

REGISTRATION REPORT
Part B
Section 9
Ecotoxicology
Detailed summary of the risk assessment

Product code: ADM.00900.I.1.C
Product name: COSAYR 200 SC
Chemical active substance:
Chlorantraniliprole, 200 g/L SC

Central Zone
Zonal Rapporteur Member State: Poland

CORE ASSESSMENT
(New authorization)

Applicant: Adama country organisation / representative
as specified in Part A
Submission date: October 2022
MS Finalisation date: June 2023 (initial Core Assessment)
November 2023 (final Core Assessment)

Version history

When	What
October 2022	Part B – Section 9 – Core Assessment – Central Zone, Initial version
June 2023	<p>Initial zRMS assessment</p> <p>The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are struck through and shaded for transparency.</p>
November 2023	<p>Final report (Core Assessment updated following the commenting period)</p> <p>Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in yellow. Not agreed or not relevant information are struck through and shaded for transparency.</p>

DATA PROTECTION CLAIM

Under Article 59, Regulation No. 1107/2009/EC, the applicant claims data protection for these studies. The data protection status and corresponding justification as valid for the respective country will be confirmed in the respective PART A

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9 Ecotoxicology (KCP 10)

9.1 Critical GAP and overall conclusions

Table 9.1-1: Table of critical GAPs

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15						
Use- No. *	Member state(s)	Crop and/or situation (crop desti- nation / purpose of crop)	F, Fn, G, Gn, Gpn or I **	Pests or Group of pests con- trolled (additionally: developmen- tal stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ syn- ergist per ha	Conclusion						
					Method / Kind	Timing / Growth stage of crop & season	Max. num- ber a) per use b) per crop/ season	Min. inter- val between applications (days)	kg or L product/ha a) max. rate per appl. b) max. to- tal rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. to- tal 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	AT, CZ, DE, HU, PL, SI, SK	Head cabbage , cauliflower, broccoli	F	Caterpillars (<i>Plutella xy- lostella</i> , <i>Mamestra brassicae</i> <i>Pieris brassi- cae</i>)	Foliar spraying, overall, LCTM	15 - 49	a) 1 b) 1	-	a) 0.14 L/ha b) 0.14 L/ha	a) 28 b) 28	400-600	3	Label range for CZ, HU, PL, SI and SK: 0.105-0.14 L/ha	A	A	R-N Sediment dwelling organism D4 (p), D5 (p)	A	A	A	A
																R Aquatic organism R4				
																A Remained scenarios				
2	AT, CZ, DE, HU, SI, SK	Wine grape, Table grape	F	<i>Lobesia botrana</i>	Foliar, air-as- sisted broad- cast, HCTM	57 - 83	a) 1 b) 1	-	a) 0.18 L/ha b) 0.18 L/ha	a) 36 b) 36	400-1600	Wine:30 Table: 3	BAD rate AT & DE: 140 ml/10,000m² LWA BAD rate CZ, HU, SI & SK: 120 - 140 ml/10,000m² LWA	A	A	R-N Sediment dwelling organism D4 (p), D5 (p),D3	A	A	A	A
																R Aquatic organism R3, D3,D4s, D5s				

													Label range for CZ, HU, SI & SK: 0.15 - 0.18 L/ha			A Remained scenarios				
3	AT, CZ, DE, PL	Corn (grain and silage)	F	<i>Ostrinia nubialis</i>	Foliar, spraying overall, LCTM	20 – 87	a) 1 b) 1	-	a) 0.14 L :ha b) 0.14 L/ha	a) 28 b) 28	400 – 500	14		A	A	R N Sediment dwelling organism D4 (p), D5 (p)	A	A	A	A
																R Aquatic organism R4				
																A Remained scenarios				
4	HU, SI, SK	Corn (grain and silage)	F	<i>Ostrinia nubialis, Helicoverpa armigera</i>	Foliar, spraying overall, LCTM	20 – 87	a) 1 b) 1	-	a) 0.14 L/ha b) 0.14 L/ha	a) 28 b) 28	400 – 500	14		A	A	R N Sediment dwelling organism D4 (p), D5 (p)	A	A	A	A
																R Aquatic organism R4				
																A Remained scenarios				
5	AT, CZ, DE, HU, PL, SI, SK	Apple, Pear, Quince	F	<i>Cydia pomonella</i>	Foliar, air-as- sisted broad- cast, HCTM	70 – 87	a) 1 b) 1	-	a) 0.155 L/ha b) 0.155 L/ha	a) 31 b) 31	500 – 1500	14	BAD rate: 130 ml/10,000m²/LWA	A	A	R N Sediment dwelling organism D4 (p), D5 (p),D3	A	A	A	A
																R Aquatic organism D3, D4s, D5s, R1,R3,R4				
																A Remained scenarios				
6	AT, CZ, DE,	Apple, Pear,	F	<i>Cydia pomonella</i>	Foliar,	70 – 87	a) 1 b) 1	-	a) 0.12 L/ha	a) 24 b) 24	500 – 1500	14	BAD rate 100 ml/10,000 m².	A	A	R N Sediment	A	A	A	A

	HU, PL, SI, SK	Quince			air-as-sisted broadcast, HCTM				b) 0.12 L/ha							dwelling organism D4 (p), D5 (p)				
																R Aquatic organism D3, D4s, D5s, R1,R3,R4				
																A Remained scenarios				
7	CZ, PL	Potato	F	<i>Leptinotarsa decemlineata</i>	Foliar, spraying overall, LCTM	31 – 60	a) 1 b) 1	-	a) 0.06 L/ha b) 0.06 L/ha	a) 12 b) 12	400 – 600	14		A	A	A	A	A	A	a
8	AT, DE, HU, SI, SK	Potato	F	<i>Leptinotarsa decemlineata</i>	Foliar, spraying overall, LCTM	31 – 60	a) 2 b) 2	7	a) 0.06 L/ha b) 0.12 L/ha	a) 12 b) 24	400 – 600	14	Label range for HU, SI & SK: 0.05 - 0.06 L/ha	A	A	R N Sediment dwelling organism D4 (p)	A	A	A	A
																A Remained scenarios				

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 “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:	<div> <p>(1) Numeration necessary to allow references</p> <p>(2) Use official codes/nomenclatures of EU</p> <p>(3) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (<i>e.g.</i> fumigation of a structure)</p> <p>(4) F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application</p> <p>(5) Scientific names <u>and</u> EPPO-Codes of target pests/diseases/ weeds or when relevant the common names of the pest groups (<i>e.g.</i> biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named</p> <p>(6) Method, <i>e.g.</i> high volume spraying, low volume spraying, spreading, dusting, drench Kind, <i>e.g.</i> overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated</p> <p>(7) Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application</p> <p>(8) The maximum number of application possible under practical conditions of use must be provided</p> <p>(9) Minimum interval (in days) between applications of the same product.</p> <p>(10) For specific uses other specifications might be possible, <i>e.g.</i>: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products</p> <p>(11) The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).</p> <p>(12) If water volume range depends on application equipments (<i>e.g.</i> ULVA or LVA) it should be mentioned under “application: method/kind”.</p> <p>(13) PHI - minimum pre-harvest interval</p> <p>(14) Remarks may include: Extent of use/economic importance/restrictions</p> </div>
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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), Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

Effects on birds (KCP 10.1.1)

The assessment of the risk to birds conducted for the use of ADM.00900.I.1.C in leafy vegetables (covering brassicas), vineyards, maize, pomefruit and potato according to the EFSA *Guidance Document on the Risk Assessment for Birds and Mammals* (EFSA, 2009) leads to the following conclusions:

- Acceptable dietary risk from the active substance Chlorantraniliprole (no relevant metabolite from dietary exposure)
- Acceptable risk from drinking water for the active substance Chlorantraniliprole and its relevant metabolites
- Acceptable risk for fish- and earthworm-eating birds via secondary poisoning for the active substance Chlorantraniliprole and its relevant metabolites.

It is therefore concluded that the use of ADM.00900.I.1.C in the intended crops at the recommended rates poses an acceptable risk to birds.

Effects on terrestrial vertebrates other than birds (KCP 10.1.2)

The assessment of the risk to mammals conducted for the use of ADM.00900.I.1.C in leafy vegetables (covering brassicas), vineyards, maize, pomefruit and potato according to the EFSA *Guidance Document on the Risk Assessment for Birds and Mammals* (EFSA, 2009) leads to the following conclusions:

- Acceptable dietary risk from the active substance Chlorantraniliprole (no relevant metabolite for dietary exposure)
- Acceptable risk from drinking water for the active substance Chlorantraniliprole and its relevant metabolites
- Acceptable risk for fish- and earthworm-eating mammals via secondary poisoning for the active substance Chlorantraniliprole and its relevant metabolites.

It is therefore concluded that the use of ADM.00900.I.1.C in the intended crops at the recommended rates poses an acceptable risk to mammals.

Effects on other terrestrial vertebrates wildlife (reptile and amphibians) (KCP 10.1.3)

No additional data.

9.1.1.2 Effects on aquatic organisms (KCP 10.2)

The risk for aquatic organisms from Chlorantraniliprole from the uses of ADM.00900.I.1.C in leafy vegetables (covering brassicas), maize, vines, pomefruit and potato, at the relevant intended rates, was examined according to EFSA *Guidance on tiered risk assessment for plant protection products for the organisms in edge-of-field surface waters* (2013). The most sensitive organisms were aquatic invertebrates with a HC₅ based on SSD of 2.91 µg/L for the water exposure and sediment-dwelling organisms with a NOEC of 5 µg/kg sediment for *Chironomus riparius* for the sediment exposure. The respective assessment factors of 5 and 10 were applied to these endpoints to obtain the RAC of 0.58 µg/L and 0.5 µg/kg sediment, respectively.

~~The risk for aquatic organisms from Chlorantraniliprole from the intended uses of the formulation ADM.00900.I.1.C is acceptable provided that the following mitigation measures are respected in the member states where the respective scenario is relevant:~~

Use-group		Drained-soils	VFS Mod	Drift-reduction	No-spray buffer-strip	Vegetated strip
1	Leafy-vegetables BBCH 15-49 1 x 28 g a.s./ha	No-application	Yes	-	2-m	2-m
		OK				
		No-application	-	-	10-m	10-m
2	Maize BBCH 20-87 1 x 28 g a.s./ha	No-application	Yes	-	2-m	2-m
		OK				
		No-application	-	-	10-m	10-m
3	Vines BBCH 57-83 1 x 36 g a.s./ha	-	-	50 %	-	-
		OK				
		-	-	-	5-m	-
4	Pomefruit BBCH 70-87 1 x 31 g a.s./ha	No-application	-	75%	-	-
		OK				
		No-application	-	-	10-m	10-m
5	Pomefruit BBCH 70-87 1 x 24 g a.s./ha	No-application	-	50 %	-	-
		OK				
		No-application	-	-	5-m	-
6						
7	Potato BBCH 31-60 2 x 12 g a.s./ha	No-application	-	-	-	-

Based on the performed calculations for aquatic organism and sediment dwelling organism following conclusions may be derived:

1. Leafy crops: 1 x 28 g a.s./ha, BBCH 15-49

Chlorantraniliprole: acceptable risk for aquatic organism with no need for risk mitigation measures for scenarios : D3, D4 (s,p), R1 (p,s), R3 at STEP 3 is concluded.

For remained scenario following risk mitigation measure is not required:

- R4 scenario: risk acceptable with 10 m VFS.
- ~~D5 (s, p)-scenarios: No calculations are performed for these scenarios, an unacceptable risk is concluded.~~

Chlorantraniliprole: acceptable risk for sediment dwelling organism with no need for risk mitigation measures for scenarios: D3, D4 (s), R1 (p), R1 (s), R3, R4 at STEP 3 is concluded.

For remained scenarios:

- D4 (p) scenario : an unacceptable risk for sediment dwelling organism with max mitigation measures (20 m VFS + 90% DRN or 5 m VFSmod) is concluded. **Further refinement is required at MSs level for these scenarios.**
- ~~D5 (s, p)-scenarios: No calculations are performed for these scenarios, an unacceptable risk is concluded.~~

2. Maize: 1 x 28 g a.s./ha, BBCH 20

Chlorantraniliprole: acceptable risk for aquatic organism with no need for risk mitigation measures for scenarios: D3, D4 (s,p), D5 (s,p) R1 (p), R1 (s), R3 at STEP 3 is concluded.

For remained scenario the following risk mitigation measure is required:

- R4 scenario: 10 m VFS (alternatively: 2 m or 5 m VFS calculated by VFS_{mod})

Chlorantraniliprole: an unacceptable risk for sediment dwelling organism for D4 (p) and D5 (p) scenarios with max mitigation measures (20 m VFS + 90% DRN or 5 m VFSmod) is concluded. **Further refinement is required at MSs level for these scenarios.**

2. Maize: 1 x 28 g a.s./ha, <87 BBCH:

Chlorantraniliprole: acceptable risk for aquatic organism with no need for risk mitigation measures for D3, D4 (s), D5 (s), R1 (p), R1 (s), R3, R4 at STEP 3 is concluded.

Chlorantraniliprole: D4 (p) scenarios: an unacceptable risk for dwelling sediment organism with max mitigation measures (20 m VFS + 90% DRN or with 5 m VFSmod) is concluded. Further refinement is required at MSs level for scenarios.

For remained scenario the following risk mitigation measure is required:

- D5 (p) scenario: acceptable risk with 20 m VFS+90% DRN

3. Vine : 1 x 36 g a.s/ha, BBCH 70-87

Chlorantraniliprole: acceptable risk for aquatic organism with no need for risk mitigation measures for scenarios : R1 (p,s), R4 at STEP 3 is concluded. The following risk mitigation measures is required for remained scenarios:

- R3 scenario: acceptable risk with 5 m unsprayed buffer zone or 50% drift reduction nozzles
- D3 scenario: acceptable risk with 50% DRN or 10 m VFS
- D4 (s) scenario: acceptable risk with 50% DRN or 10 m VFS
- D5 (s) scenario: acceptable risk with 75% DRN or 10 m VFS or 5 unsprayed buffer zone with 50% DRN

Chlorantraniliprole: acceptable risk for sediment dwelling organism with no need for risk mitigation measures for R -scenarios at STEP 3 is concluded.

Chlorantraniliprole: acceptable risk for sediment dwelling organism with no need for risk mitigation measures for scenarios: D4 (s), D5 (s) and R- scenarios at STEP 3 is concluded. The following risk mitigation measures are required for remained scenarios:

- D3: acceptable risk for sediment dwelling organism with 10 m VFS or 75% DRN
- D4 (p), D5 (p) scenarios: an unacceptable risk for dwelling sediment organism with max mitigation measures (20 m VFS + 90% DRN) is concluded. Further refinement is required at MSs level for these scenarios

It should be noted that in case of D-scenarios which are relevant for Central Zone (D3, D4 and D5) the scenarios from pome fruits was used by zRMS for aquatic and sediment dwelling organism.

Metabolites: IN-EQW78, IN-ECD73, IN-F6L99, IN-F9N04, IN-GAZ70, IN-LBA22, IN-LBA23, and IN-LBA 24: acceptable risk at STEP 1-2.

4. Pome fruits: 1 x 31 g a.s./ha, BBCH 70

Chlorantraniliprole: acceptable risk for aquatic organism with no need for risk mitigation measures for scenarios: D4 (p), D5 (p), at STEP 3 is concluded. The following risk mitigation measures are required for remained scenarios:

- D3 scenario: acceptable risk with 50% DRN or 10 m VFS
- D4 (s) scenario: acceptable risk with 50% DRN or 10 m VFS
- D5 (s) scenario: acceptable risk with 75% DRN or 10 m VFS or 5 unsprayed buffer zone with 50% DRN
- R1 scenario: acceptable risk with 50% DRN or 10 m VFS
- R3 scenario: acceptable risk with 75% DRN or 10 m VFS or 5 unsprayed buffer zone with 50% DRN
- R4 scenario: acceptable risk with 50% DRN or 10 m VFS

Chlorantraniliprole: acceptable risk for sediment dwelling organism with no need for risk mitigation measures: D4 (s), D5 (s) and R- scenarios at STEP 3 is concluded.

The following conclusion for remained scenarios is conducted:

- D3: acceptable risk for sediment dwelling organism with 10 m VFS or 75% DRN
- D4 (p), D5 (p) scenarios: an unacceptable risk for dwelling sediment organism with max mitigation measures (20 m VFS + 90% DRN). Further refinement is required at MSs level for these scenarios.

4. Pome fruits: 1 x 31 g a.s./ha, < 87 BBCH

Chlorantraniliprole: acceptable risk for aquatic organism with no need for risk mitigation measures: D4 (p), D5 (p), for aquatic organism at STEP 3 is concluded. The following risk mitigation measures are required for remained scenarios:

- D3 scenario: acceptable risk with 50% DRN or 10 m VFS
- D4 (s) scenario: acceptable risk with 50% DRN or 10 m VFS
- D5 (s) scenario: acceptable risk with 75% DRN or 10 m VFS or 5 unsprayed buffer zone with 50% DRN
- R1 scenario: acceptable risk with 50% DRN or 10 m VFS
- R3 scenario: acceptable risk with 75% DRN or 10 m VFS or 5 unsprayed buffer zone with 50% DRN
- R4 scenario: acceptable risk with 50% DRN or 10 m VFS

Chlorantraniliprole: acceptable risk for sediment dwelling organism with no need for risk mitigation measures for scenarios: D4 (s), D5 (s) and R- scenarios at STEP 3 is concluded. The following risk mitigation measures are required for remained scenarios:

- D3: acceptable risk for sediment dwelling organism with 10 m VFS or 75% DRN
- D4 (p), D5 (p) scenarios: **an unacceptable risk for dwelling sediment organism** with max mitigation measures (20 m VFS + 90% DRN) is concluded. **Further refinement is required at MSs level for these scenarios.**

5. Pome fruits: 1 x 24 g a.s./ha, BBCH 70

Chlorantraniliprole: acceptable risk for aquatic organism with no need for risk mitigation measures for scenarios: D4 (p), D5 (p) at STEP 3 is concluded. For remained scenarios following risk mitigation measures are required:

- D3 scenario: acceptable risk with 50% DRN or 10 m VFS
- D4 (s) scenario: acceptable risk with 50% DRN or 10 m VFS
- D5 (s) scenario: acceptable risk with 50% DRN or 10 m VFS
- R1 scenario: acceptable risk with 50% DRN or 10 m VFS
- R3 scenario: acceptable risk with 50% DRN or 10 m VFS
- R4 scenario: acceptable risk with 50% DRN or 10 m VFS

Chlorantraniliprole: acceptable risk for sediment dwelling organism with no need for risk mitigation measures: D3, D4 (s), D5 (s) and R- scenarios at STEP 3 is concluded. For remained scenario following conclusion is conducted:

- D4 (p), D5 (p) scenarios: **an unacceptable risk for sediment dwelling organism** with max mitigation measures (20 m VFS + 90% DRN). **Further refinement is required at MSs level for these scenarios.**

5. Pome fruits: x 24 g a.s./ha, <87 BBCH

Chlorantraniliprole: acceptable risk for aquatic organism with no need for risk mitigation measures for scenarios: D3, D4 (p), D5 (p) at STEP 3 is concluded. For remained scenarios following risk mitigation measures are required.

- D3 scenario: acceptable risk with 50% DRN or 10 m VFS
- D4 (s) scenario: acceptable risk with 50% DRN or 10 m VFS
- D5 (s) scenario: acceptable risk with 50% DRN or 10 m VFS
- R1 scenario: acceptable risk with 50% DRN or 10 m VFS
- R3 scenario: acceptable risk with 50% DRN or 10 m VFS
- R4 scenario: acceptable risk with 50% DRN or 10 m VFS

Chlorantraniliprole: acceptable risk with for sediment dwelling organism no need for risk mitigation measures for scenarios: D3, D4 (s), D5 (s) and R- scenarios at STEP 3 is concluded. For remained scenario following conclusion is conducted:

- D4 (p), D5 (p) scenarios: **an unacceptable risk for dwelling sediment organism** with max mitigation measures (20 m VFS + 90% DRN). **Further refinement is required at MSs level for these scenarios.**

6. Potato: 1 x 12 g a.s./ha, BBCH 31-60

Based on the calculations of PEC/RAC ratio with regard to PEC_{sw} FOCUS STEP 3 for single application: 1 x 12 g a.s./ha at 31-60 BBCH for scenarios D3, D4 R1 and R3 the risk assessment for aquatic organism and sediment dwelling organism is considered acceptable without needs to further refinement.

6. Potato: 2 x 12 g a.s./ha, BBCH 31-60

Chlorantraniliprole: acceptable risk with no need for risk mitigation measures for aquatic organism for all scenarios: D3, D4, R1, R3 at STEP 3.

Chlorantraniliprole: acceptable risk for sediment dwelling organism at STEP 3 with no need for risk mitigation measures: D3, D4 (s), and R- scenarios is concluded.

For remained scenario following conclusion is conducted:

- D4 (p) scenario: **an unacceptable risk for sediment dwelling organism** with max mitigation measures (20 m VFS + 90% DRN). **Further refinement is required at MSs level for these scenarios.**

Metabolites for all proposed uses in the GAP : IN-EQW78, IN-ECD73, IN-F6L99, IN-F9N04, IN-GAZ70, IN-LBA22, IN-LBA23, and IN-LBA24 indicated an acceptable risk at STEP 1-2.

It should be noted that for D4 pond and D5 pond for sediment dwelling organism further refinement is required at MSs level. The the following mitigation measures is proposed by the Applicant in case of D4 (p) and D5 (p) scenarios **“No application on drained soils.**

Concerned Member States must decide on applicability of indicated risk mitigation measures in their countries at the product authorisation. Please note that additional aquatic risk assessment may be required by the concerned Member States that do not accept simulations performed according to FOCUS recommendations.

9.1.1.3

zRMS overoll conclusion:

Based on the performed calculations for aquatic organism and sediment dwelling organism following conclusions may be derived:

1. Leafy crops: 1 x 28 g a.s./ha, BBCH 15-49

Chlorantraniliprole: acceptable risk for aquatic organism with no need for risk mitigation measures for scenarios : D3, D4 (s,p), R1 (p,s), R3 at STEP 3 is concluded.

For remained scenarios following risk mitigation measure **is not** required:

- R4 scenario: risk acceptable with 10 m VFS.
- ~~D5 (s, p) scenarios: No calculations are performed for these scenarios, an unacceptable risk is concluded.~~

Chlorantraniliprole: acceptable risk for sediment dwelling organism with no need for risk mitigation measures for scenarios: D3, D4 (s), R1 (p), R1 (s), R3, R4 at STEP 3 is concluded.

For remained scenarios:

- D4 (p) scenario : an unacceptable risk for sediment dwelling organism with max mitigation measures (20 m VFS + 90% DRN or 5 m VFSmod) is concluded. **Further refinement is required at MSs level for these scenarios.**
- ~~D5 (s, p) scenarios: No calculations are performed for these scenarios, an unacceptable risk is concluded.~~

2. Maize: 1 x 28 g a.s./ha, BBCH 20

Chlorantraniliprole: acceptable risk for aquatic organism with no need for risk mitigation measures for scenarios: D3, D4 (s,p), D5 (s,p) R1 (p), R1 (s), R3 at STEP 3 is concluded.

For remained scenario the following risk mitigation measure is required:

- R4 scenario: 10 m VFS (alternatively: 2 m or 5 m VFS calculated by VFSmod)

Chlorantraniliprole: an unacceptable risk for sediment dwelling organism for D4 (p) and D5 (p) scenarios with max mitigation measures (20 m VFS + 90% DRN or 5 m VFSmod) is concluded. **Further refinement is required at MSs level for these scenarios.**

2. Maize: 1 x 28 g a.s./ha ,<87 BBCH:

Chlorantraniliprole: acceptable risk for aquatic organism with no need for risk mitigation measures for D3, D4 (s), D5 (s), R1 (p), R1 (s), R3, R4 at STEP 3 is concluded.

Chlorantraniliprole: D4 (p) scenarios: an unacceptable risk for dwelling sediment organism with max mitigation measures (20 m VFS + 90% DRN or with 5 m VFSmod) is concluded. **Further refinement is required at MSs level for scenarios.**

For remained scenario the following risk mitigation measure is required:

- D5 (p) scenario : acceptable risk with 20 m VFS+90% DRN

3. Vine : 1 x 36 g a.s/ha, BBCH 70-87

Chlorantraniliprole: acceptable risk for aquatic organism with no need for risk mitigation measures for scenarios : R1 (p,s), R4 at STEP 3 is concluded. The following risk mitigation measures is required for remained scenarios:

- R3 scenario: acceptable risk with 5 m unsprayed buffer zone or 50% drift reduction nozzles
- D3 scenario: acceptable risk with 50% DRN or 10 m VFS
- D4 (s) scenario: acceptable risk with 50% DRN or 10 m VFS
- D5 (s) scenario: acceptable risk with 75% DRN or 10 m VFS or 5 unsprayed buffer zone with 50% DRN

Chlorantraniliprole: acceptable risk for sediment dwelling organism with no need for risk mitigation measures for R scenarios at STEP 3 FOCUS program is concluded.

In case of D-scenarios relevant for Central Zone (D3, D4 and D5) the risk mitigation is covered by risk mitigation for pome fruits for aquatic and sediment dwelling organism.

Chlorantraniliprole: acceptable risk for sediment dwelling organism with no need for risk mitigation measures for scenarios: D4 (s), D5 (s) and R- scenarios at STEP 3 is concluded. The following risk mitigation measures are required for remained scenarios:

- D3: acceptable risk for sediment dwelling organism with 10 m VFS or 75% DRN
- D4 (p), D5 (p) scenarios: an unacceptable risk for dwelling sediment organism with max mitigation measures (20 m VFS + 90% DRN) is concluded. **Further refinement is required at MSs level for these scenarios**

Metabolites: IN-EQW78, IN-ECD73, IN-F6L99, IN-F9N04, IN-GAZ70, IN-LBA22, IN-LBA23, and IN-LBA 24: acceptable risk at STEP 1-2.

4. Pome fruits: 1 x 31 g a.s./ha, BBCH 70

Chlorantraniliprole: acceptable risk for aquatic organism with no need for risk mitigation measures for scenarios: D4 (p), D5 (p), at STEP 3 is concluded. The following risk mitigation measures are required for remained scenarios:

- D3 scenario: acceptable risk with 50% DRN or 10 m VFS
- D4 (s) scenario: acceptable risk with 50% DRN or 10 m VFS
- D5 (s) scenario: acceptable risk with 75% DRN or 10 m VFS or 5 unsprayed buffer zone with 50% DRN
- R1 scenario: acceptable risk with 50% DRN or 10 m VFS
- R3 scenario: acceptable risk with 75% DRN or 10 m VFS or 5 unsprayed buffer zone with 50% DRN
- R4 scenario: acceptable risk with 50% DRN or 10 m VFS

Chlorantraniliprole: acceptable risk for sediment dwelling organism with no need for risk mitigation measures: D4 (s), D5 (s) and R- scenarios at STEP 3 is concluded.

The following conclusion for remained scenarios is conducted:

- D3: acceptable risk for sediment dwelling organism with 10 m VFS or 75% DRN
- D4 (p), D5 (p) scenarios: an unacceptable risk for dwelling sediment organism with max mitigation measures (20 m VFS + 90% DRN). **Further refinement is required at MSs level for these scenarios.**

4. Pome fruits: 1 x 31 g a.s./ha, < 87 BBCH

Chlorantraniliprole: acceptable risk for aquatic organism with no need for risk mitigation measures: D4 (p), D5 (p), for aquatic organism at STEP 3 is concluded. The following risk mitigation measures are required for remained scenarios:

- D3 scenario: acceptable risk with 50% DRN or 10 m VFS
- D4 (s) scenario: acceptable risk with 50% DRN or 10 m VFS
- D5 (s) scenario: acceptable risk with 75% DRN or 10 m VFS or 5 unsprayed buffer zone with 50% DRN
- R1 scenario: acceptable risk with 50% DRN or 10 m VFS
- R3 scenario: acceptable risk with 75% DRN or 10 m VFS or 5 unsprayed buffer zone with 50% DRN
- R4 scenario: acceptable risk with 50% DRN or 10 m VFS

Chlorantraniliprole: acceptable risk for sediment dwelling organism with no need for risk mitigation measures for scenarios: D4 (s), D5 (s) and R- scenarios at STEP 3 is concluded. The following risk mitigation measures are required for remained scenarios:

- D3: acceptable risk for sediment dwelling organism with 10 m VFS or 75% DRN
- D4 (p), D5 (p) scenarios: **an unacceptable risk for dwelling sediment organism** with max mitigation measures (20 m VFS + 90% DRN) is concluded. **Further refinement is required at MSs level for these scenarios.**

5. Pome fruits: 1 x 24 g a.s./ha, BBCH 70

Chlorantraniliprole: acceptable risk for aquatic organism with no need for risk mitigation measures for scenarios: D4 (p), D5 (p) at STEP 3 is concluded. For remained scenarios following risk mitigation measures are required:

- D3 scenario: acceptable risk with 50% DRN or 10 m VFS
- D4 (s) scenario: acceptable risk with 50% DRN or 10 m VFS
- D5 (s) scenario: acceptable risk with 50% DRN or 10 m VFS
- R1 scenario: acceptable risk with 50% DRN or 10 m VFS
- R3 scenario: acceptable risk with 50% DRN or 10 m VFS
- R4 scenario: acceptable risk with 50% DRN or 10 m VFS

Chlorantraniliprole: acceptable risk for sediment dwelling organism with no need for risk mitigation measures: D3, D4 (s), D5 (s) and R- scenarios at STEP 3 is concluded. For remained scenario following conclusion is conducted:

- D4 (p), D5 (p) scenarios: **an unacceptable risk for sediment dwelling organism** with max mitigation measures (20 m VFS + 90% DRN). **Further refinement is required at MSs level for these scenarios.**

5. Pome fruits: x 24 g a.s./ha, <87 BBCH

Chlorantraniliprole: acceptable risk for aquatic organism with no need for risk mitigation measures for scenarios: D3, D4 (p), D5 (p) at STEP 3 is concluded. For remained scenarios following risk mitigation measures are required.

- D3 scenario: acceptable risk with 50% DRN or 10 m VFS
- D4 (s) scenario: acceptable risk with 50% DRN or 10 m VFS
- D5 (s) scenario: acceptable risk with 50% DRN or 10 m VFS
- R1 scenario: acceptable risk with 50% DRN or 10 m VFS

- R3 scenario: acceptable risk with 50% DRN or 10 m VFS
- R4 scenario: acceptable risk with 50% DRN or 10 m VFS

Chlorantraniliprole: acceptable risk with for sediment dwelling organism no need for risk mitigation measures for scenarios: D3, D4 (s), D5 (s) and R- scenarios at STEP 3 is concluded. For remained scenario following conclusion is conducted:

- D4 (p), D5 (p) scenarios: **an unacceptable risk for dwelling sediment organism** with max mitigation measures (20 m VFS + 90% DRN). **Further refinement is required at MSs level for these scenarios.**

6. Potato: 1 x 12 g a.s./ha, BBCH 31-60

Based on the calculations of PEC/RAC ratio with regard to PEC_{sw} FOCUS STEP 3 for single application: 1 x 12 g a.s./ha at 31-60 BBCH for scenarios D3, D4 R1 and R3 the risk assessment for aquatic organism and sediment dwelling organism is considered acceptable without needs to further refinement.

6. Potato: 2 x 12 g a.s./ha, BBCH 31-60

Chlorantraniliprole: acceptable risk with no need for risk mitigation measures for aquatic organism for all scenarios: D3, D4, R1, R3 at STEP 3.

Chlorantraniliprole: acceptable risk for sediment dwelling organism at STEP 3 with no need for risk mitigation measures: D3, D4 (s), and R- scenarios is concluded. For remained scenario following conclusion is conducted:

- D4 (p) scenario: **an unacceptable risk for sediment dwelling organism** with max mitigation measures (20 m VFS + 90% DRN). **Further refinement is required at MSs level for these scenarios.**

Metabolites for all proposed uses in the GAP : IN-EQW78, IN-ECD73, IN-F6L99, IN-F9N04, IN-GAZ70, IN-LBA22, IN-LBA23, and IN-LBA24 indicated an acceptable risk at STEP 1-2.

It should be noted that for D4 pond and D5 pond for sediment dwelling organism further refinement is required at MSs level. The the following mitigation measures is proposed by the Applicant in case of D4 (p) and D5 (p) scenarios: “No application on drained soils.

Concerned Member States must decide on applicability of indicated risk mitigation measures in their countries at the product authorisation. Please note that additional aquatic risk assessment may be required by the concerned Member States that do not accept simulations performed according to FOCUS recommendations.

9.1.1.4

9.1.1.5 Effects on bees (KCP 10.3.1)

The assessment of the risk to bees from Chlorantraniliprole due to all the intended uses of ADM.00900.I.1.C was conducted according to the *Guidance Document on Terrestrial Ecotoxicology* (SANCO/10329/2002 rev. 2 (final), 2002) The risk assessment resulted in the following conclusions:

- Acute contact toxicity: both the assessments concluded to an acceptable risk for all uses
- Acute oral toxicity to adult bees: both the assessments concluded to an acceptable risk for all uses
- Chronic and larval toxicity data for honeybees were submitted with the dossiers since they are data requirements. ~~However, as for spray applications there is no noted Guidance on how to use this information in risk assessment, no deterministic chronic risk assessment for bees was provided by the applicant.~~

An acceptable risk is therefore found for all the exposure patterns. As a consequence, all the intended uses for ADM.00900.I.1.C pose an acceptable risk when applied at the recommended rates.

9.1.1.6 Effects on arthropods other than bees (KCP 10.3.2)

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.

To achieve a concise risk assessment, only the uses that lead to the highest PER in- and off-field were investigated:

- For the in-field assessment, the worst-case is represented by the use in wine and table grapes with the highest combination application rate/number of applications, resulting in a $PER_{in-field}$ of 36 g a.s./ha. With a standard laboratory $LR_{50} > 80$ g a.s./ha for both the representative species *Aphidius rhopalosiphi* and *Typhlodromus pyri*, the in-field risk to non-target arthropods from Chlorantraniliprole is considered acceptable when ADM.00900.I.1.C is applied to all the intended crops at the recommended rates.
- For the off-field assessment, the worst-case is represented by the use in pomefruit with the highest combination application rate/number of applications/drift rate, resulting in a $PER_{off-field}$ of 0.488 g a.s./ha. With a standard laboratory $LR_{50} > 80$ g a.s./ha for both the representative species *Aphidius rhopalosiphi* and *Typhlodromus pyri*, the off-field risk to non-target arthropods from Chlorantraniliprole is considered acceptable when ADM.00900.I.1.C is applied to all the intended crops at the recommended rates.

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

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

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). To achieve a concise risk assessment, the risk envelope approach was applied and the risk assessment was based on the use in vines at 1 x 36 g a.s./ha at BBCH 57-83 resulting in the highest PEC_{soil} for Chlorantraniliprole and its metabolites (please refer to Part B section 8 for details).

Based on Tier1 calculated PEC_{soil} values (please refer to Part B section 8), the risk from Chlorantraniliprole and its metabolites was found acceptable for earthworms. No unacceptable risk from the metabolites is identified for the most sensitive species, the collembolan *Folsomia candida*, while the risk from the active substance to the predatory mite *Hypoaspis aculeifer* was considered acceptable as well. However, further refinement was required for the risk to *F. candida* from the active substance Chlorantraniliprole.

The risk assessment conducted with DT_{50} -refined PEC_{soil} for Chlorantraniliprole resulted in an acceptable risk for *Folsomia candida* from Chlorantraniliprole due to the use of ADM.00900.I.1.C at the recommended rates.

It is therefore concluded that the use of ADM.00900.I.1.C in the intended crops at the recommended rates poses an acceptable risk to the soil meso- and macrofauna.

Effects on soil microbial activity (KCP 10.5)

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). To achieve a concise risk assessment, the risk envelope approach was applied and the risk assessment was based on the use in vines at 1 x 36 g a.s./ha at BBCH 57-83 resulting in the highest PEC_{soil} for Chlorantraniliprole and its metabolites (please refer to Part B section 8 for details).

The PEC_{soil} values for Chlorantraniliprole and its metabolites calculated for the use in vines at 1 x 36 g a.s./ha are far below the maximum concentrations with effects $\leq 25\%$, indicating an acceptable risk to soil microorganisms. It is therefore concluded that the use of ADM.00900.I.1.C in the intended crops at the recommended rates poses an acceptable risk to soil microorganisms.

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

The risk assessment is based on the *Guidance Document on Terrestrial Ecotoxicology*, (SANCO/10329/2002 rev.2 final, 2002). To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use in pomefruit at 31 g a.s./ha at BBCH 70-87 also covers the risk for non-target terrestrial plants from all other intended uses since the combination of the application rate (31 g a.s./ha) with a high drift rate (15.73%) results in the highest $PER_{off-field}$.

The risk assessment was conducted with data from ADM.00900.I.1.C and from the representative formulation submitted and evaluated in the EU peer review, being of same AI concentration and formulation type as ADM.00900.I.1.C. In both cases, the resulting TER values were highly above the trigger of 5, indicating an acceptable risk from Chlorantraniliprole when ADM.00900.I.1.C is applied in pomefruit at 1 x 31 g a.s./ha at BBCH 70-87. Since this use represent the worst-case for the intended uses of ADM.00900.I.1.C, by applying the risk envelop approach, it is considered that the use of ADM.00900.I.1.C in all the intended crops at the recommended rates poses an acceptable risk.

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

No further relevant data is available and considered necessary.

9.1.2 Grouping of intended uses for risk assessment

Table 9.1-2: Risk envelopes of ADM.00900.I.1.C sorted by organisms groups

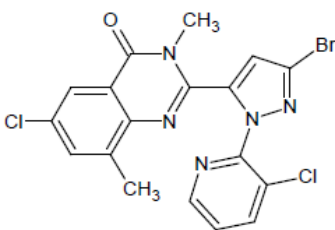
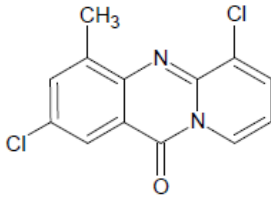
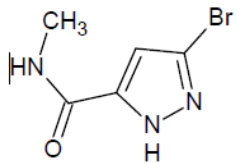
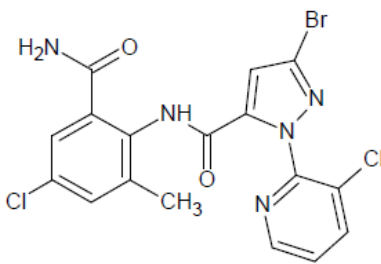
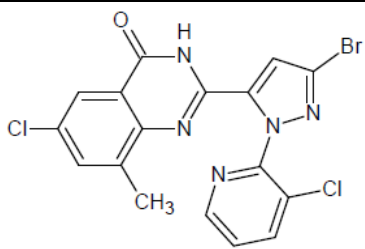
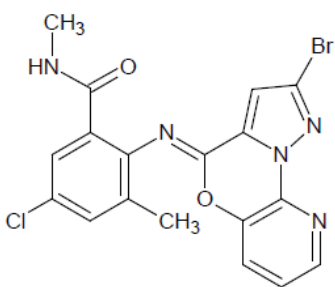
Organism group	Group No.	Uses No.	Crop	Number of applications	Application rate [g a.s./ha]	Application rate [L product/ha]	Application timing [e.g. BBCH]
Birds and Mammals	1	1	Leafy vegetables	1	28	0.14	BBCH 15-49
	2	2	Vineyards	1	36	0.18	BBCH 57-83
	3	3-4	Maize	1	28	0.14	BBCH 20-87
	4	5-6	Pomefruit	1	31	0.155	BBCH 70-87
	5	7-8	Potato	2	12	0.06	BBCH 31-60
Aquatic organisms*	1	1	Leafy vegetables	1	28	0.14	BBCH 15-49
	2	3-4	Maize	1	28	0.14	BBCH 20-87
	3	2	Vines	1	36	0.18	BBCH 57-83
	4	5	Pomefruit	1	31	0.155	BBCH 70-87
	5	6	Pomefruit	1	24	0.12	BBCH 70-87
	6	7	Potato	1	12	0.06	BBCH 31-60
	7	8	Potato	2	12	0.06	BBCH 31-60
Bees	1	2	Grapes	1	36	0.18	BBCH 57-83
	2	5-6	Pomefruit	1	31	0.155	BBCH 70-87
	3	1	Leafy vegetables	1	28	0.14	BBCH 15-49
	4	3-4	Maize	1	28	0.14	BBCH 20-87
	5	7-8	Potato	2	12	0.06	BBCH 31-60
Non-target arthropods	In-field	All	Wine and table grapes	1	36	0.18	BBCH 57-83
	Off-field	All	Pomefruit	1	31	0.155	BBCH 70-87
Soil organisms		All	Vines	1	36	0.18	BBCH 57-83
Non-target plants		All	Pomefruit	1	31	0.155	BBCH 70-87

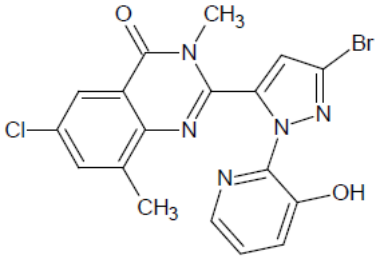
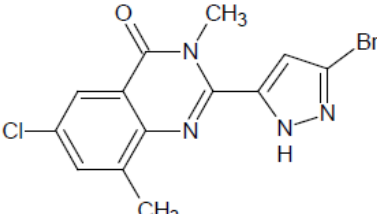
* For aquatic organisms, uses are grouped and groups numbered according to the grouping defined in Part B8, point 8.9.

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 ADM.00900.I.1.C is indicated in the table.

Table 9.1-3 Metabolites of Chlorantraniliprole

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required for
IN-EQW78 (2-[3-bromo-1-(3-chloropyridin-2-yl)-1H-pyrazol-5-yl]-6-chloro-3,8-dimethylquinazolin-4(3H)-one)	465.14		Soil: 31.7 % (Vittoria field study, Italy) Water/sediment, irradiated: 41% in total system (14 d); 6.4% in water (14d); 38.1% in sediment (14d)	PEC _{gw} PEC _{soil} PEC _{sw/sed}
IN-ECD73 (2,6-dichloro-4-methyl-11H-pyrindo[2,1-b]quinazolin-11-one)	279.13		Soil: 11.3% (Crespelano field study, Italy) Water/sediment: 4.7% in whole system (100 d); 0.3% in water (10 d); 4.6% in sediment (100 d)	PEC _{gw} : PEC _{soil} : PEC _{sw/sed}
IN-F6L99 (3-bromo-N-methyl-1H-pyrazole-5-Carboxamide)	204.03		Soil: 2.2% (Marietta sandy loam, laboratory 25°C) Water/sediment: 4.2% in whole system (100 d); 1.57% in water; 2.63% in sediment	PEC _{gw} PEC _{soil} PEC _{sw/sed}
IN-F9N04 (3-bromo-N-(2-carbamoyl-4-chloro-6-methylphenyl)-1-(3-chloropyridin-2-yl)-1H-pyrazole-5-carboxamide)	469.13		Soil: 4.8% (Marietta sandy loam, laboratory 25°C) Water/sediment: 2.7% in whole system and in sediment (100 d); 2.08% in water (0 d)	PEC _{gw} : PEC _{soil} : PEC _{sw/sed}
IN-GAZ70 (2-[3-bromo-1-(3-chloropyridin-2-yl)-1H-pyrazol-5-yl]-6-chloro-8-methylquinazolin-4(1H)-one)	451.11		Soil: 4.4% (Lleida clay loam, laboratory 25°C) Water/sediment: 3.1% in whole system (75 d); 0.7% in water (10 d); 2.7% in sediment (100 d)	PEC _{gw} PEC _{soil} PEC _{sw/sed}
IN-LBA22 (2-(([(4Z)-2-bromo-4H-pyrazolo[1,5-d]pyrido[3,2-b][1,4]oxazin-4-ylidene]amino)-5-chloro-N,3-dimethylbenzamide))	446.69		Soil: not present Water/sediment: not present Aqueous photolysis: 52.8%	PEC _{sw/sed}

Metabolite	Molar mass	Chemical structure	Maximum-observed-occurrence in compartments	Exposure assessment required for
IN-LBA23 (2-[3-bromo-1-(3-hydroxypyridin-2-yl)-1H-pyrazol-5-yl]-6-chloro-3,8-dimethylquinazolin-4(3H)-one)	446.69		Soil: not present Water/sediment: not present Aqueous photolysis: 51.4%	PEC _{sw/sed}
IN-LBA24 (2-(3-bromo-1H-pyrazol-5-yl)-6-chloro-3,8-dimethylquinazolin-4(3H)-one)	353.61		Soil: not present Water/sediment: not present Aqueous photolysis: 94.4%	PEC _{sw/sed}

zRMS comments:

Metabolites relevant for soil and water compartment listed in Table 9.1-3 are the same as indicated in EFSA Conclusion (2013); 11(6):3143.

The maximum occurrence is relevant for exposure evaluation, for information agreed in this area please refer to the Core Assessment, Part B, Section 8, where all respective data are provided and used in calculation of PEC_{soil} and PEC_{sw/sed} values, considered further in the risk assessment.

As the information on the maximum occurrence was not checked in detail, it was struck through in Table 9.1-3.

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.

However, the provision of further data on the formulation is not considered to be required, because an increased toxicity of the product is not expected as indicated by acute oral testing in mammals giving a limit dose endpoint for the formulation (LD₅₀ > 2000 mg product/kg bw; Prajapati, 2020 - KCP 7.1.1/01) as well as for the active substance (> 5000 mg/kg bw).

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

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

Species	Substance	Exposure System	Results	Reference
Bobwhite quail (<i>Colinus virginianus</i>)	Chlorantraniliprole	Oral 1 d Acute	LD ₅₀ > 2250 mg/kg bw	EFSA Conclusion (2013)
Bobwhite quail (<i>Colinus virginianus</i>)	Chlorantraniliprole	Dietary 8 d Short-term	LDD ₅₀ > 1729 mg/kg bw/d	EFSA Conclusion (2013)
Bobwhite quail (<i>Colinus virginianus</i>)	Chlorantraniliprole	Dietary Reproductive	NOEL ≥ 10.1 mg/kg bw/d (Highest tested dose)	EFSA Conclusion (2013)

Species	Substance	Exposure System	Results	Reference
		toxicity		
Bobwhite quail (<i>Colinus virginianus</i>)	IN-EQW78	Oral 1 d Acute	LD ₅₀ > 2250 mg/kg bw	EFSA Conclusion (2013)

zRMS comments:

Avian toxicity data for Chlorantraniliprole in Table 9.2-1 are in line with EU agreed endpoints reported in EFSA Conclusion (2013); 11(6):3143.

9.2.1.1 Justification for new endpoints

Not relevant.

9.2.2 Risk assessment for spray applications

The risk assessment is based on the methods presented in the EFSA *Guidance Document on Risk Assessment for Birds and Mammals* (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438). To achieve a concise risk assessment, the risk envelope approach is applied. Please refer to table 9.1-2 for the grouping of uses (see 9.1.2).

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

The risk assessment is conducted for the active substance Chlorantraniliprole. According to EFSA Conclusion (2013), exposure to metabolites through plants is negligible because no significant metabolism of Chlorantraniliprole was reported in vegetation.

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

Use group 1: Leafy vegetables

Table 9.2-2: Screening assessment of the acute and long-term/reproductive risk for birds due to the use of ADM.00900.I.1.C in Leafy vegetables (Use group 1)

Intended use		Leafy vegetables BBCH 15-49 (Head cabbage, cauliflower, broccoli, maize)				
Active substance/product		Chlorantraniliprole				
Application rate (g/ha)						
Acute toxicity (mg/kg bw)		> 2250				
TER criterion						
Crop scenario	Indicator species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Growth stage						
Leafy vegetables (screening)	Small omnivorous bird	158.8	1.0	4.45	506.0	
Reprod. toxicity (mg/kg bw/d)		10.1				
TER criterion						
Crop scenario	Indicator species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{lt}	
Growth stage						

Leafy vegetables (screening)	Small omnivorous bird	64.8	0.53	0.96	10.5
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SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

All the TER for acute and reproductive risk assessment are above the triggers of 10 and 5, respectively, indicating an acceptable risk to birds from Chlorantraniliprole when ADM.00900.I.1.C is used in leafy vegetables (head cabbage, cauliflower and broccoli) at the recommended rate.

Use group 2: Vineyard

Table 9.2-3: Screening assessment of the acute and long-term/reproductive risk for birds due to the use of ADM.00900.I.1.C in Vineyard (Use group 2)

Intended use		Vineyard BBCH 57-83				
Active substance/product		Chlorantraniliprole				
Application rate (g/ha)						
Acute toxicity (mg/kg bw)						
TER criterion						
		10				
Crop scenario	Indicator species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Growth stage						
Vineyard (screening)	Small omnivorous bird	95.3	1.0	3.43	655.8	
Reprod. toxicity (mg/kg bw/d)		10.1				
TER criterion						
		5				
Crop scenario	Indicator species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{lt}	
Growth stage						
Vineyard (screening)	Small omnivorous bird	38.9	0.53	0.74	13.6	

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.

All the TER for acute and reproductive risk assessment are above the triggers of 10 and 5, respectively, indicating an acceptable risk to birds from Chlorantraniliprole when ADM.00900.I.1.C is used in vineyards (wine and table grapes) at the recommended rate.

Use group 3: Maize (BBCH 20-87)

Maize is in the same crop group as leafy vegetables for the screening assessment of the risk to birds (i.e., same indicator species – small omnivorous bird – with the same short-cut value). Therefore, since the risk was found acceptable at the screening level for Chlorantraniliprole in leafy vegetables with the same application rate as the application rate in maize (1 x 28 g a.s.), the risk assessment for Chlorantraniliprole in leafy vegetables covers for the risk of this substance in maize.

It is therefore concluded that the risk due to Chlorantraniliprole is acceptable when ADM.00900.I.1.C is used in maize (corn – grain and silage) at the recommended rate of 28 g a.s./ha.

