crop according to polish national requirements – 20 meters buffer zone (application at BBCH 15) for dose 2 x 63 g as/ha												
D3/ditch	0.02766	0.0015	0.0025	0.4461	0.0619	0.0032	1.11	0.0318	0.0477	0.0001	0.07239	0.145	~~0.0290~~
D4/~~stream~~ pond	1.045	0.0568	0.0950	16.8548	2.3378	0.1217	41.80	1.2011	1.8017	0.0052	4.561	9.122	~~1.8244~~
D4/stream	0.9535	0.0518	0.0867	15.3790	2.1331	0.1110	38.14	1.0960	1.6440	0.0048	1.580	3.160	~~0.6320~~
D6/ditch	0.4220	0.0229	0.0384	6.8065	0.9441	0.0491	16.88	0.4851	0.7276	0.0021	0.7950	1.590	~~0.3180~~
R1/pond	0.03504	0.0019	0.0032	0.5652	0.0784	0.0041	1.40	0.0403	0.0604	0.0002	0.1256	0.251	~~0.0502~~

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. Dwell, prolonged (aquatic phase)	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell, prolonged	~~Higher-Tier information for Sed. dwell, pro-longed~~
R1/stream	0.2977	0.0162	0.0271	4.8016	0.6660	0.0347	11.91	0.3422	0.5133	0.0015	0.1134	0.227	~~0.0454~~
R2/stream	0.2026	0.0110	0.0184	3.2677	0.4532	0.0236	8.10	0.2329	0.3493	0.0010	0.06631	0.133	~~0.0265~~
~~R4/stream~~	~~0.3918~~	~~0.0213~~	~~0.0356~~			~~0.0456~~		~~0.4503~~	~~0.6755~~	~~0.0020~~	~~0.1185~~	~~0.237~~	~~0.0474~~
	Step 3 - for potatoes as surrogate crop according to polish national requirements – for dose 2x 50 g as/ha (application at BBCH 15)												
D3/ditch	~~0.2901~~ 0.2301	~~0.0158~~ 0.013	~~0.0264~~ 0.021	4.6790	0.6490	~~0.0338~~ 0.027	11.60	~~0.3334~~ 0.264	~~0.5002~~ 0.397	~~0.0015~~ 0,0012	0.1086	0.217	~~0.0434~~
D4/pond	~~1.047~~ 0.8265	~~0.0569~~ 0,045	~~0.0952~~ 0,075	16.8871	2.3423	~~0.1219~~ 0,096	41.88	~~1.2034~~ 0,95	~~1.8052~~ 1.425	~~0.0052~~ 0.004	3.621	7.242	~~1.4484~~
D4/stream	~~0.9535~~ 0.7542	~~0.0518~~ 0,041	~~0.0867~~ 0,069	15.3790	2.1331	~~0.1110~~ 0.09	38.14	~~1.0960~~ 0,867	~~1.6440~~ 1.300	~~0.0048~~ 0,004	1.252	2.504	~~0.5008~~
D6/ditch	0.4220	0.0229	0.0384	6.8065	0.9441		16.88				0.6243	1.249	~~0.2497~~
R1/pond	~~0.1561~~ 0.1238	~~0.0085~~ 0.0067	~~0.0142~~ 0.011	2.5177	0.3492	~~0.0182~~ 0.014	6.24	~~0.1794~~ 0.1423	~~0.2691~~ 0.213	~~0.0008~~ 0.0006	0.4227	0.845	~~0.1691~~
R1/stream	~~1.257~~ 0.9904	~~0.0683~~ 0,054	~~0.1143~~ 0,1143	20.2742	2.8121	~~0.1463~~ 0.115	50.28	1.4448 1.1384	~~2.1672~~ 1.708	~~0.0063~~ 0.005	0.4044	0.809	~~0.1618~~
R2/stream	0.8724	0.0474	0.0793	14.0710	1.9517	0.1016	34.90	1.0028	1.5041	0.0044	0.2518	0.504	~~0.1007~~
~~R3/stream~~	~~1.650~~	~~0.0897~~	~~0.1500~~			~~0.1921~~		~~1.8966~~	~~2.8448~~	~~0.0083~~	~~0.4041~~	~~0.808~~	~~0.1616~~
	Step 4 – for potatoes as surrogate crop according to polish national requirements for dose 2x 50 g as/ha - 20 meters buffer zone, BBCH 15												
D3/ditch	~~0.02766~~ 0.02164	~~0.0015~~ 0.001	~~0.0025~~ 0.002	0.4461	0.0619	~~0.0032~~ 0.0025	1.11	~~0.0318~~ 0.025	~~0.0477~~ 0.037	0.0001	0.05230	0.105	~~0.0209~~
D4/~~stream~~ pond	~~1.045~~ 0.8249	~~0.0568~~ 0.045	~~0.0950~~ 0.075	16.8548	2.3378	~~0.1217~~ 0.096	41.80	~~1.2011~~ 0.948	~~1.8017~~ 1.42	0.0052	3.604	7.208	~~1.4416~~
D4/stream	~~0.9535~~ 0.7542	~~0.0518~~ 0.041	~~0.0867~~ 0.069	15.3790	2.1331	~~0.1110~~ 0.088	38.14	~~1.0960~~ 0.867	~~1.6440~~ 1.300	~~0.0048~~ 0.0038	1.252	2.504	~~0.5008~~

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. Dwell, prolonged (aquatic phase)	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell, prolonged	~~Higher-Tier information for Sed. dwell, pro-longed~~
D6/ditch	0.4220	0.0229	0.0384	6.8065	0.9441	0.0491	16.88	0.4851	0.7276	0.0021	0.6232	1.246	~~0.2493~~
R1/pond	~~0.03504~~ 0.02781	~~0.0019~~ 0.0015	~~0.0032~~ 0.0025	0.5652	0.0784	~~0.0041~~ 0.0032	1.40	~~0.0403~~ 0.0320	~~0.0604~~ 0.048	~~0.0002~~ 0.0001	0.1004	0.201	~~0.0402~~
R1/stream	~~0.2977~~ 0.2345	~~0.0162~~ 0.013	~~0.0271~~ 0.0213	4.8016	0.6660	~~0.0347~~ 0.0273	11.91	~~0.3422~~ 0.2695	~~0.5133~~ 0.4043	0.0015	0.09032	0.181	~~0.0361~~
R2/stream	0.2026	0.0110	0.0184	3.2677	0.4532	0.0236	8.10	0.2329	0.3493	0.0010	0.05243	0.105	~~0.0210~~
~~R4/stream~~	~~0.3918~~	~~0.0213~~	~~0.0356~~			~~0.0456~~		~~0.4503~~	~~0.6755~~	~~0.0020~~	~~0.09412~~	~~0.188~~	~~0.0376~~
	Step 3 (application at BBCH 89) for dose 2x 63g as/ha												
R3/stream	2.047	0.1113	0.1861	33.0161	4.5794	0.2383	81.88	2.3529	3.5293	0.0102	1.178	2.356	~~0.4712~~
R4/stream	4.039	0.2195	0.3672	65.1452	9.0358	0.4702	161.56	4.6425	6.9638	0.0202	1.274	2.548	~~0.5096~~
	Step 3 - for legumes as surrogate crop for vegetables fruiting for D5 scenario (application at BBCH 89) for dose 2x 63 g as/ha												
D5/pond	0.9745	0.0530	0.0886	15.7177	2.1801	0.1134	38.98	1.1201	1.6802	0.0049	4.764	9.528	~~1.9056~~
D5/stream	0.7703	0.0419	0.0700	12.4242	1.7233	0.0897	30.81	0.8854	1.3281	0.0039	1.041	2.082	~~0.4164~~
	Step 3 - for potatoes as surrogate crop according to polish national requirements (application at BBCH 89) for dose 2x 63 g as/ha												
D3/ditch	0.2910	0.0158	0.0265	4.6935	0.6510	0.0339	11.64	0.3345	0.5017	0.0015	0.1448	0.290	~~0.0579~~
D4/pond	1.928	0.1048	0.1753	31.0968	4.3132	0.2244	77.12	2.2161	3.3241	0.0096	7.315	14.630	~~2.9260~~
D4/stream	1.980	0.1076	0.1800	31.9355	4.4295	0.2305	79.20	2.2759	3.4138	0.0099	2.698	5.396	~~1.0792~~
R1/pond	0.2150	0.0117	0.0195	3.4677	0.4810	0.0250	8.60	0.2471	0.3707	0.0011	0.8295	1.659	~~0.3318~~
R1/stream	1.931	0.1049	0.1755	31.1452	4.3199	0.2248	77.24	2.2195	3.3293	0.0097	0.4888	0.978	~~0.1955~~
	Step 3 (application at BBCH 89) 1x50g												
R3/stream	1.220	0.066	0.111	19.677	2.729	0.142	48.80	1.402	2.103	0.066	0.9411	1.882	~~0.37644~~
R4/stream	1.400	0.076	0.127	22.581	3.132	0.163	56.00	1.609	2.414	0.076	0.4345	0.869	~~0.17380~~

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. Dwell, prolonged (aquatic phase)	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell, prolonged	~~Higher-Tier information for Sed. dwell, pro-longed~~
	Step 3 for legumes as surrogate crop for vegetables fruiting for D5 scenario (application at BBCH 89) 1x50g												
D5/pond	0.3289	0.018	0.030	5.305	0.736	0.038	13.16	0.378	0.567	0.018	1.605	3.210	~~0.642~~
D5/stream	0.2637	0.014	0.024	4.253	0.590	0.031	10.55	0.303	0.455	0.014	0.3473	0.695	~~0.139~~
	Step 4 for dose 1x50 g as/ha (application at BBCH 89) 10 m vegetative strip and 10 m buffer zone												
R3/stream	0.5568	0.030	0.051	8.981	1.246	0.065	22.27	0.640	0.960	0.030	0.2605	0.521	~~0.104~~
R4/stream	0.6365	0.035	0.058	10.266	1.424	0.074	25.46	0.732	1.097	0.035	0.1932	0.386	~~0.077~~
	Step 4 for dose 1x50 g as/ha (application at BBCH 89) 20 m vegetative strip and 10 m buffer zone												
R4/stream	0.3336	0.018	0.030	5.381	0.746	0.039	13.3	0.383	0.575	0.018	0.1021	0.204	~~0.041~~
	Step 3 - for potatoes as surrogate crop according to polish national requirements – for dose 1x50 g as/ha (application at BBCH 89)												
D3/ditch	0.2628	0.0143	0.0239	4.2387	0.5879	0.0306	10.51	0.3021	0.4531	0.0013	0.08790	0.176	~~0.0352~~
D4/pond	0.7506	0.0408	0.0682	12.1065	1.6792	0.0874	30.02	0.8628	1.2941	0.0038	2.870	5.740	~~1.1480~~
D4/stream	0.7595	0.0413	0.0690	12.2500	1.6991	0.0884	30.38	0.8730	1.3095	0.0038	1.066	2.132	~~0.4264~~
R1/pond	0.05337	0.0029	0.0049	0.8608	0.1194	0.0062	2.13	0.0613	0.0920	0.0003	0.2310	0.462	~~0.0924~~
R1/stream	0.9497	0.0516	0.0863	15.3177	2.1246	0.1106	37.99	1.0916	1.6374	0.0047	0.2082	0.416	~~0.0833~~
	Step 4 - for potatoes as surrogate crop according to polish national requirements – for dose 1x50 g as/ha – 10 m vegetative strip and 10 meters buffer zone (application at BBCH 89)												
D4/pond	0.7491	0.0407	0.0681	12.0823	1.6758	0.0872	29.96	0.8610	1.2916	0.0037	2.862	5.724	~~1.1448~~
D4/stream	0.7595	0.0413	0.0690	12.2500	1.6991	0.0884	30.38	0.8730	1.3095	0.0038	1.066	2.132	~~0.4264~~
R1/~~pond~~ stream	0.4245	0.0231	0.0386	6.8468	0.9497	0.0494	16.98	0.4879	0.7319	0.0021	0.09296	0.186	~~0.0372~~
	Step 3 (Step 3 (application at BBCH 15) 1x50g)												
R3/stream	0.8766	0.0476	0.0797	14.1387	1.9611	0.1020	35.06	1.0076	1.5114	0.0044	0.3540	0.708	~~0.142~~

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. Dwell, prolonged (aquatic phase)	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged	~~Higher-Tier information for Sed. dwell. pro-longed~~
R4/stream	1.442	0.0784	0.1311	23.2581	3.2260	0.1679	57.68	1.6575	2.4862	0.0072	0.5221	1.044	~~0.209~~
	Step 3 for legumes as surrogate crop for vegetables fruiting for D5 scenario (application at BBCH 15) 1x50g												
D5/pond	0.2371	0.0129	0.0216	3.8242	0.5304	0.0276	9.48	0.2725	0.4088	0.0012	1.255	2.510	~~0.502~~
D5/stream	0.2497	0.0136	0.0227	4.0274	0.5586	0.0291	9.99	0.2870	0.4305	0.0012	0.2770	0.554	~~0.111~~
	Step 3 for potatoes as surrogate crop according to polish national requirements – for dose 1x50 g as/ha (application at BBCH 15)												
D3/ditch	0.2632	0.0143	0.0239	4.2452	0.5888	0.0306	10.53	0.3025	0.4538	0.0013	0.1021	0.204	~~0.041~~
D4/pond	0.4002	0.0218	0.0364	6.4548	0.8953	0.0466	16.01	0.4600	0.6900	0.0020	1.764	3.528	~~0.706~~
D4/stream	0.3670	0.020	0.033	5.919	0.821	0.043	14.68	0.422	0.633	0.0018	0.6135	1.227	~~0.245~~
R1/pond	0.07976	0.004	0.007	1.286	0.178	0.009	3.19	0.092	0.138	0.0004	0.2670	0.534	~~0.107~~
R1/stream	1.038	0.056	0.094	16.742	2.322	0.121	41.52	1.193	1.790	0.0052	0.3196	0.639	~~0.128~~
	Step 4 for dose 1x50 g as/ha (application at BBCH 15) 10 m vegetative strip and 10 m buffer zone												
R3/stream	0.3997	0.0217	0.0363	6.4468	0.8942	0.0465	15.99	0.4594	0.6891	0.0020	0.1519	0.304	~~0.061~~
R4/stream	0.6525	0.0355	0.0593	10.5242	1.4597	0.0760	26.10	0.7500	1.1250	0.0033	0.2282	0.456	~~0.091~~
	Step 4 for dose 1x50 g as/ha (application at BBCH 15) 20 m vegetative strip and 10 m buffer zone												
R4/stream	0.3411	0.0185	0.0310	5.5016	0.7631	0.0397	13.6	0.3921	0.5881	0.0017	0.1199	0.240	~~0.048~~
	Step 4 for potatoes as surrogate crop according to polish national requirements – for dose 1x50 g as/ha (application at BBCH 15) 10 m vegetative strip and 10 m buffer zone												
R1/stream	0.4703	0.0256	0.0428	7.5855	1.0521	0.0547	18.8	0.5406	0.8109	0.0024	0.1334	0.267	~~0.053~~

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

zRMS comments:

For algae the EU agreed endpoint - ErC50 >2000 µg/L should be used. For the PEC/RAC calculations for algae the lover value at 85.9 µg/L (worse case) was used by Applicant. This was not corrected because it had no impact on the assessment result.

The acute and chronic risk to invertebrates and chronic risk to sediment-dwelling invertebrates considering exposure via water, based on Tier 1 EU agreed endpoints is covered by the refined risk assessment for aquatic invertebrates. Therefore PEC/RAC calculations with Tier 1 EU agreed endpoints were not assessed by zRMS.

The initial dose of 2 x 63 g as/ha for fruiting vegetables, used for calculations PEC/RAC, indicated unacceptable risk. Therefore, the dose was reduced up to 1 x 50 g as/ha.

Refinement of the risk assessment for invertebrates ~~and sediment-dwelling invertebrates considering exposure via sediment~~, proposed by Applicant, should be considered on the MSs level.

Results of risk assessment with EU HC_5 for invertebrates ~~and refined endpoint for sediment-dwelling organisms considering exposure via sediment~~.

PEC/RAC based on refinement endpoints		
Scenario	**Surrogate crop**	**Acceptable -A Not acceptable - N**
Step 3, BBCH 15, 1 x 50 g as/ha		
R3 stream		**N**
R4 stream		**N**
D5 pond	Legumes	A
D5 stream	Legumes	A
D3 ditch	Potatoes	A
D4 pond	Potatoes	A
D4 stream	Potatoes	A
R1 pond	Potatoes	A
R1 stream	Potatoes	**N**
Step 4 BBCH 15, 1 x 50 g as/ha – 10 m VFS + 10 m buffer zone		
R3 stream		A
R4 stream		**N**
D5 pond	Legumes	Accepted at step 3
D5 stream	Legumes	Accepted at step 3
D3 ditch	Potatoes	Accepted at step 3
D4 pond	Potatoes	Accepted at step 3
D4 stream	Potatoes	Accepted at step 3

R1 pond	Potatoes	Accepted at step 3
R1 stream	Potatoes	A

Step 4 BBCH 15, 1 x 50 g as/ha – 20 m VFS + 10 m buffer zone		
R4 stream		A

PEC/RAC based on refinement endpoints		
Scenario	**Surrogate crop**	**Acceptable -A No acceptable - N**
Step 3, BBCH 89, 1 x 50 g as/ha		
R3 stream		**N**
R4 stream		**N**
D5 pond	Legumes	A
D5 stream	Legumes	A
D3 ditch	Potatoes	A
D4 pond	Potatoes	**N**
D4 stream	Potatoes	**N**
R1 pond	Potatoes	A
R1 stream	Potatoes	**N**
Step 4 BBCH 89, 1 x 50 g as/ha – 10 m VFS + 10 m buffer zone		
R3 stream		A
R4 stream		**N**
D5 pond	Legumes	Accepted at step 3
D5 stream	Legumes	Accepted at step 3
D3 ditch	Potatoes	Accepted at step 3
D4 pond	Potatoes	**N**
D4 stream	Potatoes	**N**
R1 pond	Potatoes	Accepted at step 3
R1 stream	Potatoes	A

Step 4 BBCH 89, 1 x 50 g as/ha – 20 m VFS + 10 m buffer zone		
R4 stream		A
D4 pond	Potatoes	**N**
D4 stream	Potatoes	**N**

In summary:

For BBCH 15 at 1 x 50 g as/L
Step 3 risk is acceptable for:
- D5 pond, D5 stream, D3 ditch, D4 pond, D4 stream, R1 pond scenarios except R3 stream, R4 stream scenarios;

Step 4 with 10 m VFS + 10 m buffer zone risk is acceptable for
- R3 stream, R1 stream scenarios;

Step 4 with 20 m VFS + 10 m buffer zone risk is acceptable for
- R4 stream scenario;

For BBCH 89 at 1 x 50 g as/L
Step 3 risk is acceptable for:
- D5 pond, D5 stream, D3 ditch, R1 pond scenarios;

Step 4 with 10 m VFS + 10 m buffer zone risk is acceptable for:
R3 stream, R1 stream scenarios;

Step 4 with 10 m VFS + 20 m buffer zone risk is acceptable for:
R4 stream scenario;

The risk for D4 pond and D4 stream scenarios (BBCH 89, 1 x 50 g as/ha) is unresolved.

Individual scenarios should be considered in accordance with the requirements of each Member State.

Results of risk assessment with refined HC5 for invertebrates ~~and refined endpoint for sediment-dwelling organisms considering exposure via sediment~~

PEC/RAC based on refinement endpoints

Scenario	Surrogate crop	Acceptable -A Not acceptable - N
Step 3, BBCH 15, 1 x 50 g as/ha		
R3 stream		N
R4 stream		N
D5 pond	Legumes	A
D5 stream	Legumes	A
D3 ditch	Potatoes	A
D4 pond	Potatoes	A
D4 stream	Potatoes	A
R1 pond	Potatoes	A
R1 stream	Potatoes	N
Step 4 BBCH 15, 1 x 50 g as/ha – 10 m VFS + 10 m buffer zone		
R3 stream		A
R4 stream		A
D5 pond	Legumes	Accepted at step 3
D5 stream	Legumes	Accepted at step 3
D3 ditch	Potatoes	Accepted at step 3
D4 pond	Potatoes	Accepted at step 3
D4 stream	Potatoes	Accepted at step 3
R1 pond	Potatoes	Accepted at step 3
R1 stream	Potatoes	A

PEC/RAC based on refinement endpoints		
Scenario	**Surrogate crop**	**Acceptable -A No acceptable - N**
Step 3, BBCH 89, 1 x 50 g as/ha		
R3 stream		**N**
R4 stream		**N**
D5 pond	Legumes	A
D5 stream	Legumes	A

D3 ditch	Potatoes	A
D4 pond	Potatoes	**N**
D4 stream	Potatoes	A
R1 pond	Potatoes	A
R1 stream	Potatoes	**N**
Step 4 BBCH 89, 1 x 50 g as/ha – 10 m VFS + 10 m buffer zone		
R3 stream		A
R4 stream		A
D5 pond	Legumes	Accepted at step 3
D5 stream	Legumes	Accepted at step 3
D3 ditch	Potatoes	Accepted at step 3
D4 pond	Potatoes	**N**
D4 stream	Potatoes	Accepted at step 3
R1 pond	Potatoes	Accepted at step 3
R1 stream	Potatoes	A

In summary:

For BBCH 15 at 1 x 50 g as/L
Step 3 risk is acceptable for:
- D5 pond, D5 stream, D3 ditch, D4 pond, D4 stream, R1 pond scenarios except R3 stream, R4 stream, R1 stream scenarios;

Step 4 with 10 m VFS + 10 m buffer zone risk is acceptable for
- R3 stream, R4 stream, R1 stream scenarios

For BBCH 89 at 1 x 50 g as/L
Step 3 risk is acceptable for:
- D5 pond, D5 stream, D3 ditch, , D4 stream, R1 pond scenarios except R3 stream, R4 stream, D4 pond, R1 stream scenarios;

Step 4 with 10 m VFS + 10 m buffer zone risk is acceptable for:
R3 stream, R4 stream, scenarios, R1 stream scenario;

The risk for D4 pond scenario (BBCH 89, 1 x 50 g as/ha) is unresolved.

Individual scenarios should be considered in accordance with the requirements of each Member State.

The use no. 33, Pumpkin, 1 x 35 g as/ha, BBCH 61-65, F was not accepted in Part B8.

Sugar beet (use 7, BBCH 31-49, 1 x 20 g as/ha)

Table 9.5-6: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for chlorantraniliprole for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CLOROL 200 SC in sugarbeet

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged
Test species		*Bluegill sunfish*	*Oncorhynchus mykiss*	*Daphnia magna*	*Daphnia magna*	*Pseudokirchn. subcapitata*	*Invertebrate*	*Invertebrate*	*Lemna Gibba*		*Chironomus riparius*
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	HC5	HC5	EC50		NOEC
(µg/L)		1840	110	6.2	4.47	85.9	2.61	2.91	2000		
AF		100	10	100	10	10	3	5	10		10
RAC (µg/L)		18.4	11	0.062	0.447	8.59 >200	0.87	0.58	200		
FOCUS Scenario	PEC gl-max (µg/L)									PEC gl-max (µg/kg)	
Step 1											
	8.65	0.4701	0.7864	139.5161	19.3512	1.0070	9.9425	14.9138	0.0433	25.70	10.2800
Step 2											
N-Europe	0.75	0.0408	0.0682	12.0968	1.6779	0.0873	0.8621	1.2931	0.0038	2.18	0.8720
Step 3											
D3/ditch	0.1839	0.0100	0.0167	2.9661	0.4114	0.0214	0.2114	0.3171	0.0009	0.06886	0.0275

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged
D4/pond	0.2140	0.0116	0.0195	3.4516	0.4787	0.0249	0.2460	0.3690	0.0011	0.9599	0.3840
D4/stream	0.2075	0.0113	0.0189	3.3468	0.4642	0.0242	0.2385	0.3578	0.0010	0.3419	0.1368
R1/pond	0.03164	0.0017	0.0029	0.5103	0.0708	0.0037	0.0364	0.0546	0.0002	0.1094	0.0438
R1/stream	0.3778	0.0205	0.0343	6.0935	0.8452	0.0440	0.4343	0.6514	0.0019	0.1080	0.0432
R3/stream	0.5910	0.0321	0.0537	9.5323	1.3221	0.0688	0.6793	1.0190	0.0030	0.2478	0.0991
Step 4 – 20 meters buffer zone											
R3/stream	0.2695	0.0146	0.0245	4.3468	0.6029	0.0314	0.3098	0.4647	0.0013	0.2432	0.0973

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

Risk assessment was updated (with sunflower as surrogate crop for D5 and R4 scenarios) by Applicant as follows:

Group		**Fish acute**	**Fish pro-longed**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. Dwell. prolonged (aquatic phase)**	**Higher-tier information**	**Higher-tier information**	**Aquatic plants**		**Sed. dwell. prolonged**	~~**Higher-Tier information for Sed. dwell. pro-longed**~~
Test spe-cies		***Bluegill sunfish***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchn. subcapitata***	***Chironomus riparius***	***Invertebrate***	***Invertebrate***	***Lemna Gibba***		***Chironomus riparius***	~~***Chironomus riparius***~~
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	NOEC	HC5	HC5	EC50		NOEC	~~NOEC~~
(µg/L)		1840	110	6.2	4.47	85.9	0.25	2.61	2.91	2000		5	~~2.5~~
AF		100	10	100	10	10	10	3	5	10		10	~~10~~
RAC (µg/L)		18.4	11	0.062	0.447	8.59	0.025	0.87	0.58	200		0.5	~~2.5~~
FOCUS Scenario	**PEC gl-max (µg/L)**										**PEC gl-max (µg/kg)**		

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. Dwell, prolonged (aquatic phase)	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged	~~Higher-Tier information for Sed. dwell. pro-longed~~
Step 1													
	8.65	0.4701	0.7864	139.5161	19.3512	1.0070	346.0	9.9425	14.9138	0.0433	25.70	51.400	~~10.2800~~
Step 2													
N-Europe	0.75	0.0408	0.0682	12.0968	1.6779	0.0873	30.0	0.8621	1.2931	0.0038	2.18	4.360	~~0.8720~~
			~~**Step 3 (application at BBCH 12)**~~										
~~D3/ditch~~	~~0.1839~~	~~0.0100~~	~~0.0167~~			~~0.0214~~		~~0.2114~~	~~0.3171~~	~~0.0009~~	~~0.06886~~	~~0.138~~	0.0275
~~D4/pond~~	~~0.2140~~	~~0.0116~~	~~0.0195~~			~~0.0249~~		~~0.2460~~	~~0.3690~~	~~0.0011~~	~~0.9599~~	~~1.920~~	0.3840
~~D4/stream~~	~~0.2075~~	~~0.0113~~	~~0.0189~~			~~0.0242~~		~~0.2385~~	~~0.3578~~	~~0.0010~~	~~0.3419~~	~~0.684~~	0.1368
~~R1/pond~~	~~0.03164~~	~~0.0017~~	~~0.0029~~			~~0.0037~~		~~0.0364~~	~~0.0546~~	~~0.0002~~	~~0.1094~~	~~0.219~~	0.0438
~~R1/stream~~	~~0.3778~~	~~0.0205~~	~~0.0343~~			~~0.0440~~		~~0.4343~~	~~0.6514~~	~~0.0019~~	~~0.1080~~	~~0.216~~	0.0432
~~R3/stream~~	~~0.5910~~	~~0.0321~~	~~0.0537~~			~~0.0688~~		~~0.6793~~	~~1.0190~~	~~0.0030~~	~~0.2478~~	~~0.496~~	0.0991
			Step 3 (application at BBCH 31)										
D3/ditch	0.1836	0.0100	0.0167	2.9613	0.4107	0.0214	7.34	0.2110	0.3166	0.0009	0.06218	0.124	~~0.0249~~
D4/pond	0.2287	0.0124	0.0208	3.6887	0.5116	0.0266	9.15	0.2629	0.3943	0.0011	0.9788	1.958	~~0.3915~~
D4/stream	0.2313	0.0126	0.0210	3.7306	0.5174	0.0269	9.25	0.2659	0.3988	0.0012	0.3541	0.708	~~0.1416~~
R1/pond	0.07381	0.0040	0.0067	1.1905	0.1651	0.0086	2.95	0.0848	0.1273	0.0004	0.2557	0.511	~~0.1023~~
R1/stream	0.5182	0.0282	0.0471	8.3581	1.1593	0.0603	20.73	0.5956	0.8934	0.0026	0.2869	0.574	~~0.1148~~
R3/stream	0.6974	0.0379	0.0634	11.2484	1.5602	0.0812	27.90	0.8016	1.2024	0.0035	0.2074	0.415	~~0.0830~~
			Step 3 for sunflower as surrogate crop for sugarbeets for D5 and R4 scenario (application at BBCH 31)										
D5/pond	0.1800	0.0098	0.0164	2.9032	0.4027	0.0210	7.20	0.2069	0.3103	0.0009	0.9820	1.964	~~0.3928~~
D5/stream	0.1828	0.0099	0.0166	2.9484	0.4089	0.0213	7.31	0.2101	0.3152	0.0009	0.2189	0.438	~~0.0876~~
R4/stream	0.8270	0.0449	0.0752	13.3387	1.8501	0.0963	33.08	0.9506	1.4259	0.0041	0.2793	0.559	~~0.1117~~

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. Dwell. prolonged (aquatic phase)	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged	~~Higher-Tier information for Sed. dwell. pro-longed~~
	Step 3 (application at BBCH 49)												
D3/ditch	0.1837	0.0100	0.0167	2.9629	0.4110	0.0214	7.35	0.2111	0.3167	0.0009	0.06702	0.134	~~0.0263~~
D4/pond	0.3881	0.0211	0.0353	6.2597	0.8682	0.0452	15.52	0.4461	0.6691	0.0019	1.419	2.838	~~0.5676~~
D4/stream	0.4572	0.0248	0.0416	7.3742	1.0228	0.0532	18.29	0.5255	0.7883	0.0023	0.5658	1.132	~~0.2263~~
R1/pond	0.07033	0.0038	0.0064	1.1344	0.1573	0.0082	2.81	0.0808	0.1213	0.0004	0.2674	0.535	~~0.1070~~
R1/stream	0.5580	0.0303	0.0507	9.0000	1.2483	0.0650	22.32	0.6414	0.9621	0.0028	0.1391	0.278	~~0.0556~~
R3/stream	0.5617	0.0305	0.0511	9.0597	1.2566	0.0654	22.47	0.6456	0.9684	0.0028	0.2974	0.595	~~0.1190~~
	Step 3 for sunflower as surrogate crop for sugarbeets for D5 and R4 scenario (application at BBCH 49)												
D5/pond	0.1235	0.0067	0.0112	1.9919	0.2763	0.0144	4.94	0.1420	0.2129	0.0006	0.7140	1.428	~~0.2856~~
D5/stream	0.1795	0.0098	0.0163	2.8952	0.4016	0.0209	7.18	0.2063	0.3095	0.0009	0.1488	0.298	~~0.0595~~
R4/stream	0.6298	0.0342	0.0573	10.1581	1.4089	0.0733	25.19	0.7239	1.0859	0.0031	0.2247	0.449	~~0.0899~~
	Step 4 – ~~20 meters buffer zone~~ 10 m vegetative buffer zone (application at BBCH 12)												
~~R3/stream*~~	~~0.2695~~	~~0.0146~~	~~0.0245~~			~~0.0314~~		~~0.3098~~	~~0.4647~~	~~0.0013~~	~~0.2432~~	~~0.486~~	0.0973

zRMS comments:

For algae the EU agreed endpoint - ErC50 >2000 µg/L should be used. For the PEC/RAC calculations for algae the lover value at 85.9 µg/L (worse case) was used by Applicant. This was not corrected because it had no impact on the assessment result.

The acute and chronic risk to invertebrates and chronic risk to sediment-dwelling invertebrates considering exposure via water, based on Tier 1 EU agreed endpoints is covered by the refined risk assessment for aquatic invertebrates. Therefore PEC/RAC calculations with Tier 1 EU agreed endpoints were not assessed by zRMS.

Refinement of the risk assessment for invertebrates ~~and sediment-dwelling invertebrates considering exposure via sediment~~, proposed by Applicant, should be considered on the MSs level.

Result of risk assessment with EU HC_5 for invertebrates ~~and refined endpoint for sediment-dwelling organisms considering exposure via sediment~~.

PEC/RAC based on refinement endpoints		
Scenario	**Surrogate crop**	**Acceptable -A Not acceptable - N**
Step 3, BBCH 31, 1 x 20 g as/ha		
R3 stream		**N**
R4 stream	Sunflower	**N**
D5 pond	Sunflower	A
D5 stream	Sunflower	A
D3 ditch		A
D4 pond		A
D4 stream		A
R1 pond		A
R1 stream		A
Step 3 BBCH 49, 1 x 20 g as/ha		
R3 stream		**N**
R4 stream	Sunflower	A
D5 pond	Sunflower	A
D5 stream	Sunflower	A
D3 ditch		A
D4 pond		A
D4 stream		A
R1 pond		A
R1 stream		A

In summary:

For BBCH 31 at 1 x 20 g as/L
Step 3 - risk is accepted for D5 pond, D5 stream, D3 ditch, D4 pond, D4 stream, R1 pond, R1 stream scenarios.
Step 4 was not provided. **The risk for R3 stream and R4 stream scenarios is unresolved.**

For BBCH 49 at 1 x 20 g as/L
Step 3 - risk is accepted for R4 stream, D5 pond, D5 stream, D3 ditch, D4 pond, D4 stream, R1 pond, R1 stream scenarios.
Step 4 was not provide. **The risk for R3 stream scenario is unresolved.**

Individual scenarios should be considered in accordance with the requirements of each Member State.

Result of risk assessment with refined HC5 for invertebrates ~~and refined endpoint for sediment-dwelling organisms considering exposure via sediment~~

PEC/RAC based on refinement endpoints		
Scenario	**Surrogate crop**	**Acceptable -A Not acceptable - N**
Step 3, BBCH 31, 1 x 20 g as/ha		
R3 stream		A
R4 stream	Sunflower	A
D5 pond	Sunflower	A
D5 stream	Sunflower	A
D3 ditch		A
D4 pond		A
D4 stream		A
R1 pond		A
R1 stream		A
Step 3 BBCH 49, 1 x 20 g as/ha		
R3 stream		A
R4 stream	Sunflower	A
D5 pond	Sunflower	A
D5 stream	Sunflower	A
D3 ditch		A
D4 pond		A
D4 stream		A
R1 pond		A
R1 stream		A

In summary:

For BBCH 31-49 at 1 x 20 g as/L
The risk is accepted at Step 3

Individual scenarios should be considered in accordance with the requirements of each Member State.

Roots vegetable, BBCH 12-49, 1 x 35 g as/ha

10, Carrot, BBCH 12-49, 1 x 35 g as/ha,
11, Beetroot, BBCH 12-49, 1 x 35 g as/ha
12, Horseradish, BBCH 12-49, 1 x 35 g/ha
13, Radish, BBCH 12-49, 1 x 35 g as/ha
14, Celery, BBCH 12-49, 1 x 35 g as/ha
15, Jerusalem artichoke, BBCH 12-49, 1 x 35 g/ha
16, Parsley, BBCH 12-49, 1 x 35 g/ha
17, Parsnip, BBCH 12-49, 1 x 35 g/ha
18, Salsify, BBCH 12-49, 1 x 35 g/ha
19, Rutabaga, BBCH 12-49, 1 x 35 g as/ha
20, Turnip, BBCH 12-49, 1 x 35 g as/ha
21, Scorzonera, BBCH 12-49, 1 x 35 g as/ha

Table 9.5-7: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for chlorantraniliprole for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CLOROL 200 SC in roots vegetable

Group	Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Higher-tier information	Higher-tier information	Aquatic plants	Sed. dwell. prolonged
Test species	*Bluegill sunfish*	*Oncorhynchus mykiss*	*Daphnia magna*	*Daphnia magna*	*Pseudokirchn. subcapitata*	*Invertebrate*	*Invertebrate* acute and chronic SSD	*Lemna Gibba*	*Chironomus riparius*
Endpoint	LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	HC5	HC5	EC50	NOEC
(µg/L)	1840*	110	6.2	4.47	~~85.9~~ > 2 000	2.61	2.91	2000	~~25.5~~

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged
AF		100	10	100	10	10	3	5	10		10
RAC (µg/L)		18.4	11	0.062	0.447	8.59 >200	0.87	0.58	200		2.5 0.5
FOCUS Scenario	PEC gl-max (µg/L)									PEC gl-max (µg/kg)	
Step 1											
	8.95	0.4864	0.8136	144.3548	20.0224	1.0419	10.2874	15.4310	0.0448	25.70	10.2800
Step 2											
N-Europe	1.50	0.0815	0.1364	24.1935	3.3557	0.1746	1.7241	2.5862	0.0075	4.42	1.7680
Step 3											
D3/ditch	0.2222	0.0121	0.0202	3.5839	0.4971	0.0259	0.2554	0.3831	0.0011	0.08238	0.0330
D6/ditch	0.2629	0.0143	0.0239	4.2403	0.5881	0.0306	0.3022	0.4533	0.0013	0.2667	0.1067
R1/pond	0.04167	0.0023	0.0038	0.6721	0.0932	0.0049	0.0479	0.0718	0.0002	0.1446	0.0578
R1/stream	0.5186	0.0282	0.0471	8.3645	1.1602	0.0604	0.5961	0.8941	0.0026	0.1489	0.0596
R2/stream	0.2544	0.0138	0.0231	4.1032	0.5691	0.0296	0.2924	0.4386	0.0013	0.1953	0.0781
R3/stream	0.5988	0.0325	0.0544	9.6581	1.3396	0.0697	0.6883	1.0324	0.0030	0.1652	0.0661
R4/stream	0.9649	0.0524	0.0877	15.5629	2.1586	0.1123	1.1091	1.6636	0.0048	0.3564	0.1426
Step 4 -											
R3/stream	0.2701	0.0147	0.0246	4.3565	0.6043	0.0314	0.3105	0.4657	0.0014	0.07431	0.0297
R4/stream	0.4377	0.0238	0.0398	7.0597	0.9792	0.0510	0.5031	0.7547	0.0022	0.1561	0.0624

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

Risk assessment was updates (with Legumes as surrogate crops for D4 and D5 scenarios) by Applicant as follows:

Group		**Fish acute**	**Fish pro-longed**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. Dwell. prolonged (aquatic phase)**	**Higher-tier information**	**Higher-tier information**	**Aquatic plants**		**Sed. dwell. prolonged**	~~**Higher-Tier information for Sed. dwell. pro-longed**~~
Test spe-cies		***Bluegill sunfish***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchn. subcapitata***	***Chironomus riparius***	***Invertebrate* acute abd chronic**	***Invertebrate* acute abd chronic**	***Lemna Gibba***		***Chironomus riparius***	~~***Chironomus riparius***~~
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	NOEC	HC5	HC5	EC50		NOEC	~~NOEC~~
(µg/L)		1840	110	6.2	4.47	85.9	0.25	2.61	2.91	2000		5	~~25~~
AF		100	10	100	10	10	10	3	5	10		10	~~10~~
RAC (µg/L)		18.4	11	0.062	0.447	8.59	0.025	0.87	0.58	200		0.5	~~2.5~~
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**										**PEC $_{gl-max}$ (µg/kg)**		
Step 1													
	8.95	0.4864	0.8136	144.3548	20.0224	1.0419	358.0	10.2874	15.4310	0.0448	25.70	51.400	~~10.2800~~
Step 2													
N-Europe	1.50	0.0815	0.1364	24.1935	3.3557	0.1746	60.0	1.7241	2.5862	0.0075	4.42	8.840	~~1.7680~~
Step 3 (application at BBCH 12)													
D3/ditch	0.2222	0.0121	0.0202	3.5839	0.4971	0.0259	8.89	0.2554	0.3831	0.0011	0.08238	0.165	~~0.0330~~
D6/ditch	0.2629	0.0143	0.0239	4.2403	0.5881	0.0306	10.52	0.3022	0.4533	0.0013	0.2667	0.533	~~0.1067~~
R1/pond	0.04167	0.0023	0.0038	0.6721	0.0932	0.0049	1.67	0.0479	0.0718	0.0002	0.1446	0.289	~~0.0578~~
R1/stream	0.5186	0.0282	0.0471	8.3645	1.1602	0.0604	20.74	0.5961	0.8941	0.0026	0.1489	0.298	~~0.0596~~
R2/stream	0.2544	0.0138	0.0231	4.1032	0.5691	0.0296	10.18	0.2924	0.4386	0.0013	0.1953	0.391	~~0.0781~~
R3/stream	0.5988	0.0325	0.0544	9.6581	1.3396	0.0697	23.95	0.6883	1.0324	0.0030	0.1652	0.330	~~0.0661~~
R4/stream	0.9649	0.0524	0.0877	15.5629	2.1586	0.1123	38.60	1.1091	1.6636	0.0048	0.3564	0.713	~~0.1426~~

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. Dwell. prolonged (aquatic phase)	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged	Higher-Tier information for Sed. dwell. pro-longed
	Step 3 for legumes as surrogate crop for vegetables root for D4 and D5 (application at BBCH 12)												
D4/pond	0.2288	0.0124	0.0208	3.6903	0.5119	0.0266	9.15	0.2630	0.3945	0.0011	1.006	2.012	0.4024
D4/stream	0.2116	0.0115	0.0192	3.4129	0.4734	0.0246	8.46	0.2432	0.3648	0.0011	0.3566	0.713	0.1426
D5/pond	0.1640	0.0089	0.0149	2.6452	0.3669	0.0191	6.56	0.1885	0.2828	0.0008	0.8763	1.753	0.3505
D5/stream	0.1740	0.0095	0.0158	2.8065	0.3893	0.0203	6.96	0.2000	0.3000	0.0009	0.1931	0.386	0.0772
	Step 3 (application at BBCH 49)												
D3/ditch	0.2221	0.0121	0.0202	3.5823	0.4969	0.0259	8.88	0.2553	0.3829	0.0011	0.08706	0.174	0.0348
R1/pond	0.01875	0.0010	0.0017	0.3024	0.0419	0.0022	0.75	0.0216	0.0323	0.0001	0.08766	0.175	0.0351
R1/stream	0.3598	0.0196	0.0327	5.8032	0.8049	0.0419	14.39	0.4136	0.6203	0.0018	0.09664	0.193	0.0387
R3/stream	0.8849	0.0481	0.0804	14.2726	1.9796	0.1030	35.40	1.0171	1.5257	0.0044	0.3052	0.610	0.1221
R4/stream	1.044	0.0567	0.0949	16.8387	2.3356	0.1215	41.76	1.2000	1.8000	0.0052	0.3722	0.744	0.1489
	Step 3 for legumes as surrogate crop for vegetables root for D4 and D5 (application at BBCH 49)												
D4/pond	0.2240	0.0122	0.0204	3.6129	0.5011	0.0261	8.96	0.2575	0.3862	0.0011	0.9732	1.946	0.3893
D4/stream	0.2088	0.0113	0.0190	3.3677	0.4671	0.0243	8.35	0.2400	0.3600	0.0010	0.3449	0.690	0.1380
D5/pond	0.1437	0.0078	0.0131	2.3177	0.3215	0.0167	5.75	0.1652	0.2478	0.0007	0.8007	1.601	0.3203
D5/stream	0.1810	0.0098	0.0165	2.9194	0.4049	0.0211	7.24	0.2080	0.3121	0.0009	0.1761	0.352	0.0704
	Step 4 – 10 meters vegetative buffer zone (application at BBCH 12)												
R3/stream	0.2701	0.0147	0.0246	4.3565	0.6043	0.0314	10.80	0.3105	0.4657	0.0014	0.07431	0.149	0.0297
R4/stream	0.4377	0.0238	0.0398	7.0597	0.9792	0.0510	17.51	0.5031	0.7547	0.0022	0.1561	0.312	0.0624
	Step 4 – 10 meters vegetative buffer zone (application at BBCH 49)												
R3/stream	0.4033	0.0219	0.0367	6.5048	0.9022	0.0469	16.13	0.4636	0.6953	0.0020	0.1193	0.239	0.0477
R4/stream	0.4742	0.0258	0.0431	7.6484	1.0609	0.0552	18.97	0.5451	0.8176	0.0024	0.1525	0.305	0.0610

zRMS comments:

For algae the EU agreed endpoint - ErC50 >2000 µg/L should be used. For the PEC/RAC calculations for algae the lover value at 85.9 µg/L (worse case) was used by Applicant. This was not corrected because it had no impact on the assessment result.

The acute and chronic risk to invertebrates and chronic risk to sediment-dwelling invertebrates considering exposure via water, based on Tier 1 EU agreed endpoints is covered by the refined risk assessment for aquatic invertebrates. Therefore PEC/RAC calculations with Tier 1 EU agreed endpoints were not assessed by zRMS.

Refinement of the risk assessment for invertebrates ~~and sediment-dwelling invertebrates considering exposure via sediment,~~ proposed by Applicant, should be considered on the MSs level.

Result of risk assessment with EU HC_5 for invertebrates ~~and refined endpoint for sediment-dwelling organisms considering exposure via sediment.~~

PEC/RAC based on refinement endpoints		
Scenario	**Surrogate crop**	**Acceptable -A** **Not acceptable - N**
Step 3, BBCH 12, 1 x 35 g as/ha		
R3 stream		**N**
R4 stream		**N**
D5 pond	Legumes	A
D5 stream	Legumes	A
D3 ditch		A
D6 ditch		A
D4 pond	Legumes	A
D4 stream	Legumes	A
R1 pond		A
R1 stream		A
R2 stream		A
Step 4 BBCH 12, 1 x 35 g as/ha – 10 m VFS		
R3 stream		A
R4 stream		A

PEC/RAC based on refinement endpoints		
Scenario	**Surrogate crop**	**Acceptable -A No acceptable - N**
Step 3, BBCH 49, 1 x 35 g as/ha		
R3 stream		**N**
R4 stream		**N**
D5 pond	Legumes	A
D5 stream	Legumes	A
D3 ditch		A
D4 pond	Legumes	A
D4 stream	Legumes	A
R1 pond		A
R1 stream		A
Step 4 BBCH 49, 1 x 35 g as/ha – 10 m VFS		
R3 stream		A
R4 stream		A

In summary:

For BBCH 12 at 1 x 35 g as/L
Step 3 risk is not acceptable for: R3 stream and R4 stream scenario;
s
Step 4 with 10 m VFS: R3 stream and R4 stream – risk is acceptable

For BBCH 49 at 1 x 35 g as/L
Step 3 risk is not acceptable for: R3 stream and R4 stream scenarios

Step 4 with 10 m VFS: R3 stream, R4 stream risk is acceptable

Individual scenarios should be considered in accordance with the requirements of each Member State.

Result of risk assessment with refined HC5 for invertebrates ~~and refined endpoint for sediment-dwelling organisms considering exposure via sediment~~

PEC/RAC based on refinement endpoints		
Scenario	**Surrogate crop**	**Acceptable -A Not acceptable - N**
Step 3, BBCH 12, 1 x 35 g as/ha		
R3 stream		A
R4 stream		**N**
D5 pond	Legumes	A
D5 stream	Legumes	A
D3 ditch		A
D6 ditch		A
D4 pond	Legumes	A
D4 stream	Legumes	A
R1 pond		A
R1 stream		A
R2 stream		A
Step 4 BBCH 12, 1 x 35 g as/ha – 10 m VFS		
R3 stream		Acceptable at Step 3
R4 stream		A

PEC/RAC based on refinement endpoints		
Scenario	**Surrogate crop**	**Acceptable -A No acceptable - N**
Step 3, BBCH 49, 1 x 35 g as/ha		
R3 stream		**N**
R4 stream		**N**
D5 pond	Legumes	A
D5 stream	Legumes	A
D3 ditch		A
D4 pond	Legumes	A
D4 stream	Legumes	A
R1 pond		A

R1 stream		A
Step 4 BBCH 49, 1 x 35 g as/ha – 10 m VFS		
R3 stream		A
R4 stream		A

In summary:

For BBCH 12 at 1 x 35 g as/L
Step 3 risk is not acceptable for: R4 stream scenario;

Step 4 with 10 m VFS: R4 stream – risk is acceptable

For BBCH 49 at 1 x 35 g as/L
Step 3 risk is not acceptable for: R3 stream and R4 stream scenarios

Step 4 with 10 m VFS: R3 stream, R4 stream risk is acceptable

Individual scenarios should be considered in accordance with the requirements of each Member State.

Vegetable leafy

68, Lettuce, BBCH 12-49, 2 x 42,
69, Corn salad, BBCH 12-49, 2 x 42,
70, Endive, BBCH 12-49, 2 x 42,
71, Garden cress, BBCH 12-49, 2 x 42,
72, Arugula, BBCH 12-49, 2 x 42,
73, Escaroles, BBCH 12-49, 2 x 42,
74, Cresses and other sprouts and shoots, BBCH 12-49, 2 x 42,
75, Land creses, BBCH 12-49, 2 x 42,
76, Roman rocket/rucola, BBCH 12-49, 2 x 42,
77, Red Mustard, BBCH 12-49, 2 x 42,
78, Baby leaf crops, BBCH 12-49, 2 x 42,
79, Spinach, BBCH 12-49, 2 x 42,

80, Swiss Chard, BBCH 12-49, 2 x 42,
81, Chards/beet leaves, BBCH 12-49, 2 x 42,
82, Purslane, BBCH 12-49, 2 x 42,
96, Watercresses, BBCH 12-49, 2 x 42,
35, White cabbage, BBCH 20-49, 2 x 25 g as/ha,
36, Red cabbage, BBCH 12x 25 g as/ha,
37, Kale, BBCH 12-49, 2 x 25 g as/ha,
38, Chinese cabbage/pe-tsai, BBCH 12-49, 2 x 25 g as/ha,
39, Brussels sprout, BBCH 12-49, 2 x 25 g as/ha,
40, Cauliflower, BBCH 12-49, 2 x 25 g as/ha,
41, Broccoli, BBCH 12-49, 2 x 25 g as/ha,
77, Red mustard, BBCH 20-49, 2 x 42 g as/ha

Table 9.5-8: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for chlorantraniliprole for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CLOROL 200 SC in vegetable leafy

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged
Test species		*Bluegill sunfish*	*Oncorhynchus mykiss*	*Daphnia magna*	*Daphnia magna*	*Pseudokirchn. subcapitata*	*Invertebrate*	*Invertebrate*	*Lemna Gibba*		*Chironomus riparius*
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	HC5	HC5	EC50		NOEC
(µg/L)		1840	110	6.2	4.47	85.9	2.61	2.91	2000		25
AF		100	10	100	10	10	3	5	10		10
RAC (µg/L)		18.4	11	0.062	0.447	8.59	0.87	0.58	200		2.5
FOCUS Scenario	PEC $_{gl-max}$ (µg/L)									PEC $_{gl-max}$ (µg/kg)	
Step 1											
	20.75	1.1277	1.8864	334.6774	46.4206	2.4156	23.8506	35.7759	0.1038	61.68	24.6720
Step 2											

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged
N-Europe	2.91	0.1582	0.2645	46.9355	6.5101	0.3388	3.3448	5.0172	0.0146	8.59	3.4360
Step 3											
D3/ditch	0.1836	0.0100	0.0167	2.9613	0.4107	0.0214	0.2110	0.3166	0.0009	0.06351	0.0254
D4/pond	0.3024	0.0164	0.0275	4.8774	0.6765	0.0352	0.3476	0.5214	0.0015	1.139	0.4556
D4/stream	0.3102	0.0169	0.0282	5.0032	0.6940	0.0361	0.3566	0.5348	0.0016	0.4177	0.1671
D5/pond	0.09676	0.0053	0.0088	1.5606	0.2165	0.0113	0.1112	0.1668	0.0005	0.5538	0.2215
D5/stream	0.1795	0.0098	0.0163	2.8952	0.4016	0.0209	0.2063	0.3095	0.0009	0.1184	0.0474
D6/ditch	0.1878	0.0102	0.0171	3.0290	0.4201	0.0219	0.2159	0.3238	0.0009	0.1126	0.0450
R1/pond	0.01239	0.0007	0.0011	0.1998	0.0277	0.0014	0.0142	0.0214	0.0001	0.06259	0.0250
R1/stream	0.2227	0.0121	0.0202	3.5919	0.4982	0.0259	0.2560	0.3840	0.0011	0.05593	0.0224
R2/stream	0.1706	0.0093	0.0155	2.7516	0.3817	0.0199	0.1961	0.2941	0.0009	0.1562	0.0625
R3/stream	0.6335	0.0344293	0.05759	10.217742	1.417226	0.07375	0.728161	1.0922	0.0032	0.3380	0.1352
R4/stream	0.6907	0.0375380	0.06279	11.140323	1.545190	0.08041	0.793908	1.1909	0.0035	0.2567	0.1027
Step 4 – 10 meters buffer zone											
R3/stream	0.56	0.0304	0.0509	9.0323	1.2528	0.0652	0.6437	0.9655	0.0028	0.2236	0.0894
R4/stream	0.6576	0.0357	0.0598	10.6065	1.4711	0.0766	0.7559	1.1338	0.0033	0.2669	0.1068
Step 4 – 20 meters buffer zone											
R4/stream	0.3445	0.0187	0.0313	5.5565	0.7707	0.0401	0.3960	0.5940	0.0017	0.1404	0.0562

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

Risk assessment was updates (with Legumes as surrogate crops for D5 scenarios) by Applicant as follows:

Group		**Fish acute**	**Fish pro-longed**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. Dwell. prolonged (aquatic phase)**	**Higher-tier information**	**Higher-tier information**	**Aquatic plants**		**Sed. dwell. prolonged**	~~**Higher-Tier information for Sed. dwell. pro-longed**~~
Test spe-cies		***Bluegill sunfish***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchn. subcapitata***	***Chironomus riparius***	***Invertebrate***	***Invertebrate***	***Lemna Gibba***		***Chironomus riparius***	~~***Chironomus riparius***~~
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	NOEC	HC5	HC5	EC50		NOEC	~~NOEC~~
(µg/L)		1840	110	6.2	4.47	85.9	0.25	2.61	2.91	2000		5	~~2.5~~
AF		100	10	100	10	10	10	3	5	10		10	~~10~~
RAC (µg/L)		18.4	11	0.062	0.447	8.59	0.025	0.87	0.58	200		0.5	~~2.5~~
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**										**PEC $_{gl-max}$ (µg/kg)**		
Step 1													
	20.75	1.1277	1.8864	334.6774	46.4206	2.4156	830.0	23.8506	35.7759	0.1038	61.68	123.360	~~24.6720~~
Step 2													
N-Europe	2.91	0.1582	0.2645	46.9355	6.5101	0.3388	116.4	3.3448	5.0172	0.0146	8.59	17.180	~~3.4360~~
	Step 3 (application at BBCH 12) for dose 2x42 g as/ha												
D3/ditch	~~0.1836~~ 0.2345	~~0.0100~~ 0.0127	~~0.0167~~ 0.0213	2.9613	0.4107	~~0.0214~~ 0.0273	0.025	~~0.2110~~ 0.2695	~~0.3166~~ 0.4043	~~0.0009~~ 0.0012	0.06351	0.127	~~0.0254~~
D4/pond	~~0.3024~~ 0.5989	~~0.0164~~ 0.0325	~~0.0275~~ 0.0544	4.8774	0.6765	~~0.0352~~ 0.0697	7.34	~~0.3476~~ 0.6884	~~0.5214~~ 1.0326	~~0.0015~~ 0.0030	1.139	2.278	~~0.4556~~
D4/stream	~~0.3102~~ 0.5421	~~0.0169~~ 0.0295	~~0.0282~~ 0.0493	5.0032	0.6940	~~0.0361~~ 0.0631	12.10	~~0.3566~~ 0.6231	~~0.5348~~ 0.9347	~~0.0016~~ 0.0027	0.4177	0.835	~~0.1671~~
D6/ditch		0.0102	0.0171	3.0290	0.4201	0.0219	12.41	0.2159	0.3238	0.0009	0.1126	0.225	~~0.0450~~
R1/pond	~~0.01239~~ 1.119	~~0.0007~~ 0.0608	~~0.0011~~ 0.102	0.1998	0.0277	~~0.0014~~ 0.1303	7.51	~~0.0142~~ **1.2862**	~~0.0214~~ **1.9293**	~~0.0001~~ 0.0056	0.06259	0.125	~~0.0250~~

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. Dwell. prolonged (aquatic phase)	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged	~~Higher-Tier information for Sed. dwell. pro-longed~~
R1/stream	~~0.2227~~ 0.1706	~~0.0121~~ 0,009	~~0.0202~~ 0.0155	3.5919	0.4982	~~0.0259~~ 0.0199	0.50	~~0.2560~~ 0.1961	~~0.3840~~ 0.2941	~~0.0011~~ 0.0009	0.05593	0.112	~~0.0224~~
R2/stream		0.0093	0.0155	2.7516	0.3817	0.0199	8.91	0.1961	0.2941	0.0009	0.1562	0.312	~~0.0625~~
R3/stream	~~0.6335~~ 1.446	~~0.0344293~~ 0.0786	~~0.05759~~ 0.131	10.217742	1.417226	~~0.07375~~ 0.1683	6.82	~~0.728161~~ **1.6621**	~~1.0922~~ **2.4931**	~~0.0032~~ 0.0072	0.3380	0.676	~~0.1352~~
R4/stream	0.6907	0.0375380	0.06279	11.140323	1.545190	0.08041	25.34	0.793908	1.1909	0.0035	0.2567	0.513	~~0.1027~~
		Step 3 for legumes as surrogate crop according to polish national requirements (application at BBCH 12)) for dose 2x42 g as/ha											
D5/pond	0.4011	0.0218	0.0365	6.4694	0.8973	0.0467	16.04	0.4610	0.6916	0.0020	2.119	4.238	~~0.8476~~
D5/stream	0.2991	0.0163	0.0272	4.8242	0.6691	0.0348	11.96	0.3438	0.5157	0.0015	0.4677	0.935	~~0.1871~~
		Step 3 (application at BBCH 49) for dose 2x42 g as/ha											
D3/ditch	0.2350	0.0128	0.0214	3.7903	0.5257	0.0274	9.40	0.2701	0.4052	0.0012	0.1303	0.261	~~0.0521~~
D4/pond	1.211	0.0658	0.1101	19.5323	2.7092	0.1410	48.44	1.3920	2.0879	0.0061	4.589	9.178	~~1.8356~~
D4/stream	1.247	0.0678	0.1134	20.1129	2.7897	0.1452	49.88	1.4333	2.1500	0.0062	1.718	3.436	~~0.6872~~
R1/pond	0.1504	0.0082	0.0137	2.4258	0.3365	0.0175	6.02	0.1729	0.2593	0.0008	0.5788	1.158	~~0.2315~~
R1/stream	1.099	0.0597	0.0999	17.7258	2.4586	0.1279	43.96	1.2632	1.8948	0.0055	0.4682	0.936	~~0.1873~~
R3/stream	1.855	0.1008	0.1686	29.9194	4.1499	0.2159	74.20	2.1322	3.1983	0.0093	3.730	7.460	~~1.4920~~
R4/stream	1.765	0.0959	0.1605	28.4677	3.9485	0.2055	70.60	2.0287	3.0431	0.0088	0.8176	1.635	~~0.3270~~
		Step 3 for legumes as surrogate crop according to polish national requirements (application at BBCH 49)for dose 2x42 g as/ha											
D5/pond	0.3451	0.0188	0.0314	5.5661	0.7720	0.0402	13.80	0.3967	0.5950	0.0017	2.029	4.058	~~0.8116~~
D5/stream	0.2231	0.0121	0.0203	3.5984	0.4991	0.0260	8.92	0.2564	0.3847	0.0011	0.4443	0.889	~~0.1777~~
		Step 3 for dose 1x42 g as/ha (application at BBCH 49)											
D3/ditch	~~0.2660~~ 0.2672	0.0145	~~0.0242~~ 0.0243	4.2903	0.5951	~~0.0310~~ 0.0311	10.64	~~0.3057~~ 0.3071	~~0.4586~~ 0.4607	0.0013	~~0.08527~~ 0.1061	~~0.171~~ 0.2122	0.0341 0.0424

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. Dwell. prolonged (aquatic phase)	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged	~~Higher-Tier information for Sed. dwell. pro-longed~~
D4/pond	0.5819	0.0316	0.0529	9.3855	1.3018	0.0677	23.28	0.6689	1.0033	0.0029	2.211	4.422	0.8844
D4/stream	0.5891	0.0320	0.0536	9.5016	1.3179	0.0686	23.56	0.6771	1.0157	0.0029	0.8289	1.658	0.3316
D6/ditch	1.343	0.0730	0.1221	21.6613	3.0045	0.1563	53.72	1.5437	2.3155	0.0067	1.260	2.520	0.5040
R1/pond	0.08204	0.0045	0.0075	1.3232	0.1835	0.0096	3.28	0.0943	0.1414	0.0004	0.3514	0.703	0.1406
R1/stream	0.8810	0.0479	0.0801	14.2097	1.9709	0.1026	35.24	1.0126	1.5190	0.0044	0.4159	0.832	0.1664
R2/stream	0.3450	0.0188	0.0314	5.5645	0.7718	0.0402	13.80	0.3966	0.5948	0.0017	0.8899	1.780	0.3560
R3/stream	0.7795	0.0424	0.0709	12.5726	1.7438	0.0907	31.18	0.8960	1.3440	0.0039	0.8278	1.656	0.3311
R4/stream	0.7055	0.0383	0.0641	11.3790	1.5783	0.0821	28.22	0.8109	1.2164	0.0035	0.2622	0.524	0.1049
		Step 3 for dose 2x25 g as/ha (application at BBCH 49)											
D3/ditch	0.2263	0.0123	0.0206	3.6500	0.5063	0.0263	9.05	0.2601	0.3902	0.0011	0.1040	0.208	~~0.0416~~
D4/pond	0.7056	0.0383	0.0641	11.3806	1.5785	0.0821	28.22	0.8110	1.2166	0.0035	2.666	5.332	~~1.0664~~
D4/stream	0.7165	0.0389	0.0651	11.5565	1.6029	0.0834	28.66	0.8236	1.2353	0.0036	0.9996	1.999	~~0.3998~~
D6/ditch	1.617	0.0879	0.1470	26.0806	3.6174	0.1882	64.68	1.8586	2.7879	0.0081	1.548	3.096	~~0.6192~~
R1/pond	0.09666	0.0053	0.0088	1.5590	0.2162	0.0113	3.87	0.1111	0.1667	0.0005	0.4119	0.824	~~0.1648~~
R1/stream	1.056	0.0574	0.0960	17.0323	2.3624	0.1229	42.24	1.2138	1.8207	0.0053	0.4940	0.988	~~0.1976~~
R2/stream	0.4354	0.0237	0.0396	7.0226	0.9740	0.0507	17.42	0.5005	0.7507	0.0022	1.091	2.182	~~0.4364~~
R3/stream	0.9336	0.0507	0.0849	15.0581	2.0886	0.1087	37.34	1.0731	1.6097	0.0047	0.9763	1.953	~~0.3905~~
R4/stream	0.8401	0.0457	0.0764	13.5500	1.8794	0.0978	33.60	0.9656	1.4484	0.0042	0.3105	0.621	~~0.1242~~
		Step 3 for dose 1x35 g as/ha (application at BBCH 49)											
D3/ditch	0.2225	0.0121	0.0202	3.5887	0.4978	0.0259	8.90	0.2557	0.3836	0.0011	0.08827	0.177	~~0.0353~~
D4/pond	0.4820	0.0262	0.0438	7.7742	1.0783	0.0561	19.28	0.5540	0.8310	0.0024	1.838	3.676	~~0.7352~~
D4/stream	0.4871	0.0265	0.0443	7.8565	1.0897	0.0567	19.48	0.5599	0.8398	0.0024	0.6910	1.382	~~0.2764~~

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. Dwell. prolonged (aquatic phase)	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged	~~Higher-Tier information for Sed. dwell. pro-longed~~
D6/ditch	1.113	0.0605	0.1012	17.9516	2.4899	0.1296	44.52	1.2793	1.9190	0.0056	1.046	2.092	~~0.4184~~
R1/pond	0.06855	0.0037	0.0062	1.1056	0.1534	0.0080	2.74	0.0788	0.1182	0.0003	0.2946	0.589	~~0.1178~~
R1/stream	0.7303	0.0397	0.0664	11.7790	1.6338	0.0850	29.21	0.8394	1.2591	0.0037	0.3480	0.696	~~0.1392~~
R2/stream	0.2850	0.0155	0.0259	4.5968	0.6376	0.0332	11.40	0.3276	0.4914	0.0014	0.7529	1.506	~~0.3012~~
R3/stream	0.6464	0.0351	0.0588	10.4258	1.4461	0.0753	25.86	0.7430	1.1145	0.0032	0.6978	1.396	~~0.2791~~
R4/stream	0.5884	0.0320	0.0535	9.4903	1.3163	0.0685	23.54	0.6763	1.0145	0.0029	0.2198	0.440	~~0.0879~~
		Step 4 – 10 meters buffer zone (application at BBCH 12) for dose 2x42 g as/ha											
R3/stream	0.56	0.0304	0.0509	9.0323	1.2528	0.0652	22.40	0.6437	0.9655	0.0028	0.2236	0.447	~~0.0894~~
R4/stream	0.6576	0.0357	0.0598	10.6065	1.4711	0.0766	26.30	0.7559	1.1338	0.0033	0.2669	0.534	~~0.1068~~
		Step 4 – 20 meters buffer zone (application at BBCH 12) for dose 2x42 g as/ha											
R4/stream	0.3445	0.0187	0.0313	5.5565	0.7707	0.0401	13.8	0.3960	0.5940	0.0017	0.1404	0.281	~~0.0562~~
		Step 4 for dose 1x42 g as/ha (application at BBCH 49) – 20 m vegetative strip and 20 meters meters buffer zone											
D4/pond	0.5798	0.0315	0.0527	9.3516	1.2971	0.0675	23.19	0.6664	0.9997	0.0029	~~0.005266~~ 2.199	0.011	~~0.0021~~
D4/stream	0.5891	0.0320	0.0536	9.5016	1.3179	0.0686	23.56	0.6771	1.0157	0.0029	0.8285	1.657	~~0.3314~~
D6/ditch	1.343	0.0730	0.1221	21.6613	3.0045	0.1563	53.72	1.5437	2.3155	0.0067	1.152	2.304	~~0.4608~~
R1/stream	0.4005	0.0218	0.0364	6.4597	0.8960	0.0466	16.02	0.4603	0.6905	0.0020	0.1351	0.270	~~0.0540~~
R3/stream	0.3559	0.0193	0.0324	5.7403	0.7962	0.0414	14.24	0.4091	0.6136	0.0018	0.2055	0.411	~~0.0822~~
R4/stream	0.3219	0.0175	0.0293	5.1919	0.7201	0.0375	12.88	0.3700	0.5550	0.0016	0.1138	0.228	~~0.0455~~
		Step 4 for dose 2x25 g as/ha (application at BBCH 49) – 20 m vegetative strip and 20 meters meters buffer zone											
D4/pond	0.7035	0.0382	0.0640	11.3468	1.5738	0.0819	28.14	0.8086	1.2129	0.0035	2.655	5.310	~~1.0620~~
D4/stream	0.7165	0.0389	0.0651	11.5565	1.6029	0.0834	28.66	0.8236	1.2353	0.0036	0.9992	1.998	~~0.3997~~

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. Dwell. prolonged (aquatic phase)	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged	~~Higher-Tier information for Sed. dwell. pro-longed~~
D6/ditch	1.617	0.0879	0.1470	26.0806	3.6174	0.1882	64.68	1.8586	2.7879	0.0081	1.436	2.872	~~0.5744~~
R1/stream	0.2515	0.0137	0.0229	4.0565	0.5626	0.0293	10.06	0.2891	0.4336	0.0013	0.07917	0.158	~~0.0317~~
R3/stream	0.2238	0.0122	0.0203	3.6097	0.5007	0.0261	8.95	0.2572	0.3859	0.0011	0.1100	0.220	~~0.0440~~
R4/stream	0.2010	0.0109	0.0183	3.2419	0.4497	0.0234	8.04	0.2310	0.3466	0.0010	0.07103	0.142	~~0.0284~~
		Step 4 for dose 1x35 g as/ha (application at BBCH 49) – ~~20 meters meters buffer zone~~ 10 m vegetative strip and no buffor zone											
D6/ditch	1.113	0.0605	0.1012	17.9516	2.4899	0.1296	44.52	1.2793	1.9190	0.0056	1.067	2.134	~~0.4268~~
R1/stream	0.3320	0.0180	0.0302	5.3548	0.7427	0.0386	13.28	0.3816	0.5724	0.0017	0.1158	0.232	~~0.0463~~
R3/stream	0.3392	0.0184	0.0308	5.4710	0.7588	0.0395	13.57	0.3899	0.5848	0.0017	0.1801	0.360	~~0.0720~~
R4/stream	0.2684	0.0146	0.0244	4.3290	0.6004	0.0312	10.74	0.3085	0.4628	0.0013	0.09711	0.194	~~0.0388~~

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

zRMS comments:

For algae the EU agreed endpoint - ErC50 >2000 µg/L should be used. For the PEC/RAC calculations for algae the lover value at 85.9 µg/L (worse case) was used by Applicant. This was not corrected because it had no impact on the assessment result.

