REGISTRATION REPORT

Part B

Section 6:

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: ADM.00900.I.1.C

Product name: COSAYR

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 6 - Core Assessment – Central Zone, Initial version
June 2023	Initial zRMS assessment 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.
November 2023	Final report (Core Assessment updated following the commenting period) 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.

DATA PROTECTION CLAIM

Under Article 59, Regulation 1107/2009/EC, on behalf of the Sponsor Company 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

STATEMENT FOR OWNERSHIP

The summaries and evaluations contained in this review report may be based on unpublished proprietary data submitted for the purpose of the assessment undertaken by the regulatory authority that prepared it. Other registration authorities should not grant, amend, or renew a registration on the basis of the summaries and evaluation of unpublished proprietary data contained in this document unless they have received the data on which the summaries and evaluation are based, either –

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Reviewer comments:

This dossier has been prepared to support registration of ADM.00900.I.1.C / COSAYR in Poland and zonal registration for which PL was designated zRMS.
Current application has been submitted for the approval under Art.33 of EU Regulation 1107/2009 of the product with commercial name COSAYR (developmental code ADM.00900.I.1.C) suspension concentrate [Code: SC] containing Chlorantraniliprole, 200 g/L, intended use is an insecticide (details see GAP dRR B0).
ADM.00900.I.1.C was not a representative formulation reviewed during the Annex I inclusion/active substance renewal and has not previously been evaluated in any EU countries according to the Uniform Principles, thus it is not possible to refer to the DRAR conclusion on chlorantraniliprole with regard to the formulation studies. Therefore, relevant data on the plant protection product ADM.00900.I.1.C had to be generated for authorization purposes.
NOTE: Applicant clarified that *in vivo* studies were not performed with intention for use within the EU. It was however performed to satisfy the regulatory requirements of countries outside of the EU. Clarification has been accepted by the zRMS PL:

Justification for submission of new in vivo vertebrate studies for Annex III data. Contains Confidential Information. Product code: ADM.00900.I.1.C (former code used in the toxicity studies ADM.0900.I.1.C). Product contains 200 g/L Chlorantraniliprole. This justification for provision of new studies is submitted in the context of the Art. 33 submission of ADM.00900.I.1.C (COSAYR) in Central Zone with zRMS PL.

Annex point	Study reference	Justification for provision of new vertebrate data
KCP 7.1.1/01	[redacted] (2020) *Acute oral toxicity study of Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C) in rats (acute toxic class method)* Report No.: 401-1-01-23748; Sponsor reference No.: 000103527	*The in vivo study has been generated to satisfy the regulatory requirements of the countries outside of the EU. The study is included in the dRR for ADM.00900.I.1.C and the submission for completeness of information.*
KCP 7.1.2/01	[redacted]. (2020) *Acute dermal toxicity of Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C) in rats (fixed dose procedure)* Report No.: 403-1-01-23749; Sponsor reference No.: 000103526	
KCP 7.1.3/01	[redacted] (2020) *Acute inhalation toxicity study of Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C) in rats (acute toxic class method);* Report No.: 405-1-01-23750; Sponsor reference No.: 000103525	
KCP 7.1.4/03	[redacted] (2020) *Acute dermal irritation study of Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C) in rabbits* Report No.: 406-1-01-23751; Sponsor reference No.: 000103524	
KCP 7.1.5/03	[redacted] (2020) *Acute eye irritation study of Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C) in rabbits* Report No.: 407-1-01-23752; Sponsor reference No.: 000103523	
KCP 7.1.6/03	[redacted] (2020) *Skin sensitization study of Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C) by Local Lymph Node Assay in mice* Report No.: 409-1-01-23753; Sponsor reference No.: 000103522	

Regarding studies on acute toxicity including irritancy for eye and skin– based on alternative (*in vitro*) studies zRMS decided as follow:
1) In case of *in vitro* study [redacted] 2020 zRMS reviewer draws attention to the following information available in GD OECD 439 revision 14 June 2021 INITIAL CONSIDERATIONS AND LIMITATIONS Subsection 8: p.2 (..) data indicates a lack of applicability of the RhE based in vitro skin irritation test for agrochemical formulations (47). (..). See also: Kolle S.N, van Ravenzwaay B. and Landsiedel R. (2017). Regulatory accepted but out of domain: In vitro skin irritation tests for agrochemical formulations. Regul. Toxicol. Pharmacol 89, 125-130. Therefore study outcome is not accepted.