Use group 4: Pomefruit

Table 9.2-4: Screening assessment of the acute and long-term/reproductive risk for birds due to the use of ADM.00900.I.1.C in Pomefruit (Use group 4)

Intended use		Pomefruit BBCH 70-87				
Active substance/product		Chlorantraniliprole				
Application rate (g/ha)		1 × 31				

Acute toxicity (mg/kg bw)		> 2250				
TER criterion						
Crop scenario	Indicator species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Growth stage						
Orchards (screening)	Small insectivorous bird	46.8	1.0	1.45	1550.9	
Reprod. toxicity (mg/kg bw/d)		10.1				
TER criterion						
		5				
Crop scenario	Indicator species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{lt}	
Growth stage						
Orchards (screening)	Small insectivorous bird	18.2	0.53	0.30	33.8	

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.

All the TER for acute and reproductive risk assessment are above the triggers of 10 and 5, respectively, indicating an acceptable risk to birds from Chlorantraniliprole when ADM.00900.I.1.C is used in pomefruit (apple, pear and quince) at the recommended rate.

Use group 5: Potato

Potato is in the same crop group as leafy vegetables for the screening assessment of the risk to birds (i.e., same indicator species – small omnivorous bird – with the same short-cut value). Therefore, since the risk was found acceptable at the screening level for Chlorantraniliprole in leafy vegetables with a higher effective application rate (1 x 28 g a.s./ha) than the application rate in potato (2 x 12 g a.s.), the risk assessment for Chlorantraniliprole covers for the risk of this substance in potato.

It is therefore concluded that the risk due to Chlorantraniliprole is acceptable when ADM.00900.I.1.C is used in potato at the recommended rate of 2 x 12 g a.s./ha.

zRMS comments:

Screening step in the risk assessment

The screening step risk assessment for active substance Chlorantraniliprole performed for use groups 1-5 is agreed by zRMS.

TER_A and TER_{LT} values for the exposure to the active substance when ADM.00900.I.1.C is applied to all proposed uses are above the trigger of 10 and 5 for acute and long-term exposure, indicating acceptable risk for birds.

Overall, acceptable acute and long-term risk may be concluded for birds exposed to ADM.00900.I.1.C.

9.2.2.2 Higher-tier risk assessment

Not required.

9.2.2.3 Drinking water exposure

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

Leaf scenario

Since ADM.00900.I.1.C 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 use in vineyard also covers the risk for birds from all other intended uses since it corresponds to the highest spray concentration (36 g a.s. in 400 L/ha).

Table 9.2-5: Assessment of the acute risk for birds due to exposure to Chlorantraniliprole via contaminated drinking water in leaf whorls

Intended use		Vineyard BBCH 57-83				
Active substance		Chlorantraniliprole				
Application rate (g/ha)		1 × 36				
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
36	400	0.09	18	0.46	8.28	> 271.7

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.

The TER_a value is highly above the trigger of 10 for acute toxicity, indicating a low-risk drinking water contaminated by Chlorantraniliprole in the leaf scenario when ADM.00900.I.1.C is used in the intended crops at the recommended rates.

zRMS comments:

The assessment risk for birds due to exposure to Chlorantraniliprole via contaminated drinking water in leaf whorls based on the worst-case scenario (vineyard also covers the risk for birds from all other intended uses since it corresponds to the highest spray concentration (36 g a.s. in 400 L/ha) is validated by zRMS.

Overall, the acceptable risk drinking water contaminated by Chlorantraniliprole in the leaf scenario when ADM.00900.I.1.C is used in the intended crops at the recommended rates is concluded.

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).

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group 2 also covers the risk for birds for all other intended uses (see 9.1.2) since this group corresponds to the highest effective application rate (36 g a.s./ha).

Chlorantraniliprole:

With a K(f)_{oc} of 301.4 L/kg, Chlorantraniliprole belongs to the group of less sorptive substances (trigger = 50).

Effective application rate (g/ha)	=	36		
Acute toxicity (mg/kg bw)	>	2250	quotient <	0.016
Reprod. toxicity (mg/kg bw/d)	=	10.1	quotient =	3.56

Both quotients are lower than the trigger of 50, and therefore, no further assessment is required for the active substance Chlorantraniliprole.

IN-EQW78:

With a $K(f)_{oc}$ of 10 787 L/Kg, IN-EQW78 belongs to the group of more sorptive substances (trigger = 3000)

Effective application rate (g/ha)	=	10.99		
Acute toxicity (mg/kg bw)	>	2250	quotient <	0.005
Reprod. toxicity (mg/kg bw/d)	=	1.01	quotient =	10.88

Both quotients are lower than the trigger of 3000, and therefore, no further assessment is required for the metabolite IN-EQW78.

IN-ECD73:

With a $K(f)_{oc}$ of 29 849 L/Kg, IN-ECD73 belongs to the group of more sorptive substances (trigger = 3000).

Effective application rate (g/ha)	=	2.35		
Acute toxicity (mg/kg bw)	>	2250	quotient <	0.010
Reprod. toxicity (mg/kg bw/d)	=	1.01	quotient =	2.33

Both quotients are lower than the trigger of 3000, and therefore, no further assessment is required for the metabolite IN-ECD73.

Conclusion on the risk from drinking water from puddles:

The ratios of effective application rate to relevant endpoints (in mg/kg bw/d) do not exceed the relevant triggers for Chlorantraniliprole and its relevant metabolites. No further assessment is required. The risk to birds from drinking water from puddles is acceptable when ADM.00900.I.1.C is used in all intended crops at the recommended rates.

zRMS comments:

Since the ratio of effective application rate to relevant endpoint does not exceed the trigger of 3000 for more sorptive substances, no further considerations have to be taken into account for the a.s. and their relevant metabolites. Overall, the risk to birds from drinking water from puddles is acceptable when ADM.00900.I.1.C is used in all intended crops at the recommended rates.

9.2.2.4 Effects of secondary poisoning

The log P_{ow} of Chlorantraniliprole amounts to 2.76 and thus does not exceed the trigger value of 3 (same is true for the metabolites IN-F6L99 and IN-F9N04 with log P_{ow} values of 0.7 and 2.4, respectively). A risk assessment for effects due to secondary poisoning is not required. However, the soil metabolites IN-EQW78, IN-ECD73 and IN-GAZ70 each have measured log K_{ow} > 3 and should be included in a risk assessment for piscivores and vermivores. The endpoint for all metabolites for secondary poisoning is the parent compound endpoint (NOEL = 10.1 mg/kg bw/day) as set in the EU peer review (EFSA Journal 2013;11(6):3143).

Risk assessment for earthworm-eating birds via secondary poisoning

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

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use in vineyards at 36 g a.s./ha also covers the risk for earthworm-eating birds via secondary poisoning from all other intended uses (see 9.1.2) since it results in the highest PEC_{soil} values (please refer to Part B section 8, point 8.7.2, vines scenario).

Metabolite: IN-EQW78

Table 9.2-6: Assessment of the risk for earthworm-eating birds due to exposure the metabolite IN-EQW78 via bioaccumulation in earthworms (secondary poisoning) for the intended use in vineyards (1 x 36 g a.s./ha, BBCH 57-83)

Parameter	IN-EQW78	comments
PEC _{soil} (accumulation) (mg/kg soil)	0.032	
log P _{ow}	3.9	
Kf _{oc}	10 787	
f _{oc}	0.02	Default
BCF _{worm}	0.45	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw}) = (0.84 + 0.012 \times P_{ow}) / f_{oc} \times Kf_{oc}$
PEC _{worm}	0.014	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	0.015	$DDD = PEC_{worm} \times 1.05$
NOEL (mg/kg bw/d)	10.1	Parent compound endpoint
TER _{lt}	674	

TER values shown in bold fall below the relevant trigger.

The TER_{lt} is above the trigger of 5 for chronic toxicity, indicating an acceptable risk to earthworm-eating birds via secondary poisoning from the metabolite IN-EQW78 when ADM.00900.I.1.C is applied at the recommended rates.

Metabolite: IN-ECD73

Table 9.2-7: Assessment of the risk for earthworm-eating birds due to exposure to the metabolite IN-ECD73 via bioaccumulation in earthworms (secondary poisoning) for the intended use in vineyards (1 x 36 g a.s./ha, BBCH 57-83)

Parameter	IN-ECD73	comments
PEC _{soil} (accumulation) (mg/kg soil)	0.050	
log P _{ow}	5.1	
Kf _{oc}	29 849	
f _{oc}	0.02	Default
BCF _{worm}	2.53	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw}) = (0.84 + 0.012 \times P_{ow}) / f_{oc} \times Kf_{oc}$
PEC _{worm}	0.127	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	0.133	$DDD = PEC_{worm} \times 1.05$
NOEL (mg/kg bw/d)	10.1	Parent compound endpoint
TER _{lt}	76	

TER values shown in bold fall below the relevant trigger.

The TER_{lt} is above the trigger of 5 for chronic toxicity, indicating an acceptable risk to earthworm-eating birds via secondary poisoning from the metabolite IN-ECD73 when ADM.00900.I.1.C is applied at the recommended rates.

Metabolite: IN-GAZ70

Table 9.2-8: Assessment of the risk for earthworm-eating birds due to exposure to the metabolite IN-GAZ70 via bioaccumulation in earthworms (secondary poisoning) for the intended use in vineyards (1 x 36 g a.s./ha, BBCH 57-83)

Parameter	IN-GAZ 70	comments
PEC _{soil} (accumulation) (mg/kg soil)	0.017	
log P _{ow}	3.8	
Kf _{oc}	23 581	
f _{oc}	0.02	Default
BCF _{worm}	0.161	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw}) = (0.84 + 0.012 \times P_{ow}) / f_{oc} \times Kf_{oc}$
PEC _{worm}	0.003	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	0.003	$DDD = PEC_{worm} \times 1.05$
NOEL (mg/kg bw/d)	10.1	
TER _{lt}	3486	

TER values shown in bold fall below the relevant trigger.

The TER_{lt} is above the trigger of 5 for chronic toxicity, indicating an acceptable risk to earthworm-eating birds via secondary poisoning from the metabolite IN-GAZ70 when ADM.00900.I.1.C is applied at the recommended rates.

Conclusion on the risk for earthworm-eating birds via secondary poisoning

No unacceptable risk to earthworm-eating birds was identified for Chlorantraniliprole soil relevant metabolites when ADM.00900.I.1.C is applied in the intended crops at the recommended rates.

Risk assessment for fish-eating birds via secondary poisoning

According to EFSA/2009/1438, the risk for piscivorous birds is assessed for a bird of 1000 g body weight with a daily food consumption of 159 g. Bioaccumulation in fish is assumed to be the same for all compounds and based on the measured BCF value from the active substance Chlorantraniliprole.

To achieve a concise risk assessment, the risk envelop approach is applied and only the highest PEC_{sw} of Chlorantraniliprole relevant metabolites will be considered. The highest FOCUS Step 1 PEC_{sw} are reported for the use in pomefruit at 1 x 31 g a.s./ha (please refer to part B8 for details):

Substance	FOCUS Step 1 PEC _{sw} (mg/L) ¹	Use
IN-EQW78	0.00111	Pomefruit, 1 x 31 g a.s./ha
IN-ECD73	0.000068	Pomefruit, 1 x 31 g a.s./ha
IN-GAZ70	0.000069	Pomefruit, 1 x 31 g a.s./ha
IN-LBA22	0.000889	Pomefruit, 1 x 31 g a.s./ha
IN-LBA23	0.000805	Pomefruit, 1 x 31 g a.s./ha
IN-LBA24	0.00326	Pomefruit, 1 x 31 g a.s./ha

¹ Overall worst case values from modelled uses (FOCUS Step 1, see chapter 8.9.2 in part B8)

Metabolite: IN-EQW78

Table 9.2-9: Assessment of the risk for fish-eating birds due to exposure to the metabolite IN-EQW78 via bioaccumulation in fish (secondary poisoning) for the intended use in pomefruit (1 x 31 g a.s./ha, BBCH 70-87)

Parameter	IN-EQW78	comments
PEC _{sw} (max) (mg/L)	0.00111	
BCF _{fish}	15	
BMF	-	biomagnification factor (relevant for BCF ≥ 2000)

Parameter	IN-EQW78	comments
PEC _{fish}	0.017	PEC _{fish} = PEC _{water} × BCF _{fish}
Daily dietary dose (mg/kg bw/d)	0.003	DDD = PEC _{fish} × 0.159
NOEL (mg/kg bw/d)	10.1	
TER _{lt}	3 815	

TER values shown in bold fall below the relevant trigger.

The TER_{lt} is above the trigger of 5 for chronic toxicity, indicating an acceptable risk to fish-eating birds via secondary poisoning from the metabolite IN-EQW78 when ADM.00900.I.1.C is applied at the recommended rates.

Metabolite: IN-ECD73

Table 9.2-10: Assessment of the risk for fish-eating birds due to exposure to the metabolite IN-ECD73 via bioaccumulation in fish (secondary poisoning) for the intended use in pomefruit (1 x 31 g a.s./ha, BBCH 70-87)

Parameter	IN-ECD73	comments
PEC _{sw} (max) (mg/L)	0.000068	
BCF _{fish}	15	
BMF	-	biomagnification factor (relevant for BCF ≥ 2000)
PEC _{fish}	0.001	PEC _{fish} = PEC _{water} × BCF _{fish}
Daily dietary dose (mg/kg bw/d)	0.0002	DDD = PEC _{fish} × 0.159
NOEL (mg/kg bw/d)	10.1	
TER _{lt}	62 276	

TER values shown in bold fall below the relevant trigger.

The TER_{lt} is above the trigger of 5 for chronic toxicity, indicating an acceptable risk to fish-eating birds via secondary poisoning from the metabolite IN-ECD73 when ADM.00900.I.1.C is applied at the recommended rates.

Metabolite: IN-GAZ70

Table 9.2-11: Assessment of the risk for fish-eating birds due to exposure to the metabolite IN-GAZ70 via bioaccumulation in fish (secondary poisoning) for the intended use in pomefruit (1 x 31 g a.s./ha, BBCH 70-87)

Parameter	IN-GAZ70	comments
PEC _{sw} (max) (mg/L)	0.000069	
BCF _{fish}	15	
BMF	-	biomagnification factor (relevant for BCF ≥ 2000)
PEC _{fish}	0.001	PEC _{fish} = PEC _{water} × BCF _{fish}
Daily dietary dose (mg/kg bw/d)	0.0002	DDD = PEC _{fish} × 0.159
NOEL (mg/kg bw/d)	10.1	
TER _{lt}	61 374	

TER values shown in bold fall below the relevant trigger.

The TER_{lt} is above the trigger of 5 for chronic toxicity, indicating an acceptable risk to fish-eating birds via secondary poisoning from the metabolite IN-GAZ70 when ADM.00900.I.1.C is applied at the recommended rates.

Metabolite: IN-LBA22

Table 9.2-12: Assessment of the risk for fish-eating birds due to exposure to the metabolite IN-LBA22 via bioaccumulation in fish (secondary poisoning) for the intended use in pomefruit (1 x 31 g a.s./ha, BBCH 70-87)

Parameter	IN-LBA22	comments
PEC _{sw} (max) (mg/L)	0.000889	
BCF _{fish}	15	
BMF	-	biomagnification factor (relevant for BCF ≥ 2000)
PEC _{fish}	0.013	PEC _{fish} = PEC _{water} × BCF _{fish}
Daily dietary dose (mg/kg bw/d)	0.002	DDD = PEC _{fish} × 0.159
NOEL (mg/kg bw/d)	10.1	
TER _{lt}	4 764	

TER values shown in bold fall below the relevant trigger.

The TER_{lt} is above the trigger of 5 for chronic toxicity, indicating an acceptable risk to fish-eating birds via secondary poisoning from the metabolite IN-LBA22 when ADM.00900.I.1.C is applied at the recommended rates.

Metabolite: IN-LBA23

Table 9.2-13: Assessment of the risk for fish-eating birds due to exposure to the metabolite IN-LBA23 via bioaccumulation in fish (secondary poisoning) for the intended use in pomefruit (1 x 31 g a.s./ha, BBCH 70-87)

Parameter	IN-LBA23	comments
PEC _{sw} (max) (mg/L)	0.000805	
BCF _{fish}	15	
BMF	-	biomagnification factor (relevant for BCF ≥ 2000)
PEC _{fish}	0.012	PEC _{fish} = PEC _{water} × BCF _{fish}
Daily dietary dose (mg/kg bw/d)	0.002	DDD = PEC _{fish} × 0.159
NOEL (mg/kg bw/d)	10.1	
TER _{lt}	5 261	

TER values shown in bold fall below the relevant trigger.

The TER_{lt} is above the trigger of 5 for chronic toxicity, indicating an acceptable risk to fish-eating birds via secondary poisoning from the metabolite IN-LBA23 when ADM.00900.I.1.C is applied at the recommended rates.

Metabolite: IN-LBA24

Table 9.2-14: Assessment of the risk for fish-eating birds due to exposure to the metabolite IN-LBA24 via bioaccumulation in fish (secondary poisoning) for the intended use in pomefruit (1 x 31 g a.s./ha, BBCH 70-87)

Parameter	IN-LBA24	comments
PEC _{sw} (max) (mg/L)	0.00326	
BCF _{fish}	15	
BMF	-	biomagnification factor (relevant for BCF ≥ 2000)
PEC _{fish}	0.050	PEC _{fish} = PEC _{water} × BCF _{fish}
Daily dietary dose (mg/kg bw/d)	0.008	DDD = PEC _{fish} × 0.159

Parameter	IN-LBA24	comments
NOEL (mg/kg bw/d)	10.1	
TER _{It}	1 299	

TER values shown in bold fall below the relevant trigger.

The TER_{It} is above the trigger of 5 for chronic toxicity, indicating an acceptable risk to fish-eating birds via secondary poisoning from the metabolite IN-LBA24 when ADM.00900.I.1.C is applied at the recommended rates.

Conclusion on the risk for fish-eating birds via secondary poisoning

No unacceptable risk to fish-eating birds was identified for Chlorantraniliprole relevant metabolites when ADM.00900.I.1.C is applied in the intended crops at the recommended rates.

zRMS comments:

The Applicants' approach in evaluation of the risk of secondary poisoning is in line with EFSA (2009). Compounds selected for this assessment are agreed by the zRMS. Evaluation was not triggered for remaining metabolites of active substance due to their log Pow <3.

Risk assessment for earthworm-eating birds via secondary poisoning

The risk envelope approach has been accepted by zRMS. The assessment for the use in vineyards at 36 g a.s./ha also covers the risk for earthworm-eating birds via secondary poisoning from all other intended uses since it results in the highest PEC_{soil} values (please refer to Part B section 8, point 8.7.2, vines scenario).

Risk assessment for fish-eating birds via secondary poisoning

The risk envelope approach has been accepted by zRMS. The highest PEC_{sw} of Chlorantraniliprole relevant metabolites has been used (calculated at FOCUS Step 1 PEC_{sw} for the use in pome fruit at 1 x 31 g a.s./ha, please refer to part B8 for details):

Bioaccumulation in fish is assumed to be the same for all compounds and based on the measured BCF value from the active substance Chlorantraniliprole.

Overall, no unacceptable risk to fish-eating birds and earthworms-eating birds was identified for Chlorantraniliprole relevant metabolites when ADM.00900.I.1.C is applied in the intended crops at the recommended rates.

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 assessment of the risk to birds conducted for the use of ADM.00900.I.1.C in leafy vegetables, vineyards, maize, pomefruit and potato according to the EFSA *Guidance Document on the Risk Assessment for Birds and Mammals* (EFSA, 2009) leads to the following conclusions:

- Acceptable dietary risk from the active substance Chlorantraniliprole (no relevant metabolite from dietary exposure)
- Acceptable risk from drinking water for the active substance Chlorantraniliprole and its relevant metabolites

- Acceptable risk for fish- and earthworm-eating birds via secondary poisoning for the active substance Chlorantraniliprole and its relevant metabolites.

It is therefore concluded that the use of ADM.00900.I.1.C in the intended crops at the recommended rates poses an acceptable risk to birds.

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

Effects on mammals of ADM.00900.I.1.C were not evaluated as part of the EU assessment of Chlorantraniliprole. New data submitted with this application are listed in Appendix 1 and summarised in Section 6 (Mammalian Toxicology) of this report.

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

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

Species	Substance	Exposure System	Results	Reference
Rat	Chlorantraniliprole	Oral 1 d Acute	LD ₅₀ > 5000 mg a.s./kg bw	EFSA Conclusion (2013)
Rat	Chlorantraniliprole	Dietary Reproductive toxicity Two-generation study	NOAEL = 1199 mg a.s./kg bw/d (parental, reproductive, and offspring effects)	EFSA Conclusion (2013)
Rat	ADM.00900.I.1.C	Oral 1 d Acute	LD ₅₀ > 2000 mg f.p./kg bw	Prajapati, 2020 (KCP 7.1.1/01)
Rat	IN-EQW78	Oral 1 d Acute	LD ₅₀ > 2000 mg/kg bw	EFSA Conclusion (2013)
Mouse	IN-ECD73	Oral 1 d Acute	LD ₅₀ > 2000 mg/kg bw	EFSA Conclusion (2013)
Mouse	IN-F6L99	Oral 1 d Acute	LD ₅₀ > 2000 mg/kg bw	EFSA Conclusion (2013)
Rat	IN-LBA24	Oral 1 d Acute	LD ₅₀ > 2000 mg/kg bw	EFSA Conclusion (2013)

zRMS comments:

Mammalian toxicity data for Chlorantraniliprole in Table 9.2-1 are in line with EU agreed endpoints reported in EFSA Conclusion (2013); 11(6):3143.

9.3.1.1 Justification for new endpoints

Not relevant.

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 Birds and Mammals* (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).

To achieve a concise risk assessment, the risk envelope approach is applied. Please refer to table 9.1-2 for the grouping of uses (see 9.1.2).

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

The risk assessment is conducted for the active substance Chlorantraniliprole. According to EFSA Conclusion (2013), exposure to metabolites through plants is negligible because no significant metabolism of chlorantraniliprole was reported in vegetation.

Crops in use groups 1, 2 3 and 4 belong to the same crop group for the screening assessment of the risk to mammals with small herbivorous mammal as indicator species with shortcut values of 136.4 and 72.3 for the acute and reproductive assessment respectively. To achieve a concise risk assessment, a screening assessment conducted for the use group 2 with the highest application rate (1 x 36 g a.s./ha) covers for the screening risk assessment for use groups1, 3 and 4. Group 5 (Potatoes, 2 x 12 g a.s. at BBCH 31-60) covering for uses 7 and 8 is assessed separately. These assessments are displayed in the tables below:

Use group2: Vineyard

Table 9.3-2: Screening assessment of the acute and long-term/reproductive risk for mammals due to the use of ADM.00900.I.1.C in vineyards (Use group 2)

Intended use		Vineyard BBCH 57-83 (risk env)				
Active substance/product		Chlorantraniliprole				
Application rate (g/ha)		1 × 36				
Acute toxicity (mg/kg bw)		> 5000				
TER criterion		10				
Crop scenario	Indicator species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Growth stage						
Vineyard (screening)	Small herbivorous mammal	136.4	1.0	4.91	1018.2	
Reprod. toxicity (mg/kg bw/d)		1199				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{lt}	
Growth stage						
Vineyard (screening)	Small herbivorous mammal	72.3	0.53	1.38	869.1	

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.

All the TER for acute and reproductive risk assessment are above the respective triggers of 10 and 5, indicating an acceptable risk to mammals from Chlorantraniliprole when ADM.00900.I.1.C is used in vineyard (wine and table grapes) at the recommended rate. Since the risk from the use in vineyards also covers for

the uses in leafy vegetables (use group 1: head cabbage, cauliflower, broccoli), maize (use group 2: corn – grain and silage) and pomefruit (use group 3: apple, pear and quince), the use of ADM.00900.I.1.C in those crop poses an acceptable risk as well.

Use group 5: Potatoes

Table 9.3-3: Screening assessment of the acute and long-term/reproductive risk for mammals due to the use of ADM.00900.I.1.C in potato (Use group 5)

Intended use		Potato BBCH 31-60				
Active substance/product		Chlorantraniliprole				
Application rate (g/ha)		2 × 12				
Acute toxicity (mg/kg bw)		> 5000				
TER criterion		10				
Crop scenario	Indicator species		SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a
Growth stage						
Potato (screening)	Small herbivorous mammal		118.4	1.4	1.99	2513.7
Reprod. toxicity (mg/kg bw/d)		1199				
TER criterion		5				
Crop scenario	Indicator/generic focal species		SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{lt}
Growth stage						
Potato (screening)	Small herbivorous mammal		48.3	0.848	0.49	2439.47

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.

All the TER for acute and reproductive risk assessment are above the respective triggers of 10 and 5, indicating an acceptable risk to mammals from Chlorantraniliprole when ADM.00900.I.1.C is used in potato at the recommended rate.

zRMS comments:

Screening step in the risk assessment

The screening step risk assessment for active substance Chlorantraniliprole performed in the Tables 9.3-2 and 9.3-3 is validated by zRMS.

We agree with the Applicant's calculation of the risk conducted for the use group 2 with the highest application rate (1 x 36 g a.s./ha) covers for the screening risk assessment for use groups 1, 3 and 4 and in case Group 5 (Potatoes, 2 x 12 g a.s. at BBCH 31-60) covering for uses 7 and 8 is assessed separately.

TER_A and TER_{LT} values for the exposure to the active substance when ADM.00900.I.1.C is applied to all proposed uses are above the trigger of 10 and 5 for acute and long-term exposure, indicating acceptable risk for mammals.

Overall, acceptable acute and long-term risk may be concluded for mammals exposed to ADM.00900.I.1.C.

9.3.2.2 Higher-tier risk assessment

Not required.

9.3.2.3 Drinking water exposure

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

Puddle scenario

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

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group 2 also covers the risk for mammals from all other intended uses (see 9.1.2) since this group corresponds to the highest effective application rate (36 g a.s./ha).

Active substance: *Chlorantraniliprole*

With a K_{oc} of 301.4 L/kg, Chlorantraniliprole belongs to the group of less sorptive substances.

Effective application rate (g/ha) =	36			
Acute toxicity (mg/kg bw) >	5000	quotient	<	0.0072
Reprod. toxicity (mg/kg bw/d) =	1199	quotient	=	0.0300

Both quotients are lower than the trigger of 50, and therefore, no further assessment is required for the active substance Chlorantraniliprole.

Metabolite: *IN-EQW78*

With a K_{oc} of 10787 L/kg, IN-EQW78 belongs to the group of more sorptive substances.

Effective application rate (g/ha) =	10.99			
Acute toxicity (mg/kg bw) >	2000	quotient	<	0.0055
Reprod. toxicity (mg/kg bw/d) =	119.9	quotient	=	0.0917

Both quotients are lower than the trigger of 3000, and therefore, no further assessment is required for the metabolite IN-EQW78.

Metabolite: *IN-ECD73*

With a K_{oc} of 29849 L/kg, IN-EQW78 belongs to the group of more sorptive substances.

Effective application rate (g/ha) =	2.35			
Acute toxicity (mg/kg bw) >	2000	quotient	<	0.0012
Reprod. toxicity (mg/kg bw/d) =	119.9	quotient	=	0.0196

Both quotients are lower than the trigger of 3000, and therefore, no further assessment is required for the metabolite IN-ECD73.

Conclusion on the risk from drinking water

The ratios of effective application rate to relevant endpoints (in mg/kg bw/d) do not exceed the relevant triggers for Chlorantraniliprole and its relevant metabolites. No further assessment is required. The risk to mammals from drinking water is acceptable when ADM.00900.I.1.C is used in all intended crops at the recommended rates.

zRMS comments:

Since the ratio of effective application rate to relevant endpoint does not exceed the trigger of 3000 for more sorptive substances, no further considerations have to be taken into account for the a.s. and their relevant metabolites. Overall, the risk to **mammals** **birds** from drinking water from puddles is acceptable when ADM.00900.I.1.C is used in all intended crops at the recommended rates.

9.3.2.4 Effects of secondary poisoning

The log P_{ow} of Chlorantraniliprole amounts to 2.76 and thus does not exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is not required. However, the soil metabolites IN-EQW78, IN-ECD73 and IN-GAZ70 each have measured log K_{ow} > 3 and should be included in a risk assessment for piscivores and vermivores.

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 predicted concentrations in soil.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use in vineyards at 36 g a.s./ha also covers for the risk for earthworm-eating mammals from all other intended uses (see 9.1.2) since it results in the highest PEC_{soil} values (please refer to Part B section 8, point 8.7.2, vines scenario).

Metabolite: IN-EQW78

Table 9.3-4: Assessment of the risk for earthworm-eating mammals due to exposure to the metabolite IN-EQW78 via bioaccumulation in earthworms (secondary poisoning) for the intended use in vineyards (1 x 36 g a.s./ha, BBCH 57-83)

Parameter	IN-EQW78	comments
PEC_{soil} (accumulation) (mg/kg soil)	0.032	
log P_{ow}	3.9	
K_{foc}	10 787	
foc	0.02	Default
BCF_{worm}	0.45	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw}) = (0.84 + 0.012 \times P_{ow}) / foc \times K_{oc}$
PEC_{worm}	0.014	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	0.018	$DDD = PEC_{worm} \times 1.28$
NOEL (mg/kg bw/d)	1199	
TER_{lt}	65 675	

TER values shown in bold fall below the relevant trigger.

The TER_{lt} is above the trigger of 5 for chronic toxicity, indicating an acceptable risk to earthworm-eating mammals via secondary poisoning from the metabolite IN-EQW78 when ADM.00900.I.1.C is applied at the recommended rates.

Metabolite: IN-ECD73

Table 9.3-5: Assessment of the risk for earthworm-eating mammals due to exposure to the metabolite IN-ECD73 via bioaccumulation in earthworms (secondary poisoning) for the intended use in vineyards (1 x 36 g a.s./ha, BBCH 57-83)

Parameter	IN-ECD73	comments
PEC_{soil} (accumulation) (mg/kg soil)	0.050	
log P_{ow}	5.1	
K_{foc}	29 849	
foc	0.02	Default
BCF_{worm}	2.53	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw}) = (0.84 + 0.012 \times P_{ow}) / foc \times K_{oc}$

Parameter	IN-ECD73	comments
PEC _{worm}	0.127	PEC _{worm} = PEC _{soil} × BCF _{worm/soil}
Daily dietary dose (mg/kg bw/d)	0.162	DDD = PEC _{worm} × 1.28
NOEL (mg/kg bw/d)	1199	
TER _{lt}	7399	

TER values shown in bold fall below the relevant trigger.

The TER_{lt} is above the trigger of 5 for chronic toxicity, indicating an acceptable risk to earthworm-eating mammals via secondary poisoning from the metabolite IN-ECD73 when ADM.00900.I.1.C is applied at the recommended rates.

Metabolite: IN-GAZ70

Table 9.3-6: Assessment of the risk for earthworm-eating mammals due to exposure to the metabolite IN-GAZ70 via bioaccumulation in earthworms (secondary poisoning) for the intended use in vineyards (1 x 36 g a.s./ha, BBCH 57-83)

Parameter	IN-GAZ70	comments
PEC _{soil} (accumulation) (mg/kg soil)	0.017	
log P _{ow}	3.8	
K _{foc}	23 581	
foc	0.02	Default
BCF _{worm}	0.162	BCF _{worm/soil} = (PEC _{worm,ww} /PEC _{soil,dw}) = (0.84 + 0.012 × P _{ow}) / foc × K _{oc}
PEC _{worm}	0.003	PEC _{worm} = PEC _{soil} × BCF _{worm/soil}
Daily dietary dose (mg/kg bw/d)	0.004	DDD = PEC _{worm} × 1.28
NOEL (mg/kg bw/d)	1199	
TER _{lt}	339 453	

TER values shown in bold fall below the relevant trigger.

The TER_{lt} is above the trigger of 5 for chronic toxicity, indicating an acceptable risk to earthworm-eating mammals via secondary poisoning from the metabolite IN-GAZ70 when ADM.00900.I.1.C is applied at the recommended rates.

Conclusion on the risk for earthworm-eating mammals via secondary poisoning

No unacceptable risk to earthworm-eating mammals was identified neither for Chlorantraniliprole nor for its soil metabolites when ADM.00900.I.1.C is applied in the intended crops at the recommended rates.

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 assumed to be the same for all compounds and based on the measured BCF value from the active substance Chlorantraniliprole.

To achieve a concise risk assessment, the risk envelop approach is applied and only the highest PEC_{sw} of Chlorantraniliprole and its relevant metabolites will be considered. The highest FOCUS Step 1 PEC_{sw} are detailed in the following table:

Substance	FOCUS Step 1 PEC _{sw} (mg/L) ¹	Use
IN-EQW78	0.00111	Pomefruit, 1 x 31 g a.s./ha
IN-ECD73	0.000068	Pomefruit, 1 x 31 g a.s./ha
IN-GAZ70	0.000069	Pomefruit, 1 x 31 g a.s./ha

IN-LBA22	0.000889	Pomefruit, 1 x 31 g a.s./ha
IN-LBA23	0.000805	Pomefruit, 1 x 31 g a.s./ha
IN-LBA24	0.00326	Pomefruit, 1 x 31 g a.s./ha

1 Overall worst case values from modelled uses (FOCUS Step 1, see chapter 8.9.2 in part B8)

Metabolite: IN-EQW78

Table 9.3-7: Assessment of the risk for fish-eating mammals due to exposure to the metabolite IN-EQW78 via bioaccumulation in fish (secondary poisoning) for the intended use in pomefruit (1 x 31 g a.s./ha, BBCH 70-87)

Parameter	IN-EQW78	comments
PEC _{sw} (maximum) (mg/L)	0.00111	
BCF _{fish}	15	
BMF	-	biomagnification factor (relevant for BCF ≥ 2000)
PEC _{fish}	0.017	PEC _{fish} = PEC _{water} × BCF _{fish}
Daily dietary dose (mg/kg bw/d)	0.002	DDD = PEC _{fish} × 0.142
NOEL (mg/kg bw/d)	1199	
TER _{lt}	507 127	

TER values shown in bold fall below the relevant trigger.

The TER_{lt} is above the trigger of 5 for chronic toxicity, indicating an acceptable risk to fish-eating mammals via secondary poisoning from the metabolite IN-EQW78 when ADM.00900.I.1.C is applied at the recommended rates.

Metabolite: IN-ECD73

Table 9.3-8: Assessment of the risk for fish-eating mammals due to exposure to the metabolite IN-ECD73 via bioaccumulation in fish (secondary poisoning) for the intended use in pomefruit (1 x 31 g a.s./ha, BBCH 70-87)

Parameter	IN-ECD73	comments
PEC _{sw} (maximum) (mg/L)	0.000068	
BCF _{fish}	15	
BMF	-	biomagnification factor (relevant for BCF ≥ 2000)
PEC _{fish}	0.001	PEC _{fish} = PEC _{water} × BCF _{fish}
Daily dietary dose (mg/kg bw/d)	0.0001	DDD = PEC _{fish} × 0.142
NOEL (mg/kg bw/d)	1199	
TER _{lt}	8 278 100	

TER values shown in bold fall below the relevant trigger.

The TER_{lt} is above the trigger of 5 for chronic toxicity, indicating an acceptable risk to fish-eating mammals via secondary poisoning from the metabolite IN-ECD73 when ADM.00900.I.1.C is applied at the recommended rates.

Metabolite: IN-GAZ70

Table 9.3-9: Assessment of the risk for fish-eating mammals due to exposure to the metabolite IN-GAZ70 via bioaccumulation in fish (secondary poisoning) for the intended use in pomefruit (1 x 31 g a.s./ha, BBCH 70-87)

Parameter	IN-GAZ70	comments
PEC _{sw} (maximum) (mg/L)	0.000069	
BCF _{fish}	15	

Parameter	IN-GAZ70	comments
BMF	-	biomagnification factor (relevant for $BCF \geq 2000$)
PEC_{fish}	0.001	$PEC_{fish} = PEC_{water} \times BCF_{fish}$
Daily dietary dose (mg/kg bw/d)	0.0001	$DDD = PEC_{fish} \times 0.142$
NOEL (mg/kg bw/d)	1199	
TER_{lt}	8 158 128	

TER values shown in bold fall below the relevant trigger.

The TER_{lt} is above the trigger of 5 for chronic toxicity, indicating an acceptable risk to fish-eating mammals via secondary poisoning from the metabolite IN-GAZ70 when ADM.00900.I.1.C is applied at the recommended rates.

Metabolite: IN-LBA22

Table 9.3-10: Assessment of the risk for fish-eating mammals due to exposure to the metabolite IN-LBA22 via bioaccumulation in fish (secondary poisoning) for the intended use in pomefruit (1 x 31 g a.s./ha, BBCH 70-87)

Parameter	IN-LBA22	comments
PEC_{sw} (maximum) (mg/L)	0.000889	
BCF_{fish}	15	
BMF	-	biomagnification factor (relevant for $BCF \geq 2000$)
PEC_{fish}	0.013	$PEC_{fish} = PEC_{water} \times BCF_{fish}$
Daily dietary dose (mg/kg bw/d)	0.002	$DDD = PEC_{fish} \times 0.142$
NOEL (mg/kg bw/d)	1199	
TER_{lt}	633 195	

TER values shown in bold fall below the relevant trigger.

The TER_{lt} is above the trigger of 5 for chronic toxicity, indicating an acceptable risk to fish-eating mammals via secondary poisoning from the metabolite IN-LBA22 when ADM.00900.I.1.C is applied at the recommended rates.

Metabolite: IN-LBA23

Table 9.3-11: Assessment of the risk for fish-eating mammals due to exposure to the metabolite IN-LBA23 via bioaccumulation in fish (secondary poisoning) for the intended use in pomefruit (1 x 31 g a.s./ha, BBCH 70-87)

Parameter	IN-LBA23	comments
PEC_{sw} (maximum) (mg/L)	0.000805	
BCF_{fish}	15	
BMF	-	biomagnification factor (relevant for $BCF \geq 2000$)
PEC_{fish}	0.012	$PEC_{fish} = PEC_{water} \times BCF_{fish}$
Daily dietary dose (mg/kg bw/d)	0.002	$DDD = PEC_{fish} \times 0.142$
NOEL (mg/kg bw/d)	1199	
TER_{lt}	699 268	

TER values shown in bold fall below the relevant trigger.

Metabolite: IN-LBA24

Table 9.3-12: Assessment of the risk for fish-eating mammals due to exposure to the metabolite IN-LBA24 via bioaccumulation in fish (secondary poisoning) for the intended use in pomefruit (1 x 31 g a.s./ha, BBCH 70-87)

Parameter	IN-LBA24	comments
PEC _{sw} (maximum) (mg/L)	0.00326	
BCF _{fish}	15	
BMF	-	biomagnification factor (relevant for BCF ≥ 2000)
PEC _{fish}	0.049	PEC _{fish} = PEC _{water} × BCF _{fish}
Daily dietary dose (mg/kg bw/d)	0.007	DDD = PEC _{fish} × 0.142
NOEL (mg/kg bw/d)	1199	
TER _{lt}	1720672	

TER values shown in bold fall below the relevant trigger.

The TER_{lt} is above the trigger of 5 for chronic toxicity, indicating an acceptable risk to fish-eating mammals via secondary poisoning from the metabolite IN-LBA24 when ADM.00900.I.1.C is applied at the recommended rates.

Conclusion on the risk for fish-eating mammals via secondary poisoning

No unacceptable risk to fish-eating mammals was identified neither for Chlorantraniliprole water metabolites when ADM.00900.I.1.C is applied in the intended crops at the recommended rates.

zRMS comments:

The Applicants' approach in evaluation of the risk of secondary poisoning is in line with EFSA (2009). Compounds selected for this assessment are agreed by the zRMS. Evaluation was not triggered for remaining metabolites of active substance due to their log Pow <3.

Risk assessment for earthworm-eating birds via secondary poisoning

The risk envelope approach has been accepted by zRMS. The assessment for the use in vineyards at 36 g a.s./ha also covers the risk for earthworm-eating mammals via secondary poisoning from all other intended uses since it results in the highest PEC_{soil} values (please refer to Part B section 8, point 8.7.2, vines scenario).

Risk assessment for fish-eating birds via secondary poisoning

The risk envelope approach has been accepted by zRMS. The highest PEC_{sw} of Chlorantraniliprole relevant metabolites has been used (calculated at FOCUS Step 1 PEC_{sw} for the use in pome fruit at 1 x 31 g a.s./ha, please refer to part B8 for details):

Bioaccumulation in fish is assumed to be the same for all compounds and based on the measured BCF value from the active substance Chlorantraniliprole.

Overall, no unacceptable risk to fish-eating mammals and earthworms-eating mammals was identified for Chlorantraniliprole relevant metabolites when ADM.00900.I.1.C is applied in the intended crops at the recommended rates.

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 assessment of the risk to mammals conducted for the use of ADM.00900.I.1.C in leafy vegetables, vineyards, maize, pomefruit and potato according to the EFSA *Guidance Document on the Risk Assessment for Birds and Mammals* (EFSA, 2009) leads to the following conclusions:

- Acceptable dietary risk from the active substance Chlorantraniliprole (no relevant metabolite for dietary exposure)
- Acceptable risk from drinking water for the active substance Chlorantraniliprole and its relevant metabolites
- Acceptable risk for fish- and earthworm-eating mammals via secondary poisoning for the active substance Chlorantraniliprole and its relevant metabolites.

It is therefore concluded that the use of ADM.00900.I.1.C in the intended crops at the recommended rates poses an acceptable risk to mammals.

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

No additional relevant data is available and also not required. Please refer to the EU review of the active substance.

zRMS comments:

As currently there are no agreed rules or criteria for evaluation of the risk to other terrestrial vertebrates like reptiles and amphibians, this issue should be addressed once respective guidance is available and EU agreed endpoints concluded.

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 ADM.00900.I.1.C were not 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.

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

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

Species	Substance	Exposure System	Results	Reference
Sheephead minnow (<i>Cyprinodon variegatus</i>)	Chlorantraniliprole	96 h, f	LC ₅₀ > 12 mg a.s./L _{mm}	EFSA Conclusion (2013)
Bluegill sunfish (<i>Lepomis macrochirus</i>)	Chlorantraniliprole 20SC	96h, f	LC ₅₀ > 9.9 mg f.p./L _{mm} (LC ₅₀ > 1.84 mg a.s./L _{mm})	EFSA Conclusion (2013)
Rainbow trout (<i>Oncorhynchus mykiss</i>)	Chlorantraniliprole 35WG	96h, f	LC ₅₀ > 9.9 mg f.p./L _{mm} (LC ₅₀ > 1.84 mg a.s./L _{mm})	EFSA Conclusion (2013)
Rainbow trout	Chlorantraniliprole	90d (FELS), f	NOEC = 0.11 mg a.s./L _{mm}	EFSA Conclusion

Species	Substance	Exposure System	Results	Reference
(<i>Oncorhynchus mykiss</i>)				(2013)
<i>Daphnia magna</i>	Chlorantraniliprole	48h, s	EC₅₀ = 0.0116 mg a.s./L_{mm}	EFSA Conclusion (2013)
<i>Centropilum triangulifer</i>	Chlorantraniliprole	48h, s	EC ₅₀ = 0.0116 mg a.s./L _{mm}	EFSA Conclusion (2013)
<i>Chimarra atterima</i>	Chlorantraniliprole	48h, s	EC ₅₀ = 0.0117 mg a.s./L _{mm}	EFSA Conclusion (2013)
<i>Gammarus pseudolimnaeus</i>	Chlorantraniliprole	48h, s	EC ₅₀ = 0.0351 mg a.s./L _{mm}	EFSA Conclusion (2013)
<i>Crassostrea virginica</i>	Chlorantraniliprole	96h, s	EC ₅₀ = 0.0399 mg a.s./L _{mm}	EFSA Conclusion (2013)
<i>Hyallela azteca</i>	Chlorantraniliprole	48h, f	LC ₅₀ > 0.389 mg a.s./L _{mm}	EFSA Conclusion (2013)
<i>Procambarus clarki</i>	Chlorantraniliprole	96h, s	LC ₅₀ = 0.951 mg a.s./L _{mm}	EFSA Conclusion (2013)
<i>Soyedina carolinensis</i>	Chlorantraniliprole	48h, s	LC ₅₀ = 0.258 mg a.s./L _{mm}	EFSA Conclusion (2013)
<i>Americamysis bahia</i>	Chlorantraniliprole	96h, s	LC ₅₀ = 1.15 mg a.s./L _{mm}	EFSA Conclusion (2013)
<i>Oronectes viridis</i>	Chlorantraniliprole	48h, s	EC ₅₀ > 1.42 mg a.s./L _{mm}	EFSA Conclusion (2013)
<i>Daphnia magna</i>	Chlorantraniliprole 20SC	48h, s	EC ₅₀ = 0.035 mg f.p./L _{mm} (EC ₅₀ = 0.0071 mg a.s./L _{mm})	EFSA Conclusion (2013)
<i>Daphnia magna</i>	Chlorantraniliprole 35WG	48h, s	EC ₅₀ = 0.29 mg f.p./L _{mm} (EC ₅₀ = 0.011 mg a.s./L _{mm})	EFSA Conclusion (2013)
<i>Daphnia magna</i>	Chlorantraniliprole	21 d, ss	NOEC = 0.00447 mg a.s./L_{mm}	EFSA Conclusion (2013)
<i>Chironomus riparius</i>	Chlorantraniliprole	48h, s	LC ₅₀ = 0.0859 mg a.s./L	EFSA Conclusion (2013)
<i>Lumbriculus variegatus</i>	Chlorantraniliprole	48h, s	LC ₅₀ > 1.49 mg a.s./L _{mm}	EFSA Conclusion (2013)
<i>Chironomus riparius</i>	Chlorantraniliprole	28 d, spiked water	NOEC = 0.0025 mg a.s./L_{nom}	EFSA Conclusion (2013)
<i>Chironomus riparius</i>	Chlorantraniliprole	28 d, spiked sediment	NOEC = 0.005 mg a.s./kg sed. (dw)_{nom}	EFSA Conclusion (2013)
<i>Pseudokirchneriella subcapitata</i>	Chlorantraniliprole	120h, s	E_rC₅₀ > 2 mg a.s./L_{nom} E _b C ₅₀ > 2 mg a.s./L _{nom}	EFSA Conclusion (2013)
<i>Pseudokirchneriella subcapitata</i>	Chlorantraniliprole 20SC	120h, s	E _r C ₅₀ > 20 mg f.p./L _{mm} (E _r C ₅₀ > 4.0 mg a.s./L _{mm}) E _b C ₅₀ > 20 mg f.p./L _{mm} (E _b C ₅₀ > 4.0 mg a.s./L _{mm})	EFSA Conclusion (2013)
<i>Pseudokirchneriella subcapitata</i>	Chlorantraniliprole 35WG	120h, s	E _r C ₅₀ > 20 mg f.p./L _{mm} (E _r C ₅₀ > 1.78 mg a.s./L _{mm}) E _b C ₅₀ > 20 mg f.p./L _{mm} (E _b C ₅₀ > 1.78 mg a.s./L _{mm})	EFSA Conclusion (2013)
<i>Lemna gibba</i>	Chlorantraniliprole	14d, s	E_rC₅₀ > 200 mg a.s./L_{nom} (frond number and biomass)	EFSA Conclusion (2013)
<i>Daphnia magna</i>	IN-EQW78	48h, s	EC₅₀ > 0.138 mg/L	EFSA Conclusion (2013)

Species	Substance	Exposure System	Results	Reference
<i>Daphnia magna</i>	IN-ECD73	48h, s	EC ₅₀ > 0.138 mg/L	EFSA Conclusion (2013)
<i>Daphnia magna</i>	IN-F6L99	48h, s	EC ₅₀ = 46.8 mg/L	EFSA Conclusion (2013)
<i>Daphnia magna</i>	IN-F9N04	48h, s	EC ₅₀ > 0.138 mg/L	EFSA Conclusion (2013)
<i>Daphnia magna</i>	IN-EQW78	48h, s	EC ₅₀ = 0.03 mg/L	EFSA Conclusion (2013)
<i>Daphnia magna</i>	IN-GAZ70	48h, s	EC ₅₀ = 0.00987 mg/L	EFSA Conclusion (2013)
<i>Daphnia magna</i>	IN-LBA22	48h, s	EC ₅₀ > 0.85 mg/L	Addendum to the DAR (2016)
<i>Daphnia magna</i>	IN-LBA23	48h, s	EC ₅₀ > 1.1 mg/L	Addendum to the DAR (2016)
<i>Daphnia magna</i>	IN-LBA24	48h, s	EC ₅₀ > 0.54 mg/L	Addendum to the DAR (2016)
Higher-tier refined regulatory endpoint – active substance (Chlorantraniliprole)				
Based on an SSD calculated using Etx2.0 (Van Vlaardingen <i>et al.</i> , 2004) for 9 species the median HC₅ value is 2.91 µg a.s./L and with an assessment factor of 5 this gives a RAC of 0.58 µg a.s./L (EFSA Conclusion, 2013) ¹				


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

1: Higher Tier endpoint to refine the acute and chronic invertebrate risk assessment

zRMS comments:

Aquatic toxicity data for Chlorantraniliprole in Table 9.2-1 are in line with EU agreed endpoints reported in EFSA Conclusion (2013); 11(6):3143.

Table 9.5-2: Endpoints and effect values relevant for the risk assessment for aquatic organisms – ADM.00900.I.1.C

Species	Substance	Exposure System	Results	Reference
Rainbow trout (<i>Oncorhynchus mykiss</i>)	ADM.00900.I.1.C (Chlorantraniliprole 200SC)	96 h, ss	LC ₅₀ > 100 mg f.p./L _{nom} (LC ₅₀ > 18.1 mg a.s./L _{nom})	 (KCP 10.2.1/01)
<i>Daphnia magna</i>	ADM.00900.I.1.C (Chlorantraniliprole 200SC)	48 h, s	EC ₅₀ = 41.29 µg f.p./L _{nom} (EC ₅₀ = 7.47 µg a.s./L _{nom})	Mantilacci, 2020a (KCP 10.2.1/02)
<i>Pseudokirchneriella subcapitata</i>	ADM.00900.I.1.C (Chlorantraniliprole 200SC)	72 h, s	E _y C ₅₀ = 19.62 mg f.p./L _{nom} (E _y C ₅₀ = 3.71 mg a.s./L _{nom}) E _r C ₅₀ > 100 mg f.p./L _{mm} (E _r C ₅₀ > 18.9 mg a.s./L _{mm})	Mantilacci, 2020b (KCP 10.2.1/03)
<i>Lemna minor</i>	ADM.00900.I.1.C (Chlorantraniliprole 200SC)	7d, ss	EC ₅₀ > 100 mg f.p./L _{nom} (EC ₅₀ > 18.9 mg a.s./L _{nom}) (frond number and dryweight growth rate and yield)	Mantilacci, 2020c (KCP 10.2.1/04)
Higher-tier studies (micro- or mesocosm studies)				
No additional data				

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

zRMS comments:

Studies on effects of the formulated product on aquatic organisms listed in Table 9.5-2 were evaluated by the zRMS and considered acceptable.