The acute and chronic risk to invertebrates and chronic risk to sediment-dwelling invertebrates considering exposure via water, based on Tier 1 EU agreed endpoints is covered by the refined risk assessment for aquatic invertebrates. Therefore PEC/RAC calculations with Tier 1 EU agreed endpoints were not assessed by zRMS.

Refinement of the risk assessment for invertebrates ~~and sediment-dwelling invertebrates considering exposure via sediment~~, proposed by Applicant, should be considered on the MSs level.

According to Part B8 additionally, the applicant calculated PECsw and PECsed for the following doses:
- 1x42g a.s./ha at BBCH 49;
- 2x25 g a.s./ha at BBCH 49;
- 1x35 g a.s./ha at BBCH 49.

Result of risk assessment with EU HC_5 for invertebrates ~~and refined endpoint for sediment-dwelling organisms considering exposure via sediment~~.

PEC/RAC based on refinement endpoints		
Scenario	**Surrogate crop**	**Acceptable -A Not acceptable - N**
Step 3, BBCH 12, 2 x 42 g as/ha		
D3 ditch		A
D4 pond		**N**
D4 stream		A
D5 pond	Legumes	A
D5 stream	Legumes	A
R1 pond		**N**
R1 stream		A
R3 stream		**N**
R4 stream		**N**
Step 4, BBCH 12, 2 x 42 g as/ha, 10 m buffer zone		
D3 ditch		Acceptable at Step 3
D4 pond		**Not Calculated**
D4 stream		Acceptable at Step 3
D5 pond		Acceptable at Step 3
D5 stream		Acceptable at Step 3
R1 pond		**Not calculated**
R1 stream		Acceptable at Step 3
R3 stream		A
R4 stream		**N**

Step 4, BBCH 12, 2 x 42 g as/ha, 20 m buffer zone		
R4 stream		**A**

Step 3, BBCH 49, 2 x 42 g as/ha

D3 ditch		A
D4 pond		**N**
D4 stream		**N**
D5 pond	Legumes	A
D5 stream	Legumes	A
R1 pond		A
R1 stream		**N**
R3 stream		**N**
R4 stream		**N**
Step 4, BBCH 49, 2 x 42 g as/ha		
D3 ditch		Acceptable at Step 3
D4 pond		**Not calculated**
D4 stream		**Not calculated**
D5 pond	Legumes	Acceptable at Step 3
D5 stream	Legumes	Acceptable at Step 3
R1 pond		Acceptable at Step 3
R1 stream		**Not calculated**
R3 stream		**Not calculated**
R4 stream		**Not calculated**

PEC/RAC based on refinement endpoints		
Scenario	**Surrogate crop**	**Acceptable -A** **Not acceptable - N**
Step 3, BBCH 49, 1 x 42 g as/ha		
D3 ditch		A
D4 pond		**N**
D4 stream		**N**
D5 pond	Legumes	Accepted at Step 3, 2 x 42 g as/ha
D5 stream	Legumes	Accepted at Step 3, 2 x 42 g as/ha
R1 pond		A
R1 stream		**N**
R3 stream		**N**

R4 stream		**N**
Step 4, BBCH 49, 1 x 42 g as/ha, 20 m vegetative strip and 20 meters buffer zone		
D3 ditch		Acceptable at Step 3
D4 pond		A
D4 stream		**N**
D5 pond	Legumes	Accepted at Step 3, 2 x 42 g as/ha
D5 stream	Legumes	Accepted at Step 3, 2 x 42 g as/ha
R1 pond		Acceptable at Step 3
R1 stream		A
R3 stream		A
R4 stream		A
Step 3, BBCH 49, 2 x 25 g as/ha		
D3 ditch		A
D4 pond		**N**
D4 stream		**N**
D5 pond	Legumes	Accepted at Step 3, 2 x 42 g as/ha
D5 stream	Legumes	Accepted at Step 3, 2 x 42 g as/ha
R1 pond		A
R1 stream		**N**
R3 stream		**N**
R4 stream		**N**
Step 4, BBCH 49, 2 x 25 g as/ha 20 m vegetative strip and 20 meters meters buffer zone		
D3 ditch		Acceptable at Step 3
D4 pond		**N**
D4 stream		**N**
D5 pond	Legumes	Accepted at Step 3, 2 x 42 g as/ha
D5 stream	Legumes	Accepted at Step 3, 2 x 42 g as/ha
R1 pond		Acceptable at Step 3
R1 stream		A
R3 stream		A

R4 stream		A

Step 3, BBCH 49, 1 x 35 g as/ha

D3 ditch		A
D4 pond		A
D4 stream		A
D5 pond	Legumes	Accepted at Step 3, 2 x 42 g as/ha
D5 stream	Legumes	Accepted at Step 3, 2 x 42 g as/ha
R1 pond		A
R1 stream		**N**
R3 stream		**N**
R4 stream		**N**

Step 4, BBCH 49, 1 x 35 g as/ha 10 m vegetative strip and no buffor zone

D3 ditch		Accept at Step 3
D4 pond		Accepted at Step 3
D4 stream		Accepted at Step 3
D5 pond	Legumes	Accepted at Step 3, 2 x 42 g as/ha
D5 stream	Legumes	Accepted at Step 3, 2 x 42 g as/ha
R1 pond		Accepted at Step 3
R1 stream		A
R3 stream		A
R4 stream		A

In summary:

BBCH 12, 2 x 42 g as/ha
At Step 3 risk is acceptable for: D3 ditch, D4 stream, D5 pond, D5 stream, R1 stream scenarios;

At Step 4 with 10 m buffer zone risk is acceptable for: : R3 stream

At Step 4 with 20 m buffer zone risk is acceptable for: : R4 stream
At Step 4 with 20 m buffer zone for D4 pond and R1 pond scenario the PEC/RAC value was not calculated and the risk is unresolved.

BBCH 49, 2 x 42 g as/ha
At Step 3 risk is acceptable for: D3 ditch, D5 pond, D5 stream, R1 pond scenarios.

At Step 4 PEC/RAC values were not calculated for D4 pond, D4 stream, R1 stream, R3 stream and R4 stream scenarios and the risk is unresolved.

BBCH 49, 1 x 42 g as/ha
At Step 3 risk is acceptable for: D3 ditch, R1 pond, scanarios;
D5 pond and D5 stream scenarios is acceptable at dose 2 x 42 g as/ha

At Step 4 with 20 m vegetative strip and 20 meters buffer zone risk is acceptable for: D4 pond, R1 stream, R3 stream, R4 stream scenarios.

At Step 4 with 20 m vegetative strip and 20 meters buffer zone risk is unresolved for D4 stream scenario

BBCH 49, 2 x 25 g as/ha
At Step 3 risk is acceptable for: D3 ditch, , R1 pond scenarios;
D5 pond and D5 stream scenarios is acceptable at dose 2 x 42 g as/ha

At Step 4 with 20 m vegetative strip and 20 meters buffer zone risk is acceptable for: R1 stream and R3 stream, R4 stream scenarios.

At Step 4, with 20 m vegetative strip and 20 meters buffer zone for D4 pond and D4 stream scenarios the risk is unresolved.

BBCH 49, 1 x 35 g as/ha
At Step 3 risk is acceptable for: D3 ditch, D4 pond, D4 stream, R1 pond scenarios;
D5 pond and D5 stream scenarios is acceptable at dose 2 x 42 g as/ha

At step 4, with 10 m vegetative strip and no buffor zone risk is acceptable for R1 stream, R3 stream, R4 stream scenarios.

Individual scenarios should be considered in accordance with the requirements of each Member State.

Result of risk assessment with refined HC5 for invertebrates ~~and refined endpoint for sediment-dwelling organisms considering exposure via sediment~~

PEC/RAC based on refinement endpoints		
Scenario	**Surrogate crop**	**Acceptable -A Not acceptable - N**
Step 3, BBCH 12, 2 x 42 g as/ha		
D3 ditch		A
D4 pond		A
D4 stream		A
D5 pond	Legumes	A
D5 stream	Legumes	A
R1 pond		**N**
R1 stream		A
R3 stream		**N**
R4 stream		A
Step 4, BBCH 12, 2 x 42 g as/ha, 10 m buffer zone		
D3 ditch		Acceptable at Step 3
D4 pond		Acceptable at Step 3
D4 stream		Acceptable at Step 3
D5 pond		Acceptable at Step 3
D5 stream		Acceptable at Step 3
R1 pond		**Not calculated**
R1 stream		Acceptable at Step 3
R3 stream		A
R4 stream		Acceptable at Step 3
Step 3, BBCH 49, 2 x 42 g as/ha		
D3 ditch		A
D4 pond		**N**
D4 stream		**N**
D5 pond	Legumes	A
D5 stream	Legumes	A
R1 pond		A

R1 stream		**N**
R3 stream		**N**
R4 stream		**N**
Step 4, BBCH 49, 2 x 42 g as/ha		
D3 ditch		Acceptable at Step 3
D4 pond		**Not calculated**
D4 stream		**Not calculated**
D5 pond	Legumes	Acceptable at Step 3
D5 stream	Legumes	Acceptable at Step 3
R1 pond		Acceptable at Step 3
R1 stream		**Not calculated**
R3 stream		**Not calculated**
R4 stream		**Not calculated**

PEC/RAC based on refinement endpoints		
Scenario	**Surrogate crop**	**Acceptable -A** **Not acceptable - N**
Step 3, BBCH 49, 1 x 42 g as/ha		
D3 ditch		A
D4 pond		A
D4 stream		A
D5 pond	Legumes	Accepted at Step 3, 2 x 42 g as/ha
D5 stream	Legumes	Accepted at Step 3, 2 x 42 g as/ha
R1 pond		A
R1 stream		**N**
R3 stream		A
R4 stream		A
Step 4, BBCH 49, 1 x 42 g as/ha, 20 m vegetative strip and 20 meters buffer zone		
D3 ditch		Acceptable at Step 3
D4 pond		Acceptable at Step 3
D4 stream		Acceptable at Step 3

D5 pond	Legumes	Accepted at Step 3, 2 x 42 g as/ha
D5 stream	Legumes	Accepted at Step 3, 2 x 42 g as/ha
R1 pond		Acceptable at Step 3
R1 stream		A
R3 stream		Acceptable at Step 3
R4 stream		Acceptable at Step 3
Step 3, BBCH 49, 2 x 25 g as/ha		
D3 ditch		A
D4 pond		**N**
D4 stream		A
D5 pond	Legumes	Accepted at Step 3, 2 x 42 g as/ha
D5 stream	Legumes	Accepted at Step 3, 2 x 42 g as/ha
R1 pond		A
R1 stream		**N**
R3 stream		**N**
R4 stream		A
Step 4, BBCH 49, 2 x 25 g as/ha 20 m vegetative strip and 20 meters meters buffer zone		
D3 ditch		Acceptable at Step 3
D4 pond		A
D4 stream		Acceptable at Step 3
D5 pond	Legumes	Accepted at Step 3, 2 x 42 g as/ha
D5 stream	Legumes	Accepted at Step 3, 2 x 42 g as/ha
R1 pond		Acceptable at Step 3
R1 stream		A
R3 stream		A
R4 stream		Acceptable at Step 3
Step 3, BBCH 49, 1 x 35 g as/ha		
D3 ditch		A

D4 pond		A
D4 stream		A
D5 pond	Legumes	Accepted at Step 3, 2 x 42 g as/ha
D5 stream	Legumes	Accepted at Step 3, 2 x 42 g as/ha
R1 pond		A
R1 stream		A
R3 stream		A
R4 stream		A
Step 4, BBCH 49, 1 x 35 g as/ha 10 m vegetative strip and no buffor zone		
D3 ditch		Acceptable at Step 3
D4 pond		Acceptable at Step 3
D4 stream		Acceptable at Step 3
D5 pond	Legumes	Accepted at Step 3, 2 x 42 g as/ha
D5 stream	Legumes	Accepted at Step 3, 2 x 42 g as/ha
R1 pond		Acceptable at Step 3
R1 stream		Acceptable at Step 3
R3 stream		Acceptable at Step 3
R4 stream		Acceptable at Step 3

In summary:

BBCH 12, 2 x 42 g as/ha
At Step 3 risk is acceptable for: D3 ditch, D4 pond, D4 stream, D5 pond, D5 stream, R1 stream, R4 stream;

At Step 4 with 10 m buffer zone risk is acceptable for: R3 stream

At Step 4 with 10 m buffer zone for R1 pond scenario the PEC/RAC value was not calculated and the risk is unresolved.

BBCH 49, 2 x 42 g as/ha

At Step 3 risk is acceptable for: D3 ditch, D5 pond, D5 stream scenarios.

At Step 4 PEC/RAC values were not calculated for D4 pond, D4 stream, R1 stream, R3 stream and R4 stream scenarios and the risk is unresolved.

BBCH 49, 1 x 42 g as/ha
At Step 3 risk is acceptable for: D3 ditch, D4 pond, D4 stream, R1 pond, R3 stream, R4 stream;
D5 pond and D5 stream scenarios is acceptable at dose 2 x 42 g as/ha

At Step 4 with 20 m vegetative strip and 20 meters buffer zone risk is acceptable for: R1 stream scenario

BBCH 49, 2 x 25 g as/ha
At Step 3 risk is acceptable for: D3 ditch, D4 stream, R1 pond, R4 stream;
D5 pond and D5 stream scenarios is acceptable at dose 2 x 42 g as/ha

At Step 4 with 20 m vegetative strip and 20 meters buffer zone risk is acceptable for: D4 pond, R1 stream, R3 stream.

BBCH 49, 1 x 35 g as/ha
At Step 3 risk is acceptable for: all scenarios;
D5 pond and D5 stream scenarios is acceptable at dose 2 x 42 g as/ha

Individual scenarios should be considered in accordance with the requirements of each Member State.

Soyabean, use no.

32, Soyabean, BBCH 61-65, 1 x 35 g as/ha

Table 9.5-9: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for chlorantraniliprole for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CLOROL 200 SC in soyabean

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged
Test species		*Bluegill sunfish*	*Oncorhynchus mykiss*	*Daphnia magna*	*Daphnia magna*	*Pseudokirchn. subcapitata*	*Invertebrate*	*Invertebrate*	*Lemna Gibba*		*Chironomus riparius*
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	HC5	HC5	EC50		NOEC
(µg/L)		1840	110	6.2	4.47	85.9	2.61	2.91	2000		25
AF		100	10	100	10	10	3	5	10		10
RAC (µg/L)		18.4	11	0.062	0.447	8.59	0.87	0.58	200		2.5
FOCUS Scenario	PEC $_{gl-max}$ (µg/L)									PEC $_{gl-max}$ (µg/kg)	
Step 1											
	8.65	0.4701	0.7864	139.5161	19.3512	1.0070	9.9425	14.9138	0.0433	25.7	10.2800
Step 2											
N-Europe	1.08	0.0587	0.0982	17.4194	2.4161	0.1257	1.2414	1.8621	0.0054	3.18	1.2720
Step 3											
R3/stream	0.5529	0.0300	0.0503	8.9177	1.2369	0.0644	0.6355	0.9533	0.0028	0.2784	0.1114
R4/stream	0.5743	0.0312	0.0522	9.2629	1.2848	0.0669	0.6601	0.9902	0.0029	0.1777	0.0711
Step 3 – For Legumes as surrogate crop according to national polish requirements											
D3/ditch	0.1837	0.0100	0.0167	2.9629	0.4110	0.0214	0.2111	0.3167	0.0009	0.06555	0.0262
D4/pond	0.2133	0.0116	0.0194	3.4403	0.4772	0.0248	0.2452	0.3678	0.0011	0.9338	0.3735
D4/stream	0.1981	0.0108	0.0180	3.1952	0.4432	0.0231	0.2277	0.3416	0.0010	0.3338	0.1335
D5/pond	0.1424	0.0077	0.0129	2.2968	0.3186	0.0166	0.1637	0.2455	0.0007	0.8925	0.3570
D5/stream	0.1796	0.0098	0.0163	2.8968	0.4018	0.0209	0.2064	0.3097	0.0009	0.1952	0.0781
D6/ditch	0.2801	0.0152	0.0255	4.5177	0.6266	0.0326	0.3220	0.4829	0.0014	0.2016	0.0806

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged
R1/pond	0.06271	0.0034	0.0057	1.0115	0.1403	0.0073	0.0721	0.1081	0.0003	0.1950	0.0780
R1/stream	0.3815	0.0207	0.0347	6.1532	0.8535	0.0444	0.4385	0.6578	0.0019	0.1880	0.0752
R2/stream	0.1702	0.0093	0.0155	2.7452	0.3808	0.0198	0.1956	0.2934	0.0009	0.1154	0.0462
R3/stream	0.4253	0.0231	0.0387	6.8597	0.9515	0.0495	0.4889	0.7333	0.0021	0.1759	0.0704
R4/stream	0.5219	0.0284	0.0474	8.4177	1.1676	0.0608	0.5999	0.8998	0.0026	0.1904	0.0762

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

Risk assessment was updates by Applicant as follows:

Group		**Fish acute**	**Fish pro-longed**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. Dwell, prolonged (aquatic phase)**	**Higher-tier information**	**Higher-tier information**	**Aquatic plants**		**Sed. dwell, prolonged**	~~**Higher Tier information for Sed. dwell. pro-longed**~~
Test spe-cies		***Bluegill sunfish***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchn. subcapitata***	***Chironomus riparius***	***Invertebrate***	***Invertebrate***	***Lemna Gibba***		***Chironomus riparius***	~~***Chironomus riparius***~~
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	NOEC	HC5	HC5	EC50		NOEC	~~NOEC~~
(µg/L)		1840	110	6.2	4.47	85.9	0.25	2.61	2.91	2000		5	~~25~~
AF		100	10	100	10	10	10	3	5	10		10	~~10~~
RAC (µg/L)		18.4	11	0.062	0.447	8.59	0.025	0.87	0.58	200		0.5	~~2.5~~
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**										**PEC $_{gl-max}$ (µg/kg)**		
Step 1													
	8.65	0.4701	0.7864	139.5161	19.3512	1.0070	346.0	9.9425	14.9138	0.0433	25.7	51.400	10.2800
Step 2													

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. Dwell, prolonged (aquatic phase)	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged	~~Higher-Tier information for Sed. dwell. pro-longed~~
N-Europe	1.08	0.0587	0.0982	17.4194	2.4161	0.1257	43.2	1.2414	1.8621	0.0054	3.18	6.360	~~1.2720~~
Step 3 for dose 1x35 g as/ha (application at BBCH 61)													
R3/stream	0.5529	0.0300	0.0503	8.9177	1.2369	0.0644	22.12	0.6355	0.9533	0.0028	0.2784	0.557	~~0.1114~~
R4/stream	0.5743	0.0312	0.0522	9.2629	1.2848	0.0669	22.97	0.6601	0.9902	0.0029	0.1777	0.355	~~0.0711~~
		Step 3 – For Legumes as surrogate crop according to national polish requirements for dose 1x35 g as/ha (application at BBCH 61)											
~~D3/ditch~~	~~0.1837~~	~~0.0100~~	~~0.0167~~	~~2.9629~~	~~0.4110~~	~~0.0214~~	~~7.35~~	~~0.2111~~	~~0.3167~~	~~0.0009~~	~~0.06555~~	~~0.131~~	~~0.0262~~
~~D4/pond~~	~~0.2133~~	~~0.0116~~	~~0.0194~~	~~3.4403~~	~~0.4772~~	~~0.0248~~	~~8.53~~	~~0.2452~~	~~0.3678~~	~~0.0011~~	~~0.9338~~	~~1.868~~	~~0.3735~~
~~D4/stream~~	~~0.1981~~	~~0.0108~~	~~0.0180~~	~~3.1952~~	~~0.4432~~	~~0.0231~~	~~7.92~~	~~0.2277~~	~~0.3416~~	~~0.0010~~	~~0.3338~~	~~0.668~~	~~0.1335~~
D5/pond	0.1424	0.0077	0.0129	2.2968	0.3186	0.0166	5.70	0.1637	0.2455	0.0007	0.8925	1.785	~~0.3570~~
D5/stream	0.1796	0.0098	0.0163	2.8968	0.4018	0.0209	7.18	0.2064	0.3097	0.0009	0.1952	0.390	~~0.0781~~
~~D6/ditch~~	~~0.2801~~	~~0.0152~~	~~0.0255~~	~~4.5177~~	~~0.6266~~	~~0.0326~~	~~11.20~~	~~0.3220~~	~~0.4829~~	~~0.0014~~	~~0.2016~~	~~0.403~~	~~0.0806~~
~~R1/pond~~	~~0.06271~~	~~0.0034~~	~~0.0057~~	~~1.0115~~	~~0.1403~~	~~0.0073~~	~~2.51~~	~~0.0721~~	~~0.1081~~	~~0.0003~~	~~0.1950~~	~~0.390~~	~~0.0780~~
~~R1/stream~~	~~0.3815~~	~~0.0207~~	~~0.0347~~	~~6.1532~~	~~0.8535~~	~~0.0444~~	~~15.26~~	~~0.4385~~	~~0.6578~~	~~0.0019~~	~~0.1880~~	~~0.376~~	~~0.0752~~
~~R2/stream~~	~~0.1702~~	~~0.0093~~	~~0.0155~~	~~2.7452~~	~~0.3808~~	~~0.0198~~	~~6.81~~	~~0.1956~~	~~0.2934~~	~~0.0009~~	~~0.1154~~	~~0.231~~	~~0.0462~~
~~R3/stream~~	~~0.4253~~	~~0.0231~~	~~0.0387~~	~~6.8597~~	~~0.9515~~	~~0.0495~~	~~17.012~~	~~0.4889~~	~~0.7333~~	~~0.0021~~	~~0.1759~~	~~0.352~~	~~0.0704~~
~~R4/stream~~	~~0.5219~~	~~0.0284~~	~~0.0474~~	~~8.4177~~	~~1.1676~~	~~0.0608~~	~~20.876~~	~~0.5999~~	~~0.8998~~	~~0.0026~~	~~0.1904~~	~~0.381~~	~~0.0762~~
		Step 3 for field beans as surrogate crops for D3, D4 and R1 scenario (application at BBCH 61) for dose 1x35 g as/ha											
D3/ditch	0.1841	0.0100	0.0167	2.9694	0.4119	0.0214	7.36	0.2116	0.3174	0.0009	0.07797	0.156	~~0.0312~~
D4/pond	0.2295	0.0125	0.0209	3.7016	0.5134	0.0267	9.18	0.2638	0.3957	0.0011	0.8939	1.788	~~0.3576~~
D4/stream	0.2351	0.0128	0.0214	3.7919	0.5260	0.0274	9.40	0.2702	0.4053	0.0012	0.3210	0.642	~~0.1284~~
R1/pond	0.03364	0.0018	0.0031	0.5426	0.0753	0.0039	1.35	0.0387	0.0580	0.0002	0.1056	0.211	~~0.0422~~
R1/stream	0.5290	0.0288	0.0481	8.5323	1.1834	0.0616	21.16	0.6080	0.9121	0.0026	0.1886	0.377	~~0.0754~~

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. Dwell, prolonged (aquatic phase)	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged	~~Higher-Tier information for Sed. dwell. pro-longed~~
		~~**Step 3 (application at BBCH 65)** for dose 1x35 g as/ha~~											
R3/stream	0.4506	0.4506	0.0245	0.0410	7.2677	1.0081	18.02	0.0525	0.5179	0.7769	0.3213	0.643	~~0.1285~~
R4/stream	0.6690	0.669	0.0364	0.0608	10.7903	1.4966	26.76	0.0779	0.7690	1.1534	0.2079	0.416	~~0.0832~~
		Step 3 for field beans as surrogate crops for D3, D4 and R1 scenario (application at BBCH 65) for dose 1x35 g as/ha											
D3/ditch	0.1841	0.0100	0.0167	2.9694	0.4119	0.0214	7.36	0.2116	0.3174	0.0009	0.07795	0.156	~~0.0312~~
D4/pond	0.2331	0.0127	0.0212	3.7597	0.5215	0.0271	9.32	0.2679	0.4019	0.0012	0.8993	1.799	~~0.3597~~
D4/stream	0.2386	0.0130	0.0217	3.8484	0.5338	0.0278	9.54	0.2743	0.4114	0.0012	0.3230	0.646	~~0.1292~~
R1/pond	0.008247	0.0004	0.0007	0.1330	0.0184	0.0010	0.33	0.0095	0.0142	0.0000	0.04429	0.089	~~0.0177~~
R1/stream	0.1496	0.0081	0.0136	2.4129	0.3347	0.0174	5.98	0.1720	0.2579	0.0007	0.03189	0.064	~~0.0128~~
		Step 3 for legumes as surrogate crops for D5 scenario (application at BBCH 65) for dose 1x35 g as/ha											
D5/pond	0.1644	0.0089	0.0149	2.6516	0.3678	0.0191	6.58	0.1890	0.2834	0.0008	1.072	2.144	~~0.4288~~
D5/stream	0.1796	0.0098	0.0163	2.8968	0.4018	0.0209	7.18	0.2064	0.3097	0.0009	0.2358	0.472	~~0.0943~~

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

zRMS comments:

For algae the EU agreed endpoint - ErC50 >2000 µg/L should be used. For the PEC/RAC calculations for algae the lover value at 85.9 µg/L (worse case) was used by Applicant. This was not corrected because it had no impact on the assessment result.

The acute and chronic risk to invertebrates and chronic risk to sediment-dwelling invertebrates considering exposure via water, based on Tier 1 EU agreed endpoints is covered by the refined risk assessment for aquatic invertebrates. Therefore PEC/RAC calculations with Tier 1 EU agreed endpoints were not assessed by zRMS.

Refinement of the risk assessment for invertebrates ~~and sediment-dwelling invertebrates considering exposure via sediment~~, proposed by Applicant, should be considered on the MSs level.
According to Part B8 for D3, D4 and R1 scenarios: surrogate crop is field beans and for D5 scenario: surrogate crop is legumes

Result of risk assessment with EU HC_5 for invertebrates ~~and refined endpoint for sediment-dwelling organisms considering exposure via sediment.~~

1 x 35 g as/ha BBCH 61-65

PEC/RAC based on refinement endpoints		
Scenario	**Surrogate crop**	**Acceptable -A Not acceptable - N**
Step 3, BBCH 61, 1 x 35 g as/ha		
D3 ditch	field beans	A
D4 pond	field beans	A
D4 stream	field beans	A
D5 pond	Legumes	A
D5 stream	Legumes	A
R1 pond	field beans	A
R1 stream	field beans	A
R3 stream		A
R4 stream		A

PEC/RAC based on refinement endpoints		
Scenario	**Surrogate crop**	**Acceptable -A Not acceptable - N**
Step 3, BBCH 65, 1 x 35 g as/ha		
D3 ditch	field beans	A
D4 pond	field beans	A
D4 stream	field beans	A
D5 pond	Legumes	A
D5 stream	Legumes	A
R1 pond	field beans	A
R1 stream	field beans	A
R3 stream		A
R4 stream		A

In summary:

BBCH 61, 1 x 35 g as/ha
At Step 3 risk is acceptable for all scenarios.

BBCH 65, 1 x 35 g as/ha
At Step 3 risk is acceptable for all scenarios.

Individual scenarios should be considered in accordance with the requirements of each Member State.

Result of risk assessment with refined HC5 for invertebrates ~~and refined endpoint for sediment-dwelling organisms considering exposure via sediment~~

PEC/RAC based on refinement endpoints		
Scenario	**Surrogate crop**	**Acceptable -A Not acceptable - N**
Step 3, BBCH 61, 1 x 35 g as/ha		
D3 ditch	field beans	A
D4 pond	field beans	A
D4 stream	field beans	A
D5 pond	Legumes	A
D5 stream	Legumes	A
R1 pond	field beans	A
R1 stream	field beans	A
R3 stream		A
R4 stream		A

PEC/RAC based on refinement endpoints		
Scenario	**Surrogate crop**	**Acceptable -A Not acceptable - N**
Step 3, BBCH 65, 1 x 35 g as/ha		
D3 ditch	field beans	A
D4 pond	field beans	A
D4 stream	field beans	A

D5 pond	Legumes	A
D5 stream	Legumes	A
R1 pond	field beans	A
R1 stream	field beans	A
R3 stream		A
R4 stream		A

Use no. 3, 1 x 35 g as/ha BBCH 61-71

In summary:

BBCH 61, 1 x 35 g as/ha
At Step 3 risk is acceptable for all scenarios.

BBCH 65, 1 x 35 g as/ha
At Step 3 risk is acceptable for all scenarios.

If refinement of the risk assessment for invertebrates ~~and sediment-dwelling invertebrates considering exposure via sediment~~ is not accepted further refinement is required.

Individual scenarios should be considered in accordance with the requirements of each Member State.

Maize, use no.:

2, Maize, BBCH 53-69, 1 x 25 g/ha
23, Sweet cane, BBCH 53-69, 1 x 25 g/ha
24, Sorghum, BBCH 53-69, 1 x 25 g/ha
25, Millet, BBCH 53-69, 1 x 25 g/ha
22, Sweet corn, BBCH 53-69, 1 x 35 g/ha

Table 9.5-10: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for chlorantraniliprole for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CLOROL 200 SC in maize

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged
Test species		*Bluegill sunfish*	*Oncorhynchus mykiss*	*Daphnia magna*	*Daphnia magna*	*Pseudokirchn. subcapitata*	*Invertebrate*	*Invertebrate*	*Lemna Gibba*		*Chironomus riparius*
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	HC5	HC5	EC50		NOEC
(µg/L)		1840	110	6.2	4.47	85.9	2.61	2.91	2000		25
AF		100	10	100	10	10	3	5	10		10
RAC (µg/L)		18.4	11	0.062	0.447	8.59	0.87	0.58	200		2.5
FOCUS Scenario	PEC $_{gl-max}$ (µg/L)									PEC $_{gl-max}$ (µg/kg)	
Step 1											
	8.65	0.4701	0.7864	139.5161	19.3512	1.0070	9.9425	14.9138	0.0433	25.7	10.2800
Step 2											
N-Europe	1.08	0.0587	0.0982	17.4194	2.4161	0.1257	1.2414	1.8621	0.0054	3.18	1.2720
Step 3											
D3/ditch	0.1836	0.0100	0.0167	2.9613	0.4107	0.0214	0.2110	0.3166	0.0009	0.06351	0.0254
D4/pond	0.3024	0.0164	0.0275	4.8774	0.6765	0.0352	0.3476	0.5214	0.0015	1.139	0.4556
D4/stream	0.3102	0.0169	0.0282	5.0032	0.6940	0.0361	0.3566	0.5348	0.0016	0.4177	0.1671
D5/pond	0.09676	0.0053	0.0088	1.5606	0.2165	0.0113	0.1112	0.1668	0.0005	0.5538	0.2215
D5/stream	0.1795	0.0098	0.0163	2.8952	0.4016	0.0209	0.2063	0.3095	0.0009	0.1184	0.0474
D6/ditch	0.1878	0.0102	0.0171	3.0290	0.4201	0.0219	0.2159	0.3238	0.0009	0.1126	0.0450
R1/pond	0.01239	0.0007	0.0011	0.1998	0.0277	0.0014	0.0142	0.0214	0.0001	0.06259	0.0250
R1/stream	0.2227	0.0121	0.0202	3.5919	0.4982	0.0259	0.2560	0.3840	0.0011	0.05593	0.0224

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged
R2/stream	0.1706	0.0093	0.0155	2.7516	0.3817	0.0199	0.1961	0.2941	0.0009	0.1562	0.0625
R3/stream	0.6335	0.0344	0.0576	10.2177	1.4172	0.0737	0.7282	1.0922	0.0032	0.3380	0.1352
R4/stream	0.6907	0.0375	0.0628	11.1403	1.5452	0.0804	0.7939	1.1909	0.0035	0.2567	0.1027
Step 4 – 10 meters vegetative buffer zone											
R3/stream	0.2889	0.0157	0.0263	4.6597	0.6463	0.0336	0.3321	0.4981	0.0014	0.1219	0.0488
R4/stream	0.3142	0.0171	0.0286	5.0677	0.7029	0.0366	0.3611	0.5417	0.0016	0.1146	0.0458

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

Risk assessment was updates by Applicant as follows:

Group		**Fish acute**	**Fish pro-longed**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. Dwell. prolonged (aquatic phase)**	**Higher-tier information**	**Higher-tier information**	**Aquatic plants**		**Sed. dwell. prolonged**	~~**Higher-Tier information for Sed. dwell. pro-longed**~~
Test spe-cies		***Bluegill sunfish***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchn. subcapitata***	***Chironomus riparius***	***Invertebrate***	***Invertebrate***	***Lemna Gibba***		***Chironomus riparius***	~~***Chironomus riparius***~~
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	NOEC	HC5	HC5	EC50		NOEC	~~NOEC~~
(µg/L)		1840	110	6.2	4.47	85.9	0.25	2.61	2.91	2000		5	~~25~~
AF		100	10	100	10	10	10	3	5	10		10	~~10~~
RAC (µg/L)		18.4	11	0.062	0.447	8.59	0.25	0.87	0.58	200		0.5	~~2.5~~
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**										**PEC $_{gl-max}$ (µg/kg)**		

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. Dwell. prolonged (aquatic phase)	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged	~~Higher Tier information for Sed. dwell. pro-longed~~
Step 1													
	8.65	0.4701	0.7864	139.5161	19.3512	1.0070	346.0	9.9425	14.9138	0.0433	25.7	51.400	~~10.2800~~
Step 2													
N-Europe	1.08	0.0587	0.0982	17.4194	2.4161	0.1257	43.2	1.2414	1.8621	0.0054	3.18	6.360	~~1.2720~~
		Step 3 (application at BBCH 53) for dose 1x35 g as/ha											
D3/ditch	0.1836	0.0100	0.0167	2.9613	0.4107	0.0214	7.34	0.2110	0.3166	0.0009	0.06351	0.127	~~0.0254~~
D4/pond	0.3024	0.0164	0.0275	4.8774	0.6765	0.0352	12.10	0.3476	0.5214	0.0015	1.139	2.278	~~0.4556~~
D4/stream	0.3102	0.0169	0.0282	5.0032	0.6940	0.0361	12.41	0.3566	0.5348	0.0016	0.4177	0.835	~~0.1671~~
D5/pond	0.09676	0.0053	0.0088	1.5606	0.2165	0.0113	3.87	0.1112	0.1668	0.0005	0.5538	1.108	~~0.2215~~
D5/stream	0.1795	0.0098	0.0163	2.8952	0.4016	0.0209	7.18	0.2063	0.3095	0.0009	0.1184	0.237	~~0.0474~~
D6/ditch	0.1878	0.0102	0.0171	3.0290	0.4201	0.0219	7.51	0.2159	0.3238	0.0009	0.1126	0.225	~~0.0450~~
R1/pond	0.01239	0.0007	0.0011	0.1998	0.0277	0.0014	0.50	0.0142	0.0214	0.0001	0.06259	0.125	~~0.0250~~
R1/stream	0.2227	0.0121	0.0202	3.5919	0.4982	0.0259	8.91	0.2560	0.3840	0.0011	0.05593	0.112	~~0.0224~~
R2/stream	0.1706	0.0093	0.0155	2.7516	0.3817	0.0199	6.82	0.1961	0.2941	0.0009	0.1562	0.312	~~0.0625~~
R3/stream	0.6335	0.0344	0.0576	10.2177	1.4172	0.0737	25.340	0.7282	1.0922	0.0032	0.3380	0.676	~~0.1352~~
R4/stream	0.6907	0.0375	0.0628	11.1403	1.5452	0.0804	27.628	0.7939	1.1909	0.0035	0.2567	0.513	~~0.1027~~
		Step 3 (application at BBCH 69) for dose 1x35 g as/ha											
D3/ditch	0.1839	0.0100	0.0167	2.9661	0.4114	0.0214	7.36	0.2114	0.3171	0.0009	0.07102	0.142	~~0.0284~~
D4/pond	0.2067	0.0112	0.0188	3.3339	0.4624	0.0241	8.27	0.2376	0.3564	0.0010	0.7949	1.590	~~0.3180~~
D4/stream	0.2128	0.0116	0.0193	3.4323	0.4761	0.0248	8.51	0.2446	0.3669	0.0011	0.2899	0.580	~~0.1160~~
D5/pond	0.1104	0.0060	0.0100	1.7806	0.2470	0.0129	4.42	0.1269	0.1903	0.0006	0.6737	1.347	~~0.2695~~
D5/stream	0.1795	0.0098	0.0163	2.8952	0.4016	0.0209	7.18	0.2063	0.3095	0.0009	0.1307	0.261	~~0.0523~~

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. Dwell. prolonged (aquatic phase)	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged	~~Higher Tier information for Sed. dwell. pro-longed~~
R1/pond	0.01690	0.0009	0.0015	0.2726	0.0378	0.0020	0.68	0.0194	0.0291	0.0001	0.08104	0.162	~~0.0324~~
R1/stream	0.2814	0.0153	0.0256	4.5387	0.6295	0.0328	11.26	0.3234	0.4852	0.0014	0.07110	0.142	~~0.0284~~
R3/stream	0.5495	0.0299	0.0500	8.8629	1.2293	0.0640	21.98	0.6316	0.9474	0.0027	0.3153	0.631	~~0.1261~~
R4/stream	0.7543	0.0410	0.0686	12.1661	1.6875	0.0878	30.17	0.8670	1.3005	0.0038	0.2889	0.578	~~0.1156~~
	Step 4 – 10 meters vegetative buffer zone (application at BBCH 53)												
R3/stream	0.2889	0.0157	0.0263	4.6597	0.6463	0.0336	11.56	0.3321	0.4981	0.0014	0.1219	0.244	~~0.0488~~
R4/stream	0.3142	0.0171	0.0286	5.0677	0.7029	0.0366	12.57	0.3611	0.5417	0.0016	0.1146	0.229	~~0.0458~~

zRMS comments:

For algae the EU agreed endpoint - ErC50 >2000 µg/L should be used. For the PEC/RAC calculations for algae the lover value at 85.9 µg/L (worse case) was used by Applicant. This was not corrected because it had no impact on the assessment result.

The acute and chronic risk to invertebrates and chronic risk to sediment-dwelling invertebrates considering exposure via water, based on Tier 1 EU agreed endpoints is covered by the refined risk assessment for aquatic invertebrates. Therefore PEC/RAC calculations with Tier 1 EU agreed endpoints were not assessed by zRMS.

Refinement of the risk assessment for invertebrates ~~and sediment-dwelling invertebrates considering exposure via sediment~~, proposed by Applicant, should be considered on the MSs level.

According to Part B8 for scenarios R3 and R4 (application in BBCH 69) PECsw/sed values were not calculated in Step 4. These scenarios are not relevant for Poland, where the product CLOROL 200 SC will be used, therefore zRMS did not ask for supplementary calculations for them.

Result of risk assessment with EU HC_5 for invertebrates ~~and refined endpoint for sediment-dwelling organisms considering exposure via sediment~~.

PEC/RAC based on refinement endpoints

Scenario	Surrogate crop	Acceptable -A Not acceptable - N
Step 3, BBCH 53, 1 x 35 g as/ha		
D3 ditch		A
D4 pond		A
D4 stream		A
D5 pond		A
D5 stream		A
R1 pond		A
R1 stream		A
R3 stream		**N**
R4 stream		**N**
Step 4, BBCH 53, 10 meters vegetative buffer zone		
R3 stream		**A**
R4 stream		**A**
Step 3, BBCH 69, 1 x 35 g as/ha		
D3 ditch		A
D4 pond		A
D4 stream		A
D5 pond		A
D5 stream		A
R1 pond		A
R1 stream		A
R3 stream		A
R4 stream		**N**

In summary:

BBCH 53, 1 x 35 g as/ha
At Step 3 risk is acceptable for: all scenarios except R3 stream and R4 stream.
At Step 4, for R3 stream and R4 stream 10 m vegetative buffer zone is required.

BBCH 69, 1 x 35 g as/ha
At Step 3 risk is acceptable for: all scenarios except R4 stream.
The risk for R4 stream scenario is unresolved.

Individual scenarios should be considered in accordance with the requirements of each Member State.

Result of risk assessment with refined HC5 for invertebrates ~~and refined endpoint for sediment-dwelling organisms considering exposure via sediment~~

PEC/RAC based on refinement endpoints		
Scenario	**Surrogate crop**	**Acceptable -A Not acceptable - N**
Step 3, BBCH 53, 1 x 35 g as/ha		
D3 ditch		A
D4 pond		A
D4 stream		A
D5 pond		A
D5 stream		A
R1 pond		A
R1 stream		A
R3 stream		A
R4 stream		A
Step 3, BBCH 69, 1 x 35 g as/ha		
D3 ditch		A
D4 pond		A
D4 stream		A
D5 pond		A
D5 stream		A
R1 pond		A

R1 stream		A
R3 stream		A
R4 stream		A

In summary:

BBCH 53, 1 x 35 g as/ha
At Step 3 risk is acceptable for: all scenarios

BBCH 69, 1 x 35 g as/ha
At Step 3 risk is acceptable for: all scenarios

Individual scenarios should be considered in accordance with the requirements of each Member State.

Sunflower, use no. 31, BBCH 61-65, 1 x 35 g as/ha

Table 9.5-11: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for chlorantraniliprole for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CLOROL 200 SC in sunflower

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged
Test species		*Bluegill sunfish*	*Oncorhynchus mykiss*	*Daphnia magna*	*Daphnia magna*	*Pseudokirchn. subcapitata*	*Invertebrate*	*Invertebrate*	*Lemna Gibba*		*Chironomus riparius*
Endpoint (µg/L)		LC_{50} 1840	NOEC 110	EC_{50} 6.2	NOEC 4.47	EC_{50} 85.9	HC5 2.61	HC5 2.91	EC50 2000		NOEC 25
AF		100	10	100	10	10	3	5	10		10
RAC (µg/L)		18.4	11	0.062	0.447	8.59	0.87	0.58	200		2.5
FOCUS Scenario	PEC $_{gl-max}$ (µg/L)									PEC $_{gl-max}$ (µg/kg)	

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged
Step 1											
	8.65	0.4701	0.7864	139.5161	19.3512	1.0070	9.9425	14.9138	0.0433	25.70	10.2800
Step 2											
N-Europe	1.08	0.0587	0.0982	17.4194	2.4161	0.1257	1.2414	1.8621	0.0054	3.18	1.2720
Step 3											
D5/pond	0.05479	0.0030	0.0050	0.8837	0.1226	0.0064	0.0630	0.0945	0.0003	0.4776	0.1910
D5/stream	0.1795	0.0098	0.0163	2.8952	0.4016	0.0209	0.2063	0.3095	0.0009	0.1036	0.0414
R1/pond	0.03206	0.0017	0.0029	0.5171	0.0717	0.0037	0.0369	0.0553	0.0002	0.1040	0.0416
R1/stream	0.4889	0.0266	0.0444	7.8855	1.0937	0.0569	0.5620	0.8429	0.0024	0.1791	0.0716
R3/stream	0.5466	0.0297	0.0497	8.8161	1.2228	0.0636	0.6283	0.9424	0.0027	0.3265	0.1306
R4/stream	0.7079	0.0385	0.0644	11.4177	1.5837	0.0824	0.8137	1.2205	0.0035	0.2708	0.1083
Step 4 – 10 meters buffer zone											
R4/stream	0.3219	0.0175	0.0293	5.1919	0.7201	0.0375	0.3700	0.5550	0.0016	0.1185	0.0474

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

Risk assessment was updates by Applicant as follows:

Group		**Fish acute**	**Fish pro-longed**	Inverteb. acute	Inverteb. prolonged	**Algae**	**Sed. Dwell. prolonged (aquatic phase)**	**Higher-tier information**	**Higher-tier information**	**Aquatic plants**		**Sed. dwell. prolonged**	~~**Higher-Tier information for Sed. dwell. pro-longed**~~
Test spe-cies		***Bluegill sunfish***	***Oncorhynchus mykiss***	*Daphnia magna*	*Daphnia magna*	***Pseudokirchn. subcapitata***	***Chironomus riparius***	***Invertebrate***	***Invertebrate***	***Lemna Gibba***		***Chironomus riparius***	~~***Chironomus riparius***~~
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	NOEC	HC5	HC5	EC50		NOEC	~~NOEC~~
(µg/L)		1840	110	6.2	4.47	85.9	0.25	2.61	2.91	2000		5	~~25~~

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. Dwell. prolonged (aquatic phase)	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged	~~Higher-Tier information for Sed. dwell. pro-longed~~
AF		100	10	100	10	10	10	3	5	10		10	~~10~~
RAC (µg/L)		18.4	11	0.062	0.447	8.59	0.025	0.87	0.58	200		0.5	~~2.5~~
FOCUS Scenario	**PEC gl-max (µg/L)**										**PEC gl-max (µg/kg)**		
Step 1													
	8.65	0.4701	0.7864	139.5161	19.3512	1.0070	346.0	9.9425	14.9138	0.0433	25.70	51.400	~~10.2800~~
Step 2													
N-Europe	1.08	0.0587	0.0982	17.4194	2.4161	0.1257	43.2	1.2414	1.8621	0.0054	3.18	6.360	~~1.2720~~
		Step 3 (application at BBCH 61) for dose 1x35 g as/ha											
D5/pond	0.05479	0.0030	0.0050	0.8837	0.1226	0.0064	2.19	0.0630	0.0945	0.0003	0.4776	0.955	~~0.1910~~
D5/stream	0.1795	0.0098	0.0163	2.8952	0.4016	0.0209	7.18	0.2063	0.3095	0.0009	0.1036	0.207	~~0.0414~~
R1/pond	0.03206	0.0017	0.0029	0.5171	0.0717	0.0037	1.28	0.0369	0.0553	0.0002	0.1040	0.208	~~0.0416~~
R1/stream	0.4889	0.0266	0.0444	7.8855	1.0937	0.0569	19.56	0.5620	0.8429	0.0024	0.1791	0.358	~~0.0716~~
R3/stream	0.5466	0.0297	0.0497	8.8161	1.2228	0.0636	21.86	0.6283	0.9424	0.0027	0.3265	0.653	~~0.1306~~
R4/stream	0.7079	0.0385	0.0644	11.4177	1.5837	0.0824	28.32	0.8137	1.2205	0.0035	0.2708	0.542	~~0.1083~~
		Step 3 (application at BBCH 65) for dose 1x35 g as/ha											
D5/pond	0.09263	0.0050	0.0084	1.4940	0.2072	0.0108	3.71	0.1065	0.1597	0.0005	0.4790	0.958	~~0.1916~~
D5/stream	0.1795	0.0098	0.0163	2.8952	0.4016	0.0209	7.18	0.2063	0.3095	0.0009	0.1040	0.208	~~0.0416~~
R1/pond	0.009207	0.0005	0.0008	0.1485	0.0206	0.0011	0.37	0.0106	0.0159	0.0000	0.04868	0.097	~~0.0195~~
R1/stream	0.1648	0.0090	0.0150	2.6581	0.3687	0.0192	6.59	0.1894	0.2841	0.0008	0.03556	0.071	~~0.0142~~

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. Dwell. prolonged (aquatic phase)	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged	~~Higher-Tier information for Sed. dwell. pro-longed~~
R3/stream	0.5466	0.0297	0.0497	8.8161	1.2228	0.0636	21.86	0.6283	0.9424	0.0027	0.3265	0.653	~~0.1306~~
R4/stream	0.6658	0.0362	0.0605	10.7387	1.4895	0.0775	26.63	0.7653	1.1479	0.0033	0.2549	0.510	~~0.1020~~
		Step 3 for maize as surrogate crop for sunflower for D3 and D4 scenrio (application at BBCH 61) for dose 1x35 g as/ha											
D3/ditch	0.1838	0.0100	0.0167	2.9645	0.4112	0.0214	7.35	0.2113	0.3169	0.0009	0.07024	0.140	~~0.028~~
D4/pond	0.1643	0.0089	0.0149	2.6500	0.3676	0.0191	6.57	0.1889	0.2833	0.0008	0.6606	1.321	~~0.264~~
D4/stream	0.1624	0.009	0.015	2.619	0.363	0.019	6.50	0.187	0.280	0.0008	0.2377	0.475	~~0.095~~
		Step 3 for maize as surrogate crop for sunflower for D3 and D4 scenrio (application at BBCH 65) for dose 1x35 g as/ha											
D3/ditch	0.1838	0.0100	0.0167	2.9645	0.4112	0.0214	7.35	0.2113	0.3169	0.0009	0.07042	0.141	~~0.0282~~
D4/pond	0.1671	0.0091	0.0152	2.6952	0.3738	0.0195	6.68	0.1921	0.2881	0.0008	0.6740	1.348	~~0.2696~~
D4/stream	0.1651	0.0090	0.0150	2.6629	0.3694	0.0192	6.60	0.1898	0.2847	0.0008	0.2422	0.484	~~0.0969~~
		Step 4 – 10 meters buffer zone for dose 1x35 g as/ha (application at BBCH 61)											
R4/stream	0.3219	0.0175	0.0293	5.1919	0.7201	0.0375	12.9	0.3700	0.5550	0.0016	0.1185	0.237	~~0.0474~~

zRMS comments:

For algae the EU agreed endpoint - ErC50 >2000 µg/L should be used. For the PEC/RAC calculations for algae the lover value at 85.9 µg/L (worse case) was used by Applicant. This was not corrected because it had no impact on the assessment result.

The acute and chronic risk to invertebrates and chronic risk to sediment-dwelling invertebrates considering exposure via water, based on Tier 1 EU agreed endpoints is covered by the refined risk assessment for aquatic invertebrates. Therefore PEC/RAC calculations with Tier 1 EU agreed endpoints were not assessed by zRMS.

Refinement of the risk assessment for invertebrates ~~and sediment-dwelling invertebrates considering exposure via sediment~~, proposed by Applicant, should be considered on the MSs level.

According to Part B8 for D3, D4 scenarios: surrogate crop is maize.

Result of risk assessment with EU HC_5 for invertebrates ~~and refined endpoint for sediment-dwelling organisms considering exposure via sediment.~~

PEC/RAC based on refinement endpoints		
Scenario	**Surrogate crop**	**Acceptable -A Not acceptable - N**
Step 3, BBCH 61, 1 x 35 g as/ha		
D3 ditch	maize	A
D4 pond	maize	A
D4 stream	maize	A
D5 pond		A
D5 stream		A
R1 pond		A
R1 stream		A
R3 stream		A
R4 stream		**N**
Step 4, BBCH 61, 10 meters buffer zone for dose 1x35 g as/ha		
R4 stream		**A**
Step 3, BBCH 65, 1 x 35 g as/ha		
D3 ditch	maize	A
D4 pond	maize	A
D4 stream	maize	A
D5 pond		A
D5 stream		A
R1 pond		A
R1 stream		A
R3 stream		A
R4 stream		**N**

In summary:

BBCH 61, 1 x 35 g as/ha
At Step 3 risk is acceptable for: all scenarios except R4 stream.
At Step 4, with 10 m buffer zone, the risk is acceptable for R4 stem scenario.

BBCH 65, 1 x 35 g as/ha
At Step 3 risk is acceptable for: all scenarios except R4 stream.
For R4 stream scenario the risk is unresolved.

Individual scenarios should be considered in accordance with the requirements of each Member State.

Result of risk assessment with refined HC5 for invertebrates ~~and refined endpoint for sediment-dwelling organisms considering exposure via sediment~~

PEC/RAC based on refinement endpoints		
Scenario	**Surrogate crop**	**Acceptable -A Not acceptable - N**
Step 3, BBCH 61, 1 x 35 g as/ha		
D3 ditch	maize	A
D4 pond	maize	A
D4 stream	maize	A
D5 pond		A
D5 stream		A
R1 pond		A
R1 stream		A
R3 stream		A
R4 stream		A
Step 3, BBCH 65, 1 x 35 g as/ha		
D3 ditch	maize	A
D4 pond	maize	A
D4 stream	maize	A
D5 pond		A
D5 stream		A
R1 pond		A

R1 stream		A
R3 stream		A
R4 stream		A

In summary:

BBCH 61, 1 x 35 g as/ha
At Step 3 risk is acceptable for: all scenarios

BBCH 65, 1 x 35 g as/ha
At Step 3 risk is acceptable for: all scenarios

If refinement of the risk assessment for invertebrates ~~and sediment-dwelling invertebrates considering exposure via sediment~~ is not accepted the further refinement is required:
at BBCH 61for D4 pond, R4 stream
at BBCH 69 for: D4 pond, R4 stream

Individual scenarios should be considered in accordance with the requirements of each Member State.

Tobacco, use no. 58, BBCH 20-85, 1 x 54 g as/ha

Table 9.5-12: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for chlorantraniliprole for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CLOROL 200 SC in tobacco

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged
Test species		*Bluegill sunfish*	*Oncorhynchus mykiss*	*Daphnia magna*	*Daphnia magna*	*Pseudokirchn. subcapitata*	*Invertebrate*	*Invertebrate*	*Lemna Gibba*		*Chironomus riparius*
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	HC5	HC5	EC50		NOEC
(µg/L)		1840	110	6.2	4.47	85.9	2.61	2.91	2000		25
AF		100	10	100	10	10	3	5	10		10
RAC (µg/L)		18.4	11	0.062	0.447	8.59	0.87	0.58	200		2.5

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged
FOCUS Scenario	PEC gl-max (µg/L)									PEC gl-max (µg/kg)	
Step 1											
	54.35	2.9538	4.9409	876.6129	121.5884	6.3271	62.4713	93.7069	0.2718	161.53	64.6120
Step 2											
N-Europe	4.51	0.2451	0.4100	72.7419	10.0895	0.5250	5.1839	7.7759	0.0226	13.15	5.2600
Step 3											
R3/stream	4.164	0.2263	0.3785	67.1613	9.3154	0.4847	4.7862	7.1793	0.0208	1.864	0.7456
Step 4											
R3/stream	0.9952	0.0541	0.0905	16.0516	2.2264	0.1159	1.1439	1.7159	0.0050	0.3974	0.1590
Step 3	For dose 2x 90gas/ha										
R3/stream	3.385	0.1840	0.3077	54.5968	7.5727	0.3941	3.8908	5.8362	0.0169	1.525	0.6100
Step 4	20 meters buffer zone for dose 2x 90 g as/ha										
R3/stream	0.8092	0.0440	0.0736	13.0516	1.8103	0.0942	0.9301	1.3952	0.0040	0.3099	0.1240
Step 3	For dose 2x 54gas/ha										
R3/stream	1.999	0.1086	0.1817	32.2419	4.4720	0.2327	2.2977	3.4466	0.0100	0.9165	0.3666
Step 4	20 meters buffer zone for dose 2x 54 g as/ha										
R3/stream	0.4779	0.0260	0.0434	7.7081	1.0691	0.0556	0.5493	0.8240	0.0024	0.1853	0.0741
Step 3											
D3/ditch	7.352	0.3996	0.6684	118.5806	16.4474	0.8559	8.4506	12.6759	0.0368	3.088	1.2352
D4/pond	0.8039	0.0437	0.0731	12.9661	1.7984	0.0936	0.9240	1.3860	0.0040	4.194	1.6776
D4/stream	7.437	0.4042	0.6761	119.9516	16.6376	0.8658	8.5483	12.8224	0.0372	0.7974	0.3190

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged
D5/pond	1.090	0.0592	0.0991	17.5806	2.4385	0.1269	1.2529	1.8793	0.0055	4.831	1.9324
D5/stream	7.917	0.4303	0.7197	127.6935	17.7114	0.9217	9.1000	13.6500	0.0396	0.8255	0.3302
R1/pond	0.8645	0.0470	0.0786	13.9435	1.9340	0.1006	0.9937	1.4905	0.0043	2.379	0.9516
R1/stream	5.896	0.3204	0.5360	95.0968	13.1902	0.6864	6.7770	10.1655	0.0295	0.6009	0.2404
R3/stream	7.822	0.4251	0.7111	126.1613	17.4989	0.9106	8.9908	13.4862	0.0391	0.5013	0.2005
R4/stream	8.342	0.4534	0.7584	134.5484	18.6622	0.9711	9.5885	14.3828	0.0417	1.898	0.7592
Step 4 – 20 meters buffer zone											
D3/ditch	7.352	0.3996	0.6684	118.5806	16.4474	0.8559	8.4506	12.6759	0.0368	0.3836	0.1534
D4/pond	0.8039	0.0437	0.0731	12.9661	1.7984	0.0936	0.9240	1.3860	0.0040	2.498	0.9992
D4/stream	7.437	0.4042	0.6761	119.9516	16.6376	0.8658	8.5483	12.8224	0.0372	0.7828	0.3131
D5/pond	1.090	0.0592	0.0991	17.5806	2.4385	0.1269	1.2529	1.8793	0.0055	2.936	1.1744
D5/stream	7.917	0.4303	0.7197	127.6935	17.7114	0.9217	9.1000	13.6500	0.0396	0.5552	0.2221
R1/pond	0.8645	0.0470	0.0786	13.9435	1.9340	0.1006	0.9937	1.4905	0.0043	0.4747	0.1899
R1/stream	5.896	0.3204	0.5360	95.0968	13.1902	0.6864	6.7770	10.1655	0.0295	0.07937	0.0317
R3/stream	7.822	0.4251	0.7111	126.1613	17.4989	0.9106	8.9908	13.4862	0.0391	0.06880	0.0275
R4/stream	8.342	0.4534	0.7584	134.5484	18.6622	0.9711	9.5885	14.3828	0.0417	0.4164	0.1666
Step 3											
D3/ditch	3.609	0.1961	0.3281	58.2097	8.0738	0.4201	4.1483	6.2224	0.0180	1.539	0.6156
D4/pond	0.3936	0.0214	0.0358	6.3484	0.8805	0.0458	0.4524	0.6786	0.0020	2.079	0.8316
D4/stream	3.651	0.1984	0.3319	58.8871	8.1678	0.4250	4.1966	6.2948	0.0183	0.3964	0.1586
D5/pond	0.5309	0.0289	0.0483	8.5629	1.1877	0.0618	0.6102	0.9153	0.0027	2.377	0.9508

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged
D5/stream	3.885	0.2111	0.3532	62.6613	8.6913	0.4523	4.4655	6.6983	0.0194	0.4006	0.1602
R1/pond	0.4243	0.0231	0.0386	6.8435	0.9492	0.0494	0.4877	0.7316	0.0021	1.187	0.4748
R1/stream	2.894	0.1573	0.2631	46.6774	6.4743	0.3369	3.3264	4.9897	0.0145	0.2968	0.1187
R3/stream	3.840	0.2087	0.3491	61.9355	8.5906	0.4470	4.4138	6.6207	0.0192	0.2477	0.0991
R4/stream	4.095	0.2226	0.3723	66.0484	9.1611	0.4767	4.7069	7.0603	0.0205	0.9344	0.3738
Step 4 – 20 meters buffer zone											
D3/ditch	0.4257	0.0231	0.0387	6.8661	0.9523	0.0496	0.4893	0.7340	0.0021	0.1908	0.0763
D4/stream	0.4751	0.0258	0.0432	7.6629	1.0629	0.0553	0.5461	0.8191	0.0024	0.3891	0.1556
D5/stream	0.5201	0.0283	0.0473	8.3887	1.1635	0.0605	0.5978	0.8967	0.0026	0.2687	0.1075
R1/stream	0.3757	0.0204	0.0342	6.0597	0.8405	0.0437	0.4318	0.6478	0.0019	0.03918	0.0157
R3/stream	0.4985	0.0271	0.0453	8.0403	1.1152	0.0580	0.5730	0.8595	0.0025	0.03393	0.0136
R4/stream	0.5316	0.0289	0.0483	8.5742	1.1893	0.0619	0.6110	0.9166	0.0027	0.2047	0.0819

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

Risk assessment was updates by Applicant as follows with pome/stone fruits as surrogate crop for D3, D4, D5 and R4 scenarios:

Group		**Fish acute**	**Fish pro-longed**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. Dwell, prolonged (aquatic phase)**	**Higher-tier information**	**Higher-tier information**	**Aquatic plants**		**Sed. dwell. prolonged**	~~**Higher-Tier information for Sed. dwell. pro-longed**~~
Test species		***Bluegill sunfish***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchn. subcapitata***	***Chironomus riparius***	***Invertebrate***	***Invertebrate***	***Lemna Gibba***		***Chironomus riparius***	~~***Chironomus riparius***~~
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	NOEC	HC5	HC5	EC50		NOEC	~~NOEC~~
(µg/L)		1840	110	6.2	4.47	85.9	0.25	2.61	2.91	2000		5	~~25~~

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. Dwell, prolonged (aquatic phase)	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged	~~Higher-Tier information for Sed. dwell. pro-longed~~
AF		100	10	100	10	10	10	3	5	10		10	~~10~~
RAC (µg/L)		18.4	11	0.062	0.447	8.59	0.025	0.87	0.58	200		0.5	~~2.5~~
FOCUS Scenario	**PEC gl-max (µg/L)**										**PEC gl-max (µg/kg)**		
Step 1													
	54.35	2.9538	4.9409	876.6129	121.5884	6.3271	2174.0	62.4713	93.7069	0.2718	161.53	323.060	~~64.6120~~
Step 2													
N-Europe	4.51	0.2451	0.4100	72.7419	10.0895	0.5250	180.4	5.1839	7.7759	0.0226	13.15	26.300	~~5.2600~~
Step 3 For dose 2x 110g as/ha (applicationa at BBCH 20)													
R3/stream	4.164	0.2263	0.3785	67.1613	9.3154	0.4847	166.6	4.7862	7.1793	0.0208	1.864	3.728	~~0.7456~~
Step 4 For dose 2x 110g as/ha (applicationa at BBCH 20)													
R3/stream	0.9952	0.0541	0.0905	16.0516	2.2264	0.1159	39.8	1.1439	1.7159	0.0050	0.3974	0.795	~~0.1590~~
Step 3	For dose 2x 90gas/ha(applicationa at BBCH 20)												
R3/stream	3.385	0.1840	0.3077	54.5968	7.5727	0.3941	135.4	3.8908	5.8362	0.0169	1.525	3.050	~~0.6100~~
Step 4	20 meters buffer zone for dose 2x 90 g as/ha(applicationa at BBCH 20)												
R3/stream	0.8092	0.0440	0.0736	13.0516	1.8103	0.0942	32.4	0.9301	1.3952	0.0040	0.3099	0.620	~~0.1240~~
Step 3			For dose 2x 54gas/ha(applicationa at BBCH 20)										
R3/stream	1.999	0.1086	0.1817	32.2419	4.4720	0.2327	80.0	2.2977	3.4466	0.0100	0.9165	1.833	~~0.3666~~
Step 4	20 meters buffer zone for dose 2x 54 g as/ha(applicationa at BBCH 20)												
R3/stream	0.4779	0.0260	0.0434	7.7081	1.0691	0.0556	19.1	0.5493	0.8240	0.0024	0.1853	0.371	~~0.0741~~

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. Dwell, prolonged (aquatic phase)	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged	~~Higher-Tier information for Sed. dwell. pro-longed~~
	Step 3 for apple as surrogate crop for dose 2x110 as/ha (applicationa at BBCH 20)												
D3/ditch	7.352	0.3996	0.6684	118.5806	16.4474	0.8559	294.08	8.4506	12.6759	0.0368	3.088	6.176	~~1.2352~~
D4/pond	0.8039	0.0437	0.0731	12.9661	1.7984	0.0936	32.16	0.9240	1.3860	0.0040	4.194	8.388	~~1.6776~~
D4/stream	7.437	0.4042	0.6761	119.9516	16.6376	0.8658	297.48	8.5483	12.8224	0.0372	0.7974	1.595	~~0.3190~~
D5/pond	1.090	0.0592	0.0991	17.5806	2.4385	0.1269	43.60	1.2529	1.8793	0.0055	4.831	9.662	~~1.9324~~
D5/stream	7.917	0.4303	0.7197	127.6935	17.7114	0.9217	316.68	9.1000	13.6500	0.0396	0.8255	1.651	~~0.3302~~
R1/pond	0.8645	0.0470	0.0786	13.9435	1.9340	0.1006	34.58	0.9937	1.4905	0.0043	2.379	4.758	~~0.9516~~
R1/stream	5.896	0.3204	0.5360	95.0968	13.1902	0.6864	235.84	6.7770	10.1655	0.0295	0.6009	1.202	~~0.2404~~
R2/stream	7.822	0.4251	0.7111	126.1613	17.4989	0.9106	312.88	8.9908	13.4862	0.0391	0.5013	1.003	~~0.2005~~
~~R3/stream~~	~~8.342~~	~~0.4534~~	~~0.7584~~	~~134.5484~~	~~18.6622~~	~~0.9711~~	~~333.68~~	~~9.5885~~	~~14.3828~~	~~0.0417~~	~~1.898~~	~~3.796~~	~~0.7592~~
R4/stream	5.931	0.3223	0.5392	95.6613	13.2685	0.6905	237.240	6.8172	10.2259	0.0297	0.7996	1.599	~~0.3198~~
	Step 4 – 20 meters buffer zone for dose 2x110 as/ha (applicationa at BBCH 20)												
D3/ditch	0.8673	0.0471	0.0788	13.9887	1.9403	0.1010	34.69	0.9969	1.4953	0.0043	0.3836	0.767	~~0.1534~~
D4/pond	0.6091	0.0331	0.0554	9.8242	1.3626	0.0709	24.36	0.7001	1.0502	0.0030	2.498	4.996	~~0.9992~~
D4/stream	0.9684	0.0526	0.0880	15.6194	2.1664	0.1127	38.74	1.1131	1.6697	0.0048	0.7828	1.566	~~0.3131~~
D5/pond	0.5103	0.0277	0.0464	8.2306	1.1416	0.0594	20.41	0.5866	0.8798	0.0026	2.936	5.872	~~1.1744~~
D5/stream	1.062	0.0577	0.0965	17.1290	2.3758	0.1236	42.48	1.2207	1.8310	0.0053	0.5552	1.110	~~0.2221~~
R1/pond	0.1660	0.0090	0.0151	2.6774	0.3714	0.0193	6.64	0.1908	0.2862	0.0008	0.4747	0.949	~~0.1899~~
R1/stream	0.7655	0.0416	0.0696	12.3468	1.7125	0.0891	30.62	0.8799	1.3198	0.0038	0.07937	0.159	~~0.0317~~
R2/stream	1.016	0.0552	0.0924	16.3871	2.2729	0.1183	40.64	1.1678	1.7517	0.0051	0.06880	0.138	~~0.0275~~
~~R3/stream~~	~~1.083~~	~~0.0589~~	~~0.0985~~			~~0.1261~~		~~1.2448~~	~~1.8672~~	~~0.0054~~	~~0.4164~~	~~0.833~~	~~0.1666~~

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. Dwell, prolonged (aquatic phase)	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged	~~Higher-Tier information for Sed. dwell. pro-longed~~
R4/stream	0.7701	0.0419	0.0700	12.4210	1.7228	0.0897	30.804	0.8852	1.3278	0.0039	0.1445	0.289	~~0.0578~~
	Step 3 for apple as surrogate crope fo dose 2x54 g as/ha (applicationa at BBCH 20)												
D3/ditch	3.609	0.1961	0.3281	58.2097	8.0738	0.4201	144.36	4.1483	6.2224	0.0180	1.539	3.078	~~0.6156~~
D4/pond	0.3936	0.0214	0.0358	6.3484	0.8805	0.0458	15.74	0.4524	0.6786	0.0020	2.079	4.158	~~0.8316~~
D4/stream	3.651	0.1984	0.3319	58.8871	8.1678	0.4250	146.04	4.1966	6.2948	0.0183	0.3964	0.793	~~0.1586~~
D5/pond	0.5309	0.0289	0.0483	8.5629	1.1877	0.0618	21.24	0.6102	0.9153	0.0027	2.377	4.754	~~0.9508~~
D5/stream	3.885	0.2111	0.3532	62.6613	8.6913	0.4523	155.40	4.4655	6.6983	0.0194	0.4006	0.801	~~0.1602~~
R1/pond	0.4243	0.0231	0.0386	6.8435	0.9492	0.0494	16.97	0.4877	0.7316	0.0021	1.187	2.374	~~0.4748~~
R1/stream	2.894	0.1573	0.2631	46.6774	6.4743	0.3369	115.76	3.3264	4.9897	0.0145	0.2968	0.594	~~0.1187~~
R2/stream	3.840	0.2087	0.3491	61.9355	8.5906	0.4470	153.60	4.4138	6.6207	0.0192	0.2477	0.495	~~0.0991~~
~~R3/stream~~	~~4.095~~	~~0.2226~~	~~0.3723~~			~~0.4767~~		~~4.7069~~	~~7.0603~~	~~0.0205~~	~~0.9344~~	~~1.869~~	~~0.3738~~
R4/stream	2.911	0.1582	0.2646	46.9516	6.5123	0.3389	116.440	3.3460	5.0190	0.0146	0.3960	0.792	~~0.1584~~
	Step 4 – 20 meters buffer zone 2x54 g as/ha (applicationa at BBCH 20)												
D3/ditch	0.4257	0.0231	0.0387	6.8661	0.9523	0.0496	17.03	0.4893	0.7340	0.0021	0.1908	0.382	~~0.0763~~
D4/stream	0.4751	0.0258	0.0432	7.6629	1.0629	0.0553	19.00	0.5461	0.8191	0.0024	0.3891	0.778	~~0.1556~~
D5/stream	0.5201	0.0283	0.0473	8.3887	1.1635	0.0605	20.80	0.5978	0.8967	0.0026	0.2687	0.537	~~0.1075~~
R1/stream	0.3757	0.0204	0.0342	6.0597	0.8405	0.0437	15.03	0.4318	0.6478	0.0019	0.03918	0.078	~~0.0157~~
R2/stream	0.4985	0.0271	0.0453	8.0403	1.1152	0.0580	19.94	0.5730	0.8595	0.0025	0.03393	0.068	~~0.0136~~
~~R3/stream~~	~~0.5316~~	~~0.0289~~	~~0.0483~~			~~0.0619~~		~~0.6110~~	~~0.9166~~	~~0.0027~~	~~0.2047~~	~~0.409~~	~~0.0819~~
R4/stream	0.3780	0.0205	0.0344	6.0968	0.8456	0.0440	15.12	0.4345	0.6517	0.0019	0.07101	0.142	~~0.0284~~
	Step 3 (application at BBCH ~~83~~ 85) for dose 2x110 a.s./ha												

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. Dwell, prolonged (aquatic phase)	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged	~~Higher-Tier information for Sed. dwell. pro-longed~~
R3/stream	3.497	0.1901	0.3179	56.4032	7.8233	0.4071	139.9	4.0195	6.0293	0.0175	1.536	3.072	~~0.6144~~
	Step 3 for apple as surrogate crop for D3,D4,D5,R1 and R4 scenario (applicationa at BBCH 85) for dose 2x110 a.s./ha												
D3/ditch	3.211	0.1745	0.2919	51.7903	7.1834	0.3738	128.44	3.6908	5.5362	0.0161	1.934	3.868	~~0.7736~~
D4/pond	1.917	0.1042	0.1743	30.9194	4.2886	0.2232	76.68	2.2034	3.3052	0.0096	6.790	13.580	~~2.7160~~
D4/stream	3.174	0.1725	0.2885	51.1935	7.1007	0.3695	126.96	3.6483	5.4724	0.0159	2.407	4.814	~~0.9628~~
D5/pond	1.952	0.1061	0.1775	31.4839	4.3669	0.2272	78.08	2.2437	3.3655	0.0098	8.470	16.940	~~3.3880~~
D5/stream	3.506	0.1905	0.3187	56.5484	7.8434	0.4081	140.24	4.0299	6.0448	0.0175	2.016	4.032	~~0.8064~~
R1/pond	0.2887	0.0157	0.0262	4.6565	0.6459	0.0336	11.55	0.3318	0.4978	0.0014	0.8527	1.705	~~0.3411~~
R1/stream	2.486	0.1351	0.2260	40.0968	5.5615	0.2894	99.44	2.8575	4.2862	0.0124	0.3542	0.708	~~0.1417~~
R4/stream	2.485	0.1351	0.2259	40.0806	5.5593	0.2893	99.40	2.8563	4.2845	0.0124	0.9258	1.852	~~0.3703~~
	Step 3 for apple as surrogate crop for D3,D4,D5,R1 and R4 scenario (applicationa at BBCH 85) for dose 1x54 g as/ha												
D3/ditch	1.985	0.1079	0.1805	32.0161	4.4407	0.2311	79.40	2.2816	3.4224	0.0099	0.8937	1.787	~~0.3575~~
D4/pond	0.5812	0.0316	0.0528	9.3742	1.3002	0.0677	23.25	0.6680	1.0021	0.0029	2.093	4.186	~~0.8372~~
D4/stream	1.945	0.1057	0.1768	31.3710	4.3512	0.2264	77.80	2.2356	3.3534	0.0097	0.7718	1.544	~~0.3087~~
D5/pond	0.3402	0.0185	0.0309	5.4871	0.7611	0.0396	13.61	0.3910	0.5866	0.0017	1.755	3.510	~~0.7020~~
D5/stream	2.149	0.1168	0.1954	34.6613	4.8076	0.2502	85.96	2.4701	3.7052	0.0107	0.4867	0.973	~~0.1947~~
R1/pond	0.08881	0.0048	0.0081	1.4324	0.1987	0.0103	3.55	0.1021	0.1531	0.0004	0.2580	0.516	~~0.1032~~
R1/stream	1.524	0.0828	0.1385	24.5806	3.4094	0.1774	60.96	1.7517	2.6276	0.0076	0.1868	0.374	~~0.0747~~
R2/stream	2.042	0.1110	0.1856	32.9355	4.5682	0.2377	81.68	2.3471	3.5207	0.0102	0.1773	0.355	~~0.0709~~
~~R3/stream~~	~~2.148~~	~~0.1167~~	~~0.1953~~			~~0.2501~~		~~2.4690~~	~~3.7034~~	~~0.0107~~	~~0.3906~~	~~0.781~~	~~0.1562~~
R4/stream	1.523	0.0828	0.1385	24.5645	3.4072	0.1773	60.920	1.7506	2.6259	0.0076	0.2875	0.575	~~0.1150~~

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. Dwell, prolonged (aquatic phase)	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged	~~Higher-Tier information for Sed. dwell. pro-longed~~
	Step 4 (applicationa at BBCH ~~83~~ 85) – 20 meters buffer zone for dose 2x110 as/ha												
R3/stream	0.8357	0.0454	0.0760	13.4790	1.8696	0.0973	33.4	0.9606	1.4409	0.0042	0.2562	0.512	~~0.1025~~
	Step 4 for apple as surrogate crop for D3,D4,D5,R1, R4 scenario (applicationa at BBCH 85) – 20 meters buffer zone for dose 2x110 as/ha												
D3/ditch	0.3047	0.0166	0.0277	4.9145	0.6817	0.0355	12.19	0.3502	0.5253	0.0015	0.1944	0.389	~~0.0778~~
D4/pond	1.815	0.0986	0.1650	29.2742	4.0604	0.2113	72.60	2.0862	3.1293	0.0091	6.308	12.616	~~2.5232~~
D4/stream	2.003	0.1089	0.1821	32.3065	4.4810	0.2332	80.12	2.3023	3.4534	0.0100	2.385	4.770	~~0.9540~~
D5/pond	1.952	0.1061	0.1775	31.4839	4.3669	0.2272	78.08	2.2437	3.3655	0.0098	7.868	15.736	~~3.1472~~
D5/stream	2.635	0.1432	0.2395	42.5000	5.8949	0.3068	105.40	3.0287	4.5431	0.0132	2.016	4.032	~~0.8064~~
R1/stream	0.2697	0.0147	0.0245	4.3500	0.6034	0.0314	10.79	0.3100	0.4650	0.0013	0.03945	0.079	~~0.0158~~
R4/stream	0.4871	0.0265	0.0443	7.8565	1.0897	0.0567	19.48	0.5599	0.8398	0.0024	0.2110	0.422	~~0.0844~~
	Step 4 for apple as surrogate crop for D3,D4,D5,R1, R4 scenario (applicationa at BBCH 85) – 20 meters buffer zone for dose 1x54 g as/ha												
D3/ditch	0.1847	0.0100	0.0168	2.9790	0.4132	0.0215	7.39	0.2123	0.3184	0.0009	0.08776	0.176	~~0.0351~~
D4/pond	0.5545	0.0301	0.0504	8.9435	1.2405	0.0646	22.18	0.6374	0.9560	0.0028	1.950	3.900	~~0.7800~~
D4/stream	0.5932	0.0322	0.0539	9.5677	1.3271	0.0691	23.73	0.6818	1.0228	0.0030	0.7643	1.529	~~0.3057~~
~~D5/pond~~	~~0.4669~~	~~0.0254~~	~~0.0424~~	~~7.5306~~	~~1.0445~~	~~0.0544~~	~~18.68~~	~~0.5367~~	~~0.8050~~	~~0.0023~~	~~0.3717~~	~~0.743~~	~~0.1487~~
D5/stream	~~0.1639~~ 0.4669	~~0.0089~~ 0.0254	0.0149 0.0424	2.6435	0.3667	0.0191 0.0544	6.56	0.1884 0.5367	0.2826 0.805	0.0008 0.0023	~~0.02051~~ 0.3717	~~0.041~~ 0.7434	~~0.0082~~ ~~0.1487~~
R1/stream	~~0.2197~~ 0.1639	~~0.0119~~ 0.0089	~~0.0200~~ 0.0149	3.5435	0.4915	~~0.0256~~ 0.0191	8.79	0.2525 0.1884	~~0.3788~~ 0.2826	~~0.0011~~ 0.0008	~~0.03717~~ 0.02051	~~0.074~~ 0.0410	~~0.0149~~ ~~0.0082~~
R2/stream	0.2310	0.0126	0.0210	3.7258	0.5168	0.0269	9.24	0.2655	0.3983	0.0012	0.05643	0.113	~~0.0226~~
~~R3/stream~~	~~0.1639~~	~~0.0089~~	~~0.0149~~			~~0.0191~~		~~0.1884~~	~~0.2826~~	~~0.0008~~	~~0.06567~~	~~0.131~~	~~0.0263~~

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. Dwell, prolonged (aquatic phase)	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged	~~Higher-Tier information for Sed. dwell. pro-longed~~
R4/stream	~~0.1847~~ 0.1639	0.0100	0.0168	2.9790	0.4132	0.0215	7.39	0.2123	0.3184	0.0009	~~0.08776~~ 0.06567	0.176	~~0.0351~~

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

zRMS comments:

For algae the EU agreed endpoint - ErC50 >2000 µg/L should be used. For the PEC/RAC calculations for algae the lover value at 85.9 µg/L (worse case) was used by Applicant. This was not corrected because it had no impact on the assessment result.