Thus, taking into account mentioned above information zRMS decided to con-clude assessment for Skin irritation hazard category for the ADM.00900.I.1.C taking into account outcome of the in vivo study [redacted] 2020 Acute dermal irritation study of Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C) in rabbits.
2) Regarding *in vitro* study [redacted] 2019, (Bovine corneal opacity and permeability assay for identifying test item inducing serious eye damage and test item not requiring classification – OECD 437), zRMS reviewer draws attention to the following information available in the paper: Kolle S.N., van Cott A., van Ravenzwaay B. and Landsiedel R. (2017): *Lacking applicability of in vitro eye irritation methods to identify seriously eye irritating agrochemical formulations: Results of bovine cornea opacity and permeability assay, isolated chicken eye test and the EpiOcular™ ET-50 method to classify according to UN GHS.* Regulatory Toxicology and Pharmacology 85 (2017) 33-47. Therefore study outcome is not accepted.
Thus, taking into account mentioned above information zRMS decided to conclude assessment in this hazard category for the product based on *in vivo* study: *Acute eye irritation study of Chlorantraniliprole 200 SC* (product code: ADM.0900.I.1.C) in rabbits; [redacted] 2020.

NDE assessment for operator, workers and B&R exposure to the chlorantraniliprole considering all critical use(s) and all tasks, identify safe use of the product ADM.00900.I.1.C / COSAYR

Based on the results of the acute toxicity and non-dietary risk assessments conducted for ADM.00900.I.1.C / COSAYR the following personal protective equipment (PPE)/risk management measures (RMM) are recommended:
Operator: Operators must wear adequate workwear covering arms, body and legs during M/L and A
Worker: Worker should use adequate workwear covering arms, body and legs when entering in a treated area.
Additional NDE calculations/assessments reflecting cMS comments have been added in the revised RR

6 Mammalian Toxicology (KCP 7)

6.1 Summary

Table 6.1-1: Information on ADM.00900.I.1.C*

Product name and code	Chlorantraniliprole 200 SC / ADM.00900.I.1.C
Formulation type	Suspension concentrate [SC]
Active substance (incl. content)	Chlorantraniliprole; 200 g/L
Function	Insecticide
Product already evaluated as the 'representative formulation' during the approval of the active substance	No
Product previously evaluated in another MS according to Uniform Principles	No

* Information on the detailed composition of ADM.00900.I.1.C can be found in the confidential dRR Part C.

Justified proposals for classification and labelling

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

Table 6.1-2: Justified proposals for classification and labelling for ADM.00900.I.1.C according to Regulation (EC) No 1272/2008

Hazard class(es), categories	None
Hazard pictograms or Code(s) for hazard pictogram(s)	None
Signal word	None
Hazard statement(s)	None
Precautionary statement(s)	None
Additional labelling phrases	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]
	Contains 1,2-Benzisothiazol-3(2H)-one (2634-33-5). May produce an allergic reaction. [EUH208]

Table 6.1-3: Summary of risk assessment for operators, workers, residents and bystanders for ADM.00900.I.1.C

	Result	PPE / Risk mitigation measures
Operators	Acceptable	None (Work wear - arms, body and legs covered (no gloves))
Workers	Acceptable	None (Work wear - arms, body and legs covered (no gloves))
Residents	Acceptable	None
Bystanders	Acceptable	None

No unacceptable risk for operators, workers, residents and bystanders was identified when the product is used as intended.

A summary of the critical uses and the overall conclusion regarding exposure for operators, workers and residents/bystanders is presented in the following table.