Summaries of the performed studies together with zRMS evaluation may be found in Appendix 2.

9.5.1.1 Justification for new endpoints

Not relevant.

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).

During the Pesticide Peer Review 99 (November 2012), the experts agreed that the available SSD was suitable to address both the acute and chronic risk to aquatic invertebrates given the toxicological profile to aquatic invertebrates (EFSA Conclusion, 2013). The risk assessment for exposure of aquatic invertebrates through surface water is therefore conducted based on the HC₅ with an assessment factor of 5. A risk assessment is proposed for all the invertebrate groups for information.

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.

The following text is added due to agreements during the Central Zone harmonisation meetings. It should be noted that this text has no impact on the outcome of zonal evaluation of ADM.00900.I.1.C formulation which was performed in line with the EU agreed methodology.

“The endpoint E_rC_{50} is selected in this Core Assessment but there are some uncertainties regarding the level of protection reached for primary producers. This is indicated for macrophytes in the aquatic Guidance Document (EFSA Journal 2013;11(7):3290) that recommends: “... a proper calibration between different tiers (higher and lower tier data) for macrophytes should be performed in the future”. Such calibration should be extended to algae. Until available relevant information on the level of protection reached is considered at EU level, it is recommended to address this uncertainty at each Member State level in the National Addendum if considered necessary, although it would be highly appreciated to have a harmonised approach in the Central zone.”

To achieve a concise risk assessment, the risk envelope approach is applied. Please refer to table 9.1-2, point 9.1.2 for details.

In the following tables, 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.

Use group 1: Leafy vegetables

Table 9.5-3: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Chlorantranilprole for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of ADM.00900.I.1.C in leafy vegetables (1 x 28 g a.s./ha, BBCH 15-49)

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. pro- longed	Algae	Aquatic plants	Sed. dwell. prolonged	Higher-tier in- vertebrate acute/chronic		Sed. dwell. prolonged
Test species		<i>Cyprinodon variegatus</i>	<i>Oncorhyn- chus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudokirchn. subcapitata</i>	<i>Lemna gibba</i>	<i>Chironomus riparius</i>	SSD		<i>Chironomus riparius</i>
Endpoint (µg/L)		LC ₅₀ > 12 000	NOEC 110	EC ₅₀ 11.6	NOEC 4.47	E _r C ₅₀ > 2 000	EC ₅₀ > 2 000	NOEC 2.5	HC ₅ 2.91	Endpoint (µg/kg)	NOEC 5
AF		100	10	100	10	10	10	10	5	AF	10
RAC (µg/L)		> 120	11	0.116	0.447	> 200	> 200	0.25	0.58	RAC µg/kg	0.5
FOCUS Scenario	PEC _{sw- max} (µg/L)	PEC/RAC ratios								PEC _{sed-max} (µg/kg)	PEC/RAC ratio
Step 1											
	6.92	0.058	0.629	59.7	15.5	0.035	0.035	27.7	11.9	20.6	41.2
Step 2											
N-Europe	2.65	-	-	18.6	4.83	-	-	8.64	3.71	7.91	15.8
S-Europe	2.16	-	-	18.6	4.83	-	-	8.64	3.71	6.44	12.9
Step 3											
D3/ditch 1	0.178	-	-	1.534	0.398	-	-	0.712	0.306	0.066	0.132
D3/ditch 2	0.177	-	-	1.526	0.396	-	-	0.708	0.304	0.051	0.102
D4/pond	0.183	-	-	1.578	0.409	-	-	0.732	0.314	0.800	1.60
D4/stream	0.171	-	-	1.474	0.383	-	-	0.684	0.294	0.294	0.588
R1/pond 1	0.046	-	-	0.397	0.103	-	-	0.184	0.079	0.163	0.326
R1/pond 2	0.022	-	-	0.190	0.049	-	-	0.088	0.038	0.096	0.192
R1/stream1	0.504	-	-	4.345	1.128	-	-	2.016	0.866	0.169	0.338

R1/stream2	0.281	-	-	2.422	0.629	-	-	1.124	0.483		0.104	0.208
R3/stream1	0.426	-	-	3.672	0.953	-	-	1.704	0.732		0.187	0.374
R3/stream2	0.510	-	-	4.397	1.141	-	-	2.040	0.876		0.247	0.494
R4/stream1	0.629	-	-	5.422	1.407	-	-	2.516	1.081		0.238	0.476
R4/stream2	0.616	-	-	5.310	1.378	-	-	2.464	1.058		0.234	0.468

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

For the intended uses on leafy vegetables at BBCH 15-49, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for aquatic invertebrates characterized by a HC_5 for SSD of 2.91 µg/L in connection with an assessment factor of 5 for R4 scenario and for sediment-dwelling organisms as characterised by a NOEC for *Chironomus riparius* of 5 µg/kg sediment in connection with an assessment factor of 10) in several for D4 (pond) scenario-FOCUS Steps 1-3. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} and PEC_{SED} considering reduced exposure of surface water bodies.

Table 9.5-4: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Chlorantraniliprole based on FOCUS Step 4 calculations and toxicity data on SSD (water exposure) and sediment-dwelling organisms (sediment exposure) with mitigation of spray drift and run-off for the use of ADM.00900.I.1.C in Leafy Vegetables (1 x 28 g a.s./ha, BBCH 15-49)

Intended use		Leafy vegetables BBCH 15-49			
Active substance		Chlorantraniliprole			
Application rate (g/ha)		1 × 28			
Nozzle reduction	No-spray buffer (m)	10	20	2	5
	Vegetated filter strip (m)	10	20	2	5
	VFS mod	No	No	Yes	Yes
PEC _{sw} -Water scenarios (µg/L)					
None	R4 Stream 1 st	0.286	-	0.149	0.058
90 %		-	0.150	-	-
None	R4 Stream 2 nd	0.280	-	0.231	0.162
90 %		-	0.147	-	-
RAC (µg/L)					
0.58		PEC/RAC ratio			
None	R4 Stream	0.491	-	0.256	0.100
90 %		-	0.258	-	-
None	R4 Stream 2 nd	0.481	-	0.397	0.278
90 %		-	0.253	-	-
PEC _{sed} -Sediment scenarios (µg/kg dw sediment)					
None	D4 Pond	0.796	-	0.802	0.799
90 %		-	0.790	-	-
	No-spray buffer (m)	10	20	2	5
	Vegetated filter strip (m)	10	20	2	5
	90%	No	Yes	No	No
	VFS mod	No	No	Yes	Yes
	D4	0.796	0.79	0.802	0.799
RAC (µg/kg)					
0.5		PEC/RAC ratio			
None	D4 Pond	1.592	-	1.604	1.598
90 %		-	1.580	-	-
	No-spray buffer (m)	10	20	2	5
	Vegetated filter strip (m)	10	20	2	5
	90% DRN	-	Yes	-	-
	D4	1.59	1.58 0.63	0.62	1.598

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

All Step 4 scenarios lead to an acceptable risk for water invertebrates HC₅ for SSD of 2.91 µg/L in connection with an assessment factor of 5. However, Step 4 D4 pond scenario for sediment failed indicating a potential risk for sediment-dwelling organisms as characterised by a NOEC for *Chironomus riparius* of 5 µg/kg sediment in connection with an assessment factor of 10.

Mitigation measures are efficient for limiting the exposure through water to an acceptable level. For the sediment exposure, the scenarios where PEC/RAC ratios are above the trigger of 1 are all drainage scenarios. ~~Therefore, it is considered that avoiding the application on drained soil makes the use of ADM.00900.I.1.C at the recommended rate in leafy vegetables at BBCH 15-49 acceptable provided that:~~

- ~~➤ either a no-spray buffer strip and a vegetated buffer strip of 2 m is respected with VFS mod~~
- ~~➤ or a no-spray buffer strip and a vegetated buffer strip of 10 m is respected.~~

Table 9.5-5: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for IN-EQW78, IN-ECD73, IN-F6L99, IN-F9N04, IN-GAZ70, IN-LBA22, IN-LBA23, and IN-LBA24 for *Daphnia magna* based on FOCUS Steps 1 and 2 calculations for the use of ADM.00900.I.1.C in leafy vegetables (1 x 28 g a.s./ha, BBCH 15-49)

Metabolite	IN-EQW78	IN-ECD73	IN-F6L99	IN-F9N04	IN-GAZ70	IN-LBA22	IN-LBA23	IN-LBA24
Endpoint (µg/L)	EC ₅₀ > 138	EC ₅₀ > 138	EC ₅₀ 46800	EC ₅₀ 30	EC ₅₀ 9.87	EC ₅₀ 850	EC ₅₀ 1100	EC ₅₀ 540
AF	100	100	100	100	100	100	100	100
RAC (µg/L)	> 1.38	> 1.38	468	0.30	0.0987	8.5	11	5.4
FOCUS Step 1								
PEC	0.526	0.028	0.215	0.492	0.028	0.212	0.152	2.100
PEC/RAC	0.381	0.020	0.0005	1.640	0.284	0.025	0.014	0.389
FOCUS Step 2								
N-Europe (worst case)								
PEC	-	-	-	0.183	-	-	-	-
PEC/RAC	-	-	-	0.314	-	-	-	-
S-Europe (worst case)								
PEC	-	-	-	0.148	-	-	-	-
PEC/RAC	-	-	-	0.493	-	-	-	-

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

For the intended uses in leafy vegetables, calculated PEC/RAC ratios indicate an acceptable risk for the most sensitive group of aquatic organisms (acute risk for aquatic invertebrates) in all FOCUS Step 1 or 2 scenarios for all the metabolites. Therefore, no further assessment is necessary.

The risk to aquatic organisms from the use of ADM.00900.I.1.C in leafy vegetables at the recommended rate is acceptable with the following mitigations measures:

- No application on drained soils and
- No Spray buffer strip/Vegetated strip of 10 m or No spray buffer strip/Vegetated strip of 2 m with VFS mod

zRMS comments:

Leafy crops: 1 x 28 g a.s./ha, BBCH 15-49

Based on the performed calculations following conclusions may be derived:

Chlorantraniliprole: acceptable risk for aquatic organism with no need for risk mitigation measures for scenarios: D3, D4 (s,p), R1 (p,s), R3 at STEP 3 is concluded. For remained scenario, following risk mitigation measures is required:

- R4 scenario: risk acceptable with 10 m VFS.

~~• D5 (s, p) scenarios: No calculations are performed for these scenarios, an unacceptable risk is concluded.~~

Chlorantraniliprole: acceptable risk for sediment dwelling organism with no need for risk mitigation measures for scenarios: D3, D4 (s), R1 (p), R1 (s), R3, R4 is concluded. In addition, for remained scenario, the following risk mitigation measures is required:

- D4 (p) scenario : an unacceptable risk for dwelling sediment organism with max mitigation measures (20 m VFS + 90% DRN or 5 m VFSmod).

~~• D5 (s, p) scenarios: No calculations are performed for these scenarios, an unacceptable risk is concluded.~~ Therefore, further refinement is required for this scenario at MSs level.

Metabolites: IN-EQW78, IN-ECD73, IN-F6L99, IN-F9N04, IN-GAZ70, IN-LBA22, IN-LBA23, and IN-LBA24: acceptable risk at STEP 1-2.

Use group 2: Maize BBCH 20-87

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 ADM.00900.I.1.C in maize (1 x 28 g a.s./ha, BBCH 20-87)

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. pro- longed	Algae	Aquatic plants	Sed. dwell. prolonged	Higher-tier in- vertebrate acute/chronic		Sed. Dwell. Prolonged
Test species		<i>Cyprinodon variegatus</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudokirchn. Subcapitata</i>	<i>Lemna gibba</i>	<i>Chironomus riparius</i>	SSD		<i>Chironomus riparius</i>
Endpoint (µg/L)		LC ₅₀ > 12 000	NOEC 110	EC ₅₀ 11.6	NOEC 4.47	ErC ₅₀ > 2 000	EC ₅₀ > 2 000	NOEC 2.5	HC ₅ 2.91	Endpoint (µg/kg)	NOEC 5
AF		100	10	100	10	10	10	10	5	AF	10
RAC (µg/L)		> 120	11	0.116	0.447	> 200	> 200	0.25	0.58	RAC µg/kg	0.5
FOCUS Scenario	PEC _{sw- max} (µg/L)	PEC/RAC ratios								PEC _{sed-max} (µg/kg)	PEC/RAC ratio
Step 1											
	6.92	0.058	0.629	59.7	15.5	0.035	0.035	27.7	11.9	20.6	41.2
Step 2											
N-Europe	0.854	-	-	7.63	1.91	-	-	3.42	1.47	2.51	5.02
S-Europe	1.51	-	-	13.0	3.38	-	-	6.04	2.59	4.48	8.96
Step 3											
BBCH 20											
D3/ditch	0.147	-	-	1.27	0.329	-	-	0.588	0.253	0.049	0.098
D4/pond	0.200	-	-	1.72	0.447	-	-	0.800	0.344	0.775	1.55
D4/stream	0.205	-	-	1.77	0.459	-	-	0.820	0.352	0.285	0.570
D5/pond	0.149	-	-	1.28	0.333	-	-	0.596	0.256	0.798	1.60
D5/stream	0.147	-	-	1.27	0.329	-	-	0.588	0.253	0.187	0.374
R1/pond	0.063	-	-	0.543	0.141	-	-	0.252	0.108	0.215	0.430
R1/stream	0.453	-	-	3.91	1.01	-	-	1.81	0.778	0.239	0.478

R3/stream	0.414	-	-	3.57	0.926	-	-	1.66	0.711		0.176	0.352
R4/stream	0.717	-	-	6.18	1.60	-	-	2.87	1.23		0.264	0.528
BBCH < 87												
D3/ditch	0.147	-	-	1.27	0.329	-	-	0.588	0.253		0.057	0.114
D4/pond	0.127	-	-	1.09	0.284	-	-	0.508	0.218		0.515	1.03
D4/stream	0.125	-	-	1.08	0.280	-	-	0.500	0.215		0.189	0.378
D5/pond	0.087	-	-	0.750	0.195	-	-	0.348	0.149		0.509	1.02
D5/stream	0.144	-	-	1.24	0.322	-	-	0.576	0.247		0.105	0.210
R1/pond	0.013	-	-	0.112	0.029	-	-	0.052	0.022		0.063	0.126
R1/stream	0.211	-	-	1.82	0.472	-	-	0.844	0.363		0.054	0.108
R3/stream	0.436	-	-	3.76	0.975	-	-	1.74	0.749		0.253	0.506
R4/stream	0.500	-	-	4.31	1.12	-	-	2.00	0.859		0.192	0.384

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

For the intended uses on maize at BBCH 20-87, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for aquatic invertebrates characterized by a HC₅ for SSD of 2.91 µg/L in connection with an assessment factor of 5 and for sediment-dwelling organisms as characterised by a NOEC for *Chironomus riparius* of 5 µg/kg sediment in connection with an assessment factor of 10) in several FOCUS Steps 1-3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} and PEC_{SED} considering reduced exposure of surface water bodies.

Table 9.5-7: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Chlorantraniliprole based on FOCUS Step 4 calculations and toxicity data on SSD (water exposure) and sediment-dwelling organisms (sediment exposure) with mitigation of spray drift and run-off for the use of ADM.00900.I.1.C in Maize (1 x 28 g a.s./ha, BBCH 20-87) – BBCH 20

Intended use		Maize BBCH 20-87			
Active substance		Chlorantraniliprole			
Application rate (g/ha)		1 × 28			
Nozzle reduction	No-spray buffer (m)	2	5	10	
	Vegetated filter strip (m)	2	5	10	
	VFS mod	Yes	Yes	No	
Water scenarios (µg/L)					
None	R4 Stream	0.167	0.042	0.325	
90 %		-	-	0.170	
RAC (µg/L)		PEC/RAC ratio			
0.58					
None	R4 Stream	0.287	0.072	0.558	
90 %		-	-	0.292	
Sediment scenarios (µg/kg dw sediment)					
None	D4 Pond	0.778	0.773	0.770	
90 %		-	-	0.762	
None	D5 Pond	0.802	0.796	0.792	
90 %		-	-	0.783	
No-spray buffer (m)	10	20	2	5	
Vegetated filter strip (m)	10	20	2	5	
90%	No	Yes	No	No	
VFS mod	No	No	Yes	Yes	
D4	0.770	0.762	0.778	0.773	
D5	0.792	0.783	0.802	0.796	
RAC (µg/kg)		PEC/RAC ratio			
0.5					
None	D4 Pond	1.56	1.55	1.54	
90 %		-	-	1.52	
None	D5 Pond	1.60	1.59	1.58	
90 %		-		1.57	
	No-spray buffer (m)	10	20	2	5

	Vegetated filter strip (m)	10	20	2	5
	VFS mod	No	No	Yes	Yes
	D4 Pond	1.54	1.524	1.556	1.546
	D5 pond	1.584	1.566	1.604	1.592

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

zRMS comments:

Maize at rate 1 x 28 g a.s./ha, 20 BBCH

Based on the performed calculations following conclusions may be derived:

Chlorantraniliprole: acceptable risk for aquatic organism with no need for risk mitigation measures for scenarios : D3, D4 (s,p), D5 (s,p) R1 (p), R1 (s), R3 at STEP 3 is concluded.

In addition, for remained scenario the following risk mitigation measure is required:

- R4 scenario: 10 m VFS (alternatively: 5 m VFS calculated by VFS_{mod})

Chlorantraniliprole: an unacceptable risk for sediment dwelling organism for D4 (p) and D5 (p) scenarios with max mitigation measures (20 m VFS + 90% DRN or 5 m VFS_{mod}) is concluded. **Therefore, further refinement is required for these scenarios at MSs level.**

Metabolites: IN-EQW78, IN-ECD73, IN-F6L99, IN-F9N04, IN-GAZ70, IN-LBA22, IN-LBA23, and IN-LBA24: acceptable risk at STEP 1-2.

Table 9.5-8: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Chlorantraniliprole based on FOCUS Step 4 calculations and toxicity data sediment-dwelling organisms with mitigation of spray drift and run-off for the use of ADM.00900.I.1.C in Maize (1 x 28 g a.s./ha, BBCH 20-87) – BBCH <87

Intended use		Maize BBCH 20-87			
Active substance		Chlorantraniliprole			
Application rate (g/ha)		1 × 28			
Nozzle reduction	No-spray buffer (m)	2	5	10	
	Vegetated filter strip (m)	2	5	10	
	VFS _{mod}	Yes	Yes	No	
Sediment scenarios (µg/kg dw sediment)					
None	D4 Pond	0.518	0.513	0.510	
90 %		-	-	0.502	
None	D5 Pond	0.513	0.507	0.503	
90 %		-	-	0.493	
No-spray buffer (m)	10	20	2	5	
Vegetated filter strip (m)	10	20	2	5	
90%	No	Yes	No	No	
VFS _{mod}	No	No	Yes	Yes	
D4	0.510	0.502	0.518	0.513	
D5	0.503	0.493	0.513	0.507	

<i>Sediment scenarios</i>					
RAC (µg/kg)		PEC/RAC ratio			
0.5					
None	D4 Pond	1.04	1.03	1.02	
90 %		-	-	1.00	
None	D5 Pond	1.03	1.01	1.01	
90 %		-	-	0.986	
	No-spray buffer (m)	10	20	2	5
	Vegetated filter strip (m)	10	20	2	5
	VFS mod	No	No	Yes	Yes
	90% DRN	-	Yes	-	-
	D4 Pond	1.02	1.004	1.036	1.026
	D5 pond	1.006	0.986	1.026	1.014

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

All Step 4 scenarios lead to an acceptable risk for water invertebrates HC₅ for SSD of 2.91 µg/L in connection with an assessment factor of 5. D4 pond and D5 pond Step 4 scenarios (except D5 pond with no-spray buffer/vegetated strip of 10 m together with 90% drift reduction) failed, indicating a potential risk for sediment-dwelling organisms as characterised by a NOEC for *Chironomus riparius* of 5 µg/kg sediment in connection with an assessment factor of 10.

In both cases, mitigation measures are efficient for limiting the exposure through water to an acceptable level. For the sediment exposure, the scenarios where PEC/RAC ratios are above the trigger of 1 are all drainage scenarios. ~~Therefore, it is considered that avoiding the application on drained soil makes the use of ADM.00900.I.1.C at the recommended rate in maize at BBCH 20-87 acceptable provided that:~~

- ~~➤ either a no-spray buffer strip and a vegetated buffer strip of 2 m is respected with VFS mod~~
- ~~➤ or a no-spray buffer strip and a vegetated buffer strip of 10 m is respected.~~

Table 9.5-9: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for IN-EQW78, IN-ECD73, IN-F6L99, IN-F9N04, IN-GAZ70, IN-LBA22, IN-LBA23, and IN-LBA24 for *Daphnia magna* based on FOCUS Steps 1 and 2 calculations for the use of ADM.00900.I.1.C in maize (1 x 28 g a.s./ha, BBCH 20-87)

Metabolite	IN-EQW78	IN-ECD73	IN-F6L99	IN-F9N04	IN-GAZ70	IN-LBA22	IN-LBA23	IN-LBA24
Endpoint	EC ₅₀	EC ₅₀	EC ₅₀	EC ₅₀	EC ₅₀	EC ₅₀	EC ₅₀	EC ₅₀
(µg/L)	> 138	> 138	46800	30	9.87	850	1100	540
AF	100	100	100	100	100	100	100	100
RAC (µg/L)	> 1.38	> 1.38	468	0.30	0.0987	8.5	11	5.4
FOCUS Step 1								
PEC	0.526	0.028	0.215	0.492	0.028	0.212	0.152	0.258
PEC/RAC	0.381	0.020	0.0005	1.64	0.284	0.025	0.014	0.048
FOCUS Step 2								
N-Europe (worst case)								
PEC	-	-	-	0.053	-	-	-	-
PEC/RAC	-	-	-	0.177	-	-	-	-
S-Europe (worst case)								
PEC	-	-	-	0.100	-	-	-	-
PEC/RAC	-	-	-	0.333	-	-	-	-

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

For the intended uses in maize at BCH 20-87, calculated PEC/RAC ratios indicate an acceptable risk for the most sensitive group of aquatic organisms (acute risk for aquatic invertebrates) in all FOCUS Step 1 or 2 scenarios for all the metabolites. Therefore, no further assessment is necessary.

zRMS comments:

Maize at rate 1 x 28 g a.s./ha, < 87 BBCH

Based on the performed calculations following conclusions may be derived:

Chlorantraniliprole: acceptable risk for aquatic organism with no need for risk mitigation measures for scenarios: D3, D4 (s), D5 (s), R1 (p), R1 (s), R3, R4 at STEP 3 is concluded.

Chlorantraniliprole: D4 (p) scenarios: an unacceptable risk for sediment dwelling organism with max mitigation measures (20 m VFS + 90% DRN or 5 m VFSmod) is concluded. **Therefore, further refinement is required for this scenario at MSs level.**

For remained scenario the following risk mitigation measures for sediment dwelling organism is required:

- D5 (p) scenario: acceptable risk with 20 m VFS + 90% DRN

Metabolites: IN-EQW78, IN-ECD73, IN-F6L99, IN-F9N04, IN-GAZ70, IN-LBA22, IN-LBA23, and IN-LBA24: acceptable risk at STEP 1-2.

~~The risk to aquatic organisms from the use of ADM.00900.I.1.C in maize at BBCH 20-87 at the recommended rate is acceptable with the following mitigations measures:~~

- ~~➤ No application on drained soils~~
- ~~➤ No spray buffer strip and vegetated buffer trip of 2 m with VFS mod or 10 m without VFS mod.~~

Use group 3: Vines

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 ADM.00900.I.1.C in Vines (1 x 36g a.s./ha, BBCH 57-83)

Group	Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Aquatic plants	Sed. dwell. prolonged	Higher-tier invertebrate acute/chronic		Sed. dwell. prolonged
Test species	<i>Cyprinodon variegatus</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudokirchn. subcapitata</i>	<i>Lemna gibba</i>	<i>Chironomus riparius</i>	SSD		<i>Chironomus riparius</i>
Endpoint (µg/L)	LC ₅₀ > 12 000	NOEC 110	EC ₅₀ 11.6	NOEC 4.47	ErC ₅₀ > 2 000	EC ₅₀ > 2 000	NOEC 2.5	HC ₅ 2.91	Endpoint (µg/kg)	NOEC 5
AF	100	10	100	10	10	10	10	5	AF	10
RAC (µg/L)	> 120	11	0.116	0.447	> 200	> 200	0.25	0.58	RAC µg/kg	0.5

FOCUS Scenario	PEC _{sw-max} (µg/L)	PEC/RAC ratios								PEC _{sed-max} (µg/kg)	PEC/RAC ratio
Step 1											
	9.52	0.079	0.865	82.1	21.3	0.048	0.048	38.1	16.4	27.8	55.6
Step 2											
N-Europe	2.43	-	-	21.0	5.44	-	-	9.72	4.18	7.1	14.2
S-Europe	2.10	-	-	18.1	4.70	-	-	8.40	3.61	6.09	12.2
Step 3											
June - May											
R1/pond	0.025	-	-	0.216	0.056	-	-	0.100	0.043	0.076	0.152
R1/stream	0.452	-	-	3.90	1.01	-	-	1.81	0.777	0.164	0.328
R3/stream	0.636	-	-	5.48	1.42	-	-	2.54	1.09	0.106	0.212
R4/stream	0.444	-	-	3.83	0.993	-	-	1.78	0.763	0.078	0.156
July - September											
R1/pond	0.022	-	-	0.190	0.049	-	-	0.088	0.038	0.065	0.130
R1/stream	0.453	-	-	3.91	1.013	-	-	1.81	0.778	0.056	0.112
R3/stream	0.639	-	-	5.51	1.43	-	-	2.56	1.10	0.130	0.260
R4/stream	0.453	-	-	3.91	1.01	-	-	1.81	0.778	0.138	0.276

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

For the intended uses in vines, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for aquatic invertebrates characterized by a HC₅ for SSD of 2.91 µg/L in connection with an assessment factor of 5) in several FOCUS Steps 1-3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies.

Table 9.5-11: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Chlorantraniliprole based on FOCUS Step 4 calculations and toxicity data for aquatic invertebrates with mitigation of spray drift and run-off for the use of ADM.00900.I.1.C in vines (1 x 36 g a.s./ha, BBCH 57-83)

Intended use		Vines BBCH 57-83	
Active substance		Chlorantraniliprole	
Application rate (g/ha)		1 × 36	
Nozzle reduction	No-spray buffer (m)	None	5
	Vegetated filter strip (m)	None	None
June - May			
None	R3 Stream	-	0.463
50 %		0.318	-
July - September			
None	R3 Stream	-	0.465
50 %		0.319	-
RAC (µg/L)			
0.58			
June - May			
None	R3 Stream	-	0.796
50 %		0.546	-
July - September			
None	R3 Stream	-	0.799
50 %		0.548	-

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

All the RAC/PEC ratio values are above the trigger of 1, indicating an acceptable risk for all Step 4 scenarios.

In both cases, mitigation measures are efficient for limiting the exposure through water to an acceptable level. Therefore, it is considered that the use of ADM.00900.I.1.C at the recommended rate in vineyard at BBCH 57-83 acceptable provided that:

- either a no-spray buffer strip of 5 m is respected
- a drift reduction of 50 % is applied.

Table 9.5-12: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for IN-EQW78, IN-ECD73, IN-F6L99, IN-F9N04, IN-GAZ70, IN-LBA22, IN-LBA23, and IN-LBA24 for *Daphnia magna* based on FOCUS Steps 1 and 2 calculations for the use of ADM.00900.I.1.C in vines (1 x 36 g a.s./ha, BBCH 57-83)

Metabolite	IN-EQW78	IN-ECD73	IN-F6L99	IN-F9N04	IN-GAZ70	IN-LBA22	IN-LBA23	IN-LBA24
Endpoint	EC ₅₀	EC ₅₀	EC ₅₀	EC ₅₀	EC ₅₀	EC ₅₀	EC ₅₀	EC ₅₀
(µg/L)	> 138	> 138	46800	30	9.87	850	1100	540
AF	100	100	100	100	100	100	100	100
RAC (µg/L)	> 1.38	> 1.38	468	0.30	0.0987	8.5	11	5.4
FOCUS Step 1								
PEC	0.926	0.053	0.287	0.649	0.054	0.581	0.496	3.14
PEC/RAC	0.671	0.038	0.001	2.16	0.547	0.068	0.045	0.581
FOCUS Step 2								
N-Europe (worst case)								
PEC	-	-	-	0.143	-	-	-	-
PEC/RAC	-	-	-	0.473	-	-	-	-
S-Europe (worst case)								
PEC	-	-	-	0.118	-	-	-	-
PEC/RAC	-	-	-	0.393	-	-	-	-

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

For the intended uses in vines, calculated PEC/RAC ratios indicate an acceptable risk for the most sensitive group of aquatic organisms (acute risk for aquatic invertebrates) in all FOCUS Step 1 or 2 scenarios for all the metabolites. Therefore, no further assessment is necessary.

The risk to aquatic organisms from the use of ADM.00900.I.1.C in vineyard at BBCH 57-83 at the recommended rate is acceptable with the following mitigations measures:

- No-spray buffer strip: 5 m or drift reduction of 50%

zRMS comments:

Vine: at rate 1 x 36 g a.s./ha, BBCH 57-83

Based on the performed calculations following conclusions may be derived:

Chlorantraniliprole: acceptable risk w for aquatic organism with no need for risk mitigation measures: R1 (p,s), R4 at STEP 3 is concluded.

The following risk mitigation measures is required for remained scenarios:

- R3 scenario: acceptable risk with 5 m unsprayed buffer zone or 50% drift reduction nozzles
- D3 scenario: acceptable risk with 50% DRN or 10 m VFS
- D4 (s) scenario: acceptable risk with 50% DRN or 10 m VFS
- D5 (s) scenario: acceptable risk with 75% DRN or 10 m VFS or 5 unsprayed buffer zone with 50% DRN

Chlorantraniliprole: acceptable risk for sediment dwelling organism with no need for risk mitigation measures. Risk acceptable for R scenarios at STEP 3 FOCUS program.
In case of D scenarios relevant for Central Zone the risk mitigation is covered by risk mitigation for pome fruits.

It is noted that D scenarios relevant for the Central Zone (D3, D4 and D5) are not defined for vines. Since the formulation is intended to be applied to pome fruits, the Applicant decided to cover surface water exposure in D scenarios with results obtained for pome fruits, which are considered to be the relevant surrogate crop for vines. Although the application rate in pome fruits is slightly lower than in vines (31 vs. 36 g a.s./ha, respectively) and there is only partial overlap of the application timing (BBCH 70-87 in pome fruits and BBCH 57-83 in vines), the analysis of results in R scenarios demonstrated considerably higher PECSW derived for pome fruits due to much higher spray drift relevant for this crop (15.7% vs. 8% in pome fruits and vines, respectively). Taking this into account, in opinion of the zRMS in Section 8, higher PEC_{SW} values following application to pome fruits may be also expected in D scenarios and the approach proposed by the Applicant is considered acceptable.

In order to mitigate the risk, Step 4 simulations were performed with assumption of 5 m spray drift buffer or 50% nozzle reduction in simulations performed specifically for vines and with assumption of 5, 10 and 20 m spray drift buffer and 50%, 75%, 90% nozzle reduction for pome fruits as a surrogate crop.

Chlorantraniliprole: acceptable risk for sediment dwelling organism with no need for risk mitigation measures: D4 (s), D5 (s) and R- scenarios at STEP 3 is concluded.

The following risk mitigation measures are required for remained scenarios:

- D3: acceptable risk for soil dwelling organism with 10 m VFS or 75% DRN
- D4 (p), D5 (p) scenarios: an unacceptable risk for sediment dwelling organism with max mitigation measures (20 m VFS + 90% DRN) is concluded. Therefore, further refinement is required for these scenarios at MSs level.

Metabolites: IN-EQW78, IN-ECD73, IN-F6L99, IN-F9N04, IN-GAZ70, IN-LBA22, IN-LBA23, and IN-LBA 24: acceptable risk at STEP 1-2.

Use group 4: Pomefruit (31 g a.s./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 ADM.00900.I.1.C in Pomefruit (1 x 31 g a.s./ha, BBCH 70-87)

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. pro- longed	Algae	Aquatic plants	Sed. dwell. prolonged	Higher-tier in- vertebrate acute/chronic		Sed. dwell. prolonged	
Test species		<i>Cyprinodon variegatus</i>	<i>Oncorhyn- chus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudokirchn. subcapitata</i>	<i>Lemna gibba</i>	<i>Chironomus riparius</i>	SSD		<i>Chironomus riparius</i>	
Endpoint (µg/L)		LC ₅₀ > 12 000	NOEC 110	EC ₅₀ 11.6	NOEC 4.47	ErC ₅₀ > 2 000	EC ₅₀ > 2 000	NOEC 2.5	HC ₅ 2.91	Endpoint (µg/kg)	NOEC 5	
AF		100	10	100	10	10	10	10	5	AF	10	
RAC (µg/L)		> 120	11	0.116	0.447	> 200	> 200	0.25	0.58	RAC µg/kg	0.5	
FOCUS Scenario	PEC _{sw- max} (µg/L)	PEC/RAC ratios								PEC _{sed-max} (µg/kg)	PEC/RAC ratio	
Step 1												
	9.00	0.075	0.818	77.6	20.1	0.045	0.045	36.0	15.5	25.6	51.2	
Step 2												
N-Europe	2.54	-	-	21.9	5.68	-	-	10.2	4.36	7.27	14.5	
S-Europe	2.29	-	-	19.7	5.12	-	-	9.2	3.93	6.51	13.0	
Step 3												
BBCH 70												
D3/ditch	1.140		-	9.83	2.55	-	-	4.56	1.96	0.518	1.036	
D4/pond	0.209	-	-	1.80	0.468	-	-	0.836	0.359	0.825	1.65	
D4/stream	1.140	-	-	9.83	2.55	-	-	4.56	1.96	0.279	0.558	
D5/pond	0.138	-	-	1.19	0.309	-	-	0.552	0.237	0.878	1.76	
D5/stream	1.23	-	-	10.6	2.75	-	-	4.92	2.11	0.316	0.632	
R1/pond	0.051	-	-	0.440	0.114	-	-	0.204	0.088	0.144	0.288	
R1/stream	0.857	-	-	7.39	1.92	-	-	3.43	1.47	0.070	0.140	
R3/stream	1.230	-	-	10.6	2.75	-	-	4.92	2.11	0.226	0.452	

R4/stream	0.875	-	-	7.54	1.96	-	-	3.50	1.50		0.195	0.390
BBCH < 87												
D3/ditch	1.140	-	-	9.83	2.55	-	-	4.56	1.96		0.519	1.04
D4/pond	0.313	-	-	2.70	0.700	-	-	1.25	0.538		1.160	2.32
D4/stream	1.110	-	-	9.57	2.483	-	-	4.44	1.91		0.420	0.840
D5/pond	0.142	-	-	1.22	0.318	-	-	0.568	0.244		0.907	1.81
D5/stream	1.230	-	-	10.6	2.75	-	-	4.92	2.11		0.284	0.568
R1/pond	0.051	-	-	0.440	0.114	-	-	0.204	0.088		0.148	0.296
R1/stream	0.875	-	-	7.54	1.96	-	-	3.50	1.50		0.108	0.216
R3/stream	1.230	-	-	10.6	2.75	-	-	4.92	2.11		0.226	0.452
R4/stream	0.875	-	-	7.54	1.957	-	-	3.50	1.50		0.115	0.230

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

For the intended uses in Pomefruit at BBCH 70-87 with an application rate of 31 g a.s./ha, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive groups of aquatic organisms (risk for aquatic invertebrates characterized by a HC₅ for SSD of 2.91 µg/L in connection with an assessment factor of 5 and sediment-dwelling organisms as characterised by a NOEC for *Chironomus riparius* of 5 µg/kg sediment in connection with an assessment factor of 10) in several FOCUS Steps 1-3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} and PEC_{SED} considering reduced exposure of surface water bodies.

Table 9.5-14: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Chlorantraniliprole based on FOCUS Step 4 calculations and toxicity data for aquatic invertebrates (water exposure) and sediment-dwelling organisms (sediment exposure) with mitigation of spray drift and run-off for the use of ADM.00900.I.1.C in pomefruit (1 x 31 g a.s./ha, BBCH 70-87) – BBCH 70

Intended use		Pomefruit BBCH 70-87			
Active substance		Chlorantraniliprole			
Application rate (g/ha)		1 x 31			
Nozzle reduction	No-spray buffer (m)	None	5	10	20
	Vegetated filter strip (m)	None	None	10	20
Water exposure (µg/L)					
None	D3 Ditch	-	-	0.344	-
50 %		0.570	0.385	-	-
75 %		0.285	-	-	-
90 %		-	-	-	0.011
None	D4 Stream	-	-	0.399	-
50 %		0.572	0.446	-	-
75 %		0.286	-	-	-
90 %		-	-	-	0.214
None	D5 Stream	-	-	0.430	-
50 %		0.617	0.481	-	-
75 %		0.308	-	-	-
90 %		-	-	-	0.105
None	R1 Stream	-	-	0.299	-
50 %		0.429	0.335	-	-
75 %		0.214	-	-	-
90 %		-	-	-	0.036
None	R3 Stream	-	-	0.430	-
50 %		0.616	0.481	-	-
75 %		0.308	-	-	-
90 %		-	-	-	0.027
None	R4 Stream	-	-	0.305	-
50 %		0.486	0.486	-	-
75 %		0.486	-	-	-
90 %		-	-	-	0.110
RAC (µg/L)		PEC/RAC ratio			
0.58					

None	D3 Ditch	-	-	0.591	-
50 %		0.979	0.662	-	-
75 %		0.490	-	-	-
90 %		-	-	-	0.019
None	D4 Stream	-	-	0.686	-
50 %		0.983	0.766	-	-
75 %		0.491	-	-	-
90 %		-	-	-	0.368
None	D5 Stream	-	-	0.739	-
50 %		1.06	0.826	-	-
75 %		0.529	-	-	-
90 %		-	-	-	0.180
None	R1 Stream	-	-	0.514	-
50 %		0.737	0.576	-	-
75 %		0.368	-	-	-
90 %		-	-	-	0.062
None	R3 Stream	-	-	0.739	-
50 %		1.06	0.826	-	-
75 %		0.529	-	-	-
90 %		-	-	-	0.046
None	R4 Stream	-	-	0.524	-
50 %		0.835	0.835	-	-
75 %		0.835	-	-	-
90 %		-	-	-	0.189
Sediment exposure (µg/kg)					
None	D3 Ditch	-	-	0.161	-
50 %		0.263	0.179	-	-
75 %		0.134	-	-	-
90 %		-	-	-	0.263
None	D4 Pond	-	-	0.781	-
50 %		0.765	0.774	-	-
75 %		0.735	-	-	-
90 %		-	-	-	1.100
None	D5 Pond	-	-	0.830	-
50 %		0.812	0.821	-	-
75 %		0.778	-	-	-
90 %		-	-	-	0.838
RAC (µg/kg)					
0.5		PEC/RAC ratio			
None	D3 Ditch	-	-	0.322	-
50 %		0.526	0.358	-	-
75 %		0.268	-	-	-

90 %		-	-	-	0.010
None	D4 Pond	-	-	1.56	-
50 %		1.53	1.55	-	-
75 %		1.53	-	-	-
90 %		-	-	-	1.41
None	D5 Pond	-	-	1.66	-
50 %		1.62	1.64	-	-
75 %		1.56	-	-	-
90 %		-	-	-	1.50

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

zRMS comments:

Based on the performed calculations following conclusions may be derived:

Pome fruits at rate 1 x 31 g a.s./ha, 70 BBCH

Chlorantraniliprole: acceptable risk for aquatic organism with no need for risk mitigation measures for scenarios: D4 (p), D5 (p) at STEP 3 is concluded. The following risk mitigation measures are required for remained scenarios:

- D3 scenario: acceptable risk with 50% DRN or 10 m VFS
- D4 (s) scenario: acceptable risk with 50% DRN or 10 m VFS
- D5 (s) scenario: acceptable risk with 75% DRN or 10 m VFS or 5 unsprayed buffer zone with 50% DRN
- R1 scenario: acceptable risk with 50% DRN or 10 m VFS
- R3 scenario: acceptable risk with 75% DRN or 10 m VFS or 5 unsprayed buffer zone with 50% DRN
- R4 scenario: acceptable risk with 50% DRN or 10 m VFS

Chlorantraniliprole: acceptable risk for sediment dwelling organism with no need for risk mitigation measures: D4 (s), D5 (s) and R-scenarios at STEP 3 is concluded.

The following risk mitigation measures are required for remained scenarios:

- D3: acceptable risk for sediment dwelling organism with 10 m VFS or 75% DRN
- D4 (p), D5 (p) scenarios: an unacceptable risk for sediment dwelling organism with max mitigation measures (20 m VFS + 90% DRN). **Therefore, further refinement is required for these scenarios at MSs level.**

Metabolites: IN-EQW78, IN-ECD73, IN-F6L99, IN-F9N04, IN-GAZ70, IN-LBA22, IN-LBA23, and IN-LBA 24: acceptable risk at STEP 1-2.

Table 9.5-15: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Chlorantraniliprole based on FOCUS Step 4 calculations and toxicity data for aquatic invertebrates (water exposure) and sediment-dwelling organisms (sediment exposure) with mitigation of spray drift and run-off for the use of ADM.00900.I.1.C in pomefruit (1 x 31 g a.s./ha, BBCH 70-87) – BBCH < 87

Intended use		Pomefruit BBCH 70-87			
Active substance		Chlorantraniliprole			
Application rate (g/ha)		1 x 31			
Nozzle reduction	No-spray buffer (m)	None	5	10	20
	Vegetated filter strip (m)	None	None	10	20
Water exposure (µg/L)					
None	D3 Ditch	-	-	0.344	-
50 %		0.570	0.385	-	-
75 %		0.285	-	-	-
90 %		-	-	-	0.011
None	D4 Stream	-	-	0.386	-
50 %		0.552	0.431	-	-
75 %		0.320	-	-	-
90 %		-	-	-	0.320
None	D5 Stream	-	-	0.430	-
50 %		0.617	0.481	-	-
75 %		0.308	-	-	-
90 %		-	-	-	0.154
None	R1 Stream	-	-	0.305	-
50 %		0.437	0.341	-	-
75 %		0.219	-	-	-
90 %		-	-	-	0.009
None	R3 Stream	-	-	0.430	-
50 %		0.616	0.481	-	-
75 %		0.465	-	-	-
90 %		-	-	-	0.110
None	R4 Stream	-	-	0.305	-
50 %		0.437	0.341	-	-
75 %		0.241	-	-	-
90 %		-	-	-	0.056
RAC (µg/L)		PEC/RAC ratio			
0.58					
None	D3 Ditch	-	-	0.591	-
50 %		0.979	0.662	-	-
75 %		0.490	-	-	-
90 %		-	-	-	0.019
None	D4 Stream	-	-	0.663	-
50 %		0.948	0.741	-	-

75 %		0.550	-	-	-
90 %		-	-	-	0.550
None		-	-	0.739	-
50 %	D5 Stream	1.06	0.826	-	-
75 %		0.529	-	-	-
90 %		-	-	-	0.265
None		-	-	0.524	-
50 %	R1 Stream	0.751	0.586	-	-
75 %		0.376	-	-	-
90 %		-	-	-	0.015
None		-	-	0.739	-
50 %	R3 Stream	1.06	0.826	-	-
75 %		0.799	-	-	-
90 %		-	-	-	0.189
None		-	-	0.524	-
50 %	R4 Stream	0.751	0.586	-	-
75 %		0.414	-	-	-
90 %		-	-	-	0.096
Sediment exposure (µg/kg)					
None		-	-	0.161	-
50 %	D3 Ditch	0.263	0.179	-	-
75 %		0.134	-	-	-
90 %		-	-	-	0.005
None		-	-	1.120	-
50 %	D4 Pond	1.100	1.100	-	-
75 %		1.070	-	-	-
90 %		-	-	-	1.050
None		-	-	0.857	-
50 %	D5 Pond	0.838	0.848	-	-
75 %		0.804	-	-	-
90 %		-	-	-	0.774
RAC (µg/kg)					
0.5		PEC/RAC ratio			
None		-	-	0.322	-
50 %	D3 Ditch	0.526	0.358	-	-
75 %		0.268	-	-	-
90 %		-	-	-	0.010
None		-	-	2.24	-
50 %	D4 Pond	2.20	2.22	-	-
75 %		2.14	-	-	-
90 %		-	-	-	2.10
None	D5 Pond	-	-	1.71	-

50 %		1.68	1.70	-	-
75 %		1.61	-	-	-
90		-	-	-	1.55

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

The outcome of the risk assessment is identical for both BBCH70 and BBCH < 87. All Step 4 scenarios lead to an acceptable risk for water invertebrates HC₅ for SSD of 2.91 µg/L in connection with an assessment factor of 5, except scenarios D5 Stream and R3 Stream when only 50% drift reduction is applied. For sediment-dwelling organisms as characterised by a NOEC for *Chironomus riparius* of 5 µg/kg sediment in connection with an assessment factor of 10, the risk is acceptable for D3 Ditch scenario, whatever the mitigation measure considered. However, a potential risk is identified in all cases for D4 Pond and D5 Pond.

In both cases, mitigation measures are efficient for limiting the exposure through water to an acceptable level, except when only a drift reduction of 50 % is applied. For the sediment exposure, the scenarios where PEC/RAC ratios are above the trigger of 1 are all drainage scenarios. Therefore, it is considered that avoiding the application on drained soil makes the use of formulation at the recommended rate in pomefruit at BBCH 70-87 acceptable provided that:

- either a 75% drift reduction is applied
- or a no-spray buffer strip and a vegetated buffer strip of 10 m is respected.

Table 9.5-16: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for IN-EQW78, IN-ECD73, IN-F6L99, IN-F9N04, IN-GAZ70, IN-LBA22, IN-LBA23, and IN-LBA24 for *Daphnia magna* based on FOCUS Steps 1 and 2 calculations for the use of ADM.00900.I.1.C in pomefruit (1 x 31 g a.s./ha, BBCH 70-87)

Metabolite	IN-EQW78	IN-ECD73	IN-F6L99	IN-F9N04	IN-GAZ70	IN-LBA22	IN-LBA23	IN-LBA24
Endpoint	EC ₅₀	EC ₅₀	EC ₅₀	EC ₅₀	EC ₅₀	EC ₅₀	EC ₅₀	EC ₅₀
(µg/L)	> 138	> 138	46800	30	9.87	850	1100	540
AF	100	100	100	100	100	100	100	100
RAC (µg/L)	> 1.38	> 1.38	468	0.30	0.0987	8.5	11	5.4
FOCUS Step 1								
PEC	1.11	0.068	0.261	0.579	0.069	0.889	0.805	3.26
PEC/RAC	0.804	0.049	0.001	1.93	0.699	0.105	0.073	0.604
FOCUS Step 2								
N-Europe (worst case)								
PEC	-	-	-	0.126	-	-	-	-
PEC/RAC	-	-	-	0.420	-	-	-	-
S-Europe (worst case)								
PEC	-	-	-	0.107	-	-	-	-
PEC/RAC	-	-	-	0.357	-	-	-	-

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

For the intended uses in pomefruit at 31 g a.s./ha, calculated PEC/RAC ratios indicate an acceptable risk for the most sensitive group of aquatic organisms (acute risk for aquatic invertebrates) in all FOCUS Step or 2 scenarios for all the metabolites. Therefore, no further assessment is necessary.

The risk to aquatic organisms from the use of ADM.00900.I.1.C in pomefruit at BBCH 70-87 at the recommended rate of 31 g a.s./ha is acceptable with the following mitigations measures:

- no application on drained soils
- 75% drift reduction or No-spray buffer strip/vegetated buffer strip of 10 m

zRMS comments:

Pome fruits at rate 1 x 31 g a.s./ha, < 87 BBCH

Based on the performed calculations following conclusions may be derived:

Chlorantraniliprole: acceptable risk for aquatic organism with no need for risk mitigation measures for scenarios: D4 (p), D5 (p) at STEP 3 is concluded. The following risk mitigation measures are required for remained scenarios:

- D3 scenario: acceptable risk with 50% DRN or 10 m VFS
- D4 (s) scenario: acceptable risk with 50% DRN or 10 m VFS
- D5 (s) scenario: acceptable risk with 75% DRN or 10 m VFS or 5 unsprayed buffer zone with 50% DRN
- R1 scenario: acceptable risk with 50% DRN or 10 m VFS
- R3 scenario: acceptable risk with 75% DRN or 10 m VFS or 5 unsprayed buffer zone with 50% DRN
- R4 scenario: acceptable risk with 50% DRN or 10 m VFS

Chlorantraniliprole: acceptable risk for sediment dwelling organism with no need for risk mitigation measures: D4 (s), D5 (s) and R- scenarios at STEP 3 is concluded. For remained scenarios:

- D3: acceptable risk for sediment dwelling organism with 10 m VFS or 75% DRN
- D4 (p), D5 (p) scenarios: an unacceptable risk for sediment dwelling organism with max mitigation measures (20 m VFS + 90% DRN). Therefore, further refinement is required for these scenarios at MSs level.

Metabolites: IN-EQW78, IN-ECD73, IN-F6L99, IN-F9N04, IN-GAZ70, IN-LBA22, IN-LBA23, and IN-LBA24: acceptable risk at STEP 1-2.