The acute and chronic risk to invertebrates and chronic risk to sediment-dwelling invertebrates considering exposure via water, based on Tier 1 EU agreed endpoints is covered by the refined risk assessment for aquatic invertebrates. Therefore PEC/RAC calculations with Tier 1 EU agreed endpoints were not assessed by zRMS.

According to Part B8 for D3, D4, D5, R1 and R4 scenarios: surrogate crop is pome/stone fruits.
For calculations of PECsw/sed the worst case scenario was used (dose of 2x110g a.s./ha at BBCH 20-85). It is in accordance with the old GAP Table. Additionally, PECsw/sed values were provided for a dose of 2x54g a.s./ha at BBCH 20 and 1x54g a.s./ha at BBCH85.

Refinement of the risk assessment for invertebrates ~~and sediment-dwelling invertebrates considering exposure via sediment~~, proposed by Applicant, should be considered on the MSs level.

Result of risk assessment with EU HC_5 for invertebrates ~~and refined endpoint for sediment-dwelling organisms considering exposure via sediment.~~

PEC/RAC based on refinement endpoints		
Scenario	**Surrogate crop**	**Acceptable -A Not acceptable - N**
Step 3, BBCH 20, 2 x 110 g as/ha		
D3 ditch	Pome/stone fruits	**N**
D4 pond	Pome/stone fruits	**N**
D4 stream	Pome/stone fruits	**N**
D5 pond	Pome/stone fruits	**N**

D5 stream	Pome/stone fruits	**N**
R1 pond	Pome/stone fruits	**A**
R1 stream	Pome/stone fruits	**N**
R3 stream		**N**
R4 stream	Pome/stone fruits	**N**
Step 4, BBCH 20, 2 x 110 g as/ha, 20 meters buffer zone		
D3 ditch	Pome/stone fruits	**N**
D4 pond	Pome/stone fruits	**N**
D4 stream	Pome/stone fruits	**N**
D5 pond	Pome/stone fruits	**N**
D5 stream	Pome/stone fruits	**N**
R1 pond	Pome/stone fruits	Accepted at Step 3
R1 stream	Pome/stone fruits	**N**
R3 stream		**N**
R4 stream	Pome/stone fruits	**N**

Step 3, BBCH 20, 2 x 90 g as/ha		
D3 ditch	Pome/stone fruits	Not calculated
D4 pond	Pome/stone fruits	Not calculated
D4 stream	Pome/stone fruits	Not calculated
D5 pond	Pome/stone fruits	Not calculated
D5 stream	Pome/stone fruits	Not calculated
R1 pond	Pome/stone fruits	Not calculated
R1 stream	Pome/stone fruits	Not calculated
R3 stream		**N**
R4 stream	Pome/stone fruits	Not calculated
Step 4, BBCH 20, 2 x 90 g as/ha, 20 meters buffer zone		
D3 ditch	Pome/stone fruits	Not calculated
D4 pond	Pome/stone fruits	Not calculated
D4 stream	Pome/stone fruits	Not calculated
D5 pond	Pome/stone fruits	Not calculated

D5 stream	Pome/stone fruits	Not calculated
R1 pond	Pome/stone fruits	Not calculated
R1 stream	Pome/stone fruits	Not calculated
R3 stream		**N**
R4 stream	Pome/stone fruits	Not calculated

Step 3, BBCH 20, 2 x 54 g as/ha		
D3 ditch	Pome/stone fruits	**N**
D4 pond	Pome/stone fruits	A
D4 stream	Pome/stone fruits	**N**
D5 pond	Pome/stone fruits	A
D5 stream	Pome/stone fruits	**N**
R1 pond	Pome/stone fruits	A
R1 stream	Pome/stone fruits	**N**
R3 stream		**N**
R4 stream	Pome/stone fruits	**N**
Step 4, BBCH 20, 2 x 54 g as/ha, 20 meters buffer zone		
D3 ditch	Pome/stone fruits	A
D4 pond	Pome/stone fruits	Accepted at Step 3
D4 stream	Pome/stone fruits	A
D5 pond	Pome/stone fruits	Accepted at Step 3
D5 stream	Pome/stone fruits	A
R1 pond	Pome/stone fruits	Accepted at Step 3
R1 stream	Pome/stone fruits	A
R3 stream		A
R4 stream	Pome/stone fruits	A

Step 3, BBCH 85, 2 x 110 g as/ha		
D3 ditch	Pome/stone fruits	**N**

D4 pond	Pome/stone fruits	**N**
D4 stream	Pome/stone fruits	**N**
D5 pond	Pome/stone fruits	**N**
D5 stream	Pome/stone fruits	**N**
R1 pond	Pome/stone fruits	A
R1 stream	Pome/stone fruits	**N**
R3 stream		**N**
R4 stream	Pome/stone fruits	**N**
Step 4, BBCH 85, 2 x 110 g as/ha, 20 meters buffer zone		
D3 ditch	Pome/stone fruits	A
D4 pond	Pome/stone fruits	**N**
D4 stream	Pome/stone fruits	**N**
D5 pond	Pome/stone fruits	**N**
D5 stream	Pome/stone fruits	**N**
R1 pond	Pome/stone fruits	Accepted at Step 3
R1 stream	Pome/stone fruits	A
R3 stream		**N**
R4 stream	Pome/stone fruits	A

Step 3, BBCH 85, 1 x 54 g as/ha		
D3 ditch	Pome/stone fruits	**N**
D4 pond	Pome/stone fruits	**N**
D4 stream	Pome/stone fruits	**N**
D5 pond	Pome/stone fruits	A
D5 stream	Pome/stone fruits	**N**
R1 pond	Pome/stone fruits	A
R1 stream	Pome/stone fruits	**N**
R3 stream		Not calculated
R4 stream	Pome/stone fruits	**N**
Step 4, BBCH 85, 1 x 54 g as/ha, 20 meters buffer zone		

D3 ditch	Pome/stone fruits	A
D4 pond	Pome/stone fruits	A
D4 stream	Pome/stone fruits	**N**
D5 pond	Pome/stone fruits	Accepted at Step 3
D5 stream	Pome/stone fruits	A
R1 pond	Pome/stone fruits	Accepted at Step 3
R1 stream	Pome/stone fruits	A
R3 stream		Not calculated
R4 stream	Pome/stone fruits	A

In summary:

BBCH 20, 2 x 110 g as/ha
At Step 3 risk is acceptable for: R1 pond scenario
At Step 4 with 20 m buffer zone risk is unresolved for: D3 ditch, D4 pond, D4 stream, D5 pond, D5 stream, R1 stream, R3 stream, R4 stream scenarios.

BBCH 85, 2 x 110 g as/ha
At Step 3 risk is acceptable for: R1 pond scenario
At Step 4 with 20 m buffer zone risk is acceptable for: D3 ditch, R1 stream, R4 stream scenarios.
At Step 4 with 20 m buffer zone risk is unresolved for: D4 pond, D4 stream, D5 pond, D5 stream R3 stream scenarios.

BBCH 20, 2 x 54 g as/ha
At Step 3 risk is acceptable for: D4 pond, D5 pond, R1 pond scenarios.
At Step 4 with 20 m buffer zone risk is acceptable for: D3 ditch, D4 stream, D5 stream, R1 stream, R3 stream, R4 stream scenarios.

BBCH 85, 1 x 54 g as/ha
At Step 3 risk is acceptable for: D5 pond, R1 pond scenarios.
At Step 4 with 20 m buffer zone risk is acceptable for: D3 ditch, D4 pond, D5 stream, R1 stream, R4 stream scenarios.
R3 stream scenario was not calculated at Step 3 and 4.
For D4 stream scenario the risk is unresolved.

Result of risk assessment with refined HC5 for invertebrates ~~and refined endpoint for sediment-dwelling organisms considering exposure via sediment~~

PEC/RAC based on refinement endpoints		
Scenario	**Surrogate crop**	**Acceptable -A Not acceptable - N**
Step 3, BBCH 20, 2 x 110 g as/ha		
D3 ditch	Pome/stone fruits	**N**
D4 pond	Pome/stone fruits	**N**
D4 stream	Pome/stone fruits	**N**
D5 pond	Pome/stone fruits	**N**
D5 stream	Pome/stone fruits	**N**
R1 pond	Pome/stone fruits	**A**
R1 stream	Pome/stone fruits	**N**
R3 stream		**N**
R4 stream	Pome/stone fruits	**N**
Step 4, BBCH 20, 2 x 110 g as/ha, 20 meters buffer zone		
D3 ditch	Pome/stone fruits	A
D4 pond	Pome/stone fruits	A
D4 stream	Pome/stone fruits	**N**
D5 pond	Pome/stone fruits	**N**
D5 stream	Pome/stone fruits	**N**
R1 pond	Pome/stone fruits	Accepted at Step 3
R1 stream	Pome/stone fruits	A
R3 stream		**N**
R4 stream	Pome/stone fruits	A
Step 3, BBCH 20, 2 x 90 g as/ha		
D3 ditch	Pome/stone fruits	Not calculated
D4 pond	Pome/stone fruits	Not calculated
D4 stream	Pome/stone fruits	Not calculated
D5 pond	Pome/stone fruits	Not calculated
D5 stream	Pome/stone fruits	Not calculated
R1 pond	Pome/stone fruits	Not calculated

R1 stream	Pome/stone fruits	Not calculated
R3 stream		N
R4 stream	Pome/stone fruits	Not calculated
Step 4, BBCH 20, 2 x 90 g as/ha, 20 meters buffer zone		
D3 ditch	Pome/stone fruits	Not calculated
D4 pond	Pome/stone fruits	Not calculated
D4 stream	Pome/stone fruits	Not calculated
D5 pond	Pome/stone fruits	Not calculated
D5 stream	Pome/stone fruits	Not calculated
R1 pond	Pome/stone fruits	Not calculated
R1 stream	Pome/stone fruits	Not calculated
R3 stream		A
R4 stream	Pome/stone fruits	Not calculated

Step 3, BBCH 20, 2 x 54 g as/ha		
D3 ditch	Pome/stone fruits	**N**
D4 pond	Pome/stone fruits	A
D4 stream	Pome/stone fruits	**N**
D5 pond	Pome/stone fruits	A
D5 stream	Pome/stone fruits	**N**
R1 pond	Pome/stone fruits	A
R1 stream	Pome/stone fruits	**N**
R3 stream		**N**
R4 stream	Pome/stone fruits	**N**
Step 4, BBCH 20, 2 x 54 g as/ha, 20 meters buffer zone		
D3 ditch	Pome/stone fruits	A
D4 pond	Pome/stone fruits	Accepted at Step 3
D4 stream	Pome/stone fruits	A
D5 pond	Pome/stone fruits	Accepted at Step 3
D5 stream	Pome/stone fruits	A

R1 pond	Pome/stone fruits	Accepted at Step 3
R1 stream	Pome/stone fruits	A
R3 stream		A
R4 stream	Pome/stone fruits	A

Step 3, BBCH 85, 2 x 110 g as/ha		
D3 ditch	Pome/stone fruits	**N**
D4 pond	Pome/stone fruits	**N**
D4 stream	Pome/stone fruits	**N**
D5 pond	Pome/stone fruits	**N**
D5 stream	Pome/stone fruits	**N**
R1 pond	Pome/stone fruits	A
R1 stream	Pome/stone fruits	**N**
R3 stream		**N**
R4 stream	Pome/stone fruits	**N**
Step 4, BBCH 85, 2 x 110 g as/ha, 20 meters buffer zone		
D3 ditch	Pome/stone fruits	A
D4 pond	Pome/stone fruits	**N**
D4 stream	Pome/stone fruits	**N**
D5 pond	Pome/stone fruits	**N**
D5 stream	Pome/stone fruits	**N**
R1 pond	Pome/stone fruits	Accepted at Step 3
R1 stream	Pome/stone fruits	A
R3 stream		A
R4 stream	Pome/stone fruits	A

Step 3, BBCH 85, 1 x 54 g as/ha		
D3 ditch	Pome/stone fruits	**N**
D4 pond	Pome/stone fruits	A

D4 stream	Pome/stone fruits	**N**
D5 pond	Pome/stone fruits	A
D5 stream	Pome/stone fruits	**N**
R1 pond	Pome/stone fruits	A
R1 stream	Pome/stone fruits	**N**
R3 stream		Not calculated
R4 stream	Pome/stone fruits	**N**
Step 4, BBCH 85, 1 x 54 g as/ha, 20 meters buffer zone		
D3 ditch	Pome/stone fruits	A
D4 pond	Pome/stone fruits	Accepted at Step 3
D4 stream	Pome/stone fruits	A
D5 pond	Pome/stone fruits	Accepted at Step 3
D5 stream	Pome/stone fruits	A
R1 pond	Pome/stone fruits	Accepted at Step 3
R1 stream	Pome/stone fruits	A
R3 stream		Not calculated
R4 stream	Pome/stone fruits	A

In summary:

BBCH 20, 2 x 110 g as/ha
At Step 3 risk is acceptable for: R1 pond scenario
At Step 4 with 20 m buffer zone risk is acceptable for: D3 ditch, D4 pond, R1 stream, R4 strem
At Step 4 with 20 m buffer zone risk is not acceptable for: D4 stream, D5 pond, D5 stream, R3 stream scenarios.

BBCH 85, 2 x 110 g as/ha
At Step 3 risk is acceptable for: R1 pond scenario
At Step 4 with 20 m buffer zone risk is acceptable for: D3 ditch, R1 stream, R3 stream, R4 stream
At Step 4 with 20 m buffer zone risk is not acceptable for: D4 pond, D4 stream, D5 pond, D5 stream scenarios.

BBCH 20, 2 x 54 g as/ha
At Step 3 risk is acceptable for: D4 pond, D5 pond, R1 pond scenarios.
At Step 4 with 20 m buffer zone risk is acceptable for: D3 ditch, D4 stream, D5 stream, R1 stream, R3 stream, R4 stream scenarios.

BBCH 85, 1 x 54 g as/ha
At Step 3 risk is acceptable for: D4 pond, D5 pond, R1 pond scenarios.
At Step 4 with 20 m buffer zone risk is acceptable for: D3 ditch, D4 stream, D5 stream, R1 stream, R4 stream scenarios.
R3 stream scenario was not calculated at Step 3 and 4

Individual scenarios should be considered in accordance with the requirements of each Member State.

However tobacco was not accepted in Part B8.

Grass, use no. 59, BBCH 53-69, 1 x 35 g as/ha

Table 9.5-13: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for chlorantraniliprole for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CLOROL 200 SC in grass

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged
Test species		*Bluegill sunfish*	*Oncorhynchus mykiss*	*Daphnia magna*	*Daphnia magna*	*Pseudokirchn. subcapitata*	*Invertebrate*	*Invertebrate*	*Lemna Gibba*		*Chironomus riparius*
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	HC5	HC5	EC50		NOEC
(µg/L)		1840	110	6.2	4.47	85.9	2.61	2.91	2000		25
AF		100	10	100	10	10	3	5	10		10
RAC (µg/L)		18.4	11	0.062	0.447	8.59	0.87	0.58	200		2.5
FOCUS Scenario	PEC $_{gl-max}$ (µg/L)									PEC $_{gl-max}$ (µg/kg)	
Step 1											
	8.65	0.4701	0.7864	139.5161	19.3512	1.0070	9.9425	14.9138	0.0433	25.70	10.2800
Step 2											
N-Europe	0.92	0.0500	0.0836	14.8387	2.0582	0.1071	1.0575	1.5862	0.0046	2.68	1.0720
Step 3											

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged
D3/ditch	0.2214	0.0120	0.0201	3.5710	0.4953	0.0258	0.2545	0.3817	0.0011	0.07112	0.0284
D4/pond	0.007687	0.0004	0.0007	0.1240	0.0172	0.0009	0.0088	0.0133	0.0000	0.02466	0.0099
D4/stream	0.1789	0.0097	0.0163	2.8855	0.4002	0.0208	0.2056	0.3084	0.0009	0.009286	0.0037
D5/pond	0.04594	0.0025	0.0042	0.7410	0.1028	0.0053	0.0528	0.0792	0.0002	0.3487	0.1395
D5/stream	0.1882	0.0102	0.0171	3.0355	0.4210	0.0219	0.2163	0.3245	0.0009	0.06421	0.0257
R3/stream	0.2057	0.0112	0.0187	3.3177	0.4602	0.0239	0.2364	0.3547	0.0010	0.03956	0.0158

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

Risk assessment was updates by Applicant as follows with winter cereals as surrogate crop for R1 and R4 scenarios:

Group		**Fish acute**	**Fish pro-longed**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. Dwell, prolonged (aquatic phase)**	**Higher-tier information**	**Higher-tier information**	**Aquatic plants**		**Sed. dwell. prolonged**	~~**Higher-Tier information for Sed. dwell. pro-longed**~~
Test spe-cies		***Bluegill sunfish***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchn. subcapitata***	***Chironomus riparius***	***Invertebrate***	***Invertebrate***	***Lemna Gibba***		***Chironomus riparius***	~~***Chironomus riparius***~~
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	NOEC	HC5	HC5	EC50		NOEC	~~NOEC~~
(µg/L)		1840	110	6.2	4.47	85.9	0.25	2.61	2.91	2000		5	~~25~~
AF		100	10	100	10	10	10	3	5	10		10	~~10~~
RAC (µg/L)		18.4	11	0.062	0.447	8.59	0.025	0.87	0.58	200		0.5	~~2.5~~
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**										**PEC $_{gl-max}$ (µg/kg)**		
Step 1													
	8.65	0.4701	0.7864	139.5161	19.3512	1.0070	346.0	9.9425	14.9138	0.0433	25.70	51.400	10.2800

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. Dwell, prolonged (aquatic phase)	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged	~~Higher-Tier information for Sed. dwell. pro-longed~~
Step 2													
N-Europe	0.92	0.0500	0.0836	14.8387	2.0582	0.1071	36.8	1.0575	1.5862	0.0046	2.68	5.360	~~1.0720~~
	Step 3 (application at BBCH 53) for dose 1x35 g as/ha												
D3/ditch	0.2214	0.0120	0.0201	3.5710	0.4953	0.0258	8.86	0.2545	0.3817	0.0011	0.07112	0.142	~~0.0284~~
D4/pond	0.007687	0.0004	0.0007	0.1240	0.0172	0.0009	0.31	0.0088	0.0133	0.0000	0.02466	0.049	~~0.0099~~
D4/stream	0.1789	0.0097	0.0163	2.8855	0.4002	0.0208	7.16	0.2056	0.3084	0.0009	0.009286	0.019	~~0.0037~~
D5/pond	0.04594	0.0025	0.0042	0.7410	0.1028	0.0053	1.84	0.0528	0.0792	0.0002	0.3487	0.697	~~0.1395~~
D5/stream	0.1882	0.0102	0.0171	3.0355	0.4210	0.0219	7.53	0.2163	0.3245	0.0009	0.06421	0.128	~~0.0257~~
R3/stream	0.2057	0.0112	0.0187	3.3177	0.4602	0.0239	8.23	0.2364	0.3547	0.0010	0.03956	0.079	~~0.0158~~
	Step 3 (application at BBCH 53) For winter cereals as surrogate crop according to national polish requirements for dose 1x35 g as/ha												
~~R1/stream~~	~~0.5723~~	~~0.0311~~	~~0.0520~~	~~9.2396~~	~~1.2803~~	~~0.0666~~		~~0.6578~~	~~0.9867~~	~~0.0029~~	~~0.1723~~		0.0689
R1/pond	0.07946	0.0043	0.0072	1.2816	0.1778	0.0093	3.18	0.0913	0.1370	0.0004	0.2635	0.527	0.105
R1/stream	0.7452	0.0405	0.0677	12.0194	1.6671	0.0868	29.81	0.8566	1.2848	0.0037	0.4340	0.868	0.174
R4/stream	0.5261	0.0286	0.0478	8.4855	1.1770	0.0612	21.04	0.6047	0.9071	0.0026	0.2212	0.442	0.0885
	Step 3 (application at BBCH 69) for dose 1x35 g as/ha												
D3/ditch	0.2233	0.0121	0.0203	3.6016	0.4996	0.0260	8.93	0.2567	0.3850	0.0011	0.1419	0.284	~~0.0568~~
D4/pond	0.007702	0.0004	0.0007	0.1242	0.0172	0.0009	0.31	0.0089	0.0133	0.0000	0.02901	0.058	~~0.0116~~
D4/stream	0.1919	0.0104	0.0174	3.0952	0.4293	0.0223	7.68	0.2206	0.3309	0.0010	0.03018	0.060	~~0.0121~~
D5/pond	0.1696	0.0092	0.0154	2.7355	0.3794	0.0197	6.78	0.1949	0.2924	0.0008	0.8427	1.685	~~0.3371~~
D5/stream	0.2425	0.0132	0.0220	3.9113	0.5425	0.0282	9.70	0.2787	0.4181	0.0012	0.2013	0.403	~~0.0805~~
R3/stream	0.2317	0.0126	0.0211	3.7371	0.5183	0.0270	9.27	0.2663	0.3995	0.0012	0.1123	0.225	~~0.0449~~
	Step 3 (application at BBCH 69) For winter cereals as surrogate crop for dose 1x35 g as/ha												

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. Dwell, prolonged (aquatic phase)	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged	Higher-Tier information for Sed. dwell. pro-longed
R1/stream	0.2069	0.0112	0.0188	2.3371	0.4629	0.0241		0.2378	0.3567	0.0010	0.06750		0.0270
R1/pond	0.09536	0.0052	0.0087	1.5381	0.2133	0.0111	3.81	0.1096	0.1644	0.0005	0.3026	0.605	0.121
R1/stream	0.8193	0.0445	0.0745	13.2145	1.8329	0.0954	32.77	0.9417	1.4126	0.0041	0.2497	0.499	0.100
R4/stream	0.2297	0.0125	0.0209	3.7048	0.5139	0.0267	9.19	0.2640	0.3960	0.0011	0.07125	0.143	0.0285
		Step 4 for winter cereals as surrogate crop for R1 scenario (applicationa at BBCH 53) 10 m vegetative and 10 m buffer zone											
R1/stream	0.3389	0.0184	0.0308	5.4661	0.7582	0.0395	13.6	0.3895	0.5843	0.0017	0.1493	0.299	0.060
		Step 4 for winter cereals as surrogate crop for R1 scenario (applicationa at BBCH 69) 10 m vegetative and 10 m buffer zone											
R1/stream	0.3693	0.0201	0.0336	5.9565	0.8262	0.0430	14.8	0.4245	0.6367	0.0018	0.1008	0.202	0.040

zRMS comments:

For algae the EU agreed endpoint - ErC50 >2000 µg/L should be used. For the PEC/RAC calculations for algae the lover value at 85.9 µg/L (worse case) was used by Applicant. This was not corrected because it had no impact on the assessment result.

The acute and chronic risk to invertebrates and chronic risk to sediment-dwelling invertebrates considering exposure via water, based on Tier 1 EU agreed endpoints is covered by the refined risk assessment for aquatic invertebrates. Therefore PEC/RAC calculations with Tier 1 EU agreed endpoints were not assessed by zRMS.

According to Part B8 for for R1 and R4 scenarios: surrogate crop is winter cereals.

Refinement of the risk assessment for invertebrates ~~and sediment-dwelling invertebrates considering exposure via sediment~~, proposed by Applicant, should be considered on the MSs level.

Result of risk assessment with EU HC_5 for invertebrates ~~and refined endpoint for sediment-dwelling organisms considering exposure via sediment~~.

PEC/RAC based on refinement endpoints		
Scenario	**Surrogate crop**	**Acceptable -A Not acceptable - N**

Step 3, BBCH 53, 1 x 35 g as/ha		
D3 ditch		A
D4 pond		A
D4 stream		A
D5 pond		A
D5 stream		A
R1 pond	Winter cereals	A
R1 stream	Winter cereals	**N**
R3 stream		A
R4 stream	Winter cereals	A
Step 4, BBCH 53, 1 x 35 g as/ha, 10 m vegetative and 10 m buffer zone		
R1 stream	Winter cereals	A
Step 1, BBCH 69, 1 x 35 g as/ha,		
D3 ditch		A
D4 pond		A
D4 stream		A
D5 pond		A
D5 stream		A
R1 pond	Winter cereals	A
R1 stream	Winter cereals	**N**
R3 stream		A
R4 stream	Winter cereals	A
Step 4, BBCH 69, 1 x 35 g as/ha, 10 m vegetative and 10 m buffer zone		
R1 stream	Winter cereals	A

In summary:

BBCH 53, 1 x 35 g as/ha
At Step 3 risk is acceptable for all scenarios except R1 stream.

At Step 4, with 10 m vegetative filter strip, risk is acceptable for R1 stream scenario.

BBCH 69, 1 x 35 g as/ha
At Step 3 risk is acceptable for all scenarios except R1 stream.
At Step 4, with 10 m vegetative filter strip, risk is acceptable for R1 stream scenario.

Individual scenarios should be considered in accordance with the requirements of each Member State.

Result of risk assessment with refined HC5 for invertebrates ~~and refined endpoint for sediment-dwelling organisms considering exposure via sediment~~

PEC/RAC based on refinement endpoints		
Scenario	**Surrogate crop**	**Acceptable -A Not acceptable - N**
Step 3, BBCH 53, 1 x 35 g as/ha		
D3 ditch		A
D4 pond		A
D4 stream		A
D5 pond		A
D5 stream		A
R1 pond	Winter cereals	A
R1 stream	Winter cereals	A
R3 stream		A
R4 stream	Winter cereals	A
Step 1, BBCH 69, 1 x 35 g as/ha,		
D3 ditch		A
D4 pond		A
D4 stream		A
D5 pond		A
D5 stream		A
R1 pond	Winter cereals	A
R1 stream	Winter cereals	A
R3 stream		A
R4 stream	Winter cereals	A

In summary:

BBCH 53, 1 x 35 g as/ha
At Step 3 risk is acceptable for all scenarios.

BBCH 69, 1 x 35 g as/ha
At Step 3 risk is acceptable for all scenarios..

Individual scenarios should be considered in accordance with the requirements of each Member State.

Spring oilseed rape, 1 x 35 g as/ha, BBCH 61-71
use no:
26, Spring oilseed rape, BBCH 61-71, 1 x 35 g as/ha
27, Flax, BBCH 61-71, 1 x 35 g as/ha
28. Opium poppy, BBCH 61-65, 1 x 35 g as/ha
29. White mustard, BBCH 61-65, 1 x 35 g as/ha
30. Winter turnip, BBCH 61-65, 1 x 35 g as/ha
34, Hemp, BBCH 61-65, 1 x 35 g as/ha

Table 9.5-14: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for chlorantraniliprole for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CLOROL 200 SC in spring oilseed rape

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged
Test species		*Bluegill sunfish*	*Oncorhynchus mykiss*	*Daphnia magna*	*Daphnia magna*	*Pseudokirchn. subcapitata*	*Invertebrate*	*Invertebrate*	*Lemna Gibba*		*Chironomus riparius*
Endpoint (µg/L)		LC_{50} 1840	NOEC 110	EC_{50} 6.2	NOEC 4.47	EC_{50} 85.9	HC5 2.61	HC5 2.91	EC50 2000		NOEC 25
AF		100	10	100	10	10	3	5	10		10
RAC (µg/L)		18.4	11	0.062	0.447	8.59	0.87	0.58	200		2.5
FOCUS Scenario	PEC $_{gl-max}$ (µg/L)									PEC $_{gl-max}$ (µg/kg)	

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged
Step 1											
	8.65	0.4701	0.7864	139.5161	19.3512	1.0070	9.9425	14.9138	0.0433	25.70	10.2800
Step 2											
N-Europe	0.75	0.0408	0.0682	12.0968	1.6779	0.0873	0.8621	1.2931	0.0038	2.18	0.8720
Step 3											
D3/ditch	0.2224	0.0121	0.0202	3.5871	0.4975	0.0259	0.2556	0.3834	0.0011	0.09596	0.0384
D4/pond	0.1521	0.0083	0.0138	2.4532	0.3403	0.0177	0.1748	0.2622	0.0008	0.5922	0.2369
D4/stream	0.1919	0.0104	0.0174	3.0952	0.4293	0.0223	0.2206	0.3309	0.0010	0.2106	0.0842
D5/pond	0.1097	0.0060	0.0100	1.7694	0.2454	0.0128	0.1261	0.1891	0.0005	0.7028	0.2811
D5/stream	0.2072	0.0113	0.0188	3.3419	0.4635	0.0241	0.2382	0.3572	0.0010	0.1474	0.0590
R1/pond	0.06323	0.0034	0.0057	1.0198	0.1415	0.0074	0.0727	0.1090	0.0003	0.2205	0.0882
R1/stream	0.4394	0.0239	0.0399	7.0871	0.9830	0.0512	0.5051	0.7576	0.0022	0.2655	0.1062

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

Risk assessment was updates by Applicant as follows with winter oilseed rape as surrogate crop for R3 scenarios and legumes as surrogate crop R4 scenario:

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. Dwell, prolonged (aquatic phase)**	**Higher-tier information**	**Higher-tier information**	**Aquatic plants**		**Sed. dwell. prolonged**	~~**Higher Tier information for Sed. dwell. prolonged**~~
Test species		***Bluegill sunfish***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchn. subcapitata***	***Chironomus riparius***	***Invertebrate***	***Invertebrate***	***Lemna Gibba***		***Chironomus riparius***	~~***Chironomus riparius***~~
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	NOEC	HC5	HC5	EC50		NOEC	~~NOEC~~
(µg/L)		1840	110	6.2	4.47	85.9	0.25	2.61	2.91	2000		5	~~25~~

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. Dwell, prolonged (aquatic phase)	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged	~~Higher-Tier information for Sed. dwell. pro-longed~~
AF		100	10	100	10	10	10	3	5	10		10	~~10~~
RAC (µg/L)		18.4	11	0.062	0.447	8.59	0.025	0.87	0.58	200		0.5	~~2.5~~
FOCUS Scenario	**PEC gl-max (µg/L)**										**PEC gl-max (µg/kg)**		
Step 1													
	8.65	0.4701	0.7864	139.5161	19.3512	1.0070	346.0	9.9425	14.9138	0.0433	25.70	51.400	~~10.2800~~
Step 2													
N-Europe	0.75	0.0408	0.0682	12.0968	1.6779	0.0873	30.0	0.8621	1.2931	0.0038	2.18	4.360	~~0.8720~~
	Step 3 (application at BBCH 61) for dose 1x35 g as/ha												
D3/ditch	0.2224	0.0121	0.0202	3.5871	0.4975	0.0259	8.90	0.2556	0.3834	0.0011	0.09596	0.192	~~0.0384~~
D4/pond	0.1521	0.0083	0.0138	2.4532	0.3403	0.0177	6.08	0.1748	0.2622	0.0008	0.5922	1.184	~~0.2369~~
D4/stream	0.1919	0.0104	0.0174	3.0952	0.4293	0.0223	7.68	0.2206	0.3309	0.0010	0.2106	0.421	~~0.0842~~
D5/pond	0.1097	0.0060	0.0100	1.7694	0.2454	0.0128	4.39	0.1261	0.1891	0.0005	0.7028	1.406	~~0.2811~~
D5/stream	0.2072	0.0113	0.0188	3.3419	0.4635	0.0241	8.29	0.2382	0.3572	0.0010	0.1474	0.295	~~0.0590~~
R1/pond	0.06323	0.0034	0.0057	1.0198	0.1415	0.0074	2.53	0.0727	0.1090	0.0003	0.2205	0.441	~~0.0882~~
R1/stream	0.4394	0.0239	0.0399	7.0871	0.9830	0.0512	17.58	0.5051	0.7576	0.0022	0.2655	0.531	~~0.1062~~
	Step 3 for winter oilssed rape as surroate crop for R3 scenario (application at BBCH 61) for dose 1x35 g as/ha												
~~D3/ditch~~ R3 stream	0.3571	0.0194	0.0325	5.7597	0.7989	0.0416	14.3	0.4105	0.6157	0.0018	0.09387	0.188	~~0.0375~~
	Step 3 for legumes as surroate crop for R4 scenario (application at BBCH 61) for dose 1x35 g as/ha												
R4/stream	0.6965	0.0379	0.0633	11.2339	1.5582	0.0811	27.9	0.8006	1.2009	0.0035	0.2493	0.499	0.100

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. Dwell, prolonged (aquatic phase)	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged	~~Higher-Tier information for Sed. dwell. pro-longed~~
			Step 4 for legumes as surrogate crop for R4 scenerio (application at BBCH 61) – 10 m vegetative and 10 m buffer, 1 x 35, g/ha										
~~R4~~/stream	0.3161	0.0172	0.0287	5.0984	0.7072	0.0368	12.6	0.3633	0.5450	0.0016	0.1138	0.228	~~0.046~~
			Step 3 (application at BBCH 71) for dose 1x35 g as/ha										
D3/ditch	0.2228	0.0121	0.0203	3.5935	0.4984	0.0259	8.91	0.2561	0.3841	0.0011	0.1129	0.226	~~0.0452~~
D4/pond	0.2237	0.0122	0.0203	3.6081	0.5004	0.0260	8.95	0.2571	0.3857	0.0011	0.8468	1.694	~~0.3387~~
D4/stream	0.2322	0.0126	0.0211	3.7452	0.5195	0.0270	9.29	0.2669	0.4003	0.0012	0.3033	0.607	~~0.1213~~
D5/pond	0.08321	0.0045	0.0076	1.3421	0.1862	0.0097	3.33	0.0956	0.1435	0.0004	0.4412	0.882	~~0.1765~~
D5/stream	0.2071	0.0113	0.0188	3.3403	0.4633	0.0241	8.28	0.2380	0.3571	0.0010	0.09652	0.193	~~0.0386~~
R1/pond	0.02752	0.0015	0.0025	0.4439	0.0616	0.0032	1.10	0.0316	0.0474	0.0001	0.08700	0.174	~~0.0348~~
R1/stream	0.4718	0.0256	0.0429	7.6097	1.0555	0.0549	18.87	0.5423	0.8134	0.0024	0.1653	0.331	~~0.0661~~
			Step 3 for winter oilssed rape as surroate crop for R4 scenario (application at BBCH 71) for dose 1x35 g as/ha										
~~D3/ditch~~ R3 stream	0.5680	0.0309	0.0516	9.1613	1.2707	0.0661	22.7	0.6529	0.9793	0.0028	0.1675	0.335	~~0.0670~~
			Step 3 for legumes as surroate crop for R4 scenario (application at BBCH 71) for dose 1x35 g as/ha										
R4/stream	0.9916	0.0539	0.0901	15.9935	2.2183	0.1154	39.7	1.1398	1.7097	0.0050	0.3625	0.725	~~0.145~~
			Step 4 for legumes as surrogate crop for R4 scenerio (application at BBCH 71) – 10 m vegetative and 10 m buffer for dose 1x35 g as/ha										
R4/stream	0.4489	0.0244	0.0408	7.2403	1.0043	0.0523	18.0	0.5160	0.7740	0.0022	0.1622	0.324	~~0.065~~

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

zRMS comments:

For algae the EU agreed endpoint - ErC50 >2000 µg/L should be used. For the PEC/RAC calculations for algae the lover value at 85.9 µg/L (worse case) was used by Applicant. This was not corrected because it had no impact on the assessment result.

The acute and chronic risk to invertebrates and chronic risk to sediment-dwelling invertebrates considering exposure via water, based on Tier 1 EU agreed endpoints is covered by the refined risk assessment for aquatic invertebrates. Therefore PEC/RAC calculations with Tier 1 EU agreed endpoints were not assessed by zRMS.

According to Part B8 for for R3 scenarios: surrogate crop is winter oilseed rape and for R4 scenario: surrogate crop is legumes.

Refinement of the risk assessment for invertebrates ~~and sediment-dwelling invertebrates considering exposure via sediment~~, proposed by Applicant, should be considered on the MSs level.

Result of risk assessment with EU HC_5 for invertebrates ~~and refined endpoint for sediment-dwelling organisms considering exposure via sediment~~.

PEC/RAC based on refinement endpoints		
Scenario	**Surrogate crop**	**Acceptable -A Not acceptable - N**
Step 3, BBCH 61, 1 x 35 g as/ha		
D3 ditch		A
D4 pond		A
D4 stream		A
D5 pond		A
D5 stream		A
R1 pond		A
R1 stream		A
R3 stream	winter oilssed rape	A
R4 stream	legumes	**N**
Step 4, BBCH 61, 1 x 35, g/ha, 10 m vegetative and 10 m buffer		
Step 3, BBCH 71, 1 x 35 g as/ha,		
D3 ditch		A
D4 pond		A
D4 stream		A
D5 pond		A

D5 stream		A
R1 pond		A
R1 stream		A
R3 stream	winter oilssed rape	A
R4 stream	legumes	**N**
Step 4, BBCH 71, 1 x 35 g as/ha, 10 m vegetative and 10 m buffer		
R4 stream	legumes	A

In summary:

BBCH 61, 1 x 35 g as/ha
At Step 3 risk is acceptable for all scenarios except R4 stream.
For R4 stream scenario 10 m VFS and 10 m buffer zone is required.

BBCH 71, 1 x 35 g as/ha
At Step 3 risk is acceptable for all scenarios except R4 stream.
For R4 stream scenario 10 m VFS and 10 m buffer zone is required.

Individual scenarios should be considered in accordance with the requirements of each Member State.

Result of risk assessment with refined HC5 for invertebrates ~~and refined endpoint for sediment-dwelling organisms considering exposure via sediment~~

PEC/RAC based on refinement endpoints		
Scenario	**Surrogate crop**	**Acceptable -A** **Not acceptable - N**
Step 3, BBCH 61, 1 x 35 g as/ha		
D3 ditch		A
D4 pond		A
D4 stream		A
D5 pond		A
D5 stream		A
R1 pond		A
R1 stream		A

R3 stream	winter oilssed rape	A
R4 stream	legumes	A
Step 3, BBCH 71, 1 x 35 g as/ha,		
D3 ditch		A
D4 pond		A
D4 stream		A
D5 pond		A
D5 stream		A
R1 pond		A
R1 stream		A
R3 stream	winter oilssed rape	A
R4 stream	legumes	**N**
Step 4, BBCH 71, 1 x 35 g as/ha, 10 m vegetative and 10 m buffer		
R4 stream	legumes	A

In summary:

BBCH 61, 1 x 35 g as/ha
At Step 3 risk is acceptable for all scenarios.

BBCH 71, 1 x 35 g as/ha
At Step 3 risk is acceptable for all scenarios except R4 stream.
For R4 stream scenario 10 m VFS and 10 m buffer zone is required.

Individual scenarios should be considered in accordance with the requirements of each Member State.

Winter oilseed rape, use no.:

3, Winter oilseed rape, BBCH 61-71, 1 x 35 g as/ha

4, Winter oilseed rape, BBCH 30-50 and BBCH 61-71, 2 x 35 g as/ha

Table 9.5-15: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for chlorantraniliprole for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CLOROL 200 SC in winter oilseed rape

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged
Test species		*Bluegill sunfish*	*Oncorhynchus mykiss*	*Daphnia magna*	*Daphnia magna*	*Pseudokirchn. subcapitata*	*Invertebrate*	*Invertebrate*	*Lemna Gibba*		*Chironomus riparius*
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	HC5	HC5	EC50		NOEC
(µg/L)		1840	110	6.2	4.47	85.9	2.61	2.91	2000		25
AF		100	10	100	10	10	3	5	10		10
RAC (µg/L)		18.4	11	0.062	0.447	8.59	0.87	0.58	200		2.5
FOCUS Scenario	PEC $_{gl-max}$ (µg/L)									PEC $_{gl-max}$ (µg/kg)	
Step 1											
	17.29	0.9397	1.5718	278.8710	38.6801	2.0128	19.8736	29.8103	0.0865	51.40	20.5600
Step 2											
N-Europe	2.42	0.1315	0.2200	39.0323	5.4139	0.2817	2.7816	4.1724	0.0121	7.13	2.8520
Step 3											
D3/ditch	0.2222	0.0121	0.0202	3.5839	0.4971	0.0259	0.2554	0.3831	0.0011	0.09168	0.0367
D4/pond	0.1411	0.0077	0.0128	2.2758	0.3157	0.0164	0.1622	0.2433	0.0007	0.5443	0.2177
D4/stream	0.1919	0.0104	0.0174	3.0952	0.4293	0.0223	0.2206	0.3309	0.0010	0.1938	0.0775
D5/pond	0.08821	0.0048	0.0080	1.4227	0.1973	0.0103	0.1014	0.1521	0.0004	0.5630	0.2252
D5/stream	0.2071	0.0113	0.0188	3.3403	0.4633	0.0241	0.2380	0.3571	0.0010	0.1171	0.0468
R1/pond	0.05402	0.0029	0.0049	0.8713	0.1209	0.0063	0.0621	0.0931	0.0003	0.1883	0.0753
R1/stream	0.4448	0.0242	0.0404	7.1742	0.9951	0.0518	0.5113	0.7669	0.0022	0.2833	0.1133
R3/stream	0.3571	0.0194	0.0325	5.7597	0.7989	0.0416	0.4105	0.6157	0.0018	0.09387	0.0375

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

Risk assessment was updates by Applicant as follows with legumes as surrogate crop R4 scenario:

Group		**Fish acute**	**Fish pro-longed**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. Dwell. prolonged (aquatic phase)**	**Higher-tier information**	**Higher-tier information**	**Aquatic plants**		**Sed. dwell. prolonged**	~~**Higher Tier information for Sed. dwell. pro-longed**~~
Test spe-cies		***Bluegill sunfish***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchn. subcapitata***	***Chironomus riparius***	***Invertebrate***	***Invertebrate***	***Lemna Gibba***		***Chironomus riparius***	~~***Chironomus riparius***~~
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	NOEC	HC5	HC5	EC50		NOEC	~~NOEC~~
(µg/L)		1840	110	6.2	4.47	85.9	0.25	2.61	2.91	2000		5	~~25~~
AF		100	10	100	10	10	10	3	5	10		10	~~10~~
RAC (µg/L)		18.4	11	0.062	0.447	8.59	0.025	0.87	0.58	200		0.5	~~2.5~~
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**										**PEC $_{gl-max}$ (µg/kg)**		
Step 1													
	17.29	0.9397	1.5718	278.8710	38.6801	2.0128	691.6	19.8736	29.8103	0.0865	51.40	102.800	~~20.5600~~
Step 2													
N-Europe	2.42	0.1315	0.2200	39.0323	5.4139	0.2817	96.8	2.7816	4.1724	0.0121	7.13	14.260	~~2.8520~~
	Step 3 (application at BBCH 30) for dose 1x35 g as/ha												
D3/ditch	0.2222	0.0121	0.0202	3.5839	0.4971	0.0259	8.89	0.2554	0.3831	0.0011	0.09168	0.183	~~0.0367~~
D4/pond	0.1411	0.0077	0.0128	2.2758	0.3157	0.0164	5.64	0.1622	0.2433	0.0007	0.5443	1.089	~~0.2177~~
D4/stream	0.1919	0.0104	0.0174	3.0952	0.4293	0.0223	7.68	0.2206	0.3309	0.0010	0.1938	0.388	~~0.0775~~
D5/pond	0.08821	0.0048	0.0080	1.4227	0.1973	0.0103	3.53	0.1014	0.1521	0.0004	0.5630	1.126	~~0.2252~~
D5/stream	0.2071	0.0113	0.0188	3.3403	0.4633	0.0241	8.28	0.2380	0.3571	0.0010	0.1171	0.234	~~0.0468~~

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. Dwell. prolonged (aquatic phase)	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged	~~Higher Tier information for Sed. dwell. pro-longed~~
R1/pond	0.05402	0.0029	0.0049	0.8713	0.1209	0.0063	2.16	0.0621	0.0931	0.0003	0.1883	0.377	~~0.0753~~
R1/stream	0.4448	0.0242	0.0404	7.1742	0.9951	0.0518	17.79	0.5113	0.7669	0.0022	0.2833	0.567	~~0.1133~~
R3/stream	0.3571	0.0194	0.0325	5.7597	0.7989	0.0416	14.28	0.4105	0.6157	0.0018	0.09387	0.188	~~0.0375~~
		Step 3 for legumes as surrogate crop for R4 scenario (application at BBCH 30) for dose 1x35 g as/ha											
R4/stream	0.7189	0.0391	0.0654	11.5952	1.6083	0.0837	28.8	0.8263	1.2395	0.0036	0.2551	0.510	~~0.1020~~
		Step 4 for legumes as surrogate crop for R4 scenario (application at BBCH 30) – 10 meters vegetative buffer zone for dose 1x35 g as/ha											
R4/stream	0.3206	0.0174	0.0291	5.1710	0.7172	0.0373	12.8	0.3685	0.5528	0.0016	0.1152	0.230	~~0.0461~~
		Step 3 (application at BBCH 30) for dose 2x35 g as/ha											
D3/ditch	0.2539	0.0138	0.0231	4.0952	0.5680	0.0296	10.16	0.2918	0.4378	0.0013	0.09971	0.199	~~0.040~~
D4/pond	0.4034	0.0219	0.0367	6.5065	0.9025	0.0470	16.14	0.4637	0.6955	0.0020	0.03968	0.079	~~0.016~~
D4/stream	0.4257	0.023	0.039	6.866	0.952	0.050	17.03	0.489	0.734	0.0021	0.5404	1.081	~~0.216~~
D5/pond	0.2849	0.015	0.026	4.595	0.637	0.033	11.40	0.327	0.491	0.0014	1.573	3.146	~~0.629~~
D5/stream	0.2064	0.011	0.019	3.329	0.462	0.024	8.26	0.237	0.356	0.0010	0.3382	0.676	~~0.135~~
R1/pond	0.07513	0.004	0.007	1.212	0.168	0.009	3.01	0.086	0.130	0.0004	0.2641	0.528	~~0.106~~
R1/stream	0.8622	0.047	0.078	13.906	1.929	0.100	34.49	0.991	1.487	0.0043	0.2905	0.581	~~0.116~~
R3/stream	0.7894	0.043	0.072	12.732	1.766	0.092	31.58	0.907	1.361	0.0039	0.3361	0.672	~~0.134~~
		Step 3 for legumes as surrogate crop for R4 scenario (application at BBCH 30) for dose 2x35 g as/ha											
R4/stream	1.794	0.0975	0.1631	28.9355	4.0134	0.2088	71.8	2.0621	3.0931	0.0090	0.6145	1.229	~~0.246~~
		Step 4 for legumes as surrogate crop for ~~R1, R3, and~~ R4 scenario (application at BBCH 30) for dose 2x35 g as/ha – 10 meters vegetative buffer zone											
R4/stream	0.7999	0.0435	0.0727	12.9016	1.7895	0.0931	32.0	0.9194	1.3791	0.0040	0.2702	0.540	~~0.108~~
		Step 4 for legumes as surrogate crop for R4 scenario (application at BBCH 30) for dose 2x35 g as/ha – 20 meters vegetative buffer zone											

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. Dwell, prolonged (aquatic phase)	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged	~~Higher-Tier information for Sed. dwell. pro-longed~~
R4/stream	0.4160	0.0226	0.0378	6.7097	0.9306	0.0484	16.6	0.4782	0.7172	0.0021	0.1415	0.283	~~0.057~~
						Step 3 (application at BBCH 50) for dose 2x35 g as/ha							
D3/ditch	0.1939	0.0105	0.0176	3.1274	0.4338	0.0226	7.76	0.2229	0.3343	0.0010	0.08455	0.169	~~0.0338~~
D4/pond	0.3077	0.0167	0.0280	4.9629	0.6884	0.0358	12.31	0.3537	0.5305	0.0015	1.202	2.404	~~0.4808~~
D4/stream	0.3197	0.0174	0.0291	5.1565	0.7152	0.0372	12.79	0.3675	0.5512	0.0016	0.4177	0.835	~~0.1671~~
D5/pond	0.2549	0.0139	0.0232	4.1113	0.5702	0.0297	10.20	0.2930	0.4395	0.0013	1.397	2.794	~~0.5588~~
D5/stream	0.1965	0.0107	0.0179	3.1694	0.4396	0.0229	7.86	0.2259	0.3388	0.0010	0.3035	0.607	~~0.1214~~
R1/pond	0.09900	0.0054	0.0090	1.5968	0.2215	0.0115	3.96	0.1138	0.1707	0.0005	0.3424	0.685	~~0.1370~~
R1/stream	0.5476	0.0298	0.0498	8.8323	1.2251	0.0637	21.90	0.6294	0.9441	0.0027	0.3612	0.722	~~0.1445~~
R3/stream	0.9586	0.0521	0.0871	15.4613	2.1445	0.1116	38.34	1.1018	1.6528	0.0048	0.4444	0.889	~~0.1778~~
						Step 4 (application at BBCH 50) – 10 meters vegetative buffer zone for dose 2x35 g as/ha							
R4/stream	0.4374	0.0238	0.0398	7.0548	0.9785	0.0509	17.5	0.5028	0.7541	0.0022	0.1921	0.384	~~0.0768~~
						Step 3 for legumes as surrogate crop for R4 scenario (application at BBCH 50) for dose 2x35 g as/ha							
R4/stream	0.9871	0.0536	0.0897	15.9210	2.2083	0.1149	39.5	1.1346	1.7019	0.0049	0.4008	0.802	~~0.1603~~
						Step 4 for legumes as surrogate crop for R4 scenario (application at BBCH 30) – 10 meters vegetative buffer zone for dose 2x35 g as/ha							
R4/stream	0.4467	0.0243	0.0406	7.2048	0.9993	0.0520	17.9	0.5134	0.7702	0.0022	0.1855	0.371	~~0.0742~~
						Step 3 (application at BBCH 61) for dose 2x35 g as/ha							
D3/ditch	0.1946	0.0106	0.0177	3.1387	0.4353	0.0227	7.78	0.2237	0.3355	0.0010	0.1081	0.500	~~0.0432~~
D4/pond	0.3541	0.0192	0.0322	5.7113	0.7922	0.0412	14.16	0.4070	0.6105	0.0018	1.325	0.216	~~0.5300~~
D4/stream	0.3761	0.0204	0.0342	6.0661	0.8414	0.0438	15.04	0.4323	0.6484	0.0019	0.4735	2.650	~~0.1894~~
D5/pond	0.2375	0.0129	0.0216	3.8306	0.5313	0.0276	9.50	0.2730	0.4095	0.0012	1.506	0.947	~~0.6024~~
D5/stream	0.1789	0.0097	0.0163	2.8855	0.4002	0.0208	7.16	0.2056	0.3084	0.0009	0.3295	3.012	~~0.1318~~

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. Dwell. prolonged (aquatic phase)	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged	~~Higher Tier information for Sed. dwell. pro-longed~~
R1/pond	0.07706	0.0042	0.0070	1.2429	0.1724	0.0090	3.08	0.0886	0.1329	0.0004	0.2959	0.659	~~0.1184~~
R1/stream	0.8935	0.0486	0.0812	14.4113	1.9989	0.1040	35.74	1.0270	1.5405	0.0045	0.3841	0.592	~~0.1536~~
R3/stream	0.7527	0.0409	0.0684	12.1403	1.6839	0.0876	30.11	0.8652	1.2978	0.0038	0.2438	0.768	~~0.0975~~
	Step 4 (application at BBCH 61) – 10 meters vegetative buffer zone for dose 2x35 g as/ha												
R1/stream	0.4039	0.0220	0.0367	6.5145	0.9036	0.0470	16.2	0.4643	0.6964	0.0020	0.1469	0.294	~~0.0588~~
R3/stream	0.3415	0.0186	0.0310	5.5081	0.7640	0.0398	13.7	0.3925	0.5888	0.0017	0.1187	0.237	~~0.0475~~
	Step 3 for legumes as surrogate crop for R4 scenario (application at BBCH 61) for dose 2x35 g as/ha												
R4/stream	0.9871	0.0536	0.0897	15.9210	2.2083	0.1149	16.2	1.1346	1.7019	0.0049	0.4008	0.802	~~0.1603~~
	Step 4 for legumes as surrogate crop for R4 scenario (application at BBCH 61) – 10 meters vegetative buffer zone for dose 2x35 g as/ha												
R4/stream	0.4467	0.0243	0.0406	7.2048	0.9993	0.0520	17.9	0.5134	0.7702	0.0022	0.1855	0.371	~~0.0742~~
	Step 3 (application at BBCH 71) for dose 2x35 g as/ha												
D3/ditch	0.1950	0.0106	0.0177	3.1452	0.4362	0.0227	7.80	0.2241	0.3362	0.0010	0.1269	0.254	~~0.0508~~
D4/pond	0.4004	0.0218	0.0364	6.4581	0.8957	0.0466	16.02	0.4602	0.6903	0.0020	1.489	2.978	~~0.5956~~
D4/stream	0.4266	0.0232	0.0388	6.8806	0.9544	0.0497	17.06	0.4903	0.7355	0.0021	0.5291	1.058	~~0.2116~~
D5/pond	0.2050	0.0111	0.0186	3.3065	0.4586	0.0239	8.20	0.2356	0.3534	0.0010	1.253	2.506	~~0.5012~~
D5/stream	0.1789	0.0097	0.0163	2.8855	0.4002	0.0208	7.16	0.2056	0.3084	0.0009	0.2675	0.535	~~0.1070~~
R1/pond	0.1615	0.0088	0.0147	2.6048	0.3613	0.0188	6.46	0.1856	0.2784	0.0008	0.5368	1.074	~~0.2147~~
R1/stream	0.6519	0.0354	0.0593	10.5145	1.4584	0.0759	26.08	0.7493	1.1240	0.0033	0.3948	0.790	~~0.1579~~
R3/stream	0.5680	0.0309	0.0516	9.1613	1.2707	0.0661	22.72	0.6529	0.9793	0.0028	0.1666	0.333	~~0.0666~~
	Step 4 (application at BBCH ~~61~~ 71) – 10 meters vegetative buffer zone for dose 2x35 g as/ha												
R1/stream	0.2933	0.0159	0.0267	4.7306	0.6562	0.0341	11.7	0.3371	0.5057	0.0015	0.1388	0.278	~~0.0555~~
	Step 3 for legumes as surrogate crop for R4 scenario (application at BBCH71) for dose 2x35 g as/ha												

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. Dwell. prolonged (aquatic phase)	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged	~~Higher-Tier information for Sed. dwell. pro-longed~~
R4/stream	0.7083	0.0385	0.0644	11.4242	1.5846	0.0825	28.3	0.8141	1.2212	0.0035	0.2614	0.523	~~0.1046~~
			Step 4 for legumes as surrogate crop for R4 scenario (application at BBCH 71) – 10 meters vegetative buffer zone for dose 2x35 g as/ha										
R4/stream	0.3206	0.0174	0.0291	5.1710	0.7172	0.0373	12.8	0.3685	0.5528	0.0016	0.1219	0.244	~~0.0488~~

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

zRMS comments:

For algae the EU agreed endpoint - ErC50 >2000 µg/L should be used. For the PEC/RAC calculations for algae the lover value at 85.9 µg/L (worse case) was used by Applicant. This was not corrected because it had no impact on the assessment result.

The acute and chronic risk to invertebrates and chronic risk to sediment-dwelling invertebrates considering exposure via water, based on Tier 1 EU agreed endpoints is covered by the refined risk assessment for aquatic invertebrates. Therefore PEC/RAC calculations with Tier 1 EU agreed endpoints were not assessed by zRMS.

Refinement of the risk assessment for invertebrates ~~and sediment-dwelling invertebrates considering exposure via sediment~~, proposed by Applicant, should be considered on the MSs level.

According to Part B8 for for R3 scenarios: surrogate crop is winter oilseed rape and for R4 scenario: surrogate crop is legumes.

Result of risk assessment with EU HC_5 for invertebrates ~~and refined endpoint for sediment-dwelling organisms considering exposure via sediment~~.

Use no. 4, 2 x 35 g as/ha BBCH 30-50 and BBCH 61-71 covers use no. 3, 1 x 35 g as/ha, BBCH 61-71

PEC/RAC based on refinement endpoints		
Scenario	**Surrogate crop**	**Acceptable -A Not acceptable - N**
Step 3, BBCH 30, 2 x 35 g as/ha		
D3 ditch		A
D4 pond		A

D4 stream		A
D5 pond		A
D5 stream		A
R1 pond		A
R1 stream		**N**
R3 stream		**N**
R4 stream	legumes	**N**
Step 4, BBCH 30, 2 x 35 g as/ha, 10 m vegetative and 10 m buffer		
R4 stream	legumes	**N**
Step 4, BBCH 30, 2 x 35 g as/ha, 20 m vegetative and 10 m buffer		
R4 stream	legumes	A
Step 3, BBCH 50, 2 x 35 g as/ha		
D3 ditch		A
D4 pond		A
D4 stream		A
D5 pond		A
D5 stream		A
R1 pond		A
R1 stream		A
R3 stream		**N**
R4 stream	legumes	**N**
Step 4, BBCH 50, 2 x 35 g as/ha, 10 m vegetative buffer zone and 10 m buffer		
R3 stream		**Not calculated**
R4 stream	legumes	A

PEC/RAC based on refinement endpoints		
Scenario	**Surrogate crop**	**Acceptable -A** **Not acceptable - N**
Step 3, BBCH 61, 2 x 35 g as/ha		

D3 ditch		A
D4 pond		A
D4 stream		A
D5 pond		A
D5 stream		A
R1 pond		A
R1 stream		**N**
R3 stream		**N**
R4 stream	legumes	**N**
Step 4, BBCH 61, 2 x 35 g as/ha, 10 m vegetative buffer zone and 10 m buffer		
R1 stream		A
R4 stream	legumes	A

PEC/RAC based on refinement endpoints		
Scenario	**Surrogate crop**	**Acceptable -A Not acceptable - N**
Step 3, BBCH 71, 2 x 35 g as/ha		
D3 ditch		A
D4 pond		A
D4 stream		A
D5 pond		A
D5 stream		A
R1 pond		A
R1 stream		**N**
R3 stream		A
R4 stream	legumes	**N**
Step 4, BBCH 71, 2 x 35 g as/ha, 10 meters vegetative buffer zone		
R1 stream		A
R4 stream	legumes	A

In summary:

Use no. 3, 1 x 35 g as/ha BBCH 61-71

BBCH 61, 2 x 35 g as/ha
At Step 3 risk is acceptable for all scenarios except R1 stream, R3 stream and R4 stream.
At Step 4, for R1 stream and R4 stream scenarios 10 m vegetative and 10 m buffer zone is required.
For R3 stream scenario the risk is unacceptable.

BBCH 71, 2 x 35 g as/ha
At Step 3 risk is acceptable for all scenarios except R1 stream and R4 stream..
At Step 4, for R1 stream and R4 stream scenarios 10 m vegetative and 10 m buffer zone is required.

Use no. 4, 2 x 35 g as/ha BBCH 30-50 and BBCH 61-71

BBCH 30, 2 x 35 g as/ha
At Step 3 risk is acceptable for all scenarios except R1 stream, R3 stream and R4 stream..
At Step 4, for R4 stream scenario 10 m vegetative and 10 m buffer zone is required.
Risk for R1 stream and R3 stream scenarios is not resolved.

BBCH 50, 2 x 35 g as/ha
At Step 3 risk is acceptable for all scenarios except R3 stream and R4 stream..
At Step 4, for R4 stream scenario 10 m vegetative and 10 m buffer zone is required.
Risk for R1 stream and R3 stream scenarios is not resolved.

BBCH 61, 2 x 35 g as/ha
At Step 3 risk is acceptable for all scenarios except R1 stream, R3 stream and R4 stream..
At Step 4, for R1 and R4 stream scenario 10 m vegetative and 10 m buffer zone is required.
Risk for R3 stream scenario is not resolved.

BBCH 71, 2 x 35 g as/ha
At Step 3 risk is acceptable for all scenarios except R1 stream and R4 stream..
At Step 4, for R1 and R4 stream scenario 10 m vegetative and 10 m buffer zone is required.

Individual scenarios should be considered in accordance with the requirements of each Member State.