Use group 5: Pomefruit 24 g a.s./ha

Table 9.5-17: 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 ADM.00900.I.1.C in pomefruit (1 x 24 g a.s./ha, BBCH 70-87)

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. pro- longed	Algae	Aquatic plants	Sed. dwell. prolonged	Higher-tier in- vertebrate acute/chronic		Sed. dwell. prolonged
Test species		<i>Cyprinodon variegatus</i>	<i>Oncorhyn- chus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudokirchn. subcapitata</i>	<i>Lemna gibba</i>	<i>Chironomus riparius</i>	SSD		<i>Chironomus riparius</i>
Endpoint (µg/L)		LC ₅₀ > 12 000	NOEC 110	EC ₅₀ 11.6	NOEC 4.47	E _r C ₅₀ > 2 000	EC ₅₀ > 2 000	NOEC 2.5	HC ₅ 2.91	Endpoint (µg/kg)	NOEC 5
AF		100	10	100	10	10	10	10	5	AF	10
RAC (µg/L)		> 120	11	0.116	0.447	> 200	> 200	0.25	0.58	RAC µg/kg	0.5
FOCUS Scenario	PEC _{sw- max} (µg/L)	-								PEC _{sed-max} (µg/kg)	
Step 1											
	6.96	0.058	0633	60.0	15.6	0.035	0.035	27.8	12.0	19.9	39.8
Step 2											
N-Europe	1.97	-	-	17.0	4.41	-	-	7.88	3.38	5.63	11.3
S-Europe	1.77	-	-	15.3	3.96	-	-	7.08	3.04	5.04	10.1
Step 3											
BBCH 70											
D3/ditch	0.882	-	-	7.60	1.97	-	-	3.53	1.52	0.404	0.808
D4/pond	0.162	-	-	1.40	0.362	-	-	0.648	0.278	0.641	1.28
D4/stream	0.885	-	-	7.63	1.98	-	-	3.54	1.52	0.217	0.434
D5/pond	0.105	-	-	0.905	0.234	-	-	0.420	0.180	0.676	1.35
D5/stream	0.955	-	-	8.23	2.14	-	-	3.82	1.64	0.244	0.488
R1/pond	0.040	-	-	0.345	0.089	-	-	0.160	0.069	0.112	0.224
R1/stream	0.664	-	-	5.72	1.49	-	-	2.66	1.14	0.054	0.108
R3/stream	0.955	-	-	8.23	2.14	-	-	3.82	1.64	0.176	0.352

R4/stream	0.677	-	-	5.84	1.51	-	-	2.71	2.26		0.151	0.302
BBCH < 87												
D3/ditch	0.882	-	-	7.60	1.97	-	-	3.53	1.52		0.404	0.808
D4/pond	0.241	-	-	2.08	0.539	-	-	0.964	0.414		0.901	1.80
D4/stream	0.855	-	-	7.37	1.91	-	-	3.42	1.47		0.326	0.652
D5/pond	0.109	-	-	0.940	0.244	-	-	0.436	0.187		0.703	1.41
D5/stream	0.955	-	-	8.23	2.14	-	-	3.82	1.64		0.221	0.442
R1/pond	0.040	-	-	0.345	0.089	-	-	0.160	0.069		0.115	0.230
R1/stream	0.677	-	-	5.84	1.51	-	-	2.71	1.16		0.084	0.168
R3/stream	0.955	-	-	8.23	2.14	-	-	3.82	1.64		0.176	0.352
R4/stream	0.677	-	-	5.84	1.51	-	-	2.71	1.16		0.090	0.180

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

For the intended uses in pomefruit at 24 g a.s./ha, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for aquatic invertebrates characterized by a HC₅ for SSD of 2.91 µg/L in connection with an assessment factor of 5 and for sediment-dwelling organisms as characterised by a NOEC for *Chironomus riparius* of 5 µg/kg sediment in connection with an assessment factor of 10) in several FOCUS Steps 1-3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} and PEC_{SED} considering reduced exposure of surface water bodies.

Table 9.5-18: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Chlorantraniliprole based on FOCUS Step 4 calculations and toxicity data for aquatic invertebrates (water exposure) and sediment-dwelling organisms (sediment exposure) with mitigation of spray drift and run-off for the use of ADM.00900.I.1.C in pomefruit (1 x 24 g a.s./ha, BBCH 70-87) – BBCH 70

Intended use		Pomefruit BBCH 70-87			
Active substance		Chlorantraniliprole			
Application rate (g/ha)		1 x 24			
Nozzle re- duction	No-spray buffer (m)	None	5	10	20
	Vegetated filter strip (m)	None	None	10	20
Water exposure (µg/L)					
None	D3 Ditch	-	-	0.266	-
50 %		0.441	0.298	-	-
75 %		0.221	-	-	-
90 %		-	-	-	0.008
None	D4 Stream	-	-	0.309	-
50 %		0.443	0.346	-	-
75 %		0.221	-	-	-
90 %		-	-	-	0.165
None	D5 Stream	-	-	0.333	-
50 %		0.478	0.373	-	-
75 %		0.239	-	-	-
90 %		-	-	-	0.081
None	R1 Stream	-	-	0.232	-
50 %		0.332	0.259	-	-
75 %		0.166	-	-	-
90 %		-	-	-	0.027
None	R3 Stream	-	-	0.333	-
50 %		0.477	0.373	-	-
75 %		0.239	-	-	-
90 %		-	-	-	0.020
None	R4 Stream	-	-	0.236	-
50 %		0.374	0.374	-	-
75 %		0.374	-	-	-
90 %		-	-	-	0.084
RAC (µg/L)		PEC/RAC ratio			
0.58					

None	D3 Ditch	-	-	0.457	-
50 %		0.758	0.512	-	-
75 %		0.380	-	-	-
90 %		-	-	-	0.014
None	D5 Stream	-	-	0.531	-
50 %		0.761	0.595	-	-
75 %		0.380	-	-	-
90 %		-	-	-	0.284
None	D4 Stream	-	-	0.572	-
50 %		0.821	0.641	-	-
75 %		0.411	-	-	-
90 %		-	-	-	0.139
None	R1 Stream	-	-	0.399	-
50 %		0.570	0.445	-	-
75 %		0.285	-	-	-
90 %		-	-	-	0.046
None	R3 Stream	-	-	0.572	-
50 %		0.820	0.641	-	-
75 %		0.411	-	-	-
90 %		-	-	-	0.034
None	R4 Stream	-	-	0.405	-
50 %		0.643	0.643	-	-
75 %		0643		-	-
90 %		-		-	0.144
Sediment exposure (µg/kg)					
None	D4 Pond	-	-	0.607	-
50 %		0.595	0.601	-	-
75 %		0.571	-	-	-
90 %		-	-	-	0.550
None	D5 Pond	-	-	0.638	-
50 %		0.624	0.632	-	-
75 %		0.598	-	-	-
90 %		-	-	-	0.575
RAC (µg/kg)					
0.5		PEC/RAC ratio			
None	D4 Pond	-	-	1.21	-
50 %		1.19	1.20	-	-
75 %		1.14	-	-	-
90 %		-	-	-	1.10
None	D5 Pond	-	-	1.28	-
50 %		1.25	1.26	-	-
75 %		1.20	-	-	-

90 %		-	-	-	1.15
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PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

zRMS comments:

Pome fruits at rate 1 x 24 g a.s./ha, 70 BBCH

Based on the performed calculations following conclusions may be derived:

Chlorantraniliprole: acceptable risk for aquatic organism with no need for risk mitigation measures for scenarios: D4 (p), D5 (p) at STEP 3 is concluded. For remained scenarios following risk mitigation measures are required:

- D3 scenario: acceptable risk with 50% DRN or 10 m VFS
- D4 (s) scenario: acceptable risk with 50% DRN or 10 m VFS
- D5 (s) scenario: acceptable risk with 50% DRN or 10 m VFS
- R1 scenario: acceptable risk with 50% DRN or 10 m VFS
- R3 scenario: acceptable risk with 50% DRN or 10 m VFS
- R4 scenario: acceptable risk with 50% DRN or 10 m VFS

Chlorantraniliprole: acceptable risk for sediment dwelling organism with no need for risk mitigation measures: D3, D4 (s), D5 (s) and R- scenarios at STEP 3 is concluded.

For remained scenarios:

- D4 (p), D5 (p) scenarios: an unacceptable risk for sediment dwelling organism with max mitigation measures (20 m VFS + 90% DRN) is concluded. **Therefore, further refinement is required for these scenarios at MSs level.**

Metabolites: IN-EQW78, IN-ECD73, IN-F6L99, IN-F9N04, IN-GAZ70, IN-LBA22, IN-LBA23, and IN-LBA24: acceptable risk at STEP 1-2.

Table 9.5-19: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Chlorantraniliprole based on FOCUS Step 4 calculations and toxicity data for aquatic invertebrates (water exposure) and sediment-dwelling organisms (sediment exposure) with mitigation of spray drift and run-off for the use of ADM.00900.I.1.C in pomefruit (1 x 24 g a.s./ha, BBCH 70-87) – BBCH < 87

Intended use		Pomefruit BBCH 70-87			
Active substance		Chlorantraniliprole			
Application rate (g/ha)		1 x 24			
Nozzle reduction	No-spray buffer (m)	None	5	10	20
	Vegetated filter strip (m)	None	None	10	20
Water exposure (µg/L)					
None	D3 Ditch	-	-	0.266	-
50 %		0.441	0.298	-	-
75 %		0.221	-	-	-
90 %		-	-	-	0.008
None	D4 Stream	-	-	0.298	-
50 %		0.428	0.334	-	-
75 %		0.245	-	-	-
90 %		-	-	-	0.245
None	D5 Stream	-	-	0.333	-
50 %		0.478	0.373	-	-

75 %		0.239	-	-	-
90 %		-	-	-	0.120
None	R1 Stream	-	-	0.236	-
50 %		0.339	0.262	-	-
75 %		0.169	-	-	-
90 %		-	-	-	0.007
None	R3 Stream	-	-	0.333	-
50 %		0.477	0.373	-	-
75 %		0.357	-	-	-
90 %		-	-	-	0.084
None	R4 Stream	-	-	0.326	-
50 %		0.339	0.264	-	-
75 %		0.186	-	-	-
90 %		-	-	-	0.043
RAC (µg/L)					
0.58		PEC/RAC ratio			
None	D3 Ditch	-	-	0.457	-
50 %		0.758	0.512	-	-
75 %		0.380	-	-	-
90 %		-	-	-	0.014
None	D5 Stream	-	-	0.512	-
50 %		0.735	0.574	-	-
75 %		0.421	-	-	
90 %		-	-	-	0.421
None	D4 Stream	-	-	0.572	-
50 %		0.821	0.641	-	-
75 %		0.411	-	-	-
90 %		-	-	-	0.206
None	R1 Stream	-	-	0.405	-
50 %		0.582	0.454	-	-
75 %		0.290	-	-	-
90 %		-	-	-	0.012
None	R3 Stream	-	-	0.572	-
50 %		0.820	0.641	-	-
75 %		0.613	-	-	-
90 %		-	-	-	0.144
None	R4 Stream	-	-	0.405	-
50 %		0.582	0.454	-	-
75 %		0.320	-	-	-
90 %		-	-	-	0.074
Sediment exposure (µg/kg)					
None	D4 Pond	-	-	0867	-

50 %		1.100	0.862	-	-
75 %		0.832	-	-	-
90 %		-	-	-	0.812
None	D5 Pond	-	-	0.664	-
50 %		0.838	0.658	-	-
75 %		0.623	-	-	-
90 %		-	-	-	0.600
RAC (µg/kg)					
0.5		PEC/RAC ratio			
None	D4 Pond	-	-	1.73	-
50 %		2.20	1.72	-	-
75 %		1.66	-	-	-
90 %		-	-	-	1.62
None	D5 Pond	-	-	1.33	-
50 %		1.68	1.32	-	-
75 %		1.25	-	-	-
90 %		-	-	-	1.20

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

The outcome of the risk assessment is identical for both BBCH70 and BBCH < 87. All Step 4 scenarios lead to an acceptable risk for water invertebrates HC₅ for SSD of 2.91 µg/L in connection with an assessment factor of 5. For sediment-dwelling organisms as characterised by a NOEC for *Chironomus riparius* of 5 µg/kg sediment in connection with an assessment factor of 10, the risk is acceptable for D3 Ditch scenario, whatever the mitigation measure considered. However, a potential risk is identified in all cases for D4 Pond and D5 Pond.

In both cases, mitigation measures are efficient for limiting the exposure through water to an acceptable level. For the sediment exposure, the scenarios where PEC/RAC ratios are above the trigger of 1 are all drainage scenarios. Therefore, it is considered that avoiding the application on drained soil makes the use of formulation at the recommended rate of 24 g a.s./ha in pomefruit at BBCH 70-87 acceptable provided that:

- either a no-spray buffer strip 5 m is respected
- or a drift reduction of 50% is applied.

Table 9.5-20: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for IN-EQW78, IN-ECD73, IN-F6L99, IN-F9N04, IN-GAZ70, IN-LBA22, IN-LBA23, and IN-LBA24 for *Daphnia magna* based on FOCUS Steps 1 and 2 calculations for the use of ADM.00900.I.1.C in pomefruit (1 x 24 g a.s./ha, BBCH 70-87)

Metabolite	IN-EQW78	IN-ECD73	IN-F6L99	IN-F9N04	IN-GAZ70	IN-LBA22	IN-LBA23	IN-LBA24
Endpoint	EC ₅₀	EC ₅₀	EC ₅₀	EC ₅₀	EC ₅₀	EC ₅₀	EC ₅₀	EC ₅₀
(µg/L)	> 138	> 138	46800	30	9.87	850	1100	540
AF	100	100	100	100	100	100	100	100
RAC (µg/L)	> 1.38	> 1.38	468	0.30	0.0987	8.5	11	5.4
FOCUS Step 1								
PEC	0.861	0.052	0.202	0.449	0.054	0.688	0.623	0.024
PEC/RAC	0.624	0.038	0.0004	1.50	0.547	0.081	0.057	0.004
FOCUS Step 2								
N-Europe (worst case)								
PEC	-	-	-	0.097	-	-	-	-
PEC/RAC	-	-	-	0.323	-	-	-	-
S-Europe (worst case)								
PEC	-	-	-	0.083	-	-	-	-
PEC/RAC	-	-	-	0.277	-	-	-	-

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

For the intended uses in pomefruit at 24 g a.s./ha, calculated PEC/RAC ratios indicate an acceptable risk for the most sensitive group of aquatic organisms (acute risk for aquatic invertebrates) in all FOCUS Step 1 or 2 scenarios for all the metabolites. Therefore, no further assessment is necessary.

The risk to aquatic organisms from the use of ADM.00900.I.1.C in pomefruit at the recommended rate of 24 g a.s./ha is acceptable with the following mitigations measures:

- no application on drained soils
- 50% drift reduction or No-spray buffer strip/vegetated buffer strip of 5 m

zRMS comments:

Pome fruits at rate 1 x 24 g a.s./ha, <87 BBCH

Based on the performed calculations following conclusions may be derived:

Chlorantraniliprole: acceptable risk for aquatic organism with no need for risk mitigation measures for scenarios: D3, D4 (p), D5 (p) at STEP 3 is concluded.

For remained scenarios the following risk mitigation are required:

- D3 scenario: acceptable risk with 50% DRN or 10 m VFS
- D4 (s) scenario: acceptable risk with 50% DRN or 10 m VFS
- D5 (s) scenario: acceptable risk with 50% DRN or 10 m VFS
- R1 scenario: acceptable risk with 50% DRN or 10 m VFS
- R3 scenario: acceptable risk with 50% DRN or 10 m VFS
- R4 scenario: acceptable risk with 50% DRN or 10 m VFS

Chlorantraniliprole: acceptable risk for sediment dwelling organism with no need for risk mitigation measures: D3, D4 (s), D5 (s) and R- scenarios at STEP 3 is concluded.
For remained scenarios:

- D4 (p), D5 (p) scenarios: an unacceptable risk for sediment dwelling organism with max mitigation measures (20 m VFS + 90% DRN). Therefore, further refinement is required for these scenarios at MSs level.

Use group 6: Potato single application

Table 9.5-21: 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 ADM.00900.I.1.C in potato (1 x 12 g a.s./ha, BBCH 31-60)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Aquatic plants	Sed. dwell. prolonged	Higher-tier invertebrate acute/chronic		Sed. dwell. prolonged
Test species		<i>Cyprinodon variegatus</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudokirchn. subcapitata</i>	<i>Lemna gibba</i>	<i>Chironomus riparius</i>	SSD		<i>Chironomus riparius</i>
Endpoint (µg/L)		LC ₅₀ > 12 000	NOEC 110	EC ₅₀ 11.6	NOEC 4.47	ErC ₅₀ > 2 000	EC ₅₀ > 2 000	NOEC 2.5	HC ₅ 2.91	Endpoint (µg/kg)	NOEC 5
AF		100	10	100	10	10	10	10	5	AF	10
RAC (µg/L)		> 120	11	0.116	0.447	> 200	> 200	0.25	0.58	RAC µg/kg	0.5

FOCUS Scenario	PEC _{sw-max} (µg/L)	PEC/RAC ratios								PEC _{sed-max} (µg/kg)	PEC/RAC ratio
Step 1											
	2.96	0.025	0.269	25.5	6.62	0.015	0.015	11.8	5.09	8.81	17.6
Step 2											
N-Europe	0.785	-	-	6.77	1.76	-	-	3.14	1.35	2.34	4.68
S-Europe	0.646	-	-	5.57	1.45	-	-	2.58	1.11	1.92	3.84
Step 3											
BBCH 30											
D3/ditch	0.063	-	-	0.543	0.141	-	-	0.252	0.108	0.023	0.046
D4/pond	0.105	-	-	0.905	0.235	-	-	0.420	0.180	0.450	0.900
D4/stream	0.100	-	-	0.862	0.224	-	-	0.400	0.172	0.166	0.332
R1/pond	0.021	-	-	0.181	0.047	-	-	0.084	0.036	0.075	0.150
R1/stream	0.152	-	-	1.31	0.340	-	-	0.608	0.261	0.072	0.144
R3/stream	0.224	-	-	1.93	0.501	-	-	0.896	0.385	0.069	0.138
BBCH up to 69											
D3/ditch	0.063			0.543	0.141	-	-	0.252	0.108	0.023	0.046
D4/pond	0.085			0.73	0.19			0.34	0.14	0.369	0.738
D4/stream	0.079			0.68	0.176			0.316	0.316	0.135	0.27
R1/pond	0.026			0.224	0.058			0.104	0.104	0.091	0.18
R1/stream	0.182			1.56	0.407			0.407	0.728	0.106	0.212
R3/stream	0.224	-	-	1.93	0.501	-	-	0.896	0.385	0.068	0.136

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

For the intended uses in potato with single application, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for aquatic invertebrates characterized by a HC₅ for SSD of 2.91 µg/L in connection with an assessment factor of 5) in all FOCUS Steps 1-3 scenarios. Therefore, no further assessment is necessary.

Table 9.5-22: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for IN-EQW78, IN-ECD73, IN-F6L99, IN-F9N04, IN-GAZ70, IN-LBA22, IN-LBA23, and IN-LBA24 for *Daphnia magna* based on FOCUS Steps 1 and 2 calculations for the use of ADM.00900.I.1.C in potato (1 x 12 g a.s./ha, BBCH 31-60)

Metabolite	IN-EQW78	IN-ECD73	IN-F6L99	IN-F9N04	IN-GAZ70	IN-LBA22	IN-LBA23	IN-LBA24
Endpoint	EC ₅₀	EC ₅₀	EC ₅₀	EC ₅₀	EC ₅₀	EC ₅₀	EC ₅₀	EC ₅₀
(µg/L)	> 138	> 138	46800	30	9.87	850	1100	540
AF	100	100	100	100	100	100	100	100
RAC (µg/L)	> 1.38	> 1.38	468	0.30	0.0987	8.5	11	5.4
FOCUS Step 1								
PEC	0.451	0.024	0.184	0.421				
PEC/RAC	0.327	0.017	0.0004	1.40				
FOCUS Step 2								
N-Europe (worst case)								
PEC	-	-	-	0.053	-	-	-	-
PEC/RAC	-	-	-	0.177	-	-	-	-
S-Europe (worst case)								
PEC	-	-	-	0.043	-	-	-	-
PEC/RAC	-	-	-	0.143	-	-	-	-

For the intended uses in potato at BCH 31-60 (1 x 12 g a.s./ha), calculated PEC/RAC ratios indicate an acceptable risk for the most sensitive group of aquatic organisms (acute risk for aquatic invertebrates) in all FOCUS Step 1 or 2 scenarios for all the metabolites. Therefore, no further assessment is necessary. The risk to aquatic organisms from the use of ADM.00900.I.1.C in potato at BBCH 31-60 at the recommended rate of 1 x 12 g a.s./ha is acceptable without any mitigation measure.

zRMS comments:

Potato at rate 1 x 12 ga.s./ha, 31-60 BBCH

Based on the calculations of PEC/RAC ratio with regard to PEC_{sw} FOCUS STEP 3 for single application 1 x 12 g a.s./ha at 31-60 BBCH for scenarios D3, D4, R1 and R3 the risk assessment for aquatic organism and sediment dwelling organism is considered acceptable without needs to further refinement. Metabolites: IN-EQW78, IN-ECD73, IN-F6L99, IN-F9N04, IN-GAZ70, IN-LBA22, IN-LBA23, and IN-LBA24: acceptable risk at STEP 1-2.

Use group 7: Potato multiple application

Table 9.5-23: 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 ADM.00900.I.1.C in potato (2 x 12 g a.s./ha, BBCH 31-60)

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. pro- longed	Algae	Aquatic plants	Sed. dwell. prolonged	Higher-tier in- vertebrate		Sed. dwell. prolonged
Test species		<i>Cyprinodon variegatus</i>	<i>Oncorhyn- chus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudokirchn. subcapitata</i>	<i>Lemna gibba</i>	<i>Chironomus riparius</i>	SSD		<i>Chironomus riparius</i>
Endpoint (µg/L)		LC ₅₀ > 12 000	NOEC 110	EC ₅₀ 11.6	NOEC 4.47	ErC ₅₀ > 2 000	EC ₅₀ > 2 000	NOEC 2.5	HC ₅ 2.91	Endpoint (µg/kg)	NOEC 5
AF		100	10	100	10	10	10	10	5	AF	10
RAC (µg/L)		> 120	11	0.116	0.447	> 200	> 200	0.25	0.58	RAC µg/kg	0.5
FOCUS Scenario	PEC ^{sw-} max (µg/L)	-								PEC _{sed-max} (µg/kg)	
Step 1											
	5.93	0.049	0.539	51.1	13.3	0.030	0.030	23.7	10.2	17.6	35.2
Step 2											
N-Europe	1.53	-	-	13.2	3.42	-	-	6.12	2.63	4.54	9.08
S-Europe	1.25	-	-	10.8	2.80	-	-	5.00	2.15	3.72	7.44
Step 3											
BBCH 30											
D3/ditch	0.055	-	-	0.474	0.123	-	-	0.220	0.095	0.025	0.050
D4/pond	0.215	-	-	1.85	0.481	-	-	0.860	0.369	0.904	1.81
D4/stream	0.205	-	-	1.77	0.459	-	-	0.820	0.352	0.333	0.666
R1/pond	0.046	-	-	0.397	0.103	-	-	0.184	0.079	0.157	0.314
R1/stream	0.330	-	-	2.84	0.738	-	-	1.32	0.567	0.169	0.338
R3/stream	0.239	-	-	2.06	0.535	-	-	0.956	0.411	0.115	0.230
BBCH up 69											
D3/ditch	0.055			0.474	0.123	-	-	0.220	0.095	0.025	0.050

D4/pond	0.194			3.63	0.434			0.776	0.334		0.817	1.634
D4/stream	0.182			1.568	0.407			0.728	0.313		0.300	0.6
R1/pond	0.056			2.07	0.125			0.224	0.096		0.183	0.366
R1/stream	0.236			2.03	1.89				0.406		0.143	0.286
R3/stream	0.239			2.06	0.535	-	-	0.956	0.411		0.114	0.228

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

For the intended uses in potato at 2 x 12 g a.s./ha, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for sediment-dwelling organisms as characterised by a NOEC for *Chironomus riparius* of 5 µg/kg sediment in connection with an assessment factor of 10) in several FOCUS Steps 1-3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SED} considering reduced exposure of surface water bodies.

Table 9.5-24: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Chlorantraniliprole based on FOCUS Step 4 calculations and toxicity data for sediment-dwelling organisms with mitigation of spray drift and run-off for the use of ADM.00900.I.1.C in potato (2x x12 g a.s./ha, BBCH 31-60)

Intended use		Potato, BBCH 31-60
Active substance		Chlorantraniliprole
Application rate (g/ha)		2 × 12
Nozzle reduction	No-spray buffer (m)	20
	Vegetated filter strip (m)	20
90 %	D4 pond*	0.897
90 %	D4 pond**	0.808
RAC (µg/kg)		
0.5		PEC/RAC ratio
90 %	D4 Pond	1.79
90%	D4 Pond	1.61

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

*BBCH 31

**BBCH up 69

The PEC/RAC ratio remains above the trigger of 1, despite the high-level mitigation measures. However, D4 Pond scenario is a drainage scenario. Therefore, it is considered that avoiding the application on drained soil makes the use of ADM.00900.I.1.C at the recommended rate of 2 x 12 g a.s./ha in potato at BBCH 31-60 acceptable with no other mitigation measure.

Table 9.5-25: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for IN-EQW78, IN-ECD73, IN-F6L99, IN-F9N04, IN-GAZ70, IN-LBA22, IN-LBA23, and IN-LBA24 for *Daphnia magna* based on FOCUS Steps 1 and 2 calculations for the use of ADM.00900.I.1.C in potato (2 x 12 g a.s./ha, BBCH 31-60)

Metabolite	IN-EQW78	IN-ECD73	IN-F6L99	IN-F9N04	IN-GAZ70	IN-LBA22	IN-LBA23	IN-LBA24
Endpoint	EC ₅₀	EC ₅₀	EC ₅₀	EC ₅₀	EC ₅₀	EC ₅₀	EC ₅₀	EC ₅₀
(µg/L)	> 138	> 138	46800	30	9.87	850	1100	540
AF	100	100	100	100	100	100	100	100
RAC (µg/L)	> 1.38	> 1.38	468	0.30	0.0987	8.5	11	5.4
FOCUS Step 1								
PEC	0.451	0.024	0.184	0.421	0.024	0.091	0.130	1.80
PEC/RAC	0.327	0.017	0.0004	1.4	0.243	0.011	0.012	0.333
FOCUS Step 2								
N-Europe (worst case)								
PEC	-	-	-	0.104	-	-	-	-
PEC/RAC	-	-	-	0.347	-	-	-	-
S-Europe (worst case)								
PEC	-	-	-	0.084	-	-	-	-
PEC/RAC	-	-	-	0.280	-	-	-	-

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

For the intended uses in potato at 2 x 12 g a.s./ha, calculated PEC/RAC ratios indicate an acceptable risk for the most sensitive group of aquatic organisms (acute risk for aquatic invertebrates) in all FOCUS Step 1 or 2 scenarios for all the metabolites. Therefore, no further assessment is necessary.

The risk to aquatic organisms from the use of ADM.00900.I.1.C in maize at BBCH 20-87 at the recommended rate is acceptable with the following mitigations measures:

- No application on drained soils

zRMS comments:

Potato at rate 2 x 12 g a.s./ha, 31-60 BBCH

Based on the performed calculations following conclusions may be derived:

Chlorantraniliprole: acceptable risk with no need for risk mitigation measures for aquatic organism for all scenarios: D3, D4, R1, R3 at STEP 3 is concluded.

Chlorantraniliprole: acceptable risk for dwelling sediment organism at STEP 3 with no need for risk mitigation measures: D3, D4 (s), and R- scenarios

For remixed scenarios:

- D4 (p) scenario: an unacceptable risk for sediment dwelling organism with max mitigation measures (20 m VFS + 90% DRN) is concluded. **Therefore, further refinement is required for these scenarios at MSs level.**

Metabolites for all proposed uses in the GAP : IN-EQW78, IN-ECD73, IN-F6L99, IN-F9N04, IN-GAZ70, IN-LBA22, IN-LBA23, and IN-LBA24: acceptable risk at STEP 1-2.

9.5.3 Overall conclusions

The risk for aquatic organisms from Chlorantraniliprole due to the uses of ADM.00900.I.1.C in leafy vegetables, maize, vineyard, pomefruit and potato, at the relevant intended rates, was examined according to EFSA *Guidance on tiered risk assessment for plant protection products for the organisms in edge-of-field surface waters* (2013). The most sensitive organisms were aquatic invertebrates with a HC₅ based on SSD of 2.91 µg/L for the water exposure and sediment-dwelling organisms with a NOEC of 5 µg/kg sediment for *Chironomus riparius* for the sediment exposure. The respective assessment factors of 5 and 10 were applied to these endpoints to obtain the RAC of 0.58 µg/L and 0.5 µg/kg sediment respectively.

The risk for aquatic organisms from Chlorantraniliprole due to the intended uses of the formulation ADM.00900.I.1.C is acceptable provided that the following mitigation measures are respected in the member states where the respective scenario is relevant:

Use-group		Drained soils	VFS Mod	Drift reduction	No-spray buffer-strip	Vegetated strip
1	Leafy-vegetables BBCH 15-49 1 x 28 g a.s./ha	No-application	Yes	-	2-m	2-m
		OK				
		No-application	-	-	10-m	10-m
2	Maize BBCH 20-87 1 x 28 g a.s./ha	No-application	Yes	-	2-m	2-m
		OK				
		No-application	-	-	10-m	10-m
3	Vines BBCH 57-83 1 x 36 g a.s./ha	-	-	50-%	-	-
		OK				
		-	-	-	5-m	-
4	Pomefruit BBCH 70-87 1 x 31 g a.s./ha	No-application	-	75-%	-	-
		OK				
		No-application	-	-	10-m	10-m
5	Pomefruit BBCH 70-87	No-application	-	50-%	-	-
		OK				

	1 x 24 g a.s./ha	No application	-	-	5-m	-
6	Potato BBCH 31-60 1 x 12 g a.s./ha	No mitigation measure required				
7	Potato BBCH 31-60 2 x 12 g a.s./ha	No application	-	-	-	-

zRMS overoll conclusion:

Based on the performed calculations for aquatic organism and sediment dwelling organism following conclusions may be derived:

1. Leafy crops: 1 x 28 g a.s./ha, BBCH 15-49

Chlorantraniliprole: acceptable risk for aquatic organism with no need for risk mitigation measures for scenarios : D3, D4 (s,p), R1 (p,s), R3 at STEP 3 is concluded.

For remained scenarios following risk mitigation measure is ~~not~~ required:

- R4 scenario: risk acceptable with 10 m VFS.
- ~~D5 (s, p) scenarios: No calculations are performed for these scenarios, an unacceptable risk is concluded.~~

Chlorantraniliprole: acceptable risk for sediment dwelling organism with no need for risk mitigation measures for scenarios: D3, D4 (s), R1 (p), R1 (s), R3, R4 at STEP 3 is concluded.

For remained scenarios:

- D4 (p) scenario : an unacceptable risk for sediment dwelling organism with max mitigation measures (20 m VFS + 90% DRN or 5 m VFSmod) is concluded. Further refinement is required at MSs level for these scenarios.
- ~~D5 (s, p) scenarios: No calculations are performed for these scenarios, an unacceptable risk is concluded.~~

2. Maize: 1 x 28 g a.s./ha, BBCH 20

Chlorantraniliprole: acceptable risk for aquatic organism with no need for risk mitigation measures for scenarios: D3, D4 (s,p), D5 (s,p) R1 (p), R1 (s), R3 at STEP 3 is concluded.

For remained scenario the following risk mitigation measure is required:

- R4 scenario: 10 m VFS (alternatively: 2 m or 5 m VFS calculated by VFS_{mod})

Chlorantraniliprole: an unacceptable risk for sediment dwelling organism for D4 (p) and D5 (p) scenarios with max mitigation measures (20 m VFS + 90% DRN or 5 m VFSmod) is concluded. Further refinement is required at MSs level for these scenarios.

2. Maize: 1 x 28 g a.s./ha ,<87 BBCH:

Chlorantraniliprole: acceptable risk for aquatic organism with no need for risk mitigation measures for D3, D4 (s), D5 (s), R1 (p), R1 (s), R3, R4 at STEP 3 is concluded.

Chlorantraniliprole: D4 (p) scenarios: an unacceptable risk for dwelling sediment organism with max mitigation measures (20 m VFS + 90% DRN or with 5 m VFSmod) is concluded. Further refinement is required at MSs level for scenarios.

For remained scenario the following risk mitigation measure is required:

- D5 (p) scenario : acceptable risk with 20 m VFS+90% DRN

3. Vine : 1 x 36 g a.s./ha, BBCH 70-87

Chlorantraniliprole: acceptable risk for aquatic organism with no need for risk mitigation measures for scenarios : R1 (p,s), R4 at STEP 3 is concluded. The following risk mitigation measures is required for remained scenarios:

- R3 scenario: acceptable risk with 5 m unsprayed buffer zone or 50% drift reduction nozzles
- D3 scenario: acceptable risk with 50% DRN or 10 m VFS

- D4 (s) scenario: acceptable risk with 50% DRN or 10 m VFS
- D5 (s) scenario: acceptable risk with 75% DRN or 10 m VFS or 5 unsprayed buffer zone with 50% DRN

Chlorantraniliprole: acceptable risk for sediment dwelling organism with no need for risk mitigation measures for R scenarios at STEP 3 FOCUS program is concluded.

In case of D-scenarios relevant for Central Zone (D3, D4 and D5) the risk mitigation is covered by risk mitigation for pome fruits for aquatic and sediment dwelling organism.

Chlorantraniliprole: acceptable risk for sediment dwelling organism with no need for risk mitigation measures for scenarios: D4 (s), D5 (s) and R- scenarios at STEP 3 is concluded. The following risk mitigation measures are required for remained scenarios:

- D3: acceptable risk for sediment dwelling organism with 10 m VFS or 75% DRN
- D4 (p), D5 (p) scenarios: an unacceptable risk for dwelling sediment organism with max mitigation measures (20 m VFS + 90% DRN) is concluded. **Further refinement is required at MSs level for these scenarios**

Metabolites: IN-EQW78, IN-ECD73, IN-F6L99, IN-F9N04, IN-GAZ70, IN-LBA22, IN-LBA23, and IN-LBA 24: acceptable risk at STEP 1-2.

4. Pome fruits: 1 x 31 g a.s./ha, BBCH 70

Chlorantraniliprole: acceptable risk for aquatic organism with no need for risk mitigation measures for scenarios: D4 (p), D5 (p), at STEP 3 is concluded. The following risk mitigation measures are required for remained scenarios:

- D3 scenario: acceptable risk with 50% DRN or 10 m VFS
- D4 (s) scenario: acceptable risk with 50% DRN or 10 m VFS
- D5 (s) scenario: acceptable risk with 75% DRN or 10 m VFS or 5 unsprayed buffer zone with 50% DRN
- R1 scenario: acceptable risk with 50% DRN or 10 m VFS
- R3 scenario: acceptable risk with 75% DRN or 10 m VFS or 5 unsprayed buffer zone with 50% DRN
- R4 scenario: acceptable risk with 50% DRN or 10 m VFS

Chlorantraniliprole: acceptable risk for sediment dwelling organism with no need for risk mitigation measures: D4 (s), D5 (s) and R- scenarios at STEP 3 is concluded.

The following conclusion for remained scenarios is conducted:

- D3: acceptable risk for sediment dwelling organism with 10 m VFS or 75% DRN
- D4 (p), D5 (p) scenarios: an unacceptable risk for dwelling sediment organism with max mitigation measures (20 m VFS + 90% DRN). **Further refinement is required at MSs level for these scenarios.**

4. Pome fruits: 1 x 31 g a.s./ha, < 87 BBCH

Chlorantraniliprole: acceptable risk for aquatic organism with no need for risk mitigation measures: D4 (p), D5 (p), for aquatic organism at STEP 3 is concluded. The following risk mitigation measures are required for remained scenarios:

- D3 scenario: acceptable risk with 50% DRN or 10 m VFS
- D4 (s) scenario: acceptable risk with 50% DRN or 10 m VFS
- D5 (s) scenario: acceptable risk with 75% DRN or 10 m VFS or 5 unsprayed buffer zone with 50% DRN
- R1 scenario: acceptable risk with 50% DRN or 10 m VFS
- R3 scenario: acceptable risk with 75% DRN or 10 m VFS or 5 unsprayed buffer zone with 50% DRN
- R4 scenario: acceptable risk with 50% DRN or 10 m VFS

Chlorantraniliprole: acceptable risk for sediment dwelling organism with no need for risk mitigation measures for scenarios: D4 (s), D5 (s) and R- scenarios at STEP 3 is concluded. The following risk mitigation measures are required for remained scenarios:

- D3: acceptable risk for sediment dwelling organism with 10 m VFS or 75% DRN
- D4 (p), D5 (p) scenarios: **an unacceptable risk for dwelling sediment organism** with max mitigation measures (20 m VFS + 90% DRN) is concluded. **Further refinement is required at MSs level for these scenarios.**

5. Pome fruits: 1 x 24 g a.s./ha, BBCH 70

Chlorantraniliprole: acceptable risk for aquatic organism with no need for risk mitigation measures for scenarios: D4 (p), D5 (p) at STEP 3 is concluded. For remained scenarios following risk mitigation measures are required:

- D3 scenario: acceptable risk with 50% DRN or 10 m VFS
- D4 (s) scenario: acceptable risk with 50% DRN or 10 m VFS
- D5 (s) scenario: acceptable risk with 50% DRN or 10 m VFS
- R1 scenario: acceptable risk with 50% DRN or 10 m VFS
- R3 scenario: acceptable risk with 50% DRN or 10 m VFS
- R4 scenario: acceptable risk with 50% DRN or 10 m VFS

Chlorantraniliprole: acceptable risk for sediment dwelling organism with no need for risk mitigation measures: D3, D4 (s), D5 (s) and R- scenarios at STEP 3 is concluded. For remained scenario following conclusion is conducted:

- D4 (p), D5 (p) scenarios: **an unacceptable risk for sediment dwelling organism** with max mitigation measures (20 m VFS + 90% DRN). **Further refinement is required at MSs level for these scenarios.**

5. Pome fruits: x 24 g a.s./ha, <87 BBCH

Chlorantraniliprole: acceptable risk for aquatic organism with no need for risk mitigation measures for scenarios: D3, D4 (p), D5 (p) at STEP 3 is concluded. For remained scenarios following risk mitigation measures are required.

- D3 scenario: acceptable risk with 50% DRN or 10 m VFS
- D4 (s) scenario: acceptable risk with 50% DRN or 10 m VFS
- D5 (s) scenario: acceptable risk with 50% DRN or 10 m VFS
- R1 scenario: acceptable risk with 50% DRN or 10 m VFS
- R3 scenario: acceptable risk with 50% DRN or 10 m VFS
- R4 scenario: acceptable risk with 50% DRN or 10 m VFS

Chlorantraniliprole: acceptable risk with for sediment dwelling organism no need for risk mitigation measures for scenarios: D3, D4 (s), D5 (s) and R- scenarios at STEP 3 is concluded. For remained scenario following conclusion is conducted:

- D4 (p), D5 (p) scenarios: **an unacceptable risk for dwelling sediment organism** with max mitigation measures (20 m VFS + 90% DRN). **Further refinement is required at MSs level for these scenarios.**

6. Potato: 1 x 12 g a.s./ha, BBCH 31-60

Based on the calculations of PEC/RAC ratio with regard to PEC_{sw} FOCUS STEP 3 for single application: 1 x 12 g a.s./ha at 31-60 BBCH for scenarios D3, D4 R1 and R3 the risk assessment for aquatic organism and sediment dwelling organism is considered acceptable without needs to further refinement.

6. Potato: 2 x 12 g a.s./ha, BBCH 31-60

Chlorantraniliprole: acceptable risk with no need for risk mitigation measures for aquatic organism for all scenarios: D3, D4, R1, R3 at STEP 3.

Chlorantraniliprole: acceptable risk for sediment dwelling organism at STEP 3 with no need for risk mitigation measures: D3, D4 (s), and R- scenarios is concluded. For remained scenario following conclusion is conducted:

- D4 (p) scenario: **an unacceptable risk for sediment dwelling organism** with max mitigation measures (20 m VFS + 90% DRN). **Further refinement is required at MSs level for these scenarios.**

Metabolites for all proposed uses in the GAP : IN-EQW78, IN-ECD73, IN-F6L99, IN-F9N04, IN-GAZ70, IN-LBA22, IN-LBA23, and IN-LBA24 indicated an acceptable risk at STEP 1-2.

It should be noted that for D4 pond and D5 pond for sediment dwelling organism further refinement is required at MSs level. The the following mitigation measures is proposed by the Applicant in case of D4 (p) and D5 (p) scenarios: “No application on drained soils.

Concerned Member States must decide on applicability of indicated risk mitigation measures in their countries at the product authorisation. Please note that additional aquatic risk assessment may be required by the concerned Member States that do not accept simulations performed according to FOCUS recommendations.

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

Effects on bees of ADM.00900.I.1.C were not 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.

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

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

Species	Substance	Exposure System	Results	Reference
<i>Apis mellifera</i>	Chlorantraniliprole	Oral, acute, 48h	LD₅₀ > 104.1 µg/bee (signs of intoxication)	EFSA Conclusion (2013)
<i>Apis mellifera</i>	Chlorantraniliprole	Contact, acute, 48h	LD₅₀ > 4 µg/bee (signs of intoxication)	EFSA Conclusion (2013)
<i>Apis mellifera</i>	Chlorantraniliprole 20SC	Oral, acute, 48h	LD ₅₀ > 114.1 µg a.s./bee (signs of intoxication)	EFSA Conclusion (2013)
<i>Apis mellifera</i>	Chlorantraniliprole 20SC	Contact, acute, 48h	LD ₅₀ > 100 µg a.s./bee (signs of intoxication)	EFSA Conclusion (2013)
<i>Apis mellifera</i>	Chlorantraniliprole 35WG	Oral, acute, 48h	LD ₅₀ > 119.19 µg a.s./bee	EFSA Conclusion (2013)
<i>Apis mellifera</i>	Chlorantraniliprole 35 WG	Contact, acute, 48h	LD ₅₀ > 100 µg a.s./bee	EFSA Conclusion (2013)
<i>Apis mellifera</i>	ADM.00900.I.1.C (Chlorantraniliprole 200SC)	Oral, acute, 48h	LD₅₀ > 1000 µg f.p./bee (LD ₅₀ > 189.00 µg a.s./bee)	Colli, 2019a KCP 10.3.1.1/01
<i>Apis mellifera</i>	ADM.00900.I.1.C (Chlorantraniliprole 200 SC)	Contact, acute, 48h	LD₅₀ > 1000 µg f.p./bee (LD ₅₀ > 189.00 µg a.s./bee)	Colli, 2019a KCP 10.3.1.1/01
<i>Apis mellifera</i>	ADM.00900.I.1.C (Chlorantraniliprole 200SC)	Chronic oral toxicity, adults, 10d	LDD ₅₀ = 115.71 (CL: 103.6-127.62) µg f.p./bee/d	Colli, 2022 (KCP 10.3.1.2/01)

Species	Substance	Exposure System	Results	Reference
			(LDD ₅₀ = 21.87 µg a.s./bee/d) NOED = 37.86 µg f.p./bee/d (NOED = 7.19 µg a.s./bee/d)	
<i>Apis mellifera</i>	ADM.00900.I.1.C (Chlorantraniliprole 200SC)	Larval toxicity, repeated exposure	NOED = 1.50 µg f.p./larva/dev. period (NOED = 0.28 µg a.s./larva/dev. period) NOEC = 9.74 mg f.p./kg diet (NOEC = 1.84 mg a.s./kg diet)	Colli, 2022 (KCP 10.3.1.3/01)
Higher-tier studies (tunnel test, field studies)				
<i>Apis mellifera</i>	Chlorantraniliprole 35 WG	Extended laboratory study – Foliage residues (OPPTS 850.3030) - Alfalfa	No behavioural nor other sublethal effects after 24h exposure to 3, 8, 24 and 48h-aged residues from chopped alfalfa plants	EFSA Conclusion (2013) DAR (2008)
<i>Apis mellifera carnica</i>	Chlorantraniliprole 20SC – 200 g a.s./L	Semi-field study (EPPO GL No 170-3) – <i>Phacelia tanacetifolia</i> – Foliage application - 7 days - Germany 2004	52.5 g a.s./ha in 400L/ha No harmful effect on honeybees and on brood development when applied to flowering <i>P. tanacetifolia</i> during foraging activity of honeybees	EFSA Conclusion (2013) DAR (2008)
<i>Apis mellifera mellifera</i>	Chlorantraniliprole 20SC – 200 g a.s./L	Semi-field study (EPPO GL No 170-3) – <i>Phacelia tanacetifolia</i> – Foliage application - 7 days - Spain 2004	52.5 g a.s./ha in 400L/ha No harmful effect on honeybees and on brood development when applied to flowering <i>P. tanacetifolia</i> during foraging activity of honeybees	EFSA Conclusion (2013) DAR (2008)
<i>Apis mellifera carnica</i>	Chlorantraniliprole 20SC – 200 g a.s./L	Semi-field study (EPPO GL No 170-3) – <i>Phacelia tanacetifolia</i> – Foliage application - 7 days – France 2006 2004	52.5 g a.s./ha in 400L/ha No harmful effect on honeybees and on brood development when applied to flowering <i>P. tanacetifolia</i> during foraging activity of honeybees	EFSA Conclusion (2013) DAR (2008)
<i>Apis mellifera carnica</i>	Chlorantraniliprole 20SC – 200 g a.s./L	Semi-field study (CEB GL No. 230; EPPO GL No 170-3) – <i>Phacelia tanacetifolia</i> – Foliage application - 5 days – Northern France 2005	60 g a.s./ha in 300L/ha No harmful effect on honeybees and on brood development when applied to flowering <i>P. tanacetifolia</i> during foraging activity of honeybees	EFSA Conclusion (2013) DAR (2008)
<i>Apis mellifera mellifera</i>	Chlorantraniliprole 20SC – 200 g a.s./L	Semi-field study (CEB GL No. 230; EPPO GL No 170-3) – <i>Phacelia</i>	60 g a.s./ha in 200L/ha No harmful effect on honeybees and on brood	EFSA Conclusion (2013) DAR (2008)

Species	Substance	Exposure System	Results	Reference
		<i>tanacetifolia</i> – Foliage application - 6 days – France 2005	development when applied to flowering <i>P. tanacetifolia</i> during foraging activity of honeybees	
<i>Apis mellifera mellifera</i>	Chlorantraniliprole 20SC – 200 g a.s./L	Semi-field study (CEB GL No. 230; EPPO GL No 170-3) – <i>Phacelia tanacetifolia</i> – Foliage application - 6 days – France 2005	60 g a.s./ha in 200L/ha No harmful effect on honeybees and on brood development when applied to flowering <i>P. tanacetifolia</i> during foraging activity of honeybees	EFSA Conclusion (2013) DAR (2008)
<i>Apis mellifera carnica</i>	Chlorantraniliprole 20SC – 200 g a.s./L	Semi-field study (CEB GL No. 230; EPPO GL No 170-3) – Winter wheat – Foliage application - 6 days – France 2006	60 g a.s./ha in 300L/ha No harmful effect on honeybees and on brood development when applied to Winter wheat in sugar solution to mimic honeydew.	EFSA Conclusion (2013) DAR (2008)
<i>Apis mellifera carnica</i>	Chlorantraniliprole 20SC – 200 g a.s./L	Semi-field study (CEB GL No. 230; EPPO GL No 170-3) – Winter wheat – Foliage application - 5 days – Northern France 2005	60 g a.s./ha in 300L/ha No harmful effect on honeybees and on brood development when applied to Winter wheat in sugar solution to mimic honeydew.	EFSA Conclusion (2013) DAR (2008)
<i>Apis mellifera mellifera</i>	Chlorantraniliprole 20SC – 200 g a.s./L	Semi-field study (CEB GL No. 230; EPPO GL No 170-3) – Winter wheat – Foliage application - 5 days – France 2005	60 g a.s./ha in 200L/ha No harmful effect on honeybees and on brood development when applied to Winter wheat in sugar solution to mimic honeydew.	EFSA Conclusion (2013) DAR (2008)
<i>Apis mellifera mellifera</i>	Chlorantraniliprole 20SC – 200 g a.s./L	Semi-field study (CEB GL No. 230; EPPO GL No 170-3) – Winter wheat – Foliage application - 6 days – France 2006	60 g a.s./ha in 200L/ha No harmful effect on honeybees and on brood development when applied to Winter wheat in sugar solution to mimic honeydew.	EFSA Conclusion (2013) DAR (2008)
<i>Apis mellifera carnica</i>	Chlorantraniliprole 20SC – 200 g a.s./L	Semi-field study (EPPO GL No 170-3) – <i>Phacelia tanacetifolia</i> – Foliage and soil application - 8 days – France 2006	156.16 (before planting)+ 150 (after sowing) g a.s./ha on soil and 156.16 (before planting) + 150 (8 d later) + 75 (flowering) g a.s./ha on plants. No harmful effect on honeybees and on brood development.	EFSA Conclusion (2013) DAR (2008)
<i>Apis mellifera carnica</i>	Chlorantraniliprole 20SC – 200 g a.s./L	Semi-field study (EPPO GL No 170-3) – <i>Phacelia tanacetifolia</i> – Foliage and soil application - 28 days – Germany 2005	253.6 (sowing) + 60 (after sowing) g a.s./ha on soil and 60 (flowering) g a.s./ha on plants. No harmful effect on honeybees and on brood development. Maximum residues in the hive: 0.1080	EFSA Conclusion (2013) DAR (2008)

Species	Substance	Exposure System	Results	Reference
			(pollen), 0.0013 (nectar) and 0.0757 (wax) mg/kg after 7 days. Maximum residues in foraging bees: 2.836 (pollen) and 0.0472 (nectar) mg a.s./kg 1 day after application	

zRMS comments:

Acute bee toxicity data for active substance Chlorantraniliprole provided in Table 9.6-1 are in line with EU agreed endpoints reported in EFSA Conclusion (2013); 11(6):3143.

To fulfil the data requirements as set by Commission Regulation (EU) No 284/2013, studies on acute toxicity to adult bees and chronic and larvae toxicity to bees were submitted with the formulated product.