Result of risk assessment with refined HC5 for invertebrates ~~and refined endpoint for sediment-dwelling organisms considering exposure via sediment~~

PEC/RAC based on refinement endpoints		
Scenario	**Surrogate crop**	**Acceptable -A Not acceptable - N**
Step 3, BBCH 30, 2 x 35 g as/ha		
D3 ditch		A
D4 pond		A
D4 stream		A
D5 pond		A
D5 stream		A
R1 pond		A
R1 stream		A
R3 stream		A
R4 stream	legumes	**N**
Step 4, BBCH 30, 2 x 35 g as/ha, 10 m vegetative and 10 m buffer		
R4 stream	legumes	A
Step 3, BBCH 50, 2 x 35 g as/ha		
D3 ditch		A
D4 pond		A
D4 stream		A
D5 pond		A
D5 stream		A
R1 pond		A
R1 stream		A
R3 stream		**N**
R4 stream	legumes	**N**
Step 4, BBCH 50, 2 x 35 g as/ha, 10 m vegetative buffer zone and 10 m buffer		
R3 stream		**Not calculated**
R4 stream	legumes	A

PEC/RAC based on refinement endpoints		
Scenario	**Surrogate crop**	**Acceptable -A Not acceptable - N**
Step 3, BBCH 61, 2 x 35 g as/ha		
D3 ditch		A
D4 pond		A
D4 stream		A
D5 pond		A
D5 stream		A
R1 pond		A
R1 stream		**N**
R3 stream		A
R4 stream	legumes	**N**
Step 4, BBCH 61, 2 x 35 g as/ha, 10 m vegetative buffer zone and 10 m buffer		
R1 stream		A
R4 stream	legumes	A

PEC/RAC based on refinement endpoints		
Scenario	**Surrogate crop**	**Acceptable -A Not acceptable - N**
Step 3, BBCH 71, 2 x 35 g as/ha		
D3 ditch		A
D4 pond		A
D4 stream		A
D5 pond		A
D5 stream		A
R1 pond		A
R1 stream		A
R3 stream		A
R4 stream	legumes	A

Use no. 3, 1 x 35 g as/ha BBCH 61-71

For dose 1 x 35 g as/ha PEC/RAC ratios were calculated for BBCH 30 (Step 3 and Step 4).

In summary:

BBCH 61, 2 x 35 g as/ha
At Step 3 risk is acceptable for all scenarios except R1 stream and R4 stream.
At Step 4, for R1 stream and R4 stream scenarios 10 m vegetative and 10 m buffer zone is required.

BBCH 71, 2 x 35 g as/ha
At Step 3 risk is acceptable for all scenarios.

Use no. 4, 2 x 35 g as/ha BBCH 30-50 and BBCH 61-71

BBCH 30, 2 x 35 g as/ha
At Step 3 risk is acceptable for all scenarios except R4 stream.
At Step 4, for R4 stream scenario 10 m vegetative and 10 m buffer zone is required.

BBCH 50, 2 x 35 g as/ha
At Step 3 risk is acceptable for all scenarios except R3 stream and R4 stream.
At Step 4, for R4 stream scenario 10 m vegetative and 10 m buffer zone is required.
Risk for R3 stream scenario is unresolved.

BBCH 61, 2 x 35 g as/ha
At Step 3 risk is acceptable for all scenarios except R1 stream and R4 stream.
At Step 4, for R1 stream and R4 stream scenarios 10 m vegetative and 10 m buffer zone is required.

BBCH 71, 2 x 35 g as/ha
At Step 3 risk is acceptable for all scenarios.

If refinement of the risk assessment for invertebrates ~~and sediment dwelling invertebrates considering exposure via sediment~~ is not accepted further refinement is required.

Individual scenarios should be considered in accordance with the requirements of each Member State.

Vine, use no.:
56, Table grape, BBCH 57-83, 1 x 54 g as/ha
57, Grapevine, BBCH 57-83, 1 x 54 g as/ha

Table 9.5-16: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for chlorantraniliprole for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CLOROL 200 SC in vine

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged
Test species		*Bluegill sunfish*	*Oncorhynchus mykiss*	*Daphnia magna*	*Daphnia magna*	*Pseudokirchn. subcapitata*	*Invertebrate*	*Invertebrate*	*Lemna Gibba*		*Chironomus riparius*
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	HC5	HC5	EC50		NOEC
(µg/L)		1840	110	6.2	4.47	85.9	2.61	2.91	2000		25
AF		100	10	100	10	10	3	5	10		10
RAC (µg/L)		18.4	11	0.062	0.447	8.59	0.87	0.58	200		2.5
FOCUS Scenario	PEC $_{gl-max}$ (µg/L)									PEC $_{gl-max}$ (µg/kg)	
Step 1											
	14.29	0.7766	1.2991	230.4839	31.9687	1.6636	16.4253	24.6379	0.0715	41.68	16.672
Step 2											
N-Europe	2.41	0.1310	0.2191	38.8710	5.3915	0.2806	2.7701	4.1552	0.0121	6.93	2.772
Step 3											
D6/ditch	0.9258	0.0503	0.0842	14.9323	2.0711	0.1078	1.0641	1.5962	0.0046	0.4450	0.1780
R1/pond	0.03731	0.0020	0.0034	0.6018	0.0835	0.0043	0.0429	0.0643	0.0002	0.1157	0.0463
R1/stream	0.6780	0.0368	0.0616	10.9355	1.5168	0.0789	0.7793	1.1690	0.0034	0.2465	0.0986
R2/stream	0.9110	0.0495	0.0828	14.6935	2.0380	0.1061	1.0471	1.5707	0.0046	0.1024	0.0410

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged
R3/stream	0.9542	0.0519	0.0867	15.3903	2.1347	0.1111	1.0968	1.6452	0.0048	0.1577	0.0631
R4/stream	0.6666	0.0362	0.0606	10.7516	1.4913	0.0776	0.7662	1.1493	0.0033	0.1160	0.0464
Step 4 – 20 meters buffer zone											
D6/ditch	0.2097	0.0114	0.0191	3.3823	0.4691	0.0244	0.2410	0.3616	0.0010	0.1356	0.0542
R1/stream	0.02191	0.0012	0.0020	0.3534	0.0490	0.0026	0.0252	0.0378	0.0001	0.06896	0.0276
R2/stream	0.2747	0.0149	0.0250	4.4306	0.6145	0.0320	0.3157	0.4736	0.0014	0.1041	0.0416
R3/stream	0.2403	0.0131	0.0218	3.8758	0.5376	0.0280	0.2762	0.4143	0.0012	0.04161	0.0166
R4/stream	0.2517	0.0137	0.0229	4.0597	0.5631	0.0293	0.2893	0.4340	0.0013	0.05745	0.0230
Step 3											
D3/ditch	1.984	0.1078	0.1804	32.0000	4.4385	0.2310	2.2805	3.4207	0.0099	0.8399	0.3360
D4/pond	0.2738	0.0149	0.0249	4.4161	0.6125	0.0319	0.3147	0.4721	0.0014	1.127	0.4508
D4/stream	1.988	0.1080	0.1807	32.0645	4.4474	0.2314	2.2851	3.4276	0.0099	0.3566	0.1426
D5/pond	0.1840	0.0100	0.0167	2.9677	0.4116	0.0214	0.2115	0.3172	0.0009	1.143	0.4572
D5/stream	2.044	0.1111	0.1858	32.9677	4.5727	0.2380	2.3494	3.5241	0.0102	0.2408	0.0963
R1/pond	0.0893	0.0049	0.0081	1.4403	0.1998	0.0104	0.1026	0.1540	0.0004	0.2896	0.1158
R1/stream	1.524	0.0828	0.1385	24.5806	3.4094	0.1774	1.7517	2.6276	0.0076	0.2764	0.1106
R2/stream	2.042	0.1110	0.1856	32.9355	4.5682	0.2377	2.3471	3.5207	0.0102	0.1414	0.0566
R3/stream	2.132	0.1159	0.1938	34.3871	4.7696	0.2482	2.4506	3.6759	0.0107	0.3218	0.1287
R4/stream	1.489	0.0809	0.1354	24.0161	3.3311	0.1733	1.7115	2.5672	0.0074	0.2292	0.0917
Step 4 – 20 meters buffer zone											
D3/ditch	0.1845	0.0100	0.0168	2.9758	0.4128	0.0215	0.2121	0.3181	0.0009	0.08260	0.0330

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged
D4/stream	0.2736	0.0149	0.0249	4.4129	0.6121	0.0319	0.3145	0.4717	0.0014	0.3482	0.1393
D5/stream	0.2307	0.0125	0.0210	3.7210	0.5161	0.0269	0.2652	0.3978	0.0012	0.1992	0.0797
R1/stream	0.1639	0.0089	0.0149	2.6435	0.3667	0.0191	0.1884	0.2826	0.0008	0.06030	0.0241
R2/stream	0.2197	0.0119	0.0200	3.5435	0.4915	0.0256	0.2525	0.3788	0.0011	0.02534	0.0101
R3/stream	0.2294	0.0125	0.0209	3.7000	0.5132	0.0267	0.2637	0.3955	0.0011	0.03553	0.0142
R4/stream	0.1602	0.0087	0.0146	2.5839	0.3584	0.0186	0.1841	0.2762	0.0008	0.04770	0.0191

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

Risk assessment was updates by Applicant as follows with pome fruits as surrogate crop D3, D4 and D5 scenarios:

Group		**Fish acute**	**Fish pro-longed**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. Dwell, prolonged (aquatic phase)**	**Higher-tier information**	**Higher-tier information**	**Aquatic plants**		**Sed. dwell. prolonged**	~~**Higher-Tier information for Sed. dwell. pro-longed**~~
Test species		***Bluegill sunfish***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchn. subcapitata***	***Chironomus riparius***	***Invertebrate***	***Invertebrate***	***Lemna Gibba***		***Chironomus riparius***	~~***Chironomus riparius***~~
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	NOEC	HC5	HC5	EC50		NOEC	~~NOEC~~
(µg/L)		1840	110	6.2	4.47	85.9	0.25	2.61	2.91	2000		5	~~25~~
AF		100	10	100	10	10	10	3	5	10		10	~~10~~
RAC (µg/L)		18.4	11	0.062	0.447	8.59	0.025	0.87	0.58	200		0.5	~~2.5~~
FOCUS Scenario	**PEC gl-max (µg/L)**										**PEC gl-max (µg/kg)**		
Step 1													
	14.29	0.7766	1.2991	230.4839	31.9687	1.6636	571.60	16.4253	24.6379	0.0715	41.68	83.360	~~16.672~~

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. Dwell, prolonged (aquatic phase)	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged	~~Higher-Tier information for Sed. dwell. pro-longed~~
Step 2													
N-Europe	2.41	0.1310	0.2191	38.8710	5.3915	0.2806	96.40	2.7701	4.1552	0.0121	6.93	13.860	~~2.772~~
	Step 3 (application at BBCH 57) for dose 1x54 g as/ha												
D6/ditch	0.9258	0.0503	0.0842	14.9323	2.0711	0.1078	37.03	1.0641	1.5962	0.0046	0.4450	0.890	~~0.1780~~
R1/pond	0.03731	0.0020	0.0034	0.6018	0.0835	0.0043	1.49	0.0429	0.0643	0.0002	0.1157	0.231	~~0.0463~~
R1/stream	0.6780	0.0368	0.0616	10.9355	1.5168	0.0789	27.12	0.7793	1.1690	0.0034	0.2465	0.493	~~0.0986~~
R2/stream	0.9110	0.0495	0.0828	14.6935	2.0380	0.1061	36.44	1.0471	1.5707	0.0046	0.1024	0.205	~~0.0410~~
R3/stream	0.9542	0.0519	0.0867	15.3903	2.1347	0.1111	38.17	1.0968	1.6452	0.0048	0.1577	0.315	~~0.0631~~
R4/stream	0.6666	0.0362	0.0606	10.7516	1.4913	0.0776	26.66	0.7662	1.1493	0.0033	0.1160	0.232	~~0.0464~~
Step 4 – 10 meters vegetative and no-spray buffer zone for dose 1x54 g as/ha, BBCH 57													
D6/ditch	0.2097	0.0114	0.0191	3.3823	0.4691	0.0244	0.2097	0.2410	0.3616	0.0010	0.1356	0.271	~~0.0542~~
R1/stream	0.02191	0.0012	0.0020	0.3534	0.0490	0.0026	0.02191	0.0252	0.0378	0.0001	0.06896	0.138	~~0.0276~~
~~R2~~ R1/stream	0.2747	0.0149	0.0250	4.4306	0.6145	0.0320	0.2747	0.3157	0.4736	0.0014	0.1041	0.208	~~0.0416~~
R3/stream	~~0.2403~~ 0.2517	~~0.0131~~ 0.01368	~~0.0218~~ 0.02288	3.8758	0.5376	~~0.0280~~ 0.0293	0.2403	~~0.2762~~ 0.28931	~~0.4143~~ 0.43397	~~0.0012~~ 0.00126	~~0.04161~~ 0.05745	~~0.083~~ 0.1149	~~0.0166~~ ~~0.02298~~
R4/stream	~~0.2517~~ 0.1759	~~0.0137~~ 0.00956	~~0.0229~~ 0.01599	4.0597	0.5631	~~0.0293~~ 0.02048	0.2517	~~0.2893~~ 0.20218	~~0.4340~~ 0.30328	~~0.0013~~ 0.0009	~~0.05745~~ 0.05281	~~0.115~~ 0.1056	~~0.0230~~ ~~0.0211~~
	Step 3 (application at BBCH 83) for dose 1x54 g as/ha												
R1/pond	0.03303	0.0018	0.0030	0.5327	0.0739	0.0038	1.32	0.0380	0.0569	0.0002	0.09721	0.194	~~0.0389~~
R1/stream	0.6796	0.0369	0.0618	10.9613	1.5204	0.0791	27.18	0.7811	1.1717	0.0034	0.08398	0.168	~~0.0336~~
R3/stream	0.9354	0.0508	0.0850	15.0871	2.0926	0.1089	37.42	1.0752	1.6128	0.0047	0.09904	0.198	~~0.0396~~
R4/stream	0.9014	0.0490	0.0819	14.5387	2.0166	0.1049	36.06	1.0361	1.5541	0.0045	0.4068	0.814	~~0.1627~~

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. Dwell, prolonged (aquatic phase)	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged	~~Higher-Tier information for Sed. dwell. pro-longed~~
		Step 4 10 meters vegetative and no-spray buffer zone (application at BBCH 83) for dose 1x54 g as/ha											
R1/stream	0.1793	0.0097	0.0163	2.8919	0.4011	0.0209	7.17	0.2061	0.3091	0.0009	0.02242	0.045	~~0.0090~~
R3/stream	0.2468	0.0134	0.0224	3.9806	0.5521	0.0287	9.87	0.2837	0.4255	0.0012	0.02647	0.053	~~0.0106~~
R4/stream	0.3905	0.0212	0.0355	6.2984	0.8736	0.0455	15.62	0.4489	0.6733	0.0020	0.1799	0.360	~~0.0720~~
		Step 3 for apple as surrogate crop for dose 1x54 g as/ha (application at BBCH 57)											
D3/ditch	1.984	0.1078	0.1804	32.0000	4.4385	0.2310	1.984	2.2805	3.4207	0.0099	0.8399	1.680	~~0.3360~~
D4/pond	0.2738	0.0149	0.0249	4.4161	0.6125	0.0319	0.2738	0.3147	0.4721	0.0014	1.127	2.254	~~0.4508~~
D4/stream	1.988	0.1080	0.1807	32.0645	4.4474	0.2314	1.988	2.2851	3.4276	0.0099	0.3566	0.713	~~0.1426~~
D5/pond	0.1840	0.0100	0.0167	2.9677	0.4116	0.0214	0.1840	0.2115	0.3172	0.0009	1.143	2.286	~~0.4572~~
D5/stream	2.044	0.1111	0.1858	32.9677	4.5727	0.2380	2.044	2.3494	3.5241	0.0102	0.2408	0.482	~~0.0963~~
~~R1/pond~~	~~0.0893~~	~~0.0049~~	~~0.0081~~			~~0.0104~~		~~0.1026~~	~~0.1540~~	~~0.0004~~	~~0.2896~~	~~0.579~~	~~0.1158~~
~~R1/stream~~	~~1.524~~	~~0.0828~~	~~0.1385~~			~~0.1774~~		~~1.7517~~	~~2.6276~~	~~0.0076~~	~~0.2764~~	~~0.553~~	~~0.1106~~
~~R2/stream~~	~~2.042~~	~~0.1110~~	~~0.1856~~			~~0.2377~~		~~2.3471~~	~~3.5207~~	~~0.0102~~	~~0.1414~~	~~0.283~~	~~0.0566~~
~~R3/stream~~	~~2.132~~	~~0.1159~~	~~0.1938~~			~~0.2482~~		~~2.4506~~	~~3.6759~~	~~0.0107~~	~~0.3218~~	~~0.644~~	~~0.1287~~
~~R4/stream~~	~~1.489~~	~~0.0809~~	~~0.1354~~			~~0.1733~~		~~1.7115~~	~~2.5672~~	~~0.0074~~	~~0.2292~~	~~0.458~~	~~0.0917~~
		Step 3 for apple as surrogate crop for D3, D4 and D5 scenraio(application at BBCH 83) for dose 1x54 g as/ha											
D3/ditch	1.985	0.1079	0.1805	32.0161	4.4407	0.2311	79.40	2.2816	3.4224	0.0099	0.8946	1.789	~~0.3578~~
D4/pond	0.5808	0.0316	0.0528	9.3677	1.2993	0.0676	23.23	0.6676	1.0014	0.0029	2.094	4.188	~~0.8376~~
D4/stream	1.945	0.1057	0.1768	31.3710	4.3512	0.2264	77.80	2.2356	3.3534	0.0097	0.7725	1.545	~~0.3090~~
D5/pond	0.3396	0.0185	0.0309	5.4774	0.7597	0.0395	13.58	0.3903	0.5855	0.0017	1.754	3.508	~~0.7016~~
D5/stream	2.149	0.1168	0.1954	34.6613	4.8076	0.2502	85.96	2.4701	3.7052	0.0107	0.4868	0.974	~~0.1947~~
		Step 4 – 20 meters buffer zone and no spray buffer zone (for apple as surrogate crope) for dose 1x54 g as/ha(application at BBCH 57)											

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. Dwell, prolonged (aquatic phase)	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged	~~Higher-Tier information for Sed. dwell. pro-longed~~
D3/ditch	0.1845	0.0100	0.0168	2.9758	0.4128	0.0215	7.38	0.2121	0.3181	0.0009	0.08260	0.165	~~0.0330~~
D4/stream	0.2736	0.0149	0.0249	4.4129	0.6121	0.0319	10.94	0.3145	0.4717	0.0014	0.3482	0.696	~~0.1393~~
D5/stream	0.2307	0.0125	0.0210	3.7210	0.5161	0.0269	9.23	0.2652	0.3978	0.0012	0.1992	0.398	~~0.0797~~
~~R1/stream~~	~~0.1639~~	~~0.0089~~	~~0.0149~~			~~0.0191~~		~~0.1884~~	~~0.2826~~	~~0.0008~~	~~0.06030~~	~~0.121~~	~~0.0241~~
~~R2/stream~~	~~0.2197~~	~~0.0119~~	~~0.0200~~			~~0.0256~~		~~0.2525~~	~~0.3788~~	~~0.0011~~	~~0.02534~~	~~0.051~~	~~0.0101~~
~~R3/stream~~	~~0.2294~~	~~0.0125~~	~~0.0209~~			~~0.0267~~		~~0.2637~~	~~0.3955~~	~~0.0011~~	~~0.03553~~	~~0.071~~	~~0.0142~~
~~R4/stream~~	~~0.1602~~	~~0.0087~~	~~0.0146~~			~~0.0186~~		~~0.1841~~	~~0.2762~~	~~0.0008~~	~~0.04770~~	~~0.095~~	~~0.0191~~
		Step 4 - for apple as surrogate crop for D3, D4 and D5 scenraio(application at BBCH 83) - 10 meters vegetative and no spray buffer zone (for apple as surrogate crope) for dose 1x54 g as/ha											
D3/ditch	0.5989	0.0325	0.0544	9.6597	1.3398	0.0697	23.96	0.6884	1.0326	0.0030	0.2773	0.555	~~0.1109~~
D4/pond	0.5671	0.0308	0.0516	9.1468	1.2687	0.0660	22.68	0.6518	0.9778	0.0028	2.021	4.042	~~0.8084~~
D4/stream	0.6785	0.0369	0.0617	10.9435	1.5179	0.0790	27.14	0.7799	1.1698	0.0034	0.7670	1.534	~~0.3068~~
D5/pond	0.3396	0.0185	0.0309	5.4774	0.7597	0.0395	13.58	0.3903	0.5855	0.0017	1.664	3.328	~~0.6656~~
D5/stream	0.7494	0.0407	0.0681	12.0871	1.6765	0.0872	29.98	0.8614	1.2921	0.0037	0.3715	0.743	~~0.1486~~

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

zRMS comments:

For algae the EU agreed endpoint - ErC50 >2000 µg/L should be used. For the PEC/RAC calculations for algae the lover value at 85.9 µg/L (worse case) was used by Applicant. This was not corrected because it had no impact on the assessment result.

The acute and chronic risk to invertebrates and chronic risk to sediment-dwelling invertebrates considering exposure via water, based on Tier 1 EU agreed endpoints is covered by the refined risk assessment for aquatic invertebrates. Therefore PEC/RAC calculations with Tier 1 EU agreed endpoints were not assessed by zRMS.

According to Part B8 for D3, D4 and D5 scenarios: surrogate crop is pome fruits.

Refinement of the risk assessment for invertebrates ~~and sediment-dwelling invertebrates considering exposure via sediment,~~ proposed by Applicant, should be considered on the MSs level.

Result of risk assessment with EU HC_5 for invertebrates and refined endpoint for sediment-dwelling organisms considering exposure via sediment.

PEC/RAC based on refinement endpoints		
Scenario	**Surrogate crop**	**Acceptable -A Not acceptable - N**
Step 3, BBCH 57, 1 x 54 g as/ha		
D3 ditch	apple	**N**
D4 pond	apple	A
D4 stream	apple	**N**
D5 pond	apple	A
D5 stream	apple	**N**
R1 pond		A
R1 stream		**N**
R3 stream		**N**
R4 stream		**N**

PEC/RAC based on refinement endpoints		
Scenario	**Surrogate crop**	**Acceptable -A Not acceptable - N**
Step 4, BBCH 57, 1 x 54 g as/ha, 10 meters vegetative and no-spray buffer zone		
D3 ditch	apple	**Not calculated**
D4 pond	apple	Accepted at Step 3
D4 stream	apple	**Not calculated**
D5 pond	apple	Accepted at Step 3
D5 stream	apple	**Not calculated**
R1 pond		Accepted at Step 3
R1 stream		A
R3 stream		A

R4 stream		A
Step 4, BBCH 57, 1 x 54 g as/ha, 20 meters vegetative and no-spray buffer zone		
D3 ditch	apple	A
D4 stream	apple	A
D5 stream	apple	A
PEC/RAC based on refinement endpoints		
Scenario	**Surrogate crop**	**Acceptable -A** **Not acceptable - N**
Step 3, BBCH 83, 1 x 54 g as/ha		
D3 ditch	apple	**N**
D4 pond	apple	**N**
D4 stream	apple	**N**
D5 pond	apple	A
D5 stream	apple	**N**
R1 pond		A
R1 stream		**N**
R3 stream		**N**
R4 stream		**N**
PEC/RAC based on refinement endpoints		
Scenario	**Surrogate crop**	**Acceptable -A** **Not acceptable - N**
Step 4, BBCH 83, 1 x 54 g as/ha, 10 meters vegetative and no-spray buffer zone		
D3 ditch		**N**
D4 pond		A
D4 stream		**N**
D5 pond		Accepted at Step 3
D5 stream		**N**

R1 pond		Accepted at Step 3
R1 stream		A
R3 stream		A
R4 stream		A

Use no. 56, 57, BBCH 57-83, 1 x 54 g as/ha

In summary:

BBCH 57, 1 x 54 g as/ha
At Step 3 risk is acceptable for scenarios D4 pond, D5 pond, R1 pond, R1.
At Step 4, with 10 meters vegetative and no-spray buffer zone, risk is acceptable for scenarios R1 stream, R3 stream, R 4 stream.
At Step 4, with 20 meters vegetative and no-spray buffer zone, risk is acceptable for scenarios D3 ditch, D4 stream, D5 stream.

BBCH 83, 1 x 54 g as/ha
At Step 3 risk is acceptable for scenarios D5 pond, R1 pond.
At Step 4, with 10 meters vegetative and no-spray buffer zone, risk is acceptable for scenarios D4 pond, R1 stream, R3 stream, R4 stream.
At Step 4, with 10 m vegetative filter strip, risk is unresolved for D3 ditch, D4 stream, D5 stream scenarios.

Individual scenarios should be considered in accordance with the requirements of each Member State.

Result of risk assessment with refined HC5 for invertebrates ~~and refined endpoint for sediment-dwelling organisms considering exposure via sediment~~

PEC/RAC based on refinement endpoints		
Scenario	**Surrogate crop**	**Acceptable -A Not acceptable - N**
Step 3, BBCH 57, 1 x 54 g as/ha		
D3 ditch	apple	**N**
D4 pond	apple	A
D4 stream	apple	**N**
D5 pond	apple	A
D5 stream	apple	**N**
R1 pond		A
R1 stream		A

R3 stream		**N**
R4 stream		A
Step 4, BBCH 57, 1 x 54 g as/ha, 10 meters vegetative and no-spray buffer zone		
D3 ditch	apple	**Not calculated**
D4 pond	apple	Accepted at Step 3
D4 stream	apple	**Not calculated**
D5 pond	apple	Accepted at Step 3
D5 stream	apple	**Not calculated**
R1 pond		Accepted at Step 3
R1 stream		Accepted at Step 3
R3 stream		A
R4 stream		Accepted at Step 3

Step 4, BBCH 57, 1 x 54 g as/ha, 20 meters vegetative and no-spray buffer zone		
D3 ditch	apple	A
D4 stream	apple	A
D5 stream	apple	A

PEC/RAC based on refinement endpoints		
Scenario	**Surrogate crop**	**Acceptable -A** **Not acceptable - N**
Step 3, BBCH 83, 1 x 54 g as/ha		
D3 ditch	apple	**N**
D4 pond	apple	A
D4 stream	apple	**N**
D5 pond	apple	A
D5 stream	apple	**N**
R1 pond		A
R1 stream		A
R3 stream		**N**

R4 stream		**N**
Step 4, BBCH 83, 1 x 54 g as/ha, 10 meters vegetative and no-spray buffer zone		
D3 ditch		A
D4 pond		Accepted at Step 3
D4 stream		A
D5 pond		Accepted at Step 3
D5 stream		A
R1 pond		Accepted at Step 3
R1 stream		Accepted at Step 3
R3 stream		A
R4 stream		A

Use no. 56, 57, BBCH 57-83, 1 x 54 g as/ha

In summary:

BBCH 57, 1 x 54 g as/ha
At Step 3 risk is acceptable for scenarios D4 pond, D5 pond, R1 pond, R1 stream, R4 stream.
At Step 4, with 10 meters vegetative and no-spray buffer zone, risk is acceptable for scenario R3 stream,
At Step 4, with 20 meters vegetative and no-spray buffer zone, risk is acceptable for scenarios D3 ditch, D4 stream, D5 stream.

BBCH 83, 1 x 54 g as/ha
At Step 3 risk is acceptable for scenarios D4 pond, D5 pond, R1 pond, R1 stream,
At Step 4, with 10 meters vegetative and no-spray buffer zone, risk is acceptable for scenarios D3 ditch, D4 stream, D5 stream, R3 stream, R4 stream.

If refinement of the risk assessment for invertebrates ~~and sediment-dwelling invertebrates considering exposure via sediment~~ is not accepted further refinement is required.

Individual scenarios should be considered in accordance with the requirements of each Member State.

Ornamentals, use no. 62, BBCH 11-69, 1 x 35 g as/ha

Table 9.5-4: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for chlorantraniliprole for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CLOROL 200 SC in ornamentals

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. Dwell, prolonged (aquatic phase)	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged	~~Higher-Tier information for Sed. dwell. pro-longed~~
Test spe-cies		*Bluegill sunfish*	*Oncorhynchus mykiss*	*Daphnia magna*	*Daphnia magna*	*Pseudokirchn. subcapitata*	*Chironomus riparius*	*Invertebrate*	*Invertebrate*	*Lemna Gibba*		*Chironomus riparius*	~~*Chironomus riparius*~~
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	NOEC	HC5	HC5	EC50		NOEC	~~NOEC~~
(µg/L)		1840	110	6.2	4.47	85.9	0.25	2.61	2.91	2000		5	~~25~~
AF		100	10	100	10	10	10	3	5	10		10	~~10~~
RAC (µg/L)		18.4	11	0.062	0.447	8.59	0.025	0.87	0.58	200		0.5	~~2.5~~
FOCUS Scenario	PEC $_{gl-max}$ (µg/L)										PEC $_{gl-max}$ (µg/kg)		
Step 1													
I	20.75	1.1277	1.8864	334.6774	46.4206	2.4156	830	23.8506	35.7759	0.1038	61.68	123.360	~~24.6720~~
Step 2													
N-Europe	2.91	0.1582	0.2645	46.9355	6.5101	0.3388	116.40	3.3448	5.0172	0.0146	8.59	17.180	~~3.4360~~
		Step 3 for leafy vegetables as surrogate crops for ornamental for D3,D4, R1,R3, R4 scenario (application at BBCH 11) for dose 1x35 g as/ha											
D3/ditch	0.2225	0.0121	0.0202	3.5887	0.4978	0.0259	8.90	0.2557	0.3836	0.0011	0.08374	0.167	~~0.0335~~
D4/pond	0.2491	0.0135	0.0226	4.0177	0.5573	0.0290	9.96	0.2863	0.4295	0.0012	1.140	2.280	~~0.4560~~
D4/stream	0.2230	0.0121	0.0203	3.5968	0.4989	0.0260	8.92	0.2563	0.3845	0.0011	0.4028	0.806	~~0.1611~~
R1/pond	0.03286	0.0018	0.0030	0.5300	0.0735	0.0038	1.31	0.0378	0.0567	0.0002	0.1158	0.232	~~0.0463~~
R1/stream	0.3878	0.0211	0.0353	6.2548	0.8676	0.0451	15.51	0.4457	0.6686	0.0019	0.1108	0.222	~~0.0443~~
R3/stream	0.6036	0.0328	0.0549	9.7355	1.3503	0.0703	24.14	0.6938	1.0407	0.0030	0.1665	0.333	~~0.0666~~

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. Dwell, prolonged (aquatic phase)	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged	~~Higher-Tier information for Sed. dwell. pro-longed~~
R4/stream	0.1854	0.0101	0.0169	2.9903	0.4148	0.0216	7.42	0.2131	0.3197	0.0009	0.06786	0.136	~~0.0271~~
	Step 3 for legumes as surrogate crops for ornamental for D5 scenario (application at BBCH 11) for dose 1x35 g as/ha												
D5/pond	0.1641	0.0089	0.0149	2.6468	0.3671	0.0191	6.56	0.1886	0.2829	0.0008	0.8767	1.753	~~0.3507~~
D5/stream	0.1740	0.0095	0.0158	2.8065	0.3893	0.0203	6.96	0.2000	0.3000	0.0009	0.1932	0.386	~~0.0773~~
	Step 3 for leafy vegetables as surrogate crops for ornamental for D3, D4, R1,R3, R4 scenario (application at BBCH 69) for dose 1x35 g as/ha												
D3/ditch	0.2225	0.0121	0.0202	3.5887	0.4978	0.0259	8.90	0.2557	0.3836	0.0011	0.08825	0.177	~~0.0353~~
D4/pond	0.5174	0.0281	0.0470	8.3452	1.1575	0.0602	20.70	0.5947	0.8921	0.0026	1.984	3.968	~~0.7936~~
D4/stream	0.5238	0.0285	0.0476	8.4484	1.1718	0.0610	20.95	0.6021	0.9031	0.0026	0.7460	1.492	~~0.2984~~
R1/pond	0.07308	0.0040	0.0066	1.1787	0.1635	0.0085	2.92	0.0840	0.1260	0.0004	0.2686	0.537	~~0.1074~~
R1/stream	0.6378	0.0347	0.0580	10.2871	1.4268	0.0742	25.51	0.7331	1.0997	0.0032	0.2123	0.425	~~0.0849~~
R3/stream	0.7264	0.0395	0.0660	11.7161	1.6251	0.0846	29.06	0.8349	1.2524	0.0036	0.8696	1.739	~~0.3478~~
R4/stream	1.054	0.0573	0.0958	17.0000	2.3579	0.1227	42.16	1.2115	1.8172	0.0053	0.4463	0.893	~~0.1785~~
	Step 3 for legumes as surrogate crops for ornamental for D5 scenario (application at BBCH 69) for dose 1x35 g as/ha												
D5/pond	0.1052	0.0057	0.0096	1.6968	0.2353	0.0122	4.21	0.1209	0.1814	0.0005	0.5201	1.040	~~0.2080~~
D5/stream	0.1795	0.0098	0.0163	2.8952	0.4016	0.0209	7.18	0.2063	0.3095	0.0009	0.1180	0.236	~~0.0472~~
	Step 4 for leafy vegetables as surrogate crops for ornamental for ~~R1~~, R3,~~R4~~ scenario – 10 meters buffer zone (application at BBCH 11) for dose 1x35 g as/ha												
R3/stream	0.2722	0.0148	0.0247	4.3903	0.6089	0.0317	10.89	0.3129	0.4693	0.0014	0.07494	0.150	~~0.0300~~
	Step 4 for leafy vegetables as surrogate crops for ornamental for R1, R3,R4 scenario – 10 meters buffer zone (application at BBCH 69) for dose 1x35 g as/ha												
R1/pond	0.03093	0.0017	0.0028	0.4989	0.0692	0.0036	1.24	0.0356	0.0533	0.0002	0.1182	0.236	~~0.0473~~
R1/stream	0.2869	0.0156	0.0261	4.6274	0.6418	0.0334	11.48	0.3298	0.4947	0.0014	0.09273	0.185	~~0.0371~~

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. Dwell, prolonged (aquatic phase)	Higher-tier information	Higher-tier information	Aquatic plants		Sed. dwell. prolonged	~~Higher-Tier information for Sed. dwell. pro-longed~~
R3/stream	0.3317	0.0180	0.0302	5.3500	0.7421	0.0386	13.27	0.3813	0.5719	0.0017	0.2195	0.439	~~0.0878~~
R4/stream	0.4805	0.0261	0.0437	7.7500	1.0749	0.0559	19.22	0.5523	0.8284	0.0024	0.1801	0.360	~~0.0720~~

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

zRMS comments:

For algae the EU agreed endpoint - ErC50 >2000 µg/L should be used. For the PEC/RAC calculations for algae the lover value at 85.9 µg/L (worse case) was used by Applicant. This was not corrected because it had no impact on the assessment result.

The acute and chronic risk to invertebrates and chronic risk to sediment-dwelling invertebrates considering exposure via water, based on Tier 1 EU agreed end-points is covered by the refined risk assessment for aquatic invertebrates. Therefore PEC/RAC calculations with Tier 1 EU agreed endpoints were not assessed by zRMS.

According to Part B8 for D3, D4 and R1, R3, R4 scenarios: surrogate crop is leafy vegetables. For D5 scenario surrogate crop is legumes.

Refinement of the risk assessment for invertebrates ~~and sediment-dwelling invertebrates considering exposure via sediment~~, proposed by Applicant, should be considered on the MSs level.

Result of risk assessment with EU HC_5 for invertebrates ~~and refined endpoint for sediment-dwelling organisms considering exposure via sediment.~~

PEC/RAC based on refinement endpoints		
Scenario	**Surrogate crop**	**Acceptable -A Not acceptable - N**
Step 3, BBCH 11, 1 x 35 g as/ha		
D3 ditch	for leafy vegetables	A
D4 pond	for leafy vegetables	A
D4 stream	for leafy vegetables	A
D5 pond	legumes	A

D5 stream	legumes	A
R1 pond	for leafy vegetables	A
R1 stream	for leafy vegetables	A
R3 stream	for leafy vegetables	**N**
R4 stream	for leafy vegetables	A
Step 4, BBCH 11, 1 x 35 g as/ha, 10 m buffer zone		
R3 stream	for leafy vegetables	A

Step 3, BBCH 69, 1 x 35 g as/ha		
D3 ditch	for leafy vegetables	A
D4 pond	for leafy vegetables	A
D4 stream	for leafy vegetables	A
D5 pond	legumes	A
D5 stream	legumes	A
R1 pond	for leafy vegetables	A
R1 stream	for leafy vegetables	**N**
R3 stream	for leafy vegetables	**N**
R4 stream	for leafy vegetables	**N**

Step 4, BBCH 69, 1 x 35 g as/ha, 10 meters vegetative and no-spray buffer zone		
D3 ditch	for leafy vegetables	Acceptable at Step 3
D4 pond	for leafy vegetables	Acceptable at Step 3
D4 stream	for leafy vegetables	Acceptable at Step 3
D5 pond	legumes	Acceptable at Step 3
D5 stream	legumes	Acceptable at Step 3
R1 pond	for leafy vegetables	Acceptable at Step 3
R1 stream	for leafy vegetables	A
R3 stream	for leafy vegetables	A
R4 stream	for leafy vegetables	A

In summary:

BBCH 11, 1 x 35 g as/ha
At Step 3 risk is acceptable for all scenarios except R3 stream.
At Step 4, with 10 m buffer zone, the risk for R3 stream scenario is acceptable

BBCH 69, 1 x 35 g as/ha
At Step 3 risk is acceptable for D3 ditch, D4 pond, D4 stream, D5 pond, D5 stream, R1 pond scenarios.
At Step 4, with 10 m buffer zone, risk is acceptable for R1 stream, R3 stream, R4 stream scenario.

Individual scenarios should be considered in accordance with the requirements of each Member State.

Result of risk assessment with refined HC5 for invertebrates ~~and refined endpoint for sediment-dwelling organisms considering exposure via sediment~~

PEC/RAC based on refinement endpoints		
Scenario	**Surrogate crop**	**Acceptable -A Not acceptable - N**
Step 3, BBCH 11, 1 x 35 g as/ha		
D3 ditch	for leafy vegetables	A
D4 pond	for leafy vegetables	A
D4 stream	for leafy vegetables	A
D5 pond	legumes	A
D5 stream	legumes	A
R1 pond	for leafy vegetables	A
R1 stream	for leafy vegetables	A
R3 stream	for leafy vegetables	A
R4 stream	for leafy vegetables	A

Step 3, BBCH 69, 1 x 35 g as/ha		
D3 ditch	for leafy vegetables	A
D4 pond	for leafy vegetables	A

D4 stream	for leafy vegetables	A
D5 pond	legumes	A
D5 stream	legumes	A
R1 pond	for leafy vegetables	A
R1 stream	for leafy vegetables	A
R3 stream	for leafy vegetables	A
R4 stream	for leafy vegetables	**N**

Step 4, BBCH 69, 1 x 35 g as/ha, 10 meters vegetative and no-spray buffer zone		
D3 ditch	for leafy vegetables	Acceptable at Step 3
D4 pond	for leafy vegetables	Acceptable at Step 3
D4 stream	for leafy vegetables	Acceptable at Step 3
D5 pond	legumes	Acceptable at Step 3
D5 stream	legumes	Acceptable at Step 3
R1 pond	for leafy vegetables	Acceptable at Step 3
R1 stream	for leafy vegetables	Acceptable at Step 3
R3 stream	for leafy vegetables	Acceptable at Step 3
R4 stream	for leafy vegetables	A

In summary:

BBCH 11, 1 x 35 g as/ha
At Step 3 risk is acceptable for all scenarios.

BBCH 69, 1 x 35 g as/ha
At Step 3 risk is acceptable for all scenarios except R4 stream.
At Step 4 risk is acceptable for R4 stream scenario with 10 m buffer zone.

Individual scenarios should be considered in accordance with the requirements of each Member State.

Table 9.5-5: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for IN-EQW78 for each organism group based on FOCUS Steps 1, 2 calculations for the use of CLOROL 200 SC

Group		**Inverteb. acute**
Metabolite		**IN-EQW78**
Test species		***Daphnia magna***
Endpoint (µg/L)		EC_{50} 138
AF		100
RAC (µg/L)		1.38
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**	
Step 1		
Maize	0.66	0.4783
Potatoes	0.47	0.3406
Winter oilseed rape	1.38	1.0000
Apples	2.51	1.8188
Tobbaco	4.14	3.0000
Vines	1.39	1.0072
Leafy vegetable	1.58	1.1449
Roots vegetable	0.66	0.4783
Sugarbeet	0.66	0.4783
Soya	0.66	0.4783

Group		**Inverteb. acute**
Metabolite		**IN-EQW78**
sunflower	0.66	0.4783
Spring oilseed rape	0.66	0.4783
Fruiting vegetable	2.37	1.7174
Grass	0.66	0.4783
Step 2		
N-Europe - Apples	0.61	0.4420
N. Europe – Tobbaco	0.39	0.2826
N. Europe - Vines	0.57	0.4130
N.Europe – Leafy vegetable	~~0.08~~ 0.22	~~0.0580~~ 0.1594
N. Europe – Fruiting vegetable	0.32	0.2319

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

zRMS comment:

For metabolite IN-EQW78 the risk is acceptable at Step 2.

Table 9.5-6: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolites for each organism group based on FOCUS Steps 1, 2 calculations for the use of CLOROL 200 SC

Group		**Inverteb. acute**
Metabolite		**IN-ECD73**
Test species		***Daphnia magna***
Endpoint (µg/L)		EC_{50} 13.8
AF		100
RAC (µg/L)		0.138
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**	
Step 1		
Maize	0.04	0.2899
Potatoes	0.03	0.2174
Winter oilseed rape	0.07	0.5072
Apples	0.15	1.0870
Tobbaco	0.22	1.5942
Vines	0.08	0.5797
Leafy vegetable	0.08	0.5797
Roots vegetable	0.04	0.2899
Sugarbeet	0.04	0.2899
Soya	0.04	0.2899
sunflower	0.04	0.2899

Group		**Inverteb. acute**
Metabolite		**IN-ECD73**
Spring oilseed rape	0.04	0.2899
Fruiting vegetable	0.13	0.9420
Grass	0.04	0.2899
Step 2		
N-Europe - Apples	0.04	0.2899
N. Europe – Tobbaco	0.03	0.2174

zRMS comment:

For metabolite IN-ECD73 the risk is acceptable at Step 2.

Table 9.5-7: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for IN-GAZ70 for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CLOROL 200 SC

Group		**Inverteb. acute**
Metabolite		**IN-GAZ70**
Test species		***Daphnia magna***
Endpoint		EC_{50}
(µg/L)		9.87
AF		100
RAC (µg/L)		0.0987

Group		**Inverteb. acute**
Metabolite		**IN-GAZ70**
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**	
Step 1		
Maize	0.03	0.3040
Potatoes	0.02	0.2026
Winter oilseed rape	0.07	0.7092
Apples	0.16	1.6211
Tobbaco	0.22	2.2290
Vines	0.08	0.8105
Leafy vegetable	0.08	0.8105
Roots vegetable	0.03	0.3040
Sugarbeet	0.03	0.3040
Soya	0.03	0.3040
sunflower	0.03	0.3040
Spring oilseed rape	0.03	0.3040
Fruiting vegetable	0.12	1.2158
Grass	0.03	0.3040
Step 2		
N-Europe - Apples	0.04	0.4053

Group		**Inverteb. acute**
Metabolite		**IN-GAZ70**
N. Europe – Tobbaco	0.03	0.3040
N. Europe – Fruiting vegetable	0.02	0.2026

zRMS comment:

For metabolite IN-GAZ70 the risk is acceptable at Step 2.

Table 9.5-8: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for IN-F6L99 for each organism group based on FOCUS Steps 1 calculations for the use of CLOROL 200 SC

Group		**Inverteb. acute**
Metabolite		**IN-F6L99**
Test species		***Daphnia magna***
Endpoint (µg/L)		EC_{50} 46800
AF		100
RAC (µg/L)		468
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**	
Step 1		
Maize	0.27	0.0006
Potatoes	0.19	0.0004

Group		**Inverteb. acute**
Metabolite		**IN-F6L99**
Winter oilseed rape	0.54	0.0012
Apples	0.59	0.0013
Tobbaco	1.69	0.0036
Vines	0.43	0.0009
Leafy vegetable	0.64	0.0014
Roots vegetable	0.27	0.0006
Sugarbeet	0.27	0.0006
Soya	0.27	0.0006
sunflower	0.27	0.0006
Spring oilseed rape	0.27	0.0006
Fruiting vegetable	0.97	0.0021
Grass	0.27	0.0006

zRMS comment:

For metabolite IN-F6L99 the risk is acceptable at Step 1.

Table 9.5-9: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for IN-LBA22 for each organism group based on FOCUS Steps 1 calculations for the use of CLOROL 200 SC

Group		**Inverteb. acute**
Metabolite		**IN-LBA22**
Test species		***Daphnia magna***
Endpoint (µg/L)		EC_{50} 240
AF		100
RAC (µg/L)		2.4
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**	
Step 1		
Maize	0.24	0.1000
Potatoes	0.09	0.0375
Winter oilseed rape	0.27	0.1125
Apples	1	0.4167
Tobbaco	0.83	0.3458
Vines	0.87	0.3625
Leafy vegetable	0.32	0.1333
Roots vegetable	0.27	0.1125
Sugarbeet	0.27	0.1125

Group		**Inverteb. acute**
Metabolite		**IN-LBA22**
Soya	0.27	0.1125
sunflower	0.27	0.1125
Spring oilseed rape	0.27	0.1125
Fruiting vegetable	0.48	0.2000
Grass	0.27	0.1125

zRMS comment:

For the risk assessment confirmatory data EC_{50} > 0.85 mg/L for metabolite IN-LBA22 should be used. But the risk assessment was performed based on the lowest endpoint LC_{50} = 0.24 mg met./L (worst-case). Therefore the PEC/RAC calculations were not updated because they will not affect the assessment results. Risk is acceptable at Step 1.

Table 9.5-10: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for IN-LBA23 for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CLOROL 200 SC

Group		**Inverteb. acute**
Metabolite		**IN-LBA23**
Test species		***Daphnia magna***
Endpoint (µg/L)		EC_{50} 100
AF		100
RAC (µg/L)		1

Group		**Inverteb. acute**
Metabolite		**IN-LBA23**
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**	
Step 1		
Maize	0.19	0.1900
Potatoes	0.07	0.0700
Winter oilseed rape	0.19	0.1900
Apples	0.91	0.9100
Tobbaco	0.6	0.6000
Vines	0.74	0.7400
Leafy vegetable	0.23	0.2300
Roots vegetable	0.19	0.1900
Sugarbeet	0.19	0.1900
Soya	0.19	0.1900
sunflower	0.19	0.1900
Spring oilseed rape	0.19	0.1900
Fruiting vegetable	0.34	0.3400
Grass	0.19	0.1900

zRMS comment:

For the risk assessment confirmatory data EC_{50} > 1.1 mg/L for metabolite IN-LBA23 should be used. But the risk assessment was performed based on the lowest

endpoint LC_{50} = 0.1 mg met./L (worst-case). Therefore the PEC/RAC calculations were not updated because they will not affect the assessment results. Risk is acceptable at Step 1.

Table 9.5-11: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for IN-LBA24 for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CLOROL 200 SC

Group		**Inverteb. acute**
Metabolite		**IN-LBA24**
Test species		***Daphnia magna***
Endpoint (µg/L)		EC_{50} 10000
AF		100
RAC (µg/L)		100
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**	
Step 1		
Maize	2.63	0.0263
Potatoes	1.88	0.0188
Winter oilseed rape	5.28	0.0528
Apples	7.35	0.0735
Tobbaco	16.54	0.1654
Vines	4.71	0.0471
Leafy vegetable	6.31	0.0631
Roots vegetable	2.63	0.0263

Group		**Inverteb. acute**
Metabolite		**IN-LBA24**
Sugarbeet	2.63	0.0263
Soya	2.63	0.0263
sunflower	2.63	0.0263
Spring oilseed rape	2.63	0.0263
Fruiting vegetable	4.74	0.0474
Grass	2.63	0.0263

zRMS comments:

For the risk assessment confirmatory data EC_{50} = 0.54 mg/L for metabolite IN-LBA24 should be used. For the risk assessment the LC_{50} = 10 mg met./L was used. Therefore the PEC/RAC calculations were updated below.

Group		**Inverteb. acute**
Metabolite		**IN-LBA24**
Test species		***Daphnia magna***
Endpoint		EC_{50}
(µg/L)		540
AF		100
RAC (µg/L)		5.4
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**	
Step 1		

Maize	2.63	0.4870
Potatoes	1.88	0,3482
Winter oilseed rape	5.28	0,9778
Apples	7.35	**1.3611**
Tobbaco	16.54	**3,0630**
Vines	4.71	0,8722
Leafy vegetable	6.31	**1,1685**
Roots vegetable	2.63	0,4840
Sugarbeet	2.63	0,4840
Soya	2.63	0,4840
sunflower	2.63	0,4840
Spring oilseed rape	2.63	0,4840
Fruiting vegetable	4.74	0.8278
Grass	2.63	0,4840

For metabolite IN-LBA24 the risk is not accepted for Apples, Tobbaco and Leafy vegetable at Step 1.

PEC/RAC values with PECsw at Step 2 (calculated in Part B8 by zRMS) were provided below.

Group		**Inverteb. acute**
Metabolite		**IN-LBA24**

Test species		***Daphnia magna***
Endpoint		EC_{50}
(µg/L)		540
AF		100
RAC (µg/L)		5.4
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**	
Step 2		
Apples	1.36	0,25185
Tobbaco	1.38	0,25556
Leafy vegetable	1.04	0,19259

For Apples, Tobbaco and Leafy vegetable the risk is acceptable at Step 2.

Table 9.5-12: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for IN-F9N04 for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CLOROL 200 SC

Group		**Inverteb. acute**
Metabolite		**IN-F9N04**
Test species		***Daphnia magna***
Endpoint		EC_{50}
(µg/L)		30
AF		100

Group		**Inverteb. acute**
Metabolite		**IN-F9N04**
RAC (µg/L)		0.3
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**	
Step 1		
Maize	0.61	2.0333
Potatoes	0.44	1.4667
Winter oilseed rape	1.23	4.1000
Apples	1.31	4.3667
Tobbaco	3.86	12.8667
Vines	0.97	3.2333
Leafy vegetable	1.48	4.9333
Roots vegetable	0.61	2.0333
Sugarbeet	0.61	2.0333
Soya	0.61	2.0333
sunflower	0.61	2.0333
Spring oilseed rape	0.61	2.0333
Fruiting vegetable	2.21	7.3667
Grass	0.61	2.0333
Step 2 – North Europe		
Maize	0.07	0.2333

Group		**Inverteb. acute**
Metabolite		**IN-F9N04**
Potatoes	0.08	0.2667
Winter oilseed rape	0.08	0.2667
Apples	0.2	0.6667
Tobbaco	0.64	2.1333
Vines	0.12	0.4000
Leafy vegetable	0.23	0.7667
Roots vegetable	0.1	0.3333
Sugarbeet	0.04	0.1333
Soya	0.07	0.2333
sunflower	0.07	0.2333
Spring oilseed rape	0.04	0.1333
Fruiting vegetable	0.35	1.1667
Grass	0.05	0.1667
Step 3 for tobbaco		
R3/stream	0.01151	0.0384
Step 3 for tobbaco at BBCH 83		
R3/stream	0.003718	0.0124
Step 3 for apple as surrogate crope for tobbaco according to polish national requirements		

Group		**Inverteb. acute**
Metabolite		**IN-F9N04**
D3/ditch	0.000102	0.0003
D4/pond	0.02164	0.0721
D4/stream	0.02125	0.0708
D5/pond	0.02233	0.0744
D5/stream	0.01507	0.0502
R1/pond	0.000584	0.0019
R1/stream	0.001582	0.0053
R3/stream	0.003432	0.0114
R4/stream	0.004775	0.0159
Step 3 for apple as surrogate crope for tobbaco according to polish national requirements at BBCH85		
D3/ditch	0.000066	0.0002
D4/pond	0.03481	0.1160
D4/stream	0.03524	0.1175
D5/pond	0.03166	0.1055
D5/stream	0.03026	0.1009
R1/pond	0.000088	0.0003
R1/stream	0.000394	0.0013
R4/stream	0.004248	0.0142
Step 3 for fruiting vegetable		
R3/stream	0.006504	0.0217

Group		**Inverteb. acute**
Metabolite		**IN-F9N04**
R4/stream	0.001279	0.0043
Step 3 for potatoes as surrogate crop for fruiting vegetable according to polish national requirements		
D3/ditch	0.000716	0.0024
D4/pond	0.03758	0.1253
D4/stream	0.02983	0.0994
D5/pond	0.02860	0.0953
D5/stream	0.01860	0.062
D6/ditch	0.02426	0.0809
R1/pond	0.000454	0.0015
R1/stream	0.002954	0.0098
R2/stream	0.003636	0.0121
R3/stream	0.003826	0.0128
Step 3 for fruiting vegetable and surrogate crops at BBCH 89		
D3/ditch	0.000681	0.0023
D4/pond	0.03484	0.1161
D4/stream	0.02792	0.0931
D5/pond	0.02973	0.0991
D5/stream	0.01996	0.0665
R1/pond	0.000702	0.0023
R1/stream	0.003550	0.0118

Group		Inverteb. acute
Metabolite		IN-F9N04
R3/stream	0.01086	0.0362
R4/stream	0.01439	0.0480

zRMS comment:

For metabolite IN-F9N04 the risk is acceptable at Step 3.

Table 9.5-13: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CLOROL 200 SC for most sensitive species based on Drift Calculator calculations

Crop	Dose and results	PEC/RAC RAC = 0.35 µg [prod]/L based on Daphnia magna study conduct on product (worst case scenario)
Application rate potatoes	12.5 a.s/ha equivalent to 69.4 g [prod]/ha	
Resulting PECsw potatoes	0.3686 µg[prod]/L	1.0531
	~~0.1209~~ 0.1192 µg[prod]/L with use of 5 meters buffer zone	~~0.3454~~ 0.3406
Application rate apple	35 a.s/ha equivalent to 191.6 g [prod]/ha	
Resulting PECsw apple	15.07 µg[prod]/L	43.0571
	0.3203 µg[prod]/L with use of 40 meters buffer zone	0.9151

Application rate winter oilseed rape	35 a.s/ha equivalent to 191.6 g [prod]/ha	
Resulting PECsw winter oilseed rape	1.2310 µg[prod]/L	3.5171
	0.3337 µg[prod]/L with use of 5 meters buffer zone	0.9534
Application rate Sunflow-er	35 a.s/ha equivalent to 191.6 g [prod]/ha	
Resulting PECsw sun-flower	1.0178 µg[prod]/L	2.9080
	0.3337 µg[prod]/L with use of 5 meters buffer zone	0.9534
Application rate Maize	35 a.s/ha equivalent to 191.6 g [prod]/ha	
Resulting PECsw maize	1.0178 µg[prod]/L	2.9080
	0.3337 µg[prod]/L with use of 5 meters buffer zone	0.9534
Application rate soyabean	35 a.s/ha equivalent to 191.6 g [prod]/ha	
Resulting PECsw soy-abean	1.0178 µg[prod]/L	2.9080
	0.3337 µg[prod]/L with use of 5 meters buffer zone	0.9534
Application rate spring oilseed rape	35 a.s/ha equivalent to 191.6 g [prod]/ha	
Resulting PECsw spring oilseed rape	1.2310 µg[prod]/L	3.5171
	0.3337 µg[prod]/L with use of 5 meters buffer zone	0.9534
Application rate vegetable leafy	42 a.s/ha equivalent to 229.95 g [prod]/ha	

Resulting PECsw vegetable leafy	1.4773 µg[prod]/L	4.2209
	0.3398 µg[prod]/L with use of 6 meters buffer zone	0.9709
Application rate vegetable roots	35 a.s/ha equivalent to 191.6 g [prod]/ha	
Resulting PECsw vegetable roots	1.2310 µg[prod]/L	3.5171
	0.3337 µg[prod]/L with use of 5 meters buffer zone	0.9534
Application rate vegetable fruiting	63 a.s/ha equivalent to 344.9 g [prod]/ha	
Resulting PECsw vegetable fruiting	2.25159 µg[prod]/L	6.4331
	0.3185 µg[prod]/L with use of 10 meters buffer zone	0.9100
Application rate vine	54 a.s/ha equivalent to 295.7 g [prod]/ha	
Resulting PECsw vine	5.0989 µg[prod]/L	14.5683
	0.2783 µg[prod]/L with use of 25 meters buffer zone	0.7951
Application rate Tobbaco	110 a.s/ha equivalent to 602.253 g [prod]/ha	
Resulting PECsw Tobbaco	2.8714 µg[prod]/L	8.2040
	0.3195 µg[prod]/L with use of 18 meters buffer zone	0.9129
Application rate Tobbaco	54 a.s/ha equivalent to 295.7 g [prod]/ha	
Resulting PECsw Tobbaco	1.4099 µg[prod]/L	4.0283
	0.2731 µg[prod]/L with use of 10 meters buffer zone	0.7803

Application rate Grass	35 a.s/ha equivalent to 191.6 g [prod]/ha	
Resulting PECsw Grass	1.2310 µg[prod]/L	3.5171
	0.3337 µg[prod]/L with use of 5 meters buffer zone	0.9534
Application rate Sugar beets	35 a.s/ha equivalent to 191.6 g [prod]/ha	
Resulting PECsw Sugar beets	1.0178 µg[prod]/L	2.9080
	0.3337 µg[prod]/L with use of 5 meters buffer zone	0.9534
Application rate Lgumes	35 a.s/ha equivalent to 191.6 g [prod]/ha	
Resulting PECsw Leg-umes	1.0178 µg[prod]/L	2.9080
	0.3337 µg[prod]/L with use of 5 meters buffer zone	0.9534

zRMS comment:

For formulation the risk assessment was performed based on the result of study with formulation on daphnia as the worst-case.

The risk is acceptable when the following risk mitigation measures are applied:
- Potatoes – 5 meters buffer zone,
- Apple - 40 meters buffer zone,
- Winter oilseed rape - 5 meters buffer zone,
- Sunflower - 5 meters buffer zone,
- Maize - 5 meters buffer zone,
- Soyabean - 5 meters buffer zone,
- Spring oilseed rape - 5 meters buffer zone,
- Vegetable leafy - 6 meters buffer zone,
- Vegetable roots - 5 meters buffer zone,
- Vegetable fruiting - 10 meters buffer zone,

- Vine - 25 meters buffer zone,
- Tobbaco (110 a.s/ha) - 18 meters buffer zone,
- Tobbaco (54 a.s/ha) - 10 meters buffer zone,
- Grass - 5 meters buffer zone,
- Sugar beets - 5 meters buffer zone,
- Lgumes as surrogate crop- 5 meters buffer zone.

9.5.3 Overall conclusions

The water route is the most relevant exposure pathway for risk assessment of sediment-dwelling organisms such as Chironomus potentially exposed to chlorantraniliprole. Upon reaching water, chlorantraniliprole may degrade abiotically at higher pH and could be degraded rapidly via aqueous photolysis. Upon reaching sediment, chlorantraniliprole binds weakly to moderately to organic matter because of the low Kfom value (average Kfom = 174 mL g-1). Chlorantraniliprole is not expected to accumulate in sediment; therefore, increased exposure via this route over the longer-term is not anticipated. In the laboratory sediment toxicity studies, there was limited retention of chlorantraniliprole in sediment in the sediment-spiked study and no movement of chlorantraniliprole into sediment in the water-spiked study. Thus, the NOECs reflect water exposures and the relevant risk assessment for sediment organisms potentially exposed to chlorantraniliprole should be based only on the water-spiked sediment study with Chironomus. Therefore, Higher Tier Information based on HC5 covered risk assessment for sed.dwell organisms as Chironomus as a worst case scenario.
All greenhouses uses are calculated as field uses, but it is a conservative and worse case approach for them and shows unrealistic PECsw/sed for them. It can be assume the residue of chlorantraniliprole in surface water and sediment for all greenhouses uses should be lower at least 50% lower than presented above calculation as field uses.

The average K_{fom} value of 174 mL/g indicates low to moderate organic matter sorption, suggesting limited partitioning of chlorantraniliprole into the sediment and a preference for remaining in the aqueous phase. With a K_{oc} value of 301 mL/kg, the substance is classified within the lower sorption group (K_{oc} < 500 mL/kg). The 1/n exponent of 0.95 indicates near-linear and reversible sorption behavior, without strong, irreversible binding to the sediment matrix. According to FOCUS guidance (EFSA Journal 2017; 15(10):4982), significant accumulation in sediment is primarily expected for substances characterized by both high sorption and high persistence criteria which chlorantraniliprole does not meet.
Available anaerobic metabolism data [*Anaerobic soil metabolism of ^{14}C-DPX-E2Y45*; DuPont-14568, 2006] demonstrate that chlorantraniliprole undergoes biochemical degradation in sediment into safe metabolites, such as IN-EQW78 and IN-F9N04. This evidence confirms that the presence of the substance in the sediment is transient rather than cumulative. The lack of potential for long-term accumulation is further supported by the "aged sorption" phenomenon, which progressively binds residues within the sediment matrix, rendering them biologically inactive. Degradation occurs predominantly in the water phase, while it remains limited within the sediment itself. Consequently, the dissipation of chlorantraniliprole in sediment is primarily driven by back-transfer to the water column, and the overall half-life is mainly dependent on aqueous degradation processes.
With reference to toxicity studies on living organisms (*^{14}C-DPX-EY245: A prolonged sediment toxicity test with Chironomus riparius using spiked sediment*; DuPont-14396, 2005; and *^{14}C-DPX-E2Y45: A prolonged sediment toxicity test with Chironomus riparius using spiked water;* DuPont-14395, 2006)), analytical recoveries of ^{14}C-chlorantraniliprole equivalents in sediment, overlying water, and pore water on days 0, 7, and 28 showed that the test material leached from the sediment back into the water. This result is consistent with the moderate K_d and K_{oc} values calculated for sandy soils, where adsorbed chlorantraniliprole readily undergoes desorption and may return to the aqueous phase (e.g., groundwater or flowing surface water).
Furthermore, in column and batch studies, chlorantraniliprole concentrations in sediment over 28 days remained below the Limit of Quantification LOQ = 1.88 µg/kg at all sampling points (days 0, 7, 14, 21, and 28), while the majority of the total radioactive residue was detected in the overlying and pore water. These findings indicate that chlorantraniliprole does not undergo significant accumulation in sediment during short-term exposure. Although the study duration was 28 days, the data strongly suggest that under natural conditions, sediment does not serve as a primary sink or retention site for this substance.
Under the presented conditions, all relevant exposure scenarios are effectively covered by exposure in the water phase, which represents a conservative worst-case assessment. In the case of Catanga 200 SC, the risk characterization is further refined through a higher-tier assessment based on a Species Sensitivity Distribution (SSD) approach for *Chironomus riparius* (using ETX 2.0 for 9 species), as well as new stud-

ies in which the median HC5 value is 2.61 mg a.s./L. These include representatives of different taxonomic groups, including bluegill, *Daphnia magna*, and *Pseudokirchneriella subcapitata*. This approach provides a realistic and ecologically relevant evaluation of the potential risk of chlorantraniliprole to aquatic organisms, as it accounts for interspecies variability and reflects the sensitivity of a broad range of taxa under environmentally relevant exposure conditions.

BBCH 87 in apple trees means that the fruit has reached full harvest maturity. No insecticide treatments are performed at this stage because of harvesting time and the biggest pest infestation and damage occurs much earlier – in BBCH 70-79 (fruit development) stages. Regards to this, exposure for aquatic species at BBCH 87 in apples trees is negligible, because of no application in this BBCH and information for exposure should be extrapolated from BBCH 70 in this case.

zRMS comment:

For pome/stone fruits, for BBCH 70 the risk is acceptable when 20 m buffer zone for active substance and 40 m buffer zone for formulation is applied.
For BBCH 87 the risk is not acceptable for D4 pond, D4 stream and D5 pond.
For BBCH 79, proposed in conclusion by Applicant, the risk was not assessed.

Therefore only the risk at BBCH 56-70 can be accepted.

Therefore, CLOROL 200 SC pose safe exposure to aquatic species when applying:

1) on field and no fully-closed glass house:

~~A) Poland:~~
~~- without buffer zone – Fruiting vegetable, sugar beets, roots vegetable, leafy vegetable, soyabean, sunflower, grass, , potatoes, maize, winter oilseed rape, spring oilseed rape,~~
~~- 20 meters buffer zone – Apples, vines, tobacco, ornamentals,~~

zRMS comment:

For Poland the risk assessment was based on the refined HC5 for invertebrates ~~and refined endpoint for sediment-dwelling~~ organisms considering exposure via sediment. A detailed analysis of risk mitigation measures for individual crops is presented in Part A for Poland.

1 Pome/stone fruits
For BBCH 87 risk is not accepted based for D4 pond and D4 stream scenarios
For pome/stone fruits the risk is acceptable at 2 x 35 g a.s./ha, BBCH 56 - 70 when 40 m buffer zone containing 20 meters vegetative buffer zone is applied.
2. Potatoes
For potatoes the risk is acceptable at BBCH 31-60 when 5 meters buffer zone is applied.
3. Fruiting vegetables
For fruiting vegetables the risk is acceptable at BBCH 15 when 10 m VFS + 10 m buffer zone is applied. However, taking into account the risk to soil microorganism the BBCH was changed from 15-89 to 20-89.
For BBCH 20, PEC/RAC calculations were not performed.
For BBCH 89 the risk is unresolved due to D4 pond scenario (with 10 m vegetative strip and 10 meters buffer zone).
For fruiting vegetables the risk is not acceptable.
4. Sugar beet
For Sugar beet the risk is acceptable at BBCH 31-49 with 5 meters buffer zone.

5. Roots vegetable
For Roots vegetable the risk is acceptable at BBCH 12-49 with 5 meters buffer zone.
6. Vegetable leafy
For vegetable leafy the risk is acceptable at 1 x 42 g as/ha, BBCH 49, when 20 m vegetative filter strip and 20 meters buffer zone is applied,
7. Soyaben
For soyabean the risk is acceptable at BBCH 61-65 with 5 meters buffer zone.
8. Maize
For maize the risk is acceptable at BBCH 53-69 with 5 meters buffer zone.
9. Sunflower
For sunflower the risk is acceptable at BBCH 61-65 with 5 meters buffer zone.
10. Tobacco
The use in tobacco was not accepted in Part B8.
11. Grass
For grass the risk is acceptable at BBCH 53-69 when 5 meters buffer zone is applied.
12. Spring oilseed rape
For spring oilseed rape the risk is acceptable at BBCH 61-71 when 5 meters buffer zone is applied.
13. Winter oilseed rape
For winter oilseed rape the risk is acceptable at BBCH 30-50 and BBCH 61-71 when 10 m vegetative filter strip and 10 m buffer zone is applied.
14. Vine
For vine the risk is acceptable at BBCH 57-83 when 40 m buffer zone containing 20 m vegetative filter strip is applied.
15. Ornamentals
For ornamentals the risk is acceptable at BBCH 11-69 when 6 m buffer zone is applied.

b) Central Zone:
~~- without buffer zone – fruiting vegetable, winter oilseed rape, spring oilseed rape and their extrapolations, grass, soyabean, roots vegetables,~~
~~- 10 meters buffer zone – sugarbeets, maize, sunflower, vines~~
~~- 20 meters buffer zone – Apples, Tobbaco, ornamentals~~

zRMS comment:

Should be considered on the MSs level.

A) Poland:
~~- without buffer zone 5 meters buffer zone – potatoes, sugar beet, vegetables root,soyabean, maize, sunflower, grass, spring oilseed rape, ornamentals <50 cm,~~
~~- 10 meters zone - fruting vegetables with redcution dose to one application of 50 g as/ha, vines~~
~~- 20 meters buffer zone – vegetable leafy with reduction fose to one application of 42 g as/ha or 2 appliaction of dose 25 g as/ha; apples; Tobbaco with reduction dose to one application of 54 g as/ha~~
~~- 25 meters buffer zone for vines~~
~~- 40 meters buffer zone with for apple~~

zRMS comment:

Specified risk mitigation measures per crops are provided in Part A for Poland.

b) Central Zone:
~~- without buffer zone 5 meters buffer zone – potatoes, sugar beet, soyabean, maize, sunflower, grass~~
~~- 10 meters buffer zone – fruting vegetables with recution dose to one applicationof 50 g as/ha; root vegetables; vines; ornamentals <50cm, winter oilseed rape~~
~~- 20 meters buffer zone – vegetable leafy with reduction fose to one application of 42 g as/ha or 2 appliaction of dose 25 g as/ha; Apples, Tobbaco with reduction dose to one application of 54 g as/ha~~
~~- 25 meters buffer zone for vines~~
~~- 40 meters buffer zone for apple~~

~~Tobbaco pose unaaceptable risk to aquatic organisms.~~

zRMS comment:

Should be considered on the MSs level.

2) fully-closed greenhouse (only 1% of dose is taking into account for environmental exposure):

zRMS comment:

No separated risk assessment for fully-closed greenhouse was provided by Applicant, therefore all uses were treated as field uses.

A) Poland:
~~- without buffer zone – leafy vegetable, fruiting vegetables~~

b) Central Zone:
~~- without buffer zone – vegetables leafy, fruiting vegetables~~

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 chlorantraniliprole and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents as well as in Appendix 2 of this document (new studies).