Studies on effects of the formulated product to bees listed in Table above were evaluated by the zRMS and considered acceptable. The reported endpoints are confirmed.

Summary of the performed studies together with zRMS evaluation may be found in Appendix 2.

9.6.1.1 Justification for new endpoints

ADM.00900.I.1.C was not the representative formulation in the EU peer review process for Chlorantraniliprole. Moreover, the DAR (December 2008) was submitted before 2016, when the studies on oral chronic toxicity to adults and the repeated toxicity to larvae were not required.

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).

The EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees) (EFSA Journal 2013; 11(7):3295) is currently under evaluation and is not yet voted and therefore not taken into account.

To achieve a concise risk assessment, the risk envelope approach is applied (see 9.1.2).

9.6.2.1 Hazard quotients for bees

ACTIVE SUBSTANCE: CHLORANTRANILIPROLE

Acute risk assessment according to SANCO/10329/2002 rev.2

The risk assessment conducted according to SANCO/10329/2002 rev.2 considers only the exposure to the highest single application rate of the formulation. For ADM.00900.I.1.C, the highest rate is applied to wine and table grapes (36 g a.s./ha).

Table 9.6-2: First-tier assessment of the risk for bees due to the use of ADM.00900.I.1.C in wine and table grapes (1 x 36 g a.s., BBCH 57-83)

Intended use		Wine and table grapes BBCH 57-83	
Active substance		Chlorantraniliprole	
Application rate (g/ha)		1 × 36	
Test design	LD₅₀ (lab.) (µg/bee)	Single application rate (g/ha)	Q_{HO}, Q_{HC} criterion: Q_H ≤ 50
Oral toxicity	> 104.1	36	< 0.35
Contact toxicity	> 4		< 9.0
Product		ADM.00900.I.1.C	
Application rate (g/ha)		1 × 196.2*	
Test design	LD₅₀ (lab.) (µg/bee)	Single application rate (g/ha)	Q_{HO}, Q_{HC} criterion: Q_H ≤ 50
Oral toxicity	> 1000	196.2	< 0.196
Contact toxicity	> 1000		< 0.196

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

* Based on a relative density of the product of 1.09 g/mL

The hazard quotients are all below the trigger of 50, indicating a low acute risk to honeybees from Chlorantraniliprole when ADM.00900.I.1.C is applied at the recommended rates (according to SANCO/10329/2002 rev.2).

zRMS comments:

The acute risk assessment for bees presented in Table 9.6-2 is validated by the zRMS. HQ_{oral, contact} values for the active substances and the formulated product are below the trigger of 50, indicating a low acute risk for bees. Please note that the evaluation has been performed in line with SANCO/10329/2002 rev 2 final.

Overall, acceptable risk to bees may be concluded from the intended uses of ADM.00900.I.1.C.

Chronic oral risk assessment for adult honeybees and for honeybee larvae:

Chronic oral toxicity data on adult honeybees were generated to address the new data requirements set in the Annex to Reg. (EU) 283 and 284/2013. For the details of the studies, please refer to KCP 10.3.1.2/01 and KCP 10.3.1.3/01 in Appendix 2. However, no deterministic risk assessment was conducted for chronic exposure, as there is currently no approved assessment scheme.

zRMS comments:

The chronic and larvae risk assessment is not required according to SANCO/10329/2002 rev 2 final. Due to the fact that the chronic tests are available for adult bee and larvae, the screening step and Tier 1 risk assessment in line with EFSA (2013) for request of some cMS in Central Zone has been performed by the zRMS below, using endpoints from submitted studies.

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.

Screening step risk assessment

The acute and chronic risks to adult honey bees and honey bee larvae bees from the use of ADM.00900.I.1.C. were assessed using the maximum single application rates and the respective ‘hazard quotients’ (HQs) and ‘exposure toxicity ratios’ (ETRs).

HO/ETR values in bold are above the trigger value

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 (see Table below).

1st tier, oral risk assessment

In the screening step, potential risk was indicated for adult honey bees following the chronic exposure as well as for honey bee larvae. In the following, a crop and life stage-specific (adult/larvae) risk assessment is carried out, which is a first step of refinement. On the one hand, this takes into account crop dependent exposure factors (Ef), and on the other hand it considers SV values, which depend on default values for pollen and nectar consumption, sugar content in nectar, residues (RUDs) in pollen and nectar as well as crop attractiveness (see table below). It is noted that 1st tier risk assessment scheme in EFSA (2013) allows for distinguishing between particular BBCH stages of the crop in question. Therefore, it was decided by the zRMS to perform separate risk assessment for particular stages at which will be applied.

1st tier oral risk assessment for honey bees (chronic and larvae)

[illegible]

Maize	adult, chronic	0.005	0.004	0.000	0.000	0.003	0.03
	larvae	0.01	0.05	0.00	0.00	0.003	0.2
Maximum single application rate: 0.1526 kg product/ha, > 70 BBCH							
Maize	adult, chronic	0.000	0.004	0.000	0.000	0.003	0.03
	larvae	0.00	0.05	0.00	0.00	0.003	0.2
Maximum single application rate: 0.169 kg product/ha, 70-87 BBCH							
Orchards	adult, chronic	0.000	0.005	0.002	0.002	0.003	0.03
	larvae	0.00	0.06	0.02	0.03	0.04	0.2
Maximum single application rate: 0.0654 kg product/ha, 10-39 BBCH							
Potato	adult, chronic	0.002	0.006	0.000	0.000	0.001	0.03
	larvae	0.01	0.08	0.00	0.00	0.01	0.2
Potato	adult, chronic	0.002	0.002	0.000	0.000	0.001	0.03
	larvae	0.01	0.02	0.00	0.00	0.01	0.2

Based on provided above calculations for application ADM.00900.I.1.C an acceptable chronic risk could be concluded for all uses except vine (adult and larvae) and leafy vegetables (larva) for scenario:treated crop.

Risk assessment based on EFSA (2013) is provided above for informative purposes only and is not the basis for derivation of conclusion regarding the risk to bees at the zonal level.

This issue should be further resolved at the product authorisation in Member States considering indications of the not yet noted EFSA guidance in their national assessments.

In order to resolve the chronic risk for ADM.00900.I.1.C higher tier studies performed with formulation of the individual active compounds is considered, which are available in the DAR (2008). Among them, 8 semi-field (tunnel) studies were conducted with another SC formulation (concentration identical to that of ADM.00900.I.1.C at 200 g a.s./L) applied to *Phacelia tanacetifolia*, a species highly attractive for bees, with application rates higher (52.5, 60 and 75 g a.s./ha for foliage application, plus, in some cases, applications to the soil) than the ones recommended for wine and table grapes (36 g a.s./ha) and leafy vegetables (28 g a.s./ha).

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.

Based on these studies the chronic risk from ADM.00900.I.1.C is considered as acceptable by zRMS.

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

Several higher-tier studies are available in the DAR (2008). Among them, 8 semi-field (tunnel) studies were conducted with another SC formulation (concentration identical to that of ADM.00900.I.1.C at 200 g a.s./L) applied to *Phacelia tanacetifolia*, a species highly attractive for bees, with application rates higher (52.5, 60 and 75 g a.s./ha for foliage application, plus, in some cases, applications to the soil) than the ones recommended for wine and table grapes (36 g a.s./ha) and leafy vegetables (28 g a.s./ha). 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.

It is therefore concluded that all the intended uses of ADM.00900.I.1.C at the recommended rates pose an acceptable risk to bees.

9.6.3 Effects on bumble bees

In the absence of official guidance for Non-Apis bees regarding acute (solitary bees) and/or chronic toxicity (solitary bees and bumblebees), no toxicity tests with bumblebees and solitary bees were provided and are not considered to be required according to the EU data requirements. This is in line with the recommendations of the guidance document SANCO/10181/2013, Section 4, where it is stated that waivers are acceptable for data requirements for which no agreed test methods or guidance documents are available.

9.6.4 Effects on solitary bees

No additional data. For justification, please refer to point 9.6.2.2.

9.6.5 Overall conclusions

The assessment of the risk to bees from Chlorantraniliprole due to all the intended uses of ADM.00900.I.1.C was conducted according to SANCO/10329/2002 rev. 2 recommendations and resulted in the following conclusions:

- Acute contact toxicity: the assessment concluded to an acceptable risk for all uses
- Acute oral toxicity to adult bees: the assessment concluded to an acceptable risk for all uses
- Chronic oral toxicity to adults and toxicity to larvae: studies were conducted according to OECD TG 245 and OECD GD 239 respectively to comply with Regulations EU 283/2013 and 284/2013. However, in the absence of an official guidance no risk assessment could be conducted.
- Semi-field (tunnel) studies submitted and evaluated by the RMS Ireland (DAR, 2008) show that the hive strength is not affected when a similar Chlorantraniliprole formulation is applied to a highly attractive crop (*Phacelia tanacetifolia*) at higher application rates than the highest ADM.00900.I.1.C ones, those recommended for leafy vegetables and wine and table grapes. The risk to honeybees is therefore considered acceptable for all uses.

An acceptable risk is therefore found for all the exposure patterns. As a consequence, all the intended uses for ADM.00900.I.1.C pose an acceptable risk when applied at the recommended rates.

9.7 Effects on arthropods other than bees (KCP 10.3.2)

9.7.1 Toxicity data

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

Effects on non-target arthropods of ADM.00900.I.1.C were not 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.

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

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

Species	Substance	Exposure System	Results	Reference
<i>Typhlodromus pyri</i> (protonymphs)	Chlorantraniliprole 20SC	Laboratory test glass plates (2D)	LR ₅₀ > 750 g a.s./ha ER ₅₀ > 750 g a.s./ha	EFSA Conclusion (2013)
<i>Aphidius rhopalosiphii</i> (adults)	Chlorantraniliprole 20SC	Laboratory test glass plates (2D)	LR ₅₀ > 750 g a.s./ha ER ₅₀ > 750 g a.s./ha	EFSA Conclusion (2013)
<i>Typhlodromus pyri</i> (protonymphs)	Chlorantraniliprole 20SC	Laboratory test glass plates (2D)	LR ₅₀ > 750 g a.s./ha ER ₅₀ > 750 g a.s./ha	EFSA Conclusion (2013)
<i>Aphidius rhopalosiphii</i> (adults)	Chlorantraniliprole 35WG	Laboratory test glass plates (2D)	LR ₅₀ > 750 g a.s./ha ER ₅₀ > 750 g a.s./ha	EFSA Conclusion (2013)
<i>Coccinella septempunctata</i> ;	chlorantraniliprole 20SC	Rate-response extended laboratory test with dwarf bean leaves, <i>Phaseolus vulgaris</i> . Exposure of larvae to fresh-dried spray	LR ₅₀ = 79.5 g a.s./ha ER ₅₀ = 13.3 g a.s./ha	EFSA Conclusion (2013)

Species	Substance	Exposure System	Results	Reference
		deposits on leaves for 15 days, followed by 7 day fecundity assessment beginning after adult emergence.		
<i>Coccinella septempunctata</i> ;	chlorantraniliprole 20SC	Extended laboratory test with exposure to field-aged spray deposits of potted apple tree leaves (aged 28 and 78 days). Exposure of larvae in lab for 12 days (1st bioassay) or 11 days (2nd bioassay). Reproduction evaluated for 15 days (1st) or 10 days (2nd) in test units with bean stems, pollen, honey and aphids. Reproduction assay began after adults emerged and began ovipositing.	2 x 60 g/ha, 7-day spray interval, 28- or 78- day aging period. Control mortality: 1st: 10%, 2nd: 20% Corrected mortality 1st: 18.6%, 2nd: -7.8% Reproduction: No effects in both assay	EFSA Conclusion (2013)
<i>Orius laevigatus</i> ;	chlorantraniliprole 20SC	Rate-response extended laboratory test: with dwarf bean leaves (<i>P. vulgaris</i>). Exposure of nymphs to fresh-dried spray deposits for 9 days, followed by 2 day fecundity assessments twice beginning Day 16 and 18 after treatment-	LR ₅₀ >120 g a.s./ha ER ₅₀ >120 g a.s./ha	EFSA Conclusion (2013)
<i>Episyrphus balteatus</i> ;	chlorantraniliprole 20SC	Rate-response extended laboratory test: with winter rape (<i>Brassica napus</i>) leaves. Exposure of larvae to fresh-dried spray deposits, followed by a reproduction bioassays.	LR ₅₀ = 12.6 g a.s./ha ER ₅₀ = 13.3 g a.s./ha	EFSA Conclusion (2013)
<i>Episyrphus balteatus</i> ;	chlorantraniliprole 20SC	Extended laboratory test with exposure to field-aged spray deposits of potted apple tree leaves (aged 28 and 42 days). Exposure of larvae in lab for 12 days (1st bioassay) or 11 days (2nd bioassay). Reproduction evaluated for 15 days (1st) or 10 days (2nd) in test units with bean leaves and aphids. Reproduction assay began after adults emerged and began ovipositing.	2 x 60 g/ha, 7-day spray interval Control Mortality 1st: 64.4%, 2nd: 28% Corrected Mortality 1st: 43.8%; 2nd: 33.5% Reproduction: No effects in both assays.	EFSA Conclusion (2013)
<i>Typhlodromus pyri</i> (protonymphs)	Chlorantraniliprole 200SC	Laboratory test glass plates (2D)	LR ₅₀ > 423.3 g f.p./ha (LR ₅₀ > 80 g a.s./ha)	Venturi, 2020b (KCP 10.3.2.1/02)

Species	Substance	Exposure System	Results	Reference
			ER ₅₀ > > 423.3 g f.p./ha (ER ₅₀ > 80 g a.s./ha)	
<i>Aphidius rhopalosiphi</i> (adults)	Chlorantraniliprole 200SC	Laboratory test glass plates (2D)	LR ₅₀ > 423.3 g f.p./ha (LR ₅₀ > 80 g a.s./ha) ER ₅₀ > > 423.3 g f.p./ha (ER ₅₀ > 80 g a.s./ha)	Venturi, 2020a (KCP 10.3.2.1/01)
Field or semi-field tests				
No additional data				

zRMS comments:

The studies performed with the formulated product were evaluated and agreed by the zRMS (for details, please refer to respective points in Appendix 2). Endpoints reported in Table 9.7-1 are confirmed to be correct.

9.7.1.1 Justification for new endpoints

ADM.00900.I.1.C was not evaluated as part of the EU assessment of Chlorantraniliprole.

9.7.2 Risk assessment

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

9.7.2.1 Risk assessment for in-field exposure

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use in wine and table grapes (highest application rate leading to the highest PER) also covers the risk for non-target arthropods from all other intended uses (see 9.1.2).

Table 9.7-2: First-tier assessment of the in-field risk for non-target arthropods due to the use of ADM.00900.I.1.C in wine and table grapes (36 g a.s./ha, BBCH 57-83)

Intended use		Wine and Table grapes BBCH 57-83		
Active substance/product		Chlorantraniliprole		
Application rate (g/ha)		1 × 36		
MAF		1		
Test species Tier I	LR ₅₀ (lab.) (g a.s./ha)	PER _{in-field} (g a.s./ha)	HQ _{in-field} criterion: HQ ≤ 2	
<i>Typhlodromus pyri</i>	> 80	36	0.45	
<i>Aphidius rhopalosiphi</i>	> 80		0.45	

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 LR₅₀ or ER₅₀ from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

Both HQ_{in-field} are below the trigger indicating an acceptable in-field risk for the non-target arthropods from Chlorantraniliprole when ADM.00900.I.1. is used in all the intended crops at the recommended rates.

zRMS comments:

The risk assessment presented in Table 9.7-2 is validated by the zRMS. Based on calculations performed with consideration of the Tier I laboratory data and worst-case scenario.

(Wine and Table grapes BBCH 57-83, covering remained uses) an acceptable in-field risk to non-target arthropods from all intended uses of ADM.00900.I.1 may be concluded for two indicator species.

According to EFSA Conclusion, 2013 the additional data for NTA species such as: *Episyrphus balteatus* and *Coccinella Septempunctata* and *Orius laevigatus*; were evaluated at UE level. Based on the most sensitive organism *Episyrphus Balteatus* evaluated for different formulation including $LR_{50}=12.6$ g a.s./ha value for 20 SC formulation, the risk assessment in-field required further refinement.

For this reason, the age residue studies at rate 2 x 60 g a.s./ha for this species were considered and acceptable risk for in-field was concluded.

9.7.2.2 Risk assessment for off-field exposure

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use in pomefruit also covers the risk for non-target arthropods from all other intended uses because of a high application rate combined with the highest drift factor leading to the highest $PER_{off-field}$ (see 9.1.2).

Table 9.7-3: First-tier assessment of the off-field risk for non-target arthropods due to the use of ADM.00900.I.1.C in pomefruit (1 x 31 g a.s./ha, BBCH 70-87)

Intended use		Pomefruit BBCH 70-87			
Active substance/product		Chlorantraniliprole			
Application rate (g/ha)		1 x 31			
MAF		1			
vdf		10 (2D), 5 (2D)			
Test species Tier I	LR ₅₀ (lab.) (g a.s./ha)	Drift rate	PER _{off-field} (g/ha)	CF	HQ _{off-field} criterion: HQ ≤ 2
<i>Typhlodromus pyri</i>	> 80	15.73%	0.488	10	< 0.061 <0.12 0.033
<i>Aphidius rhopalosiphi</i>	> 80		0.975 0.48		< 0.061 <0.12 0.033

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.

Both $HQ_{off-field}$ are below the trigger indicating an acceptable off-field risk for the non-target arthropods from Chlorantraniliprole when ADM.00900.I.1.C is used in all the intended crops at the recommended rates.

zRMS comments:

The risk assessment presented in Table 9.7-3 is validated by the zRMS.

Based on calculations performed with consideration of the Tier I laboratory data with consideration the max application rate and drift values for pome fruits (covering remained uses) an acceptable in-field risk to ~~non-target arthropods~~ for two indicator species from all intended uses of ADM.00900.I.1 C may be concluded.

In addition, as a worst case the VDF of 5 has been considered by zRMS since available investigations indicate that VDF of 10 recommended by ESCORT 2 guidance document is not appropriate and may lead to underestimation of the exposure.

It should be, however, noted that according to EFSA Supporting publication 2019:EN-1673, VDF of 5 should be considered as the interim solution that will be reflected in the SANCO/10329/2002 rev 2 final with its implementation considered further.

Since use of VDF of 5 was not reflected in the current SANCO terrestrial guidance, its use is not yet mandatory. We are aware that VDF of 10 should be used until the update of the guidance document.

However, despite these agreements, we constantly receive comments from several Central Zone Member States to present the off-field risk assessment performed with consideration of VDF of 5. Taking this into account, it was decided to present such calculation to avoid these potential comments. Instead, we receive comment that we should not use VDF of 5.

For this reason, final decision of using VDF is left at MSs level.

In addition to above risk for two indicator species, it should be noted that for the most sensitive species *Episyrphus balteatus* evaluated at EU level with LR_{50} of 12.6 g a.s./ha (20 SC formulation), the risk with consideration worst case scenario (max. rate 31 g a.s./ha, drift rate value of 15.73%, $VDF = 10/5$, $CF = 5$, for extended laboratory study) is considered acceptable the off -field $PER_{corrected}$ being 2.44/4.88 g a.s./ha, respectively is below rate with $\leq 50\%$ effect?

Overall, no unacceptable risk to NTA was identified when ADM.00900.I.1.C is applied in the intended crops at the recommended rates.

9.7.2.3 Additional higher-tier risk assessment

Not relevant.

9.7.2.4 Risk mitigation measures

No risk mitigation needed.

9.7.3 Overall conclusions

The 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.

To achieve a concise risk assessment, only the uses that lead to the highest PER in- and off-field were investigated:

- For the in-field assessment, the worst-case is represented by the use in wine and table grapes with the highest combination application rate/number of applications, resulting in a $PER_{in-field}$ of 36 g a.s./ha. With a standard laboratory $LR_{50} > 80$ g a.s./ha for both the representative species, the in-field risk to non-target arthropods from Chlorantraniliprole is considered acceptable when ADM.00900.I.1.C is applied to all the intended crops at the recommended rates.
- For the off-field assessment, the worst-case is represented by the use in pomefruit with the highest combination application rate/number of applications/drift rate, resulting in a $PER_{off-field}$ of 0.488 g a.s./ha. With a standard laboratory $LR_{50} > 80$ g a.s./ha for both the representative species, the off-field risk to non-target arthropods from Chlorantraniliprole is considered acceptable when ADM.00900.I.1.C is applied to all the intended crops at the recommended rates.

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.

Effects on earthworms and other non-target soil organisms (meso- and macrofauna) of ADM.00900.I.1.C

were not 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.

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

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

Species	Substance	Exposure System	Results*	Reference
<i>Eisenia fetida</i>	Chlorantraniliprole	Mixed into substrate 14 d, acute 10 % peat content	LC ₅₀ > 1000 mg/kg dw	EFSA Conclusion (2013)
<i>Eisenia fetida</i>	Chlorantraniliprole 20 SC	Mixed into substrate 14 d, acute 10 % peat content	LC ₅₀ > 1000 mg f.p./kg dw (LC ₅₀ > 200 mg a.s./kg dw)	EFSA Conclusion (2013)
<i>Eisenia fetida</i>	Chlorantraniliprole 35WG	Mixed into substrate 14 d, acute 10 % peat content	LC ₅₀ > 1000 mg f.p./kg dw (LC ₅₀ > 350 mg a.s./kg dw)	EFSA Conclusion (2013)
<i>Eisenia fetida</i>	Chlorantraniliprole 35WG	Mixed into substrate 56 d, chronic 10 % peat content	NOEC = 1000 mg f.p./kg dw NOEC=350 mg a.s./kg dws) (NOEC = 200 mg a.s./kg dw)	EFSA Conclusion (2013)
<i>Eisenia fetida</i>	Chlorantraniliprole 200SC	Mixed into substrate 56 d, chronic 10 % peat content	NOEC=555.6 ≥1000 mg f.p./kg dw (NOEC= 105 ≥189 mg a.s./kg dw)	Pecorari, 2020 (KCP 10.4.1.1/01)
<i>Eisenia fetida</i>	IN-EQW78	Mixed into substrate 14 d, acute 10 % peat content	LC ₅₀ > 1000 mg/kg dw	EFSA Conclusion (2013)
<i>Eisenia fetida</i>	IN-EQW78	Mixed into substrate 56 d, chronic 10 % peat content	NOEC = 1000 mg/kg dw	EFSA Conclusion (2013)
<i>Eisenia fetida</i>	IN-ECD73	Mixed into substrate 14 d, acute 10 % peat content	LC ₅₀ > 1000 mg/kg dw	EFSA Conclusion (2013)
<i>Eisenia fetida</i>	IN-ECD73	Mixed into substrate 56 d, chronic 10 % peat content	NOEC = 1000 mg/kg dw	EFSA Conclusion (2013)
<i>Eisenia fetida</i>	IN-F6L99	Mixed into substrate 14 d, acute 10 % peat content	LC ₅₀ = 632.5 mg/kg dw	EFSA Conclusion (2013)
<i>Eisenia fetida</i>	IN-GAZ70	Mixed into substrate 14 d, acute 10 % peat content	LC ₅₀ > 1000 mg/kg dw	EFSA Conclusion (2013)
<i>Eisenia fetida</i>	IN-GAZ70	Mixed into substrate 56 d, chronic 10 % peat content	NOEC = 1000 mg/kg dw	EFSA Conclusion (2013)
<i>Folsomia candida</i>	Chlorantraniliprole	Mixed into substrate 28 d, chronic 10% peat content	NOEC = 0.39 mg/kg dw EC ₅₀ = 0.85 mg/kg dw	EFSA Conclusion (2013)
<i>Folsomia candida</i>	Chlorantraniliprole 200SC	Mixed into substrate 28 d, chronic 5 % peat content	NOEC = 4.23 mg product/kg dw (equivalent 0.80 mg a.s./kg dws) EC ₁₀ =3.49 mg product/kg dws (equivalent 0.66 mg as./kg dws) NOEC=5.46 mg product/kg dws	Grandolini, 2020 (KCP 10.4.2.1/01)

Species	Substance	Exposure System	Results*	Reference
			equivalent 0.81 mg a.s./kg dw EC ₁₀ = 3.4 mg product/kg dw equivalent 0.61 mg a.s./kg dw	
<i>Folsomia candida</i>	IN-EQW78	Mixed into substrate 28 d, chronic 10% peat content	NOEC = 100 mg/kg dw	EFSA Conclusion (2013)
<i>Folsomia candida</i>	IN-ECD73	Mixed into substrate 28 d, chronic 10% peat content	NOEC = 100 mg/kg dw	EFSA Conclusion (2013)
<i>Folsomia candida</i>	IN-F6L99	Mixed into substrate 28 d, chronic	NOEC = 100 mg/kg dw	EFSA Conclusion (2013)
<i>Folsomia candida</i>	IN-GAZ70	Mixed into substrate 28 d, chronic 10% peat content	NOEC = 100 mg/kg dw	EFSA Conclusion (2013)
<i>Hypoaspis aculeifer</i>	Chlorantraniliprole	Mixed into substrate 16 d, chronic 5 % peat content	NOEC = 100 mg/kg dw	EFSA Conclusion (2013)
<i>Hypoaspis aculeifer</i>	Chlorantraniliprole 200SC	Mixed into substrate 14 d, chronic 5 % peat content	NOEC ≥ 1000 mg f.p./kg dw (NOEC ≥ 189 mg a.s./kg dw)	Colli, 2020 (KCP 10.4.2.1/02)
Field studies				
No additional data				
Litter bag test				
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. (EFSA Conclusion, 2013)				

* No toxicity values were corrected for log Kow because a scientifically reasoned case was accepted for parent and metabolites in the EU peer review.

zRMS comments:

Data for soil organism for active substance Chlorantraniliprole and its metabolite provided in Table 9.7-1 are in line with EU agreed endpoints reported in EFSA Conclusion (2013); 11(6):3143.

Studies on toxicity of ADM.00900.I.1.C (Chlorantraniliprole 200 SC) to earthworms and other soil macro-organisms were evaluated by the zRMS and are considered acceptable. For details of evaluation, please refer to Appendix 2. Endpoints reported in Table 9.8-1 are confirmed to be correct.

The acute toxicity data for a.s. to earthworms and other soil microorganism has been struck through in tables above as being no longer a data requirement.

9.8.1.1 Justification for new endpoints

No new endpoint.

9.8.2 Risk assessment

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

9.8.2.1 First-tier risk assessment

The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, Table 8.7-3. According to the assessment of environmental-fate data, multi-annual accumulation in soil is to be considered for Chlorantraniliprole.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use in vines at 36 g a.s./ha also covers the risk for earthworms and other non-target soil organisms (meso- and macrofauna) from all other intended uses (see 9.1.2) since it results in the highest PEC_{soil} values (please refer to Part B section 8, point 8.7.2).

The risk assessment for Chlorantraniliprole metabolites is only conducted for the earthworms and the most sensitive arthropod species *Folsomia candida*.

Table 9.8-2: First-tier assessment of the chronic risk for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use of ADM.00900.I.1.C in vines (1 x 36 g a.s./ha, BBCH 57-83)

Intended use	Vines, 1 x 36 g a.s./ha, BBCH 57-83		
Chronic effects on earthworms			
Product/active substance	NOEC (mg/kg dw)	PEC _{soil} (mg/kg dw)	TER _{it} (criterion TER ≥ 5)
Chlorantraniliprole (formulation 35 WG)	350 200	0.120**	2916.66 1667
Chlorantraniliprole in ADM.00900.I.1.C	105	0.120**	1575
IN-EQW78	1000	0.032	31 250
IN-ECD73	1000	0.050	20 000
IN-F6L99*	10.5 18.0 20	< 0.001	10 500 18 000 20 000
IN-F9N04*	10.5 18.0 20	0.006**	1750 3150 20 000
In-GAZ70	1000	0.017	58 824
Chronic effects on other soil macro- and mesofauna			
Product/active substance	NOEC/EC10 (mg/kg dw)	PEC _{soil} (mg/kg dw)	TER _{it} (criterion TER ≥ 5)
Folsomia candida			
Chlorantraniliprole	0.39	0.120**	3.25
Chlorantraniliprole in ADM.00900.I.1.C	0.64 0.66	0.12**	5.08 5.5
IN-EQW78	100	0.032	3 125
IN-ECD73	100	0.050	2 000
IN-F6L99	100	< 0.001	> 100 000
IN-F9N04*	0.039	0.006**	6.50
IN-GAZ70	100	0.017	5 882
Hypoaspis aculeifer			
Chlorantraniliprole	100	0.120**	833
Chlorantraniliprole in ADM.00900.I.1.C	189	0.120**	1575

*No toxicity data available; factor 10 applied to the parent compound toxicity. TER values shown in bold fall below the relevant

trigger.
** PEC_{accum}

All the TER values are above the relevant triggers except for the chronic toxicity of the active substance to the collembolan *Folsomia candida* where the TER_{lt} value is below the chronic trigger of 5. A further assessment is required, based on refined PEC_{soil}.

zRMS comments:

The risk assessment for soil macro- and meso-fauna has been amended by the zRMS.
The risk assessment for formulation ADM.00900.I.1.C expressed in a.s./kg dws has been added by zRMS in the Table 10.8-2.
Based on calculations performed in the Table 9.8-2 the risk is considered acceptable except the risk from exposure to a.s. for *Folsomia candida*.
In the same time the risk for formulation ADM.00900.I.1.C (expressed in a.s./kg dws) for this species is considered acceptable.
However, further refinement for this species for the a.s. is provided in the Point 9.8.2.2.

9.8.2.2 Higher-tier risk assessment

Table 9.8-3: Higher-tier assessment of the chronic risk for collembolans due to the use of ADM.00900.I.1.C in vines (1 x 36 g a.s./ha, BBCH 57-83)

ADM-00900.I.F.C in vines (1 x 36 g a.s./ha, BBCH 57-83)			
Intended use	Vines, 1 x 36 g a.s./ha, BBCH 57-83		
Acute effects on earthworms			
Product/active substance	NOEC (mg/kg dw)	PEC _{soil} ¹ (mg/kg dw)	TER _t (criterion TER ≥ 5)
Chlorantraniliprole	0.39	0.063	6.19

¹ PEC soil (accum) at Tier 2 based on a soil DT₅₀ value of 697.9 days for Chlorantraniliprole. Please refer to part B8, point 8.7.2 for further details.

The TER_{lt} value is above the trigger, indicating an acceptable risk to collembolans from Chlorantraniliprole due to the use of ADM.00900.I.1.C in the intended crops at the recommended rates. As a consequence, the risk from Chlorantraniliprole to the meso- and macrofauna is considered acceptable when ADM.00900.I.1.C is applied at the recommended rates.

zRMS comments:

The calculation performed in the Table 9.8-3 with consideration of PEC_{acc} agreed in Section 8, the TER_{LT} value is above trigger of 5 indicating an acceptable risk for *Folsomia candida*.
Overall, no unacceptable risk to soil meso and macro-fauna was identified when ADM.00900.I.1.C is applied in the intended crops at the recommended rates.

9.8.3 Overall conclusions

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). To achieve a concise risk assessment, the risk envelope approach was applied and the risk assessment was based on the use in vines at 1 x 36 g a.s./ha at BBCH 57-83 resulting in the highest PEC_{soil} for Chlorantraniliprole and its metabolites (please refer to Part B section 8 for details).

Based on Tier1 calculated PEC_{soil} values (please refer to Part B section 8), the risk from Chlorantraniliprole and its metabolites was found acceptable for earthworms. No unacceptable risk from the metabolites is identified for the most sensitive species, the collembolan *Folsomia candida*, while the risk from the active

substance to the predatory mite *Hypoaspis aculeifer* was considered acceptable as well. However, further refinement was required for the risk to *F. candida* from the active substance Chlorantraniliprole.

The risk assessment conducted with refined PEC_{soil} for Chlorantraniliprole resulted in an acceptable risk for *Folsomia candida* from Chlorantraniliprole due to the use of ADM.00900.I.1.C at the recommended rates.

It is therefore concluded that the use of ADM.00900.I.1.C in the intended crops at the recommended rates poses an acceptable risk to the soil meso- and macrofauna.

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 and related documents.

Effects on soil microorganisms of ADM.00900.I.1.C were not 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.

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

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

Endpoint	Substance	Exposure System	Results	Reference
N-mineralisation	Chlorantraniliprole	28 d, aerobic agricultural silty sandy soil	Nitrate formation rate 0.700 mg/kg soil dw < 25 %	EFSA Conclusion (2013)
C-mineralisation	Chlorantraniliprole	28 d, aerobic agricultural silty sandy soil	CO ₂ -formation 0.700 mg/kg soil dw < 25 %	EFSA Conclusion (2013)
N-mineralisation	Chlorantraniliprole 20SC	28 d, aerobic agricultural loamy sandy soil	Nitrate formation rate 0.814 mg a.s./kg soil dw < 25 %	EFSA Conclusion (2013)
C-mineralisation	Chlorantraniliprole 20SC	28 d, aerobic agricultural loamy sandy soil	CO ₂ -formation 0.814 mg/kg soil dw < 25 %	EFSA Conclusion (2013)
N-mineralisation	Chlorantraniliprole 35WG	28 d, aerobic agricultural loamy sandy soil	Nitrate formation rate 0.802 mg a.s./kg soil dw < 25 %	EFSA Conclusion (2013)
C-mineralisation	Chlorantraniliprole 35WG	28 d, aerobic agricultural loamy sandy soil	CO ₂ -formation 0.802 mg/kg soil dw < 25 %	EFSA Conclusion (2013)
N-mineralisation	Chlorantraniliprole 200SC	28 d, aerobic agricultural sandy loamy soil (LUFA, type F2.3)	Nitrate formation rate 4233 mg f.p. $\frac{4233}{600} = 7.055$ mg a.s./kg ha soil-dw equivalent to 6.51 mg product (1.23 mg a.s./kg dws < 25 %	Rossini, 2020 KCP 10.5/01
N-mineralisation	IN-EQW78	28 d, aerobic, common agricultural soil	Nitrate formation rate 0.800 mg/kg soil dw < 25 %	EFSA Conclusion (2013)

Endpoint	Substance	Exposure System	Results	Reference
C-mineralisation	IN-EQW78	28 d, aerobic common agricultural soil	CO ₂ formation 0.800 mg/kg soil dw < 25 %	EFSA Conclusion (2013)
N-mineralisation	IN-ECD73	28 d, aerobic, common agricultural soil	Nitrate formation rate 0.800 mg/kg soil dw < 25 %	EFSA Conclusion (2013)
C-mineralisation	IN-ECD73	28 d, aerobic common agricultural soil	CO ₂ formation 0.800 mg/kg soil dw < 25 %	EFSA Conclusion (2013)
N-mineralisation	IN-GAZ70	28 d, aerobic, agricultural loamy sandy soil	Nitrate formation rate 0.840 mg/kg soil dw < 25 %	EFSA Conclusion (2013)
C-mineralisation	IN-GAZ70	28 d, aerobic agricultural loamy sandy soil	CO ₂ formation 0.840 mg/kg soil dw < 25 %	EFSA Conclusion (2013)

zRMS comments:

Data for soil micro-organism for Chlorantraniliprole and its metabolites provided in Table 9.9-1 are in line with EU agreed endpoints reported in EFSA Conclusion (2013); 11(6):3143.

Studies on toxicity of ADM.00900.I.1.C (Chlorantraniliprole 200SC) to micro-organisms were evaluated by the zRMS and are considered acceptable. For details of evaluation, please refer to Appendix 2. Endpoints reported in Table 9.9-1 are confirmed to be correct.

Information regarding effects on carbon mineralisation is no longer a data requirement and for this reason is struck through in tables above.

9.9.1.1 Justification for new endpoints

ADM.00900.I.1.C was not evaluated as part of the EU assessment of Chlorantraniliprole.

9.9.2 Risk assessment

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

The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, Table 8.7-3 and were already used in the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna) (see 9.8).

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use in vines at 36 g a.s./ha also covers the risk for soil micro-organisms from all other intended uses (see 9.1.2) since it results in the highest PEC_{soil} values (please refer to Part B section 8).

Table 9.9-2: Assessment of the risk for effects on N-mineralization by soil micro-organisms due to the use of ADM.00900.I.1.C in vines (1 x 36 g a.s./ha, BBCH 57-83)

Intended use	Vines, 1 x 36 g a.s./ha, BBCH 57-83			
Product/active substance	Max. conc. with effects ≤ 25 % (mg/kg dw)	PEC _{soil} (mg/kg dw)	Safety factor	Risk acceptable?
Chlorantraniliprole	0.700 (at 28 d)	0.120**	5.83	yes

IN-EQW78	0.800 (at 28 d)	0.032	25.0	yes
IN-ECD73	0.800 (at 28 days)	0.050	16.0	yes
IN-F6L99*	0.07 (at 28 days)	< 0.001	> 70.0	yes
IN-F9N04*	0.07 (at 28 days)	0.006**	11.7	yes
IN-GAZ70	0.840 (at 28 days)	0.017	49.4	yes
Chlorantraniliprole in ADM.00900.I.1.	1.23-0.665 (at 42-59 days)	0.120**	10.25-5.12	yes

*No available data. Factor 10 applied to the parent compound toxicity.

**PECaccum

zRMS comments:

The risk assessment to soil microflora was performed following a risk envelope approach and has been validated by zRMS.

In addition, the risk for formulation expressed in a.s./kg dws was added in the Table 9.9-2.

The effects on the nitrogen transformations are acceptable (<25%) at concentration which is higher than the maximum relevant PECs for the maximum application rate of active substances and the product.

Overall, no unacceptable risk to soil micro fauna are expected when ADM.00900.I.1.C is applied in the intended crops at the recommended rates.

9.9.3 Overall conclusions

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). To achieve a concise risk assessment, the risk envelope approach was applied and the risk assessment was based on the use in vines at 1 x 36 g a.s./ha at BBCH 57-83 resulting in the highest PEC_{soil} for Chlorantraniliprole and its metabolites (please refer to Part B section 8 for details).

The PEC_{soil} values for Chlorantraniliprole and its metabolites calculated for the use in vines at 1 x 36 g a.s./ha are far below the maximum concentrations with effects ≤ 25%, indicating an acceptable risk to soil micro-organisms. It is therefore concluded that the use of ADM.00900.I.1.C in the intended crops at the recommended rates poses an acceptable risk to soil microorganisms.

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

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

Species	Substance	Exposure System	Results	Reference
<i>Rye grass</i>	Chlorantraniliprole 20 SC	21 d Seedling emergence	¹⁾ ER ₅₀ emergence >300 g a.s./ha ²⁾ ER ₅₀ plant weight >300 g a.s./ha ³⁾ ER ₅₀ plant height > 300 g a.s./ha	EFSA Conclusion (2013)
<i>Rye grass</i>	Chlorantraniliprole 20SC	21 d Vegetative vigour	¹⁾ ER ₅₀ plant weight > 300 g a.s./ha ²⁾ ER ₅₀ plant height > 300 g a.s./ha	EFSA Conclusion (2013)
<i>Beta vulgaris</i>	Chlorantraniliprole 200SC	21 d Vegetative vigour	¹⁾ ER ₅₀ plant weight > 846.56 g f.p. (> 160 g a.s./ha) ²⁾ ER ₅₀ plant height > 846.56 g f.p. (> 160 g	Colli, 2020b (KCP 10.6/01)

Species	Substance	Exposure System	Results	Reference
			a.s.)/ha	

m: monocotyledonous; d: dicotyledonous

zRMS comments:

Data for soil NTPP for Chlorantraniliprole and its metabolites provided in Table 9.9-1 are in line with EU agreed endpoints reported in EFSA Conclusion (2013); 11(6):3143.

Study on toxicity of ADM.00900.I.1.C (Chlorantraniliprole 200SC) to vegetative vigour test was evaluated by the zRMS and is considered acceptable. For details of evaluation, please refer to Appendix 2.

Endpoints reported in Table 9.10-1 are confirmed to be correct.

9.10.1.1 Justification for new endpoints

ADM.00900.I.1.C was not the representative formulation evaluated in the EU peer review for Chlorantraniliprole. New data needed to be generated.

9.10.2 Risk assessment

9.10.2.1 Tier-1 risk assessment (based screening data)

Not relevant.

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

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

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use in pomefruit at 31 g a.s./ha at BBCH 70-87 also covers the risk for non-target terrestrial plants from all other intended uses since the combination of the application rate (31 g a.s./ha) with a high drift rate (15.73%) results in the highest PER_{off-field}.

Table 9.10-2: Assessment of the risk for non-target plants due to the use of ADM.00900.I.1.C in pomefruit (1 x 31 g a.s./ha, BBCH 70-87)

Intended use		Pomefruit, BBCH 70-87		
Active substance/product		Chlorantraniliprole		
Application rate (g/ha)		1 × 31		
MAF		1		
Test species	ER₅₀ (g a.s./ha)	Drift rate	PER_{off-field} (g a.s./ha)	TER criterion: TER ≥ 5
<i>Beta vulgaris</i>	> 160 (ADM.00900.I.1.C; vegetative vigour)	15.73%	4.88	32.8

Ryegrass	> 300 (Chlorantraniliprole 20 SC; vegetative vigour and seedling emergence)			61.5
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MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Both the TER values are highly above the trigger of 5, indication a low risk from chlorantraniliprole for non-target terrestrial plant seedling emergence and vegetative vigour.

zRMS comments:

The risk assessment to non-target plants was performed in accordance with SANCO/10329/2002 rev 2 (final) and following a risk envelope approach.

It should be noted that only vegetative vigour test for formulation ADM.00900.I.1.C; is available.

The Applicant referred and used the results from seedling emergence test obtained from representative formulation Chlorantraniliprole 20 SC with the same content of a.s. as in ADM.00900.I.1.C.

This approach is considered acceptable by zRMS.

Overall, based on the results from the new submitted vegetative vigour and seedling emergence studies, an acceptable risk to non-target plants can be concluded for NTTP from exposure to ADM.00900.I.1.C.

9.10.2.3 Higher-tier risk assessment

Not relevant.

9.10.2.4 Risk mitigation measures

No risk mitigation needed.

9.10.3 Overall conclusions

The risk assessment is based on the “Guidance Document on Terrestrial Ecotoxicology”, (SANCO/10329/2002 rev.2 final, 2002). To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use in pomefruit at 31 g a.s./ha at BBCH 70-87 also covers the risk for non-target terrestrial plants from all other intended uses since the combination of the application rate (31 g a.s./ha) with a high drift rate (15.73%) results in the highest PER_{off-field}.

The risk assessment was conducted with data from ADM.00900.I.1.C and from the representative formulation submitted and evaluated in the EU peer review, being of same AI concentration and formulation type as ADM.00900.I.1.C. In both cases, the resulting TER values were highly above the trigger of 5, indicating an acceptable risk from Chlorantraniliprole when ADM.00900.I.1.C is applied in pomefruit at 1 x 31 g a.s./ha at BBCH 70-87. Since this use represent the worst-case for the intended uses of ADM.00900.I.1.C, by applying the risk envelop approach, it is considered that the use of ADM.00900.I.1.C in all the intended crops at the recommended rates poses an acceptable risk.

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

No further relevant data is available and considered necessary.

9.12 Monitoring data (KCP 10.8)

No monitoring data is available and to be considered.

9.13 Classification and Labelling

Classification:

Acute hazard:

Aquatic testing on ADM.00900.I.1.C has been conducted for acute toxicity. The following data are considered for acute hazard classification:

Group	Species	L(E)C ₅₀ (mg/L)
Fish	<i>Oncorhynchus mykiss</i>	> 100
Invertebrates	<i>Daphnia magna</i>	41.29 x 10 ⁻³
Algae	<i>Pseudokirchneriella subcapitata</i>	> 100
Aquatic plants	<i>Lemna minor</i>	> 100

The most sensitive species is *Daphnia magna* with an EC₅₀ of 41.29 µg/L. This value is below the trigger of 1 mg/L for classification. Therefore, the classification for acute hazard is:

Acute hazard: Acute cat. 1

Chronic hazard:

No data on the chronic toxicity of ADM.00900.I.1.C is available. The classification of ADM.00900.I.1.C for chronic hazard will therefore be based on the summation of the concentrations of classified components. The available agreed classification of the active substance Chlorantraniliprole in the EFSA review is based on Directive 67/548/EEC (EFSA Conclusion, 2013):

RMS / peer review proposal	
N	Dangerous for the environment
R50/53	Very toxic to aquatic organisms. May cause long term adverse effects in the aquatic environment.

According to Regulation (EC) No.1272/2008, based on the lowest acute endpoint for *Daphnia magna* of 0.0116 mg/L, Chlorantraniliprole should be classified Aquatic acute cat. 1 with an M factor of 10. Considering the formulation co-formulants, only one of them is classified. Therefore, the following information is to be considered for the chronic classification using the summation of the concentrations of classified components:

Substance	Concentration (% w/w)	Classification
Chlorantraniliprole	18.5	Aquatic acute cat.1, M = 10
Co-formulant	0.10	Aquatic chronic cat. 3

Aquatic acute 1 x M = 18.5 x 10 = 185 > 25%

The sum of the concentrations of the Aquatic acute cat.1 classified components multiplied by their respective M factor (here, only Chlorantraniliprole concentration multiplied by its M factor of 10) is higher than the trigger of 25 %, leading to the following classification for chronic hazard:

Chronic hazard: Aquatic chronic cat. 1

GHS pictogram and hazard statement under Regulation (EC) No. 1272/2008:

GHS Pictogram:



Signal word:

Warning

Hazard statements:

H400 Very toxic to aquatic life

H410 Very toxic to aquatic life with long lasting effects

zRMS comments:

The zRMS agrees with the environmental classification proposed by the Applicant.

The formulation Chlorantraniliprole 200 g/L SC should be classified as Aquatic Acute 1 (H400) based on the lowest acute toxicity endpoint on *Daphnia magna* (48-hour $EC_{50} = 0.004129$ mg Chlorantraniliprole 200SC/L) and as Aquatic Chronic 1 (H410) using the summation method based on the classification of the active substance chlorantraniliprole. Regarding the chronic classification, a M-factor = 10 is determined for chlorantraniliprole based on the active substance toxicity endpoint on *Daphnia magna* (21-day NOEC = 0.00447 mg a.s./L).

According to Table 4.1.2 from EU Regulation 1272/2008: Chronic Category $1 \times M \geq 25 \% = 20\% \times 10 \geq 25 \%$.

GHS pictogram and hazard statement under Regulation (EC) No. 1272/2008:

GHS Pictogram:



Signal word:

Warning

Hazard statements:

H400 Very toxic to aquatic life

H410 Very toxic to aquatic life with long lasting effects

P391 Collect spillage

P501 Dispose of contents/container to an approved waste disposal plant

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on – Formulated product study summaries included in Appendix 2.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	*Owner
KCP 10.2.1/01	████	████	Chlorantraniliprole 200 SC (product code ADM.00900.I.1.C): Acute Toxicity to Rainbow Trout (<i>Onchorynchus mykiss</i>) in a 96-hour Study under Semi-static Exposure Conditions ████ GLP Unpublished	Y	ADM
KCP 10.2.1/02	Mantilacci, S.	2020a	Acute immobilization test on <i>Daphnia magna</i> with test item Chlorantraniliprole 200 SC (product code ADM.00900.I.1.C) under static conditions. Report No. BT154/19 Reference No. 000103370 BioTecnologie BT Srl GLP Unpublished	N	ADM
KCP 10.2.1/03	Mantilacci, S.	2020a	Effect evaluation of Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C) on the green alga <i>Pseudokirchneriella subcapitata</i> in a growth inhibition test. Report No. BT153/19 BioTecnologie BT Srl GLP Unpublished	N	ADM
KCP 10.2.1/04	Mantilacci, S.	2020b	Effect evaluation of Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C) on <i>Lemna minor</i> in a semi-static growth inhibition limit test. Report n.: BT155/19 BioTecnologie BT Srl GLP Unpublished	N	ADM
KCP 10.3.1.1/01	Colli, M.	2019a	Acute oral and acute contact toxicity effects of ADM.0900.I.1.C to adult worker honeybees <i>Apis mellifera</i> L., Laboratory Test. Report n.: BT139/19 BioTecnologie BT Srl GLP Unpublished	N	ADM

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	*Owner
KCP 10.3.1.2/01	Colli, M.	2022	Chronic oral effects of ADM.0900.I.1.C to adult worker honeybees <i>Apis mellifera</i> L., 10-day feeding laboratory test. Report n°: BT140/19 BioTecnologie BT Srl GLP Unpublished	N	ADM
KCP 10.3.1.3/01	Colli, M.	2022	Effects of ADM.0900.I.1.C on honeybees (<i>Apis mellifera</i> L.) 22-day larval toxicity test with repeated exposure. Report n°: BT141/19 BioTecnologie BT Srl GLP Unpublished	N	ADM
KCP 10.3.2.1/01	Venturi, S.	2020a	Effects of Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C) on the par-asitic wasp <i>Aphidius rhopalosiphi</i> under Laboratory Conditions. Report n.: BT145/19. BioTecnologie BT Srl GLP Unpublished	N	ADM
KCP 10.3.2.1/02	Venturi, S.	2020b	Effects of Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C) on the predatory mite <i>Typhlodromus pyri</i> Scheuten (Acari: Phytoseiidae) under Laboratory Conditions. Report n.: BT146/19 BioTecnologie BT Srl GLP Unpublished	N	ADM
KCP 10.4.1.1/01	Pecorari, F.	2020	Effects of Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C) on reproduction of the earthworm <i>Eisenia andrei</i> in artificial soil containing 10 % peat. Report No.: BT142/19 Reference No.: 000103368 BioTecnologie BT Srl GLP Unpublished	N	ADM
KCP 10.4.2.1/01	Grandolini, G.	2020	Effects of Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C) on reproduction of the collembolan <i>Folsomia candida</i> in artificial soil. Report No.: BT143/19 Reference No.: 000103367 BioTecnologie BT Srl GLP	N	ADM

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 10.4.2.1/02	Colli, M.	2020a	Effects of Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C) on reproduction of the predatory mite <i>Hypoaspis aculeifer</i> in soil. Report n.: BT144/19 BioTecnologie BT Srl GLP Unpublished	N	ADM
KCP 10.5/01	Rossini, L.	2020	Assessment of the effects of Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C) on soil microorganisms nitrification. Report n°: BT148/19 BioTecnologie BT Srl GLP Unpublished	N	ADM
KCP 10.6/01	Colli, M.	2020b	Effects of Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C) on terrestrial plants - Vegetative Vigour Test. Report n° BT147/19 BioTecnologie BT Srl GLP Unpublished	N	ADM

* ADM = proprietary of ADAMA Agricultural Solutions and all affiliates

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
The most of endpoints for active substance and its relevant metabolites was taken from the EU review, for the list of respective studies please refer to Volume 2 of the monograph.					

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
There were no data submitted by the applicant and not relied on.					

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
There were no data relied on not submitted by the applicant but necessary for evaluation.					

Appendix 2 Detailed evaluation of the new studies – Formulated product

A 2.1 KCP 10.1 Effects on birds and other terrestrial vertebrates

A 2.1.1 KCP 10.1.1 Effects on birds

A 2.1.1.1 KCP 10.1.1.1 Acute oral toxicity

No data. The provision of further data on the formulation is not considered to be required, because an increased toxicity of the product is not expected as indicated by acute oral testing in mammals giving a limit dose endpoint ($LD_{50} > 2000$ mg product/kg bw).

A 2.1.1.2 KCP 10.1.1.2 Higher tier data on birds

No additional data.

A 2.1.1.3 KCP 10.1.2 Effects on terrestrial vertebrates other than birds

A 2.1.1.4 KCP 10.1.2.1 Acute oral toxicity to mammals

Please refer to dRR Part B6.

A 2.1.1.5 KCP 10.1.2.2 Higher tier data on mammals

No additional data.

A 2.1.2 KCP 10.1.3 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians)

No additional data.

A 2.2 KCP 10.2 Effects on aquatic organisms

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

A 2.2.1.1 Study 1: Acute toxicity to Rainbow trout

The following acute fish (*Onchorynchus mykiss*) toxicity study performed with Chlorantraniliprole 200 SC (product code ADM.00900.I.1.C) was provided in support of the assessment.

Comments of zRMS:	<p>The study was conducted in line with OECD 203 (2019) with deviation such as:</p> <ul style="list-style-type: none"> - On Day 4 fish were checked only once a day (instead of twice a day as reported in the Study Plan). This was due because the test finished in the morning and so only one observation was made in the morning. <p>This deviation is considered to have no impact on the outcome of the study as all the validity criteria were met.</p> <p>The actual test concentrations of active substance Chlorantraniliprole were analytically measured at the beginning of the test, after 2 days (in fresh and aged solutions) and at the end of the test period (4 days).</p> <p>The analytical recoveries of the concentrations of active substance Chlorantraniliprole were in the range of 92.50 % to 98.80 % of the nominal value in the fresh and aged solutions of the limit test concentrations.</p> <p>Since all analytical recoveries were in the range 80 % - 120 % of the nominal concentrations, the results were referred to the test item nominal concentrations.</p> <p>Overall, the study is considered acceptable with the following endpoint relevant for the risk assessment:</p> <p>LC₅₀ >100 mg product/L</p> <p>(Based on nominal concentration)</p>
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Reference:	KCP 10.2.1/01
Report	Chlorantraniliprole 200 SC (product code ADM.00900.I.1.C): Acute Toxicity to Rainbow Trout (<i>Onchorynchus mykiss</i>) in a 96-hour Study under [REDACTED] Semi-static Exposure Conditions. [REDACTED]
Guideline(s):	OECD Test Guideline 203 (2019)
Deviations:	On Day 4 fish were checked only once a day (instead of twice a day as reported in the Study Plan). This was due because the test finished in the morning and so only one observation was made in the morning. Deviation is stated to have no impact in test results.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No, representative product study.

Executive summary

The acute toxicity test was performed in order to evaluate the effects of the test item Chlorantraniliprole 200 SC (product code ADM.00900.I.1.C) on mortality of rainbow trout (*Oncorhynchus mykiss*) during 96

hours of exposure in a limit test at the limit concentration of 100 mg/L under semi-static conditions with a medium renewal after 48 h.

Mortality and visible abnormalities were determined for the control and limit concentration at each observation time (LC₅₀ at 24, 48, 72 and 96 hours). The analytical recoveries of the concentrations of active ingredient Chlorantraniliprole were in the range of 92.50 % to 98.80 % of the nominal value in the fresh and aged solutions of the limit test concentrations.

All the validity criteria was stated to be met. In the negative control, no mortality was observed during the test period. No mortality nor sublethal effects occurred at 24, 48, 72 and 96 hours, indicating a LC₅₀ > 100.0 mg test item/L.

I. MATERIAL AND METHODS

A. MATERIALS

1. **Test Material:** Chlorantraniliprole 200 SC (product code ADM.00900.I.1.C)
Description: Off-white liquid
Lot/batch : 1221-010320-0111
Concentration/Purity: Chlorantraniliprole 18.1 % w/w (198 g/L)
Density: 1.09 g/mL
Stability of test compound: Stable under storage conditions (15-25 °C; dark; well-ventilated room)
Expiry date: 09th March 2022
2. **Vehicle and/or control:** Vehicle control: reconstituted ISO test water without test item
3. **Test animals (Species)** Rainbow trout (*Oncorhynchus mykiss*)
Age at test start: Juvenile
Source: Research Foundation “Edmund Mach” (S. Michele all’Adige - Italy)
Acclimation period: At least 9 days at the same conditions regarding water quality, temperature and illumination as in the main test.
Feeding: During holding period (59 days), the fish were fed daily with specific fish food (Food “Vita 0.2”, Supplier Veronesi). Feeding was stopped at least 24 hours before the test start.
Number of study organisms per concentration and control: 7 fish per treatment and test water control. 14 fish in total
Number of animals per test vessel: 7 fish each were tested for the control and the limit concentration with one replicate each.
Number of replicates: 1 replicate per concentration
Test vessel: 60 L capacity glass aquaria with 20 L test solution
Test medium: Reconstituted water (ISO Test water 6341)
Reference standard: Not stated
4. **Environmental conditions during testing**
Temperature: 10.5 – 12.1 °C
pH: 7.11 – 7.89
Hardness: 40 - 250 mg/L as CaCO₃
Oxygen-concentration: ≥ 65.8%
Aeration: Not stated
Photoperiod: 12 h light – 12 h dark
Light intensity: 589 – 628 lux

B. STUDY DESIGN AND METHODS

1. **In-life dates:** 19 Oct 2020 – 05 Nov 2020 (experimental period)

2. Experimental design:

The aim of this study was to determine the acute toxicity of the test item on fish. The parameter measured in this study was rainbow trout (*Oncorhynchus mykiss*) survival and visible abnormalities (appearance and behavior). Juvenile rainbow trout of similar age and size were exposed in a 96-hour test to an aqueous medium containing the test item at the single limit concentration of 100.0 mg/L under semi-static conditions (medium renewal after 48 hours). Concentration was chosen according to the results of a preliminary range-finding test, which was conducted as a non-GLP screening test, where no mortality was observed at the tested concentrations (1 mg/L, 10 mg/L, 100 mg/L).

Test concentration:

The limit test was performed to show that there was no acute effect on mortality on fish at the test concentration. The LC₅₀ at 24, 48, 72 and 96 hours were determined. Negative control (test medium without test item) and 100.0 mg/L of the test item Chlorantraniliprole 200 SC (product code ADM.00900.I.1.C) equivalent to a Chlorantraniliprole concentration of 18.1 mg a.i./L (analysed content).

Chemical analysis and validation:

Performed to determine the content of the active ingredient Chlorantraniliprole in fresh and aged solutions. The analyses were performed at the test site Biotechnologie BT Srl.

Test duration:

96 hours

3. Observations:

The fish were checked for mortality and visible abnormalities 2 hours and 5 hours after test start (Day 0) and then twice a day from Day 1 up to Day 3 of exposure (in the morning and in the afternoon). On Day 4 fish were checked only once a day since the test finished in the morning.

Timepoints indicated as Day 1, 2, 3 and 4 correspond to 24 hour, 48 hour, 72 hour and 96 hour.

Mortality and any visible anomalies were recorded and compared to the negative control.

4. Statistics

As a limit test with a single test item concentration was performed, no statistical analyses was performed. The effect value is taken directly from the result.

II. Results and Discussion

A. ANALYTICAL RESULTS

The actual test concentrations of active ingredient Chlorantraniliprole were analytically measured at the beginning of the test, after 2 days (in fresh and aged solutions) and at the end of the test period (4 days).

The analytical recoveries of the concentrations of active ingredient Chlorantraniliprole were in the range of 92.50 % to 98.80 % of the nominal value in the fresh and aged solutions of the limit test concentrations.

Since all analytical recoveries were in the range 80 % - 120 % of the nominal concentrations, the biological results were referred to the test item nominal concentrations.

Measured concentration and recoveries of the a.s. Chlorantraniliprole during the study

Test solution	Day	Solution code	Nominal Chlorantraniliprole (mg/L)	Measured Chlorantraniliprole (mg/L)	Recovery (%)
Negative control	0	CTRL T0 001	-	Signal < LOD	-
Negative control	0	CTRL T0 002	-	Signal < LOD	-
100.0 mg/L	0	C1 T0 001	18.1	17.0635	94.27
100.0 mg/L	0	C1 T0 002	18.1	17.1024	94.49
Negative control	2 aged	CTRL T2 AGED 001	-	Signal < LOD	-
Negative control	2 aged	CTRL T2 AGED 002	-	Signal < LOD	-
100.0 mg/L	2 aged	C1 T2 AGED 001	18.1	17.1365	94.68
100.0 mg/L	2 aged	C1 T2 AGED 002	18.1	17.8829	98.80
Negative control	2 fresh	CTRL T2 FRESH 001	-	Signal < LOD	-
Negative control	2 fresh	CTRL T2 FRESH 002	-	Signal < LOD	-
100.0 mg/L	2 fresh	C1 T2 FRESH 001	18.1	16.8576	93.14
100.0 mg/L	2 fresh	C1 T2 FRESH 002	18.1	17.4347	96.32
Negative control	4 aged	CTRL T4 AGED 001	-	Signal < LOD	-
Negative control	4 aged	CTRL T4 AGED 002	-	Signal < LOD	-
100.0 mg/L	4 aged	C1 T4 AGED 001	18.1	16.7418	92.50
100.0 mg/L	4 aged	C1 T4 AGED 002	18.1	17.2259	95.17

CTRL: Negative control
Code C1 corresponds to the test concentration 100.0 mg/L
Codes 001 and 002 at the end of solution codes are the analysis replicates.

In the table, minimum and maximum recovery (%) are highlighted in bold.

B. BIOLOGICAL RESULTS

The test organisms were checked for mortality after 2, 5, 24, 48, 72 and 96 hours from test initiation (day 0, 1, 2, 3 and 4). Additionally, afternoon monitoring was performed at day 1, 2 and 3. In following tables, lethal and sublethal effects referred to the nominal concentration of the test item are reported.

Table A 2.2.1-01 Lethal effects of the test item to rainbow trout

Nominal test item concentration (mg/L)	No. of exposed fish	Number of dead fish								
		2 hours	5 hours	Day 1 a.m.	Day 1 p.m.	Day 2 a.m.	Day 2 p.m.	Day 3 a.m.	Day 3 p.m.	Day 4 a.m.
Negative control	7	0	0	0	0	0	0	0	0	0
100.0	7	0	0	0	0	0	0	0	0	0

a.m.: morning

p.m.: afternoon

Table A 2.2.1-02: Sublethal effects of the test item to rainbow trout

Nominal test item concentration (mg/L)	No. of exposed fish	Number of fish showing sub-lethal effects								
		2 hours	5 hours	Day 1 a.m.	Day 1 p.m.	Day 2 a.m.	Day 2 p.m.	Day 3 a.m.	Day 3 p.m.	Day 4 a.m.
Negative control	7	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
100.0	7	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

a.m.: morning

p.m.: afternoon

n.a. = not applicable (sublethal effect)

In the negative control, no mortality was observed during the test period. This value complies with the validity criterion reported in the guidelines (maximum mortality of one fish, if seven fish are used, in the negative control medium at the end of the test).

The absence of mortality at 24, 48, 72 and 96 hours (corresponding to day 1, 2, 3 and 4 in the morning) showed that LC₅₀ is greater than 100.0 mg test item/L.

C. VALIDITY CRITERIA

The test was considered valid, since validity criteria were met:

- All fish in the negative control survived;
- Dissolved oxygen concentration was always greater than 60 %;
- Analytical measurements were performed.

III. CONCLUSION

The acute toxicity of test item Chlorantraniliprole 200 SC (ADM.00900.I.1.C) was tested on rainbow trout under semi-static conditions.

The LC₅₀ (24, 48, 72 and 96 h) values assessed in terms of nominal test item concentrations were > 100.0 mg/L

A 2.2.1.2 Study 2: Acute toxicity to Invertebrates (*Daphnia magna*)

The following aquatic invertebrate toxicity study with *Daphnia magna* performed with Chlorantraniliprole 200 SC (product code ADM.00900.I.1.C) was provided in support of the assessment.

Comments of zRMS:	<p>The study was conducted in line with OECD 202 (2004) with no deviation. All validity criteria were met.</p> <p>The analytical determination of the chlorantraniliprole active substance content showed recovery values in the range of 93.83 - 106.20% in the fresh samples and 88.40 - 98.55% in the 48 h old aged samples.</p> <p>Since all analytical recoveries were in the range 80 % - 120 % of the nominal concentrations, the results were referred to the product nominal concentrations.</p> <p>Overall, the study is considered acceptable with the following endpoint relevant for the risk assessment:</p> <p>EC₅₀=41.29 µg product /L (correspond to 7.47 µg a.s./L)</p> <p>(Based on nominal concentration)</p>
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Reference:	KCP 10.2.1/02
Report	Acute immobilization test on <i>Daphnia magna</i> with test item Chlorantraniliprole 200 SC (product code ADM.00900.I.1.C) under static conditions. Mantilacci, S., 2020a, Report No: BT154/19. Reference No: 000103370.
Guideline(s):	OECD Guideline for testing of chemicals, No. 202, 2004.
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	-

Executive summary

The acute immobilisation test was performed under static conditions to assess the effects of the test item Chlorantraniliprole 200 SC (product code ADM.00900.I.1.C) on *Daphnia magna* after 48 hours of exposure.

Young daphnids, less than 24 hours old at start of the test, were exposed to nominal concentrations of 4.27, 9.39, 20.66, 45.45 and 100.00 µg test item/L (corresponding to 0.773, 1.700, 3.739, 8.226 and 18.100 µg a.i./L) in ISO medium containing 0.01 % of the solvent dimethylformamide (DMF), plus two untreated control groups (with and without solvent).

The analytical determination of the chlorantraniliprole active ingredient content showed recovery values in the range of 93.83 - 106.20% in the fresh samples and 88.40 - 98.55% in the 48 h old aged samples.

Accordingly, the assessment of the effects was based on the nominal concentrations of test item and active ingredient.

The immobilisation endpoints at 48 hours based on the nominal concentrations of the test item were estimated to be the following:

- EC₁₀ 22.87 µg/L (95% C.L. 14.61 - 29.04 µg/L)
- EC₂₀ 28.01 µg/L (95% C.L. 19.84 - 34.50 µg/L)
- EC₅₀ 41.29 µg/L (95% C.L. 33.37 - 51.17 µg/L)
- LOEC 20.66 µg/L
- NOEC 9.39 µg/L

The immobilisation endpoints at 48 hours based on the nominal concentrations of the active ingredient Chlorantraniliprole, were estimated to be the following:

- EC₁₀ 4.14 µg/L (95% C.L. 2.64 - 5.26 µg/L)
- EC₂₀ 5.07 µg/L (95% C.L. 3.59 - 6.25 µg/L)
- EC₅₀ 7.47 µg/L (95% C.L. 6.04 - 9.26 µg/L)
- LOEC 3.74 µg/L
- NOEC 1.70 µg/L

No other effects were observed on the exposed organisms in the tested concentration range.
The validity criteria of OECD 202 (2004) were fulfilled.

I. MATERIAL AND METHODS

A. MATERIALS

- | | |
|------------------------------------|--|
| 1. Test Material: | Chlorantraniliprole 200 SC (product code ADM.00900.I.1.C) |
| Description: | Off-white liquid |
| Lot/batch : | 1221-010320-0111 |
| Concentration/Purity: | Chlorantraniliprole 18.1 % w/w (198 g/L)
Density: 1.09 g/mL |
| Stability of test compound: | Stable under storage conditions (Dark, cool and dry conditions at ambient temperature (15-25°C), container tightly closed in a well-ventilated room)
Expiry date: 09th March 2022 |
| 2. Vehicle and/or control: | Vehicle control: ISO medium according to OECD 202 containing 0.01 % DMF as solvent |
| 3. Test animals (Species) | <i>Daphnia magna</i> (Straus) |
| Age at test start: | < 24 hours old |
| Source: | In house breeding at the Test Facility |
| Acclimation period: | Under breeding conditions; the test organisms were fed with algae suspension (<i>Pseudokirchneriella subcapitata</i>) and were maintained in Elendt M4 medium. |

Feeding:	The pH of medium was in the range of 6 - 9 and the dissolved oxygen content was ≥ 3 mg/L.
Number of study organisms per concentration and control:	The organisms were maintained in a thermostatic chamber at $20 \pm 2^\circ\text{C}$, with a photoperiod of 16 hours light and 8 hours dark.
Number of animals per test vessel:	No feeding during the test
Number of replicates:	Twenty daphnids per treatment and test water control.
Test vessel:	5 organisms
Untreated variant:	4 replicates per concentration
Reference standard:	Glass vessels (volume of 100 mL)
	Test medium without test substance
	Potassium dichromate (Batch No.: BCBX0868, 100% purity)

Data reported in the GLP study BT228/20, an immobilisation test performed using potassium dichromate as toxic reference item and carried out on 01st - 02nd July 2020.

The most recent test with *Daphnia magna* in Jul 2020 resulted in an EC₅₀ (24 h) of 1.63 mg/L.

4. Environmental conditions during testing	
Temperature:	19.5 - 20.2°C (temperature of the test medium)
pH:	7.71 - 7.80
Hardness:	240 mg/L as CaCO ₃
Oxygen-concentration:	8.15 - 8.89 mg/L
Aeration:	The medium was aerated for at least 2 hours with an air pump prior to use
Photoperiod:	16 h light – 8 h dark
Light intensity:	865 - 918 lux

B. STUDY DESIGN AND METHODS

1. In-life dates:	20 th October - 04 th November 2020
2. Experimental design:	<p>A static dose response test was conducted at nominal concentrations of 4.27, 9.39, 20.66, 45.45 and 100.00 µg test item/L (corresponding to 0.773, 1.700, 3.739, 8.226 and 18.100 µg a.i./L) in ISO medium containing 0.01 % of the solvent DMF, plus two untreated control groups (with and without solvent).</p> <p>Twenty daphnids, divided in four replicates of five daphnids, were used for each treatment group.</p> <p>The test organisms were exposed to the test solutions for 48 hours.</p> <p>The number of mobile and immobile daphnids was counted at 24 and 48 hours after the beginning of the test.</p> <p>The concentration of the active ingredient chlorantraniliprole was determined by UHPLC-MS/MS analyses, in samples of the test solutions collected at test start and at test end.</p>
Test concentration:	Nominal concentrations: 4.27, 9.39, 20.66, 45.45 and 100.00 µg test item/L (corresponding to 0.773, 1.700, 3.739, 8.226 and 18.100 µg a.i./L)
Chemical analysis and validation:	content of active ingredient chlorantraniliprole was performed by UHPLC-MS/MS
Test duration:	48 hours

3. Observations:

Observations for *Daphnia* immobilisation and mortality were made after 24 and 48 hours. All daphnids not able to swim within 15 seconds after gentle agitation of the test vessel were considered to be immobilised. No other effects on controls and treated daphnids like signs of disease or stress (for example, discoloration or unusual behaviour such as trapping at surface of water) were observed during the test period.

4. Statistics

Probit analysis to calculate the LC_x values with 95 % confidence limits. Step-Down Cochran-Armitage test procedure to estimate the LOEC/NOEC values after 48 hours of exposure, using the software ToxRat Professional 3.3.0.

II. Results and Discussion

A. Analytical results

The analytical determination of the content of active ingredient chlorantraniliprole was performed by UHPLC-MS/MS. The analytical method was validated according to SANCO/3029/99 rev.4 in a separate GLP study (BT281/20; ADAMA reference number 000105396).

In this study, the analytical determination of the active ingredient chlorantraniliprole in the test media samples showed recovery values in the range of 93.83 - 106.20% in the fresh samples and 88.40 - 98.55% in the aged samples.

Summary of the analytical results for chlorantraniliprole in fresh (test start) and aged (test end) test media samples from the biological part of the acute test with *Daphnia magna*

Treatment code	Sampling time	Nominal conc. [µg a.i./L]	Measured conc. [µg a.i./L]	Recovery [%]
CTRL	T0 (fresh)	0	< LOD *	n.d.
	T48 (aged)	0	< LOD *	n.d.
CT SOLV	T0 (fresh)	0	< LOD *	n.d.
	T48 (aged)	0	< LOD *	n.d.
C1	T0 (fresh)	0.773	0.7687	99.44
	T48 (aged)	0.773	0.6833	88.40
C2	T0 (fresh)	1.700	1.6691	98.19
	T48 (aged)	1.700	1.6754	98.55
C3	T0 (fresh)	3.739	3.9706	106.20
	T48 (aged)	3.739	3.6818	98.47
C4	T0 (fresh)	8.226	7.7183	93.83
	T48 (aged)	8.226	7.8882	95.89
C5	T0 (fresh)	18.100	17.8300	98.51
	T48 (aged)	18.100	17.3683	95.96

* Parameter from the validated analytical method (GLP study BT281/20): LOD 0.1020 µg/L; n.d. = not determinable.
The measured conc. and the recovery values are arithmetic mean values from double injection of each sample.

B. Biological results

The percentage of immobilisation (%I) obtained in the concentration-response test is reported in the table below, where %I = (number of immobilised organisms / numbers of exposed organisms) × 100.

Table A 2.2.1-03 Immobilisation of *Daphnia magna* in percent (%I) after 24 and 48 h exposure to the test item

Code	Nominal test item conc. [µg/L]	Nominal chlorantraniliprole conc. [µg a.i./L]	Response after 24 h		Response after 48 h	
			Number of immobilised daphnids	%I	Number of immobilised daphnids	%I
CTRL	0	0	0/20	0	0/20	0
CT SOLV	0	0	0/20	0	0/20	0
C1	4.27	0.773	0/20	0	0/20	0
C2	9.39	1.700	0/20	0	0/20	0
C3	20.66	3.739	1/20	5	2/20	10 +
C4	45.45	8.226	2/20	10 +	10/20	50 +
C5	100.00	18.100	15/20	75 +	20/20	100 +

+ indicates a significant difference compared to the untreated control (Step-down Cochran-Armitage Test Procedure ($\alpha = 0.050$; one-sided greater))

C. Validity criteria

The validity criteria of OECD 202 (2004) were fulfilled, as reported in the following table, thus the study is valid.

Table A 2.2.1-04 Validity criteria of the study

Validity criteria	Threshold	Observed
Immobilised daphnids in the untreated group, at the end of the test	< 10%	0%
Dissolved oxygen concentration at the end of the test in treated and untreated groups	≥ 3 mg/L	8.15 - 8.32 mg/L

III. CONCLUSION

The acute immobilisation test was performed under static conditions to assess the effects of the test item Chlorantraniliprole 200 SC (product code ADM.00900.I.1.C) on *Daphnia magna* after 48 hours of exposure to a geometric series of test item concentrations.

Calculated endpoints based on the nominal concentrations of test item and active ingredient are shown in the following table.

Table A 2.2.1-05: Immobilisation of *Daphnia magna* in percent (%I) after 24 and 48 h exposure to the test item

Endpoint (48 hours)	Nominal test item conc. [µg/L]	Confidence limits		Nominal chlorantraniliprole conc. [µg a.i./L]	Confidence limits	
		Lower	Upper		Lower	Upper
EC10	22.87	14.61	29.04	4.14	2.64	5.26
EC20	28.01	19.84	34.50	5.07	3.59	6.25
EC50	41.29	33.37	51.17	7.47	6.04	9.26
LOEC	20.66	-	-	3.74	-	-
NOEC	9.39	-	-	1.70	-	-

No other effects were observed on the exposed organisms.

A 2.2.1.3 Study 3: Toxicity to algae (*Pseudokirchneriella subcapitata*)

The following algal toxicity study performed on Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C) is provided in sup-port of the assessment.

Comments of zRMS:	<p>The study was conducted in line with OECD 202 (2004) with no deviation. All validity criteria were met.</p> <p>The analytical determination of the content of active substance Chlorantraniliprole in the test solutions showed recovery values within the range 80-120% of the nominal values (with a mean recovery of 91.88% in the fresh samples and 98.43 % in the aged samples).</p> <p>Since all analytical recoveries were in the range 80 % - 120 % of the nominal concentrations, the results were referred to the product nominal concentrations.</p> <p>Overall, the study is considered acceptable with the following endpoint relevant for the risk assessment:</p> <p>$EyC_{50} = 19.62$ mg product/L (correspond to $EyC_{50} = 3.71$ mg a.s./L $ErC_{50} > 100.00$ mg product/L (correspond to $ErC_{50} > 18.9$ mg a.s./L) $NOEC_{y,r} = 0.95$ mg product/L (correspond to $NOEC_{y,r} = 0.18$ mg a.s./L)</p>
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Reference:	KCP 10.2.1/03
Report	Effect evaluation of Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C) on the green alga <i>Pseudokirchneriella subcapitata</i> in a growth inhibition test. Mantilacci, S. (2020a). Report n.: BT153/19.
Guideline(s):	OECD Test Guideline 201 (adopted 2006, corrected 2011)
Deviations:	No
GLP:	Yes (Laboratory certified by Italian Ministry of Health)
Acceptability:	Yes
Duplication (if vertebrate study)	-

Executive Summary

The growth inhibition test was performed in order to evaluate the effects of the test item Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C) on green alga *Pseudokirchneriella subcapitata*, after 72 hours of exposure.

The cultures were exposed to 0.95, 3.05, 9.77, 31.25 and 100.00 mg test item/L, corresponding to 0.18, 0.58, 1.85, 5.91 and 18.9 mg a.i./L, plus an untreated control group. The analytical determination of the active ingredient content showed a mean recovery of 91.88 % in the fresh samples and 98.43 % in the aged samples. Accordingly, the assessment of the effects was based on the nominal concentrations of the test item and the active ingredient.

After 72 hours exposure, no cells with abnormal appearance were observed in any of the treatment groups.

The endpoints, based on the nominal concentrations of test item, were estimated to be the following:

- Growth inhibition based on yield: $EyC_{50} = 19.62$ mg/L (95 % C.L. 18.11 - 21.26 mg/L);
- Corresponding $LOEyC = 3.05$ mg/L and $NOEyC = 0.95$ mg/L;
- Growth inhibition based on growth rate: $ErC_{50} > 100.00$ mg/L;
- Corresponding $LOErC = 3.05$ mg/L and $NOErC = 0.95$ mg/L.

The endpoints, based on the nominal concentrations of the active ingredient Chlorantraniliprole, were estimated to be the following:

- Growth inhibition based on yield: EyC50 = 3.71 mg a.i./L (95 % C.L. 3.43 - 4.02 mg a.i./L);
- Corresponding LOEyC = 0.58 mg a.i./L and NOEyC = 0.18 mg a.i./L;
- Growth inhibition based on growth rate: ErC50 > 18.9 mg a.i./L;
- Corresponding LOErC = 0.58 mg a.i./L and NOErC = 0.18 mg a.i./L.

The validity criteria of OECD 201 (2011) were fulfilled.

I. MATERIAL AND METHODS

A. MATERIALS

1. **Test Material:** Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C)
Description: Off-white liquid
Lot/batch, density: 3188-220519-01
Concentration/Purity: Chlorantraniliprole 18.9% (206 g/L)
Stability of test compound: Stability: Not stated
Expiry date: 22nd May 2021
2. **Vehicle and/or control:** AAP growth medium
3. **Test animals (Species):** *Pseudokirchneriella subcapitata* (strain No. 61.81)
Age or pre-culture: Exponential growth
Source: In-house culturing at the Test Facility, originating from SAG Culture collection of algae (Germany)

Acclimation period: Not stated

Feeding: -
Culture medium: AAP medium
Test vessel: Glass conical flasks (volume of 250 mL) with air-permeable cellulose caps
Initial cell density: 10⁴ cells/mL in each culture

Number of replicates: Three replicates were prepared for the treated groups and six replicates for the control group
Untreated variant: AAP-medium without test substance
Reference substance: A growth inhibition test is performed twice a year using 3,5-dichlorophenol as toxic reference item.
4. **Environmental conditions during testing**
Temperature 21.9 - 24.0 °C
pH 7.22 – 7.64
Hardness: Not stated
Oxygen-concentration [mg/L] Not stated
Aeration CO₂ supply by orbital shaker at 100 rpm
Photoperiod Continuous illumination
Light intensity 6071 - 6737 Lux

B. STUDY DESIGN AND METHODS

1. **In-life dates:** 17th February - 13th March 2020

2. Experimental design:

A concentration-response test was conducted at 0.95, 3.05, 9.77, 31.25 and 100.00 mg test item/L in EPA's AAP growth medium, plus an untreated control group.

Three replicates were prepared for the treated groups and six replicates for the control group, each replicate containing 100 mL of test solution.

The initial cell concentration in the test cultures was 10^4 cells/mL and the cell density in each flask was counted daily during the test. The exposure period was 72 hours.

The concentration of the active ingredient was determined by UHPLC-MS/MS analyses, in samples of the test solutions at test start and test end.

Test concentrations:

0.95, 3.05, 9.77, 31.25 and 100.00 mg test item/L

Chemical analysis and validation:

The analytical determination of the active ingredient content was performed by UHPLC-MS/MS. The analytical method was validated according to SANCO/3029/99 rev.4 in a separate GLP study (BT207/19). The analytical determination of the active ingredient content showed a mean recovery of 91.88 % in the fresh samples and 98.43 % in the aged samples. Accordingly, the results are presented based on nominal concentrations of the test item and the active ingredient.

Test duration:

72 hours

3. Observations:

In the samples of all treatment groups, no cells with abnormal appearance were observed. Cells in the control group were inconspicuous as well.

The biomass (cell density) in each test vessel was evaluated after 24, 48 and 72 hours of exposure. The biomass in each flask and the appearance of the cells were assessed daily during the test period, by direct microscope counts (each sample was evaluated with six counts using a Thoma cell counting chamber and the cell density was expressed as mean of the six obtained values). Microscopic observations were also performed to assess any abnormal appearance of the algal cells that may have been caused by exposure to the test item.

The effect on the growth was evaluated using two response variables:

- based on the average specific growth rate, calculated on the basis of the logarithmic increase of biomass (cell density) during the test period, expressed per day;
- based on yield, that is the biomass (cell density) at the end of the test minus the starting biomass.

Samples for analytics were collected at 0 and 72h.

4. Statistics:

The determination of the EC_x values was performed by Probit analysis using linear maximum likelihood regression.

Williams multiple sequential t-test procedure and Multiple sequentially-rejective Welsh-t-test after Bonferroni-Holm were used to estimate the LOEC/NOEC values at 72 hours (for growth rate and yield respectively).

II. RESULTS AND DISCUSSION

A. Analytical results

The analytical determination of the content of active ingredient Chlorantraniliprole in the test solutions showed recovery values within the range 80-120% of the nominal values (with a mean recovery of 91.88% in the fresh samples and 98.43 % in the aged samples), therefore the data evaluation was performed using the nominal concentrations.

Measured concentration and recoveries of the a.s. Chlorantraniliprole during the study

Code		Nominal a.i. conc. (mg/L)	Mean measured a.i. conc. (mg/L)	Mean measured a.i. conc. (mg/L) for treatment group [arithmetic mean]	Mean Recovery (%)	Mean Recovery (%) for treatment group
C1	C1 T0	0,18	0,16	0,177	91,11	98,20
	C1 T72		0,19		105,28	
C2	C2 T0	0,58	0,54	0,549	93,45	94,66
	C2 T72		0,56		95,86	
C3	C3 T0	1,85	1,74	1,730	93,79	93,51
	C3 T72		1,73		93,24	
C4	C4 T0	5,91	5,46	5,613	92,30	94,97
	C4 T72		5,77		97,63	
C5	C5 T0	18,90	16,78	17,850	88,76	94,44
	C5 T72		18,93		100,13	

Mean Recovery Fresh (%) 91.88
Mean Recovery Spent (%) 98.43

B. Biological results

The inhibition of growth was estimated in percent based on growth rate (Ir) and yield (Iy), compared to the control, and is reported in Table A 2.2.1-1.

Table A 2.2.1-06: Inhibition of growth of *Pseudokirchneriella subcapitata* based on growth rate (Ir) and yield (Iy) in percent after 72 h-exposure to test item, in relation to the control

Code	Nominal test item conc. [mg/L]	Nominal Chlorantraniliprole conc. [mg a.i./L]	%Ir ^A	%Iy ^B
C1	0.95	0.18	0.25	1.13
C2	3.05	0.58	2.23 ⁺	10.06 ⁺
C3	9.77	1.85	6.80 ⁺	27.63 ⁺
C4	31.25	5.91	23.08 ⁺	66.81 ⁺
C5	100.00	18.90	40.11 ⁺	85.68 ⁺

^A ⁺ indicates a significant difference compared to the untreated control (Williams Multiple Sequential t-test, $\alpha = 0.05$, one-sided smaller)

^B ⁺ indicates a significant difference compared to the untreated control (Multiple Sequentially-rejective Welsh-t-test after Bonferroni-Holm, $\alpha = 0.05$, one-sided smaller)

C. Validity criteria (Cell Density)

According to the OECD 201 (2011), the test results are valid if in the control cultures:

- the cell concentration increases by a factor of at least 16 within 3 days, corresponding to a specific growth rate of 0.92 day⁻¹;
- the mean coefficient of variation for section-by-section specific growth rates (days 0 - 1, 1 - 2 and 2 - 3) does not exceed 35%;
- the coefficient of variation of average specific growth rates during the whole test period in the replicates does not exceed 7%.

According to the data reported in this Final Report (see also paragraph 7.3), the validity criteria were satisfied, and the study is valid.

III. CONCLUSION

The growth inhibition test was performed in order to evaluate the effects of the test item Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C) on the green alga *Pseudokirchneriella subcapitata*, after 72 hours of exposure to a geometric series of test item concentrations. Calculated endpoints based on the nominal concentrations of test item and active ingredient are shown in the following table:

Table A 2.2.1-07: Effect concentrations of test item for growth rate and yield of *Pseudokirchneriella subcapitata* after 72 h exposure

Endpoint (72 hours)	Nominal test item concentration [mg/L]	Nominal Chlorantraniliprole concentration [mg a.i./L]	Endpoint (72 hours)	Nominal test item concentration [mg/L]	Nominal Chlorantraniliprole concentration [mg a.i./L]
EyC10	3.43 (95% C.L. 2.86-4.00)	0.65 (95% C.L. 0.54-0.76)	ErC10	11.94 (95% C.L. 10.32-13.54)	2.26 (95% C.L. 1.95-2.56)
EyC20	6.24 (95% C.L. 5.46-7.01)	1.18 (95% C.L. 1.03-1.33)	ErC20	29.09 (95% C.L. 26.70-31.45)	5.50 (95% C.L. 5.05-5.95)
EyC50	19.62 (95% C.L. 18.11-21.26)	3.71 (95% C.L. 3.43-4.02)	ErC50	> 100.00	> 18.90
LOEyC	3.05	0.58	LOErC	3.05	0.58
NOEyC	0.95	0.18	NOErC	0.95	0.18

C.L.: Confidence Limit

Effect concentrations of test item for growth rate and yield of *Pseudokirchneriella subcapitata* after 72 h exposure.

No cells with abnormal appearance were observed in any of the control or test item treatment groups. The validity criteria of OECD 201 (2011) were fulfilled, thus the study is valid.

A 2.2.1.4 Study 4: Toxicity to aquatic plant (*Lemna minor*)

The following *Lemna* toxicity study performed on Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C) is provided in sup-port of the assessment.

Comments of zRMS:	<p>The study was conducted in line with OECD 221 (adopted 2006, corrected 2011) with no deviation. All validity criteria were met.</p> <p>The analytical determination of the content of active ingredient Chlorantraniliprole in the test solutions showed recovery values within the range 80-120% of the nominal values (with a mean recovery of 91.59% in the fresh samples and 97.65 % in the aged samples).</p> <p>Since all analytical recoveries were in the range 80 % - 120 % of the nominal concentrations, the results were referred to the product nominal concentrations.</p> <p>Overall, the study is considered acceptable with the following endpoint relevant for the risk assessment:</p> <p>$E_{ry}C_{50} > 100$ mg product /L (corresponding to 18.9 mg a.s./L) $NOEC_{ry} \geq 100$ mg/L (corresponding to 18.9 mg a.s./L)</p>
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Reference: KCP 10.2.1/04

Report Effect evaluation of Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C) on *Lemna minor* in a semi-static growth inhibition limit test. Mantilacci, S. (2020b). Report n.: BT155/19

Guideline(s): OECD Test Guideline 221 (adopted 2006, corrected 2011)

Deviations:	No
GLP:	Yes (Laboratory certified by Italian Ministry of Health)
Acceptability:	Yes
Duplication (if vertebrate study)	-

Executive Summary

The growth inhibition limit test was performed in order to evaluate the effects of the test item Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C) on the aquatic plant *Lemna minor*, after 7 days of exposure under semi-static conditions.

The cultures were exposed to the limit concentration of 100 mg test item/L, corresponding to 18.9 mg a.i./L, plus an untreated control group, to demonstrate that the test item has no inhibitory effect on the plant growth at the test concentration.

The analytical determination of the active ingredient content showed a mean recovery of 91.59% in the fresh samples and 97.65% in the aged samples. Accordingly, the assessment of the effects was based on the nominal concentrations of the test item and active ingredient.

After 7 days of exposure, no effects were observed in the treated cultures.

The following values of inhibition compared to the control were observed on the cultures exposed at 100 mg test item/L (equivalent to 18.9 mg a.i./L):

- Based on frond number: 1.19 % for growth rate; 3.19 % for yield
- Based on dry weight: 1.34 % for growth rate; 3.34 % for yield
- The EC10/20/50 values are > 100 mg/L (corresponding to 18.9 mg a.i./L)

No statistically significant difference between the control and the treated group was found.

- The NOEC is \geq 100 mg/L (corresponding to 18.9 mg a.i./L)

The validity criterion of OECD 221 (2006) was fulfilled, thus the study is valid.

I. MATERIAL AND METHODS

A. MATERIALS

1. Test Material:	Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C)
Description:	Off-white liquid
Lot/batch, density:	3188-220519-01 Density: 1.09 g/mL
Concentration/Purity:	Chlorantraniliprole 18.9% (206 g/L)
Stability of test compound:	Stability: Not stated Expiry date: 22 nd May 2021
2. Vehicle and/or control:	SIS medium
3. Test animals (Species):	<i>Lemna minor</i>
Age or pre-culture:	Not stated
Source:	In-house culturing at the Test Facility, originating from Botanical Institute of the University of Jena (Germany)
Acclimation period:	Not stated
Feeding:	-
Culture medium:	SIS medium
Test vessel:	300 mL glass vessel with 100 mL of solution

Initial culture:	Colonies with a total of 12 fronds
Number of replicates:	For treated and untreated group, six replicates were prepared
Untreated variant:	SIS medium
Reference substance:	A growth inhibition test is performed twice a year using 3,5-dichlorophenol as toxic reference item

4. Environmental conditions during testing

Temperature	22.6 - 23.2 °C
pH	6.40 - 6.88
Hardness:	Not stated
Oxygen-concentration [mg/L]	Not stated
Aeration	Not stated
Photoperiod	Continuous illumination
Light intensity	7135 - 7800 Lux

B. STUDY DESIGN AND METHODS

- In-life dates:** 19th February - 17th March 2020
- Experimental design:**

The study was performed as limit test, with one test item concentration (100 mg/L). The test concentration was chosen based on non-GLP screening test results. The test was carried out with six replicates for the test concentration and six replicates for the un-treated control group. The test duration is of 7 days and the test was performed under semi-static condition (the renewal of the test solutions was performed at days 2 and 5). Colonies with a total of 12 fronds were transferred from the inoculum culture to each test vessel, for the treated and untreated groups.

Test concentrations: 0 and 100.00 mg test item/L

Chemical analysis and validation: The analytical determination of the active ingredient content was performed by UHPLC-MS/MS. The analytical method was validated according to SANCO/3029/99 rev.4 in a separate GLP study (BT207/19). The analytical determination of the active ingredient content showed a mean recovery of 91.59 % in the fresh samples and 97.65 % in the aged samples. Accordingly, the results are presented based on nominal concentrations of test item and active ingredient.

Test duration: 7 days
- Observations:**

The frond number in the test vessels was counted at the start (T0) and at the end (T7) of the test and on two occasions during the 7 days exposure period (at medium renewals after 2 and 5 days of exposure: T2 and T5). Changes in plant development, e.g. in frond size, appearance, indication of chlorosis, changes in root appearance were observed. Dry weight was measured at the start (in representative samples) and at the end of the test.

Analytical determinations were evaluated at the start of the test from fresh test solutions (T0), at each renewal in the freshly prepared and in the spent test solutions (T2 and T5), as well as at the end of the test from the spent test solutions (T7); the spent samples were collected after the pooling of the replicates.

4. Statistics:

Student-t test (after testing normal distribution with Shapiro Wilk's test and variance homogeneity with Levene's test) was performed to compare control and treated group.

II. RESULTS AND DISCUSSION

A. Analytical results

The analytical determination of the content of active ingredient Chlorantraniliprole in the test solutions showed recovery values within the range 80-120% of the nominal values (with a mean recovery of 91.59% in the fresh samples and 97.65 % in the aged samples), therefore the data evaluation was performed using the nominal concentrations.

Measured concentration and recoveries of the a.s. Chlorantraniliprole during the study

Code		Nominal a.i. conc. (mg/L)	Mean measured a.i. conc. (mg/L)	Mean measured a.i. conc. (mg/L) for treatment group [arithmetic mean]	Mean Recovery (%)	Mean Recovery (%) for treatment group
C1	C1 T0	18,90	16,63	17,88	88,01	94,62
	C1 T2S		18,87		99,82	
	C1 T2F		16,10		85,19	
	C1 T5S		18,67		98,77	
	C1 T5F		19,20		101,59	
	C1 T7		17,83		94,36	
			Mean Recovery Fresh (%)		91,59	
			Mean Recovery Spent (%)		97,65	

B. Biological results

The inhibition of growth was estimated in percent based on growth rate (Ir) and yield (Iy), elaborated with the data of frond number and dry weight compared to the control, and is reported in Table A 2.2.1-3.

Table A 2.2.1-08: Inhibition of growth of *Lemna minor* based on growth rate (Ir) and yield (Iy) in percent after 7 d-exposure to test item, in relation to the control

Code	Nominal test item conc. [mg/L]	Nominal Chlorantraniliprole conc. [mg a.i./L]	Frond number		Dry weight	
			%Ir	%Iy	%Ir	%Iy
C1	100	18.9	1.19	3.19	1.34	3.34

C. Validity criteria

According to OECD 221 (2006), the test results are valid if in the control cultures the doubling time of frond number is less than 2.5 days (60 h), corresponding to approximately a seven-fold increase in seven days and an average specific growth rate of 0.275 d⁻¹. The doubling time of frond number was of 2.06 days, the factor of frond number increase was of 10.57 days and the a specific growth rate of 0.337 was achieved.

All the validity criterion was met.

III. CONCLUSION

The growth inhibition test was performed as limit test, in order to demonstrate that the test item has no inhibitory effect on the plant vegetative growth at the concentration of 100 mg/L.

After 7 days of exposure, no effects were observed in the treated cultures.

The following values of inhibition were observed on the cultures exposed at 100 mg test item/L (equivalent to 18.9 mg a.i./L):

- Based on frond number: 1.19 % for growth rate; 3.19 % for yield
- Based on dry weight: 1.34 % for growth rate; 3.34 % for yield
- No inhibition rates ≥ 10 % occurred, therefore the $EC_{10/20/50}$ values are > 100 mg/L (corresponding to 18.9 mg a.i./L)

No statistically significant difference between control and treated group was found.

- The NOEC is ≥ 100 mg/L (corresponding to 18.9 mg a.i./L)

The validity criterion of OECD 221 (2006) was fulfilled, thus the study is valid.

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

No additional data.

A 2.2.3 KCP 10.2.3 Further testing on aquatic organisms

No additional data.

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 2.3.1.1.1.1 Study 1: Acute oral and contact toxicity to honey bees

The following bee acute oral and contact toxicity study performed on Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C) is provided in support of the assessment.

Comments of zRMS:	<p>The study was conducted in line with OECD 213 with minor deviations. The humidity was in range from 63.7 – 71.9% (recommended value 50-70%) As control performance met the guideline validity criteria, these short-term deviations are considered to have no impact on the validity of the study. All the validity criteria were met and the study is considered acceptable with the following endpoints relevant for the risk assessment:</p> <p>The contact LD_{50} (48 h) > 1000 μg ADM.0900.I.1.C/bee The oral LD_{50} (48 h) > 1000 μg ADM.0900.I.1.C /bee</p>
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Reference: KCP 10.3.1.1/01

Report Acute oral and acute contact toxicity effects of ADM.0900.I.1.C to adult worker honeybees *Apis mellifera* L., Laboratory Test. Colli, M., 2019a. Report n.: BT139/19.

Guideline(s): OECD 213 and 2014 (1998)

Deviations: The no. of honeybees treated in the control groups (water treated and wetting agent treated groups) and in the test item groups was 50 instead of 30, and the replicates are 5 instead of 3. No effects on the outcome of the study was caused

because this is the requirement for the limit test (a typo was made in the Study plan, but the experimental phase was carried out following the procedure).

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study) -

Executive Summary

Young *Apis mellifera* L. worker honeybees were randomly collected from adequately fed, healthy diseases-free and queen right beehive (no. 6), treated with no pesticides. The bees were fed with a water sucrose solution 50 % w/v.

Both oral and contact tests provided similar results. The product did not cause adverse (oral and topic) effects on honeybees when administered at the dose of 1000.00 µg prod./bee (equivalent to 189.00 µg a.s./bee).

The NOED after 24 and 48 hours was ≥ 1000.00 µg prod./bee, equivalent to 189.00 µg a.s./bee.

The contact LD₅₀ after 24 and 48 hours was ≥ 1000.00 µg prod./bee, equivalent to 189.00 µg a.s./bee.

Regarding the oral test, the bees consumed all the treated diet within the first 4 hours of the test.

I. MATERIAL AND METHODS

A. MATERIALS

- 1. Test Material:**
Description: Chlorantraniliprole 200 SC (ADM.0900.I.1.C)
Lot/batch #: Off-white liquid
3188-220519-01
Concentration/Purity: 206.0 g/L – 18.9%
Density: 1.09 g/mL
Stability of test compound: Stability: Not stated
Expiry date: 22nd May 2021
- 2. Vehicle and/or positive control:**
Oral test: aqueous sucrose solution (50%, w/v)
Contact test: deionised water and wetting agent (Triton X-100) was used at the concentration of 0.5 % v/v
- 3. Test animals (Species)** *Apis mellifera* L.
Age at test start: Young adult workers
Source: Healthy colonies (hive no. 6) maintained at BioTecnologie BT S.r.l.
Acclimation period: Not reported
Feeding:
Oral test:
The bees were starved for 2 hours before the treatment. A volume of 200 µL of treated diet (20 µL/bee) was administered to each cage inside a syringe without tip. The overall exposure lasted 4 hours until the treated diet was completely consumed. New feeders with untreated diet (ad libitum) were given to the bees after the treatment syringes were removed
Contact test:
During the test phase, the bees were supplied *ad libitum* with 50% (w/v) aqueous sucrose solution.

Test cages:	Disposable and well-ventilated cardboard cages with an internal volume not lower than 200 cm ³ were used. Each cage was equipped with frontal transparent acetate lid, for a suitable observation of the bees from outside. The upper side of the cage had two holes for inserting the feeder
Number of study organisms:	10 per test unit
Number of animals per test vessel:	10 bees per cage per treatment group
Number of replicates:	5 replicates
Control (untreated variant):	<u>Oral test:</u> Untreated 50 % (w/v) sucrose solution <u>Contact test:</u> Two control groups, with and without wetting agent (Triton X-100) and deionised water
Reference standard:	Dimethoate
4. Environmental conditions during testing	
Temperature:	25.5 - 25.9°C
Relative humidity:	63.7 – 71.9%
Photoperiod:	Constant Darkness (except during observation)

B. STUDY DESIGN AND METHODS:

- 1. In-life dates:** 17th September to 19th September 2019
- 2. Experimental design**

Concentrations used during the experiment for the acute oral test was 1000 µg prod./bee. For the acute contact test were 0.17, 0.38 and 0.84 µg prod./bee. Disposable and well-ventilated cardboard cages with an internal volume not lower than 200 cm³ were used. Each cage was equipped with frontal transparent acetate lid, for a suitable observation of the bees from outside. The upper side of the cage had two holes for inserting the feeder: a syringe filled of sucrose solution (50 % w/v sucrose/water) was inserted in one hole, a stopper obstructs the other hole. Each cage contained 10 bees and was uniquely identified with the study number, date of start of the test, replicate code and operator's signature.

Acute oral test

Adult worker honeybees were exposed to a single dose of the test item dispersed in a 50 % (w/v) aqueous sucrose solution for 4 hours. A water control group and three reference item groups were tested in parallel to the limit dose rate. The honeybees were then fed with untreated diet ad libitum. The mortality was recorded at 4, 24 and 48 hours after treatment and compared with the un-treated control. The test was conducted in the laboratory according to OECD Guideline 213 (1998).

Acute contact test

Adult worker honeybees were exposed to a single dose of the test item dissolved in deionized water, by direct application to the thorax (droplets). The wetting agent (Triton X-100) was used at the concentration of 0.5 % v/v in the preparation. Two water control groups (with and without wetting agent) and three reference item groups were tested in parallel to the limit dose rate. The mortality was recorded at 4, 24 and 48 hours after treatment and compared with the untreated control. The test was conducted in the laboratory according to OECD Guideline 214 (1998).