Effects on bees of CLOROL 200 sc were evaluated as part of the EU assessment of chlorantraniliprole..

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

Species	Substance	Exposure System	Results	Reference
Apis mellifera	Chlorantraniliprole	Oral	LD_{50} = 104.1 µg/bee	EFSA Journal 2013;11(6):3143
Apis mellifera	Chlorantraniliprole	Contact	LD_{50} = 4 µg/bee	EFSA Journal 2013;11(6):3143
Apis mellifera	Coragen 200 SC	Oral	LD_{50} = 114.1 as µg/bee	EFSA Journal 2013;11(6):3143

Species	Substance	Exposure System	Results	Reference
Apis mellifera	Coragen 200 SC	Contact	LD_{50} = 100 as µg/bee	EFSA Journal 2013;11(6):3143
Apis mellifera	~~Coragen 200 SC~~ CLOROL 200 SC	Chronic Oral	LDD50 = NOEDD ≥ 90 [µg/bee/day] for nominal dose LDD50 = NOEDD ≥ 84.4 [µg/bee/day] for dietary ingested dose	A. Fulczy, Study code: B-93-23
Apis mellifera	~~Coragen 200 SC~~ CLOROL 200 SC	Larval Repeated	ED50 = 1.736 [µg test item/larva] NOED = 0.205 [µg test item/larva]	A. Fulczyk, Study code: B-92-23
Higher-tier studies (tunnel test, field studies)				
A. m. carnica	chlorantraniliprole20SC / EPPO 170 (3)	Tunnel: Application during foragingactivity (Germany, 2004) P. tanacetifolia Application rate(52.5 g a.s./ha)	Studies evaluated field applications of DPX-E2Y45 20SC on flowering Phacelia tanacetifolia (EPPO 170 (3) and CEB 230 guideline) or onto wheat sprayed with sugar solution to simulate hon-ey dew (CEB 230 guideline). Both crops were treated either during or after bee flight activity at rates of 52.5, 60.0 or 75 g DPX-E2Y45/ha. Exposure to spray solutions either by direct overspray onto for-aging honey bees or via spray deposits on plant surfaces from the previous day resulted in mortality at levels comparable to the control group. No behavioural changes were observed that could be attributed to the treatment with DPX-E2Y45 20SC. Honey bees	EFSA Journal 2013;11(6):3143
A. m. mellifera	chlorantraniliprole20SC / EPPO 170 (3)	Tunnel: Application during foragingactivity (Spain, 2004) P. tanacetifolia Application rate(52.5 g a.s./ha)		EFSA Journal 2013;11(6):3143
A. m. carnica	chlorantraniliprole20SC / EPPO 170 (3)	Tunnel: Application during foragingactivity (France, 2006) P. tanacetifolia Application rate(60 g a.s./ha)		EFSA Journal 2013;11(6):3143
A. m. mellifera	chlorantraniliprole20SC / CEB 230	Tunnel: Application during bee-flight and in the evening afterbee-flight (France, 2005) P. tanacetifolia Application rate(60 g a.s./ha)		EFSA Journal 2013;11(6):3143
A. m. carnica	chlorantraniliprole20SC / CEB 230	Tunnel: Application during bee-flight and in the evening afterbee-flight (France, 2005) P. tanacetifolia Application rate(60 g a.s./ha)		EFSA Journal 2013;11(6):3143
A. m. mellifera	chlorantraniliprole20SC / CEB 230	Tunnel: Application during bee-flight and in the evening afterbee-flight (France, 2006)		EFSA Journal 2013;11(6):3143

Species	Substance	Exposure System	Results	Reference
		P. tanacetifolia Application rate(60 g a.s./ha)	gathered in front of the hive and fanned on some occasions, behaviours that likely are related to temperatures exceeding 30°C in the test tents. Flight intensity was not influenced by the treatment with DPX-E2Y45 20SC. In one trial flight in-tensity was slightly inhibited one day after application of the test item in the evening after bee flight, which was not judged to be treatment related. Development of honey bee colonies was not influenced by the treatment with DPX-E2Y45 20SC. The increase in number of storage combs in some cases was related to the presence of highly prof-itable food sources. The lack of larvae stages and eggs in trials in wheat may be related to the lack of sufficient proteins from pollen. Thus, this effect is not treatment related but a consequence of the trial design. Two studies were conducted with DPX-E2Y45 20SC to evaluate the possibility of exposure to hon-ey bees from soil residues that may carry over from previous applications to	
A. m. mellifera	chlorantraniliprole20SC / CEB 230	Tunnel: Application during bee-flight and in the evening afterbee-flight (France, 2005) Wheat Application rate(60 g a.s./ha)		EFSA Journal 2013;11(6):3143
A. m. carnica	chlorantraniliprole20SC / CEB 230	Tunnel: Application during bee-flight and in the evening afterbee-flight (France, 2005) Wheat Application rate(60 g a.s./ha)		EFSA Journal 2013;11(6):3143
A. m. mellifera	chlorantraniliprole20SC / CEB 230	Tunnel: Application during bee-flight and in the evening afterbee-flight (France, 2006) Wheat Application rate(60 g a.s./ha)		EFSA Journal 2013;11(6):3143
A. m. carnica	chlorantraniliprole20SC / EPPO 170 (3)	Tunnel: T1: Application before + 8days after sowing onto soilT2: Application before + 8 daysafter sowing onto soil plusapplication during bee flight/fullflowering (France, 2003) P. tanacetifolia T 1: 1 applications of 156 ga.s./ha T 2: 1 applications of 156 ga.s./ha + 75 ga.s./ha		EFSA Journal 2013;11(6):3143
A. m. carnica	chlorantraniliprole20SC / EPPO 170 (3)	Tunnel: T1: Application before +after sowing onto soilT 2: Application during beeflight/full flowering (Germany,2005) P. tanacetifolia T 1: 1 applications of 253 ga.s./ha T 2: 1 applications of 60 ga.s./ha		EFSA Journal 2013;11(6):3143
A. m. carnica	Chlorantraniliprole 200 g/L SC OECD75	Tunnel: T: Application before +after flowering		EFSA Journal 2013;11(6):3143

Species	Substance	Exposure System	Results	Reference
		S: Application before + afterflowering(Germany, 2005) P. tanacetifolia T: 2 applications of 60 ga.s./ha S: 2 applications of 120 ga.s./ha	crops. Soil was treated with DPX-E2Y45 20SC at rates of either 313.6 or 213.6 g a.s./ha and was sown with Phacelia tanacetifolia. The studies were designed to simulate a worst-case scenario of multiple annual appli-cations to crops, followed by a crop that can pick up DPX-E2Y45 from soil and translocate it to blossoms (into nectar and pollen). The fast-growing and highly attractive (to honey bees) plant spe-cies, Phacelia tanacetifolia, was chosen as an indicator species. It develops an intensive root system in the top soil (where the DPX-E2Y45 was incorporated) and begins flowering about 6 to 8 weeks after planting. Honey bees were allowed to forage on the flowering plants and observations were made in plots either with or without an additional spray application of 60 or 75 g DPX-E2Y45/ha. In all groups treated with DPX-E2Y45 20SC mortality was similar to the control groups. No sub-stance-related behavioural changes or impact	

Species	Substance	Exposure System	Results	Reference
			on the colonies were observed in these studies. On the basis of the available extensive data set generated for honeybees (acute oral and contact laboratory studies and semi-field tunnel tests with Phacelia and wheat) exposed to DPX-E2Y45 and the formu-lated products, DPX-E2Y45 35WG and DPX-E2Y45 20SC, it can be concluded that the insecticide DPX-E2Y45 generally demonstrated low intrinsic toxicity for honey bees and should be safe to honey bees for the proposed practical use conditions	

9.6.1.1 Justification for new endpoints

No new endpoints for chlorantraniliprole were established.

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).

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the worst case scenario for whole intended uses from GAP table – two application of 110 g as/ha.

9.6.2.1 Hazard quotients for bees

Table 9.6-2: First-tier assessment of the risk for bees due to the use of CLOROL 200 SC

Intended use	

Active substance	chlorantraniliprole		
Application rate (g/ha)	2 × 110		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	104.1	110	1.05
Contact toxicity	4		27.4
Product	CLOROL 200 SC		
Application rate (g/ha)	2 x 110 as/ha		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	114.1	110	0.96
Contact toxicity	100		1.1

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

For Chronic oral and larvae risk assessment exposure have been performed below depends on worst single application dosę for each crop scenario which covered crop from Gap Table according to table below:

Single dose [g prod/ha] – worst case scenario per crop	Crops scenario	Crop covered:
344.93	Clover	Alfalfa, Clover for forage and silage
191.63	Flax	Linseed, Mustard seed
273.75	Fruiting vegetables 1	Chillies, Peppers, Cucumbers, Gherkins, Pumpkins, Squash, Gourds, Melon, Watermelons
344.93	Fruiting vegetables 2	Tomatoes, Eggplants (aubergines)
295.65	Grapes	Grapes
191.63	Grasses	Grasses for forage, Silage
602.25	Hops	Hops, Tobbaco
229.95	Leafy vegetables	Artichokes, Asparagus, Cabbages and other brassicas, Cauliflowers and broccoli, Chicory roots, Spinach
229.95	Lettuce	Lettuce
136.88	Maize	Maize
191.63	Oilseed rape	Oilseed rape
191.63	Orchards 1	Almonds, Apples, Apricots, Cherries, Peaches and nectarines, Pears, Persimmons, Plums and sloes, Quinces
191.63	Orchards 2 (evergreens)	Avocados, Grapefruit (including pomelos), Lemons, Limes, Oranges, Tangerines, Mandarins, Clementines
191.63	Orchards 3	Hazelnuts with shell, Pistachios, Kiwi fruit
191.63	Poppy seed	Poppy seed
68.44	Potatoes	Potatoes

191.63	Pulses	Beans, Broad beans, Horse beans, Buckwheat, Chick peas, Cow peas, Leguminous for silage, Leguminous vegetables, Lentis, Lupins, Peas, Soybeans, Vetches
191.63	Root vegetables	Anise, Badian, Fennel, Corian, Carrots, Turnips for Fodder, Viper's grass
136.88	Sorghum	Sorghum
109.5	Sugar beet	Sugar beet
191.63	Sunflower	Sunflower
68.44	Sweet potatoes	Sweet potatoes

Risk assessment for chronic and larvae for all crops from Gap Table:

CROP Scenario	Application	BBCH	scenario	EF	SV HB	TWA HB	ETR	Trigger
Screening step for chronic for dose 344.93 g prod/ha (fruiting vegetable 2)	SPRAY DW	-	Chronic	1	7.6	-	**0.031**	0.03
Screening step for chronic oral for dose 295.65 g prod/ha and lower	Spray DW	-	Chronic	1	7.6	-	0.027	0.03
Screening step for chronic oral for dose 602.25 g prod/ha (hops)	SPRAY SUW	-	Chronic	1	10.6	-	**0.076**	0.03
Screening step for chronic oral for dose 295.65 g prod/ha (grapes)	Spray SUW	-	Chronic	1	10.6	-	**0.037**	0.03
Screening step for chronic oral for dose 191.63 g prod/ha and lower	Spray SUW	-	Chronic	1	10.6	-	0.024	0.03
Screening step for larvae for dose 344.93 g prod/ha and lower	SPRAY DW	-	larvae	1	4.4	-	**7.40**	0.2
Screening step for larvae for dose 602.25 g prod/ha and lower	SPRAY SUW	-	larvae	1	6.1	-	**17.92**	0.2
TIER 1 for Grapes for chronic oral exposure:								
Grapes	spray SUW	10 - 19	treated crop	1	8.2	0.72	0.021	0.03
Grapes	spray SUW	20 - 39	treated crop	1	8.2	0.72	0.021	0.03
Grapes	spray SUW	40 - 69	treated crop	1	8.2	0.72	0.021	0.03
Grapes	spray SUW	≥ 70	treated crop	1	0	0.72	0.000	0.03
Grapes	spray SUW	10 - 19	weeds	0.6	2.9	0.72	0.004	0.03
Grapes	spray SUW	20 - 39	weeds	0.5	2.9	0.72	0.004	0.03
Grapes	spray SUW	40 - 69	weeds	0.3	2.9	0.72	0.002	0.03
Grapes	spray SUW	≥ 70	weeds	0.3	2.9	0.72	0.002	0.03
Grapes	spray SUW	10 - 19	field margin	0.009	2.9	0.72	0.000	0.03
Grapes	spray SUW	20 - 39	field margin	0.027	2.9	0.72	0.000	0.03
Grapes	spray SUW	40 - 69	field margin	0.027	2.9	0.72	0.000	0.03
Grapes	spray SUW	≥ 70	field	0.027	2.9	0.72	0.000	0.03

			margin					
Grapes	spray SUW	10 - 19	adjacent crop	0.0047	5.8	0.72	0.000	0.03
Grapes	spray SUW	20 - 39	adjacent crop	0.0143	5.8	0.72	0.000	0.03
Grapes	spray SUW	40 - 69	adjacent crop	0.0143	5.8	0.72	0.000	0.03
Grapes	spray SUW	≥ 70	adjacent crop	0.0143	5.8	0.72	0.000	0.03
Grapes	spray SUW	10 - 19	next crop	1	0.54	0.72	0.001	0.03
Grapes	spray SUW	20 - 39	next crop	1	0.54	0.72	0.001	0.03
Grapes	spray SUW	40 - 69	next crop	1	0.54	0.72	0.001	0.03
Grapes	spray SUW	≥ 70	next crop	1	0.54	0.72	0.001	0.03
TIER 1 for Grapes for larvae exposure:								
Grapes	spray SUW	10 - 19	treated crop	1	6.1	0.85	**7.48**	0.2
Grapes	spray SUW	20 - 39	treated crop	1	6.1	0.85	**7.48**	0.2
Grapes	spray SUW	40 - 69	treated crop	1	6.1	0.85	**7.48**	0.2
Grapes	spray SUW	≥ 70	treated crop	1	0	0.85	0.00	0.2
Grapes	spray SUW	10 - 19	weeds	0.6	2.2	0.85	**1.62**	0.2
Grapes	spray SUW	20 - 39	weeds	0.5	2.2	0.85	**1.35**	0.2
Grapes	spray SUW	40 - 69	weeds	0.3	2.2	0.85	**0.81**	0.2
Grapes	spray SUW	≥ 70	weeds	0.3	2.2	0.85	**0.81**	0.2
Grapes	spray SUW	10 - 19	field margin	0.009	2.2	0.85	0.02	0.2
Grapes	spray SUW	20 - 39	field margin	0.027	2.2	0.85	0.07	0.2
Grapes	spray SUW	40 - 69	field margin	0.027	2.2	0.85	0.07	0.2
Grapes	spray SUW	≥ 70	field margin	0.027	2.2	0.85	0.07	0.2
Grapes	spray SUW	10 - 19	adjacent crop	0.0047	4.4	0.85	0.03	0.2
Grapes	spray SUW	20 - 39	adjacent crop	0.0047	4.4	0.85	0.03	0.2
Grapes	spray SUW	40 - 69	adjacent crop	0.0143	4.4	0.85	0.08	0.2
Grapes	spray SUW	≥ 70	adjacent crop	0.0143	4.4	0.85	0.08	0.2
Grapes	spray SUW	10 - 19	next crop	1	0.4	0.85	**0.49**	0.2
Grapes	spray SUW	20 - 39	next crop	1	0.4	0.85	**0.49**	0.2
Grapes	spray SUW	40 - 69	next crop	1	0.4	0.85	**0.49**	0.2
Grapes	spray SUW	≥ 70	next crop	1	0.4	0.85	**0.49**	0.2
TIER 1 for Orchards 1 for larvae exposure:								
Orchards 1: Almonds, Apples, Apricots, Cherries, Peaches and nectarines, Pears, Persimmons, Plums and sloes, Quinces	spray SUW	10 - 19	treated crop	1	6.1	0.85	**4.85**	0.2
Orchards 1: Almonds, Apples, Apricots, Cherries, Peaches and nectarines, Pears, Persimmons, Plums and sloes, Quinces	spray SUW	20 - 39	treated crop	1	6.1	0.85	**4.85**	0.2
Orchards 1: Almonds, Apples, Apricots, Cherries,	spray SUW	40 - 69	treated crop	1	6.1	0.85	**4.85**	0.2

Peaches and nectarines, Pears, Persimmons, Plums and sloes, Quinces								
Orchards 1: Almonds, Apples, Apricots, Cherries, Peaches and nectarines, Pears, Persimmons, Plums and sloes, Quinces	spray SUW	≥ 70	treated crop	1	0	0.85	0.00	0.2
Orchards 1: Almonds, Apples, Apricots, Cherries, Peaches and nectarines, Pears, Persimmons, Plums and sloes, Quinces	spray SUW	10 - 19	weeds	0.8	2.2	0.85	**1.40**	0.2
Orchards 1: Almonds, Apples, Apricots, Cherries, Peaches and nectarines, Pears, Persimmons, Plums and sloes, Quinces	spray SUW	20 - 39	weeds	0.6	2.2	0.85	**1.05**	0.2
Orchards 1: Almonds, Apples, Apricots, Cherries, Peaches and nectarines, Pears, Persimmons, Plums and sloes, Quinces	spray SUW	40 - 69	weeds	0.3	2.2	0.85	**0.52**	0.2
Orchards 1: Almonds, Apples, Apricots, Cherries, Peaches and nectarines, Pears, Persimmons, Plums and sloes, Quinces	spray SUW	≥ 70	weeds	0.3	2.2	0.85	**0.52**	0.2
Orchards 1: Almonds, Apples, Apricots, Cherries, Peaches and nectarines, Pears, Persimmons, Plums and sloes, Quinces	spray SUW	10 - 19	field margin	0.097	2.2	0.85	0.17	0.2
Orchards 1: Almonds, Apples, Apricots, Cherries, Peaches and nectarines, Pears, Persimmons, Plums and sloes, Quinces	spray SUW	20 - 39	field margin	0.097	2.2	0.85	0.17	0.2
Orchards 1: Almonds, Apples, Apricots, Cherries, Peaches and nectarines, Pears, Persimmons, Plums and sloes, Quinces	spray SUW	40 - 69	field margin	0.097	2.2	0.85	0.17	0.2
Orchards 1: Almonds, Apples, Apricots, Cherries, Peaches and nectarines, Pears, Persimmons, Plums and sloes, Quinces	spray SUW	≥ 70	field margin	0.097	2.2	0.85	0.17	0.2
Orchards 1: Almonds, Apples, Apricots, Cherries, Peaches and nectarines, Pears, Persimmons, Plums and sloes, Quinces	spray SUW	10 - 19	adjacent crop	0.066	4.4	0.85	**0.23**	0.2
Orchards 1: Almonds, Apples, Apricots, Cherries, Peaches and nectarines, Pears, Persimmons, Plums and sloes, Quinces	spray SUW	20 - 39	adjacent crop	0.066	4.4	0.85	**0.23**	0.2
Orchards 1: Almonds, Apples, Apricots, Cherries,	spray SUW	40 - 69	adjacent crop	0.066	4.4	0.85	**0.23**	0.2

Peaches and nectarines, Pears, Persimmons, Plums and sloes, Quinces								
Orchards 1: Almonds, Apples, Apricots, Cherries, Peaches and nectarines, Pears, Persimmons, Plums and sloes, Quinces	spray SUW	≥ 70	adjacent crop	0.066	4.4	0.85	**0.23**	0.2
Orchards 1: Almonds, Apples, Apricots, Cherries, Peaches and nectarines, Pears, Persimmons, Plums and sloes, Quinces	spray SUW	10 - 19	next crop	1	0.4	0.85	**0.32**	0.2
Orchards 1: Almonds, Apples, Apricots, Cherries, Peaches and nectarines, Pears, Persimmons, Plums and sloes, Quinces	spray SUW	20 - 39	next crop	1	0.4	0.85	**0.32**	0.2
Orchards 1: Almonds, Apples, Apricots, Cherries, Peaches and nectarines, Pears, Persimmons, Plums and sloes, Quinces	spray SUW	40 - 69	next crop	1	0.4	0.85	**0.32**	0.2
Orchards 1: Almonds, Apples, Apricots, Cherries, Peaches and nectarines, Pears, Persimmons, Plums and sloes, Quinces	spray SUW	≥ 70	Next crop	1	0.4	0.85	**0.32**	0.2
TIER 1 for Orchards 2 for larvae exposure:								
Orchards 2 (evergreens): Avocados, Grapefruit (inc. pomelos), Lemons, Limes, Oranges, Tangerines, Mandarins, Clementines	spray SUW	10 - 19	treated crop	1	0.4	0.85	**4.85**	0.2
Orchards 2 (evergreens): Avocados, Grapefruit (inc. pomelos), Lemons, Limes, Oranges, Tangerines, Mandarins, Clementines	spray SUW	20 - 39	treated crop	1	0.4	0.85	**4.85**	0.2
Orchards 2 (evergreens): Avocados, Grapefruit (inc. pomelos), Lemons, Limes, Oranges, Tangerines, Mandarins, Clementines	spray SUW	40 - 69	treated crop	1	0.4	0.85	**4.85**	0.2
Orchards 2 (evergreens): Avocados, Grapefruit (inc. pomelos), Lemons, Limes, Oranges, Tangerines, Mandarins, Clementines	spray SUW	≥ 70	treated crop	1	0.4	0.85	0.00	0.2
Orchards 2 (evergreens): Avocados, Grapefruit (inc. pomelos), Lemons, Limes, Oranges, Tangerines, Mandarins, Clementines	spray SUW	10 - 19	weeds	1	6.1	0.85	**1.40**	0.2
Orchards 2 (evergreens): Avocados, Grapefruit (inc. pomelos), Lemons, Limes, Oranges, Tangerines, Mandarins, Clementines	spray SUW	20 - 39	weeds	1	6.1	0.85	**1.05**	0.2
Orchards 2 (evergreens):	spray SUW	40 - 69	weeds	1	6.1	0.85	**0.52**	0.2

Avocados, Grapefruit (inc. pomelos), Lemons, Limes, Oranges, Tangerines, Mandarins, Clementines								
Orchards 2 (evergreens): Avocados, Grapefruit (inc. pomelos), Lemons, Limes, Oranges, Tangerines, Mandarins, Clementines	spray SUW	≥ 70	weeds	1	0	0.85	**0.52**	0.2
Orchards 2 (evergreens): Avocados, Grapefruit (inc. pomelos), Lemons, Limes, Oranges, Tangerines, Mandarins, Clementines	spray SUW	10 - 19	field margin	0.8	2.2	0.85	0.09	0.2
Orchards 2 (evergreens): Avocados, Grapefruit (inc. pomelos), Lemons, Limes, Oranges, Tangerines, Mandarins, Clementines	spray SUW	20 - 39	field margin	0.6	2.2	0.85	0.09	0.2
Orchards 2 (evergreens): Avocados, Grapefruit (inc. pomelos), Lemons, Limes, Oranges, Tangerines, Mandarins, Clementines	spray SUW	40 - 69	field margin	0.3	2.2	0.85	0.09	0.2
Orchards 2 (evergreens): Avocados, Grapefruit (inc. pomelos), Lemons, Limes, Oranges, Tangerines, Mandarins, Clementines	spray SUW	≥ 70	field margin	0.3	2.2	0.85	0.09	0.2
Orchards 2 (evergreens): Avocados, Grapefruit (inc. pomelos), Lemons, Limes, Oranges, Tangerines, Mandarins, Clementines	spray SUW	10 - 19	adjacent crop	0.052	2.2	0.85	0.11	0.2
Orchards 2 (evergreens): Avocados, Grapefruit (inc. pomelos), Lemons, Limes, Oranges, Tangerines, Mandarins, Clementines	spray SUW	20 - 39	adjacent crop	0.052	2.2	0.85	0.11	0.2
Orchards 2 (evergreens): Avocados, Grapefruit (inc. pomelos), Lemons, Limes, Oranges, Tangerines, Mandarins, Clementines	spray SUW	40 - 69	adjacent crop	0.052	2.2	0.85	0.11	0.2
Orchards 2 (evergreens): Avocados, Grapefruit (inc. pomelos), Lemons, Limes, Oranges, Tangerines, Mandarins, Clementines	spray SUW	≥ 70	adjacent crop	0.052	2.2	0.85	0.11	0.2
Orchards 2 (evergreens): Avocados, Grapefruit (inc. pomelos), Lemons, Limes, Oranges, Tangerines, Mandarins, Clementines	spray SUW	10 - 19	next crop	0.031	4.4	0.85	**0.32**	0.2
Orchards 2 (evergreens): Avocados, Grapefruit (inc. pomelos), Lemons, Limes, Oranges, Tangerines, Mandarins, Clementines	spray SUW	20 - 39	next crop	0.031	4.4	0.85	**0.32**	0.2
Orchards 2 (evergreens):	spray SUW	40 - 69	next crop	0.031	4.4	0.85	**0.32**	0.2

Avocados, Grapefruit (inc. pomelos), Lemons, Limes, Oranges, Tangerines, Mandarins, Clementines								
Orchards 2 (evergreens): Avocados, Grapefruit (inc. pomelos), Lemons, Limes, Oranges, Tangerines, Mandarins, Clementines	spray SUW	≥ 70	next crop	0.031	4.4	0.85	**0.32**	0.2
TIER 1 for Orchards 3 for larvae exposure:								
Orchards 3: Hazelnuts with shell, Pistachios, Kiwi fruit	spray SUW	≥ 70	treated crop	1	0	0.85	0.00	0.2
Orchards 3: Hazelnuts with shell, Pistachios, Kiwi fruit	spray SUW	10 - 19	treated crop	1	0.01	0.85	0.01	0.2
Orchards 3: Hazelnuts with shell, Pistachios, Kiwi fruit	spray SUW	20 - 39	treated crop	1	0.01	0.85	0.01	0.2
Orchards 3: Hazelnuts with shell, Pistachios, Kiwi fruit	spray SUW	40 - 69	treated crop	1	0.01	0.85	0.01	0.2
Orchards 3: Hazelnuts with shell, Pistachios, Kiwi fruit	spray SUW	≥ 70	weeds	0.3	2.2	0.85	**0.52**	0.2
Orchards 3: Hazelnuts with shell, Pistachios, Kiwi fruit	spray SUW	10 - 19	weeds	0.8	2.2	0.85	**1.40**	0.2
Orchards 3: Hazelnuts with shell, Pistachios, Kiwi fruit	spray SUW	20 - 39	weeds	0.6	2.2	0.85	**1.05**	0.2
Orchards 3: Hazelnuts with shell, Pistachios, Kiwi fruit	spray SUW	40 - 69	weeds	0.3	2.2	0.85	**0.52**	0.2
Orchards 3: Hazelnuts with shell, Pistachios, Kiwi fruit	spray SUW	≥ 70	field margin	0.097	2.2	0.85	0.17	0.2
Orchards 3: Hazelnuts with shell, Pistachios, Kiwi fruit	spray SUW	10 - 19	field margin	0.097	2.2	0.85	0.17	0.2
Orchards 3: Hazelnuts with shell, Pistachios, Kiwi fruit	spray SUW	20 - 39	field margin	0.097	2.2	0.85	0.17	0.2
Orchards 3: Hazelnuts with shell, Pistachios, Kiwi fruit	spray SUW	40 - 69	field margin	0.097	2.2	0.85	0.17	0.2
Orchards 3: Hazelnuts with shell, Pistachios, Kiwi fruit	spray SUW	≥ 70	adjacent crop	0.066	4.4	0.85	**0.23**	0.2
Orchards 3: Hazelnuts with shell, Pistachios, Kiwi fruit	spray SUW	10 - 19	adjacent crop	0.066	4.4	0.85	**0.23**	0.2
Orchards 3: Hazelnuts with shell, Pistachios, Kiwi fruit	spray SUW	20 - 39	adjacent crop	0.066	4.4	0.85	**0.23**	0.2
Orchards 3: Hazelnuts with shell, Pistachios, Kiwi fruit	spray SUW	40 - 69	adjacent crop	0.066	4.4	0.85	**0.23**	0.2
Orchards 3: Hazelnuts with shell, Pistachios, Kiwi fruit	spray SUW	≥ 70	next crop	1	0.002	0.85	0.00	0.2
Orchards 3: Hazelnuts with shell, Pistachios, Kiwi fruit	spray SUW	10 - 19	next crop	1	0.002	0.85	0.00	0.2
Orchards 3: Hazelnuts with shell, Pistachios, Kiwi fruit	spray SUW	20 - 39	next crop	1	0.002	0.85	0.00	0.2
Orchards 3: Hazelnuts with shell, Pistachios, Kiwi fruit	spray SUW	40 - 69	next crop	1	0.002	0.85	0.00	0.2
TIER 1 for Hops for larvae exposure:								
Hops	spray SUW	≥ 70	treated crop	1	0	0.85	0.00	0.2
Hops	spray SUW	10 - 19	treated crop	1	0.01	0.85	0.02	0.2
Hops	spray SUW	20 - 39	treated crop	1	0.01	0.85	0.02	0.2
Hops	spray SUW	40 - 69	treated crop	1	0.01	0.85	0.02	0.2

Hops	spray SUW	≥ 70	weeds	0.3	2.2	0.85	**1.65**	0.2
Hops	spray SUW	10 - 19	weeds	1	2.2	0.85	**5.49**	0.2
Hops	spray SUW	20 - 39	weeds	0.5	2.2	0.85	**2.75**	0.2
Hops	spray SUW	40 - 69	weeds	0.3	2.2	0.85	**1.65**	0.2
Hops	spray SUW	≥ 70	field margin	0.064	2.2	0.85	**0.35**	0.2
Hops	spray SUW	10 - 19	field margin	0.064	2.2	0.85	**0.35**	0.2
Hops	spray SUW	20 - 39	field margin	0.064	2.2	0.85	**0.35**	0.2
Hops	spray SUW	40 - 69	field margin	0.064	2.2	0.85	**0.35**	0.2
Hops	spray SUW	≥ 70	adjacent crop	0.041	4.4	0.85	**0.45**	0.2
Hops	spray SUW	10 - 19	adjacent crop	0.041	4.4	0.85	**0.45**	0.2
Hops	spray SUW	20 - 39	adjacent crop	0.041	4.4	0.85	**0.45**	0.2
Hops	spray SUW	40 - 69	adjacent crop	0.041	4.4	0.85	**0.45**	0.2
Hops	spray SUW	≥ 70	next crop	1	0.002	0.85	0.00	0.2
Hops	spray SUW	10 - 19	next crop	1	0.002	0.85	0.00	0.2
Hops	spray SUW	20 - 39	next crop	1	0.002	0.85	0.00	0.2
Hops	spray SUW	40 - 69	next crop	1	0.002	0.85	0.00	0.2
TIER 1 for Hops for chronic oral exposure:								
Hops	spray SUW	≥ 70	treated crop	1	0	0.72	0.000	0.03
Hops	spray SUW	10 - 19	treated crop	1	0.06	0.72	0.000	0.03
Hops	spray SUW	20 - 39	treated crop	1	0.06	0.72	0.000	0.03
Hops	spray SUW	40 - 69	treated crop	1	0.06	0.72	0.000	0.03
Hops	spray SUW	≥ 70	weeds	0.3	2.9	0.72	0.004	0.03
Hops	spray SUW	10 - 19	weeds	1	2.9	0.72	0.015	0.03
Hops	spray SUW	20 - 39	weeds	0.5	2.9	0.72	0.007	0.03
Hops	spray SUW	40 - 69	weeds	0.3	2.9	0.72	0.004	0.03
Hops	spray SUW	≥ 70	field margin	0.064	2.9	0.72	0.001	0.03
Hops	spray SUW	10 - 19	field margin	0.064	2.9	0.72	0.001	0.03
Hops	spray SUW	20 - 39	field margin	0.064	2.9	0.72	0.001	0.03
Hops	spray SUW	40 - 69	field margin	0.064	2.9	0.72	0.001	0.03
Hops	spray SUW	≥ 70	adjacent crop	0.041	5.8	0.72	0.001	0.03
Hops	spray SUW	10 - 19	adjacent crop	0.041	5.8	0.72	0.001	0.03
Hops	spray SUW	20 - 39	adjacent crop	0.041	5.8	0.72	0.001	0.03
Hops	spray SUW	40 - 69	adjacent crop	0.041	5.8	0.72	0.001	0.03
Hops	spray SUW	≥ 70	next crop	1	0.012	0.72	0.000	0.03
Hops	spray SUW	10 - 19	next crop	1	0.012	0.72	0.000	0.03
Hops	spray SUW	20 - 39	next crop	1	0.012	0.72	0.000	0.03
Hops	spray SUW	40 - 69	next crop	1	0.012	0.72	0.000	0.03
TIER 1 for Fruiting vegetables for larvae exposure:								

Fruiting vegetables 2: Tomatoes, Eggplants (aubergines)	spray DW	10 - 49	treated crop	1	0.15	0.85	**0.21**	0.2
Fruiting vegetables 2: Tomatoes, Eggplants (aubergines)	spray DW	50 - 69	treated crop	1	0.15	0.85	**0.21**	0.2
Fruiting vegetables 2: Tomatoes, Eggplants (aubergines)	spray DW	≥ 70	treated crop	1	0	0.85	0.00	0.2
Fruiting vegetables 2: Tomatoes, Eggplants (aubergines)	spray DW	10 - 49	weeds	1	2.2	0.85	**3.15**	0.2
Fruiting vegetables 2: Tomatoes, Eggplants (aubergines)	spray DW	50 - 69	weeds	0.3	2.2	0.85	**0.94**	0.2
Fruiting vegetables 2: Tomatoes, Eggplants (aubergines)	spray DW	≥ 70	weeds	0.3	2.2	0.85	**0.94**	0.2
Fruiting vegetables 2: Tomatoes, Eggplants (aubergines)	spray DW	10 - 49	field margin	0.0092	2.2	0.85	0.03	0.2
Fruiting vegetables 2: Tomatoes, Eggplants (aubergines)	spray DW	50 - 69	field margin	0.0092	2.2	0.85	0.03	0.2
Fruiting vegetables 2: Tomatoes, Eggplants (aubergines)	spray DW	≥ 70	field margin	0.0092	2.2	0.85	0.03	0.2
Fruiting vegetables 2: Tomatoes, Eggplants (aubergines)	spray DW	10 - 49	adjacent crop	0.0033	4.4	0.85	0.02	0.2
Fruiting vegetables 2: Tomatoes, Eggplants (aubergines)	spray DW	50 - 69	adjacent crop	0.0033	4.4	0.85	0.02	0.2
Fruiting vegetables 2: Tomatoes, Eggplants (aubergines)	spray DW	≥ 70	adjacent crop	0.0033	4.4	0.85	0.02	0.2
Fruiting vegetables 2: Tomatoes, Eggplants (aubergines)	spray DW	10 - 49	next crop	1	0.4	0.85	**0.57**	0.2
Fruiting vegetables 2: Tomatoes, Eggplants (aubergines)	spray DW	50 - 69	next crop	1	0.4	0.85	**0.57**	0.2
Fruiting vegetables 2: Tomatoes, Eggplants (aubergines)	spray DW	≥ 70	next crop	1	0.4	0.85	**0.57**	0.2
TIER 1 for Fruiting vegetables 2 for chronic oral exposure:								
Fruiting vegetables 2: Tomatoes, Eggplants (aubergines)	spray DW	10 - 49	treated crop	1	0.92	0.72	0.003	0.03
Fruiting vegetables 2: Tomatoes, Eggplants (aubergines)	spray DW	50 - 69	treated crop	1	0.92	0.72	0.003	0.03
Fruiting vegetables 2: Tomatoes, Eggplants	spray DW	≥ 70	treated crop	1	0	0.72	0.000	0.03

(aubergines)								
Fruiting vegetables 2: Tomatoes, Eggplants (aubergines)	spray DW	10 - 49	weeds	1	2.9	0.72	0.009	0.03
Fruiting vegetables 2: Tomatoes, Eggplants (aubergines)	spray DW	50 - 69	weeds	0.3	2.9	0.72	0.003	0.03
Fruiting vegetables 2: Tomatoes, Eggplants (aubergines)	spray DW	≥ 70	weeds	0.3	2.9	0.72	0.003	0.03
Fruiting vegetables 2: Tomatoes, Eggplants (aubergines)	spray DW	10 - 49	field margin	0.0092	2.9	0.72	0.000	0.03
Fruiting vegetables 2: Tomatoes, Eggplants (aubergines)	spray DW	50 - 69	field margin	0.0092	2.9	0.72	0.000	0.03
Fruiting vegetables 2: Tomatoes, Eggplants (aubergines)	spray DW	≥ 70	field margin	0.0092	2.9	0.72	0.000	0.03
Fruiting vegetables 2: Tomatoes, Eggplants (aubergines)	spray DW	10 - 49	adjacent crop	0.0033	5.8	0.72	0.000	0.03
Fruiting vegetables 2: Tomatoes, Eggplants (aubergines)	spray DW	50 - 69	adjacent crop	0.0033	5.8	0.72	0.000	0.03
Fruiting vegetables 2: Tomatoes, Eggplants (aubergines)	spray DW	≥ 70	adjacent crop	0.0033	5.8	0.72	0.000	0.03
Fruiting vegetables 2: Tomatoes, Eggplants (aubergines)	spray DW	10 - 49	next crop	1	0.54	0.72	0.002	0.03
Fruiting vegetables 2: Tomatoes, Eggplants (aubergines)	spray DW	50 - 69	next crop	1	0.54	0.72	0.002	0.03
Fruiting vegetables 2: Tomatoes, Eggplants (aubergines)	spray DW	≥ 70	Next crop	1	0.54	0.72	0.002	0.03
TIER 1 for Clovers for larvae exposure:								
Clovers: Alfalfa, Clover for forage and silage	spray DW	10 - 49	treated crop	1	4.4	0.85	**6.29**	0.2
Clovers: Alfalfa, Clover for forage and silage	spray DW	50 - 69	treated crop	1	4.4	0.85	**6.29**	0.2
Clovers: Alfalfa, Clover for forage and silage	spray DW	≥ 70	treated crop	1	0	0.85	0.00	0.2
Clovers: Alfalfa, Clover for forage and silage	spray DW	10 - 49	weeds	1	2.2	0.85	**3.15**	0.2
Clovers: Alfalfa, Clover for forage and silage	spray DW	50 - 69	weeds	0.3	2.2	0.85	0.94	0.2
Clovers: Alfalfa, Clover for forage and silage	spray DW	≥ 70	weeds	0.3	2.2	0.85	0.94	0.2
Clovers: Alfalfa, Clover for forage and silage	spray DW	10 - 49	field margin	0.0092	2.2	0.85	0.03	0.2
Clovers: Alfalfa, Clover for forage and silage	spray DW	50 - 69	field margin	0.0092	2.2	0.85	0.03	0.2

Clovers: Alfalfa, Clover for forage and silage	spray DW	≥ 70	field margin	0.0092	2.2	0.85	0.03	0.2
Clovers: Alfalfa, Clover for forage and silage	spray DW	10 - 49	adjacent crop	0.0033	4.4	0.85	0.02	0.2
Clovers: Alfalfa, Clover for forage and silage	spray DW	50 - 69	adjacent crop	0.0033	4.4	0.85	0.02	0.2
Clovers: Alfalfa, Clover for forage and silage	spray DW	≥ 70	adjacent crop	0.0033	4.4	0.85	0.02	0.2
Clovers: Alfalfa, Clover for forage and silage	spray DW	10 - 49	next crop	1	0.4	0.85	**0.57**	0.2
Clovers: Alfalfa, Clover for forage and silage	spray DW	50 - 69	next crop	1	0.4	0.85	**0.57**	0.2
Clovers: Alfalfa, Clover for forage and silage	spray DW	≥ 70	next crop	1	0.4	0.85	**0.57**	0.2
TIER 1 for Clover for chronic oral exposure:								
Clovers: Alfalfa, Clover for forage and silage	spray DW	10 - 49	treated crop	1	5.8	0.72	0.017	0.03
Clovers: Alfalfa, Clover for forage and silage	spray DW	50 - 69	treated crop	1	5.8	0.72	0.017	0.03
Clovers: Alfalfa, Clover for forage and silage	spray DW	≥ 70	treated crop	1	0	0.72	0.000	0.03
Clovers: Alfalfa, Clover for forage and silage	spray DW	10 - 49	weeds	1	2.9	0.72	0.009	0.03
Clovers: Alfalfa, Clover for forage and silage	spray DW	50 - 69	weeds	0.3	2.9	0.72	0.003	0.03
Clovers: Alfalfa, Clover for forage and silage	spray DW	≥ 70	weeds	0.3	2.9	0.72	0.003	0.03
Clovers: Alfalfa, Clover for forage and silage	spray DW	10 - 49	field margin	0.0092	2.9	0.72	0.000	0.03
Clovers: Alfalfa, Clover for forage and silage	spray DW	50 - 69	field margin	0.0092	2.9	0.72	0.000	0.03
Clovers: Alfalfa, Clover for forage and silage	spray DW	≥ 70	field margin	0.0092	2.9	0.72	0.000	0.03
Clovers: Alfalfa, Clover for forage and silage	spray DW	10 - 49	adjacent crop	0.0033	5.8	0.72	0.000	0.03
Clovers: Alfalfa, Clover for forage and silage	spray DW	50 - 69	adjacent crop	0.0033	5.8	0.72	0.000	0.03
Clovers: Alfalfa, Clover for forage and silage	spray DW	≥ 70	adjacent crop	0.0033	5.8	0.72	0.000	0.03
Clovers: Alfalfa, Clover for forage and silage	spray DW	10 - 49	next crop	1	0.54	0.72	0.002	0.03
Clovers: Alfalfa, Clover for forage and silage	spray DW	50 - 69	next crop	1	0.54	0.72	0.002	0.03
Clovers: Alfalfa, Clover for forage and silage	spray DW	≥ 70	Next crop	1	0.54	0.72	0.002	0.03
TIER 1 for Fruiting vegetables 1 for larvae exposure:								
Fruiting vegetables 1: Chillies, Peppers, Cucumbers, Gherkins, Pumpkins, Squash, Gourds, Melon, Watermelons	spray DW	10 - 49	treated crop	1	4.4	0.85	**4.99**	0.2
Fruiting vegetables 1: Chillies, Peppers, Cu-	spray DW	50 - 69	treated crop	1	4.4	0.85	**4.99**	0.2

cumbers, Gherkins, Pumpkins, Squash, Gourds, Melon, Watermelons								
Fruiting vegetables 1: Chillies, Peppers, Cucumbers, Gherkins, Pumpkins, Squash, Gourds, Melon, Watermelons	spray DW	≥ 70	treated crop	1	0	0.85	0.00	0.2
Fruiting vegetables 1: Chillies, Peppers, Cucumbers, Gherkins, Pumpkins, Squash, Gourds, Melon, Watermelons	spray DW	10 - 49	weeds	1	2.2	0.85	**2.50**	0.2
Fruiting vegetables 1: Chillies, Peppers, Cucumbers, Gherkins, Pumpkins, Squash, Gourds, Melon, Watermelons	spray DW	50 - 69	weeds	0.3	2.2	0.85	**0.75**	0.2
Fruiting vegetables 1: Chillies, Peppers, Cucumbers, Gherkins, Pumpkins, Squash, Gourds, Melon, Watermelons	spray DW	≥ 70	weeds	0.3	2.2	0.85	**0.75**	0.2
Fruiting vegetables 1: Chillies, Peppers, Cucumbers, Gherkins, Pumpkins, Squash, Gourds, Melon, Watermelons	spray DW	10 - 49	field margin	0.0092	2.2	0.85	0.02	0.2
Fruiting vegetables 1: Chillies, Peppers, Cucumbers, Gherkins, Pumpkins, Squash, Gourds, Melon, Watermelons	spray DW	50 - 69	field margin	0.0092	2.2	0.85	0.02	0.2
Fruiting vegetables 1: Chillies, Peppers, Cucumbers, Gherkins, Pumpkins, Squash, Gourds, Melon, Watermelons	spray DW	≥ 70	field margin	0.0092	2.2	0.85	0.02	0.2
Fruiting vegetables 1: Chillies, Peppers, Cucumbers, Gherkins, Pumpkins, Squash, Gourds, Melon, Watermelons	spray DW	10 - 49	adjacent crop	0.0033	4.4	0.85	0.02	0.2
Fruiting vegetables 1: Chillies, Peppers, Cu-	spray DW	50 - 69	adjacent crop	0.0033	4.4	0.85	0.02	0.2

cumbers, Gherkins, Pumpkins, Squash, Gourds, Melon, Water-melons								
Fruiting vegetables 1: Chillies, Peppers, Cucumbers, Gherkins, Pumpkins, Squash, Gourds, Melon, Water-melons	spray DW	≥ 70	adjacent crop	0.0033	4.4	0.85	0.02	0.2
Fruiting vegetables 1: Chillies, Peppers, Cucumbers, Gherkins, Pumpkins, Squash, Gourds, Melon, Water-melons	spray DW	10 - 49	next crop	1	0.4	0.85	**0.45**	0.2
Fruiting vegetables 1: Chillies, Peppers, Cucumbers, Gherkins, Pumpkins, Squash, Gourds, Melon, Water-melons	spray DW	50 - 69	next crop	1	0.4	0.85	**0.45**	0.2
Fruiting vegetables 1: Chillies, Peppers, Cucumbers, Gherkins, Pumpkins, Squash, Gourds, Melon, Water-melons	spray DW	≥ 70	next crop	1	0.4	0.85	**0.45**	0.2
TIER 1 for Lettuce for larvae exposure:								
Lettuce	spray DW	10 - 49	treated crop	1	4.4	0.85	0.14	0.2
Lettuce	spray DW	50 - 69	treated crop	1	4.4	0.85	0.14	0.2
Lettuce	spray DW	≥ 70	treated crop	1	0	0.85	0.00	0.2
Lettuce	spray DW	10 - 49	weeds	1	2.2	0.85	**2.10**	0.2
Lettuce	spray DW	50 - 69	weeds	0.3	2.2	0.85	**0.63**	0.2
Lettuce	spray DW	≥ 70	weeds	0.3	2.2	0.85	**0.63**	0.2
Lettuce	spray DW	10 - 49	field margin	0.0092	2.2	0.85	0.02	0.2
Lettuce	spray DW	50 - 69	field margin	0.0092	2.2	0.85	0.02	0.2
Lettuce	spray DW	≥ 70	field margin	0.0092	2.2	0.85	0.02	0.2
Lettuce	spray DW	10 - 49	adjacent crop	0.0033	4.4	0.85	0.01	0.2
Lettuce	spray DW	50 - 69	adjacent crop	0.0033	4.4	0.85	0.01	0.2
Lettuce	spray DW	≥ 70	adjacent crop	0.0033	4.4	0.85	0.01	0.2
Lettuce	spray DW	10 - 49	next crop	1	0.4	0.85	**0.38**	0.2

Lettuce	spray DW	50 - 69	next crop	1	0.4	0.85	**0.38**	0.2
Lettuce	spray DW	≥ 70	next crop	1	0.4	0.85	**0.38**	0.2
TIER 1 for Leafy vegetables for larvae exposure:								
Leafy vegetables: Artichokes, Asparagus, Cabbages and other brassicas, Cauliflowers and broccoli, Chicory roots, Spinach	spray DW	10 - 49	treated crop	1	4.4	0.85	**4.20**	0.2
Leafy vegetables: Artichokes, Asparagus, Cabbages and other brassicas, Cauliflowers and broccoli, Chicory roots, Spinach	spray DW	50 - 69	treated crop	1	4.4	0.85	**4.20**	0.2
Leafy vegetables: Artichokes, Asparagus, Cabbages and other brassicas, Cauliflowers and broccoli, Chicory roots, Spinach	spray DW	≥ 70	treated crop	1	0	0.85	0.00	0.2
Leafy vegetables: Artichokes, Asparagus, Cabbages and other brassicas, Cauliflowers and broccoli, Chicory roots, Spinach	spray DW	10 - 49	weeds	1	2.2	0.85	**2.10**	0.2
Leafy vegetables: Artichokes, Asparagus, Cabbages and other brassicas, Cauliflowers and broccoli, Chicory roots, Spinach	spray DW	50 - 69	weeds	0.3	2.2	0.85	**0.63**	0.2
Leafy vegetables: Artichokes, Asparagus, Cabbages and other brassicas, Cauliflowers and broccoli, Chicory roots, Spinach	spray DW	≥ 70	weeds	0.3	2.2	0.85	**0.63**	0.2
Leafy vegetables: Artichokes, Asparagus, Cabbages and other brassicas, Cauliflowers and broccoli, Chicory roots, Spinach	spray DW	10 - 49	field margin	0.0092	2.2	0.85	0.02	0.2
Leafy vegetables: Artichokes, Asparagus, Cabbages and other brassicas, Cauliflowers and broccoli, Chicory roots, Spinach	spray DW	50 - 69	field margin	0.0092	2.2	0.85	0.02	0.2
Leafy vegetables: Arti-	spray DW	≥ 70	field	0.0092	2.2	0.85	0.02	0.2

chokes, Asparagus, Cabbages and other brassicas, Cauliflowers and broccoli, Chicory roots, Spinach			margin					
Leafy vegetables: Artichokes, Asparagus, Cabbages and other brassicas, Cauliflowers and broccoli, Chicory roots, Spinach	spray DW	10 - 49	adjacent crop	0.0033	4.4	0.85	0.01	0.2
Leafy vegetables: Artichokes, Asparagus, Cabbages and other brassicas, Cauliflowers and broccoli, Chicory roots, Spinach	spray DW	50 - 69	adjacent crop	0.0033	4.4	0.85	0.01	0.2
Leafy vegetables: Artichokes, Asparagus, Cabbages and other brassicas, Cauliflowers and broccoli, Chicory roots, Spinach	spray DW	≥ 70	adjacent crop	0.0033	4.4	0.85	0.01	0.2
Leafy vegetables: Artichokes, Asparagus, Cabbages and other brassicas, Cauliflowers and broccoli, Chicory roots, Spinach	spray DW	10 - 49	next crop	1	0.4	0.85	**0.38**	0.2
Leafy vegetables: Artichokes, Asparagus, Cabbages and other brassicas, Cauliflowers and broccoli, Chicory roots, Spinach	spray DW	50 - 69	next crop	1	0.4	0.85	**0.38**	0.2
Leafy vegetables: Artichokes, Asparagus, Cabbages and other brassicas, Cauliflowers and broccoli, Chicory roots, Spinach	spray DW	≥ 70	next crop	1	0.4	0.85	**0.38**	0.2
TIER 1 for Oilseed rape for larvae exposure:								
Oilseed rape (rapeseed)	spray DW	10 - 29	treated crop	1	4.4	0.85	**3.50**	0.2
Oilseed rape (rapeseed)	spray DW	30 - 39	treated crop	1	4.4	0.85	**3.50**	0.2
Oilseed rape (rapeseed)	spray DW	40 - 69	treated crop	1	4.4	0.85	**3.50**	0.2
Oilseed rape (rapeseed)	spray DW	≥ 70	treated crop	1	0	0.85	0.00	0.2
Oilseed rape (rapeseed)	spray DW	10 - 29	weeds	1	2.2	0.85	**1.75**	0.2
Oilseed rape (rapeseed)	spray DW	30 - 39	weeds	0.3	2.2	0.85	**0.52**	0.2

Oilseed rape (rapeseed)	spray DW	40 - 69	weeds	0.25	2.2	0.85	**0.44**	0.2
Oilseed rape (rapeseed)	spray DW	≥ 70	weeds	0.25	2.2	0.85	**0.44**	0.2
Oilseed rape (rapeseed)	spray DW	10 - 29	field margin	0.0092	2.2	0.85	0.02	0.2
Oilseed rape (rapeseed)	spray DW	30 - 39	field margin	0.0092	2.2	0.85	0.02	0.2
Oilseed rape (rapeseed)	spray DW	40 - 69	field margin	0.0092	2.2	0.85	0.02	0.2
Oilseed rape (rapeseed)	spray DW	≥ 70	field margin	0.0092	2.2	0.85	0.02	0.2
Oilseed rape (rapeseed)	spray DW	10 - 29	adjacent crop	0.0033	4.4	0.85	0.01	0.2
Oilseed rape (rapeseed)	spray DW	30 - 39	adjacent crop	0.0033	4.4	0.85	0.01	0.2
Oilseed rape (rapeseed)	spray DW	40 - 69	adjacent crop	0.0033	4.4	0.85	0.01	0.2
Oilseed rape (rapeseed)	spray DW	≥ 70	adjacent crop	0.0033	4.4	0.85	0.01	0.2
Oilseed rape (rapeseed)	spray DW	10 - 29	next crop	1	0.4	0.85	**0.32**	0.2
Oilseed rape (rapeseed)	spray DW	30 - 39	next crop	1	0.4	0.85	**0.32**	0.2
Oilseed rape (rapeseed)	spray DW	40 - 69	next crop	1	0.4	0.85	**0.32**	0.2
Oilseed rape (rapeseed)	spray DW	≥ 70	next crop	1	0.4	0.85	**0.32**	0.2
TIER 1 for Sunflower for larvae exposure:								
Sunflower	spray DW	10 - 29	treated crop	1	4.4	0.85	**3.50**	0.2
Sunflower	spray DW	30 - 39	treated crop	1	4.4	0.85	**3.50**	0.2
Sunflower	spray DW	40 - 69	treated crop	1	4.4	0.85	**3.50**	0.2
Sunflower	spray DW	≥ 70	treated crop	1	0	0.85	0.00	0.2
Sunflower	spray DW	10 - 29	weeds	1	2.2	0.85	**1.75**	0.2
Sunflower	spray DW	30 - 39	weeds	0.3	2.2	0.85	**0.87**	0.2
Sunflower	spray DW	40 - 69	weeds	0.25	2.2	0.85	**0.44**	0.2
Sunflower	spray DW	≥ 70	weeds	0.25	2.2	0.85	**0.44**	0.2
Sunflower	spray DW	10 - 29	field margin	0.0092	2.2	0.85	0.02	0.2
Sunflower	spray DW	30 - 39	field margin	0.0092	2.2	0.85	0.02	0.2
Sunflower	spray DW	40 - 69	field margin	0.0092	2.2	0.85	0.02	0.2
Sunflower	spray DW	≥ 70	field margin	0.0092	2.2	0.85	0.02	0.2
Sunflower	spray DW	10 - 29	adjacent crop	0.0033	4.4	0.85	0.01	0.2
Sunflower	spray DW	30 -	adjacent	0.0033	4.4	0.85	0.01	0.2

		39	crop					
Sunflower	spray DW	40 - 69	adjacent crop	0.0033	4.4	0.85	0.01	0.2
Sunflower	spray DW	≥ 70	adjacent crop	0.0033	4.4	0.85	0.01	0.2
Sunflower	spray DW	10 - 29	next crop	1	0.4	0.85	**0.32**	0.2
Sunflower	spray DW	30 - 39	next crop	1	0.4	0.85	**0.32**	0.2
Sunflower	spray DW	40 - 69	next crop	1	0.4	0.85	**0.32**	0.2
Sunflower	spray DW	≥ 70	next crop	1	0.4	0.85	**0.32**	0.2
TIER 1 for Roots vegetables for larvae exposure:								
Root vegetables: Anise, Badian, Fennel, Corian, Carrots, Turnips for Fodder, Viper's grass	spray DW	10 - 39	treated crop	1	4.4	0.85	**3.50**	0.2
Root vegetables: Anise, Badian, Fennel, Corian, Carrots, Turnips for Fodder, Viper's grass	spray DW	40 - 69	treated crop	1	4.4	0.85	**3.50**	0.2
Root vegetables: Anise, Badian, Fennel, Corian, Carrots, Turnips for Fodder, Viper's grass	spray DW	≥ 70	treated crop	1	0	0.85	0.00	0.2
Root vegetables: Anise, Badian, Fennel, Corian, Carrots, Turnips for Fodder, Viper's grass	spray DW	10 - 39	weeds	1	2.2	0.85	**1.75**	0.2
Root vegetables: Anise, Badian, Fennel, Corian, Carrots, Turnips for Fodder, Viper's grass	spray DW	40 - 69	weeds	0.3	2.2	0.85	**0.52**	0.2
Root vegetables: Anise, Badian, Fennel, Corian, Carrots, Turnips for Fodder, Viper's grass	spray DW	≥ 70	weeds	0.3	2.2	0.85	**0.52**	0.2
Root vegetables: Anise, Badian, Fennel, Corian, Carrots, Turnips for Fodder, Viper's grass	spray DW	10 - 39	field margin	0.0092	2.2	0.85	0.02	0.2
Root vegetables: Anise, Badian, Fennel, Corian, Carrots, Turnips for Fodder, Viper's grass	spray DW	40 - 69	field margin	0.0092	2.2	0.85	0.02	0.2
Root vegetables: Anise, Badian, Fennel, Corian, Carrots, Turnips for Fodder, Viper's grass	spray DW	≥ 70	field margin	0.0092	2.2	0.85	0.02	0.2
Root vegetables: Anise, Badian, Fennel, Corian, Carrots, Turnips for Fodder, Viper's grass	spray DW	10 - 39	adjacent crop	0.0033	4.4	0.85	0.01	0.2

Root vegetables: Anise, Badian, Fennel, Corian, Carrots, Turnips for Fodder, Viper's grass	spray DW	40 - 69	adjacent crop	0.0033	4.4	0.85	0.01	0.2
Root vegetables: Anise, Badian, Fennel, Corian, Carrots, Turnips for Fodder, Viper's grass	spray DW	≥ 70	adjacent crop	0.0033	4.4	0.85	0.01	0.2
Root vegetables: Anise, Badian, Fennel, Corian, Carrots, Turnips for Fodder, Viper's grass	spray DW	10 - 39	next crop	1	0.4	0.85	**0.32**	0.2
Root vegetables: Anise, Badian, Fennel, Corian, Carrots, Turnips for Fodder, Viper's grass	spray DW	40 - 69	next crop	1	0.4	0.85	**0.32**	0.2
Root vegetables: Anise, Badian, Fennel, Corian, Carrots, Turnips for Fodder, Viper's grass	spray DW	≥ 70	next crop	1	0.4	0.85	**0.32**	0.2
TIER 1 for Pulses for larvae exposure:								
Pulses: Beans, Broad beans, Horse beans, Buckwheat, Chick peas, Cow peas, Leguminous for silage, Leguminous vegetables, Lentis, Lupins, Peas, Soybeans, Vetches	spray DW	10 - 49	treated crop	1	4.4	0.85	**3.50**	0.2
Pulses: Beans, Broad beans, Horse beans, Buckwheat, Chick peas, Cow peas, Leguminous for silage, Leguminous vegetables, Lentis, Lupins, Peas, Soybeans, Vetches	spray DW	50 - 69	treated crop	1	4.4	0.85	**3.50**	0.2
Pulses: Beans, Broad beans, Horse beans, Buckwheat, Chick peas, Cow peas, Leguminous for silage, Leguminous vegetables, Lentis, Lupins, Peas, Soybeans, Vetches	spray DW	≥ 70	treated crop	1	0	0.85	0.00	0.2
Pulses: Beans, Broad beans, Horse beans, Buckwheat, Chick peas, Cow peas, Leguminous for silage, Leguminous vegetables, Lentis, Lupins, Peas, Soybeans, Vetches	spray DW	10 - 49	weeds	1	2.2	0.85	**1.75**	0.2
Pulses: Beans, Broad	spray DW	50 -	weeds	0.3	2.2	0.85	**0.52**	0.2

beans, Horse beans, Buckwheat, Chick peas, Cow peas, Leguminous for silage, Leguminous vegetables, Lentis, Lupins, Peas, Soybeans, Vetches		69						
Pulses: Beans, Broad beans, Horse beans, Buckwheat, Chick peas, Cow peas, Leguminous for silage, Leguminous vegetables, Lentis, Lupins, Peas, Soybeans, Vetches	spray DW	≥ 70	weeds	0.3	2.2	0.85	**0.52**	0.2
Pulses: Beans, Broad beans, Horse beans, Buckwheat, Chick peas, Cow peas, Leguminous for silage, Leguminous vegetables, Lentis, Lupins, Peas, Soybeans, Vetches	spray DW	10 - 49	field margin	0.0092	2.2	0.85	0.02	0.2
Pulses: Beans, Broad beans, Horse beans, Buckwheat, Chick peas, Cow peas, Leguminous for silage, Leguminous vegetables, Lentis, Lupins, Peas, Soybeans, Vetches	spray DW	50 - 69	field margin	0.0092	2.2	0.85	0.02	0.2
Pulses: Beans, Broad beans, Horse beans, Buckwheat, Chick peas, Cow peas, Leguminous for silage, Leguminous vegetables, Lentis, Lupins, Peas, Soybeans, Vetches	spray DW	≥ 70	field margin	0.0092	2.2	0.85	0.02	0.2
Pulses: Beans, Broad beans, Horse beans, Buckwheat, Chick peas, Cow peas, Leguminous for silage, Leguminous vegetables, Lentis, Lupins, Peas, Soybeans, Vetches	spray DW	10 - 49	adjacent crop	0.0033	4.4	0.85	0.01	0.2
Pulses: Beans, Broad beans, Horse beans, Buckwheat, Chick peas, Cow peas, Leguminous for silage, Leguminous vegetables, Lentis, Lupins, Peas, Soybeans, Vetches	spray DW	50 - 69	adjacent crop	0.0033	4.4	0.85	0.01	0.2

Pulses: Beans, Broad beans, Horse beans, Buckwheat, Chick peas, Cow peas, Leguminous for silage, Leguminous vegetables, Lentis, Lupins, Peas, Soybeans, Vetches	spray DW	≥ 70	adjacent crop	0.0033	4.4	0.85	0.01	0.2
Pulses: Beans, Broad beans, Horse beans, Buckwheat, Chick peas, Cow peas, Leguminous for silage, Leguminous vegetables, Lentis, Lupins, Peas, Soybeans, Vetches	spray DW	10 - 49	next crop	1	0.4	0.85	**0.32**	0.2
Pulses: Beans, Broad beans, Horse beans, Buckwheat, Chick peas, Cow peas, Leguminous for silage, Leguminous vegetables, Lentis, Lupins, Peas, Soybeans, Vetches	spray DW	50 - 69	next crop	1	0.4	0.85	**0.32**	0.2
Pulses: Beans, Broad beans, Horse beans, Buckwheat, Chick peas, Cow peas, Leguminous for silage, Leguminous vegetables, Lentis, Lupins, Peas, Soybeans, Vetches	spray DW	≥ 70	next crop	1	0.4	0.85	**0.32**	0.2
TIER 1 for Flax for larvae exposure:								
Flax: Linseed, Mustard seed	spray DW	10 - 29	treated crop	1	4.4	0.85	**3.50**	0.2
Flax: Linseed, Mustard seed	spray DW	30 - 39	treated crop	1	4.4	0.85	**3.50**	0.2
Flax: Linseed, Mustard seed	spray DW	40 - 69	treated crop	1	4.4	0.85	**3.50**	0.2
Flax: Linseed, Mustard seed	spray DW	≥ 70	treated crop	1	0	0.85	0.00	0.2
Flax: Linseed, Mustard seed	spray DW	10 - 29	weeds	1	2.2	0.85	**1.75**	0.2
Flax: Linseed, Mustard seed	spray DW	30 - 39	weeds	0.3	2.2	0.85	**0.52**	0.2
Flax: Linseed, Mustard seed	spray DW	40 - 69	weeds	0.25	2.2	0.85	**0.44**	0.2
Flax: Linseed, Mustard seed	spray DW	≥ 70	weeds	0.25	2.2	0.85	**0.44**	0.2
Flax: Linseed, Mustard seed	spray DW	10 - 29	field margin	0.0092	2.2	0.85	0.02	0.2
Flax: Linseed, Mustard seed	spray DW	30 - 39	field margin	0.0092	2.2	0.85	0.02	0.2
Flax: Linseed, Mustard	spray DW	40 -	field	0.0092	2.2	0.85	0.02	0.2

seed		69	margin					
Flax: Linseed, Mustard seed	spray DW	≥ 70	field margin	0.0092	2.2	0.85	0.02	0.2
Flax: Linseed, Mustard seed	spray DW	10 - 29	adjacent crop	0.0033	4.4	0.85	0.01	0.2
Flax: Linseed, Mustard seed	spray DW	30 - 39	adjacent crop	0.0033	4.4	0.85	0.01	0.2
Flax: Linseed, Mustard seed	spray DW	40 - 69	adjacent crop	0.0033	4.4	0.85	0.01	0.2
Flax: Linseed, Mustard seed	spray DW	≥ 70	adjacent crop	0.0033	4.4	0.85	0.01	0.2
Flax: Linseed, Mustard seed	spray DW	10 - 29	next crop	1	0.4	0.85	**0.32**	0.2
Flax: Linseed, Mustard seed	spray DW	30 - 39	next crop	1	0.4	0.85	**0.32**	0.2
Flax: Linseed, Mustard seed	spray DW	40 - 69	next crop	1	0.4	0.85	**0.32**	0.2
Flax: Linseed, Mustard seed	spray DW	≥ 70	next crop	1	0.4	0.85	**0.32**	0.2
TIER 1 for Poppy seed for larvae exposure:								
Poppy seed	spray DW	≥ 70	treated crop	1	0	0.85	0.00	0.2
Poppy seed	spray DW	10 - 29	treated crop	1	0.15	0.85	0.12	0.2
Poppy seed	spray DW	30 - 39	treated crop	1	0.15	0.85	0.12	0.2
Poppy seed	spray DW	40 - 69	treated crop	1	0.15	0.85	0.12	0.2
Poppy seed	spray DW	≥ 70	weeds	0.25	2.2	0.85	**0.44**	0.2
Poppy seed	spray DW	10 - 29	weeds	1	2.2	0.85	**1.75**	0.2
Poppy seed	spray DW	30 - 39	weeds	0.3	2.2	0.85	**0.52**	0.2
Poppy seed	spray DW	40 - 69	weeds	0.25	2.2	0.85	**0.44**	0.2
Poppy seed	spray DW	≥ 70	field margin	0.0092	2.2	0.85	0.02	0.2
Poppy seed	spray DW	10 - 29	field margin	0.0092	2.2	0.85	0.02	0.2
Poppy seed	spray DW	30 - 39	field margin	0.0092	2.2	0.85	0.02	0.2
Poppy seed	spray DW	40 - 69	field margin	0.0092	2.2	0.85	0.02	0.2
Poppy seed	spray DW	≥ 70	adjacent crop	0.0033	4.4	0.85	0.01	0.2
Poppy seed	spray DW	10 - 29	adjacent crop	0.0033	4.4	0.85	0.01	0.2
Poppy seed	spray DW	30 - 39	adjacent crop	0.0033	4.4	0.85	0.01	0.2
Poppy seed	spray DW	40 - 69	adjacent crop	0.0033	4.4	0.85	0.01	0.2
Poppy seed	spray DW	≥ 70	next crop	1	0.4	0.85	**0.32**	0.2
Poppy seed	spray DW	10 -	next	1	0.4	0.85	**0.32**	0.2

		29	crop					
Poppy seed	spray DW	30 - 39	next crop	1	0.4	0.85	**0.32**	0.2
Poppy seed	spray DW	40 - 69	next crop	1	0.4	0.85	**0.32**	0.2
TIER 1 for Grasses for larvae exposure:								
Grasses: Grasses for forage, Silage; note that Rye grass is in a separate category!	spray DW	≥ 70	treated crop	1	0	0.85	0.00	0.2
Grasses: Grasses for forage, Silage; note that Rye grass is in a separate category!	spray DW	10 - 69	treated crop	1	4.4	0.85	**3.50**	0.2
Grasses: Grasses for forage, Silage; note that Rye grass is in a separate category!	spray DW	≥ 70	weeds	1	2.2	0.85	**1.75**	0.2
Grasses: Grasses for forage, Silage; note that Rye grass is in a separate category!	spray DW	10 - 69	weeds	1	2.2	0.85	**1.75**	0.2
Grasses: Grasses for forage, Silage; note that Rye grass is in a separate category!	spray DW	≥ 70	field margin	0.0092	2.2	0.85	0.02	0.2
Grasses: Grasses for forage, Silage; note that Rye grass is in a separate category!	spray DW	10 - 69	field margin	0.0092	2.2	0.85	0.02	0.2
Grasses: Grasses for forage, Silage; note that Rye grass is in a separate category!	spray DW	≥ 70	adjacent crop	0.0033	4.4	0.85	0.01	0.2
Grasses: Grasses for forage, Silage; note that Rye grass is in a separate category!	spray DW	10 - 69	adjacent crop	0.0033	4.4	0.85	0.01	0.2
Grasses: Grasses for forage, Silage; note that Rye grass is in a separate category!	spray DW	≥ 70	next crop	1	0.4	0.85	**0.32**	0.2
Grasses: Grasses for forage, Silage; note that Rye grass is in a separate category!	spray DW	10 - 69	next crop	1	0.4	0.85	**0.32**	0.2
TIER 1 for Maize for larvae exposure:								
Maize	spray DW	10 - 29	treated crop	1	0.15	0.85	0.09	0.2
Maize	spray DW	30 - 39	treated crop	1	0.15	0.85	0.09	0.2
Maize	spray DW	40 - 69	treated crop	1	0.15	0.85	0.09	0.2
Maize	spray DW	≥ 70	treated	1	0	0.85	0.00	0.2

			crop					
Maize	spray DW	10 - 29	weeds	1	2.2	0.85	**1.25**	0.2
Maize	spray DW	30 - 39	weeds	0.5	2.2	0.85	**0.62**	0.2
Maize	spray DW	40 - 69	weeds	0.25	2.2	0.85	**0.31**	0.2
Maize	spray DW	≥ 70	weeds	0.25	2.2	0.85	**0.31**	0.2
Maize	spray DW	10 - 29	field margin	0.0092	2.2	0.85	0.01	0.2
Maize	spray DW	30 - 39	field margin	0.0092	2.2	0.85	0.01	0.2
Maize	spray DW	40 - 69	field margin	0.0092	2.2	0.85	0.01	0.2
Maize	spray DW	≥ 70	field margin	0.0092	2.2	0.85	0.01	0.2
Maize	spray DW	10 - 29	adjacent crop	0.0033	4.4	0.85	0.01	0.2
Maize	spray DW	30 - 39	adjacent crop	0.0033	4.4	0.85	0.01	0.2
Maize	spray DW	40 - 69	adjacent crop	0.0033	4.4	0.85	0.01	0.2
Maize	spray DW	≥ 70	adjacent crop	0.0033	4.4	0.85	0.01	0.2
Maize	spray DW	10 - 29	next crop	1	0.4	0.85	**0.23**	0.2
Maize	spray DW	30 - 39	next crop	1	0.4	0.85	**0.23**	0.2
Maize	spray DW	40 - 69	next crop	1	0.4	0.85	**0.23**	0.2
Maize	spray DW	≥ 70	next crop	1	0.4	0.85	**0.23**	0.2
TIER 1 for Sorghum for larvae exposure:								
Sorghum	spray DW	10 - 29	treated crop	1	0.15	0.85	0.09	0.2
Sorghum	spray DW	30 - 39	treated crop	1	0.15	0.85	0.09	0.2
Sorghum	spray DW	40 - 69	treated crop	1	0.15	0.85	0.09	0.2
Sorghum	spray DW	≥ 70	treated crop	1	0	0.85	0.00	0.2
Sorghum	spray DW	10 - 29	weeds	1	2.2	0.85	**1.25**	0.2
Sorghum	spray DW	30 - 39	weeds	0.5	2.2	0.85	**0.62**	0.2
Sorghum	spray DW	40 - 69	weeds	0.25	2.2	0.85	**0.37**	0.2
Sorghum	spray DW	≥ 70	weeds	0.25	2.2	0.85	**0.37**	0.2
Sorghum	spray DW	10 - 29	field margin	0.0092	2.2	0.85	0.01	0.2
Sorghum	spray DW	30 - 39	field margin	0.0092	2.2	0.85	0.01	0.2
Sorghum	spray DW	40 - 69	field margin	0.0092	2.2	0.85	0.01	0.2