Test concentrations:

Oral test: 1000 µg product/bee
Contact test: 0.17, 0.38 and 0.84 µg prod./bee.

Test duration:

48 h

3. Observations:

Assessments on mortality and behavioural abnormalities were performed at 4, 24 and 48 hours after treatment started (4h AT, 24 h AT, 48 h AT).

4. Statistics:

The statistical significance of differences ($p \leq 0.05$) between the control group(s) and the test item groups were evaluated with the Step-down Cochran-Armitage Test Procedure and the Fisher's Exact Binomial Test. The two control groups of the contact test were compared with a Fisher's Exact Binomial Test. The Probit analyses was used to calculate the LD₅₀ values of the reference item. The software ToxRat Pro 3.3.0 was used to perform the statistics.

II. RESULTS AND DISCUSSION

The mortality of each replicate was calculated in percentage, comparing the number of dead bees to those introduced at the beginning. The mean value of the treated group(s) was compared to the mean mortality of each control group using the Abbott's formula (1925) modified by Schneider-Orelli (1947):

$$CM \% = ((Mt - Mc) / (100 - Mc)) \times 100$$

CM = mean corrected mortality (%)

Mc = mean mortality in the control group (%)

Mt = mean mortality in the test item group (%)

A. Oral toxicity test

The treated solution (200 µL/cage) was completely consumed within the first 4 hours of administration. No behavioural ab-normalities were observed.

Table A 2.3.1-01 Acute oral toxicity test: Mean mortality (M) and corrected mean mortality (CM)

Groups	Doses		4h AT		24h AT		48h AT	
	[µg prod./bee]	[µg a.s./bee]	M [%]	CM [%]	M	CM [%]	M [%]	CM [%]
Control	-	-	0	-	2	-	4	-
T1	1000.00	189.00	0	0	2	0	4	0

AT = After treatment

No significant effects on mortality were shown at the end of the test. The NOED was 1000.00 µg prod./bee 48 hours, corresponding to 189.00 µg a.s./bee. The LD₅₀ was greater than 1000.00 µg prod./bee after 48 hours, corresponding to 189.00 µg a.s./bee.

Table A 2.3.1-02 Acute oral toxicity test: Mean mortality (M) in the Reference item groups

Groups	Doses		4h AT	24h AT	48h AT
	[µg prod./bee]	[µg a.s./bee]	M [%]	M [%]	M [%]
R1	0.17	Dimethoate: 0.07	0	6.67	10
R2	0.38	Dimethoate: 0.16	20	86.67	93.33
R3	0.84	Dimethoate: 0.35	33.33	100	100

The oral LD₅₀ for the reference item at 24 hours was 0.12 µg a.s./bee (95% Confidence limits: 0.10 – 0.13 µg a.s./bee).

B. Contact toxicity test

Table A 2.3.1-03 Acute contact toxicity test: Mean mortality (M) and corrected mean mortality (CM)

Groups	Doses		4h AT		24h AT		48h AT	
	[µg prod./bee]	[µg a.s./bee]	M [%]	CM [%]	M [%]	CM [%]	M [%]	CM [%]
Control	-	-	0	-	4	-	6	-
Wetting Agent Control	-	-	0	-	0	-	4	-
T1	1000.00	189.00	2	0	4	2.04	6	1.05

AT = After treatment

Since no significant difference between the two control groups was evidenced, the two controls were pooled together to compare to the treated group. No significant effects on mortality was evidenced at the end of the tests. The NOED was 1000.00 µg prod./bee after 48 hours, corresponding to 189.00 µg a.s./bee. The LD₅₀ was greater than 1000.00 µg prod./bee after 48 hours, corresponding to 189.00 µg a.s./bee.

Table A 2.3.1-04 Acute contact toxicity test: Mean mortality (M) in the Reference item groups

Groups	Doses		4h AT	24h AT	48h AT
	[µg prod./bee]	[µg a.s./bee]	%M [%]	%M [%]	%M [%]
R1	0.17	Dimethoate: 0.07	0	3.33	6.67
R2	0.38	Dimethoate: 0.16	6.67	76.67	76.67
R3	0.84	Dimethoate: 0.35	16.67	100	100

The contact LD₅₀ for the reference item at 24 hours was 0.13 µg a.s./bee (95% Confidence limits: 0.11 – 0.15 µg a.s./bee).

C. Validity of the tests

Acute oral test:

- Required mortality in the control: ≤ 10%; actual = 4%
- Required 24-hour LD₅₀ of the reference item: 0.10 - 0.35 µg a.s./bee, actual: 0.12 µg a.s./bee

Acute contact test:

- Required mortality in the control: ≤ 10%; actual = 6%
- Required 24-hour LD₅₀ of the reference item: 0.10 - 0.30 µg a.s./bee; actual: 0.13 µg a.s./bee

III. CONCLUSION

Acute oral test

The effects of the oral administration of the test item ADM.0900.I.1.C on adults of honeybees (*Apis mellifera* L.), were tested in a GLP compliant laboratory study as a limit test.

The product did not cause adverse oral effects on honeybees when administered at the limit dose of 1000.00 µg prod./bee (equivalent to 189.00 µg a.s./bee).

The NOED after 24 and 48 hours was ≥ 1000.00 µg prod./bee, equivalent to 189.00 µg a.s./bee.

The oral LD₅₀ after 24 and 48 hours was greater than ≥ 1000.00 µg prod./bee, equivalent to 189.00 µg a.s./bee.

The validity criteria with regards to control mortality and toxicity on the reference item were met.

Acute contact test

The topic effects of the test item ADM.0900.I.1.C on adults of honeybees (*Apis mellifera* L.), were tested in a GLP compliant laboratory study as a limit test.

The product did not cause adverse effects on honeybees treated with the dose of 1000.00 µg prod./bee (equivalent to 189.00 µg a.s./bee).

The NOED after 24 and 48 hours was ≥ 1000.00 µg prod./bee, equivalent to 189.00 µg a.s./bee.

The contact LD₅₀ after 24 and 48 hours was greater than ≥ 1000.00 µg prod./bee, equivalent to 189.00 µg a.s./bee.

The validity criteria with regards to control mortality and toxicity on the reference item were met.

A 2.3.1.1.2 KCP 10.3.1.1.2 Acute contact toxicity to bees

Included in Section A 2.3.1.1.1

A 2.3.1.2 KCP 10.3.1.2 Chronic toxicity to bees

A 2.3.1.2.1 Study 1: Chronic oral effects to honey bees

The following bee chronic oral toxicity study performed on Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C) is provided in support of the assessment.

Comments of zRMS:	<p>The study was conducted in line with OECD 245 (2017) with no deviation.</p> <p>The concentrations of the active ingredients in the applied test item feeding solutions were within the required range of ± 20 % of the nominal concentrations.</p> <p>All the validity criteria were met and the study is considered acceptable with the following endpoints relevant for the risk assessment:</p> <p>LDD₅₀ = 115.71 µg product/bee/day NOEDD = 37.86 µg product/bee/day</p> <p>LC₅₀ = 5911.88 mg prod./kg food NOEC = 1280.00 mg prod./kg food</p>
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Reference:	KCP 10.3.1.2/01
Report	Chronic oral effects of ADM.0900.I.1.C to adult worker honeybees <i>Apis mellifera</i> L., 10-day feeding laboratory test. Colli, M., 2022. Report n°: BT140/19
Guideline(s):	OECD 245 (2017)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	-

Executive Summary

The Chronic oral effects of the product ADM.0900.I.1.C on adult worker honeybees *Apis mellifera* L. were tested in a laboratory study, according to GLP regulations. The test item was dissolved in water and the obtained stock solutions were used to prepare the feeding solutions with 50% (w/v) aqueous sucrose solution. Both the water and the sugar solutions of the test item were prepared freshly every day and administered to the bees, for a period of 10 days (from Day 0 to Day 9 of the test). The reference item Dimethoate was tested at 1.00 mg a.s./kg diet.

Mortality and sub-lethal effects were recorded every 24 ± 2 h, from Day 1 to Day 10 of the test. The amount of feeding solution consumed was determined by weighing the feeders before and after each 24-h period of feeding.

In terms of dose related to the mean food consumption/bee/day, the NOEDD was determined to be 37.86 µg prod./bee/day (equivalent to 7.19 µg a.s./bee/day), and the LDD₅₀ was 115.71 (CL: 103.06 – 127.62) µg prod./bee/day, equivalent to 21.87 µg a.s./bee/day.

In terms of concentration, the NOEC was 1280.00 mg prod./kg diet (equivalent to 241.9 mg a.s./kg diet) and the LC₅₀ was 5911.88 (CL: 4838.68 – 7076.88) mg prod./kg diet, equivalent to 1117.35 (CL: 914.51 – 1337.53) mg a.s./kg diet.

The analytical results demonstrate that the active substance content in the feeding solutions (at the lowest and highest concentrations) was in the range of ± 20% of nominal concentrations, so was demonstrated that the bees were treated with the corresponding concentrations.

All validity criteria was met (6.67% of mortality in control (<15%), and 100% mortality in the reference item treatment).

I. MATERIAL AND METHODS

A. MATERIALS

- | | |
|---|---|
| 1. Test Material: | Chlorantraniliprole 200 SC (ADM.0900.I.1.C) |
| Description: | Off-white liquid |
| Lot/batch #: | 3188-220519-01 |
| Concentration/Purity: | 206.0 g/L – 18.9% |
| | Density: 1.09 g/mL |
| Stability of test compound: | Stability: Not stated |
| | Expiry date: 22 nd May 2021 |
| 2. Vehicle and/or positive control: | Deionized water |
| 3. Test animals (Species) | <i>Apis mellifera</i> L. |
| Age at test start: | Adult workers (maximum 2 days old) |
| Source: | Healthy colonies (hive no. 11 and 12) maintained at Bio-Tecnologie BT S.r.l. |
| Acclimation period: | 24 hours |
| Feeding: | 50% (w/v) aqueous sucrose solution |
| Test cages: | Disposable and well-ventilated cardboard cages with an internal volume not lower than 200 cm ³ were used. Each cage was equipped with frontal transparent acetate lid, for a suitable observation of the bees from outside. The upper side of the cage had two holes for inserting the feeder: the syringe filled of sucrose solution (50% w/v sucrose/water) was inserted in one hole, a stopper obstructed the other hole. |
| Number of study organisms: | 30 bees per treatment |
| Number of animals per test vessel: | 10 bees per cage per treatment group |
| Number of replicates: | 3 replicates |
| Control (untreated variant): | Deionized water |
| Reference standard: | Dimethoate |
| 4. Environmental conditions during testing | |
| Temperature: | 29.0 - 33.8°C |
| Relative humidity: | 42.6 - 75.9% |
| Photoperiod: | 24 hours darkness (except during observations) |

B. STUDY DESIGN AND METHODS:

- | | |
|--------------------------|---|
| 1. In-life dates: | 28 th August – 23 rd September 2019 |
|--------------------------|---|

2. Experimental design

Test concentrations:

Test duration:

3. Observations:

4. Statistics:

The test item was dissolved in water and the obtained stock solutions were used to prepare the feeding solutions with 50% (w/v) aqueous sucrose solution. Both the water and the sugar solutions of the test item were prepared freshly every day and administered to the bees, for a period of 10 days (from Day 0 to Day 9 of the test). The reference item Dimethoate was tested at 1.00 mg a.s./kg diet.

0, 81.9, 204.8, 512.0, 1280.0, 3200.0 and 8000.0 mg prod./kg f.s.. Equivalent to 0, 15.5, 38.7, 96.8, 241.9, 604.8 and 1512.0 mg of a.s./kg f.s.

10 days

Mortality and sub-lethal effects were recorded every 24 ± 2 h, from Day 1 to Day 10 of the test. The amount of feeding solution consumed was determined by weighing the feeders before and after each 24-h period of feeding.

The software ToxRatPro 3.3.0 was used for the statistical analysis.

II. RESULTS AND DISCUSSION

A. Food uptake

Table A 2.3.1-05 Summarized mean food uptake over the course of the study

Groups	Concentrations	Mean uptake*	
		Feeding solution	Test item
	[mg test item/kg diet]	[mg diet/bee/day]	[µg test item/bee/day]
Control	0.00	30.89	0.00
Test item (T1)	81.9	31.25	2.56
Test item (T2)	204.8	25.26	5.17
Test item (T3)	512.0	27.50	14.08
Test item (T4)	1280.0	29.58	37.86
Test item (T5)	3200.0	28.56	91.38
Test item (T6)	8000.0	16.64	133.09
Reference item	1.00	23.20	0.02

* adjusted for evaporation from the feeders.

B. Mortality

Table A 2.3.1-06 Mean Mortality (%M) and Mean Corrected Mortality (%CM) at the end of the test (on day 10)

Groups	Concentrations	Doses	Cumulative Mortality			
	[mg test item/kg diet]	[µg test item/bee/day]	%M	SD	%CM	S ¹
Control	0.00	0.00	6.67	0.6	---	n.a.
Test item (T1)	81.9	2.56	3.33	0.6	0.00	-
Test item (T2)	204.8	5.36	0.00	0.0	0.00	-
Test item (T3)	512.0	14.08	6.67	0.6	0.00	-
Test item (T4)	1280.0	37.86	10.00	0.0	3.57	-
Test item (T5)	3200.0	91.38	20.00	0.0	14.29	+
Test item (T6)	8000.0	133.09	76.67	1.5	75.00	+
Reference item	1.00	0.02	100.00	0.0	100.00	n.a.

SD = Standard Deviation; S = statistical significance; n/a = not applicable; + = significant; - = not-significant; ¹Step-down Cochran-Armitage Test ($\alpha = 0.05$, one-sided greater)

C. Validity of the tests

The test was considered valid because the following criteria were satisfied:

- The average mortality for the control did not exceed 15% at the end of the test – actual value 6.67%
- The average mortality in the reference item treatment was $\geq 50\%$ at the end of the test – actual value 100%.

III. CONCLUSION

The effects of ADM.0900.I.1.C to adult worker honeybees (*Apis mellifera* L.) were assessed in a 10-day oral chronic toxicity test.

In terms of dose related to the mean food consumption/bee/day, the NOEDD was determined to be 37.86 µg prod./bee/day (equivalent to 7.19 µg a.s./bee/day), and the LDD_x values with 95% Confidence limits (CL) resulted as following:

		ADM.0900.I.1.C	Chlorantraniliprole
Critical dose [µg/bee/day]	LDD10	73.62 (CL: 46.77 – 87.57)	13.91 (CL: 8.84 – 16.55)
	LDD20	88.15 (CL: 65.24 – 99.91)	16.66 (CL: 12.33 – 18.88)
	LDD50	115.71 (CL: 103.06 – 127.62)	21.87 (CL: 19.48 – 24.12)

CL = 95% confidence limits

In terms of concentration, the NOEC was 1280.00 mg prod./kg diet (equivalent to 241.9 mg a.s./kg diet) and the LC_x values with 95% Confidence limits (CL) resulted as following:

		ADM.0900.I.1.C	Chlorantraniliprole
Critical concentration [mg/kg diet]	LC10	2563.02 (CL: 1455.47 – 3410.55)	484.41 (CL: 275.08 – 644.59)
	LC20	3575.53 (CL: 2411.21 – 4443.27)	675.78 (CL: 455.72 – 839.78)
	LC50	5911.88 (CL: 4838.68 – 7076.88)	1117.35 (CL: 914.51 – 1337.53)

CL = 95% confidence limits; n.d. = not determined.

The analytical results demonstrate that the active substance content in the feeding solutions (at the lowest and highest concentrations) was in the range of $\pm 20\%$ of nominal concentrations, so was demonstrated that the bees were treated with the corresponding concentrations.

The validity criteria with regards to control mortality and toxicity on the reference item were met.

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

The following bee chronic larval toxicity study performed on Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C) is provided in support of the assessment.

Comments of zRMS:	<p>The study was conducted in line with OECD 239 with no deviations.</p> <p>All the validity criteria were met and the study is considered acceptable with the following endpoints relevant for the risk assessment:</p> <p>EC₅₀ (D22) > 10.26 mg product /kg diet NOEC = 9.74 mg product/kg diet</p> <p>ED₅₀ > 4.12 µg product/larva NOED (D22) = 1.50 µg product/larva</p>
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Reference:	KCP 10.3.1.3/01
Report	Effects of ADM.0900.I.1.C on honeybees (<i>Apis mellifera</i> L.) 22-day larval toxicity test with repeated exposure. Colli, M., 2022. Report n°: BT141/19
Guideline(s):	OECD 239 (2016)
Deviations:	<p><u>Deviation description:</u> the temperature and the humidity were out of the respective ranges for more than two hours.</p> <p>Period of occurrence: 28th August 2019 – minimum value of temperature 33.3°C 02nd September 2019 - minimum value of temperature 33.3°C.</p> <p>From 02nd to 05th September the humidity was higher than the high range of 85% (maximum value of humidity 90.1%).</p> <p><u>Impact on the study:</u> none, because sometimes this occurrence is inevitable. Even if the desiccator was opened and closed immediately afterwards, the system needs time to recover the proper climatic condition because the desiccator is a hermetically sealed system where the humidity depends on a saturated salt solution and the temperature inside the desiccator depends on the heat exchange through the walls. Infact the historical data of the facility, even if the study showed often these deviations, showed a normal development of the honeybees.</p>
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	-

Executive Summary

The effects on honeybees' larvae following repeated exposure of the test item ADM.0900.I.1.C, were tested in a laboratory study over a period of 22 days according to GLP regulations. Three old da larvae of *Apis mellifera* L. were used during the test.

The test item was dissolved in ultrapure water in order to get the highest stock solution. The stock solutions were mixed into the diet in a range of five increasing concentrations and administered daily to the larvae at a constant concentration, from day 3 (D3) to 6 (D6) of the test. Three replicates of 12 larvae each were prepared for each experimental group. The reference item Dimethoate was dissolved in deionized water and simultaneously tested at a single concentration (equivalent to a cumulative dose of 7.39 µg a.s./larva).

Assessments on mortality and any developmental/behavioral abnormality were performed from D4 to D8 and on D15 and on D22. The pupal mortality and the adults' emergence rate on D22 were also assessed.

The validity criteria with regards to control larval mortality on D8, control adults' emergence on D22 and toxicity on the reference item were met.

Regarding the effects on larvae on D8 (developmental period), the test item ADM.0900.I.1.C caused statistically significant mortality starting from the dose of 4.50 µg test item/larva. Therefore, the NOED for larvae on D8 was determined to be 1.50 µg prod./larva/developmental period (corresponding to 0.28 µg a.s./larva/developmental period) equivalent to 9.74 mg prod./kg diet (corresponding to 1.84 mg a.s./kg diet).

Regarding the effects on adult emergence on D22, the test item ADM.0900.I.1.C caused statistically significant reduction in emergence rate at each tested dose except for the doses of 0.50 and 1.50 µg prod./larva. The NOED and the NOEC for adult emergence rate were determined to be 1.50 µg prod./larva (corresponding to 0.28 µg a.s./larva) and 9.74 mg prod./kg diet (corresponding to 1.84 mg a.s./kg diet) respectively.

The analysis of the stock solutions (at lowest and highest concentration prepared on D3, D4, D5 and D6) used to treat the diets administered to the larvae showed that the test item content was in the range of ± 20%

of nominal concentrations, so was demonstrated that the larvae were treated with the corresponding dose of test item and the endpoints were calculated on the basis of the nominal doses of test item.

I. MATERIAL AND METHODS

A. MATERIALS

- 1. Test Material:** Chlorantraniliprole 200 SC (ADM.0900.I.1.C)
Description: Off-white liquid
Lot/batch #: 3188-220519-01
Concentration/Purity: 206.0 g/L – 18.9%
Density: 1.09 g/mL
Stability of test compound: Stability: Not stated
Expiry date: 22nd May 2021
- 2. Vehicle and/or positive control:** Deionized water
- 3. Test animals (Species)** *Apis mellifera* L.
Age at test start: 3 days old larvae (D3)
Source: Healthy colony maintained at BioTecnologie BT S.r.l.
Acclimation period: Not stated
Feeding: Dependent on developmental stage.
 - Diet A (D1): 50% weight of fresh royal jelly + 50% weight of an aqueous solution containing 2% weight of yeast extract, 12% weight of glucose and 12% weight of fructose.
 - Diet B (D3): 50% weight of fresh royal jelly + 50% weight of an aqueous solution containing 3% weight of yeast extract, 15% weight of glucose and 15% weight of fructose.
 - Diet C (from D4 to D6): 50% weight of fresh royal jelly + 50% weight of an aqueous solution containing 4% weight of yeast extract, 18% weight of glucose and 18% weight of fructose.
- Test cages:** The larvae were reared in crystal polystyrene grafting cells with an internal diameter of 9 mm and a depth of 8 mm.
- Number of study organisms:** 36 larvae per treatment
- Number of animals per test vessel:** 12 larvae per cage per treatment group
- Number of replicates:** 3 replicates
- Control (untreated variant):** Ultrapure water
- Reference standard:** Dimethoate
- 4. Environmental conditions during testing**
Temperature: 34.0 – 35.0 °C
Relative humidity: range from D1 to D8 = 90.0 – 100.0% (average measured 96.2%), range from D8 to D15: 75.0 - 85.0% (average measured 84.6%), range from D15 to D22: 50.0 - 80.0% (average measured 64.6%)
Photoperiod: 24 hours darkness (except during observations)

B. STUDY DESIGN AND METHODS:

- 1. In-life dates:** 28th August – 20th September 2019
- 2. Experimental design**
The test item was dissolved in ultrapure water in order to get the highest stock solution (S5). The other stock solutions (from S4 to S1) were obtained by sequential dilution. The stock solutions were mixed into the diet in a range of five increasing concentrations and administered daily to the larvae at a constant concentration, from day 3 (D3) to 6 (D6) of the test. Three replicates of 12 larvae each were prepared for each experimental group. The reference item

Test concentrations:

Dimethoate was dissolved in deionized water and simultaneously tested at a single concentration (equivalent to a cumulative dose of 7.39 µg a.s./larva).
0, 3.25, 9.74, 29.22, 87.66 and 262.99 mg prod./kg diet. 0, 0.50, 1.50, 4.50, 13.50, 40.50 µg prod./larva

Test duration:

22 days

3. Observations:

Assessments on mortality and any developmental/behavioral abnormality were performed from D4 to D8 and on D15 and on D22. The pupal mortality and the adults' emergence rate on D22 were also assessed.

4. Statistics:

The software ToxRatPro 3.3.0 was used for the statistical analysis.

II. RESULTS AND DISCUSSION

Table A 2.3.1-07 Mortality and Corrected Mortality (CM) of larvae (on D8)

Treatment	Dose [µg prod./larva]	Concentration [mg prod./kg diet]	Larvae mortality on D8		
			Mean [%]	CM - Mean [%]	Sign.
Control	0.00	0.00	2.78	n.a.	n.a.
Test item (T1)	0.50	3.25	11.11	8.57	-
Test item (T2)	1.50	9.74	5.56	2.86	-
Test item (T3)	4.50	29.22	58.33	57.14	+
Test item (T4)	13.50	87.66	100.00	100.00	+
Test item (T5)	40.50	262.99	100.00	100.00	+

n.a. = not applicable

+ : significant; - : non-significant (Step-down Cochran-Armitage test - $\alpha = 0.05$, one-sided greater).

Table A 2.3.1-08 Pupal Mortality

Treatment	Dose [µg prod./larva]	Concentration [mg prod./kg diet]	Pupal mortality from D8 to D15*	Pupal mortality from D8 to D22**
			Mean [%]	Mean [%]
Control	0.00	0.00	2.86	11.43
Test item (T1)	0.50	3.25	0.00	6.25
Test item (T2)	1.50	9.74	5.88	11.76
Test item (T3)	4.50	29.22	6.67	13.33
Test item (T4)	13.50	87.66	0.00	0.00
Test item (T5)	40.50	262.99	0.00	0.00

*calculated in percentage comparing the number of dead pupae from D8 to D15 to the number of alive pupae on D8

**calculated in percentage comparing the number of dead pupae from D8 to D22 to the number of alive pupae on D8

Table A 2.3.1-09 Total mortality and corrected mortality (CM) from D3 to D22 and emergence on D22

Treatment	Dose [µg prod./larva]	Concentration [mg prod./kg diet]	Mortality (larvae + pupae) on D22			Adult emergence on D22	
			Mean [%]	CM - Mean [%]	Sign.	Mean [%]	Sign.
Control	0.00	0.00	13.89	n.a.	n.a.	86.11	n.a.
Test item (T1)	0.50	3.25	16.67	3.23	-	83.33	-
Test item (T2)	1.50	9.74	16.67	3.23	-	83.33	-
Test item (T3)	4.50	29.22	63.89	58.06	+	36.11	+
Test item (T4)	13.50	87.66	100.00	100.00	+	0.00	+
Test item (T5)	40.50	262.99	100.00	100.00	+	0.00	+

n.a. = not applicable

+ : significant; - : non-significant (Step-down Cochran-Armitage test - $\alpha = 0.05$, one-sided greater).

Table A 2.3.1-10 Reference item - mean mortality

Treatment	Dose [µg a.s./larva]	Concentration [mg a.s./kg diet]	Mortality on D8 Mean [%]
Reference item	7.39	48.00	100.00

C. Validity of the tests

The test was considered valid because the following criteria were satisfied:

- in the control plates the cumulative larval mortality from D3 to D8 was 2.78% (required: $\leq 15\%$);
- in the control plates the adult emergence rate on D22 was 86.11% (required: $\geq 70\%$);
- in the reference item group treated with Dimethoate larval mortality at D8 was 100% (required: $\geq 50\%$).

III. CONCLUSION

The effects of the test item ADM.0900.I.1.C on the larval development and subsequent adult emergence of honeybees (*Apis mellifera* L.), were tested in a GLP compliant laboratory study.

The validity criteria with regards to control larval mortality on D8, control adults' emergence on D22 and toxicity on the reference item were met.

Regarding the effects on larvae on D8 (developmental period), the test item ADM.0900.I.1.C caused statistically significant mortality starting from the dose of 4.50 µg test item/larva. Therefore, the NOED for larvae on D8 was determined to be 1.50 µg prod./larva/developmental period (corresponding to 0.28 µg a.s./larva/developmental period) equivalent to 9.74 mg prod./kg diet (corresponding to 1.84 mg a.s./kg diet). Regarding the effects on adult emergence on D22, the test item ADM.0900.I.1.C caused statistically significant reduction in emergence rate at each tested dose except for the doses of 0.50 and 1.50 µg prod./larva. The NOED and the NOEC for adult emergence rate were determined to be 1.50 µg prod./larva (corresponding to 0.28 µg a.s./larva) and 9.74 mg prod./kg diet (corresponding to 1.84 mg a.s./kg diet) respectively. The mortality data allowed the extrapolation of the ED/EC₁₀, ED/EC₂₀ and ED/EC₅₀.

Table A 2.3.1-11 Summary results for all endpoints in terms of formulated product (c.l.: confidence limits)

Critical dose [µg prod./larva]	Mortality D8	Emergence D22
ED ₁₀	1.30 (c.l. 95%: n.d. – 2.82)	1.70 (c.l. 95%: 0.89 – 2.28)
ED ₂₀	2.04 (c.l. 95%: n.d. – 3.96)	2.42 (c.l. 95%: 1.58 – 3.02)
ED ₅₀	4.03 (c.l. 95%: 0.52 – 13.78)	4.12 (c.l. 95%: 3.36 – 5.16)
NOED	1.50	1.50
Critical concentration [mg prod./kg diet]	Mortality D8	Emergence D22
ED ₁₀	8.47 (c.l. 95%: n.d. – 18.29)	11.02 (c.l. 95%: 5.76 – 14.83)
ED ₂₀	13.28 (c.l. 95%: n.d. – 25.73)	15.70 (c.l. 95%: 10.26 – 19.59)
ED ₅₀	26.17 (c.l. 95%: 3.39 – 89.30)	26.77 (c.l. 95%: 21.84 – 33.52)
NOEC	9.74	9.74

ED/ECx evaluated by Weibull analysis.

n.d. = not determined due to mathematical reason

Table A 2.3.1-12 Summary results for all endpoints in terms of Chlorantaniliprole (c.l.: confidence limits)

Critical dose [µg prod./larva]	Mortality D8	Emergence D22
ED ₁₀	0.25 (c.l. 95%: n.d. – 0.53)	0.32 (c.l. 95%: 0.17 – 0.43)
ED ₂₀	0.39 (c.l. 95%: n.d. – 0.75)	0.46 (c.l. 95%: 0.30 – 0.57)
ED ₅₀	0.76 (c.l. 95%: 0.10 – 2.60)	0.78 (c.l. 95%: 0.64 – 0.98)
NOED	0.28	0.28
Critical concentration [mg prod./kg diet]	Mortality D8	Emergence D22
ED ₁₀	1.60 (c.l. 95%: n.d. – 3.46)	2.08 (c.l. 95%: 1.09 – 2.80)

ED₂₀	2.51 (c.l. 95%: n.d. – 4.86)	2.97 (c.l. 95%: 1.94 – 3.70)
ED₅₀	4.74 (c.l. 95%: 0.64 – 16.88)	5.06 (c.l. 95%: 4.13 – 6.34)
NOEC	1.84	1.84

ED/ECx evaluated by Weibull analysis.

n.d. = not determined due to mathematical reason

The analysis of the stock solutions (at lowest and highest concentration prepared on D3, D4, D5 and D6) used to treat the diets administered to the larvae showed that the test item content was in the range of \pm 20% of nominal concentrations, so was demonstrated that the larvae were treated with the corresponding dose of test item and the endpoints were calculated on the basis of the nominal doses of test item.

A 2.3.1.4 KCP 10.3.1.4 Sub-lethal effects

No data.

A 2.3.1.5 KCP 10.3.1.5 Cage and tunnel tests

No additional data.

A 2.3.1.6 KCP 10.3.1.6 Field tests with honeybees

No additional data.

A 2.3.2 KCP 10.3.2 Effects on arthropods other than bees

A 2.3.2.1 KCP 10.3.2.1 Standard laboratory testing

A 2.3.2.1.1 Study 1: Standard laboratory testing (*Aphidius rhopalosiphi*)

The following extended laboratory study with *Aphidius rhopalosiphi* performed on Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C) was provided in support of the assessment.

Comments of zRMS:	<p>The study was conducted in line with the respective guideline IOBC/WPRS (Mead-Briggs et al. (2000) and Mead-Briggs et al. (2009)) with no deviations.</p> <p>All the validity criteria were met and the study is considered acceptable with the following endpoints relevant for the risk assessment:</p> <p>LR₅₀/ER₅₀> 423.3 g product/ha, equivalent to > 80.0 g a.s./ha</p>
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Reference:	KCP 10.3.2.1/01
Report	Effects of Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C) on the parasitic wasp <i>Aphidius rhopalosiphi</i> under Laboratory Conditions. Venturi, S. (2020). Report n.: BT145/19.
Guideline(s):	IOBC/WPRS (Mead-Briggs et al. (2000) and Mead-Briggs et al. (2009))
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	-

Executive Summary

The effects of the product Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C) on the survival and the reproduction of the aphid parasitoid *Aphidius rhopalosiphi* De Stefani-Perez (Hymenoptera: Bracoonidae) were tested in a laboratory study, according to GLP regulations.

The test was carried out on young adults (less than 48 hours old). A single application rate of test item of 423.3 g/ha (corresponding to 80.0 g/ha of the a.s.) was sprayed on glass plates. Deionized water and a dimethoate formulation were applied to prepare the negative and the positive control, respectively. Application volume was 200 L water/ha. The survival of the test organisms was evaluated during the first 48-hour period of exposure, then the parasitic (reproductive) capacity was evaluated by transfer of 15 randomly selected of the surviving females of the test item and control group to individual pots containing wheat seedlings infested with cereal aphids (*S. avenae*) for 24 hours. Thereafter the adult females were removed, and the number of infested aphids was assessed by counting the mummies after 12 days.

The conditions of the wasps were recorded at 2, 24 and 48 hours after exposure. The parasitized aphids were counted 12 days after the fecundity phase started. Behavioural abnormalities were also recorded. There was 10 (including a minimum of 5 females) wasps/replicate, 5 replicate per treatment. The wasps were fed ad libitum with a 1:3 v/v solution of honey-in-water via cotton plug of a small tube inserted in the test unit. The test organisms were exposed to the residues of the test item sprayed on two circular glass plates, assembled into cages – keeping the sprayed sides inside – with an aluminium frame after the sprayed layer had dried, approx. 1 h after application.

No statistically significant mortality was observed after 48 h of exposure to residues of the test item: the NOER value was ≥ 423.3 g test item/ha, equivalent to ≥ 80.0 g a.s./ha. The LR50 was estimated to be > 423.3 g test item/ha, equivalent to > 80.0 g a.s./ha. No statistically significant reduction in reproduction was found in the test item application rate when compared to the control: the NOER was ≥ 423.3 g of prod./ha, equivalent to ≥ 80.0 g a.s./ha. The ER50 was estimated to be > 423.3 g test item/ha, equivalent to > 80.0 g a.s./ha.

No behavioural abnormalities of the treated organisms were observed during the test. The validity criteria of the study were fulfilled.

I. MATERIAL AND METHODS

A. MATERIALS

- | | |
|------------------------------------|--|
| 1. Test Material: | Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C) |
| Description: | Off white liquid |
| Lot/batch #: | 3188-220519-01 |
| Concentration/Purity: | 18.9%; 206 g/L |
| | Density: 1.09 g/mL |
| Stability of test compound: | Stability: Not stated |
| | Expiry date: 22 nd May 2021 |
| 2. Vehicle and/or control: | Dimethoate |
| 3. Test animals (Species) | <i>Aphidius rhopalosiphi</i> |
| Source: | Biotechnologie BT S.r.l. internal breeding – Batch AR030220 |
| Age: | Not older than 48 hours |
| Number of test organisms: | Ten wasps per replicate |
| Number of replicates: | Five replicates per treatment |
| Food: | <u>Culture and mortality exposure phase:</u> water-honey solution (3:1 v/v), <i>ad libitum</i> . |
| | <u>Parasitisation phase:</u> honeydew from aphids (<i>Sitobion avenae</i>). |
| Acclimation | Not stated |

Test unit:

Exposure phase:

The test organisms were exposed to the residues of the test item sprayed on two circular glass plates, assembled into cages – keeping the sprayed sides inside – with an aluminium frame after the sprayed layer had dried, approx. 1 h after application.

Fecundity phase:

Pots containing 10-40 seedlings each, approx. 6-10 days old, infested with more than 100 cereal aphids (*S. avenae*), and were confined using clear Plexiglas cylinders covered with filter paper to allow ventilation.

Untreated variant:

Deionised water

Reference standard:

PERFEKTION TOP (Blue liquid)

Description

Emulsion Concentrate

Lot/Batch #

10222732A

Purity

Dimethoate 371.56 g/kg or 393.85 g/L

Stability

Stability: Not stated

Expiry date: January 2022

4. Environmental conditions

Temperature:

Mortality phase: 18.7–20.3°C

Parasitisation phase: 19.6–20.0°C

Mummies' maturation phase: 19.4–21.0°C

Relative humidity:

Mortality phase: 63.7–80.9%

Parasitisation phase: 64.9–69.1%

Mummies' maturation phase: Not recorded

Photoperiod

16 h light/8h dark

Light intensity:

Mortality phase: 938–948 lux

Parasitisation phase: 922–934 lux

Mummies' maturation phase: 16770–18810 lux

Ventilation

Four holes, covered with strips of fine mesh netting from the inner side, allowed the correct ventilation of the organisms preventing their escape

B. STUDY DESIGN AND METHODS:

1. In-life dates

18th February to 03rd March 2020.

2. Experimental design

A single application rate of test item of 423.3 g/ha (corresponding to 80.0 g/ha of the a.s. Chlorantraniliprole) was sprayed on glass plates. Deionized water and a dimethoate formulation were applied to prepare the negative and the positive control, respectively. Application volume was 200 L water/ha. The survival of the test organisms was evaluated during the first 48-hour period of exposure, then the parasitic (reproductive) capacity was evaluated by transfer of 15 randomly selected of the surviving females of the test item and control group to individual pots containing wheat seedlings infested with cereal aphids (*S. avenae*) for 24 hours. Thereafter the adult females were removed, and the number of infested aphids was assessed by counting the mummies after 12 days.

Test concentrations:

423.3 g test item/ha (80.0 g/ha of the a.s. Chlorantraniliprole), plus the control (deionized water). Reference item concentration was 0.32 mL test item/ha (0.12 g dimethoate/ha).

Test duration:

Exposure time: 48 h

3. Observations:

The conditions of the wasps were recorded at 2, 24 and 48 hours after exposure. The parasitized aphids were counted 12 days after the fecundity phase started. Behavioural abnormalities were also recorded.

4. Statistics: The software ToxRatPro ver. 3.3.0 was used.

II. RESULTS AND DISCUSSION

A. Mortality and Reproduction

Table A 2.3.2-01: Summary of mortality and reproductive performance results

Groups	Application rates (g/ha)		Mor-tality				Reproductive capacity after 12 days		
			After 24 hours		After 48 hours				
	As prod-uct	As a.s.	M%	CM%	M%	CM%	Mean no. of mummies/female	SD	R%
Control	0	0	0	n/a	0	n/a	50.67	23.06	n/a
T1	423.3	80.0	2.0	2.0	2.0	2.0	42.67	23.89	15.79
Ref. item	0.32	Dimethoate: 0.12	100	100	100	100	n/a		

M% = Mean Mortality; CM% = Corrected Mean Mortality; SD = Standard deviation; R% = Reduction in Reproduction compared to the control; n/a = not applicable.

No statistically significant mortality was observed after 48 h of exposure to residues of the test item: the NOER value was ≥ 423.3 g test item/ha, equivalent to ≥ 80.0 g a.s./ha. The LR₅₀ was estimated to be > 423.3 g test item/ha, equivalent to > 80.0 g a.s./ha.

No statistically significant reduction in reproduction was found in the test item application rate when compared to the control: the NOER was ≥ 423.3 g of prod./ha, equivalent to ≥ 80.0 g a.s./ha. The ER₅₀ was estimated to be > 423.3 g test item/ha, equivalent to > 80.0 g a.s./ha.

C. Validity criteria

According to IOBC/WSPR guidance, the test is considered valid because:

- in the control group the arithmetic mean mortality (dead and escaped individual) is 0%;
- in the control group the mean parasitisation is 50.67 aphid mummies per surviving female;
- in the control group no females failed to produce mummies;
- in the reference item group, the mean mortality (control corrected) is 100%.

III. CONCLUSION

The effects of the test item Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C) were evaluated on *Aphidius rhopalosiphii* in a GLP laboratory limit test following the IOBC/WPRS guidelines. No statistically significant effects on survival of the test organisms were shown at the test item application rate. According to the statistical analysis the NOER was ≥ 423.3 g test item/ha, equivalent to ≥ 80.0 g a.s./ha. The LR₅₀ value was estimated to be > 423.3 g test item/ha, equivalent to 80.0 g a.s./ha.

No significant adverse effects of Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C) were shown on the reproductive capacity of the test organisms at the test item application rate. According to the statistical analysis the NOER was ≥ 423.3 g test item/ha, equivalent to ≥ 80.0 g a.s./ha. The ER₅₀ value was estimated to be > 423.3 g test item/ha, equivalent to 80.0 g a.s./ha.

No behavioural abnormalities of the treated organisms were observed during the test. The validity criteria of the study were fulfilled.

A 2.3.2.1.2 Study 2: Standard laboratory testing (*Typhlodromus pyri*)

The following extended laboratory study with *Typhlodromus pyri* performed on Chlorantraniliprole 200 SC (prod-uct code ADM.0900.I.1.C) was provided in support of the assessment.

Comments of zRMS:	The study was conducted in line with the respective guideline with no deviations.
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	All the validity criteria were met and the study is considered acceptable with the following endpoints relevant for the risk assessment: LR ₅₀ /ER ₅₀ > 423.3 g product/ha, equivalent to > 80.0 g a.s./ha.
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Reference: KCP 10.3.2.1/02

Report Effects of Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C) on the predatory mite *Typhlodromus pyri* Scheuten (Acari: Phytoseiidae) under Laboratory Conditions. Venturi, S. (2020). Report n.: BT146/19.

Guideline(s): ESCORT I Guidance Document (Barrett K.L. et al., eds. 1994), the ESCORT 2 Guidance Document (Candolfi et al., eds. 2001), the IOBC/WPRS Guidelines (Mead-Briggs et al., 2000).

Deviations: No

GLP: Yes

Acceptability: Yes

Duplication -
(if vertebrate study)

Executive Summary

The effects of the product Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C) on the survival and the reproduction of the predatory mite *Typhlodromus pyri* Scheuten (Acari, Phytoseiidae) were tested in a laboratory study, according to GLP regulations

A single application rate of test item was sprayed on glass plates. Deionized water and a dimethoate formulation were applied to prepare the negative and the positive control, respectively. Application volume was 200 L water/ha. Five replicates per experimental group were prepared, each one with 20 protonymphs. The survival of mites was assessed 7 days after exposure. The number of surviving females and the number of laid and hatched eggs were recorded in three assessments during the reproduction phase, from day 7 to day 14.

No statistically significant mortality was observed after 7 days of exposure to residues of test item. The NOER was ≥ 423.3 g test item/ha, equivalent to ≥ 80.0 g a.s./ha and the L(E)R₅₀ value was estimated to be > 423.3 g test item/ha, equivalent to > 80.0 g a.s./ha.

I. MATERIAL AND METHODS

A. MATERIALS

1. **Test Material:** Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C)
 - Description:** Off white liquid
 - Lot/batch #:** 3188-220519-01
 - Concentration/Purity:** 18.9%; 206 g/L
Density: 1.09 g/mL
 - Stability of test compound:** Stability: Not stated
Expiry date: 22nd May 2021
2. **Vehicle and/or control:** Dimethoate
3. **Test animals (Species)** *Typhlodromus pyri*
 - Source:** Katz Biotech AG, Baruth, Germany
 - Age:** 24 h old protonymphs
 - Number of test organisms:** 20 mites per replicate
 - Number of replicates:** Five replicates per treatment
 - Food:** *Tetranychus urticae* and pollen (*Typha* spp.), *ad libitum*.
 - Acclimation** Not stated

Test unit: The test unit consisted of two cover glasses (coverslips, size: 50 x 24 mm) fixed together by another coverslip glued on them and placed on a layer of polystyrene covered with moist blotting paper.

Untreated variant: Deionised water
Reference standard: PERFEKTION TOP (Blue liquid)
Description Emulsion Concentrate
Lot/Batch # 10222732A
Purity Dimethoate 371.56 g/kg or 393.85 g/L
Stability Stability: Not stated
Expiry date: January 2022

4. Environmental conditions

Temperature: 23 - 27°C
Relative humidity: 60 - 90%
Photoperiod 16 h light/8h dark
Light intensity: 2472 Lux (average)
Ventilation -

B. STUDY DESIGN AND METHODS:

- 1. In-life dates** 21st February to 06th March 2020
- 2. Experimental design** A single application rate of test item was sprayed on glass plates. Deionized water and a dimethoate formulation were applied to prepare the negative and the positive control, respectively. Application volume was 200 L water/ha. Five replicates per experimental group were prepared, each one with 20 protonymphs.
Test concentrations: 423.3 g test item/ha (80.0 g/ha of the a.s. Chlorantraniliprole), plus the control (deionized water). Reference item concentration was 16.15 g test item/ha (6 g dimethoate/ha).
Test duration: Exposure time: 7 d
- 3. Observations:** The survival of mites was assessed 7 days after exposure. The number of surviving females and the number of laid and hatched eggs were recorded in three assessments during the reproduction phase, from day 7 to day 14.
- 4. Statistics:** The software ToxRatPro ver. 3.3.0 was used.

II. RESULTS AND DISCUSSION

The results of the control group indicated that the test organisms were in a good condition (mortality: 20%). The results of the reference item group indicated that the test system was sensitive to harmful substances (corrected mortality after 7 days: 53.75%). Concerning mortality and as well the susceptibility of the test organisms to the reference item the test is proved to be valid. In the test item treatment, mortality was 25% (6.25% corrected mortality rate). The mean number of eggs per female was 8.93 in the test item group compared to the control with 9.43 eggs per female.

Table A 2.3.2-02: Summary of mortality and reproductive performance results

Groups		Application rates (g/ha)		Mortality after 7 days of exposure			Reproductive capacity after 14 days of exposure			
		As product	As a.s.	M%	CM%	S1	Mean no. of eggs/female	SD	R%	S2
Control		0	0	20.0	n/a	n/a	9.43	1.65	n/a	n/a
T1		423.3	80.0	25.0	6.25	-	8.93	0.87	5.30	-
Ref. item		16.15	Dimethoate: 6.0	63.0	53.75	n/a	n/a			

M% = Mean Mortality; CM% = Corrected Mean Mortality; Eggs/♀ = Mean number of eggs per female; SD = Standard deviation;

n/a = not applicable; S = Statistical significance; “-” = not significant; R% = Reduction in reproduction compared to the control.

¹Chi² 2x2 Table ($\alpha = 0.05$, one-sided greater); ²STUDENT-t test for Homogeneous Variances ($\alpha = 0.05$, one-sided smaller).

No statistically significant mortality was observed after 7 days of exposure to residues of test item: the NOER value was ≥ 423.3 g test item/ha, equivalent to ≥ 80.0 g a.s./ha and the LR₅₀ was estimated to be > 423.3 g test item/ha, equivalent to > 80.0 g a.s./ha.

No statistically significant reduction in reproduction was found in the test item application rate when compared to the control: the NOER was ≥ 423.3 g of prod./ha, equivalent to ≥ 80.0 g a.s./ha and the ER₅₀ was estimated to be > 423.3 g test item/ha, equivalent to > 80.0 g a.s./ha.

C. Validity criteria

According to IOBC/WSPR guidance, the test is considered valid if:

- the arithmetic mean mortality of the control group (dead and escaped) is $\leq 20\%$ on Day 7 after treatment;
- the cumulative mean number of eggs per female of the control group is ≥ 4 eggs/female;
- the arithmetic mean mortality of the reference item group (control corrected) of protonymphs on Day 7 is in the range between 50% and 100%, at the proposed application rate.

III. CONCLUSION

The effects of the test item Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C) were evaluated on *Typhlodromus pyri* in a GLP laboratory test following the IOBC/WPRS guidelines.

No statistically significant effects on survival of the test organisms were shown at the single test item application rate. According to the statistical analysis the NOER was ≥ 423.3 g test item/ha, equivalent to ≥ 80.0 g a.s./ha. The LR₅₀ value was estimated to be > 423.3 g test item/ha, equivalent to > 80.0 g a.s./ha.

No statistically significant adverse effects of Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C) were shown on the reproductive capacity of the test organisms at the single test item application rate.

According to the statistical analysis the NOER was ≥ 423.3 g test item/ha, equivalent to ≥ 80.0 g a.s./ha.

The ER₅₀ value was estimated to be > 423.3 g test item/ha, equivalent to > 80.0 g a.s./ha.

No behavioural abnormalities of the treated organisms were observed during the test.

The validity criteria are fulfilled.

A 2.3.2.2 KCP 10.3.2.2 Extended laboratory testing and aged residue studies

No additional data.

A 2.3.2.3 KCP 10.3.2.3 Semi-field studies

No additional data.

A 2.3.2.4 KCP 10.3.2.4 Field studies

No additional data.

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

A 2.4.1.1.1 Study 1: Sub-lethal toxicity to Earthworms

The following study on sublethal effects on the earthworm *Eisenia andrei* performed on Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C) was provided in support of the assessment.

Comments of zRMS:	<p>The study was conducted in line with OECD 222 with no deviations.</p> <p>All the validity criteria were met and the study is considered acceptable with the following endpoints relevant for the risk assessment:</p> <p>56d NOEC \geq 555.6 mg prod./kg dw soil (correspond to 105 mg a.s./kg dws)</p> <p>56d EC₁₀ = not determined</p>
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Reference:	KCP 10.4.1.1/01
Report	Effects of Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C) on reproduction of the earthworm <i>Eisenia andrei</i> in artificial soil containing 10 % peat. Pecorari, F. 2020. Report No.: BT142/19. Reference No.: 000103368
Guideline(s):	OECD 222 (2016) and ISO Guideline 11268-2 (2012)
Deviations:	<p>During the test, the temperature went over of the outlined range (18.0-22.0 °C) for short periods from 03rd to 04th September 2020. The maximum registered value was 24.0 °C and the average temperature during the test was 20.8 °C.</p> <p>The light intensity went under the outlined range (400-800 lux) for some hours from 04th to 14th September 2020. The minimum registered value was 325 lux.</p> <p>This deviation from the recommended ranges is stated to show no disturbances in the test performance demonstrated by the validity criteria that were met in the control group.</p>
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	-

Executive Summary

The effects of the test item Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C) on the mortality and reproductive output of the earthworm *Eisenia andrei* were tested in an artificial soil substrate (10% peat) during 4 and 8 weeks, respectively. The study was conducted in a concentration range of 95.3 – 171.5 – 308.6 – 555.6 – 1000 mg/kg soil dry weight. The test item solutions were prepared in deionised water and mixed with the artificial soil. Eight replicates for the control and 4 replicates per test item concentration were tested with 10 earthworms introduced per replicate.

After four weeks of exposure to the treated soil, the surviving adult earthworms were removed from the test vessels and weighed. After further four weeks, the reproduction performance was evaluated by the assessment of the number of juveniles hatched.

The results obtained in the trial showed that the test item Chlorantraniliprole 200 SC did not cause adverse effects on survival up to the concentration of 1000.0 mg test item/kg soil dry weight (equivalent to 189.0

mg Chlorantraniliprole/kg soil dry weight), which corresponds to the NOEC value. The LC₅₀ was estimated to be > 1000.0 mg test item/kg soil dry weight. For reproduction, a statistically significant reduction of the reproductive output compared to the untreated control was found at the highest tested concentration of 1000 mg test item/kg soil dry weight. No statistically significant adverse effects were found up to the concentration of 555.6 mg test item/kg soil dry weight (equivalent to 105.0 mg Chlorantraniliprole/kg soil dry weight), corresponding to the NOEC value. The EC₅₀ was estimated to be > 1000.0 mg test item/kg soil dry weight. Some unhatched cocoons were observed in the highest test item treated group, that could indicate an adverse effect on hatching caused by the test item at the tested concentration. No abnormal behaviour of treated earthworms was assessed during the exposure phase.