Sorghum	spray DW	≥ 70	field margin	0.0092	2.2	0.85	0.01	0.2
Sorghum	spray DW	10 - 29	adjacent crop	0.0033	4.4	0.85	0.01	0.2
Sorghum	spray DW	30 - 39	adjacent crop	0.0033	4.4	0.85	0.01	0.2
Sorghum	spray DW	40 - 69	adjacent crop	0.0033	4.4	0.85	0.01	0.2
Sorghum	spray DW	≥ 70	adjacent crop	0.0033	4.4	0.85	0.01	0.2
Sorghum	spray DW	10 - 29	next crop	1	0.4	0.85	**0.23**	0.2
Sorghum	spray DW	30 - 39	next crop	1	0.4	0.85	**0.23**	0.2
Sorghum	spray DW	40 - 69	next crop	1	0.4	0.85	**0.23**	0.2
Sorghum	spray DW	≥ 70	next crop	1	0.4	0.85	**0.23**	0.2
TIER 1 for Sugarbeet for larvae exposure:								
Sugar beet	spray DW	≥ 70	treated crop	1	0	0.85	0.00	0.2
Sugar beet	spray DW	10 - 39	treated crop	1	4.4	0.85	**2.00**	0.2
Sugar beet	spray DW	40 - 69	treated crop	1	4.4	0.85	**2.00**	0.2
Sugar beet	spray DW	≥ 70	weeds	0.25	2.2	0.85	**0.25**	0.2
Sugar beet	spray DW	10 - 39	weeds	1	2.2	0.85	**1.00**	0.2
Sugar beet	spray DW	40 - 69	weeds	0.25	2.2	0.85	**0.25**	0.2
Sugar beet	spray DW	≥ 70	field margin	0.0092	2.2	0.85	0.01	0.2
Sugar beet	spray DW	10 - 39	field margin	0.0092	2.2	0.85	0.01	0.2
Sugar beet	spray DW	40 - 69	field margin	0.0092	2.2	0.85	0.01	0.2
Sugar beet	spray DW	≥ 70	adjacent crop	0.0033	4.4	0.85	0.01	0.2
Sugar beet	spray DW	10 - 39	adjacent crop	0.0033	4.4	0.85	0.01	0.2
Sugar beet	spray DW	40 - 69	adjacent crop	0.0033	4.4	0.85	0.01	0.2
Sugar beet	spray DW	≥ 70	next crop	1	0.4	0.85	0.18	0.2
Sugar beet	spray DW	10 - 39	next crop	1	0.4	0.85	0.18	0.2
Sugar beet	spray DW	40 - 69	next crop	1	0.4	0.85	0.18	0.2
TIER 1 for Potatoes for larvae exposure:								
Potatoes	spray DW	10 - 39	treated crop	1	0.15	0.85	0.04	0.2
Potatoes	spray DW	40 - 69	treated crop	1	0.15	0.85	0.04	0.2
Potatoes	spray DW	≥ 70	treated	1	0	0.85	0.00	0.2

			crop					
Potatoes	spray DW	10 - 39	weeds	1	2.2	0.85	**0.62**	0.2
Potatoes	spray DW	40 - 69	weeds	0.3	2.2	0.85	0.19	0.2
Potatoes	spray DW	≥ 70	weeds	0.3	2.2	0.85	0.19	0.2
Potatoes	spray DW	10 - 39	field margin	0.0092	2.2	0.85	0.01	0.2
Potatoes	spray DW	40 - 69	field margin	0.0092	2.2	0.85	0.01	0.2
Potatoes	spray DW	≥ 70	field margin	0.0092	2.2	0.85	0.01	0.2
Potatoes	spray DW	10 - 39	adjacent crop	0.0033	4.4	0.85	0.00	0.2
Potatoes	spray DW	40 - 69	adjacent crop	0.0033	4.4	0.85	0.00	0.2
Potatoes	spray DW	≥ 70	adjacent crop	0.0033	4.4	0.85	0.00	0.2
Potatoes	spray DW	10 - 39	next crop	1	0.4	0.85	0.11	0.2
Potatoes	spray DW	40 - 69	next crop	1	0.4	0.85	0.11	0.2
Potatoes	spray DW	≥ 70	next crop	1	0.4	0.85	0.11	0.2
TIER 1 for Sweet Potatoes for larvae exposure:								
Sweet potatoes	spray DW	10 - 39	treated crop	1	4.4	0.85	**1.25**	0.2
Sweet potatoes	spray DW	40 - 69	treated crop	1	4.4	0.85	**1.25**	0.2
Sweet potatoes	spray DW	≥ 70	treated crop	1	0	0.85	0.00	0.2
Sweet potatoes	spray DW	10 - 39	weeds	1	2.2	0.85	**0.62**	0.2
Sweet potatoes	spray DW	40 - 69	weeds	0.3	2.2	0.85	0.19	0.2
Sweet potatoes	spray DW	≥ 70	weeds	0.3	2.2	0.85	0.19	0.2
Sweet potatoes	spray DW	10 - 39	field margin	0.0092	2.2	0.85	0.01	0.2
Sweet potatoes	spray DW	40 - 69	field margin	0.0092	2.2	0.85	0.01	0.2
Sweet potatoes	spray DW	≥ 70	field margin	0.0092	2.2	0.85	0.01	0.2
Sweet potatoes	spray DW	10 - 39	adjacent crop	0.0033	4.4	0.85	0.00	0.2
Sweet potatoes	spray DW	40 - 69	adjacent crop	0.0033	4.4	0.85	0.00	0.2
Sweet potatoes	spray DW	≥ 70	adjacent crop	0.0033	4.4	0.85	0.00	0.2
Sweet potatoes	spray DW	10 - 39	next crop	1	0.4	0.85	0.11	0.2
Sweet potatoes	spray DW	40 - 69	next crop	1	0.4	0.85	0.11	0.2
Sweet potatoes	spray DW	≥ 70	next crop	1	0.4	0.85	0.11	0.2

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

Studies evaluated field applications of DPX-E2Y45 20SC on flowering Phacelia tanacetifolia (EPPO 170 (3) and CEB 230 guideline) or onto wheat sprayed with sugar solution to simulate honey dew (CEB 230 guideline). Both crops were treated either during or after bee flight activity at rates of 52.5, 60.0 or 75 g DPX-E2Y45/ha. Exposure to spray solutions either by direct overspray onto foraging honey bees or via spray deposits on plant surfaces from the previous day resulted in mortality at levels comparable to the control group.
No behavioural changes were observed that could be attributed to the treatment with DPX-E2Y45 20SC. Honey bees gathered in front of the hive and fanned on some occasions, behaviours that likely are related to temperatures exceeding 30°C in the test tents.
Flight intensity was not influenced by the treatment with DPX-E2Y45 20SC. In one trial flight intensity was slightly inhibited one day after application of the test item in the evening after bee flight, which was not judged to be treatment related.
Development of honey bee colonies was not influenced by the treatment with DPX-E2Y45 20SC. The increase in number of storage combs in some cases was related to the presence of highly profitable food sources. The lack of larvae stages and eggs in trials in wheat may be related to the lack of sufficient proteins from pollen. Thus, this effect is not treatment related but a consequence of the trial design.
Two studies were conducted with DPX-E2Y45 20SC to evaluate the possibility of exposure to honey bees from soil residues that may carry over from previous applications to crops. Soil was treated with DPX-E2Y45 20SC at rates of either 313.6 or 213.6 g a.s./ha and was sown with Phacelia tanacetifolia. The studies were designed to simulate a worst-case scenario of multiple annual applications to crops, followed by a crop that can pick up DPX-E2Y45 from soil and translocate it to blossoms (into nectar and pollen). The fast-growing and highly attractive (to honey bees) plant species, Phacelia tanacetifolia, was chosen as an indicator species. It develops an intensive root system in the top soil (where the DPX-E2Y45 was incorporated) and begins flowering about 6 to 8 weeks after planting. Honey bees were allowed to forage on the flowering plants and observations were made in plots either with or without an additional spray application of 60 or 75 g DPX-E2Y45/ha. In all groups treated with DPX-E2Y45 20SC mortality was similar to the control groups. No substance-related behavioural changes or impact on the colonies were observed in these studies.
On the basis of the available extensive data set generated for honeybees (acute oral and contact laboratory studies and semi-field tunnel tests with Phacelia and wheat) exposed to DPX-E2Y45 and the formulated products, DPX-E2Y45 35WG and DPX-E2Y45 20SC, it can be concluded that the insecticide DPX-E2Y45 generally demonstrated low intrinsic toxicity for honey bees and should be safe to honey bees for the proposed practical use conditions.

9.6.3 Effects on bumble bees

Table 9.6-3: First-tier assessment of the risk for bees due to the use of CLOROL 200 SC

Intended use **Active substance** **Application rate (g/ha)**	chlorantraniliprole 2 × 110		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	10.41	110	10.57
Contact toxicity	0.4		275
Product **Application rate (g/ha)**	CLOROL 200 SC 2 x 110 as/ha		

Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	11.41	110	9.64
Contact toxicity	10.0		11

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

zRMS Comments:

No data or information is currently available for bumble bees.

9.6.4 Effects on solitary bees

Table 9.6-4: First-tier assessment of the risk for bees due to the use of CLOROL 200 SC

~~**Intended use**~~ ~~**Active substance**~~ ~~**Application rate (g/ha)**~~	~~chlorantraniliprole~~ ~~2 × 110~~		
~~**Test design**~~	~~**LD_{50} (lab.) (µg/bee)**~~	~~**Single application rate (g/ha)**~~	~~**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**~~
~~Oral toxicity~~	~~10.41~~	~~110~~	~~10.57~~
~~Contact toxicity~~	~~0.4~~		~~275~~
~~**Product**~~ ~~**Application rate (g/ha)**~~	~~CLOROL 200 SC~~ ~~2 x 110 as/ha~~		
~~**Test design**~~	~~**LD_{50} (lab.) (µg/bee)**~~	~~**Single application rate (g/ha)**~~	~~**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**~~
~~Oral toxicity~~	~~11.41~~	~~110~~	~~9.64~~
~~Contact toxicity~~	~~10.0~~		~~11~~

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

zRMS Comments:

No data or information is currently available for solitary bees.

9.6.5 Overall conclusions

On the basis of the available extensive data set generated for honeybees (acute oral and contact laboratory studies and 10 semi-field tunnel tests with Phacelia and wheat) exposed to chlorantraniliprole and the formulated products Coragen 200 SC, it can be concluded that the insecticide chlorantraniliprole generally demonstrated low intrinsic toxicity for honey bees and should be safe to honey bees for the proposed practical use conditions. Therefore, CLOROL 200 SC pose no unacceptable risk to bees at maximum dose for melliferous crops – 2 application of 63 grams chlorantraniliprole/ha which also covering flowering weeds scenario for unmelliforous crops Tobbaco (it can be assume that 55 grams per application drop on growing weeds under tobacco (worst dose for all crops weed scenario).

zRMS Comments:

The submitted risk assessment is based on the recommendations of the Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 rev 2) and new EU guidance (2013).

The EU agreed endpoints for active substance were used in risk assessment.

In addition to that, the Applicant submitted studies on chronic toxicity of formulation CLOROL 200 SC to adult bees and larvae. New studies were accepted. Therefore, the requirements set out in Regulation 284/2013 are fulfilled.

The acute risk assessment performed in accordance with the SANCO guidance presented by the Applicant was accepted.

There is currently no EU agreed chronic risk assessment scheme for bees. However, as agreed in the Central Zone a risk assessment based on the EFSA bee GD is presented below for illustrative purposes.

Chronic risk assessment to bees:

All steps for the chronic risk assessment, i.e. the screening step, 1st and 2nd oral tier calculations were performed using the corresponding EFSA Bee calculator Tool (Bee-Tool v.3) provided by EFSA.

The acute and chronic risks to adult honey bees and honey bee larvae bees from the use of CLOROL 200 SC were assessed using the maximum single application rates and the respective 'hazard quotients' (HQs) and 'exposure toxicity ratios' (ETRs).

Considering the proposed uses of at a maximum application rate a potential risk of formulation is indicated following the chronic exposure of adults and for honey bee larvae at this stage of testing. Therefore, 1st tier oral risk assessments were carried out by applicant.

The ETR values are less than the Tier 1 trigger values for downward sprays indicating that the chronic risk to honeybee bees is acceptable following use of CLOROL 200 SC according to the proposed uses.

For all intended uses, the Tier 1 assessment shows a ETR above the trigger, indicating a potential risk for the bee brood development. Therefore, further refinements are necessary.

Higher-tier studies, compliant with EPPO 170 and OECD 75 guidelines, were conducted with the comparable EU representative formulation and evaluated during the EU peer review (*DAR (2008)*).

In most of the tunnel tests, which all cover the maximum application rate of 54 g a.s./ha (tobacco), no adverse effects on adult honeybees and honeybee larvae were observed. *All the studies concluded to the absence of effects of Chlorantraniliprole on either the survival and behaviour of foragers or the colony condition (brood development), up to 28 days after application.*

The OECD 75 brood feeding study conducted at 2 x 60 or 1 x 120 Chlorantraniliprole 200 g /ha during full flowering of Phacelia tanacetifolia found no unacceptable effects on the condition of colonies and brood development relative to the water treated control. Therefore, the application of CLOROL 200 SC, according to the GAP, should not pose any problem to bee brood development.
In some studies at application rates of 60 g a.s./ha a slight increase in mortality and decrease in flight intensity was observed at the first days of exposure.
The review concluded that, based on available data, the risk to honeybees is acceptable. However, the suitability of semi-field studies for assessing chronic risk to honeybee larvae remains under discussion due to methodological limitations in their design.

When the new guidance EFSA Journal 2023;21(5):7989 will be applied, the semi-field studies will no

longer be considered relevant to refine chronic Tier 1 assessment. This was already questioned in EFSA Journal 2013;11(7):3295. This topic was also discussed in the Ecotox harmonization meeting in 2023, but no final agreement was reached. It was decided to continue to use these studies case by case.

The final decision on this issue and its impact on the registration process will be made by the Concerned Member State (cMS) during national product authorization. The cMS will consider the EFSA (2013) recommendations at a national level, as the current zonal risk assessment is only indicative until the guidance is formally adopted at the EU level.

An acceptable risk to bees of the formulation CLOROL 200 SC can be concluded, based on the risk assessment scheme of the Guidance Document on Terrestrial Eco-toxicology (SANCO/10329/2002 rev 2).

Hence, MSs should consider appropriate risk mitigation measures to address the identified risk.

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

Effects on non-target arthropods of Coragen 200 SC were evaluated as part of the EU assessment of chlorantraniliprole.

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

Species	Substance	Exposure System	Results	Reference
Typhlodromus pyri (protonymphs)	CORAGEN 200 SC	Laboratory test glass plates (2D)	LR_{50} = 750 g/ha ER_{50} = 750 g/ha	EFSA Journal 2013;11(6):3143
Aphidius rhopalosiphi (adults)	CORAGEN 200 SC	Laboratory test glass plates (2D)	LR_{50} = 750 g/ha ER_{50} = 750 g/ha	EFSA Journal 2013;11(6):3143
Episyrphus balteatus	CORAGEN 200 SC	Extended laboratory test	LR50 = 12.6 g a.s./ha ER50 (reproduction) = >13.3 g a.s./ha	EFSA Journal 2013;11(6):3143
Episyrphus balteatus aged residue 2 ´ 60 g a.s./ha	CORAGEN 200 SC	Aged residue study	Mortality: 43.8% and 33.5% effect at 28 and 42 days aging after 2 x´ 60 g a.s./ha Reproduction: no effects	EFSA Journal 2013;11(6):3143
Chrysoperla carnea	CORAGEN 200 SC	Extended laboratory test	LR50 >120 g a.s./ha ER50 (reproduction) >120 g a.s./ha	EFSA Journal 2013;11(6):3143

Species	Substance	Exposure System	Results	Reference
Orius laevigatus	CORAGEN 200 SC	Extended laboratory test	LR50 >120 g a.s./ha ER50 (reproduction) >120 g a.s./ha	EFSA Journal 2013;11(6):3143
Episyrphus balteatus	Chlorantraniliprole 35WG	Extended laboratory test	LR50 = 4.64 g a.s./ha	EFSA Journal 2013;11(6):3143
Coccinella septempunctata	CORAGEN 200 SC	Extended laboratory test	LR50 = 79.5 g a.s./ha ER50 (reproduction) = 13.3 g a.s./ha	EFSA Journal 2013;11(6):3143
Coccinella septempunctata aged residue 2 ´ 60 g a.s./ha	CORAGEN 200 SC	Aged residue study	Mortality = -7.8 to 18.6% Reproduction = no effect	EFSA Journal 2013;11(6):3143
Episyrphus balteatus;	*Chlorantraniliprole 20SC*	Aged residues on apple leaves (2D)	2 × 60 g a.s./ha (7 days interval) Mortality: 43.8% after 28 days 33.5% after 42 days Reproduction: No effects	EFSA Journal 2013;11(6):3143
Episyrphus balteatus;	*Chlorantraniliprole 35WG*	Aged residues on apple leaves (2D)	2 × 60 g a.s./ha (7 days interval) 28 DAT Mortality: 25% after 28 days 3.6% after 42 days Reproduction: No effects	EFSA Journal 2013;11(6):3143

9.7.1.1 Justification for new endpoints

Not required.

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 worst case scenario – 2 application of 110 g as/ha – covers all intended uses from GAP Table.~~

~~Table 9.7-2: First- and higher-tier assessment of the in-field risk for non-target arthropods due to the use of CLOROL 200 SC in worst case scenario – 2 x 110 g as/ha~~

~~Intended use~~			
~~Active substance/product~~	~~Chlorantraniliprole/Clorol 200 SC~~		
~~Application rate (g/ha)~~	~~2× 110 (worst case scenario for all Gap Table)~~		
~~MAF~~	~~1.7~~		
~~Test species~~ ~~Tier I~~	**~~LR_{50} (lab.)~~ ~~(g/ha)~~**	**~~$PER_{in\text{-}field}$~~ ~~(g/ha)~~**	**~~$HQ_{in\text{-}field}$~~ ~~criterion: HQ ≤ 2~~**
~~*Typhlodromus pyri*~~	~~750~~	~~187~~	~~0.25~~
~~*Aphidius rhopalosiphi*~~	~~750~~		~~0.25~~
~~Test species~~ ~~Tier II~~	**~~LR_{50} (lab.)~~** ~~(g/ha)~~	**~~$PER_{in\text{-}field}$~~** ~~(g/ha)~~	**~~$HQ_{in\text{-}field}$~~** ~~criterion: HQ ≤ 1~~
~~*Chryspoerla carnea*~~	~~13.3~~	~~187~~	~~14.06~~
~~*Coccinella septempunctata*~~	~~120~~		~~1.55~~
~~*Orius laevigatus*~~	~~120~~		~~1,55~~
~~Episyrphus balteatus~~	~~12.6~~		~~14.86~~

~~MAF: Multiple application factor; PER: Predicted environmental rate; HQ: Hazard quotient; DALT: Days after last treatment. Criteria values shown in bold breach the relevant trigger.~~
~~* If an LR_{50} or ER_{50} from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.~~

Comments of zRMS:

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group Small fruits (2 × 63 g a.s./ha, 7 days appl. interval) also covers the risk to non-target arthropods from all other intended uses.

zRMS is still of the opinion that the most sensitive species should be considered in the risk assessment.

Intended use	Vegetables, small fruits		
Active substance/product	CLOROL 200 SC		
Application rate (g/ha)	2 × 63 (7 days appl. interval)		
MAF	1.7 (foliar)/ 1.9 (soil)		
Test species **Tier II**	**ER_{50}** **(g a.s./ha)**	**$PER_{in\text{-}field}$** **(g a.s./ha)**	**Is $PER_{in\text{-}field}$** **< LR_{50}/ ER_{50} ?**
Coccinella septempunctata	13.3	107.1 (foliar)/ 119.7 (soil)	**No (potential risk)**
Orius laevigatus	>120		Yes (acceptable risk)
Episyrphus balteatus	12.6		**No (potential risk)**

No appropriate residue decline or aged residue study for the two most sensitive species, *Coccinella septempunctata* and *Episyrphus balteatus* has been provided for further refinement, therefore the in-field risk has not been addressed for application 2 × 63 g a.s./ha (7 days appl. interval).

The assessment for the use group with lower dose small fruits (2 × 50 g a.s./ha, 7 days appl. interval) which covers the risk to non-target arthropods from all other intended uses is calculated.

Intended use	Vegetables, small fruits
Active substance/product	CLOROL 200 SC

Application rate (g/ha)	2 × 50 (7 days appl. interval)		
MAF	1.7 (foliar)/ 1.9 (soil)		
Test species Tier II	**ER_{50} (g a.s./ha)**	**$PER_{in\text{-}field}$ (g a.s./ha)**	**Is $PER_{in\text{-}field}$ < LR_{50}/ ER_{50} ?**
Coccinella septempunctata	13.3	85 (foliar)/ 95 (soil)	**No (potential risk)**
Orius laevigatus	>120		Yes (acceptable risk)
Episyrphus balteatus	12.6		**No (potential risk)**

For the two most sensitive species, *Coccinella septempunctata* and *Episyrphus balteatus*, aged residues studies are available. These studies indicate a potential of recolonization within a year after two applications of 60 g a.s./ha, covering the intended uses of CLOROL 200 SC.

In conclusion, acceptable in-field risk can be concluded when CLOROL 200 SC is applied according to the modified GAP only excluding use in tomato (2 × 63 g a.s./ha).

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 worst case scenario – 2 application of 110 g as/ha – covers all intended uses from GAP Table.~~

~~Table 9.7-3: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of CLOROL 200 SC in worst case scenario – 2 x 110 g as/ha~~

~~Intended use~~					
~~Active substance/product~~	~~Chlorantraniliprole/Clorol 200 SC~~				
~~Application rate (g/ha)~~	~~2 x 110 (worst case scenario for All Gap Table)~~				
~~MAF~~	~~1.7~~				
~~vdf~~	~~10 (Tier 1)/ 1 (TIER 2)~~				
~~Test species Tier I~~	**~~LR_{50} (lab.) (g/ha)~~**	**~~Drift rate~~**	**~~$PER_{off\text{-}field}$ (g/ha)~~**	**~~CF~~**	**~~$HQ_{off\text{-}field}$ criterion: HQ ≤ 2~~**
~~*Typhlodromus pyri*~~ ~~*Aphidius rhopalosiphi*~~	~~750~~	~~0.0277~~ ~~0.0238 (for field and h<50 cm)~~	~~0.5180~~	~~5~~	~~0.0001~~ ~~0.0035~~
		~~0.0802~~ ~~0.0723 (for vines and h>50 cm)~~	~~1.5000~~		~~0.0004~~ ~~0.01~~
		~~0.2920~~ ~~0.2553 (for fruit early)~~	~~5.46~~		~~0.002~~ ~~0.036~~
		~~0.1573~~ ~~0.1213 (for fruit late)~~	~~2.94~~		~~0.0008~~ ~~0.0196~~

~~Test species Tier II~~	~~LR_{50} (lab.) (g/ha)~~	~~Drift rate~~	~~$PER_{off\text{-}field}$ (g/ha)~~	~~CF~~	~~$HQ_{off\text{-}field}$ criterion: HQ ≤ 1~~
~~*Episyrphus balteatus (worst case scenario for TIER II species)*~~	~~12.6~~	~~0.0277 0.0238 (for field and h<50 cm)~~	~~5.180~~	~~5~~	~~2.06~~
		~~0.0802 0.0723 (for vines and h>50 cm)~~	~~15.000~~		~~5.95~~
		~~0.2920 0.2553 (for fruit early)~~	~~54.6~~		~~21.7~~
		~~0.1573 0.1213 (for fruit late)~~	~~29.4~~		~~11.67~~

~~MAF: Multiple application factor; vdf: Vegetation distribution factor; (corr.) PER: (corrected) Predicted environmental rate; CF: Correction factor; HQ: Hazard quotient. Criteria values shown in bold breach the relevant trigger.~~
~~* If an LR_{50} or ER_{50} from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.~~

Comments of zRMS:

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group vegetables, small fruits (2 × 50 g a.s./ha) and orchards (2 × 35 g a.s./ha) also covers the risk to non-target arthropods from all other intended uses (excluding use in tomato (2 × 63 g a.s./ha)).

Intended use	Vegetables, small fruits
Active substance/product	CLOROL 200 SC
Application rate (g/ha)	2 × 50
MAF	1.7
vdf	5
drift factor (% drift/100)	0.0723 (heigh > 50 cm, at a distance of 3 m) / 0.0238 (heigh > 50 cm, at a distance of 1 m)

Test species Tier I	**LR_{50} (lab.) (g a.s./ha)**	**$PER_{off\text{-}field}$ (g a.s./ha)**	**CF**	**$HQ_{off\text{-}field}$ criterion: HQ ≤ 2**
Typhlodromus pyri	>750	1.23 / 0.4	10	<0.058 / < 0.0054
Aphidius rhopalosiphi	>750			<0.058 / < 0.0054

Intended use	Orchards
Active substance/product	CLOROL 200 SC
Application rate (g/ha)	2 × 35
MAF	1.7
vdf	5
drift factor (% drift/100)	0.1213 (heigh, at a distance of 3 m) / 0.2552 (early, at a distance of 3 m)

Test species Tier I	**LR_{50} (lab.) (g a.s./ha)**	**$PER_{off\text{-}field}$ (g a.s./ha)**	**CF**	**$HQ_{off\text{-}field}$ criterion: HQ ≤ 2**

Typhlodromus pyri	>750	1.44 / 3.036	10	<0.02 / <0.04
Aphidius rhopalosiphi	>750			<0.02 / <0.04

Consistent with the approach followed in EFSA Journal 2013;11(6):3143, the off-field assessment should be based on the worst-case endpoint: the LR50 of **12.6** g a.s./ha for Episyrphus balteatus. This is required despite aged residue studies showing a potential for recolonization within the year for the two most sensitive species, which would otherwise indicate an acceptable in-field risk.

Intended uses	AR (g a.s./ha)	MAF	Drift (%)	VDF	CF	Corrected $PER_{off\text{-}field}$
Field crops (tobacco) 1 x 54 g a.s./ha	54	1	2.77	5	5	1.5
Field crops (rest) 2 x 35 g a.s./ha	35	1.7	2.38			1.42
Orchards (late) 2 x 35 g a.s./ha	35	1.7	12.13			7.22
Orchards (early) 2 x 35 g a.s./ha	35	1.7	25.53			**15.19**
Grapevine 1 x 54	54	1	8.02			4.33
Vegetables, Ornamentals, Small fruits < 50 cm 2 x 25 g a.s./ha	25	1.7	2.38			2.19
Vegetables, Ornamentals, Small fruits >50 cm 1 x 35 g a.s./ha	35	1	8.02			2.8
Vegetables, Ornamentals, Small fruits < 50 cm 2 x 43 g a.s./ha	43	1.7	2.38			1.74
Vegetables, Ornamentals, Small fruits >50 cm 2 x 43 g a.s./ha	43	1.7	7.23			5.28
Vegetables, Ornamentals, Small fruits < 50 cm 2 x 50 g a.s./ha	50	1.7	2.38			2.02
Vegetables, Ornamentals, Small fruits >50 cm 2 x 50 g a.s./ha	50	1.7	7.23			6.15
Vegetables, Ornamentals, Small fruits < 50 cm 2 x 63 g a.s./ha	63	1.7	2.38			2.55
Vegetables, Ornamentals, Small fruits >50 cm 2 x 63 g a.s./ha	63	1.7	7.23			7.74

For all intended uses in the modified GAP the corrected $PER_{off\text{-}field}$ values are below the ER_{50}, indicating acceptable risks, except for the early application in Orchards (early applications).

When considering the worst-case endpoint of **12.6** g a.s./ha (*Episyrphus balteatus, (Episyrphus balteatus, 2-D extended laboratory experiment)*, further risk mitigation measure is required for the intended uses in orchards.

Intended use	Orchards (early applications)
Active substance/product	CLOROL 200 SC
Application rate (g/ha)	2 x 35 g a.s./ha
MAF	1.7
vdf	5
CF	5

Buffer strip (m)	**Drift rate (%)**	**Corrected $PER_{off-field}$ (g a.s./ha)**	**Corrected $PER_{off-field}$ 50 % drift red. (g a.s./ha)**
3	25.53	15.19	9.04
5	16.87	10.04	-
Worst case toxicity value		**Corrected $PER_{off-field}$ < ER_{50} value?**	
ER_{50} = 12.6 g a.s./ha			
3		**no**	yes
5		yes	-

To demonstrate acceptable risks for the intended uses in orchards, the following risk management measures should be applied:

- 50% drift reduction, or
- 5m buffer zone.

However, for the the in-field Tier II assessment for Episyrphus balteatus assessment indicate an unacceptable risk for the use in tomatoes. No appropriate residue decline or aged residue study has been provided for further refinement, therefore the in-field risk has not been addressed and remains open for this use.

9.7.2.3 Additional higher-tier risk assessment

~~Not relevant.~~

According to Aged residue study conducted on Episyphis balteatus (Warmers, C. (2006e)) The effect of 28 and 42 day field-aged spray deposits after the 2nd application of the test item on apple leaves onEpisyrphus balteatus at 2 × 60 g a.s. of Coragen/ha (equivalent to 2 × 300 mL Coragen 200 SC) with a 7-day spray interval under extended laboratory conditions resulted in 43.8% and 33.5% corrected mortality, respectively.
In the test no treatment-related effects on reproduction of Episyrphus balteatus were observed when exposed to 28 day and 42 day field-aged spray deposits after the 2nd application on Episyrphus balteatus at 2 × 300 mL CORAGEN 200 SC/ha (equivalent to 2 × 60 g active substance chlorantraniliprole/ha) with a 7-day spray interval since females laid fertile eggs in both bioassays.

Mortality and reproduction of *Episyrphus balteatus* exposed to field-aged spray deposits of 2 applications of DPX-E2Y45 20SC on apple leaves

Test substance	Mortality (%)[a]	Corrected Mortality (%)[b]	Fecundity (total no. of eggs/female)	Fertility (mean no. of fertile eggs/female)
28-day field aged spray deposits				
Control	64.4	-	115.5 [c]	4.8[c]
DPX-E2Y45 20SC	80.0	43.8	29.0[d]	7.8[d]
Toxic reference item	100.0*	100	n.a.	n.a.
42-day field aged spray deposits				
Control	28	-	251.8	11.2
DPX-E2Y45 20SC	52.1*	33.5	202.7	16.1
Toxic reference item	100.0*	100	n.a.	n.a.

[a] Includes the no. of dead larvae and the no. of not emerged pupae
[b] Corrected mortality according to Abbott (1925), modified by Schneider-Orelli (1947)
[c] Reproduction assessment done only with 2 females
[d] Reproduction assessment done only with 1 female
* statistically significantly different when compared to the control (Fisher`s Exact – test, alpha= 0.05)
n.a. = not assessed

olation. Registration must not be granted on the basis of

According to Aged residue study conducted on Cocinella septempunctata (Warmers, C. (2006g)) Field-aged residues of DPX-E2Y45 20SC/ha (applied twice at 60 g DPX-E2Y45/ha) had no effects on mortality or reproduction of C. septempunctata. Corrected mortalities after 28- and 78-days of larval exposure to field-aged residues were 18.6% and -7.8%. Fertility measures were 2.7 and 10.8 fertile eggs/female/day in the 28- and 78-day aged residue exposures. According to the guideline no treatment-related effects are shown because ≥2 fertile eggs/female/day were found.

Mortality and reproduction of *Coccinella septempunctata* exposed to 28 day or 78 day field-aged spray deposits of DPX-E2Y45 20SC on apple leaves

Test substance	Mortality (%)[a]	Corrected Mortality (%)[b]	Fecundity (mean no. of eggs/female)	Mean hatching rate (%)	Fertility (mean no. of fertile eggs/ female/d)
28-d field aged residues					
Control	10.0	-	16.8	66.6	11.0
DPX-E2Y45 20SC	26.7	18.6	6.7	42.3	2.7
Toxic reference item	100.0*	100.0	n.a.	n.a.	n.a.
78-d field aged residues					
Control	20.0	-	21.2	83.0	17.7
DPX-E2Y45 20SC	13.8	-7.8	15.7	68.5	10.8

[a] Includes the no. of dead larvae and the no. of not emerged pupae
[b] Corrected mortality according to Abbott (1925), modified by Schneider-Orelli (1947)
* Significantly different compared to the control (Fisher`s Exact – test, alpha = 0.05)
n.a. = not assessed

EC evaluation data package and should not be us

9.7.2.4 Risk mitigation measures

No risk mitigation needed.

Regards to unacceptable risk exposure for most sensitive species Episyphis balteatus (LR50= 12.6 g/ha),

the risk mitigation divided on different crop group with worst case scenario for each one is presented below:

Table 9.7-4: Risk mitigation measures for field crop and vegetables with high < 50 cm

Intended use		Field crops and h<50 cm			
Active substance/product		AKO 600 SC			
Application rate (g/ha)		2 x 63 (worst case scenario)			
MAF		1			
CF		5			
VDF		1			
Buffer strip (m)	**Drift rate (%) (worst values for one and two application – don't have impact on buffer zone)**	**$PER_{off-field}$ (g/ha)**	**$PER_{off-field}$ 50 % drift red. (g/ha)**	**$PER_{off-field}$ 75 % drift red. (g/ha)**	**$PER_{off-field}$ 90 % drift red. (g/ha)**
1	0.0277	2.96	1.48	-	-
5	0.0057	0.61	-	-	-
Toxicity value					
ER_{50} = 12.6 g/ha		**criterion: HQ ≤ 1**			
1	0.0277	1.17	0.58	-	-
5	0.0057	0.24	-	-	-

Table 9.7-5: Risk mitigation measures for vines, ornamental and vegetables with high > 50 cm

Intended use		for vines and h>50 cm			
Active substance/product		AKO 600 SC			
Application rate (g/ha)		2 x 110 (worst case scenario)			
MAF		1			
CF		5			
VDF		1			
Buffer strip (m)	**Drift rate (%) Early/late (worst values fo one and two application – don't have impact on buffer zone)**	**$PER_{off-field}$ (g/ha)**	**$PER_{off-field}$ 50 % drift red. (g/ha)**	**$PER_{off-field}$ 75 % drift red. (g/ha)**	**$PER_{off-field}$ 90 % drift red. (g/ha)**
3	2.70/8.02	5.04/14.99	2.52/7.50	1.26/3.74	-/1.50
5	1.18/3.62	2.2/6.77	-/3.39	-/1.69	-

10	0.39/1.23	-/2.3	-	-	-
Toxicity value ER_{50} = 12.6 g/ha		**criterion: HQ ≤ 1**			
1	2.70/8.02	2/5.95	1/2.98	0.5/1.48	-/0.60
5	1.18/3.62	0.87/2.69	-/1.35	-/0.67	-
10	0.39/1.23	-/0.91	-	-	-

Table 9.7-6: fruit crops

Intended use		Fruit crops			
Active substance/product		AKO 600 SC			
Application rate (g/ha)		2 x 35			
MAF		1.7			
CF		5			
VDF		1			
Buffer strip (m)	**Drift rate (%) Early/late (worst values for one and two applica-tion – don't have impact on buffer zone)**	**$PER_{off-field}$ (g/ha)**	**$PER_{off-field}$ 50 % drift red. (g/ha)**	**$PER_{off-field}$ 75 % drift red. (g/ha)**	**$PER_{off-field}$ 90 % drift red. (g/ha)**
3	29.20/15.73	17.4/9.38	8.7/4.69	4.35/2.35	1.74/-
5	19.89/8.41	11.85/5.01	5.93/2.51	2.96/-	1.19/-
10	11.81/3.60	7.04/2.14	3.52/-	1.76/-	-
15	5.55/-	3.30/-	1.65/-	-	-
20	2.77/-	1.65/-	-	-	-
Toxicity value ER_{50} = 12.6 g/ha		**criterion: HQ ≤ 1**			
1	29.20/15.73	6.9/3.72	3.45/1.86	1.71/0.93	0.69/-
5	19.89/8.41	4.70/1.99	2.35/0.99	1.17/-	0.47/-
10	11.81/3.60	2.79/0.84	1.39/-	0.70/-	-
15	5.55/-	1.32/-	0.65/-		-
20	2.77/-	0.65/-			-

9.7.3 Overall conclusions

~~CLOROL 200 SC pose no unacceptable risk to nontarget arthropods than bees~~ ~~if maximum application is~~

~~lower or equival to 2 application of 0.3 L/ha (60 g as/ha) in- field scenario.~~

~~For protection non-target arthropods than bees in off-field scenario, buffer zones presented below has to be take into account:~~

~~Field crops and vegetables h <50cm:~~
- ~~5 meters buffer zone or~~
- ~~1 meters and 50% nozzle reduction~~

~~Vines and ornamentals and vegetables h > 50 cm:~~

~~e) Late application:~~
- ~~10 meters buffer zone~~
- ~~5 meters buffer zone and 75 nozzle reduction~~
- ~~1 meter buffer zone and 90% nozzle reduction~~

~~f) Early application:~~
- ~~5 meter buffer zone~~
- ~~1 meters and 75% nozzle reduction~~

~~Fruit crops:~~

~~g) Late application:~~
- ~~10 meters buffer zone~~
- ~~5 meters buffer zone and 50% nozzle reduction~~
- ~~1 meter buffer zone and 75% nozzle reduction~~

~~h) Early application:~~
- ~~20 meter buffer zone~~
- ~~15 meters buffer zone and 50% nozzle reduction~~
- ~~10 meters buffer zone and 75% nozzle reduction~~
- ~~1 meters and 90% nozzle reduction~~

zRMS Comments:
The submitted risk assessment based on the "Guidance Document on Terrestrial Ecotoxicology" (2002) was accepted.

For the intended uses of CLOROL 200 SC outlined in the modified GAP, the risk to in-field and off-field non-target arthropod populations is acceptable with the exception of the use in tomatoes. No further refinement is proposed because this use has not been demonstrated to be safe for aquatic organisms.

To demonstrate acceptable risks for the intended uses in orchards, the following risk management measures should be applied:
- 50% drift reduction, or
- 5m buffer zone.

Conclusion
The risk to arthropods other than bees is acceptable if CLOROL 200 SC is applied in accordance with the proposed use pattern, taking into account the recommended risk management measures, with the exception of proposed use in tomatoes.

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 chlorantraniliprole and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents as well as in Appendix 2 of this document (new studies).

Effects on earthworms and other non-target soil organisms (meso- and macrofauna) of Chlorantraniliprole 200 g/L SC were evaluated as part of the EU assessment of chlorantraniliprole. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

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

Species	Substance	Exposure System	Results	Reference
Eisenia fetida	IN-EQW78	Mixed into substrate / Overspray ~~28~~ 56 d, chronic 5/10 % peat content	NOEC = 1000 mg met/kg dw	Chlorantraniliprole DAR, Vol. 3, B9, Part 2, pages 32-36 (PDF pagination) DuPont-17093 EFSA Journal 2013;11(6):3143
Eisenia fetida	IN-ECD73	Mixed into substrate / Overspray ~~28~~ 56 d, chronic 5/10 % peat content	NOEC = 1000 mg met/kg dw	Chlorantraniliprole DAR, Vol. 3, B9, Part 2, pages 36-40 (PDF pagination) DuPont-17632 EFSA Journal 2013;11(6):3143
Eisenia fetida	~~IN-EQW78~~ IN-GAZ70	Mixed into substrate / Overspray ~~28~~ 56 d, chronic 5/10 % peat content	NOEC = 1000 mg met/kg dw	Chlorantraniliprole DAR, Vol. 3, B9, Part 2, pages 40-44 (PDF pagination) DuPont-17633 EFSA Journal 2013;11(6):3143
Eisenia fetida	Chlorantraniliprole 35 WG	Mixed into substrate / Overspray 56 d, chronic 5/10 % peat content	NOEC = 350 mg as/kg dw	Chlorantraniliprole DAR, Vol. 3, B9, Part 2, pages 28-32 (PDF pagination) DuPont-16694 EFSA Journal 2013;11(6):3143
Eisenia andrei	CLOROL	Mixed into substrate / Overspray 56 d, chronic 5/10 % peat content	Nominal: LC10=EC10 > 1000 mg test item/kg nom NOEC-625 mg test item/kg nom Geometric mean for	K. Wesołowska,2025 Study code:ETOX-2024-64

Species	Substance	Exposure System	Results	Reference
			as: LC10=EC10 > 159.31 mg /kg NOEC= 99.71 mg/kg	
Folsomia candida	Chlorantraniliprole	Mixed into substrate / Overspray 28 d, chronic 5 % peat content	28-d EC_{50} (reproduction): 0.85 mg a.s./kg d.w. soil 28-d EC_{10} (reproduction): 0.35 mg a.s./kg d.w. soil 28-d NOEC (reproduction): 0.39 mg a.s./kg d.w. soil	Chlorantraniliprole DAR, Vol. 3, B9, Part 1, pages 425-430 (PDF pagination) DuPont-18730 EFSA Journal 2013;11(6):3143
Folsomia candida	IN-EQW78	Mixed into substrate / Overspray 28 d, chronic 5 % peat content	28-d EC_{50} (reproduction): >100 mg met./kg d.w. soil 28-d EC_{10} (reproduction): >100 mg met./kg d.w. soil 28-d NOEC (reproduction): 100 mg met./kg d.w. soil	Chlorantraniliprole DAR, Vol. 3, B9, Part 1, pages 430-434 (PDF pagination) DuPont-16531 EFSA Journal 2013;11(6):3143
Folsomia candida	IN-ECD73	Mixed into substrate / Overspray 28 d, chronic 5 % peat content	28-d EC_{50} (reproduction): >100 mg met./kg d.w. soil 28-d EC_{10} (reproduction): >100 mg met./kg d.w. soil 28-d NOEC (reproduction): 100 mg met./kg d.w. soil	Chlorantraniliprole DAR, Vol. 3, B9, Part 1, pages 434-438 (PDF pagination) DuPont-17083 EFSA Journal 2013;11(6):3143
Folsomia candida	IN-GAZ70	Mixed into substrate / Overspray 28 d, chronic 5 % peat content	28-d EC_{50} (reproduction): >100 mg met./kg d.w. soil 28-d EC_{10} (reproduction): >100 mg met./kg d.w. soil 28-d NOEC (reproduction): 100 mg met./kg d.w. soil	Chlorantraniliprole DAR, Vol. 3, B9, Part 1, pages 438-442 (PDF pagination) DuPont-17084 EFSA Journal 2013;11(6):3143
Folsomia candida	IN-F6L99	28-day Chronic	NOEC 100 mg a.s./kg d.w. soil	EFSA Journal 2013;11(6):3143
Folsomia candid	Clorol 200 SC	Mixed into substrate / Overspray 28 d, chronic 5 % peat content	28-d EC_{50} (reproduction): >3.84 mg prot mg/kg d.w. soil 28-d EC_{10} (reproduction): >1.65 mg prod/kg d.w. soil	E. Kulec – Płoszczyca, study code: ETO-2023-13

Species	Substance	Exposure System	Results	Reference
			28-d NOEC (reproduction): 1.56 mg prod/kg d.w. soil which is equivalen to 0.25 mg/kg as/ kg dw soil	
Hypoaspis aculeifer	Chlorantraniliprole	Mixed into substrate / Overspray ~~28~~ 16 d, chronic 5 % peat content	28-d EC_{50} (reproduction): >100 mg a.s./kg d.w. soil 28-d EC_{10} (reproduction): >100 mg a.s./kg d.w. soil 28-d NOEC (reproduction): 100 mg a.s./kg d.w. soil	Chlorantraniliprole DAR, Vol. 3, B9, Part 1, pages 442-446 (PDF pagination) DuPont-19748 EFSA Journal 2013;11(6):3143
Hypoaspis aculeifer	CLOROL 200 SC	Mixed into substrate / Overspray 28 d, chronic 5 % peat content	LC10= 13.09 mg test item/kg = 2.39 mg as/kg (morality) nom NOEC = 555.6 mg item/kg = 101.54 mg as/kg (morality) nom EC10=NOEC > 1000 mg test item/kg > 182.76 mg as/ha (reproduction) Geometric mean for as: LC10 = 1.70 mg as/kg (morality) NOEC= 96.34 mg/kg (morality) EC10=NOEC > 175.58 mg a.s./kg (reproduction)	S. Groch, 2025, Study code: ETOX-2024-65
Field studies				
Litter bag test				
~~Leaf~~ Field litter bag test	Chlorantraniliprole 200 g/L SC	~~Chlorantraniliprole 200 g/L SC was applied twice to bare soil at 786.3 mL/ha (equivalent to 156.16 g a.s./ha) and then at 755.3 mL/ha (equivalent to 150 g a.s./ha). The first application was incorporated to a depth of 10 cm, the second was applied to the surface after burying the litter bags to 5 cm and seeding the plots with barley. Over a period of 12 months, a sufficient level of litter breakdown~~	Chlorantraniliprole DAR, Vol. 3, B9, Part 1, pages 446-451 (PDF pagination) DuPont-12752, Revision No. 1 EFSA Conclusion (2013)	

Species	Substance	Exposure System	Results	Reference
		~~was achieved and no statistically significant difference in litter breakdown between the control and treated plots was seen (max. deviation 5.1% 1 month after initiation).~~ Chlorantraniliprole 20SC: No effects seen on degradability of soil organic matter in 12 month litter bag study under exposure conditions simulating 10 years continual use at an annual rate of 150 g a.s./ha.		
	Chlorantraniliprole 35WG and metabolites	No effects seen on degradability of soil organic matter in 17 month litter bag study under exposure conditions simulating 10 years continual use at an annual rate of 240 g a.s./ha.		

* 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

Not required

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).

zRMS comment: According to the Terrestrial Ecotoxicology Guidance Document (SANCO/10329/2002, 17 October 2002, version 2 final), when the log Pow is greater than 2, endpoints should be divided by a factor of 2. In the DAR for chlorantraniliprole (Vol. 3B.9 Ecological Effects Assessment, December 2008) the applicant provided a scientifically justified case to support not using this correction factor, which was accepted by the RMS. Therefore, the endpoints were not corrected by the factor 2 in this application.

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, Table 8.7-3. According to the assessment of environmental-fate data, multi-annual accumulation in soil does not need to be considered for chlorantraniliprole.
To achieve a concise risk assessment, the risk envelope approach is applied. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the worst case scenario – 2 application of 110 g as/ha – covers all intended uses from GAP Table.

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 CLOROL 200 SC

Intended use	All GAP Worst case scenario – 2x 110 g as/ha		
Acute effects on earthworms			
Product/active substance	**LC_{50} (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_a (criterion TER ≥ 10)**
Not required.			
Chronic effects on earthworms			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
IN-EQW78	NOEC = 1000 mg met/kg dw	~~0.4035/ 0.018~~ 0.1447**	~~2 478/ 55 555~~ 6 911
IN-ECD73	NOEC = 1000 mg met/kg dw	~~0.0807/ 0.0038~~ 0.0782**	~~12 391/ 263 157~~ 12 788
IN-GAZ70	NOEC = 1000 mg met/kg dw	~~0.0914/ 0.0041~~ 0.1014**	~~10 940/243 902~~ 9 862
Chlorantraniliprole 35 WG	NOEC = 350 mg as/kg dw	~~1.04/ 0.0654~~ 0.5250**	~~336/5 352~~ 666.7
CLOROL 200 SC	~~NOEC = 625 mg test item/kg~~ nom ~~NOEC = 99.71 as/kg~~ NOEC = 99.71 as/kg geom.mean*	~~1.248/ 0.192~~ ~~1.04~~ 0.5246**	~~500.8/ 1 693~~ ~~95.86/~~ 189.9
Chronic effects on other soil macro- and mesofauna – Folsomia candida			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Chlorantraniliprole	28-d NOEC (reproduction): 0.39 mg a.s./kg d.w. soil	~~1.04/ 0.0654~~ 0.5249**	~~0.375/ 5.96~~ **0.743**
IN-EQW78	28-d NOEC (reproduction): 100 mg met./kg d.w. soil	~~0.4035/ 0.018~~ 0.1447**	~~247/5556~~ 691
IN-ECD73	28-d NOEC (reproduction): 100 mg met./kg d.w. soil	~~0.0807/ 0.0038~~ 0.0782**	~~1 239/26 316~~ 1 279
IN-GAZ70	28-d NOEC (reproduction): 100 mg met./kg d.w. soil	~~0.0914/ 0.0041~~ 0.1014**	~~1 094/ 24 390~~ 986
IN-F6L99	28-day Chronic: 100 mg a.s./kg d.w. soil	0.0063	15 873

Clorol 200 SC	28-d NOEC (reproduction): 1.56 mg prod/kg d.w. soil 28 -d NOEC (reproduction): 0.25 mg as/kg dw soil	~~1.2848/ 0.192~~ 0.7358** 0.5249**	~~1.2/ 8.21~~ **2.12** **0.4763**
Chronic effects on other soil macro- and mesofauna – Hypoaspis aculeifer			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Chlorantraniliprole	28-d NOEC (reproduction): 100 mg a.s./kg d.w. soil	~~1.04/ 0.0654~~ 0.5249**	~~96/~~ 190.5
CLOROL 200 SC	LC10=13.09 mg test item/kg/ ~~LC10=1.70 mg as/kg~~ LC10=1.70 mg as/kg geomen. mean*	~~1.2484/0.192~~ ~~0.2341 (PEcini was taking in the account because study show only influence on mortality after application)~~ 0.5249**	~~11.13/68.17~~ ~~7.26~~ **3.24**

TER values shown in bold fall below the relevant trigger.

*The chemical analysis of the test item showed, that the concentrations of the active ingredient has not been maintained within ± 20% of the nominal values, therefore the geometric mean of the measured concentrations should be used for the risk assessment.
** Corrected according to Part B8

zRMS comments:
For the predatory mite *Hypoaspis aculeifer* no laboratory studies were submitted with the metabolites. However, based on the results with the active substance and the intended formulation it was shown that the springtail *Folsomia candida* is the most sensitive species. Therefore can be considered that the risk to soil organisms from exposure to the soil metabolites is covered by the available data with the earthworm and the springtail.

Regards to unacceptable risk on Folsomia candida and Hypoaspis aculeifer presented above on worst case scenario, the risk assessment only for chlorantraniliprole based on tiers and group crops according to scheme presented in Part B8 is presented below:

Table 9.8-3: Tiers Risk refinment for different crop group form Gap Table for Folsomia candida

Group Crop	PECCacc [mg/kg] (TIER)	NOEC = 0.39 mg as/kg	NOEC = 0.25 mg as/kg (based on study on formulation)
Pome/Stone Fruit	0.2218 (TIER 1)	1.7583	1.1271
	0.1219 (TIER 2)	3.1993	2.0509
	0.0915 (TIER 3)	4.2623	2.7322

	~~0.0505~~ 0,0600* (TIER 4)	~~7.7228~~ 6.5	~~4.9505~~ **4.2**
	~~0.0424 (TIER 5)~~**	~~9.1981~~	~~5.8962~~
Pome/Stone Fruit in every 2nd year***	0,0483 (Tier 4)	8.07	5.18
Maize	0.0187 (TIER 1)	20.8556	13.3690
Oilseeds – two applications	0.1047 0.0417* (TIER 1)	~~3.7249~~ 9.35	~~2.3878~~ 5.995
	~~0.0729 (TIER 2)~~	~~5.3498~~	~~3.4294~~
	~~0.0633 (TIER 3)~~	~~6.1611~~	~~3.9494~~
	~~0.0499 (TIER 4)~~	~~7.8156~~	~~5.0100~~
Oilseeds – one application	~~0.0261~~ 0.0209* (TIER 1)	~~14.9425~~ 18.66	~~9.5785~~ 11.96
Sugar beet	0.0179 (TIER 1)	21.7877	13.9665
Potato	0.0298 (TIER 1)	13.0872	8.3893
Carrots and roots Vegetables	0.0784 (TIER 1)	4.9745	3.1888
	0.0550 (TIER 2)	7.0909	4.5455
	0.0479 (TIER 3)	8.1420	5.2192
Sunflower	0.0261 (TIER 1)	14.9425	9.5785
Soya	0.0157 (TIER 1)	24.8408	15.9236
Cabbage and vegetables leafy in field uses	~~0.0625~~ 0.0893* (TIER 1)	~~6.2400~~ **4.367**	~~4.0000~~ **2.799**
	~~0.0437~~ 0.0625* (TIER 2)	~~8.9245~~ 6.24	~~5.7208~~ **4.0**
	0.0542 (Tier 3)	7.20	**4.61**

	0.0455 (Tier 4)	8.57	5.49
Cabbage and vegetables leafy in field uses in every 2nd year***	0.0646 (Tier 1)	6.07	**3.87**
	0.0511 (Tier 2)	7.63	**4.89**
	0.0469 (Tier 3)	8.32	5.33
~~Cabbage and vegetables leafy in greenhouses uses at bbch 12~~**	~~0.1879 (TIER 1)~~	~~2.0756~~	~~1.3305~~
	~~0.1316 (TIER 2)~~	~~2.9635~~	~~1.8997~~
	~~0.1144 (TIER 3)~~	~~3.4091~~	~~2.1853~~
	~~0.0910 (TIER 4)~~	~~4.2857~~	~~2.7473~~
	~~0.0861 (TIER 5)~~	~~4.5296~~	~~2.9036~~
Cabbage and vegetables leafy in greenhouses uses at bbch 20	~~0.0751~~ 0.1503* (TIER 1)	~~5.1931~~ **2.59**	~~3.3289~~ **1.66**
	~~0.0526~~ 0.1053* (TIER 2)	~~7.4144~~ **3.70**	~~4.7529~~ **2.37**
	~~0.0458~~ 0.0915* (TIER 3)	~~8.5153~~ **4.26**	~~5.4585~~ **2.73**
	0.0.0772 (Tier 4)	5.05	**3.24**
Cabbage and vegetables leafy in greenhouses uses at BBCH 20 1x42g/ha***	0.0753 (Tier 1)	5.18	**3.32**
	0.0528 (Tier 2)	7.39	**4.73**
	0.046 (Tier 3)	8.48	5.43
Cabbage and vegetables leafy in greenhouses uses at BBCH 20 2x25g/ha***	0.0895 (Tier 1)	**4.36**	**2.79**
	0.0627 (Tier 2)	6.22	**3.99**
	0.0545 (Tier 3)	7.16	**4.59**
	0.0459 (Tier 4)	8.50	5.45
Pumpkin and vegeta-	0.0209	18.6603	11.9617

bles fruiting in field uses	(TIER 1)		
~~Tomato and vegetables fruiting in greenhouses uses at BBCH 15~~**	~~0.1879 (TIER1)~~	~~2.0756~~	~~1.3305~~
	~~0.1316 (TIER 2)~~	~~2.9635~~	~~1.8997~~
	~~0.1144 (TIER 3)~~	~~3.4091~~	~~2.1853~~
	~~0.0910 (TIER 4)~~	~~4.2857~~	~~2.7473~~
	~~0.0861 (TIER 5)~~	~~4.5296~~	~~2.9036~~
Tomato and vegetables fruiting in greenhouses uses at BBCH 20	0.1127 (Tier 1)	3.4605	2.2183
	0.0790 (Tier 2)	4.9367	3.1646
	0.0687 (Tier 3)	5.6769	3.6390
	0.0546 (Tier 4)	7.1429	4.5788
	~~0.0517 (Tier 50)~~**	~~7.5435~~	~~4.8356~~
Tomato and vegetables fruiting in greenhouses uses at BBCH 20 and maximum dose ~~62~~ 63 g/kg every two year	~~0.0498 (TIER 5)~~**	~~7.8313~~	~~5.0201~~
Tomato and vegetables fruiting in greenhouses uses at BBCH 20 and at dose 1x 50 g /ha	0.0448 (Tier 1)	8.71	5.58
Vines	0.1717 (TIER 1)	2.2714	1.4560
	0.0947 (TIER 2)	4.1183	2.6399
	0.0713 (TIER 3)	5.4698	3.5063
	~~0.0399~~ 0.0471* (TIER 4)	~~9.7744~~ 8.28	~~6.2657~~ 5.31
Grass	~~0.1113~~ 0.0278* (TIER 1)	~~3.5040~~ 14.03	~~2.2462~~ 8.99
	~~0.0614~~	~~6.3518~~	~~4.0717~~

	~~(TIER 2)~~		
	~~0.0462 (TIER 3)~~	~~8.4416~~	~~5.4113~~
~~Tobbaco at BBCH 20 -~~ **	~~0.1968 (TIER 1)~~	~~1.9817~~	~~1.2703~~
	~~0.1379 (TIER 2)~~	~~2.8281~~	~~1.8129~~
	~~0.1199 (TIER 3)~~	~~3.2527~~	~~2.0851~~
	~~0.0953 (TIER 4)~~	~~4.0923~~	~~2.6233~~
	~~0.0902 (TIER 5)~~	~~4.3237~~	~~2.7716~~
Tobbaco at BBCH 30 -	~~0.0656~~ 0.0484* (TIER 1)	~~5.9451~~ 8.06	~~3.8110~~ 5.17
	~~0.0460 (TIER 2)~~	~~8.4783~~	~~5.4348~~

* Corrected according to Part B8
** Not accepted in Part B8
*** Calculated by zRMS in Part B8

9.8.2.2 Higher-tier risk assessment

According to Chlorantraniliprole DAR, Vol. 3, B9, Part 1, pages 446-451 (PDF pagination) DuPont-12752, Revision No. 1. Chlorantraniliprole 200 g/L SC was applied twice to bare soil at 786.3 mL/ha (equivalent to 156.16 g a.s./ha) and then at 755.3 mL/ha (equivalent to 150 g a.s./ha). The first application was incorporated to a depth of 10 cm, the second was applied to the surface after burying the litter bags to 5 cm and seeding the plots with barley. Over a period of 12 months, a sufficient level of litter breakdown was achieved and no statistically significant difference in litter breakdown between the control and treated plots was seen (max. deviation 5.1% 1 month after initiation). Therefore, It can be assumed that chlorantraniliprole, its metabolites and CLOROL 200 SC don't pose any unaccaptabble risk to all soil organisms for all intended uses in GAP Table.

zRMS comments:
The possibility of using these studies for the refinement of the risk assessment was analysed during the registration of the reference product CHLORANTRANILIPROLE 200 G/L SC (Applicant: E. I. DU PONT de NEMOURS AND COMPANY, Core Dossier. 25 July 2014):
"*In order to establish the actual risk to OM breakdown under field conditions, two leaf litterbag studies were conducted: one non-GLP study in France, and one GLP study in Spain. The non-GLP study was conducted in conditions that are largely equivalent to the those of the Central Zone and therefore applicable for consideration in this assessment.*
The results from the first non-GLP, however, the methodology accurately followed the protocol recommended by the SETAC EPFES Workshop, Lisbon, 2002 - in which bare soil was first sprayed with 156 g DPX-E2Y45 (chlorantraniliprole)/ha which was incorporated into the top 10 cm of soil, then litter bags were buried in this soil at a depth of 5 cm and a second application of 150 g DPX-E2Y45 (chlorantraniliprole)/ha was sprayed over the soil surface. Although not statistically significant, the maximum deviation from litter breakdown in the control was -5.52% at 4.5 months after last application, and by 12 months there was -2.52% deviation. The acceptability criterion proposed by EPFES was a devia-

tion from control of 10% by 12 months (orxtended period if required) at relevant soil concentrations. No analysis of actual soil concentrations of the active substance was undertaken during the study. According to approximate calculations (not accounting for any dissipation), the applications made would lead to a total PECsoil in the top 5 cm of 0.304 mg a.s./kg soil."

9.8.3 Overall conclusions

Intended uses of the product are considered safe and acceptable.

zRMS comments:

Folsomia candida is the most sensitive non-target soil organisms with 28d NOEC = 0.39 mg a.s./kg d.w. soil for active substance and with 28d NOEC = 1.56 mg prod/kg d.w. soil (corresponding to 0.25 mg a.s./kg d.w.soli) for formulation and covers the risk for other soil macro-organisms.

No risk to Collembola from exposure to chlorantraniliprole with PECsoil at Tier 1 has been identified for:

- Maize, field use, 1 x 25 g as/ha, BBCH 53-69

major crop, use: 2
minor crop; 22, 23, 24, 25,

- Oilseeds –, field use, two applications 2 x 35 g as/ha BBCH 30-50 and 61-71:

major crop, use 4,

- Oilseeds – field use, one application 1 x 35 g as/ha, BBCH 61-71:

major crop, use: 3,
minor crop, use: 26, 27, 28, 29, 30, 34)

- Sugar beet, field use, 1 x 20 g as/ha, BBCH 31-49:

minor crop, use: 7,

- Potato, field use, 2 x 12.5 g as/ha BBCH 31-60:

major crop, use 1,
minor crop, use: 8, 9),

- Sunflower, **field use**, 1 x 35 g as/ha BBCH 61-65:

minor crop, use 31,

- Soya, **field use**, 1 x 35 g as/ha, BBCH 61-65:

minor crop, use: 32,

- Pumpkin and vegetables fruiting, **field uses** 1 x 35 g as/ha BBCH 61-65:

minor crop use: 33,

- Tomato and vegetables fruiting, **greenhouses uses,** 1x 50 g as/ha at BBCH 20-49,

minor crops, use: 65, 66, 67, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, 95,

- Grass, rate 1x 35 g as/ha BBCH 53-69:

minor use: 59,

- Tobbaco, **field use**, 1x54 g as/ha BBCH 30-85:

minor crop, use 58),

In Part B8, in addition to Tier 1, the higher Tier PECsoil values were calculated and accepted for the risk assessment.
The acceptability of calculations PECsoil values at tier 2 to 4 should be considered on the MS level.

Taking into account the higher Tier PECsoil values the no risk to Collembola from exposure to chlorantraniliprole was identified for:

- Pome/Stone Fruit in every 2nd year, field use, 2 x 35 g as/ha, BBCH 56 and 70-87:
major crops, use: 5, 6,
minor crops, use: 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 60, 61, 62, 63, 64,

- Carrots and roots Vegetables, **field uses**, 1 x 35 g as/ha, BBCH 12-49:
minor crops, use 10, 11, 12 13, 14, 15, 16, 17, 18, 19, 20, 21,),

- Cabbage and vegetables leafy, **field uses**, 2 x 25 g/ha, BBCH 20-49:
minor crops, use: 35, 36, 37, 38, 39, 40, 41,

- Cabbage and vegetables leafy, **greenhouses uses**, 1 x 42 g as/ha or 2 x 25g as/ha, BBCH 20-49:
minor crops, use: 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, 96,

- Vines, **in field uses**, 1 x 54 g as/ha, BBCH 57-83:
minor crop, use: 56, 57.

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

Effects on soil microorganisms of Chlorantraniliprole 200 g/L SC were evaluated as part of the EU assessment of chlorantraniliprole.

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

Endpoint	Substance	Exposure System	Results	Reference
N-mineralisation	Chlorantraniliprole	28-day ~~R + N~~	<25% effect at ~~doses~~ of ~~52.5 and 525 g a.s./ha~~ 0.70 mg a.s./kg soil dw	Chlorantraniliprole DAR, Vol. 3, B9, Part 2, pages 45-49 (PDF pagination) DuPont-14389 EFSA Conclusion (2013)
N-mineralisation	Chlorantraniliprole 200 g/L SC	~~28~~ 42 -day ~~R + N~~	<25% effect at ~~doses of 60 g and 600 g a.s./ha~~ 0.814 mg a.s./kg d.w. soil	Chlorantraniliprole DAR, Vol. 3, B9, Part 2, pages 49-53 (PDF pagination) DuPont-18813 EFSA Conclusion (2013)

Endpoint	Substance	Exposure System	Results	Reference
N-mineralisation	IN-EQW78	28-day ~~R + N~~	<25% effect at ~~doses of 0.08 and~~ 0.80 mg/kg dry weight soil (nominal)	Chlorantraniliprole DAR, Vol. 3, B9, Part 2, pages 58-62 (PDF pagination) DuPont-DuPont-17086, Revision No. 1 EFSA Conclusion (2013)
N-mineralisation	IN-ECD73	28-day ~~R + N~~	<25% effect at ~~doses of 0.08 and~~ 0.80 mg/kg dry weight soil (nominal)	Chlorantraniliprole DAR, Vol. 3, B9, Part 2, pages 62-66 (PDF pagination) DuPont-17627, Revision No. 1 EFSA Conclusion (2013)
N-mineralisation	IN-GAZ70	28-day ~~R + N~~	<25% effect at ~~doses of 0.08, 0.42, and~~ 0.84 mg/kg dry weight soil (nominal)	Chlorantraniliprole DAR, Vol. 3, B9, Part 2, pages 66-70 (PDF pagination) DuPont-17628 EFSA Conclusion (2013)

9.9.1.1 Justification for new endpoints

Not required

9.9.2 Risk assessment

The evaluation of the risk for soil microorganisms was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).
The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, Table 8.7-3 and were already used in the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna) (see 0).
To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the worst case scenario – 2 application of 110 g as/ha – covers all intended uses from GAP table

Table 9.9-2: Assessment of the risk for effects on soil micro-organisms due to the use of Clorol 200 SC

Intended use			
N-mineralisation			
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**Risk acceptable?**

Chlorantraniliprole	~~<25% effect at doses of 52.5 and 525 g a.s./ha~~ 0.700	~~1.0473 0.0654~~ 0.5249**	Yes
Chlorantraniliprole 200 g/L SC	~~<25% effect at doses of 60 g and 600 g a.s./ha~~ 0.814 (based on the active substance content)	~~1.2848 0.191~~ 0.5246**	Yes
IN-EQW78	~~<25% effect at doses of 0.08 and 0.80 mg/kg dry weight soil (nominal)~~ 0.800	~~0.4035 0.018~~ 0.1447**	Yes
IN-ECD73	~~<25% effect at doses of 0.08 and 0.80 mg/kg dry weight soil (nominal)~~ 0.800	~~0.0807 0.0038~~ 0.0782**	Yes
IN-GAZ70	~~<25% effect at doses of 0.08, 0.42, and 0.84 mg/kg dry weight soil (nominal)~~ 0.840	~~0.0914~~ 0.0041 0.1014**	Yes
C-mineralisation			
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**Risk acceptable?**
Not required.			

** Corrected according to Part B8

9.9.3 Overall conclusions

Intended use of CLOROL 200 SC poses an acceptable risk to soil microorganisms

zRMS comments:

For the risk assessment the worst-case PECsoil values were used.

Conclusion:
According to the performed risk assessment there is low risk to soil microorganisms since no effects (> 25%) were seen at application rates higher than the values of PECsoil for active substance, metabolites and formulation. It can be concluded that application of Clorol 200 SC / Catanga 200 SC, Boland 200 SC, according to the GAP, will not cause any detrimental effect to soil micro-organisms.

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

9.10.1 Toxicity data

Studies on the toxicity to non-target terrestrial plants have been carried out with chlorantraniliprole. Full details of these studies are provided in the respective EU DAR and related documents

Effects on non-target terrestrial plants of Chlorantraniliprole 200 g/L SC were evaluated as part of the EU assessment of chlorantraniliprole.

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

Species	Substance	Exposure System	Results	Reference
Ryegrass, corn, oat, onion, cucumber, pea, oilseed rape, soybean, sugarbeet, and tomato.	Chlorantraniliprole 200 g/L SC	21 d Seedling emergence	ER50 > 300 g as/ha	EFSA Journal 2013;11(6):3143
Ryegrass, corn, oat, onion, cucumber, pea, oilseed rape, soybean, sugarbeet, and tomato.	Chlorantraniliprole 200 g/L SC	21 d Vegetative vigour	ER50 > 300 g as/ha	EFSA Journal 2013;11(6):3143

m: monocotyledonous; d: dicotyledonous

9.10.1.1 Justification for new endpoints

Not required

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 worst case scenario – 2 application of 110 g as/ha – covers all intended uses from Gap Table.

Table 9.10-2: Assessment of the risk for non-target plants due to the use of CLOROL 200 SC in field crop

Intended use	
Active substance/product	Chlorantraniliprole/Clorol 200 SC

Application rate (g/ha)	2 × 110			
MAF	1.7			
Test species	**ER_{50} (g as/ha)**	**Drift rate (1 m)**	**$PER_{off\text{-}field}$ (g/ha)**	**TER criterion: TER ≥ 5**
Ryegrass, corn, oat, onion, cucumber, pea, oilseed rape, soybean, sugarbeet, and tomato.	300	0.0277	5.1799 3.047*	57.92 98.46*

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.
*Additional calculation if MAF for multiple applications is not required

Table 9.10-3: Assessment of the risk for non-target plants due to the use of CLOROL 200 SC in fruit crops

Intended use				
Active substance/product	Chlorantraniliprole/Clorol 200 SC			
Application rate (g/ha)	2 × 110			
MAF	1.7			
Test species	**ER_{50} (g as/ha)**	**Drift rate (3 m)**	**$PER_{off\text{-}field}$ (g/ha)**	**TER criterion: TER ≥ 5**
Ryegrass, corn, oat, onion, cucumber, pea, oilseed rape, soybean, sugarbeet, and tomato.	300	0.2920(early)/0.1573(late)	54,6/29.42 32.12/17.303*	5,49 / 10.2 9.34/17.34*

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.
*Additional calculation if MAF for multiple applications is not required

Table 9.10-4: Assessment of the risk for non-target plants due to the use of CLOROL 200 SC in grapevine

Intended use				
Active substance/product	Chlorantraniliprole/Clorol 200 SC			
Application rate (g/ha)	2 × 110			
MAF	1.7			
Test species	**ER_{50} (g as/ha)**	**Drift rate (3 m)**	**$PER_{off\text{-}field}$ (g/ha)**	**TER criterion: TER ≥ 5**
Ryegrass, corn, oat, onion, cucumber, pea, oilseed rape, soybean, sugarbeet, and tomato.	300	0.0270(early)/0.0802 (late)	5.05/15.00 2.97/8..82*	59.4 / 20 101.01/34.01*

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.
*Additional calculation if MAF for multiple applications is not required

Table 9.10-5: Assessment of the risk for non-target plants due to the use of CLOROL 200 SC in vegetables, ornamentals, small fruit

Intended use	
Active substance/product	Chlorantraniliprole/Clorol 200 SC
Application rate (g/ha)	2 × 110
MAF	1.7

Test species	**ER_{50} (g as/ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (g/ha)**	**TER criterion: TER ≥ 5**
Ryegrass, corn, oat, onion, cucumber, pea, oilseed rape, soybean, sugarbeet, and tomato.	300	0.0277(h<50cm) (Distance -1 m) /0.0802 (h>50cm) (Distance – 3 m)	5,18/15 3.03/8.82*	57.9 / 20 99.0/34.01*

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.
*Additional calculation if MAF for multiple applications is not required

9.10.2.3 Higher-tier risk assessment

Not relevant.

9.10.2.4 Risk mitigation measures

No risk mitigation needed.
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9.10.3 Overall conclusions

Intended uses of the product are considered safe and acceptable.

zRMS comments:

For the risk assessment the UE agreed endpoints and the worst-case application rate were used.

As stated in EFSA Supporting publication 2019:EN-1673 the phytotoxicity effects should be reported in the study summary and the ER_{50} based on visual injury/phytotoxicity should be calculated and considered for use in risk assessment.
Based on the art. 34 of regulation (EC) No 1107/2009, the risk assessment was based on EU agreed endpoints.
According to the DAR_14_Volumen 3_B9_part2 for CHLORANTRANILIPROLE (DPX-E2Y45), in the study summary for seedling emergence concluded that: "*Based on the results of a multiple rate test for the most sensitive monocot species, ryegrass, the ER25 and ER50 were each >300 g DPX-E2Y45/ha (equivalent to >1.5 L DPX-E2Y45 20SC/ha) based on all test parameters (emergence, shoot height, shoot dry weight, and visual response")*.

Table 202
Effects of DPX-E2Y45 20SC on ten non-target plants following pre-emergent application (soil surface application) at 300 g DPX-E2Y45/ha (Tier 1 limit test)

Plant	Family	Genus/species	Reduction from Control (%)	Most sensitive parameter
Corn	Poaceae	*Zea mays*	10	Shoot dry weight
Oat	Poaceae	*Avena sativa*	5	Shoot height
Onion	Liliaceae	*Allium cepa*	6	Shoot dry weight
Ryegrass	Poaceae	*Lolium perenne*	34	Shoot dry weight
Cucumber	Cucurbitaceae	*Cucumis sativa*	18	Visual response
Oilseed rape	Brassicaceae	*Brassica napus*	11	Shoot dry weight
Pea	Fabaceae	*Pisum sativum*	18	Emergence
Soybean	Fabaceae	*Glycine max*	0	Survival, Visual response
Sugar beet	Chenopodiaceae	*Beta vulgaris*	7	Shoot height
Tomato	Solanaceae	*Lycopersicon esculentum*	0	Visual response

In the study summary for the vegetative vigour: "*The visual response and survival of the seedlings were recorded. Based on the results of a multiple rate test for the most sensitive monocot species, ryegrass, the ER25 and ER50 were each >300 g DPX-E2Y45/ha (equivalent to >1.5 L DPX-E2Y45 20SC/ha) based on all test parameters (emergence, shoot height, shoot dry weight, and visual response)*."

Table 204
Effects of DPX-E2Y45 20SC on ten non-target plants following post-emergent application (foliar application) at 300 g DPX-E2Y45/ha (Tier 1 limit testing)

Plant	Family	Genus/species	Reduction from control (%)	Most sensitive parameter
Monocotyledons				
Corn	Poaceae	*Zea mays*	1	Shoot height
Oat	Poaceae	*Avena sativa*	0	Shoot height, Survival, Visual response
Onion	Liliaceae	*Allium cepa*	12	Shoot dry weight
Ryegrass	Poaceae	*Lolium perenne*	0	Visual response, Survival
Dicotyledons				
Cucumber	Cucurbitaceae	*Cucumis sativa*	1	Shoot dry weight
Oilseed rape	Brassicaceae	*Brassica napus*	2	Shoot height
Pea	Fabaceae	*Pisum sativum*	12	Shoot height
Soybean	Fabaceae	*Glycine max*	5	Shoot dry weight
Sugar beet	Chenopodiaceae	*Beta vulgaris*	7	Shoot dry weight
Tomato	Solanaceae	*Lycopersicon esculentum*	5	Shoot dry weight

Taking the above into account, it can be concluded that the phytotoxicity effect was addressed in both studies.

As noted in the "Working document on Risk Assessment of Plant Protection Products in the Central Zone Ecotoxicology" Version 3.0, December 2024, most, but not all, countries have agreed to use MAF in risk assessment. Therefore, the calculation without MAF was added by zRMS in the tables above.

All TER values are above the trigger value of 5 set by Commission Regulation (EU) No. 546/2011.

Conclusion
No unacceptable risk to non-target terrestrial plants is expected following the application of Clorol 200 SC / Catanga 200 SC, Boland 200 SC according to the proposed use pattern.

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

Not required

9.12 Monitoring data (KCP 10.8)

Not relevant.

9.13 Classification and Labelling

In accordance with CLP Regulation and based upon the available aquatic endpoints for Coragen 200 SC, the proposed classification and labelling of CLOROL 200 SC is driven by effects on Daphnia magna (48h EC50 = 0.035 mg/L for the acute classification).
Aquatic acute toxicity Category 1, H 400 Very toxic to aquatic life.
Aquatic chronic toxicity Category 1, H 410 Very toxic to aquatic life with long lasting effects.

Classification:
Aquatic Acute 1, H400
Aquatic Chronic 1, H410

Hazard statement:
H400 – Very toxic to aquatic life.
H410 – Very toxic to aquatic life with long lasting effects.

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

Pictogram:
GHS09

Signal word:
WARNING

Precautionary statement:
P273: Avoid release to the environment.
P391: Collect spillage.

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

zRMS agrees with the classification proposal

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
10.3.1/15	A. Fulczyk	2024	REPORT PART I (Biological Phase) CLOROL 200 SC Honeybees (Apis mellifera L.), Larval Toxicity Test, Repeated Exposure B-92-23 Łukasiewicz Research Network –Institute of Industrial Organic Chemistry, Branch Pszczyna, Ecotoxicology Research Group, Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	PUH Chemirol Sp. Z o.o.
10.3.1/16	A. Fulczyk	2024	REPORT PART I (Biological Phase) CLOROL 200 SC Honeybees (Apis mellifera L.), Chronic Oral Toxicity Test B-93-23 Łukasiewicz Research Network –Institute of Industrial Organic Chemistry, Branch Pszczyna, Ecotoxicology Research Group, Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	PUH Chemirol Sp. Z o.o.
KCP 10.4/08	E. Kulec – Płoszczyca	~~2013~~ 2023	Collembolan (Folsomia candida) Reproduction Test in soil EcoTox Alliance Sp. z o. o. ETOX-2023-13 GLP Unpublished	N	PUH Chemirol Sp. Z o.o.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.4/09	K. Wesołowska	2025	Earthworm Reproduction Test (Eisenia andrei) EcoTox Alliance Sp. z o. o. ETOX-2024-64 GLP Unpublished	N	PUH Chemirol Sp. Z o.o.
KCP 10.4/10	S. Groch	2025	Predatory mite (Hypoaspis (Geolaelaps) aculieifer) reproduction test in soil EcoTox Alliance Sp. z o. o. ETOX-2024-65 GLP Unpublished	N	PUH Chemirol 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
KCP 10.1.1/01		2004	DPX-E2Y45 technical: An acute oral toxicity study with the northern bobwhite DuPont-14378 GLP Unpublished	N	DuPont2006
KCP 10.1.1/02		2006	IN-EQW78: An acute oral toxicity study with the northern bobwhite DuPont-18859 GLP Unpublished	N	DuPont

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 10.1.1/03		2004	DPX-E2Y45 technical: A dietary LC50 study with the northern bobwhite DuPont-14379 GLP Unpublished	N	DuPont
KCP 10.1.1/04		2006	DPX-E2Y45: A reproduction study with the northern bobwhite DuPont-14383 GLP Unpublished	N	DuPont
KCP 10.1.2	[redacted]	2007	Chlorantraniliprole (DPX - E2Y45): Mammalian Toxicity: Summaries and Assessment. [redacted] GLP Unpublished	Y	DuPont
KCP 10.2/01	Singles, S.	2006	Chlorantraniliprole (DPX - E2Y45): Fate in the Environment: Summaries and Assessment. DuPont-18273 GLP Unpublished	N	DuPont
KCP 10.2/02	Samel, A.	2003	DPX-E2Y45 technical: Static, acute, 48-hour EC50 to *Daphnia magna* DuPont Haskell Laboratory DuPont-12411 GLP unpublished	N	DuPont
KCP 10.2/03	Samel, A.	2005	DPX-E2Y45 technical: Static, acute, 48-hour toxicity test to the mayfly, *Centroptilum triangulifer* DuPont Haskell Laboratory DuPont-15109 GLP Unpublished	N	DuPont
KCP 10.2/04	Samel, A.	2006	DPX-E2Y45 technical: Static, acute, 48-hour toxicity test to the caddisfly, *Chimarra atterima* DuPont Haskell Laboratory Dupont-17585	N	DuPont

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GLP Unpublished		
KCP 10.2/05	Samel, A.	2005	DPX-E2Y45 technical: Static, acute, 48-hour toxicity test to *Gammarus pseudolimnaeus* DuPont Haskell Laboratory DuPont-15877 GLP Unpublished	N	Dupont
KCP 10.2/06	Boeri, R.L., Wyskiel, D.C., Ward, T.J.	2004	DPX-E2Y45 technical: Flow-through mollusc shell deposition test using the eastern oyster, *Crassostrea virginica* T.R. Wilbury Laboratories, Inc. DuPont-12412 GLP Unpublished	N	DuPont
KCP 10.2/07	Samel, A.	2005	DPX-E2Y45 technical: Static, acute, 48-hour toxicity test to *Hyalella azteca* DuPont Haskell Laboratory DuPont-15114 GLP Unpublished	N	DuPont
KCP 10.2/08	Samel, A.	2006	DPX-E2Y45 technical: Static, acute, 48-hour toxicity test to the stonefly, *Soyedina carolinensis* DuPont Haskell Laboratory DuPont-18804 GLP Unpublished	N	DuPont
KCP 10.2/09	Boeri, R.L., Wyskiel, D.C., Ward, T.J.	2004	DPX-E2Y45 technical: Acute toxicity to the mysid, *Americamysis bahia* T.R. Wilbury Laboratories, Inc. DuPont-12335 GLP Unpublished	N	DuPont
KCP	Samel, A.	2005	DPX-E2Y45 technical: Static, acute, 48-hour toxicity test to crayfish, *Oronectes virilis*	N	DuPont

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
10.2/10			DuPont Haskell Laboratory DuPont-15872 GLP Unpublished		
KCP 10.2/11	Samel, A.	2005	DPX-E2Y45 technical: 21-Day chronic, static-renewal toxicity test to *Daphnia magna* DuPont Haskell Laboratory DuPont-15874 GLP Unpublished	N	DuPont
KCP 10.2/12	Samel, A.	2005	IN-EQW78: Static, acute, 48-hour limit test to *Daphnia magna* DuPont Haskell Laboratory DuPont-15388 GLP Unpublished	N	DuPont
KCP 10.2/13	Samel, A.	2006	IN-ECD73: Static, 48-hour limit test to *Daphnia magna* DuPont Haskell Laboratory DuPont-18472 GLP Unpublished	N	DuPont
KCP 10.2/14	Bouchelle, L.D.	2006	IN-GAZ70: Static, acute, 48-hour limit test to *Daphnia magna* DuPont Haskell Laboratory DuPont-18387 GLP Unpublished	N	DuPont
KCP 10.2/15	Samel, A.	2006	IN-F6L99: Static, 48-hour toxicity test to *Daphnia magna* DuPont Haskell Laboratory DuPont-18473 GLP Unpublished	N	DuPont

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 10.2/16	Samel, A.	2006	IN-F9N04: Static, acute, 48-hour toxicity test with *Daphnia magna* DuPont Haskell Laboratory DuPont-18474 GLP Unpublished	N	DuPont
KCP 10.2/17	Samel, A.	2005	DPX-E2Y45 technical: Static, acute, 48-hour toxicity test to *Chironomus riparius* DuPont Haskell Laboratory DuPont-15112 GLP Unpublished	N	DuPont
KCP 10.2/18	Samel, A.	2005	DPX-E2Y45 technical: Static, acute, 48-hour toxicity test to the aquatic oligochaete, *Lumbriculus variegatus* DuPont Haskell Laboratory DuPont-15873 GLP Unpublished	N	DuPont
KCP 10.2/19	Kreuger, H.O., Thomas, S. , Kendall, T.Z.	2006	14C-DPX-E2Y45: A prolonged sediment toxicity test with *Chironomus riparius* using spiked water Wildlife International Ltd (USA) DuPont-14395 GLP Unpublished	N	DuPont
KCP 10.2/20	Sloman, T.L.	2006	DPX-E2Y45 technical: Influence on growth and growth rate of the green alga *Selenastrum capricornutum* DuPont Haskell Laboratory DuPont-12408, Revision No. 1 GLP Unpublished	N	DuPont
KCP 10.2/21	Sloman, T.L.	2006	DPX-E2Y45 technical: Influence on growth and reproduction of *Lemna gibba* G3 DuPont Haskell Laboratory DuPont-12409, Revision No. 1 GLP	N	DuPont

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCP 10.2/22		2006	DPX-E2Y45 technical: Static, acute, 96-hour limit test to channel catfish, *Ictalurus punctatus* DuPont-14278 GLP Unpublished	N	DuPont
KCP 10.2/23	Samel, A.	2006	DPX-E2Y45 20SC [200 g/L (w/v); 18.5% (w/w)]: Static, acute, 48-hour toxicity test to *Daphnia magna* DuPont Haskell Laboratories DuPont-18427, Revision No. 1 GLP Unpublished	N	DuPont
KCP 10.2/24	Sloman, T.L.	2006	DPX-E2Y45 20SC [200 g/L (w/v); 18.5% (w/w)]: Static, 72-hour growth inhibition limit test to the green alga, *Pseudokirchneriella subcapitata* DuPont Haskell Laboratories DuPont-18088 GLP Unpublished	N	DuPont
KCP 10.2/25	Brougher, D.S. Martin, K.H. Gallagher, S.P. Bodle, E.S.	2014	IN-LBA22: A 48-hour static-renewal acute toxicity test with the cladoceran (Daphnia magna) Wildlife International Ltd. (USA) DuPont-39689 GLP Unpublished	N	DuPont
KCP 10.2/26	Brougher, D.S. Martin, K.H. Gallagher, S.P. Bodle, E.S.	2014	IN-LBA23: A 48-hour static acute toxicity test with the cladoceran (Daphnia magna) Wildlife International Ltd. (USA) DuPont-38899 GLP Unpublished	N	DuPont
KCP 10.2/27	Brougher, D.S. Martin, K.H. Gallagher, S.P.	2014	IN-LBA24: A 48-hour static acute toxicity test with the cladoceran (Daphnia magna) Wildlife International Ltd. (USA)	N	DuPont

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
	Bodle, E.S.		DuPont-36207, Revision No. 1 GLP Unpublished		
KCP 10.2/28	Brougher, D.S., Martin, K.H., Gallagher, S.P., Bodle, E.S.	2013	Chlorantraniliprole (DPX-E2Y45) technical: A 48-hour static acute toxicity test with *Hyalella azteca* Wildlife International Ltd. (USA) DuPont-36901 GLP: Yes Published: No	N	DuPont
KCP 10.2/29	Brougher, D.S., Martin, K.H., Gallagher, S.P., Bodle, E.S.	2013	Chlorantraniliprole (DPX-E2Y45) technical: A 48-hour static acute toxicity test with the Cladoceran (*Daphnia pulex*) Wildlife International Ltd. (USA) DuPont-36902 GLP: Yes Published: No	N	DuPont
KCP 10.2/30	Brougher, D.S., Martin, K.H., Gallagher, S.P., Bodle, E.S.	2013	Chlorantraniliprole (DPX-E2Y45) technical: A 48-hour static acute toxicity test with the Cladoceran (*Ceriodaphnia dubia*) Wildlife International Ltd. (USA) DuPont-36903 GLP: Yes Published: No	N	DuPont
~~KCP 10.2/31~~	~~Thomas, S.T., Siddiqui, A.J., Martin, K.H., Gallagher, S.P.~~	~~2014~~	~~14C Chlorantraniliprole(DPX-E2Y45) technical: A prolonged sediment toxicity test with *Chironomus riparius* using spiked natural sediment~~ ~~Wildlife International Ltd. (USA)~~ ~~DuPont-36097~~ ~~GLP: Yes~~ ~~Published: No~~	~~N~~	~~DuPont~~
KCP 10.3.1/01	Bocksch, S.	2005	DPX-E2Y45 technical: Acute oral and contact toxicity to the honeybee, Apis mellifera L. GAB Biotechnologie, GmbH DuPont-17582 GLP	N	DuPont

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCP 10.3.1/02	Bocksch, S.	2006	DPX-E2Y45 20SC [200 g/L (w/v); 18.5% (w/w)]: Acute oral and contact toxicity to the honeybee, *Apis mellifera L.* GAB Biotechnologie, GmbH DuPont-18426 GLP Unpublished	N	DuPont
KCP 10.3.1/03	Schur, A.	2005	DPX-E2Y45 20SC (200 g a.s./L (w/v), 18.5% (w/w)): A semi-field study to evaluate effects on the honey bee (*Apis mellifera carnica*; Hymenoptera, Apidae) in Phacelia in Germany 2004 GAB Biotechnologie, GmbH DuPont-14706 GLP Unpublished	N	DuPont
KCP 10.3.1/04	Sindermann, A.B., Porch, J.R., Krueger, H.O.	2005	DPX-E2Y45 35WG: Foliage residue toxicity study to the honey bee, *Apis mellifera L*. Wildlife International Ltd (USA) DuPont-16269 GLP Unpublished	N	DuPont
KCP 10.3.1/05	Schur, A.	2005	DPX-E2Y45 20SC [200 g a.s./L (w/v), 18.5% (w/w)]: A semi-field study to evaluate effects on the honey bee (*Apis mellifera mellifera*; Hymenoptera, Apidae) in Phacelia in Spain 2004 GAB Biotechnologie, GmbH DuPont-14388 GLP Unpublished	N	DuPont
KCP 10.3.1/06	Szinicz, G.	2006	DPX-E2Y45 20SC [200 g a.s./L (w/v), 18.5% (w/w)]: A semi-field study to evaluate effects on the honey bee (*Apis mellifera carnica;* Hymenoptera, Apidae) in Phacelia tanacetifolia in France 2006 eurofins-GAB GmbH DuPont-18087 GLP Unpublished	N	DuPont

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.3.1/07	Giffard, H.	2006	DPX-E2Y45 20SC [200 g a.s./L (w/v), 18.5% (w/w)]: A semi-field study to evaluate effects on the honey bee (*Apis mellifera mellifera*; Hymenoptera, Apidae) on Phacelia in France 2005 Testapi DuPont-16271 GLP Unpublished	N	DuPont
KCP 10.3.1/08	Beuschel, S.	2006	DPX-E2Y45 20SC [200 g a.s./L (w/v), 18.5% (w/w)]: A semi-field study to evaluate effects on the honey bee (*Apis mellifera carnica*; Hymenoptera, Apidae) in Phacelia tanacetifolia in Northern France 2005 GAB Biotechnologie, GmbH DuPont-16272 GLP Unpublished	N	DuPont
KCP 10.3.1/09	Giffard, H.	2006	DPX-E2Y45 20SC [200 g a.s./L (w/v), 18.5% (w/w)]: A semi field study to evaluate effects on the honey bee (*Apis mellifera mellifera*; Hymenoptera, Apidae) on phacelia in France 2006 Testapi DuPont-18085 GLP Unpublished	N	DuPont
KCP 10.3.1/10	Giffard, H.	2006	DPX-E2Y45 20SC [200 g a.s./L (w/v), 18.5% (w/w)]: A semi-field study to evaluate effects on the honey bee (*Apis mellifera mellifera*; Hymenoptera, Apidae) on wheat treated with artificial honeydew in France 2005 Testapi DuPont-17247, Revision No. 1 GLP Unpublished	N	DuPont
KCP 10.3.1/11	Beuschel, S.	2006	DPX-E2Y45 20SC (200 g a.s./L (w/w)), 18.5% (w/w): A semi-field study to evaluate the effects on the honey bee (*Apis mellifera carnica*; Hymenoptera, Apidae) on wheat treated with artificial honeydew in Northern France 2005 GAB Biotechnologie, GmbH DuPont-17248	N	DuPont

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GLP Unpublished		
KCP 10.3.1/12	Giffard, H.	2006	DPX-E2Y45 20SC [200 g a.s./L (w/v), 18.5% (w/w)]: A semi field study to evaluate effects on the honey bee (*Apis mellifera mellifera*; Hymenoptera, Apidae) on wheat treated with artificial honeydew in France 2006 Testapi DuPont-18086 GLP Unpublished	N	DuPont
KCP 10.3.1/13	Schur, A.	2006	DPX-E2Y45-105: A semi-field study (non-GLP) to evaluate effects on the honey bee (*Apis mellifera carnica*; Hymenoptera, Apidae) in Phacelia in 2003 GAB Biotechnologie, GmbH DuPont-12753, Revision No. 1 Non GLP Unpublished	N	DuPont
KCP 10.3.1/14	Szinicz, G.	2006	DPX-E2Y45 20SC (200 g a.s./L (w/w)), 18.5% (w/w): A semi-field study to determine residues in nectar and pollen from foraging honey bees (*Apis mellifera carnica*; Hymenoptera, Apidae) and residues in fresh honey, pollen and wax from combs after exposure to treated Phacelia in Germany in 2005 GAB Biotechnologie, GmbH DuPont-17208 GLP Unpublished	N	DuPont
KCP 10.3.2/01	Warmers, C.	2006	DPX-E2Y45 20SC [200 g a.s./L (w/v), 18.5% (w/w)]: A laboratory rate response test to evaluate the effects on the predatory mite *Typhlodromus pyri* Scheuten (Acari, Phytoseiidae) GAB Biotechnologie, GmbH DuPont-18424, Revision No. 1 GLP Unpublished	N	DuPont
KCP 10.3.2/02	Warmers, C.	2006	DPX-E2Y45 20SC [200 g a.s./L (w/v), 18.5% (w/w)]: A laboratory rate response test to evaluate the effects on the parasitoid *Aphidius rhopalosiphi* (Hymenoptera, Braconidae)	N	DuPont

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
			GAB Biotechnologie, GmbH DuPont-18423, Revision No. 1 GLP Unpublished		
KCP 10.4/01	Lührs, U.	2005	IN-EQW78: Acute toxicity to the earthworm, *Eisenia fetida* in artificial soil IBACON DuPont-15389, Revision No. 1 GLP Unpublished	N	DuPont
KCP 10.4/02	Lührs, U.	2005	IN-ECD73: Acute toxicity to the earthworm, *Eisenia fetida* in artificial soil IBACON DuPont-17091 GLP Unpublished	N	DuPont
KCP 10.4/03	Lührs, U.	2006	DPX-E2Y45 35WG: Acute toxicity to the earthworm, *Eisenia fetida* in artificial soil IBACON DuPont-18817 GLP Unpublished	N	DuPont
KCP 10.4/04	Lührs, U.	2006	DPX-E2Y45 technical: Effects on the collembola, *Folsomia candida* in artificial soil IBACON DuPont-18730 GLP Unpublished	N	DuPont
KCP 10.4/05	Lührs, U.	2005	IN-EQW78: Effects on the collembola, Folsomia candida in artificial soil IBACON DuPont-16531 GLP Unpublished	N	DuPont

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.4/06	Lührs, U.	2005	IN-ECD73: Effects on the collembola, *Folsomia candida* in artificial soil IBACON DuPont-17083 GLP Unpublished	N	DuPont
KCP 10.4/07	Lührs, U.	2006	IN-GAZ70: Effects on the collembola, *Folsomia candida* in artificial soil IBACON DuPont-17084 GLP Unpublished	N	DuPont
KCP 10.4/09	Lührs, U.	2006	DPX-E2Y45 technical: Effects on reproduction of the predatory mite *Hypoaspis aculeifer* in artificial soil with 5% peat IBACON DuPont-19748 GLP Unpublished	N	DuPont
KCP 10.4/10	Kölzer, U.	2006	DPX-E2Y45 20SC: Effects on the decomposition of organic matter in the field GAB Biotechnologie, GmbH DuPont-12752, Revision No. 1 GLP Unpublished	N	DuPont
KCP 10.5/01	Kölzer, U.	2004	DPX-E2Y45 technical: Assessment of the effects on soil microflora GAB Biotechnologie, GmbH DuPont-14389 GLP Unpublished	N	DuPont
KCP 10.5/02	Reis, K.-H.	2006	DPX-E2Y45 20SC [200 g/L (w/v); 18.5% (w/w)]: Assessment of the effects on soil microflora IBACON DuPont-18813 GLP	N	DuPont

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCP 10.5/03	Reis, K.H.	2006	IN-EQW78: Assessment of the effects on soil microflora IBACON DuPont-17086, Revision No. 1 GLP Unpublished	N	DuPont
KCP 10.5/04	Reis, K.H.	2006	IN-ECD73: Assessment of the effects on soil microflora IBACON DuPont-17627, Revision No. 1 GLP Unpublished	N	DuPont
KCP 10.5/05	Reis, K-H.	2006	IN-GAZ70: Assessment of the effects on soil microflora IBACON DuPont-17628 GLP Unpublished	N	DuPont
KCP 10.6/01	Porch, J.R., Martin, K.H.	2006	DPX-E2Y45 20SC [200 g/L (w/v); 18.5% (w/w)]: A greenhouse study to investigate the effects on seedling emergence and growth of ten terrestrial plants following soil exposure Wildlife International Ltd (USA) DuPont-19075 GLP	N	DuPont
KCP 10.6/02	Porch, J.R., Martin, K.H.	2006	DPX-E2Y45 20SC [200 g/L (w/v); 18.5% (w/w)]: A greenhouse study to investigate the effects on vegetative vigor of ten terrestrial plants following foliar exposure Wildlife International Ltd (USA) DuPont-19074 GLP Unpublished	N	DuPont

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

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

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

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

Appendix 2 Detailed evaluation of the new studies

A 2.1 KCP 10.1 Effects on birds and other terrestrial vertebrates

A 2.1.1 KCP 10.1.1 Effects on birds

A 2.1.1.1 KCP 10.1.1.1 Acute oral toxicity

A 2.1.1.2 KCP 10.1.1.2 Higher tier data on birds

A 2.1.2 KCP 10.1.2 Effects on terrestrial vertebrates other than birds

A 2.1.2.1 KCP 10.1.2.1 Acute oral toxicity to mammals

A 2.1.2.2 KCP 10.1.2.2 Higher tier data on mammals

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

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

zRMS comment:
The study has been assessed and accepted in Core dossier for Coragen 200 SC (CHLORANTRANILIPROLE 200 G/L SC, zRMS Ireland, APPLICANT: E. I. DU PONT de NEMOURS AND COMPANY, Part B Section 6 , 25 July 2014).

Reference:	10.3.1/15
Report	Chlorantraniliprole (DPX-E2Y45) technical: A 48-hour static acute toxicity test with Hyalella azteca; Study code: STUDY CODE: DuPont-36901Study Director: Brougher, D.S., Martin, K.H., Gallagher, S.P., Bodle, E.S.,; 2013
Guideline(s):	OECD 202 (2004), OPPTS 850.1010 (Public Draft, 1996)
Deviations:	
GLP:	Yes
Acceptability:	

Duplication No
(if vertebrate study)

Executive summary:
The acute toxicity of chlorantraniliprole to unfed *Hyalella azteca* was determined in an unaerated, static, 48-hour test. The test was conducted in accordance with the OECD Guideline for Testing of Chemicals, 202, *Daphnia sp. Acute Immobilization Test* and U.S. Environmental Protection Agency Series 850–Ecological Effects Test Guidelines (draft), OPPTS Number 850.1010, *Aquatic Invertebrate Acute Toxicity Test, Freshwater Daphnids*. Treatments consisted of a dilution water control, a solvent control (0.1 mL/L dimethylformamide), and mean measured test concentrations of 0.074, 0.16, 0.36, 0.73, 1.7 and 3.7 mg a.s./L. The 48-hour LC50 in *Hyalella azteca* was 0.26 mg a.s./L, with a 95% fiducial interval of 0.17 to 0.37 mg a.s./L, based on mean measured chlorantraniliprole test concentrations and mortality data.

I. MATERIALS AND METHODS
A. MATERIALS
1. Test material: Chlorantraniliprole technical
Lot/Batch #: E2Y45-384
Purity: 96.9%
Description: Solid
CAS#: 500008-45-7
Stability of test compound: Shown to be stable under the conditions of the test.

2. Controls: Dilution water (laboratory well water) control
Solvent control (0.1 mL/L dimethylformamide)
Test vehicle: None
Toxic reference: Not applicable
3. Test organism: Amphipod
Species: *Hyalella azteca*
Age/life stage at dosing: 7 days
Initial population: Four replicate test chambers with 5 amphipods per test chamber
Source: Wildlife International in-house culture
Diet: Unfed during test
Test chamber: 250-mL glass beaker containing approximately 200 mL of test solution (6.5-cm test solution depth)
4. Environmental conditions: Dissolved oxygen: ³8.1 mg/L (³95% of saturation)
pH: 8.2 to 8.6
Temperature: 22.5 to 24.5°C in test chambers; 23.2 to 23.6°C measured continuously in an adjacent container of water.
Photoperiod: 16 hr light (211 lux at initiation) and 8 hr dark including 30 min transitional period preceding and following the 16-hr light interval.

B. STUDY DESIGN AND METHODS

1. In-life initiated/completed
20-May-2013 to 23-May-2013

2. Experimental treatments
The acute toxicity of chlorantraniliprole to unfed *Hyalella azteca* (7 days old) was determined in an unaerated, static, 48-hour test. Treatments consisted of a dilution water control, a solvent control, and mean, measured test concentrations of 0.074 to 3.7 mg a.s./L. Five amphipods were used per replicate with four replicates per test concentration and control.

3. Observations
Mortality and behavioural observations were made at approximately 3 hours, and at 24 and 48 hours (± 1

hour) following initiation of exposure.

4. Statistics
The 48-hour mortality data were analysed using the computer program of C. E. Stephan. The program was designed to calculate the LC50 value and the 95% fiducial interval by probit analysis, the moving average method, and binomial probability with nonlinear interpolation. In this study, probit analysis was used to calculate the 24 and 48-hour LC50 values and the 95% fiducial intervals. The highest mean, measured test concentration causing no mortality at test end and the lowest mean, measured test concentration causing 100% mortality at test end were assessed by visual observation of the mortality and observation data.

II. RESULTS AND DISCUSSION
A. FINDINGS
Nominal test concentrations of chlorantraniliprole were 0.075, 0.17, 0.36, 0.80, 1.8 and 3.9 mg a.s./L. Mean, measured concentrations of chlorantraniliprole were 0.074, 0.16, 0.36, 0.73, 1.7 and 3.7 mg a.s./L and ranged from 91 to 100% of nominal concentrations.

Table 79
Summary of observed mortality of unfed *Hyalella azteca* exposed to chlorantraniliprole for 48 hours in an unaerated, static, acute test

Mean, Measured Chlorantraniliprole Concentration (mg a.s./L)	Mortality (Cumulative No. dead/No. at test start) a											
	~3 Hours				24 Hours				48 Hours			
	A	B	C	D	A	B	C	D	A	B	C	D
Dilution water control (0.0)	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
Solvent Control	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	1/5	0/5	0/5
0.074	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	1/5	2/5	1/5	0/5
0.16	0/5	0/5	0/5	0/5	0/5	0/5	1/5	0/5	2/5	1/5	3/5	1/5
0.36	0/5	0/5	0/5	0/5	0/5	1/5	2/5	0/5	3/5	4/5	4/5	2/5
0.73	0/5	0/5	0/5	0/5	1/5	0/5	2/5	1/5	2/5	3/5	4/5	4/5
1.7	0/5	0/5	0/5	0/5	2/5	3/5	4/5	3/5	5/5	5/5	4/5	5/5
3.7	0/5	0/5	0/5	0/5	3/5	4/5	4/5	3/5	5/5	5/5	5/5	5/5

[a] A–D represent replicate test chambers containing 5 amphipods each at test start.

Table 80
Summary of sublethal effects of unfed *Hyalella azteca* exposed to chlorantraniliprole for 48 hours in an unaerated, static, acute test

Mean, Measured Chlorantraniliprole Concentration (mg a.s./L)	Number affected/Number alive [a,b]											
	~ 3 Hours				24 Hours				48 Hours			
	A	B	C	D	A	B	C	D	A	B	C	D
Dilution water control (0.0)	0/5	0/5	2Q,AN/5	0/5	0/5	1Q,AN/5	1Q,AN/5	2Q,AN/5	1Q,AN/5	0/5	0/5	1Q,AN/5
Solvent Control	0/5	3Q,AN/5	2Q,AN/5	3Q,AN/5	2Q,AN/5	2Q,AN/5	2Q,AN/5	1Q,AN/5	1Q,AN/5	0/4	1Q,AN/5	2Q,AN/5
0.074	5Q,AN/5	5Q,AN/5	5Q,AN/5	1Q,AN/5	5Q,AN/5	5Q,AN/5	4Q,AN/5	3Q,AN/5	0/4	3Q,AN/3	1C/4	1Q,AN/5
0.16	1Q,AN/5	3Q,AN/5	2Q,AN/5	2Q,AN/5	4Q,AN;1C/5	3Q,AN/5	4Q,AN/4	3Q,AN;1C/5	1C/3	3C/4	2C/2	2C/4
0.36	4Q,AN/5	3Q,AN/5	3Q,AN/5	3Q,AN/5	4Q,AN/5	4Q,AN/4	3Q,AN/3	1Q,C/5	1C/2	1C/1	0/1	2Q,AN;1C/3
0.73	2Q,AN/5	3Q,AN/5	2Q,AN/5	2Q,AN/5	4Q,AN/4	1C;3Q,AN/5	3Q,AN/3	1C;3Q,AN/4	1C/3	2Q,AN/2	0/1	0/1
1.7	1Q,AN/5	2Q,AN/5	2Q,AN/5	2Q,AN/5	2Q,AN/3	0/2	0/1	2Q,AN/2	0/0	0/0	1C/1	0/0
3.7	1Q,AN/5	2Q,AN/5	1Q,AN/5	2Q,AN/5	2C/2	0/1	1C/1	2Q,AN/2	0/0	0/0	0/0	0/0

[a] A–D represent replicate test chambers containing 5 amphipods each at test start.
[b] C = lethargy; Q,AN = floating on the surface, appeared normal after being gently submerged; Q,C = floating on the surface, appeared lethargic after being gently submerged.

III. CONCLUSION

The 48-hour LC50 value, based on the mean, measured test concentrations of chlorantraniliprole and mortality, was estimated to be 0.26 mg a.s./L, with a 95% fiducial interval of 0.17 to 0.37 mg a.s./L. The highest mean, measured test concentration causing no mortality at test end was <0.074 mg a.s./L. The lowest mean, measured test concentration causing 100% mortality at test end was 3.7 mg a.s./L.

zRMS comment:
The study has been assessed and accepted in Core dossier for Coragen 200 SC (CHLORANTRANILIPROLE 200 G/L SC, zRMS Ireland, AP-PLICANT: E. I. DU PONT de NEMOURS AND COMPANY, Part B Section 6 , 25 July 2014)

Reference:	10.3.1/15
Report	Chlorantraniliprole (DPX-E2Y45) technical: A 48-hour static acute toxicity test with the Cladoceran (Daphnia pulex); Study code: STUDY CODE: DuPont-36902 Study Director: Brougher, D.S., Martin, K.H., Gallagher, S.P., Bodle, E.S.,;
Guideline(s):	OECD 202 (2004), OPPTS 850.1010 (Public Draft, 1996))
Deviations:	
GLP:	Yes
Acceptability:	
Duplication (if vertebrate study)	No

Executive summary:
The acute toxicity of chlorantraniliprole to unfed Daphnia pulex was determined in an unaerated, static, 48-hour test. The test was conducted in accordance with the OECD Guideline for Testing of Chemicals, 202, Daphnia sp. Acute Immobilization Test and U.S. Environmental Protection Agency Series 850 – Ecological Effects Test Guidelines (draft), OPPTS Number 850.1010, Aquatic Invertebrate Acute Toxicity Test, Freshwater Daphnids. Treatments consisted of a dilution water control, a solvent control and five nominal chlorantraniliprole concentrations of 1.3, 2.5, 5.0, 10 and 20 µg active substance (a.s.)/L. The corresponding mean, measured concentrations of chlorantraniliprole were 1.3, 2.2, 4.7, 9.5 and 19 µg a.s./L. The 48-hour EC50, based on mean, measured concentrations of chlorantraniliprole and immobility data, was estimated to be 12.1 µg a.s./L, with the 95% fiducial limits of 9.5 to 19 µg a.s./L. The highest mean, measured concentration causing no immobility at test end was 2.2 µg a.s./L. The lowest mean, measured test concentration causing 100% immobility at test end was 19 µg a.s./L.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test material: Chlorantraniliprole technical
Lot/Batch #: E2Y45-384
Purity: 96.9%
Description: Solid
CAS#: 500008-45-7
Stability of test compound: Shown to be stable under the conditions of the test.

2. Controls: Dilution water (UV-sterilized laboratory well water) control
Test vehicle: Solvent dimethylformamide (0.1 mL/L DMF)
Toxic reference: Not applicable

3. Test organism: Cladoceran
Species: *Daphnia pulex*
Age/life stage at dosing: <24 hours
Initial population: Four replicate test chambers with 5 daphnids per test chamber
Source: Wildlife International in-house culture
Diet: Unfed during test
Test chamber: 250-mL glass beaker containing approximately 200 mL of test solution (6.3-cm test solution depth)

4. Environmental conditions: Dissolved oxygen: ³8.0 mg/L (³89% of saturation)
pH: 8.1 to 8.5
Temperature: 20.3 to 21°C in test chambers; ranged from 19.99 to 22.30°C measured continuously in an adjacent container of water.
Photoperiod: 16 hr light (389 lux at initiation) and 8 hr dark including 30 min transitional period preceding and following the 16-hr light interval.
B. STUDY DESIGN AND METHODS
1. In-life initiated/completed
07-August-2013 to 09-August-2013

2. Experimental treatments
The acute toxicity of chlorantraniliprole to unfed *Daphnia pulex* (<24-hour old) was determined in an unaerated, static, 48-hour test. Treatments consisted of a dilution water control and mean, measured test concentrations of 1.3, 2.2, 4.7, 9.5 and 19 µg a.s./L. Five daphnids were used per replicate with four replicates per test concentration and control.

3. Observations
Immobility and behavioural observations were made at approximately 3 hours, and at 24 and 48 hours (± 1 hour) following initiation of exposure.

4. Statistics
The 48-hour mortality data were analysed using the computer program of C. E. Stephan. The program was designed to calculate the EC50 value and the 95% fiducial limits by probit analysis, the moving average method, and binomial probability with nonlinear interpolation. In this study, nonlinear interpolation was used to calculate the 24 and 48-hour EC50 values. The highest mean, measured test concentration causing no immobility at test end and the lowest mean, measured test concentration causing 100% immobility at test end were assessed by visual observation of the immobility and observation data.

II. RESULTS AND DISCUSSION

A. FINDINGS
Nominal test concentrations of chlorantraniliprole were 1.3, 2.5, 5.0, 10 and 20 µg a.s./L. Mean, measured concentrations of chlorantraniliprole were 1.3, 2.2, 4.7, 9.5 and 19 µg a.s./L and ranged from 88 to 100% of nominal concentrations. Summaries of cumulative immobility and sublethal effects are presented in Table 81 and Table 82, respectively.

Table 81
Summary of cumulative immobility of unfed *Daphnia pulex* exposed to chlorantraniliprole for 48 hours in an unaerated, static, acute test

Mean, Measured Chlorantraniliprole Concentration (µg a.s./L)	Immobility (Cumulative No. immobile/No. at test start)[a]											
	~3 Hours				24 Hours				48 Hours			
	A	B	C	D	A	B	C	D	A	B	C	D
Dilution water control (0.0)	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
Solvent control (0.0)	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
1.3	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
2.2	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
4.7	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	1/5	0/5
9.5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	1/5	0/5	2/5	0/5
19	0/5	0/5	0/5	0/5	4/5	3/5	2/5	4/5	5/5	5/5	5/5	5/5

[a] A–D represent replicate test chambers containing 5 daphnids each at test start.

Table 82
Summary of sublethal effects of unfed *Daphnia pulex* exposed to chlorantraniliprole for 48 hours in an unaerated, static, acute test

Mean, Measured Chlorantraniliprole Concentration (µg a.s./L)	Number affected/Number alive[a, b]											
	~3 Hours				24 Hours				48 Hours			
	A	B	C	D	A	B	C	D	A	B	C	D
Dilution water control (0.0)	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
Solvent control (0.0)	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
1.3	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
2.2	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
4.7	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/4	0/5
9.5	1C/5	1C/5	0/5	0/5	1C/5	1C/5	1C/5	0/5	0/4	0/5	0/3	2C/5
19	1C/5	1C/5	0/5	0/5	1C/1	2C/2	3C/3	1C/1	--	--	--	--

[a] A–D represent replicate test chambers containing 5 daphnids each at test start.
[b] C = lethargic.

III. CONCLUSION
The 48-hour EC50 value, based on the mean, measured test concentrations of chlorantraniliprole and immobility, was estimated to be 12.1 µg a.s./L. The highest mean, measured test concentration causing no immobility at test end was 2.2 µg a.s./L. The lowest mean, measured test concentration causing 100% immobility at test end was 19 µg a.s./L.

zRMS comment:
The study has been assessed and accepted in Core dossier for Coragen 200 SC (CHLORANTRANILIPROLE 200 G/L SC, zRMS Ireland, AP-PLICANT: E. I. DU PONT de NEMOURS AND COMPANY, Part B Section 6 , 25 July 2014)

Reference:	10.3.1/15
Report	Chlorantraniliprole (DPX-E2Y45) technical: A 48-hour static acute toxicity test with the Cladoceran (Ceriodaphnia dubia); Study code: STUDY CODE: DuPont-36903; Study Director: Brougher, D.S., Martin, K.H., Gallagher, S.P., Bodle, E.S.,
Guideline(s):	OECD 202 (2004), OPPTS 850.1010 (Public Draft, 1996)
Deviations:	
GLP:	Yes
Acceptability:	
Duplication (if vertebrate study)	No

Executive summary:
The acute toxicity of chlorantraniliprole to unfed *Ceriodaphnia dubia* was determined in an unaerated, static, 48-hour test. The test was conducted in accordance with the OECD Guideline for Testing of Chemicals, 202, *Daphnia sp. Acute Immobilization Test* and U.S. Environmental Protection Agency Series 850 – Ecological Effects Test Guidelines (draft), OPPTS Number 850.1010, *Aquatic Invertebrate Acute Tox-*

icity Test, Freshwater Daphnids. Treatments consisted of a dilution water control, a solvent control and five nominal chlorantraniliprole concentrations of 1.9, 3.8, 7.5, 15 and 30 µg active substance (a.s.)/L. The corresponding mean, measured concentrations of chlorantraniliprole were 2.0, 3.7, 7.2, 16 and 31 µg a.s./L. The 48-hour EC50, based on mean, measured concentrations of chlorantraniliprole and immobility data, was estimated to be 6.2 µg a.s./L, with the 95% fiducial limits of 3.7 to 16 µg a.s./L. The highest mean, measured concentration causing no immobility at test end was 3.7 µg a.s./L. The lowest mean, measured test concentration causing 100% immobility at test end was 16 µg a.s./L.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test material: Chlorantraniliprole technical
Lot/Batch #: E2Y45-384
Purity: 96.9%
Description: Solid
CAS#: 500008-45-7
Stability of test compound: Shown to be stable under the conditions of the test.

2. Controls: Dilution water (UV-sterilized laboratory well water) control
Test vehicle: Solvent dimethylformamide (0.1 mL/L DMF)
Toxic reference: Not applicable

3. Test organism: Cladoceran
Species: *Ceriodaphnia dubia*
Age/life stage at dosing: <24 hours
Initial population: Four replicate test chambers with 5 daphnids per test chamber
Source: Wildlife International in-house culture
Diet: Unfed during test
Test chamber: 250-mL glass beaker containing approximately 220 mL of test solution (6.2-cm test solution depth)

4. Environmental conditions: Dissolved oxygen: ³8.0 mg/L (³89% of saturation)
pH: 8.1 to 8.5
Temperature: 19.1 to 20.0°C in test chambers; ranged from 20.04 to 20.40°C measured continuously in an adjacent container of water.
Photoperiod: 16 hr light (350 lux at initiation) and 8 hr dark including 30 min transitional period preceding and following the 16-hr light interval.

B. STUDY DESIGN AND METHODS

1. In-life initiated/completed
04-June-2013 to 06-June-2013

2. Experimental treatments
The acute toxicity of chlorantraniliprole to unfed *Ceriodaphnia dubia* (<24-hour old) was determined in an unaerated, static, 48-hour test. Treatments consisted of a dilution water control and mean, measured test concentrations of 2.0 to 31 mg a.s./L. Five daphnids were used per replicate with four replicates per test concentration and control.

3. Observations
Immobility and behavioural observations were made at approximately 2 hours, and at 24 and 48 hours (± 1 hour) following initiation of exposure.

4. Statistics
The 48-hour mortality data were analysed using the computer program of C. E. Stephan. The program was designed to calculate the EC50 value and the 95% fiducial limits by probit analysis, the moving average method, and binomial probability with nonlinear interpolation. In this study, nonlinear interpolation

was used to calculate the 24 and 48-hour EC50 values. The highest mean, measured test concentration causing no immobility at test end and the lowest mean, measured test concentration causing 100% immobility at test end were assessed by visual observation of the immobility and observation data

II. RESULTS AND DISCUSSION

A. FINDINGS

Nominal test concentrations of chlorantraniliprole were 1.9, 3.8, 7.5, 15 and 30 µg a.s./L. Mean, measured concentrations of chlorantraniliprole were 2.0, 3.7, 7.2, 16 and 31 µg a.s./L and ranged from 96 to 107% of nominal concentrations. Summaries of cumulative immobility and sublethal effects are presented in Table 83 and Table 84, respectively

Table 83
Summary of cumulative immobility of unfed *Ceriodaphnia dubia* exposed to chlorantraniliprole for 48 hours in an unaerated, static, acute test

Mean, Measured Chlorantraniliprole Concentration (µg a.s./L)	Immobility (Cumulative No. immobile/No. at test start)[a]											
	~2 Hours				24 Hours				48 Hours			
	A	B	C	D	A	B	C	D	A	B	C	D
Dilution water control (0.0)	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
Solvent control (0.0)	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
2.0	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
3.7	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
7.2	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	5/5	5/5	4/5	0/5
16	0/5	0/5	0/5	0/5	5/5	5/5	5/5	5/5	5/5	5/5	5/5	5/5
31	2/5	4/5	4/5	4/5	5/5	5/5	5/5	5/5	5/5	5/5	5/5	5/5

[a] A–D represent replicate test chambers containing 5 daphnids each at test start.

Table 84
Summary of sublethal effects of unfed *Ceriodaphnia dubia* exposed to chlorantraniliprole for 48 hours in an unaerated, static, acute test

Mean, Measured Chlorantraniliprole Concentration (µg a.s./L)	Number affected/Number alive[a]											
	~2 Hours				24 Hours				48 Hours			
	A	B	C	D	A	B	C	D	A	B	C	D
Dilution water control (0.0)	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
Solvent control (0.0)	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
2.0	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
3.7	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
7.2	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/0	0/0	0/1	0/5
16	0/5	0/5	0/5	0/5	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
31	3C[b]/3	1C/1	1C/1	1C/1	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0

[a] A–D represent replicate test chambers containing 5 daphnids each at test start.
[b] C = lethargic

III. CONCLUSION

The 48-hour EC50 value, based on the mean, measured test concentrations of chlorantraniliprole and immobility, was estimated to be 6.2 µg a.s./L. The highest mean, measured test concentration causing no immobility at test end was 3.7 µg a.s./L. The lowest mean, measured test concentration causing 100% immobility at test end was 16 µg a.s./L.

zRMS comment:
For the risk assessment confirmatory data was used. An evaluation of the study is not necessary.

Reference:	10.3.1/15
Report	IN-LBA22: A 48-hour static-renewal acute toxicity test with the cladoceran (Daphnia magna). Study code: STUDY CODE: DuPont-39689; Study Director: Brougher, D.S., Martin, K.H., Gallagher, S.P., Bodle, E.S.,
Guideline(s):	OECD 202 (2004), OPPTS 850.1010 (Public Draft, 1996)
Deviations:	
GLP:	Yes
Acceptability:	
Duplication (if vertebrate study)	No

Executive summary:
The acute toxicity of IN-LBA22 to unfed *Daphnia magna* was determined in an unaerated, static-renewal, 48-hour test. The test was conducted in accordance with the OECD Guideline for Testing of Chemicals, 202, *Daphnia sp. Acute Immobilization Test* and U.S. Environmental Protection Agency Series 850 Ecological Effects Test Guidelines (draft), OPPTS Number 850.1010, *Aquatic Invertebrate Acute Toxicity Test, Freshwater Daphnids*. Treatments consisted of a dilution water control, a solvent control (0.1 mL DMF/L) and nominal test concentrations of 0.063, 0.13, 0.25, 0.50 and 1.0 mg IN-LBA22/L (equivalent to 0.055, 0.12, 0.23, 0.43 and 0.85 mg IN-LBA22/L based on mean measured test concentrations of IN-LBA22). The 48-hour EC50 in *Daphnia magna* was >0.85 mg IN-LBA22/L, the highest concentration tested, based on mean measured IN-LBA22 test concentrations and immobility data.

I. MATERIALS AND METHODS
A. MATERIALS
1. Test material: IN-LBA22 technical metabolite
Lot/Batch #: LBA22-001
Purity: 98.3%
Description: Solid
CAS #: Not available
Stability of test compound: Shown to be stable under the conditions of the test.

2. Controls: Dilution water (pH adjusted, UV sterilized laboratory well water) control
Solvent (0.1 mL DMF/L) control
Test vehicle: DMF
Toxic reference: Not applicable

3. Test organism: Cladoceran
Species: *Daphnia magna*
Age/life stage at dosing: <24 hours
Initial population: Four replicate test chambers with 5 daphnids per test chamber
Source: Wildlife International in-house culture
Diet: Unfed during test
Test chamber: 250-mL glass beaker containing approximately 210 mL of test solution (8.0-cm test solution depth)

4. Environmental conditions: Dissolved oxygen: ≥8.3 mg/L (≥92% of saturation)

pH: 6.4 to 6.5
Temperature: 20.3 to 20.9°C in test chambers; 20.4 to 20.7°C measured continuously in an adjacent container of water
Photoperiod: 16 hr light (228 lux at initiation) and 8 hr dark including 30 min transitional period preceding and following the 16-hr light interval

B. STUDY DESIGN AND METHODS
1. In-life initiated/completed
18-March-2014 to 20-March-2014

2. Experimental treatments
The acute toxicity of IN-LBA22 to unfed *Daphnia magna* (<24-hour old) was determined in an unaerated, static-renewal, 48-hour test. Treatments consisted of a dilution water control, solvent control (0.1 mL DMF/L) and mean, measured test concentrations of 0.055 to 0.85 mg IN-LBA22/L. Five daphnids were used per replicate with four replicates per test concentration and control.

3. Observations
Immobility and behavioural observations were made at approximately 3.5 hours, and at 24 and 48 hours (±1 hour) following initiation of exposure.

4. Statistics
The absence of immobile daphnids in any of the IN-LBA22 treatment groups during the test precluded the statistical calculation of EC50 values at 24 and 48 hours. Therefore, the EC50 values were estimated to be greater than the highest concentration tested. The highest test concentration causing no immobility at test end and the lowest test concentration causing 100% immobility at test end were assessed by visual observation of the immobility and observation data.

II. RESULTS AND DISCUSSION
A. FINDINGS
Nominal test concentrations of IN-LBA22 were 0.063, 0.13, 0.25, 0.50 and 1.0 mg IN-LBA22/L. Mean, measured concentrations of IN-LBA22 were 0.055, 0.12, 0.23, 0.43 and 0.85 mg IN-LBA22/L and ranged from 85 to 92% of nominal concentrations.

Table 47
Summary of observed immobility of unfed *Daphnia magna* exposed to IN-LBA22 for 48 hours in an unaerated, static-renewal, acute test

Mean Measured Test Concentration (mg IN-LBA22/L)	Immobility (No. immobile/No. at test start)[b]							
	24 Hours[c]				48 Hours			
	A	B	C	D	A	B	C	D
Dilution water control (0.0)	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
Solvent control (0.0)[a]	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
0.055	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
0.12	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
0.23	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
0.43	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
0.85	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5

[a] Solvent concentration: 0.1 mL DMF/L.
[b] A–D represent replicate test chambers containing 5 daphnids each at test start.
[c] There were no immobile daphnids noted at the ~3.5-hour observation interval.

Table 48
Summary of sublethal effects of unfed *Daphnia magna* exposed to IN-LBA22 for 48 hours in an unaerated, static-renewal, acute test

Mean Measured Test Concentration (mg IN-LBA22/L)	Number affected/Number alive[b]							
	24 Hours[c]				48 Hours[d]			
	A	B	C	D	A	B	C	D
Dilution water control (0.0)	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
Solvent control (0.0)[a]	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
0.055	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
0.12	0/4	0/5	0/5	0/5	0/5	0/5	0/5	0/5
0.23	0/5	0/5	0/5	0/5	0/5	0/5	1 C/5	0/5
0.43	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
0.85	0/5	0/5	0/5	0/5	1 C/5	1 C/5	0/5	0/5

[a] Solvent concentration: 0.1 mL DMF/L.
[b] A–D represent replicate test chambers containing 5 daphnids each at test start.
[c] There were no sublethal effects noted at the ~3.5-hour observation interval.
[d] C indicates lethargic *Daphnia*.

III. CONCLUSION

The 48-hour EC50 value, based on the mean, measured test concentrations of IN-LBA22 and immobility, was >0.85 mg IN-LBA22/L, the highest concentration tested. The highest mean, measured test concentration causing no immobility at test end was 0.85 mg IN-LBA22/L. The lowest mean measured test concentration causing 100% immobility at test end was >0.85 mg IN-LBA22/L.

zRMS comment:
For the risk assessment confirmatory data was used. An evaluation of the study is not necessary.

Reference:	10.3.1.15
Report	IN-LBA23: A 48-hour static acute toxicity test with the cladoceran (Daphnia magna); Study code: STUDY CODE: DuPont-38899; Study Director: Brougher, D.S., Martin, K.H., Gallagher, S.P., Bodle, E.S.,...
Gardeline(s):	OECD 202 (2004), OPPTS 850.1010 (Public Draft, 1996)
Deviations:	
GLP:	Yes
Acceptability:	
Duplication (if vertebrate study)	No

Executive summary

The acute toxicity of IN-LBA23 to unfed *Daphnia magna* was determined in an unaerated, static, 48-hour test. The test was conducted in accordance with the OECD Guideline for Testing of Chemicals, 202, *Daphnia sp. Acute Immobilization Test* and U.S. Environmental Protection Agency Series 850 – Ecological Effects Test Guidelines (draft), OPPTS Number 850.1010, *Aquatic Invertebrate Acute Toxicity Test, Freshwater Daphnids*. Treatments consisted of a dilution water control, a solvent control (0.1 mL DMF/L) and nominal test concentrations of 0.063, 0.13, 0.25, 0.50 and 1.0 IN-LBA23/L (equivalent to 0.069, 0.14, 0.21, 0.48 and 1.1 mg IN-LBA23/L based on mean measured test concentrations of IN-LBA23). The 48-hour EC50 in Daphnia magna was >1.1 mg IN-LBA23/L, the highest concentration tested, based on mean measured IN-LBA23 test concentrations and immobility data.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test material: IN-LBA23 technical metabolite
Lot/Batch #: LBA23-001
Purity: 99.6%
Description: Solid
CAS#: Not available
Stability of test compound: Shown to be stable under the conditions of the test.

2. Controls: Dilution water (laboratory well water) control.
Solvent (0.1 mL DMF/L) control
Test vehicle: DMF
Toxic reference: Not applicable

3. Test organism: Cladoceran
Species: *Daphnia magna*
Age/life stage at dosing: <24 hours
Initial population: Four replicate test chambers with 5 daphnids per test chamber
Source: Wildlife International in-house culture
Diet: Unfed during test
Test chamber: 250-mL glass beaker containing approximately 220 mL of test solution (7.3-cm test solution depth)

4. Environmental conditions: Dissolved oxygen: ≥8.3 mg/L (≥92% of saturation)
pH: 8.1 to 8.6
Temperature: 19.2 to 19.8°C in test chambers; 20.01 to 20.32°C measured continuously in an adjacent container of water
Photoperiod: 16 hr light (455 lux at initiation) and 8 hr dark including 30 min transitional period preceding and following the 16-hr light interval.

B. STUDY DESIGN AND METHODS
1. In-life initiated/completed
04-December-2013 to 06-December-2013

2. Experimental treatments
The acute toxicity of IN-LBA23 to unfed *Daphnia magna* (<24-hour old) was determined in an unaerated, static, 48-hour test. Treatments consisted of a dilution water control, solvent control (0.1 mL DMF/L) and mean, measured test concentrations of 0.069 to 1.1 mg IN-LBA23/L. Five daphnids were used per replicate with four replicates per test concentration and control.

3. Observations
Immobility and behavioural observations were made at approximately 2.5 hours, and at 24 and 48 hours (±1 hour) following initiation of exposure.

4. Statistics
There was less than 50% immobility in any of the IN-LBA23 treatment groups during the test, which precluded the statistical calculation of EC50 values at 24 and 48 hours. Therefore, the EC50 values were estimated to be greater than the highest concentration tested. The highest test concentration causing no immobility at test end and the lowest test concentration causing 100% immobility at test end were assessed by visual observation of the immobility and observation data.

II. RESULTS AND DISCUSSION
A. FINDINGS
Nominal test concentrations of IN-LBA23 were 0.063, 0.13, 0.25, 0.50 and 1.0 mg aIN-LBA23/L. Mean, measured concentrations of IN-LBA23 were 0.069, 0.14, 0.28, 0.52 and 1.1 mg IN-LBA23/L and ranged from 104 to 112% of nominal concentrations.

Table 49
Summary of observed immobility of unfed *Daphnia magna* exposed to IN-LBA23 for 48 hours in an unaerated, static, acute test

Mean Measured Test Concentration (mg IN-LBA23/L)	Immobility (No. immobile/No. at test start)[b]							
	24 Hours[c]				48 Hours			
	A	B	C	D	A	B	C	D
Dilution water control (0.0)	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
Solvent control (0.0)[a]	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
0.069	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
0.14	1/5	0/5	0/5	0/5	1/5	0/5	1/5	0/5
0.28	0/5	0/5	0/5	0/5	0/5	1/5	0/5	0/5
0.52	0/5	0/5	0/5	0/5	0/5	0/5	1/5	0/5
1.1	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5

[a] Solvent concentration: 0.1 mL DMF/L.
[b] A–D represent replicate test chambers containing 5 daphnids each at test start.
[c] There were no immobile daphnids noted at the 2-hour observation interval.

Table 50
Summary of sublethal effects of unfed *Daphnia magna* exposed to IN-LBA23 for 48 hours in an unaerated, static, acute test

Mean Measured Test Concentration (mg IN-LBA23/L)	Number affected/Number alive[b]							
	24 Hours[c]				48 Hours[d]			
	A	B	C	D	A	B	C	D
Dilution water control (0.0)	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
Solvent control (0.0)[a]	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
0.069	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
0.14	0/4	0/5	0/5	0/5	0/4	0/5	0/4	0/5
0.28	0/5	0/5	0/5	0/5	0/5	1 C/4	1 C/5	0/5
0.52	0/5	0/5	0/5	0/5	0/5	0/5	1 C/4	3 C/5
1.1	0/5	0/5	0/5	0/5	2 C/5	2 C/5	3 C/5	2 C/5

[a] Solvent concentration: 0.1 mL DMF/L.
[b] A–D represent replicate test chambers containing 5 daphnids each at test start.
[c] There were no sublethal effects noted at the 2-hour observation interval.
[d] C indicates lethargic Daphnia

III. CONCLUSION
The 48-hour EC50 value, based on the mean, measured test concentrations of IN-LBA23 and immobility, was >1.1 mg IN-LBA23/L, the highest concentration tested. The highest mean, measured test concentration causing no immobility at test end was 1.1 mg IN-LBA23/L. The lowest mean measured test concentration causing 100% immobility at test end was >1.1 mg IN-LBA23/L.

zRMS comment:
For the risk assessment confirmatory data was used. An evaluation of the study is not necessary.

Reference:	10.3.1/15
Report:	IN-LBA24: A 48-hour static acute toxicity test with the cladoceran (Daphnia magna). Study code: DuPont-38207. Revision No. 1. Study Director: Brougher, D.S., Martin, K.H., Gallagher, S.P., Bodle, E.S.,...
Guideline(s):	OECD 202 (2004), OPPTS 850.1010 (Public Draft, 1996)
Deviations:	
GLP:	Yes

Acceptability:

Duplication: No
(if vertebrate study)

Executive summary:
The acute toxicity of IN-LBA24 to unfed <24 hour old *Daphnia magna* neonates was determined in an unaerated, static, 48-hour test. The test was conducted in accordance with the OECD Guideline for Testing of Chemicals, 202, *Daphnia sp. Acute Immobilization Test*, and U.S. Environmental Protection Agency Series 850 – Ecological Effects Test Guidelines (draft), OPPTS Number 850.1010, *Aquatic Invertebrate Acute Toxicity Test, Freshwater Daphnids*. Treatments consisted of a dilution water control, a solvent control, and five nominal concentrations of 0.063, 0.13, 0.25, 0.50 and 1.0 mg IN-LBA24/L (equivalent to 0.055, 0.087, 0.16, 0.29 and 0.54 mg IN-LBA24/L, based on mean, measured IN-LBA24 concentrations). The 48-hour EC50, based on mean measured concentrations and immobility data, was determined to be greater than 0.54 mg IN-LBA24/L. The highest mean measured test concentration causing no immobility at test end was 0.54 mg IN-LBA24/L. The lowest mean measured test concentration causing 100% immobility at test end was greater than 0.54 mg IN-LBA24/L.

I. MATERIALS AND METHODS
A. MATERIALS
1. Test material: IN-LBA24 technical metabolite
Lot/Batch #: LBA24-002
Purity: 95.3%
Description: Solid
CAS#: Not available
Stability of test compound: Not shown to be stable under the conditions of the test.

2. Controls: Dilution water (laboratory well water) control, solvent control.
Test vehicle: Solvent dimethylformamide (0.1 mL/L DMF)
Toxic reference: Not applicable

3. Test organism: Cladoceran
Species: *Daphnia magna*
Age/life stage at dosing: <24 hours
Initial population: Four replicate test chambers with 5 daphnids per test chamber
Source: Wildlife International in-house culture
Diet: Unfed during test
Test chamber: 250-mL glass beaker containing 220 mL of test solution (6.5-cm test solution depth)

4. Environmental conditions: Dissolved oxygen: 7.9 mg/L (>88% of saturation)
pH: 8.1 to 8.5
Temperature: 20.2 to 20.7°C in test chambers; ranged from 20.66 to 20.79°C measured continuously in an adjacent container of water
Photoperiod: 16 hr light (483 lux at initiation) and 8 hr dark including 30-min transitional period preceding and following the 16-hr light interval.

B. STUDY DESIGN AND METHODS
1. In-life initiated/completed:
18-July-2013 to 20-July-2013
2. Experimental treatments:
The acute toxicity of IN-LBA24 to unfed *Daphnia magna* (<24-hour old) was determined in an unaerated, static, 48-hour test. Treatments consisted of a dilution water control, a solvent control, and five nominal concentrations of 0.063, 0.13, 0.25, 0.50 and 1.0 mg IN-LBA24/L (equivalent to 0.055, 0.087, 0.16, 0.29 and 0.54 mg IN-LBA24/L, based on mean, measured IN-LBA24 concentrations). Five daphnids were used per replicate with four replicates per test concentration and control.

3. Observations

Immobility and behavioural observations were made at approximately 2.5 hours, and at 24 and 48 hours (± 1 hour) following initiation of exposure.

4. Statistics

There was less than 50% immobility for daphnids in any of the IN-LBA24 treatment groups during the test, which precluded the statistical calculation of EC50 values at 24 and 48 hours. Therefore, the EC50 values were estimated to be greater than the highest concentration tested. The highest mean, measured test concentration causing no immobility at test end and the lowest mean, measured test concentration causing 100% immobility at test end were determined by visual interpretation of the immobility and observation data.

II. RESULTS AND DISCUSSION

A. FINDINGS

The cladoceran (*Daphnia magna*) was exposed to nominal test concentrations of IN-LBA24 of 0.063, 0.13, 0.25, 0.50 and 1.0 mg IN-LBA24/L. Mean, measured concentrations of IN-LBA24 were 0.055, 0.087, 0.16, 0.29 and 0.54 mg IN-LBA24/L and ranged from 54 to 87% of nominal concentrations. Summaries of cumulative immobility and sublethal effects are presented in Table 51 and Table 52, respectively.

Table 51
Summary of cumulative immobility of unfed *Daphnia magna* exposed to IN-LBA24 for 48 hours in an unaerated, static, acute test

Mean Measured IN-LBA24 Concentration (mg/L)	Immobility (Cumulative No. immobile/No. at test start)[a]											
	~2.5 Hours				24 Hours				48 Hours			
	A	B	C	D	A	B	C	D	A	B	C	D
Dilution water control (0.0)	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
Solvent control (0.0)	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
0.055	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	1/5
0.087	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	1/5
0.16	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
0.29	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
0.54	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5

[a] A–D represent replicate test chambers containing 5 daphnids each at test start.