I. MATERIAL AND METHODS

A. MATERIALS

1. **Test Material:** Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C)
Description: Off white liquid
Lot/batch #: 3188-220519-01
Concentration/Purity: 18.9%; 206 g/L
Density: 1.09 g/mL
Stability of test compound: Stability: Stable at storage conditions (dark, 15-25 °C, dry, well-ventilated room)
Expiry date: 22nd May 2021
2. **Vehicle and/or control:** Deionised water
3. **Test animals (Species)** *Eisenia andrei*
Source: BioTecnologie BT S.r.l. (internal breeding) – Batch EA241019
Age: Adults (nine months old, with clitellum)
Number of test organisms: Ten organisms per replicate
Number of replicates: Eight replicates for the control and four replicates per treatment
Food: Fresh vegetables (sliced and chopped carrots and potatoes)
Acclimation One day at the same environmental conditions of the test
Test unit: The test units consisted of glass containers with a capacity of about two litres. The containers have a cross-sectional area of approximately 200 cm² so that the moist soil depth of about 5 - 6 cm was achieved when 500-600 g dry mass of soil were added; they were covered with a perforated lid in order to allow the gaseous exchange.
Untreated variant: Deionised water
Reference standard: Boric Acid
Description White crystals
Lot/Batch # BCBR9954V
Purity 100.1%
Stability Stability: Stable at storage conditions (Dark, 20 ± 2 °C)
Retest date: March 2022
4. **Environmental conditions**
Temperature: 20.4 – 24.0 °C (temperature above the recommended range of 20 ± 2 °C for a short period of a few hours, see deviation)
Soil water content: About 25.60 mL of water/100 g of dry soil (50% of the maximum WHC of the soil)
Photoperiod 16 h light/8h dark
Light intensity: 325 – 582 lux (light intensity below the recommended range of 400 – 800 lux for a few periods, see deviation)
Artificial soil 10 % sphagnum peat; 20 % kaolin clay; 70 % industrial quartz sand, no additional CaCO₃ for pH adjustment was needed as the pH value of the artificial soil was within the recommended range of 6.0 ± 0.5 as indicated by OECD guideline No. 222 (exact value: 6.21)

B. STUDY DESIGN AND METHODS:

1. **In-life dates** 16th January to 18th September 2020
2. **Experimental design**

A dose-response test was performed with five test item concentrations set up in a geometrical series with a separation factor of 1.8 as follows: 95.3 – 171.5 – 308.6 – 555.6 – 1000 mg/kg soil dry weight. The test item solutions were prepared in deionised water and mixed with the artificial soil. Deionised water only was used for the preparation of the control replicates. The treated soil was then wetted up to reach about 50% of the maximum WHC (water holding capacity) of the artificial soil and introduced in the test containers (glass vessels).

Eight replicates for the control and 4 replicates per test item concentration were tested with 10 earthworms introduced per replicate. After four weeks of exposure to the treated soil, the surviving adult earthworms were removed from the test vessels and weighed. After further four weeks, the reproduction performance was evaluated by the assessment of the number of juveniles hatched.

Test concentrations: 95.3 – 171.5 – 308.6 – 555.6 – 1000 mg/kg soil dry weight plus a control

Test duration: Mortality: four weeks / Reproduction: eight weeks
3. **Observations:**

Mortality of the exposed adult earthworms were assessed four weeks after their introduction.

The weight of the test system was measured at the beginning of the test and after four weeks.

At the end of the test after eight weeks, the number of cocoons and hatched juveniles were determined.
4. **Statistics:**

The software ToxRat Pro 3.3.0 was used to perform the statistical analysis.

II. RESULTS AND DISCUSSION

Mortality:

Table A 2.4.1.1-01: Mortality of the earthworms after 4 weeks of exposure

Treatment	Test item concentration [mg prod./ kg dry soil]	Active substance concentration [mg a.s./ kg dry soil]	Mean mortality [%]	Corrected mortality
Control	0.0	0.0	0.0	n.a.
Test item - T1	95.3	18.0	0.0	0.0
Test item - T2	171.5	32.4	0.0	0.0
Test item - T3	308.6	58.3	0.0	0.0
Test item - T4	555.6	105.0	0.0	0.0
Test item - T5	1000.0	189.0	0.0	0.0

n.a.: not applicable

The test item did not cause mortality of the test organisms at any of the tested test item concentrations. The NOEC for reproduction therefore corresponds to ≥ 1000.0 mg/kg soil dry weight (189.0 mg Chlorantraniliprole/kg soil dry weight). The LC₅₀ value is estimated to be > 1000.0 mg test item/kg soil dry weight.

Reproduction:

Table A 2.4.1.1-02: Reproduction performance at the end of the test (8 weeks after treatment)

Treatment	Test item concentration [mg /kg soil]	Active substance concentration [mg]	Mean no. of unhatched cocoon	Mean number of juveniles	Reduction in reproduction	± SD
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	dry weight]	a.s./kg soil dry weight]			[%]	
Control	0.0	0.0	0.0	84.0	n/a	11.0
Test item - T1	95.3	18.0	0.0	81.0	3.6	11.4
Test item - T2	171.5	32.4	0.0	82.5	1.8	7.2
Test item - T3	308.6	58.3	0.0	83.8	0.3	6.7
Test item - T4	555.6	105.0	0.0	81.8	2.7	5.9
Test item - T5	1000.0	189.0	7.3	68.5	18.5*	7.4

* statistically significantly different from the control, $\alpha=0.05$, one-sided smaller (Williams Multiple Sequential t-test Procedure, ToxRat Pro 3.3.0)

n/a = not applicable; SD = standard deviation; CV% = coefficient of variation %

The test item caused a statistically significant reduction in reproduction compared to the control at the highest test concentration of 1000.0 mg/kg soil dry weight (189.0 mg Chlorantraniliprole/kg soil dry weight). The NOEC is determined to be the second highest tested concentration of 555.6 mg/kg soil dry weight (105.0 mg Chlorantraniliprole/kg soil dry weight).

No effects ≥ 50 % on reproduction were determined at any of the tested concentrations. The EC_{50} is > 1000 mg test item/kg soil dry weight.

A summary of endpoints is given in the following table:

Table A 2.4.1.1-03: NOEC and L/EC_{50} for mortality and reproduction

Endpoint	NOEC	LC_{50}/EC_{50}
Mortality	≥ 1000.0	> 1000.0
Reproduction	555.6	> 1000.0

C. Validity criteria

According to the OECD 222 Guideline, the test was considered valid because the following criteria are met for the control group:

- in each replicate (containing ten adults) ≥ 30 juveniles were produced at the end of the test (actually: 68 – 105);
- the coefficient of variation (% RSD or CV) of reproduction was $\leq 30\%$ (actually: 13.1 %);
- adult mortality over the initial 4 weeks of the test was $\leq 10\%$ (actually: 0 %).

Considering these results, the validity criteria of the study are satisfied, thus the test is valid.

III. CONCLUSION

The effects of Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C) on the reproduction of the earthworm *Eisenia andrei* in artificial soil were assessed in a laboratory study according to OECD Guideline No. 222 (2016) and ISO Guideline 11268 (2012).

The results obtained in the trial showed that the test item Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C) did not cause adverse effects on survival up to the concentration of 1000.0 mg test item/kg soil dry weight (equivalent to 189.0 mg Chlorantraniliprole/kg soil dry weight), which corresponds to the NOEC value. The LC_{50} was estimated to be > 1000.0 mg test item/kg soil dry weight.

For reproduction, a statistically significant reduction of the reproductive output compared to the untreated control was found at the highest tested concentration of 1000 mg test item/kg soil dry weight. No statistically significant adverse effects were found up to the concentration of 555.6 mg test item/kg soil dry weight (equivalent to 105.0 mg Chlorantraniliprole/kg soil dry weight), corresponding to the NOEC value. The EC_{50} was estimated to be > 1000.0 mg test item/kg soil dry weight.

Some unhatched cocoons were observed in the highest test item treated group, that could indicate an adverse effect on hatching caused by the test item at the tested concentration. No abnormal behaviour of treated earthworms was assessed during the exposure phase.

A 2.4.2 KCP 10.4.1.2 Earthworms - field studies

No additional data.

A 2.4.3 KCP 10.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms)

A 2.4.3.1 KCP 10.4.2.1 Species level testing

A 2.4.3.1.1 Study 1: Toxicity to *Folsomia candida*

The following study on sublethal effects on the collembolan *Folsomia candida* performed on Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C) was provided in support of the assessment.

Comments of zRMS:	<p>The study was conducted in line with OECD 222 with minor deviation.</p> <ul style="list-style-type: none"> - Due to a technical malfunction of the lighting system of the incubation room, value of light intensity 393 Lux. <p>As control performance met the guideline validity criteria, this short-term deviation is considered to have no impact on the validity of the study.</p> <p>The study is considered acceptable with the following endpoints relevant for the risk assessment:</p> <p>NOEC_{reproduction} = 4.23 5.46 mg prod./kg soil dw (correspond to 0.80 mg a.s./kg dws)</p> <p>EC₁₀ = 3.49 mg product/kg dry soil (correspond to 0.66 mg a.s./kgdws)</p> <p>The reliability of the EC₁₀ value was evaluated in line with recommendations of EFSA Supporting publication 2019:EN-1673:</p> <ul style="list-style-type: none"> - NW (normalised width) of 0.08 was calculated, which results in rating “excellent” in line with EFSA Supporting publication 2019:EN-1673, - median EC₁₀ (3.49 mg/kg soil dw) is lower than EC_{20,low} (4.33 mg/kg dw), - the dose-response curve is medium with steepness of 0.53 (i.e. <0.66 and >0.33). <p>Taking the above results into account, the calculated EC₁₀ is considered to be sufficiently reliable.</p>
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Reference: KCP 10.4.2.1/01

Report Effects of Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C) on reproduction of the collembolan *Folsomia candida* in artificial soil. Grandolini, G. 2020. Report No.: BT143/19. Reference No.: 000103367

Guideline(s): OECD 232 (2016)

Deviations: 1 - Due to a technical malfunction of the lighting system of the incubation room, on 19th February 2020 the recorded light intensity went below the limit

of 400 Lux for 3 hours continuously. Minimum value of light intensity 393 Lux.

2 - The determination of the initial pH of extra samples was determined five days after the test start.

Both deviations were stated to have no impact on the quality of the study, because no adverse effects are shown since the validity criterias are fulfilled.

GLP: Yes

Acceptability: Yes

Duplication -
(if vertebrate study)

Executive Summary

The effects of the test item Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C) on the mortality and reproductive output of the collembola *Folsomia candida* were tested in an artificial soil substrate during 4 weeks. The concentrations tested were 1.31, 2.35, 4.23, 7.62, 13.72, 24.69, 44.44 and 80.0 mg test item/kg dry soil. For each test item concentration, 10 juvenile springtails were carefully placed onto the surface of each of 4 replicate test vessels (8 replicates with 10 springtails each for the untreated control) and incubated under test conditions for a period of four weeks. After 4 weeks of exposure the number of the surviving adult collembolans was recorded and mortality assessed. The reproduction performance was evaluated by the assessment of the number of juveniles at test end.

The results obtained in the trial showed that the test item Chlorantraniliprole 200 SC did not cause adverse effects on survival up to the concentration of 1000.0 mg test item/kg soil dry weight (equivalent to 189.0 mg Chlorantraniliprole/kg soil dry weight), which corresponds to the NOEC value. The LC₅₀ was estimated to be > 1000.0 mg test item/kg soil dry weight. For reproduction, a statistically significant reduction of the reproductive output compared to the untreated control was found at the highest tested concentration of 1000 mg test item/kg soil dry weight. No statistically significant adverse effects were found up to the concentration of 555.6 mg test item/kg soil dry weight (equivalent to 105.0 mg Chlorantraniliprole/kg soil dry weight), corresponding to the NOEC value. The EC₅₀ was estimated to be > 1000.0 mg test item/kg soil dry weight. Some unhatched cocoons were observed in the highest test item treated group, that could indicate an adverse effect on hatching caused by the test item at the tested concentration. No abnormal behaviour of treated earthworms was assessed during the exposure phase.

In the present test, mean mortality (15%), mean number of offspring (710.3) and CV for the number of juveniles (17.8%) in the control group met the validity criteria, thus the test is valid. No significant reduction in reproduction was found up to the concentration of 4.23 mg test item/kg dry soil corresponding to 0.80 mg a.s./kg dry soil. The NOEC for reproduction was determined to be 4.23 mg test item/kg dry soil corresponding to 0.80 mg a.s./kg dry soil. The LOEC was evaluated to be 7.62 mg test item/kg dry soil corresponding to 1.44 mg a.s./kg dry soil. Effect concentrations (EC_{10/20/50}) are as following: 3.49, 4.33 and 6.54 mg test item/kg dry soil.

No significant reduction in mortality was found up to the test concentration of 13.72 mg test item/kg dry soil corresponding to 2.59 mg a.s./kg dry soil. The NOEC for mortality was determined to be 13.72 mg test item/kg dry soil corresponding to 2.59 mg a.s./kg dry soil. The LOEC was evaluated to be 24.69 mg test item/kg dry soil corresponding to 4.67 mg a.s./kg dry soil. Lethal concentrations (LC_{10/20/50}) are as following: 2.73, 5.30 and 18.81 mg test item/kg dry soil.

I. MATERIAL AND METHODS

A. MATERIALS

1. Test Material:

Description:

Lot/batch #:

Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C)

Off white liquid

3188-220519-01

Concentration/Purity:	18.9%; 206 g/L Density: 1.09 g/mL
Stability of test compound:	Stability: Stable at storage conditions (dark, 15-25 °C, dry, well-ventilated room) Expiry date: 22 nd May 2021
2. Vehicle and/or control:	Deionised water
3. Test animals (Species)	<i>Folsomia candida</i> (Collembola, Isotomidae; females from a synchronized breeding were used)
Source:	BioTecnologie BT S.r.l. (internal breeding)
Age:	Juvenile (9 days)
Number of test organisms:	Ten organisms per replicate
Number of replicates:	Eight replicates for the control and four replicates per treatment
Food:	Granulated dried baker's yeast
Acclimation	Syncronisation of organisms regarding to eggs laying was conducted according to OECD 232 (2016). Batch FC100120 was used for the test.
Test unit:	The test units were glass containers of a capacity of about 100 mL. The containers have a cross-sectional area of approximately 20 cm ² so that the moist substrate depth of about 2 - 4 cm was achieved when about 30 g of dry soil were added. The vessels have lids that are designed to reduce water evaporation whilst allowing gas exchange between the soil and the atmosphere. The containers are transparent to allow light transmission.
Untreated variant:	Deionised water
Reference standard:	Boric Acid
Description	White crystals
Lot/Batch #	BCBR9954V
Purity	100.1%
Stability	Stability: Stable at storage conditions (Dark, 20 ± 2 °C) Expiry date: 08 th March 2023
4. Environmental conditions	
Temperature:	19.0 – 20.3°C
Soil water content:	about 20.09 mL of water/100 g of dry soil (50% of the maximum WHC)
Photoperiod	16 h light/8h dark
Light intensity:	393 - 598 lux
Artificial soil	5% sphagnum peat; 20% kaolin clay; 75% industrial sand

B. STUDY DESIGN AND METHODS:

1. In-life dates	30 th January to 02 nd March 2020
2. Experimental design	The test item was diluted in deionised water and mixed into the artificial soil to obtain the test concentrations of 1.31, 2.35, 4.23, 7.62, 13.72, 24.69, 44.44 and 80.0 mg test item/kg dry soil. For each test item concentration, 10 juvenile springtails were carefully placed onto the surface of each of 4 replicate test vessels (8 replicates with 10 springtails each for the untreated control) and incubated under test conditions for a period of four weeks.
Test concentrations:	1.31, 2.35, 4.23, 7.62, 13.72, 24.69, 44.44 and 80.0 mg test item/kg dry soil plus a control
Test duration:	Four weeks
3. Observations:	After 4 weeks of exposure the number of the surviving adult collembolans was recorded and mortality assessed. The reproduction performance was evaluated by the assessment of the number of juveniles at test end.

4. Statistics:

LOEC (lowest observed effect concentration) and NOEC (no observed effect concentration) for mortality and reproduction and additionally EC₁₀, EC₂₀ and EC₅₀ values (effect concentration of 10, 20, 50 %) were derived.

Appropriate statistical methods were used to analyse mortality and fecundity data for significance (e.g. STEP-DOWN Rao-Scott-Cochran-Armitage Test Procedure, one sided greater, $\alpha = 0.05$, for mortality and Williams multiple sequential T-test one-sided smaller, $\alpha = 0.05$, for reproduction). For the statistical analysis the software ToxRat Pro 3.3.0. was used.

II. RESULTS AND DISCUSSION

Mortality:

Compared to the untreated control group, a statistically significant mortality of 65.0, 75.0 and 85.0% was observed at the three highest treatment groups 24.69, 44.44 and 80.00 mg test item/kg dry soil, respectively. Accordingly, NOEC and LOEC were defined as 13.72 and 24.69 mg test item/kg dry soil, respectively, corresponding to 2.59 and 4.67 mg a.s./kg dry soil.

The lethal concentrations for mortality were calculated to be:

LC₁₀: 2.73 mg test item/kg dry soil (95%-CI: 1.67 - 3.88 mg test item/kg dry soil), corresponding to 0.52 mg a.s./kg dry soil.

LC₂₀: 5.30 mg test item/kg dry soil (95%-CI: 3.69 - 6.99 mg test item/kg dry soil), corresponding to 1.00 mg a.s./kg dry soil.

LC₅₀: 18.81 mg test item/kg dry soil (95%-CI: 14.78 - 24.60 mg test item/kg dry soil), corresponding to 3.56 mg a.s./kg dry soil.

No adverse effects regarding morphology and colour were observed in the extracted collembolan.

Table A 2.4.3.1-01: Mortality of the adult collembolans after exposure to the test item Chlorantraniliprole 200 SC (product code ADM.0900.1.1 .C) for 4 weeks

Treatment	Concentration [mg prod./ kg dry soil]	Concentration [mg a.s./ kg dry soil]	Mean mortality [%]	*Significance
Control	0	0	15.0	n.a.
Test item - T1	1.31	0.25	7.5	-
Test item - T2	2.35	0.44	7.5	-
Test item - T3	4.23	0.80	20.0	-
Test item - T4	7.62	1.44	22.5	-
Test item - T5	13.72	2.59	25.0	-
Test item - T6	24.69	4.67	65.0	+
Test item - T7	44.44	8.40	75.0	+
Test item - T8	80.00	15.12	85.0	+

n.a.: not applicable; *+ : statistically significant compared to the control; - : statistically not significant compared to the control (Step-down Rao-Scott-Cochran-Armitage Test Procedure, one-sided greater, $\alpha = 0.05$, ToxRat Pro 3.3.0)

Reproduction:

A significant reduction in reproduction was observed at 7.62, 13.72, 24.69, 44.44 and 80.00 mg test item/kg dry soil at test end. The respective NOEC and LOEC values are thus 4.23 and 7.62 mg test item/kg dry soil, corresponding to 0.80 and 1.44 mg a.s./kg dry soil. The effect concentrations for reproduction were calculated to be:

EC₁₀: 3.49 mg test item/kg dry soil (95%-CI: 3.35 - 3.64 mg test item/kg dry soil), corresponding to 0.66 mg a.s./kg dry soil.
EC₂₀: 4.33 mg test item/kg dry soil (95%-CI: 4.16 - 4.52 mg test item/kg dry soil), corresponding to 0.82 mg a.s./kg dry soil.
EC₅₀: 6.54 mg test item/kg dry soil (95%-CI: 6.21 - 6.88 mg test item/kg dry soil), corresponding to 1.24 mg a.s./kg dry soil.

Table A 2.4.3.1-02: Reproduction output after exposure to the test item Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C) for 4 weeks

Treatment	Concentration [mg prod./kg dry soil]	Concentration [mg a.s./kg dry soil]	Mean number of juveniles/replicate	Reduction in Reproduction [%]	±SD	CV [%]	*Significance
Control	0	0	710.25	n.a.	126.78	17.85	n.a.
Test item - T1	1.31	0.25	811.25	-14.22	160.48	19.78	-
Test item - T2	2.35	0.44	728.50	-2.57	152.83	20.98	-
Test item - T3	4.23	0.80	648.75	8.66	81.40	12.55	-
Test item - T4	7.62	1.44	229.75	67.65	81.59	35.51	+
Test item - T5	13.72	2.59	122.25	82.79	79.23	64.81	+
Test item - T6	24.69	4.67	5.50	99.23	9.11	165.64	+
Test item - T7	44.44	8.40	2.25	99.68	3.30	146.85	+
Test item - T8	80.0	15.12	0.25	99.96	0.50	200.00	+

n.a.: not applicable; *+: significant compared to the control; - : not significant compared to the control (Williams Multiple seq. T-test, one-sided smaller, $\alpha = 0.05$, ToxRat Pro 3.3.0); SD: Standard deviation; CV: Coefficient of Variance.

C. Validity criteria

In the present test, mean mortality in the control groups was 15.0%; the mean number of offspring in the control vessels was 710.3 and the CV of the number of juveniles in the control was 17.8%. Considering these results, the validity criteria of the study are satisfied, thus the test is valid.

III. CONCLUSION

The effects of Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C) on survival and reproduction of the collembolan *Folsomia candida* in artificial soil were assessed in a GLP laboratory study according to OECD 232 (2016).

In the present test, mean mortality (15%), mean number of offspring (710.3) and CV for the number of juveniles (17.8%) in the control group met the validity criteria, thus the test is valid.

No significant reduction in reproduction was found up to the concentration of 4.23 mg test item/kg dry soil corresponding to 0.80 mg a.s./kg dry soil.

The NOEC for reproduction was determined to be 4.23 mg test item/kg dry soil corresponding to 0.80 mg a.s./kg dry soil.

The LOEC was evaluated to be 7.62 mg test item/kg dry soil corresponding to 1.44 mg a.s./kg dry soil.

The EC_x values (for the reproduction performance) are following reported

EC₁₀: 3.49 mg test item/kg dry soil (95%-CL lower 3.35; upper 3.64 mg test item/kg dry soil)

EC₂₀: 4.33 mg test item/kg dry soil (95%-CL lower 4.16; upper 4.52 mg test item/kg dry soil)

EC₅₀: 6.54 mg test item/kg dry soil (95%-CL lower 6.21; upper 6.88 mg test item/kg dry soil)

No significant reduction in mortality was found up to the test concentration of 13.72 mg test item/kg dry soil corresponding to 2.59 mg a.s./kg dry soil.

The NOEC for mortality was determined to be 13.72 mg test item/kg dry soil corresponding to 2.59 mg a.s./kg dry soil.

The LOEC was evaluated to be 24.69 mg test item/kg dry soil corresponding to 4.67 mg a.s./kg dry soil.

The lethal concentrations for mortality were calculated to be:

LC₁₀: 2.73 mg test item/kg dry soil (95%-CI: 1.67 - 3.88 mg test item/kg dry soil), corresponding to 0.52 mg a.s./kg dry soil.

LC₂₀: 5.30 mg test item/kg dry soil (95%-CI: 3.69 - 6.99 mg test item/kg dry soil), corresponding to 1.00 mg a.s./kg dry soil.

LC₅₀: 18.81 mg test item/kg dry soil (95%-CI: 14.78 - 24.60 mg test item/kg dry soil), corresponding to 3.56 mg a.s./kg dry soil.

The reference item showed an acceptable sensitivity of the test system in a separate GLP study.

A 2.4.3.1.2 Study 2: Toxicity to *Hypoaspis aculeifer*

The following study on sublethal effects on the predatory mite *Hypoaspis aculeifer* performed on Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C) was provided in support of the assessment.

Comments of zRMS:	<p>The study was conducted in line with OECD 226 with no deviations.</p> <p>All the validity criteria were met and the study is considered acceptable with the following endpoints relevant for the risk assessment:</p> <p>NOEC_{reproduction} ≥ 1000 mg prod./kg soil dw (correspond to 198 mg a.s./kg dws)</p> <p>EC₁₀ = n.d.</p>
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Reference:	KCP 10.4.2.1/02
Report	Effects of Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C) on reproduction of the predatory mite <i>Hypoaspis aculeifer</i> in soil. Colli, M. 2020d. Report No.: BT144/19. Reference No.: 000103366
Guideline(s):	OECD 226 (2016)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	-

Executive Summary

The effects of the test item Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C) on the reproductive output of the predatory mite *Hypoaspis aculeifer* were tested in an artificial soil substrate after 14 days of exposure following the OECD test guideline 226 (2016) and according to the principles of GLP. The study was conducted as limit test with the single application rate of 1000 mg test item/kg dry soil, corresponding to 189 mg Chlorantraniliprole/kg dry soil.

A test item stock solution in deionised water was mixed with the soil substrate before introducing it into the test containers (24.02 g wet soil per vessel). For the treatments (test item and control group), 10 mites were carefully placed onto the surface of the soil of each of the 8 replicate test vessels of the test item and control group. After 14 days of exposure to the treated soil, the surviving mites were extracted by heat extraction from the test vessels and counted. The reproduction performance was evaluated by the assessment of the number of juveniles produced per test vessel. The number of the surviving introduced adult mites was recorded at 14 days after their introduction.

Results showed that 8.8% adult mortality occurred in the control until test end. Mortality in the test item group was 11.3%. The treatment did not show a statistically significant difference compared to the control.

After 14 d of exposure, the mean number of juveniles in the treatment group is not being statistically significantly different from the control. The NOEC was determined to be 1000 mg test item/kg dry soil (equivalent to 189 mg a.s./kg dry soil). The EC₅₀ is determined to be >1000 mg test item/kg dry soil (equivalent to >189 mg a.s./kg dry soil). All the validity criteria was met.

I. MATERIAL AND METHODS

A. MATERIALS

1. **Test Material:** Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C)
Description: Off white liquid
Lot/batch #: 3188-220519-01
Concentration/Purity: 18.9%; 206 g/L
Density: 1.09 g/mL
Stability of test compound: Stable at storage conditions (dark, 15-25 °C, well-ventilated room)
Expiry date: 22nd May 2021
2. **Vehicle and/or control:** Deionised water
3. **Test animals (Species)** *Hypoaspis aculeifer* (Acari: Laelapidae)
Source: Biotechnologie BT (batch HA271219)
Age: Synchronized adult females (34 days after start of egg laying period)
Number of test organisms: Ten mites per replicate
Number of replicates: Eight replicates per treatment
Food: Cheese mites (*Tyrophagus putrescentiae*), *ad libitum*
Acclimation: 34 days after the start of egg laying period (according to Annex 4 of OECD 226)
Test unit: The test units were glass containers of a capacity of about 100 mL with screw lids. The containers had a diameter of 5 cm (height of soil ≥1.5 cm). The containers were transparent to allow light transmission.
Untreated variant: Deionised water
Reference standard: Dimethoate
Description: White powder
Lot/Batch # G941646
Purity 99.37%
Stability Stable under storage conditions (dark, -18 ± 4 °C)
Expiry date: 08th March 2023
4. **Environmental conditions**
Temperature: 19.0 – 20.3°C
Soil water content: about 20.09 mL of water/100 g of dry soil (50% of the maximum WHC)
Photoperiod 16 h light/8h dark
Light intensity: 393 - 598 lux
Artificial soil 5% sphagnum peat; 20% kaolin clay; 75% industrial quartz sand (artificial soil batch AS0220)

B. STUDY DESIGN AND METHODS:

1. **In-life dates** 30th January to 17th February 2020
2. **Experimental design** The tested single test item concentration was 1000 mg test item/kg dry soil. A test item stock solution in deionised water was mixed with the soil substrate before introducing it into the test containers (24.02 g wet soil per vessel). For the treatments (test item and control group), 10 mites were carefully placed onto the surface of the soil of each of the 8 replicate test vessels of the test item and control group.
Test concentrations: 1000 mg test item/kg dry soil

- Test duration:** Exposure time: 14 d
- 3. Observations:** After 14 days of exposure to the treated soil, the surviving mites were extracted by heat extraction from the test vessels and counted. The reproduction performance was evaluated by the assessment of the number of juveniles produced per test vessel. The number of the surviving introduced adult mites was recorded at 14 days after their introduction.
- 4. Statistics:** The data were evaluated to establish the No Observed Effect Concentrations (NOEC) for reproduction, and to demonstrate that the EC₅₀ (Effect concentrations causing 50% effect on reproduction) is greater than the tested limit concentration. The software ToxRat Pro Version 3.3.0 was used to perform the statistical analysis.

II. RESULTS AND DISCUSSION

Adult Mortality:

8.8% adult mortality occurred in the control until test end. Mortality in the test item group was 11.3%. The treatment did not show a statistically significant difference compared to the control.

Table A 2.4.3.1-03: Mortality of the adult female *Hypoaspis* after 14 days of exposure to the test item

Treatments	Concentration [mg kg dry soil]		Mortality [%]	*Significant
	Test item	A.s.		
Control	0	0	8.8	n.a.
Test item	1000	189	11.3	-

n.a.: not applicable; * + : statistically significantly different from the control; - : statistically not significantly different from the control (Fisher's exact binomial test; $\alpha = 0.05$; one-sided greater; ToxRat Pro 3.3.0)

Reproduction performance:

After 14 d of exposure, the mean number of juveniles in the treatment group is not being statistically significantly different from the control.

The NOEC was determined to be 1000 mg test item/kg dry soil (equivalent to 189 mg a.s./kg dry soil).

The EC₅₀ is determined to be >1000 mg test item/kg dry soil (equivalent to >189 mg a.s./kg dry soil).

Table A 2.4.3.1-04: Reproduction performance of *Hypoaspis* after 14 days of exposure to the test item

Treatments	Concentration [mg kg dry soil]		Mean number of juveniles/vessel	Reduction in Reproduction [%]	SD	CV%	*Significant
	Test item	A.s.					
Control	0	0	231.4	n.a.	22.2	9.6	n.a.
Test item	1000	189	223.4	3.5	62.4	27.9	-

n.a.: not applicable; * + : significantly different from the control; - : not significantly different from the control (Student t-test; $\alpha = 0.05$; one-sided smaller; ToxRat Pro 3.3.0)

C. Validity criteria

The test was considered valid because the validity criteria in the water only treated control are fulfilled:

- the mean adult female mortality at the end of the test was 8.8% (required: less than 10 %);
- the mean number of juveniles per vessel at the end of the test was 231.4 (required: at least 50);
- the coefficient of variation calculated for the number of juvenile mites per replicate at the end of the test was 9.6% (required: $\leq 30\%$).

III. CONCLUSION

The effects of the test item Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C) on the reproduction performance of the predatory mite *Hypoaspis aculeifer* were tested in a GLP compliant laboratory study according to OECD 226 (2016).

The test item Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C), tested at the limit concentration of 1000 mg/kg dry soil (mixed into artificial soil) had no significant effect on mortality of adult mites after 14 d exposure. The NOEC for mortality is ≥ 1000 mg test item/kg dry soil (corresponding to 189 mg a.s./kg dry soil).

The LC₅₀ value for mortality is >1000 mg test item/kg dry soil (corresponding to 189 mg a.s./kg dry soil).

Regarding reproduction, the number of offspring in the group treated with 1000 mg test item/kg dry soil did not decrease significantly with respect to the control group. The corresponding NOEC value for reproduction is ≥ 1000 mg test item/kg dry soil (corresponding to 189 mg a.s./kg dry soil).

The EC₅₀ for reproduction is determined to be >1000 mg test item/kg dry soil (corresponding to 189 mg a.s./kg dry soil).

A 2.4.3.2 KCP 10.4.2.2 Higher tier testing

Not required.

A 2.5 KCP 10.5 Effects on soil nitrogen transformation

A 2.5.1 Study 1: Toxicity to the soil microflora

The following laboratory study on effects on soil microbial activity (nitrogen transformation test) performed with Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C) was provided in support of the assessment.

Comments of zRMS:	<p>The study was conducted in line with OECD 216 with no deviations.</p> <p>All the validity criteria were met.</p> <p>At 42 days after treatment, the % deviations from control were less than 25% so the test ended. Being 7.73% at the concentration of 0.65 mg of product/kg dry soil and 5.03% at the concentration of 6.51 mg of product/kg dry soil.</p>
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Reference:	KCP 10.5/01
Report	Assessment of the effects of Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C) on soil microorganisms nitrification. Rossini L., 2020. Report n°: BT148/19.
Guideline(s):	OECD 216 (2000)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	-

Executive Summary

The effects of the test item Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C) on soil microbial nitrification (nitrogen transformation test) processes were studied according to OECD Guideline 216 (2000).

The test item was mixed into a sandy loam agricultural soil (LUFA soil, type F2.3) at the following concentrations (the maximum application rate is 80 g a.s./ha):

- T1 concentration: 80 g a.s./ha corresponding to 423.3 g product/ha (0.65 mg/kg soil dry weight).
- T2 concentration: 80 g a.s./ha x 10 = 800 g a.s./ha corresponding to 4233.0 g product/ha (6.51 mg/kg soil dry weight).

The control consisted of soil treated with deionized water, and incubated at the same condition of the treated soil, in the dark at $20 \pm 2^\circ\text{C}$. The reference item (Dinoseb acetate) was tested in the annual quality control to confirm the normal reaction of the soil against herbicides.

The influence of the test item on the nitrification of a lucerne meal was investigated and the results obtained in treated samples were compared to untreated samples data. The nitrogen transformation rate was assessed after 0, 7, 14, 28 and 42 days after the test item application (until the rate of nitrate formation of the treated replicates differed by less than 25% from the control replicates in two consecutive samplings).

The test item Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C) did not affect the microbial nitrogen transformation in soil at the tested concentrations since the treated samples deviated by less than 25% from the control after 28 days from treatment. The test was continued for further 14 days, because after 14 days the deviation from the control was $> 25\%$ and at least in two consecutive intervals the deviation% should be $< 25\%$. At 42 days after treatment, the % deviations from control were less than 25% so the test ended.

I. MATERIALS AND METHODS

A. MATERIALS

1. **Test Material:** Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C)
Description: Off white liquid, SC (suspension concentrate)
Lot/batch: 3188-220519-01
Concentration/Purity: 18.9% - 206 g/L
Density: 1.09 g/ml
Stability of test compound: Stable conditions: Not stated
Expiry date: 22nd May 2021
 2. **Vehicle and/or control:** Vehicle control: Deionised water (Untreated soil)
 3. **Test animals (Species):** lucerne (*Medicago sativa*) flour
Supplier: Agrimedica Spazzoni
Replicates: For each treatment/control, triplicate test units were set up
Test vessel: The soil was placed in a plastic box with a loose lid in order to have a sufficient gas exchange and was pre-incubated at $20 \pm 2^\circ\text{C}$ at approximately 45 % of its WHC_{max}, In the dark for 20 days before starting the experimental phase. For the nitrogen transformation test each treatment group contained about 1200 g of moist soil.
Lucerne flour with a C/N ratio of 13.8 was added to the soil at the rate of 0.5% of soil dry weight.
- | | | |
|------------------------|--------------------------|--|
| Test soil: | LUFA F2.3 | |
| Soil parameter: | Soil type | Sandy loam |
| | Batch # | F2.3 0520 |
| | Organic carbon (%C) | 0.65 ± 0.08 |
| | Nitrogen (%N) | 6.1 ± 0.4 |
| | pH | 6.1 ± 0.4 |
| | Cation exchange capacity | 6.8 ± 1.4 (meq/100g soil) |
| | WHC | 35.2 ± 1.8 |
| | Microbial biomass | $181.9 \text{ mg } C_{\text{microbial}}/\text{Kg of dry soil}$ |

	Particle size (cm)	≤ 0.2
	Sand (%) - 0.05-2.0 mm	59.4 ± 0.7
	Silt (%) - 0.002-0.05 mm	33.3 ± 0.6
	Clay (%) - < 0.002 mm	7.3 ± 0.9
Untreated variant:	Soil treated with deionized water	
Reference standard:	Dinoseb acetate	

4. Environmental conditions

Temperature:	19.7 – 20.4 °C
Photoperiod:	Incubation in the dark
pH	6.1 ± 0.4
Soil moisture:	45% of WHC _{max}

B. STUDY DESIGN AND METHODS

- In-life dates:** 02nd April to 19th May 2020
- Experimental design:** The test system are the microorganisms present in the soil. The soil used in the present study was an agricultural soil type (LUFA F2.3). The sandy loam soil was taken from an agricultural field in Offenbach (Rheinland-Pfalz, Germany) "rechts der Landauer Str.", Nr.826/7 on 27th January 2020. The sampling site was treated neither with pesticides for at least 5 years nor with organic fertilizer or fertilizers that affect the soil microflora (i.e. calcium cyanamide) within one year before the sampling date, as required by the OECD Guideline 216. The sampling depth was about 20 cm.

Test concentrations: Test item was tested at 0.65 mg product/kg dry soil (low dose) and 6.51 mg product/kg dry soil (high dose). Additionally, a control (deionised water) was tested in parallel.

Test duration: 42 days
- Observations:** The influence of the test item on the nitrification of a lucerne meal was investigated and the results obtained in treated samples were compared to untreated samples data. The nitrogen transformation rate was assessed after 0, 7, 14, 28 and 42 days after the test item application (until the rate of nitrate formation of the treated replicates differed by less than 25% from the control replicates in two consecutive samplings).
- Statistics:** The software Tox Rat professional version 3.3.0 was used to perform the statistical analysis (Shapiro- Wilk's Test on Normal Distribution and Student – t test for Homogeneous Variances).

II. RESULTS AND DISCUSSION

A. Nitrogen Transformation

The nitrate formation is an indicator of the nitrification activity of the soil microflora. Sandy loam soil (LUFA soil F2.3) amended with lucerne meal and treated with the test item was analyzed at 0, 7, 14, 28 and 42 days after treatment in comparison with the control soils for the nitrate concentrations. Nitrogen transformation test results are reported in table A 2.5-1.

Table A 2.5-01: Results of the nitrogen transformation test after 28 and 42 days after treatment

TREATMENT	APPLICATION RATE	NITROGEN TRANSFORMATION TEST			
	mg of product/ kg of dry soil	Mean** mg NO ₃ ⁻ / kg dry soil/day DAT* 28	Deviation from control (%) (DAT* 14-28)	Mean** mg NO ₃ ⁻ /kg dry soil/day DAT* 42	Deviation from control (%) (DAT* 28-42)

control	0.00	3.017	-	3.580	-
Test item (T1)	0.65	2.983	1.10	3.303	7.73
Test item (T2)	6.51	3.127	-3.65	3.400	5.03

* DAT = Days After Treatment

** Mean = Mean value of three replicates

C. Validity criteria

Following the OECD Guidelines 216 (2000), the results of the study are considered valid if the variation among replicates (CV%) of untreated samples is less than $\pm 15\%$ (actual: 1.08 – 11.30%). Therefore, the validity criterion of the test was fulfilled.

III. CONCLUSION

The test item Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C) did not affect the microbial nitrogen transformation in soil at the tested concentrations since the treated samples deviated by less than 25% from the control after 28 days from treatment: 1.10% at the concentration of 0.65 mg of product/kg dry soil and -3.65% at the concentration of 6.51 mg of product/kg dry soil.

The test was continued for further 14 days, because after 14 days the deviation from the control was $> 25\%$ and at least in two consecutive intervals the deviation should be $< 25\%$.

At 42 days after treatment, the % deviations from control were less than 25% so the test ended. Being 7.73% at the concentration of 0.65 mg of product/kg dry soil and 5.03% at the concentration of 6.51 mg of product/kg dry soil.

A 2.6 KCP 10.6 Effects on terrestrial non-target higher plants

The following laboratory study on effects on soil microbial activity performed with Chlorantraniliprole 200 SC was provided in support of the assessment.

Comments of zRMS:	<p>The study was conducted in line with OECD 227 (2006) with no deviation in environmental conditions.</p> <p>The nominal test concentration of chlorantraniliprole was analytically confirmed and mean recovery was 94.7%.</p> <p>All the validity criteria were met and the study is considered acceptable with the following endpoints relevant for the risk assessment:</p> <p>LR₅₀ > 846.56 g prod./ha (equivalent to 160 g a.s./ha), the highest application rate in the study.</p> <p>No phytotoxic effects were observed at any of the tested species.</p>
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Reference:	KCP 10.6/01
Report	Effects of Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C) on terrestrial plants - Vegetative Vigour Test. Colli, M., 2020b. Report n° BT147/19.
Guideline(s):	OECD 227 (2006)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	-

Executive Summary

The effects of the test item Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C) on non-target terrestrial plants were tested according to OECD test guideline 227 (2006) and in compliance with GLP regulations.

Six different plant species were planted in pots containing standard soil type 2.3 (Lufa Speyer – Germany). Experimental design consisted of 5 test item treatment groups and an untreated group (deionised water), with 24 plants per group (6 or 8 replicate pots with 4 or 3 plants each, depending on species). The test item solutions were prepared in deionised water immediately before application and were applied with spray equipment calibrated to deliver an output of 400 L/ha ($\pm 10\%$). Plants were treated at BBCH 12-14. The pots were then placed on a bench top in a climatic chamber under controlled test conditions for 21 days.

Effects on plants as mortality and visual phytotoxicity (deformations, modifications in colour, necrosis) were recorded at 7, 14 and 21 days after the treatment (DAT). At the end of the test, the biomass (fresh shoot weight) was measured in addition.

No visible phytotoxic effects (deformations, modification in colour and necrosis) were observed at any of the tested plants. The NOEAR for mortality was ≥ 846.56 g prod./ha (equivalent to 160 g a.s./ha) for all species and the LR₅₀ was considered to be > 846.56 g prod./ha (equivalent to 160 g a.s./ha), the highest application rate in the study.

Regarding the effects on biomass, measured as fresh shoot weight, *Beta vulgaris* showed a statistically significant reduction respective to the untreated control at the highest application rate of 846.56 g prod./ha, thus the resulting NOEAR for this species is set to 423.28 g prod./ha (equivalent to 80 g a.s./ha). For *Brassica napus*, *Lycopersicon esculentum*, *Pisum sativum*, *Lolium perenne* and *Allium cepa* the NOEAR is ≥ 846.56 g prod./ha (equivalent to 160 g a.s./ha) due to the absence of statistically significant effects. Due to the lack of effects $\geq 50\%$ until the end of the test the ER₅₀ values for all test species could not be calculated and were assigned to be > 846.56 g prod./ha (equivalent to 160 g a.s./ha), the highest application rate in the study.

The analytical results demonstrate that the active substance content in the test item stock solution used to prepare the solutions for the treatments, was in the range of $\pm 20\%$ of nominal concentration. The mean a.s. recovery was 94.79%. As a result, the endpoints of the test were calculated with respect to the nominal concentration of the test item. All validity criteria was met.

I. MATERIALS AND METHODS

A. MATERIALS

- | | |
|------------------------------------|---|
| 1. Test Material: | Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C) |
| Description: | Off white liquid, SC (suspension concentrate) |
| Lot/batch: | 3188-220519-01 |
| Concentration/Purity: | 18.9% - 206 g/L |
| | Density: 1.09 g/mL |
| Stability of test compound: | Stability: Not stated |
| | Expiry date: 22 nd May 2021 |
| 2. Vehicle and/or control: | Vehicle control: Deionised water |
| 3. Test animals (Species): | Monocotyledons: <i>Lolium perenne</i> , <i>Allium cepa</i> |
| | Dicotyledons: <i>Beta vulgaris</i> , <i>Brassica napus</i> , <i>Pisum sativum</i> , <i>Lycopersicon esculentum</i> |
| Stage | Plants at BBCH 12 – 14 (2 to 4 true leaves stage) |
| Replicates: | 8 replicates for <i>Pisum sativum</i> and <i>Lycopersicon esculentum</i> . 6 replicates for the others. |
| Test vessel: | The plants were grown in non-porous plastic pots (not previously used and free of toxic material) with a tray under the pots. The |

pots were large enough to allow normal growth and limit overlap of leaves among plants (diameter 10 cm and high 10 cm). Each pot contained about 500 g of dry soil.

Test soil:

Soil parameter:

Standard soil type 2.3 (Lufa Speyer – Germany)

Silty sand (μS)

Batch # Sp 2.3 0520

Organic carbon (%C) $0.65 \pm 0.08\%$

Nitrogen (%N) $0.07 \pm 0.02\%$

pH 6.1 ± 0.4

Cation exchange capacity 6.8 ± 1.4

WHC $35.2 \pm 1.8\%$

Particle size analyses USDA (%)

< 0.002 7.3 ± 0.9

0.002 – 0.05 33.3 ± 0.6

0.02 – 2.0 59.4 ± 0.7

Untreated variant:

Reference standard:

Deionized water

Boric Acid

In order to evaluate the quality of the experimental conditions, the effects of the reference item Boric Acid on *Cucumis sativus* were investigated in a GLP test (BT036/20 – March 2020). The calculated value for the mean 7-day EC_{50} for seedling shoot length of *Cucumis sativus* should be in the range of 379.00 - 961.00 mg boric acid/kg dry soil (Environmental T.C. Canada - EPS/1/RM/45 - February 2005). In the latest laboratory study, the 7-day EC_{50} for seedling shoot length was 413.82 mg boric acid/Kg dry soil.

4. Environmental conditions

Temperature:

19.4 – 24.9 °C

Photoperiod:

16 hours light and 8 hours darkness

pH

6.1 ± 0.4

Relative Humidity:

38.3 - 85.6%

B. STUDY DESIGN AND METHODS

1. In-life dates:

01st April to 22nd April 2020 for the biological phase
23rd to 24th April 2020 for the analytical phase

2. Experimental design:

Six different plant species were planted in pots containing standard soil type 2.3 (Lufa Speyer – Germany).

Experimental design consisted of 5 test item treatment groups and an untreated group (deionised water), with 24 plants per group (6 or 8 replicate pots with 4 or 3 plants each, depending on species). The test item solutions were prepared in deionised water immediately before application and were applied with spray equipment calibrated to deliver an output of 400 L/ha ($\pm 10\%$). Plants were treated at BBCH 12-14.

The pots were then placed on a bench top in a climatic chamber under controlled test conditions for 21 days.

Test concentrations:

Test item was tested at 52.91, 105.82, 211.64, 423.28, 846.56 g prod./ha (equivalent to 10, 20, 40, 80, 160 g a.s./ha), plus a control (deionised water).

Test duration:

21 days

- 3. Observations:** Effects on plants as mortality and visual phytotoxicity (deformations, modifications in colour, necrosis) were recorded at 7, 14 and 21 days after the treatment (DAT). At the end of the test, the biomass (fresh shoot weight) was measured in addition.
- 4. Statistics:** Mortality and biomass data for each plant species were analysed using appropriate statistical methods. Where possible, No Observed Effect Application Rates (NOEAR) were determined. Calculation of rates that cause 50% mortality/ effect (LR₅₀/ER₅₀) were not possible, because only effects < 50 % occurred in the study.
The software ToxRat Pro version 3.3.0 was used to perform the statistical analysis.
- 5. Analytics:** A sample of the initial stock solution was analysed in order to verify the correct application of the test item. The analysis of the a.s. content in the stock solution was carried out with an analytical method validated in a separate GLP study BT209/19.

II. RESULTS AND DISCUSSION

No visible phytotoxic effects (deformations, Modification in colour and necrosis) were observed at any of the tested plants. The results for mortality and biomass fresh weight for each species are summarised in the following table:

Table A 2.6-1: Effects of the test item on the vegetative vigour of six terrestrial plant species at day 21 [g prod./ha]

Species	Mortality		Biomass as fresh shoot weight	
	LR50	NOEAR	ER50	NOEAR
<i>Beta vulgaris</i>	> 846.56	≥ 846.56	> 846.56	423.28
<i>Brassica napus</i>	> 846.56	≥ 846.56	> 846.56	≥ 846.56
<i>Pisum sativum</i>	> 846.56	≥ 846.56	> 846.56	≥ 846.56
<i>Lycopersicum esculentum</i>	> 846.56	≥ 846.56	> 846.56	≥ 846.56
<i>Lolium perenne</i>	> 846.56	≥ 846.56	> 846.56	≥ 846.56
<i>Allium cepa</i>	> 846.56	≥ 846.56	> 846.56	≥ 846.56

C. Validity criteria

According to the OECD test guideline No. 227 (2006), the test was considered valid because the following validity criteria are met:

- The seedling emergence (before test start) was at least 70% in control and treated groups. The actual value was 97.22 – 99.48%.
- Control plants did not exhibit visible phytotoxic effects (modification in colour, necrosis, leaf and stem deformations were 0% in all tested species) and the plants exhibit only normal variation in growth and morphology for that particular species;
- The mean control plant survival was 100% at the end of the test;
- Control environmental conditions, media and soil matrix (as well as source) were identical for control and test item plants.

All validity criteria was met.

III. CONCLUSION

All six test species showed no mortality at any of the tested application rates.

The NOEAR for mortality was ≥ 846.56 g prod./ha (equivalent to 160 g a.s./ha) for all species and the LR_{50} was considered to be > 846.56 g prod./ha (equivalent to 160 g a.s./ha), the highest application rate in the study.

No phytotoxic effects were observed at any of the tested species.

Regarding the effects on biomass, measured as fresh shoot weight, *Beta vulgaris* showed a statistically significant reduction respective to the untreated control at the highest application rate of 846.56 g prod./ha, thus the resulting NOEAR for this species is set to 423.28 g prod./ha (equivalent to 80 g a.s./ha). For *Brassica napus*, *Lycopersicon esculentum*, *Pisum sativum*, *Lolium perenne* and *Allium cepa* the NOEAR is ≥ 846.56 g prod./ha (equivalent to 160 g a.s./ha) due to the absence of statistically significant effects.

Due to the lack of effects $\geq 50\%$ until the end of the test the ER_{50} values for all test species could not be calculated and were assigned to be > 846.56 g prod./ha (equivalent to 160 g a.s./ha), the highest application rate in the study.

The analytical results demonstrate that the active substance content in the test item stock solution used to prepare the solutions for the treatments, was in the range of $\pm 20\%$ of nominal concentration. The mean a.s. recovery was 94.79%. As a result, the endpoints of the test were calculated with respect to the nominal concentration of the test item.

A 2.7 KCP 10.7 Effects on other terrestrial organisms (flora and fauna)

No additional data.

A 2.8 KCP 10.8 Monitoring data

No additional data.