Table 52
Summary of sublethal effects of unfed *Daphnia magna* exposed to IN-LBA24 for 48 hours in an unaerated, static, acute test

Mean Measured IN-LBA24 Concentration (mg/L)	Number affected/Number alive[a]											
	~2.5 Hours				24 Hours				48 Hours			
	A	B	C	D	A	B	C	D	A	B	C	D
Dilution water control (0.0)	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
Solvent control (0.0)	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
0.055	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/4
0.087	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/4
0.16	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
0.29	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
0.54	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5

[a] A–D represent replicate test chambers containing 5 daphnids each at test start.

III. CONCLUSION

The 48-hour EC50 value for *Daphnia magna* exposed to IN-LBA24 was greater than 0.54 mg IN-LBA24/L based on mean measured concentrations. The highest mean measured test concentration causing no immobility at test end was 0.54 mg IN-LBA24/L. The lowest mean measured test concentration causing 100% immobility at test end was greater than 0.54 mg IN-LBA24/L.

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

zRMS comment:
The study has been assessed and accepted in Core dossier for Coragen 200 SC (CHLORANTRANILIPROLE 200 G/L SC, zRMS Ireland, AP-PLICANT: E. I. DU PONT de NEMOURS AND COMPANY, Part B Section 6 , 25 July 2014)

Reference:	10.3.1/15
Report	14C Chlorantraniliprole(DPX-E2Y45) technical: A prolonged sediment toxicity test with Chironomus riparius using spiked natural sediment; Study code: STUDY CODE: DuPont 36097; Study Director: Thomas, S.T., Siddiqui, A.I., Martin, K.H., Gallagher, S.P.;, 2014
Guideline(s):	OECD Guideline 218 (2004))
Deviations:	
GLP:	Yes
Acceptability:	
Duplication (if vertebrate study)	No

The effects of natural sediment incorporated chlorantraniliprole on survival, development time, and both emergence and development rates of the midge (Chironomus riparius) were determined in an aerated, static, 28-day natural sediment toxicity test. The test was conducted in accordance with the OECD Guideline for Testing of Chemicals 218 (2004). Treatments consisted of a negative control, solvent (acetone) control, and five nominal chlorantraniliprole concentrations of 10, 18, 31, 54 and 94 µg/kg. The corresponding mean, measured concentrations in sediment were 7.1, 15, 25, 37 and 73 µg/kg, respectively, based on total radioactive residues (TRR). The 28-day LC50 value based on emergence and mortality of Chironomus riparius exposed to sediment incorporated chlorantraniliprole was 32 µg/kg, with 95% confidence limits of 25 and 37 µg/kg. The 28-day LOEC (lowest observed effect concentration) was 37 µg/kg and the NOEC (no observed effect concentration) was 25 µg/kg for Chironomus riparius exposed to natural sediment incorporated chlorantraniliprole based on mean emergence ratios and development time.

I. MATERIALS AND METHODS
A. MATERIALS
1. Non-radiolabeled test material: Chlorantraniliprole technical
Batch/Lot #: E2Y45-384
Purity: 96.9%
Description: Solid
CAS#: 500008-45-7

2. Radiolabeled test material [Pyrazole carbonyl-^{14}C]chlorantraniliprole
Batch/Lot #: 1645309

Radiochemical purity: 97.5%
Specific activity: 48.66 µCi/mg, 23.51 mCi/mmol, 1.80 MBq/mg

3. Controls: Negative control and solvent control
Test vehicle: Solvent acetone (10 mL acetone/kg sediment- allowed to evaporate)
Toxic reference: None

4. Test organism: Midge
Species: *Chironomus riparius*
Age/life stage at dosing: 1-4 days (first instar)
Initial population: 20 larvae per test chamber
Source: Environmental Consulting and Testing of Superior, Wisconsin
Diet: Rabbit Food supplied by Hartz, Secaucus, New Jersey during holding and TetraMin® Flake food supplied by Doctors Foster and Smith, Blacksburg, Virginia during the test.
Test chamber: One quart glass jars containing approximately 2 cm of test batch sediment and 600 mL of overlying water covered with a loose plastic cover

5. Environmental conditions: Dissolved oxygen: ≥7.8 mg/L (≥87% of saturation)
pH: 7.6 to 8.4
Temperature: 20 ± 2°C in test chambers; and measured continuously in a beaker of water adjacent to the test chambers, measured to the nearest 0.01°C (19.77 to 20.33¸C).
Photoperiod: 16 hours light (512 lux at test initiation) and 8 hours dark including 30 min transitional period preceding and following the 16 hr light interval.
6. Sediment: Natural sediment collected from West Bearskin Lake,Minnesota

STUDY DESIGN AND METHODS
1. In-life initiated/completed
01 November 2013 to 29 November 2013
2. Experimental treatments
The effects of natural sediment incorporated [14C]chlorantraniliprole on the midge (Chironomus riparius) were determined in an aerated, static, 28-day natural sediment toxicity test. Natural freshwater sediment collected from West Bearskin Lake in Minnesota was used as the sediment in the test. The sediment was stored under refrigerated conditions when not in use and was homogenized prior to use in the test. A sample of the sediment was sent to Agvise Laboratories, Northwood, North Dakota to determine the sediment composition. The percent organic carbon content was found to be 1.1%.
Treatments consisted of a negative and solvent (acetone) control and five nominal chlorantraniliprole concentrations of 10, 18, 31, 54 and 94 µg/kg (mean, measured concentrations of 7.1, 15, 25, 37 and 73 µg/kg based on total radioactive residues). Each treatment group had four replicates used for biological observations. Each replicate was initiated with 20 first instar larvae. Six additional replicates were included in the test design for analytical measurements. Each analytical replicate contained 20 organisms except for those being sampled on Day 0. At each sampling interval, an entire analytical replicate from each treatment group was sacrificed for the measurement of chlorantraniliprole in sediment, overlying water and pore water.

3. Observations
The number of surviving midge larvae and any abnormal behaviour was recorded daily. The number of fully emerged males and females was recorded daily during the period of expected emergence.

4. Statistics
The 28-day LC50 was determined by analysing the number of organisms that failed to emerge during the study as well as the number of organisms that emerged and died using binomial probability with nonlinear interpolation. The NOEC and LOEC were determined by visual interpretation of the dose response

pattern and statistical analyses of the mean development times, emergence ratios, and development rates. The data were analysed by using a t-test to determine any statistical differences between the negative and solvent control groups. Since there were differences between the controls, the treatment groups were compared to both the negative and solvent controls using a Dunnett's test to identify those treatment groups that were statistically different.

An ANOVA procedure looking at the interaction between sexes was used to evaluate sensitivity between sexes for development rates. There were no significant interactions found between sex and treatments for development rate therefore the data for each sex were pooled for this variable. There was no feasible way to determine the sex of 1-4 day old larvae at the time organisms were added to test chambers. Evaluations of the sensitivity between sexes for emergence ratio were not possible because calculations require knowing how many individuals of each sex are initially exposed. Therefore, the emergence ratio data for both sexes were also pooled for analysis

II. RESULTS AND DISCUSSION

A. FINDINGS

A summary of the 28-day LC50, NOEC and LOEC are shown in Table 85.

Analytical verification of [14C]chlorantraniliprole concentrations was made in natural sediment, overlying water and pore water sampled on Days 0, 7, and 28 of the test (Table 86) and of chlorantraniliprole (by chromatographic methods) on Days 0, 7, 14, 21 and 28 (Table 87). Mean measured concentrations of [14C]chlorantraniliprole in the sediment were 7.1, 15, 25, 37 and 73 µg/kg, based on total radioactive residues. The LOQ value for radiolabeled concentrations in sediment was 2.13 µg/kg. The LOQ value for radiolabeled concentrations in overlying water and pore water was 0.0926 µg/L. For chromatographic methods, the LOQ in sediment was 2.50 µg/kg and the LOD for sediment was 0.0845 µg/kg. The LOQ for overlying water and pore water was 0.250 µg/L and the LOD was 0.00618 µg/L. A mass balance for [14C]chlorantraniliprole (based on total radioactive residue, TRR) was calculated on Days 0, 7, and 28 of the study in overlying water, pore water, and sediment. On Day 0, the total amount of [14C]chlorantraniliprole (overlying water, pore water, and sediment) in the nominal 10, 18, 31, 54 and 94 µg/kg treatment groups was 114, 112, 107, 110 and 101% of nominal, respectively. After 7 days, the total amount of [14C]chlorantraniliprole was 117, 103, 117, 100, and 116% of nominal, respectively. At study termination (Day 28), the total amount of [14C]chlorantraniliprole was 82.7, 117, 110, 91, and 109% of nominal, respectively. A summary of analytical recoveries (total radioactive residues) is shown in Table 86 and a summary of mass balance approximations is shown in Table 88 and Table 89.

Table 85
Summary of effects for chlorantraniliprole to the midge (*Chironomus riparius*)

Endpoint	Mean, measured concentration in sediment based on TRR	Effect
28-Day LC_{50}	32 µg/kg, 95% confidence interval of 25 and 37 µg/kg	Based on number failing to emerge and number that emerged and died
NOEC	25 µg/kg	Based on emergence ratios and development time
LOEC	37 µg/kg	Based on emergence ratios and development time

Table 86
Measured [^{14}C]chlorantraniliprole and analytical recoveries in sediment, overlying water, and pore water

Nominal chlorantraniliprole concentration (µg/kg)	Interval (days)	Measured chlorantraniliprole equivalents			
		Sediment[a] (µg/kg)	Sediment[a] (% of nominal)	Overlying Water[b] (µg/L)	Pore Water[b] (µg/L)
Negative control (0.0)	0	2.58	---	<LOQ	<LOQ
	7	<LOQ	---	<LOQ	0.149
	28	<LOQ	---	<LOQ	0.241
Solvent control (0.0)	0	<LOQ	---	<LOQ	<LOQ
	7	<LOQ	---	<LOQ	0.124
	28	<LOQ	---	<LOQ	0.242
10	0	9.24	92	0.398	2.45
	7	8.09	81	0.721	1.78
	28	3.85	39	0.907	1.24
18	0	18.5	103	0.645	4.26
	7	12.7	71	1.11	3.02
	28	13.2	73	1.65	2.12
31	0	27.1	87	1.07	7.09
	7	26.3	85	1.91	5.36
	28	21.2	68	2.70	3.41
54	0	49.1	91	1.89	13.4
	7	36.1	67	3.58	9.84
	28	26.7	49	4.74	6.07
94	0	76.9	82	3.29	22.2
	7	77.9	83	6.24	17.2
	28	65.2	69	8.31	11.4

[a] The LOQ value for radiolabelled concentrations in sediment was 2.13 µg/kg.

[b] The LOQ value for radiolabelled concentrations in overlying water and pore water was 0.0926 µg/L.

Table 87
Measured concentrations of chlorantraniliprole and analytical recoveries in overlying water, pore water, and sediment

Nominal chlorantraniliprole concentration (µg/kg)	Interval (days)	Measured chlorantraniliprole concentration			
		Sediment[a] (µg/kg)	Sediment (% of nominal)	Overlying water[b,c] (µg/L)	Pore water[c] (µg/L)
Negative Control (0.0)	0	ND	--	ND	ND
	7	ND	--	ND	ND
	14	ND	--	<LOQ	ND
	21	ND	--	<LOQ	ND
	28	ND	--	ND	ND
Solvent Control (0.0)	0	ND	--	ND	ND
	7	ND	--	ND	ND
	14	ND	--	<LOQ	ND
	21	ND	--	<LOQ	ND
	28	ND	--	ND	ND
10	0	5.49	54.9	0.234[d]	1.99
	7	5.37	53.7	0.432	1.21
	14	4.44	44.4	0.630	1.00
	21	3.13[d]	31.3	0.579	0.807
	28	2.93[d]	29.3	0.732	0.505
18	0	12.4	68.8	0.421	3.46
	7	7.54	41.9	0.815	2.30
	14	8.43	46.8	0.991	1.90
	21	6.12	34.0	1.04	1.59
	28	5.38	29.9	1.46	0.997
31	0	18.9	61.0	0.734	5.53
	7	17.5	56.6	1.24	4.27
	14	12.4	40.1	1.52	3.57
	21	10.1	32.7	1.69	2.72
	28	12.0	38.8	1.35	3.85
54	0	31.7	58.8	1.43	11.2
	7	57.9	107	2.39	7.34
	14	21.0	39.0	2.95	5.98
	21	21.5	39.8	3.29	5.42
	28	20.2	37.4	1.19	13.2

Table 87
Measured concentrations of chlorantraniliprole and analytical recoveries in overlying water, pore water, and sediment (continued)

Nominal chlorantraniliprole concentration (µg/kg)	Interval (days)	Measured chlorantraniliprole concentration			
		Sediment[a] (µg/kg)	Sediment (% of nominal)	Overlying water[b,c] (µg/L)	Pore water[c] (µg/L)
94	0	60.7	64.6	2.47	17.2
	7	41.3	44.0	4.29	13.3
	14	43.8	46.6	4.70	10.9
	21	34.7	36.9	5.68	8.55
	28	37.6	40.0	2.39	23.9

[a] The limit of quantitation (LOQ) was 2.50 µg/kg, calculated as the product of the lowest calibration standard concentration analysed (0.00500 µg/L) and the dilution factor of the matrix blank samples (500).

[b] The limit of quantitation (LOQ) was 0.250 µg/L, calculated as the product of the lowest calibration standard concentration analysed (0.0250 µg/L) and the dilution factor of the control samples (10.0).

[c] The limit of detection (LOD) was 0.00618 µg/L, calculated by determining the signal-to-noise (S/N) ratios for four injections of the lowest calibration standard (0.0250 µg/L) dividing the standard concentration by the S/N ratio, multiplying the quotient by three and the dilution factor (10.0). The LOD for the water sample analyses was calculated as the mean LOD of the four standard injections.

[d] Extrapolated value

ND = Not detected

Table 88
Mass balance approximations for Day 0, 7, and 28

Study day	Nominal test conc. (µg/kg)	Mass of sediment in test system (kg)	Nominal [14C]chloran-traniliprole in test system (µg)	[14C]chloran-traniliprole in sediment[a] (µg)	[14C]chloran-traniliprole in overlying water[b] (µg)	[14C]chloran-traniliprole in pore water[c] (µg)	Total [14C]chloran-traniliprole in test system (µg)	% of nominal [14C]chloran-traniliprole in test system
0	10	0.135	1.346	1.243	0.239	0.049	1.531	114
0	18	0.136	2.445	2.513	0.387	0.085	2.985	122
0	31	0.131	4.070	3.558	0.642	0.142	4.342	107
0	54	0.136	7.360	6.692	1.134	0.255	8.081	110
0	94	0.129	12.166	9.953	1.974	0.389	12.316	101
7	10	0.132	1.324	1.071	0.433	0.042	1.545	117
7	18	0.125	2.253	1.590	0.666	0.066	2.322	103
7	31	0.129	4.005	3.398	1.146	0.129	4.673	117
7	54	0.133	7.157	4.784	2.148	0.207	7.139	100
7	94	0.133	12.494	10.354	3.744	0.361	14.460	116
28	10	0.129	1.294	0.498	0.544	0.028	1.070	82.7
28	18	0.134	2.406	1.764	0.990	0.051	2.805	117
28	31	0.134	4.144	2.834	1.620	0.085	4.539	110
28	54	0.134	7.209	3.565	2.844	0.134	6.542	91
28	94	0.139	13.106	9.091	4.986	0.257	14.333	109

[a] [14C]chlorantraniliprole in sediment = concentration of [14C]chlorantraniliprole in sediment multiplied by the dry weight of sediment in the test system.
[b] [14C]chlorantraniliprole in overlying water = concentration of [14C]chlorantraniliprole in overlying water multiplied by the volume of water in the test system (0.6 L).
[c] [14C]chlorantraniliprole in pore water = concentration of [14C]chlorantraniliprole in pore water multiplied by the volume of pore water in the test system.

During the study, the mean percent [14C]chlorantraniliprole in the sediment decreased from 91.1 to 59.8% of the nominal [14C]chlorantraniliprole in the test system. The mean percent [14C]chlorantraniliprole in the overlying water increased from 16.2% on Day 0 to 40.0% on Day 28. The mean percent [14C]chlorantraniliprole in the pore water on Day 0 was 3.5% of the nominal [14C]chlorantraniliprole in the test systems and decreased slightly to 2.0% of the nominal [14C]chlorantraniliprole in the test systems by the end of the study. The results are shown in Table 89

Table 89
Mean percent of [^{14}C]chlorantraniliprole in sediment, overlying water, and pore water

Study day	% in sediment	% in overlying water	% in pore water	Total %
0	91.1	16.2	3.5	111
7	77.2	30.2	3.0	110
28	59.8	40.0	2.0	102

There were significant differences between the solvent and negative control groups for development rate, emergence ratio, and development time; therefore, the treatment groups were compared to both the negative and solvent control groups to determine if there were any significant reductions. The LC50 based on the number of emerged, surviving *Chironomus riparius* exposed to sediment incorporated [14C]chlorantraniliprole was 32 µg/kg, with 95% confidence limits of 25 and 37 µg/kg. There were statistically significant differences (p<0.05) between the emergence ratios for the negative control group and the 37 and 73 µg/kg treatment groups. There were statistically significant differences (p<0.05) between the emergence ratios for the solvent control and the 25, 37, and 73 µg/kg treatment groups. However, the statistical difference between the solvent control and 25 µg/kg treatment group is not considered biologically meaningful, since the difference is more likely due to the lack of standard deviation for the solvent control group. Therefore, the NOEC for emergence ratios was determined to be 25 µg/kg and the LOEC for emergence ratios was determined to be 37 µg/kg. The emergence ratios are reported in Table 90. There were statistically significant differences (p<0.05) between the development time for the negative control group and the 37 and 73 µg/kg treatment groups. There was also a statistically significant difference (p<0.05) between the development time for the solvent control group and the 73 µg/kg treatment group. Therefore, the NOEC for development time was determined to be 25 µg/kg and the LOEC for development time was determined to be 37 µg/kg. The development times are reported in Table 91. There was a statistically significant difference (p<0.05) between the development rate for the 73 µg/kg treatment group and both the negative and solvent control groups. Therefore, the NOEC for development rate was determined to be 37 µg/kg and the LOEC for development rate was determined to be 73 µg/kg. The development rates are reported in Table 92.

Table 90
Summary of emergence ratio of *Chironomus riparius* exposed to [^{14}C]chlorantraniliprole for 28 days in a prolonged sediment toxicity test using spiked sediment

Nominal [^{14}C]chlorantraniliprole concentrations (µg/kg dry wt sediment)	Emergence ratio[a]				
	A	B	C	D	Mean
Negative control (0.0)	0.95	0.85	0.95	1.00	0.94
Solvent control	1.00	1.00	1.00	1.00	1.00
10	0.95	0.85	0.90	1.00	0.93
18	1.00	1.00	1.00	0.95	0.99
31	0.95	0.95	1.00	0.70	0.90
54	0.30	0.20	0.25	0.20	0.24
94	0.10	0.00	0.00	0.00	0.03

[a] A–D represent replicate test chambers containing twenty midges each.

Table 91
Summary of development time of *Chironomus riparius* exposed to [^{14}C]chlorantraniliprole for 28 days in a prolonged sediment toxicity test using spiked sediment

Nominal [^{14}C]chlorantraniliprole concentrations (µg/kg dry wt sediment)	Development time[a]				
	A	B	C	D	Mean
Negative control (0.0)	16.1	15.9	15.1	15.3	15.6
Solvent control	14.9	15.2	14.7	14.6	14.9
10	15.3	15.0	15.3	15.4	15.3
18	15.4	14.7	15.8	15.6	15.4
31	15.6	15.0	15.2	15.5	15.3
54	15.0	14.3	14.4	13.8	14.4
94	22.0	--	--	--	22.0

[a] A-D represent replicate test chambers containing twenty midges each.

Table 92
Summary of development rate of *Chironomus riparius* exposed to [^{14}C]chlorantraniliprole for 28 days in a prolonged sediment toxicity test using spiked sediment

Nominal [^{14}C]chlorantraniliprole concentrations (µg/kg dry wt sediment)	Development rate[a]				
	A	B	C	D	Mean
Negative control (0.0)	0.0647	0.0659	0.0694	0.0683	0.0671
Solvent control	0.0703	0.0688	0.0712	0.0714	0.0704
10	0.0686	0.0697	0.0681	0.0683	0.0687
18	0.0681	0.0709	0.0663	0.0667	0.0680
31	0.0670	0.0696	0.0689	0.0676	0.0683
54	0.0692	0.0728	0.0720	0.0756	0.0724
94	0.0465	--	--	--	0.0465

[a] A-D represent replicate test chambers containing twenty midges each.

III. CONCLUSION

The 28-day LC50 value based on emergence and/or mortality of *Chironomus riparius* exposed to natural sediment incorporated [14C]chlorantraniliprole was 32 µg/kg, with 95% confidence limits of 25 and 37 µg/kg. There were treatment related effects observed on mean emergence ratios in the 37 and 73 µg/kg treatment groups when compared to both the negative and solvent controls. There were treatment related effects observed for development time between the negative control group and the 37 and 73 µg/kg treatment groups and between the solvent control group and the 73 µg/kg treatment group. There was also a treatment related effect observed for development rate between both the negative and solvent control and

~~the 73 µg/kg treatment group. Therefore, the 28-day LOEC was 37 µg/kg, and the 28-day NOEC was 25 µg/kg.~~

A 2.2.3 KCP 10.2.3 Further testing on aquatic organisms

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

A 2.3.1.1.2 KCP 10.3.1.1.2 Acute contact toxicity to bees

A 2.3.1.2 KCP 10.3.1.2. Chronic toxicity to bees

Comments of zRMS:	The test design is in line with the OECD Test Guideline 245 and the validity criteria are met: - Mortality in the control group at the end of the 10-day test was 0.0%, which is below the maximum acceptable limit of 15%. - Mortality in the group treated with the reference substance (dimethoate) was 100.0%, well above the required threshold of ≥50%. Consequently, this study is considered acceptable for use in the risk assessment. LDD_{50} > 84.4 µg prod/bee/day
Reference:	10.3.1/16
Report	PART I (Biological Phase) CLOROL 200 SC Honeybees (Apis mellifera L.), Chronic Oral Toxicity Test, Repeated Exposure; Study code: STUDY CODE: B-92-23 Study Director: A. Fulczyk; Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna, Ecotoxicology Research Group Doświadczalna 27, 43-200 Pszczyna, Poland
Guideline(s):	according to the OECD Guideline No. 245 (2017)
Deviations:	
GLP:	Yes
Acceptability:	
Duplication (if vertebrate study)	No

Materials and methods:

Test item:

CLOROL 200 SC
content: 199.35 g/L of chlorantraniliprole (CAS No. 500008-45-7)
batch no.: CHR/03/2023
production date: 05.04.2023
expiry date: not specified by the Sponsor

Biological test system: species: the honeybee, Apis mellifera L.; strain: carnica,
source: an apiary at the Łukasiewicz Research Network –Institute of Industrial Organic Chemistry, Branch Pszczyna; age: freshly emerged worker honeybees (max. 2 days old) from the same queen-right colony

Experimental design:
- the test item:
number of concentrations: 1 and the control (50% (w/v)
aqueous sucrose solution)
number of replicates: 5
number of insects: 10 bees/replicate
- the reference item:
number of concentrations: 1
number of replicates: 3
number of insects: 10 bees/replicate
exposure duration: 10 days

Nominal concentration of the test item: 3000.0 mg/kg
Nominal dose of the test item: 90.0 µg/bee/day
Test item dietary dose: 84.4 µg/bee/day
Nominal concentration of the reference item (dimethoate): 0.8 mg/kg
Nominal dose of the reference item (dimethoate): 0.024 µg/bee/day
Reference item dietary dose: 0.017 µg/bee/day
Test conditions: temperature: 32.4 – 33.9°C;
relative humidity: 50.1 – 70.0%;
Statistical method: due to the lack of mortality in group treated with the test item, statistical analysis was not performed
Endpoints: honeybee mortality after 10 days of exposure

Results and discussions:

The mortality of honeybees exposed to CLOROL 200 SC was investigated during 10-days chronic oral toxicity test.
The design of the definitive test was selected on the basis of the preliminary non-GLP stability test and two preliminary non-GLP range-finding tests results. One dose of the test item was used in the definitive test (limit test). The nominal concentration of the test item was 3000.0 mg of test item/kg of diet (corresponding to the nominal dose of 90.0 µg of test item/30 mg of diet/day).
Daily dose, consumed by the bees in the group treated with the test item at the nominal concentration of 3000.0 mg/kg (90.0 µg/30 mg/day) was 84.4 µg of test item/bee/day (dietary dose). Daily dose was calculated on the basis of average consumption of a treated 50% (w/v) aqueous sucrose solution and the nominal dose used for the treatment.
Each group of bees (5 replicates/group; 10 bees/replicate) was fed with 2 mL of a 50% (w/v) aqueous sucrose solution containing the test item at the concentration of 3000.0 mg/kg or 50% (w/v) aqueous sucrose solution alone (control group) for 10 days. Dimethoate, which is a recommended reference item,

was used to verify the sensitivity of the bees and the precision of the test procedure. The group treated with the reference item (3 replicates per 10 bees) was fed with 2 mL of a 50% (w/v) aqueous sucrose solution containing reference item at the nominal concentration of 0.8 mg of reference item/kg of diet (corresponding to the nominal dose of 0.024 µg of reference item/30 mg of diet). Daily weighed feeders were used. During the experiment, the insects were caged in groups of 10. Daily dose, consumed by the bees in the group treated with the reference item at the nominal concentration of 0.8 mg/kg (0.024 µg/30 mg/day) was 0.017 µg of reference item/bee/day (dietary ingested dose).
The insects were observed for mortality and behavioral abnormalities (signs of intoxication) at daily intervals up to 10 days of exposure for control and test item group. The reference item group was observed for mortality and behavioral abnormalities at daily intervals up to 9 days of exposure (100.0% mortality of reference group at 9th day (D9) of the definitive test).
Average consumption of a 50% (w/v) aqueous sucrose solution in the control group was 31.9 mg of diet/bee/day. Average consumption in the group treated with the test item at the concentration of 3000.0 mg/kg was 28.1 mg of treated diet/bee/day. Average consumption of a 50% (w/v) aqueous sucrose solution containing the reference item at the concentration of 0.8 mg/kg was 20.6 mg of treated diet/bee/day.
The concentration of chlorantraniliprole was chemically determined using the validated high performance liquid chromatographic method with Diode Array Detection. Fresh samples of the test item concentration and the control were chemically analyzed at test initiation and at the end of the maximum storage period (i.e. after 4 days). At exposure initiation, in the fresh sample of the test item of 3000.0 mg/kg, the determined concentration of chlorantraniliprole was 104.0% of nominal concentration. The results confirm that the test item concentration was prepared correctly. After 4 days of the storage period, in the sample of the test item of 3000.0 mg/kg, the determined concentration of chlorantraniliprole was 105.0% of nominal concentration. Based on the results of chemical analyses, the concentration of chlorantraniliprole was stable under storage conditions..

The validity criterion concerning mortality was met, because mortality in the control was 0.0% after 10 days of exposure.
The percentage of mortality of the honeybees exposed to the test item, at the concentration of 3000.0 mg/kg (nominal dose 90.0 µg of test item/bee/day, dietary dose 84.4 µg of test item/bee/day) at exposure termination (after 10 days) was 0.0%. On the basis of the obtained mortality results, the LC50 is higher than 3000.0 mg/kg,the LDD50 value for nominal dose is higher than 90.0 µg of test item/bee/day and the LDD50 value for dietary ingested dose is higher than 84.4 µg of test item/bee/day. Due to the lack of mortality in group treated with the test item concentration, statistical analysis was not performed. The NOEC value is higher than or equal to 3000.0 mg/kg and the NOEDD value for nominal dose is higher than or equal to 90.0 µg/bee/day. The NOEDD value for dietary ingested dose is higher than or equal to 84.4 µg/bee/day. The validity criterion concerning mortality of the honeybees exposed to the reference item, dimethoate was met, mortality was 100.0% at the end of the definitive test. The results obtained in the reference item group showed that the insects were sensitive to dimethoate.

Nominal test item concentration [mg of test item/kg of diet]	Nominal test item dose [µg of test item/30 mg of diet/day] [µg of test item/bee/day]	Ingested* dose [µg of test item/bee/day]	Number of tested bees [no]	Total mortality No.	Total mortality [%]	LC_{50} [mg of test item/kg of diet]	LDD_{50} [µg/bee/day] for nominal dose	LDD_{50} [µg of test item/bee/day] for dietary ingested dose
CLOROL 200 SC								
0.0 (Control)			50	0	0.0	> 3000.0	> 90.0	> 84.4
3000.0	90.0	84.4	50	0	0.0			
NOEC [mg/kg]			≥ 3000.0					
NOEDD [µg/bee/day] for nominal dose			≥ 90.0					
NOEDD [µg/bee/day] for dietary ingested dose			≥ 84.4					
Dimethoate (reference item)								
0.8	0.024	0.017	30	30	100.0	not determined		

*: ingested doses (dietary doses) were calculated on the basis of the concentrations of the test item/reference item and average consumption of treated 50% (*w/v*) aqueous sucrose solution

TEST VALIDITY CRITERIA:
The following validity criteria were met during the test:
- At the end of the definite test average mortality of the control groups was 0.0% (criterion: it must not exceed 15%) .
- At the end of the definitive test mortality of the honeybees exposed to the reference item at the concentration of 0.8 mg/kg (0.024 µg/bee/day), was 100.0% (criterion: it must be ≥ 50%).

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

Comments of zRMS:	The test design is in line with the OECD Test Guideline 239 and the validity criteria are met: - Cumulative mortality in the control group by day 8 (D8) was 0.0%, which is below the maximum allowed limit of ≤15% - Mortality in the group treated with the reference substance (dimethoate) was 100.0% by D8, well above the required threshold of ≥50%. - The adult emergence rate in the control group was 83.3% by D22, exceeding the required minimum of ≥70%. Consequently, this study is considered acceptable for use in the risk assessment. NOED = 0.205 µg/larva ED_{50} =1.736 µg/larva

Reference: 10.3.1/15

Report	PART I (Biological Phase) CLOROL 200 SC Honeybees (Apis mellifera L.), Larval Toxicity Test, Repeated Exposure; Study code: STUDY CODE: B-92-23 Study Director: A. Fulczyk; Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna, Ecotoxicology Research Group Doświadczalna 27, 43-200 Pszczyna, Poland
Guideline(s):	to the OECD Guidance Document No. 239 (2021)
Deviations:	
GLP:	Yes
Acceptability:	
Duplication (if vertebrate study)	No

Reference:	10.3.1/15
Report	PART I (Biological Phase) CLOROL 200 SC Honeybees (Apis mellifera L.), Larval Toxicity Test, Repeated Exposure; Study code: STUDY CODE: B-92-23 Study Director: A. Fulczyk; Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna, Ecotoxicology Research Group Doświadczalna 27, 43-200 Pszczyna, Poland
Guideline(s):	to the OECD Guidance Document No. 239 (2021)
Deviations:	
GLP:	Yes
Acceptability:	
Duplication (if vertebrate study)	No

Materials and methods

Test item: CLOROL 200 SC
content: 199.35 g/L of Chlorantraniliprole (CAS No. 500008-45-7)
batch no.: CHR/03/2023
production date: 05.04.2023
expiry date: not specified by Sponsor
Biological test system:
the honeybee, Apis mellifera L.; strain: carnica; source: an apiary at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna; age: one-day-old larvae

Experimental design:
– the test item: number of cumulative doses: 6 and a control; number of replicates: 3; number of larvae: 12/replicate
– the reference item: number of cumulative doses: 1; number of replicates: 3; number of larvae: 12/replicate
Test item doses: 0.082, 0.205, 0.512, 1.28, 3.2 and 8.0 µg/larva

Reference item dose: 7.39 µg dimethoate/larva

Test duration: 22 days

Test conditions: temperature: 34.0 – 34.9°C;
relative air humidity:
D1 – D8: 90.2 – 95.9%
D8 – D15: 75.0 – 84.9%
D15 – D22: 50.1 – 79.5%

Endpoints:
mortality of larvae and pupae, adult emergence, EC10/ED10, EC20/ED20, EC50/ED50, NOEC/NOED on day 22 (D22)
Statistical method: Tarone´s Test Procedure, Step-down Cochran-Armitage Test Procedure, Weibull analysis using linear max. likelihood regression

Statistical software: ToxRat Professional 3.3.0.

Results and discussions:

The larval toxicity test of CLOROL 200 SC was conducted to determine the median effective concentration/dose, i.e. EC50/ED50 or any other effective concentration/dose, ECx/EDx, as well as the no observed effect concentration/dose (NOEC/NOED) after 22 days of the experiment. Six cumulative doses of the test item were used. These were 0.082, 0.205, 0.512, 1.28, 3.2 and 8.0 µg/larva. They were selected on the basis of two preliminary non-GLP range-finding tests.
From day 3 (D3) to day 6 (D6) of the experiment, each larva (3 replicates; 12 larvae/replicate) was fed with treated diet in the volume of 20, 30, 40 or 50 µL, respectively (total volume of treated diet was 140 µL). During the experiment, the larvae were kept in grafting cells placed into 48-well plates.
The plates were kept in a desiccator, in an incubator. A toxic standard, i.e. dimethoate, was used to verify the sensitivity of the larvae and the precision of the test procedure.
Mortality of the larvae was recorded daily from day 4 (D4) to day 8 (D8) and additionally at day 10 (D10) and 13 (D13) (the additional mortality observations are not presented in the final report, the results are included in the raw data). On day 15 (D15) mortality of larvae and pupae was recorded. The test was ended on day 22 when the emergence of adults was evaluated.

Mortality of the control group on day 8 (D8) of the test was 0.0% (criterion: ≤ 15%). The percentages of mortality of the honeybee larvae exposed to the test item, CLOROL 200 SC, at the cumulative doses of 0.082, 0.205, 0.512, 1.28, 3.2 and 8.0 µg/larva, at D8, were: 8.3, 2.8, 11.1, 5.6, 5.6 and 75.0%, respectively. Mortality of the larvae treated with the reference item (dimethoate) on day 8 (D8) was 100.0%.
Larvae and pupae mortality of the control group on day 15 (D15) of the test was 13.9%. The percentages of mortality of the honeybee larvae and pupae exposed to the test item, CLOROL 200 SC, at the cumulative doses of 0.082, 0.205, 0.512, 1.28, 3.2 and 8.0 µg/larva at D15, were: 13.9, 27.8, 38.9, 55.6, 55.6 and 88.9%, respectively and after Abbott's correction [7] the mortality was: 0.0, 16.1, 29.0, 48.4, 48.4 and 87.1%, respectively.
Total mortality of the control group at test termination (day 22, D22) was 16.7%. The percentages of mortality of the honeybee larvae and pupae exposed to the test item, CLOROL 200 SC, at the cumulative doses of 0.082, 0.205, 0.512, 1.28, 3.2 and 8.0 µg/larva at D22, were: 22.2, 30.6, 41.7, 55.6, 61.1 and 91.7% respectively and after Abbott's correction [7] the mortality was: 6.7, 16.7, 30.0, 46.7, 53.3 and 90.0%, respectively.
The emergence of adults (emergence rate) at the end of the test (on D22) in the control group was 83.3%. In the groups treated with the test item at the cumulative doses of 0.082, 0.205, 0.512, 1.28, 3.2 and 8.0 µg/larva the adult emergence rates were: 77.8, 69.4, 58.3, 44.4, 38.9 and 8.3%, respectively.

Cumula-tive dose [µg test item/larva]	Concen-tration [mg test item/kg food]	Number of tested larvae [no.]	Total mortality (larval and pupal) and emergence rate on day 22 (D22)				
			Number [no.]	[%]	Corr[a] [%]	Number of emerged adults [no.]	Emergence rate [%]
Test item: CLOROL 200 SC							
Control (0.0)		36	6	16.7	–	30	**83.3**
0.082	**0.532**	36	8	22.2	**6.7**	28	**77.8**
0.205	**1.331**	36	11	30.6	**16.7**	25	**69.4**
0.512[+]	**3.325**	36	15	41.7	**30.0**	21	**58.3**
1.28[+]	**8.31**	36	20	55.6	**46.7**	16	**44.4**
3.2[+]	**20.8**	36	22	61.1	**53.3**	14	**38.9**
8.0[+]	**51.9**	36	33	91.7	**90.0**	3	**8.3**
ED_{50} [µg test item/larva]			**1.736** (*1.216 – 2.429*)				
EC_{50} [mg test item/kg]			**11.273** (*7.896 – 15.773*)				
ED_{20} [µg test item/larva]			**0.321** (*0.153 – 0.519*)				
EC_{20} [mg test item/kg]			**2.084** (*0.994 – 3.370*)				
ED_{10} [µg test item/larva]			**0.105** (*0.035 – 0.206*)				
EC_{10} [mg test item/kg]			**0.682** (*0.227 – 1.338*)				
NOED [µg test item/larva]			**0.205**				
NOEC [mg test item/kg]			**1.331**				
Reference item: Technical dimethoate mortality on day 8 (D8)							
7.39	**48.0**	36	36	100.0	**100.0**	not determined	

[a]: corrected according Abbott's formula [7]
[+]: statistical significant difference [6], [SOP/B/67]

TEST VALIDITY CRITERIA:
The following validity criteria were met:
- Cumulative larval mortality in the control group was 0.0% at day 8 (D8) (criterion: ≤ 15%).
- Mortality of the larvae treated with the reference item at day 8 (D8) (dimethoate) was 100.0% (criterion: ≥ 50%).
- Emergence rate in the control group on D22 was 83.3% (criterion: ≥ 70%).

A 2.3.1.4 KCP 10.3.1.4 Sub-lethal effects

A 2.3.1.5 KCP 10.3.1.5 Cage and tunnel tests

A 2.3.1.6 KCP 10.3.1.6 Field tests with honeybees

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 performed according to OECD TG 222 and principles of GLP. The validity criteria are met: For the control group: - Adult mortality: ≤ 10 % (being 1.25 %) - Number of juveniles per replicate: ≥ 30 (being 54) - Coefficient of variation of reproduction: ≤ 30 % (being 20.0 %). The following deviations from the study plan were noted: – The Sponsor did not provide the expiry date of the test material, which was his responsibility. The test material was considered valid to be used for the study, but the lack of information on the expiry date is a deviation from the GLP rules. – Earthworms were humanely euthanized by freezing at about - 20°C, instead of -80°C, as it is stated in OECD 222 Guideline. These deviations did not affect the results of the study. The chemical analysis of the test item showed, that the concentrations of the active ingredient has not been maintained within ± 20% of the nominal values, therefore the geometric mean of the measured concentrations were calculated. The study is considered acceptable and suitable for the risk assessment

Reference:	10.4/09
Report	Earthworm Reproduction Test (Eisenia andrei); Study code:ETOX-2024-64 Study Director: K. Wesołowska; ul. Michałowicza 12, 43-300 Bielsko-Biała
Guideline(s):	according to the OECD Guideline No. 232 (2016)
Deviations:	- The Sponsor did not provide the expiry date of the test material, which was his responsibility. The test material was considered valid to be used for the study, but the lack of information on the expiry date is a deviation from the GLP rules. – Earthworms were humanely euthanized by freezing at about - 20°C, instead of -80°C, as it is stated in OECD 222 Guideline. Above deviations did not affect the course of the study and obtained results. All study validity criteria were met..
GLP:	Yes

Acceptability:

Duplication (if vertebrate study) No

Materials and methods

Test item:	Product name: CLOROL 200 SC Batch number: CHR/03/2023
Active substance:	199.35 g/L of chlorantraniliprole
Artificial soil:	The earthworms were exposed to test item in a mixture with artificial soil (artificial soil without any addition of test item in a control). The artificial soil used in the study was prepared in one batch. The composition of artificial soil was based on the OECD Test Guideline No. 222 (the percentages refer to dry weight): – 10% sphagnum peat, – 20% kaolin clay, – 69.9 % quartz sand (air dried, particles between 50-200 microns >50%). – 0.1% CaCO3. Air dried deacidified peat was shredded in sieves (mesh-size 2 mm). The pH value of this peat was equal to 5.35 and there was no need to mix it together with acidic peat. Afterwards, all parts of the artificial soil (air dried) was mixed until materials visually appear homogeneous. This dry artificial substrate was stored in sealed container, at room temperature. The parameters of the artificial soil were: – maximum water holding capacity (WHCmax) = 52.6%, – pH in 1M KCl = 6.41, – dry weight = 89.486%.,
Test organism:	A biological systems used in the study were earthworms Eisenia andrei (Andre, 1963). The source of the test system was laboratory-bred synchronized culture (originating from Havelwurm Wurmkultur Brielower Landstrasse, 32b, 14772 Brandenburg) at the EcoTox Alliance. The culture was maintained in peat moss mixed with horse manure. The homogeneity of the test population was determined by individually weighing 20 worms sampled randomly from the population from which the test worms were to be taken. Adult worms with clitella and with fresh weight of 10 individuals between 3011 - 4067 mg were used in this study. Age of organisms used in the study was approximately 4 months and didn't differ in age by more than 4 weeks. The animals selected

for the experiment were acclimatized in untreated artificial soil for 45 hours prior to the start of the experiment.
The earthworms were allocated to the test groups by random sampling..

Test design:

Selection of the nominal test item concentrations in main experiment was on the basis of the results from range finding test. The concentration of the test item used in the range-finding test was: 1000, 100, 10, 1 and 0.1 mg test item / kg dry weight. There was also a concurrent untreated control group.
The main experiment was performed using 8 concentrations of test item. The concentrations were spaced by a factor of 1.6. Groups of 40 earthworms (10 worms per replicate, 4 replicates per treatment group) were exposed for 28 days to test item into artificial soil at concentrations of 37.25, 59.60, 95.37, 152.6, 244.1, 390.6, 625.0 and 1000 mg test item/kg soil dry weight. Eight control replicates (10 worms per replicate) with untreated soil were ran concurrently.
The body weights of the adult earthworms were determined on Day 0 and Day 28. Mortality, behavioural and morphological changes were assessed after 28 days of exposure and the adult earthworms were removed. The number of juveniles was determined at the end of the experiment, on Day 56

Conditions of the experiments

The conditions of the experiment were in accordance with the requirements of OECD Guideline No. 222 [1] are given below.

Temperature	19.7 – 21.9°C
Photoperiod	16 h light: 8 h dark
Light intensity	725.2 – 751.2 lux
Soil moisture	25.44 – 27.03 % (Day 0) 26.04 – 27.96 % (Day 56) 48.36 – 51.40 % WHCmax (Day 0) 49.50 – 53.16% WHCmax (Day 56)
Soil pH	6.22 – 6.41 (Day 0) 6.29 – 6.59 (Day 56)
Aeration	air and light permeable lid
Feeding	initially 5 g per container, throughout the experiment as needed

The temperature during the test was recorded continuously.

The photoperiod during the experiment was 16 hours of light and 8 hours of dark per day provided by lamps. The target light intensity during the experiment was verified three times at the beginning of the experiment, on Day 28 and at the end of the experiment on Day 56. The measurement was made at the artificial soil surface level.
The water content of the soil substrate in the test containers was maintained throughout the experiment by re-weighting the test containers on Days: 1, 7, 14, 21, 28, 35, 42, 49 and 56. Soil moisture loss was replenished by addition of ultrapure water into each vessel.
Moisture content and pH measurements were made on soil samples collected from additional containers without earthworms (abiotic control) .

The aims of the study were to assess the effects of test item CLOROL 200 SC on the mortality and reproduction of earthworms, Eisenia andrei and to determine the LC10, LC20, LC50, EC10, EC20, EC50 and the NOEC, if possible.
Eight concentrations of the test item was used. These were: 37.25, 59.60, 95.37, 152.6, 244.1, 390.6, 625.0 and 1000 mg of the test item/kg dry weight of the artificial soil. Concentrations of the test item were divided into four replicates. There was also an untreated control group divided into eight replicates. The test item in form of aqueous solutions was mixed with the artificial soil. The control artificial soil was mixed with ultrapure water alone.
The experiment lasted 56 days. On Day 28 worms were removed from the test vessels to be examined for signs of toxicity and mortality. The soil and cocoons were returned to test vessels for an additional 28 days to determine the number of juveniles produced in each replicate by the end of the experiment, on Day 56.
The sensitivity of the test mites was verified using a reference item, i.e. carbendazim at five concentrations: 0.31, 0.63, 1.25, 2.50 and 5.00 mg carbendazim / kg dry weight of artificial soil..

Study results
After 28 days of exposure to test item, mortality was observed only in control group (1.25%). No mortality was observed in any test item treatment groups. All alive adult earthworms from control and treatment groups were normal in appearance and behaviour, during the examination. Earthworms from both, the control and treatment groups, exhibited no aversion to the soil at the beginning of the experiment.
After 28-day exposure period, the mean body weight of the survived adult worms in the control and treatment groups was between 4.659 – 5.172 g. There were no significantly differences of weight for any treatment group when compared to the mean value of control group.
The mean number of juveniles in the control and treatment groups were between 60.3 and 87.8. The mean numbers of juveniles in treatment group of 1000 mg test item/kg dry soil, was significantly different when compared to the mean value of control group
The EC10, EC20, EC50, LC10, LC20, LC50 and NOEC/LOEC values determined on the basis of number of juveniles at the end of experiment, mortality of adult earthworms and weight of adult earthworms at the end of experiment expressed as mg of test item/kg dry soil are given below

Endpoints based on the nominal test item concentrations * [mg test item / kg dry soil]					
Mortality of adult earthworms		Weight of adult earthworms at the end of experiment		Number of juveniles at the end of experiment	
LC_{10}	> 1000	EC_{10}	> 1000	EC_{10}	> 1000
LC_{20}	> 1000	EC_{20}	> 1000	EC_{20}	> 1000
LC_{50}	> 1000	EC_{50}	> 1000	EC_{50}	> 1000
NOEC	≥ 1000	NOEC	≥ 1000	NOEC	625.0
LOEC	> 1000	LOEC	> 1000	LOEC	1000

* values with 95% - confidence limits

The chemical analysis of the test item showed, that the concentrations of the active ingredient has not been maintained within ± 20% of the nominal values, therefore the geometric mean of the measured concentrations were calculated. Endpoint based on the geometric mean concentrations for the chlorantraniliprole were calculated and are presented in the table below:

Endpoint values based on geometric mean concentrations for chlorantraniliprole * [mg chlorantraniliprole / kg dry soil]					
Mortality of adult earthworms		Weight of adult earthworms at the end of experiment		Number of juveniles at the end of experiment	
LC_{10}	> 159.31	EC_{10}	> 159.31	EC_{10}	> 159.31
LC_{20}	> 159.31	EC_{20}	> 159.31	EC_{20}	> 159.31
LC_{50}	> 159.31	EC_{50}	> 159.31	EC_{50}	> 159.31
NOEC	≥ 159.31	NOEC	≥ 159.31	NOEC	99.71
LOEC	> 159.31	LOEC	> 159.31	LOEC	159.31

* values with 95% - confidence limits

TEST VALIDITY CRITERIA

The following validity criteria were met during the experiment in the control group.

- Mortality of adult worms over initial 28 days of the experiment was 1.25% (criterion: it have not to exceed 10%).
- The lowest number of offspring produced in replicate was 54 (criterion: a minimum of 30 offspring are produced in each replicate containing 10 adults).
- The coefficient of variation of reproduction was equal to 20.0% (criterion: it should not exceed 30%).

Thus the study is considered valid

A 2.4.1.2 KCP 10.4.1.2 Earthworms - field studies

A 2.4.2 KCP 10.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms)

A 2.4.2.1 KCP 10.4.2.1 Species level testing

A 2.4.2.1 *Folsomia candida*

Comments of zRMS:	The study was performed according to OECD TG 232 and principles of GLP. The validity criteria are met: For the control group: Mean adult mortality: ≤ 20 % (observed: 7.5%) Mean number of juveniles per test vessel: ≥ 100 (observed:346.875) Coefficient of variation for the mean number of juveniles: < 30 % (observed: 27.4%). The following deviations from the study plan were noted: 1. In order to maintain proper moisture content, the vessels with the artificial soil were 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. 2. At the test termination, collembolans were humanely euthanized by freezing at about -20°C, instead of -80°C, as it is stated in OECD 232 Guideline. 3. On the chromatograms, the samples were named ETOX-2023-13-X-Y instead of ETOX-2023-13-X/Y (X = K, R1, R7 or R12; Y = 1, 2 or 3). These deviations did not affect the results of the study. The chemical analysis of the test item showed, that the concentrations of the active ingredient has been maintained within ± 20% of the nominal values. The study is considered acceptable and suitable for the risk assessment

Reference:	10.4/08
Report	Collembolan (Folsomia candida) Reproduction Test in soil; Study codeE-TOX-2023-13 Study Director: E. Kulec-Płoszczyca; EcoTox Alliance Sp. z o. o. Kalinowa 2, 43-520 Zaborze, Poland
Guideline(s):	according to the OECD Guideline No. 232 (2016)
Deviations:	In this study, two planned deviation s from OECD Guideline No. 232 (2016) was occurred: − in order to maintain proper moisture content, the vessels with the artificial soil were 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 were humanely euthanized by freezing at about - 20°C, instead of -80°C, as it is stated in OECD 232 Guideline. D eviation from the study plan , concerning samples naming on the chromatograms was

occurred:
- on the chromatograms, the samples were named ETOX-2023-13-X-Y instead of ETOX-2023-13-X/Y (X = K, R1, R7 or R12; Y = 1, 2 or 3).

The study was performed in compliance with the principl es of Good Laboratory Practice (Appendix No. 1 2, 3 Above deviations did not affect the study results, because validity criteria were met.

GLP:	Yes
Acceptability:	
Duplication (if vertebrate study)	No

Materials and methods

Test item:	Product name: CLOROL 200 SC Batch number: CHR/03/2023
Active substance:	199.35 g/L of chlorantraniliprole
Artificial soil:	5% sphagnum peat, 20% kaolin clay, 75% air-dried industrial sand,
Test organism:	species: collembolan Folsomia candida source: laboratory culture [SPO-H-1] at Test Facility, obtained from commercial supplier: Bias Labs Ltd. [SOP-O-7] age: synchronised 9 –12 days old; hatched from eggs laid from 07–17.11.2023 The process of culturing is described in the Standard Operating Procedure SOP-H-1. To obtain juveniles needed for the purpose of the experiment, clusters of eggs were transferred from containers to a newly prepared substrate using a small brush. After three days, they were removed from the substrate, whereas the hatched springtails were fed. After 9 days of incubation, the juveniles were collected..
Test design:	test duration: 28 days number of replicates: 4 replicates / concentration + 8 replicates / control; number of collembolans: 10 / replicate
Test conditions	The temperature during the experiment was in the range of 19.3 – 20.5°C. The temperature was recorded continuously [SOP-PM-5]. The experiment was performed under a 16-hour light and 8-hour dark regime [SOP-B-8]. The light intensity was in the range from 412.9 lux to 594.3 lux. It was measured at the begin-

ning of the test, after 14 days of exposure and at the end of the test [SPO-O-10].
For the determination of pH, the soil samples was set up at the beginning of the test, after 14 days of exposure and at the end of the test. The soil was collected from additional containers without collembolans (abiotic controls) [SPO-PM-8].
To maintain proper moisture content, the test vessels with the artificial soil were weighed at the beginning and after 2 weeks of the experiment [SOP-PM-2]. Water loss did not exceed 2%, therefore no water was added. Each test vessel was aerated once a week by lifting the lead to guarantee gaseous exchange.
The soil moisture content was checked at the beginning and at the end of the test (on day 0 and 28). The soil was collected from additional containers without collembolans (abiotic controls). The soil moisture content was determined by drying a small sample (about 10 g) at 105°C and reweighing [SPO-PM-10]. According to OECD Guideline No. 232 the vessels at the end of the test, should be weighed in order to determine soil moisture content.
The moisture of the artificial soil ranged from 44.22% to 46.96% of the maximum water holding capacity on day 0 and from 29.27% to 45.45% of the maximum water holding capacity on day 28 [SOP-PM-10].

Results and discussions

The aims of the study were to assess the impact of CLOROL 200 SC 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 EC 10 , EC 20 , EC 50 , and NOEC /LOEC values for reproduction .
Twelve concentrations of the test item were used. These were 1.56, 2.80, 5.04, 9.07, 16.33, 29.40, 52.92, 95.26, 171.47, 308.64, 555.56, and 1000.00 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 suspension 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.

Study results
Mean mortality at the concentrations ranging from 1.56 to 1000.00 mg/kg dry weight of the artificial soil ranged from 10.0 to 100.0%. As for the control group, it was equal to 7.5%.
The concentrations of the test item causing 10, 20 and 50% mortality of adults after the exposure period are equal to:
– LC10: 2.14 mg/kg dry weight of the artificial soil (95% confidence limits: 1.66 – 2.57).

– LC20: 2.74 mg/kg dry weight of the artificial soil (95% confidence limits: 2.24 – 3.19).
– LC50: 4.39 mg/kg dry weight of the artificial soil (95% confidence limits: 3.82 – 5.02).
The LOEC value for mortality is 2.80 mg/kg dry weight of the artificial soil.
The NOEC value for mortality is 1.56 mg/kg dry weight of the artificial soil.

After 28 days of the exposure of collembolans to the test item at the concentrations ranging from 1.56 to 1000.00 mg/kg dry weight of the artificial soil, the mean number of juveniles was between 2.5 – 324.5 per replicate. As for the control group, the mean number of juveniles was equal to 346.875.

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: 1.65 mg/kg dry weight of the artificial soil (95% confidence limits: 1.45 – 1.83).
– EC20: 2.21 mg/kg dry weight of the artificial soil (95% confidence limits: 2.00 – 2.39).
– EC50: 3.84 mg/kg dry weight of the artificial soil (95% confidence limits: 3.64 – 4.06).
The LOEC value for mean number of offspring is 2.80 mg/kg dry weight of the artificial soil.
The NOEC value for mean number of offspring is 1.56 mg/kg dry weight of the artificial soil.

The result of mortality and mean number of juveniles and endpoint values showing the impact of the test item on mortality and reproduction of Folsomia candida are presented in the tables given below:

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	6	7.5	346.875	–
R12	1.56	40	4	10.0	324.50	6.5
R11	2.80++	40	12	30.0	227.00	34.6
R10	5.04++	40	24	60.0	133.00	61.7
R9	9.07++	40	36	90.0	18.75	94.6
R8	16.33++	40	40	100.0	7.50	97.8
R7	29.40++	40	40	100.0	6.75	98.1
R6	52.92++	40	40	100.0	5.00	98.6
R5	95.26++	40	40	100.0	3.25	99.1
R4	171.47++	40	40	100.0	3.75	98.9
R3	308.64++	40	40	100.0	4.25	98.8
R2	555.56++	40	40	100.0	3.75	98.9
R1	1000.0++	40	40	100.0	2.50	99.3

+: statistically significant difference in mortality
++: statistically significant difference in mortality and mean number of juveniles

Endpoint [mg test item/kg dry weight of artificial soil]			
Mortality		**Reproduction**	
LC_{10}	2.14 *(1.66 – 2.57)**	**EC_{10}**	1.65 *(1.45 – 1.83)**
LC_{20}	2.74 *(2.24 – 3.19)**	**EC_{20}**	2.21 *(2.00 – 2.39)**
LC_{50}	4.39 *(3.82 – 5.02)**	**EC_{50}**	3.84 *(3.64 – 4.06)**
LOEC	2.80	**LOEC**	2.80
NOEC	1.56	**NOEC**	1.56

* LCx, ECx values (with 95% - confidence limits)

TEST VALIDITY CRITERIA

The following validity criteria were met during the experiment:
– mean adult mortality of the control group was 7.5% at the end of the test (criterion: not exceed 20%),
– mean number of juveniles per vessel in the control was 346.875 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 27.4% (criterion: less than 30%) at the end of the test.

A 2.4.2.1 *Hypoaspis aculeifer*

Comments of zRMS:	The study was performed according to OECD TG 226 and principles of GLP. The validity criteria are met: For the control group: - Mean mortality of adult females: ≤ 20 % (observed: 15%) - Mean number of juveniles per replicate: ≥ 50 (observed: 141.0) - Coefficient of variation (mean number of juveniles per replicate): ≤ 30 % (observed: 10.5%). Following deviations to the study plan were recorded: 1. Due to using the temperature extraction method, there were no need for euthanasia of the extracted organisms since the mites were fixed in a 70% ethanol solution. 2. Boric acid should be stored at the temperature of 15 – 25ºC according to the information included in the MSDS. However, during the storage period, the temperature was outside of this range, i.e.: on 16.07.2024 at 1230 it was 25.2 ºC. The deviation could last up to 1 hour. 3. During the test with the reference material, conducted between 13.11.2024 – 27.11.2024, the temperature during the study was outside of the range specified in the OECD Guideline No. 226, i.e. 20±2 ºC and on 13.11.2024 at 1205 it was 14.8ºC and at 1605 it was 22.1 ºC. The deviation could last up to 1 hour. 4. The Sponsor did not provide the expiry date of the test material, which was his responsibility. The test material was considered valid to be used for the study, but the lack of information on the expiry date is a deviation from the GLP rules. During the study, one deviation occurred concerning extraction tempera-ture. The

	duration of the extraction of the mites should last 48 hours. The temperature should increase from 25 to 45°C and the heating regime should be 25°C for 12 h, 35°C for 12 h, 45°C for 24 hours (in total 48 h). The temperature of the extraction obtained during the experiment was: 24.6 – 25.7°C for 12 h (mean value 25.25°C), 34.8 – 35.4°C for 12 h (mean value 35.08°C) and 44.5 – 45.5°C for 24 h (mean value 45.14°C), in total 48 h. These deviations did not affect the results of the study. The chemical analysis of the test item showed, that the concentrations of the active ingredient has not been maintained within ± 20% of the nominal values, therefore the geometric mean of the measured concentrations were calculated. The study is considered acceptable and suitable for the risk assessment.

Reference:	10.4/10
Report	Predatory mite (Hypoaspis (Geolaelaps) aculieifer) reproduction test in soil; Study code: ETOX-2024-65 Study Director: S. Groch; EcoTox Alliance Sp. z o. o. ul. Michałowicza 12,43-300 Bielsko-Biała
Guideline(s):	according to OECD Guideline No. 226 (2016)
Deviations:	The following deviations from OECD Guideline No. 226 (2016) was introduced to the Study Plan: 1. Due to using the temperature extraction method, there were no need for euthanasia of the extracted organisms since the mites were fixed in a 70% ethanol solution. 2. Boric acid should be stored at the temperature of 15 – 25ºC according to the information included in the MSDS. However, during the storage period, the temperature was outside of this range, i.e.: on 16.07.2024 at 1230 it was 25.2 ºC. The deviation could last up to 1 hour. 3. During the test with the reference material, conducted between 13.11.2024 – 27.11.2024, the temperature during the study was outside of the range specified in the OECD Guideline No. 226, i.e. 20±2 ºC and on 13.11.2024 at 1205 it was 14.8ºC and at 1605 it was 22.1 ºC. The deviation could last up to 1 hour. 4. The Sponsor did not provide the expiry date of the test material, which was his responsibility. The test material was considered valid to be used for the study, but the lack of information on the expiry date is a deviation from the GLP rules. During the study, one deviation occurred concerning extraction temperature. The duration of the extraction of the mites should last 48 hours. The temperature should increase from 25 to 45°C and the heating regime should be 25°C for 12 h, 35°C for 12 h, 45°C for 24 hours (in total 48 h). The temperature of the extraction obtained during the experiment was: 24.6 – 25.7°C for 12 h (mean value 25.25°C), 34.8 – 35.4°C for 12 h (mean value 35.08°C) and 44.5 – 45.5°C for 24 h (mean value 45.14°C), in total 48 h. Above deviations did not affect the course of the study and obtained results. All study validity criteria were met.
GLP:	Yes
Acceptability:	
Duplication (if vertebrate study)	No

Materials and methods

Test item:	Product name: CLOROL 200 SC Batch number: CHR/03/2023
Active substance:	199.35 g/L of chlorantraniliprole
Artificial soil:	The artificial soil was prepared before the study. It consists of the following components [1]: − 5% sphagnum peat (a particle size of 2 mm), − 20% kaolin clay, − 75% air-dried industrial sand with more than 50% of the particles between 50 and 200 µm. The values given above refer to dry weights of individual components. They were determined by drying small portions of each component at 105°C and re-weighing. Before the preparation of the artificial soil, peat was sieved to a particle size of 2 mm. All components were mixed. Then, the maximum water holding capacity (WHC) and the pH (in 1M KCl) was determined. The pH of the soil was adjusted to 6 ± 0.5 by calcium carbonate. The maximum water holding capacity of the prepared soil was 38.1%, whereas the pH was 6.18. Four days before the experiment, the soil was premoistened by adding ultra-pure water. Immediately before the experiment, the soil dry weight and moisture content was determined. The dry weight of artificial soil in the day of starting the experiment was 90.374% and it was equal to 27.955% of maximum water holding capacity. At the beginning of the experiment, the soil moisture content in control group and each test item concentration was adjusted to about 50% (40 – 60%) of the maximum WHC by the addition of ultra-pure water or the test item solution and ultra-pure water,
Test organism:	species: predatory mites, Hypoaspis aculeifer, adult females source: standard laboratory culture at the Test Facility originated from commercial supplier: Katz Biotech Ag, an der irkenpfuhlheide 10-D15837, Baruth age: 30 – 32 days old; hatched from eggs laid from 03.01.2025 – 05.01.2025
Test design:	In the main experiment eight concentrations of the test item were used, i.e. 16.3, 29.4, 52.9, 95.3, 171.5, 308.6, 555.6 and 1000.0 mg of the test item/kg dry weight of artificial soil (geometric series ratio 1.8). Each test item concentration group was divided into 4 replicates (10 mites per replicate/40 mites in total). There was also a con-

	current control group divided into 8 replicates (10 mites per replicate/80 mites in total) with untreated artificial soil. Additional vessels (abiotic controls) with the artificial soil, but without mites (3 for the control group and 3 for each test item concentrations) were prepared to determine the pH the soil moisture content at the beginning, after 7 days and at the end of the experiment and for chemical determinations
Conditions of the experiments	The temperature during the experiment was in the range 19.8 – 21.9°C (Figure 1). The temperature was recorded continuously. The experiment was performed under a 16-hour light and 8-hour dark regime. The light intensity was in the range from 434.8 to 628.4 lux. It was measured at the beginning and at the end of the test. For the determination of pH, the soil samples was set up at the beginning and at the end of the test. The soil was collected from additional containers without mites (abiotic controls). The water content of the soil substrate in the test vessels was maintained throughout the test by weighing the test vessels periodically. The soil moisture content was checked once a week (on day 0, day 7 and day 14 of the experiment). The soil was collected from additional containers without mites (abiotic controls). It was determined by drying a small sample (about 10 g) at 105°C and re-weighing. There was no need of water replenished, because the soil moisture content during the experiment did not differ by more than 10% from the initial value. Each test vessel was aerated twice to three times a week by lifting the lead while feeding to guarantee gaseous exchange.

The aims of the study were to assess the effects of test item CLOROL 200 SC on the mortality and reproduction of the predatory mites, Hypoaspis aculeifer and to determine the LC10, LC20, LC50, EC10, EC20, EC50 and the NOEC, if possible.
Eight concentrations of the test item was used. These were: 16.3, 29.4, 52.9, 95.3, 171.5, 308.6, 555.6 and 1000.0 mg of the test item/kg dry weight of the artificial soil were used. Concentration of the test item was divided into four replicates. There was also an untreated control group divided into eight replicates. The test item in form of homogeneous aqueous solution was mixed with the artificial soil. The control artificial soil was mixed with ultrapure water alone. The experiment lasted 14 days. After that, the mites were extracted from the artificial soil using heat extraction. The number of adults and juveniles were determined separately.
The sensitivity of the test mites was verified using a reference item, i.e. boric acid at the doses of 15, 22, 32, 46, 68, 100, 150, 220, 320, 460, 680 and 1000 mg/kg dry weight of artificial soil

Study results
Mean mortality at the concentrations ranging from 16.3 to 1000.0 mg test item/kg dry weight of the artificial soil, was in the range 12.5% to 37.5%. As for the control group, it was equal to 15.0%.
The concentration of the test item causing 10% mortality of adult mites within the exposure period

(LC10) is 13.09 mg test item/kg dry weight (95% confidence limits: 0.22 – 41.33 mg test item/kg dry weight).
The concentration of the test item causing 20% mortality of adult mites within the exposure period (LC10) is 124.34 mg test item/kg dry weight (95% confidence limits: 37.91 – 305.22 mg test item/kg dry weight).
The concentration of the test item causing 50% mortality of adult mites within the exposure period (LC50) were not determined due to mathematical reasons, therefore it can be concluded that this value is above the highest tested test item concentration, i.e. 1000.00 mg/kg dry weight of the artificial soil.
The LOEC value for mortality is 1000.00 mg/kg dry weight of the artificial soil.
The NOEC value for mortality is 555.60 mg/kg dry weight of the artificial soil.
After 14 days of the exposure, mean number of juveniles were between 105.5 – 133.8 in the concentrations ranging from 16.3 to 1000.0 mg test item/kg dry weight of the artificial soil. As for the control group, mean number of juveniles was equal to 141.0.
The concentrations of the test item causing a 10%, 20% and 50% reduction in the number of juvenile within the exposure period were not determined due to mathematical reasons, therefore it can be concluded that these values are above the highest tested test item concentration, i.e. 1000.00 mg/kg dry weight of the artificial soil.
The LOEC value for mean number of offspring is higher than 1000 mg/kg dry weight of the artificial soil.
The NOEC value for mean number of offspring is higher than or equal to 1000 mg/kg dry weight of the artificial soil
The result of mortality and mean number of juveniles and endpoint values showing the impact of the test item on mortality and reproduction of Hypoaspis aculeifer are summarized in the tables given below:

Concentration [mg test item/kg dry weight of artificial soil]	Number of tested mites	Total mortality		Reproduction	
		No.	%	Mean number of juveniles [no.]	Reduction [%]
Control (0.0)	80	12	15.0	141.0	-
16.3	40	5	12.5	117.5	16.7
29.4	40	6	15.0	106.5	24.5
52.9	40	5	12.5	133.8	5.1
95.3	40	7	17.5	119.5	15.2
171.5	40	9	22.5	123.3	12.6
308.6	40	9	22.5	113.0	19.9
555.6	40	11	27.5	123.3	12.6
1000.0	40	15+	37.5	105.5	25.2

+ statistically significant difference compared to the control

Endpoint values based on nominal test item concentrations [mg/kg dry weight of artificial soil]		
Mortality		
LC_{10}	CLOROL 200 SC	13.09 (0.22 – 41.33)*
	Chlorantraniliprole	2.39 (0.04 – 7.55)*
LC_{20}	CLOROL 200 SC	124.34 (37.91 – 305.22)*
	Chlorantraniliprole	22.72 (6.93 – 55.78)*
LC_{50}	CLOROL 200 SC	n.d
	Chlorantraniliprole	n.d
LOEC	CLOROL 200 SC	1000.0
	Chlorantraniliprole	182.76
NOEC	CLOROL 200 SC	555.6
	Chlorantraniliprole	101.54
Reproduction		
EC_{10}	CLOROL 200 SC	n.d
	Chlorantraniliprole	n.d
EC_{20}	CLOROL 200 SC	n.d
	Chlorantraniliprole	n.d
EC_{50}	CLOROL 200 SC	n.d
	Chlorantraniliprole	n.d
LOEC	CLOROL 200 SC	> 1000.0
	Chlorantraniliprole	> 182.76
NOEC	CLOROL 200 SC	≥ 1000.0
	Chlorantraniliprole	≥ 182.76

* Values with 95% - confidence limits; n.d. – not determined due to mathematical reasons

The chemical analysis of the test item showed, that the concentrations of the active ingredient has not been maintained within ± 20% of the nominal values, therefore the geometric mean of the measured concentrations were calculated. Endpoint based on the geometric mean concentrations for the chlorantraniliprole were calculated and are presented in the table below

Endpoint values based on geometric mean concentrations for chlorantraniliprole [mg/kg dry weight of artificial soil]			
Mortality		Reproduction	
LC_{10}	1.70 (0.02 – 5.89)*	EC_{10}	n.d.
LC_{20}	19.28 (5.33 – 50.79)*	EC_{20}	n.d.
LC_{50}	n.d.	EC_{50}	n.d.
LOEC	175.58	LOEC	> 175.58
NOEC	96.34	NOEC	≥ 175.58

* Values with 95% - confidence limits; n.d. – not determined due to mathematical reasons

TEST VALIDITY CRITERIA

The following criteria should be satisfied in the untreated control for a test result to be considered valid:
1. Mean adult female mortality should not exceed 20% at the end of the test. In the present test, mortality was 15.0%.
2. The mean number of juveniles per replicate (with 10 adult females introduced) should be at least 50 at the end of the test. In the present test, the mean offspring number was 141.0.
3. The coefficient of variation calculated for the number of juvenile mites per replicate should not be higher than 30% at the end of the definitive test. In the present test, the CV was 10.5%.
Thus the test is considered valid

A 2.4.2.2 KCP 10.4.2.2 Higher tier testing

A 2.5 KCP 10.5 Effects on soil nitrogen transformation

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

A 2.6.3 KCP 10.6.3 Extended laboratory studies on non-target plants

A 2.7 KCP 10.7 Effects on other terrestrial organisms (flora and fauna)

A 2.8 KCP 10.8 Monitoring data