Table 6.1-4: Critical uses and overall conclusion of exposure assessment

1	2	3	4	5	6	7	8	9	10			
Use-No.* &	**Crops and situation (e.g. growth stage of crop)**	**F, Fn, Fpn G, Gn, Gpn or I ****	**Application**		**Application rate**		**PHI (d)**	**Remarks: (e.g. safener/synergist (L/ha))**	**Acceptability of exposure assessment**			
			Method / Kind (incl. application technique *)**	**Max. number (min. interval between applications) a) per use b) per crop/ season**	**Max. application rate kg as/ha a) Chlorantraniliprole**	**Water L/ha min / max**			**Operator**	**Worker**	**Residents**	**Bystander**
1	Head cabbage, cauliflower, broccoli (BBCH 15-49)	F	Foliar spraying overall, LCTM	a) 1 b) 1	0.028	400-600	3	Operators, workers, bystanders and residents [EFSA Guidance]				
2	Wine grape, Table grape (BBCH 57 – 83)	F	foliar, spraying, overall HCTM	a) 1 b) 1	0.036	400 - 1600	Wine grape: 30 Table grape: 3	Operators, workers, bystanders and residents [EFSA Guidance]				
3	Corn (BBCH 20-87)	F	Foliar spraying overall, LCTM	a) 1 b) 1	0.028	400-500	14	Operators, workers, bystanders and residents [EFSA Guidance]				

1	2	3	4	5	6	7	8	9	10			
7	Apple, pear, quince (BBCH 70-87)	F	Foliar spraying overall, HCTM	a) 1 b) 1	0.031	500-1500	14	Operators, workers, bystanders and residents [EFSA Guidance]				
10	Potato (BBCH 31-60)	F	Foliar spraying overall, LCTM	a) 1 b) 2 (7)	0.012	400-600	14	Operators, workers, bystanders and residents [EFSA Guidance]				

~~* 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

*** e.g. LC: low crops, HC: high crop, TM: tractor-mounted, HH: hand-held

& due to the huge number of uses proposed in the list of all intended GAPs referring to each MS, table 6.1-4 include use numbers chosen as worst case scenarios, for details regarding each use number please refer RR B0 GAP table,

Explanation for column 10 “Acceptability of exposure assessment”

A	Exposure acceptable without PPE / risk mitigation measures
R	Further refinement and/or risk mitigation measures required
N	Exposure not acceptable/ Evaluation not possible

Data gaps

Noticed data gaps are:

- None

6.2 Toxicological Information on Active Substance(s)

Information regarding classification of the active substances and on EU endpoints and critical areas of concern identified during the EU review are given in Table 6.2-1.

Table 6.2-1: Information on active substance

	Chlorantraniliprole
Common Name	Chlorantraniliprole
CAS-No.	500008-45-7
Classification and proposed labelling	
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	Hazard classes (s), categories: not classified Code(s) for hazard pictogram(s): none Signal word: none Hazard statement(s): none Precautionary statement(s): none
Additional C&L proposal	None
Agreed EU endpoints	
AOEL systemic	0.36 mg/kg bw/day (corrected by 13% for the limited oral absorption)
Oral absorption	13%
Vapour pressure	6.3×10^{-12} Pa at 20 °C and 2.1×10^{-11} Pa at 25°C (calculated values)
Reference	EFSA Journal 2013;11(6):3143 https://www.efsa.europa.eu/fr/efsajournal/pub/3143
Conditions to take into account/critical areas of concern with regard to toxicology	
According to Review Report/EFSA Conclusion for active substance	None

6.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for ADM.00900.I.1.C is given in the following tables. Full summaries of studies on the product that have not been previously considered within an EU peer review process are described in detail in Appendix 2.

Table 6.3-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for ADM.00900.I.1.C

Type of test, species, model system (Guideline)	**Result**	**Acceptability**	**Classification (acc. to the criteria in Reg. 1272/2008)**	**Reference**
LD_{50} oral, rat (OECD 423)*	> 2000 mg/kg bw	Yes	None	[redacted] 2020
LD_{50} dermal, rat (OECD 402)*	> 2000 mg/kg bw	Yes	None	[redacted] 2020
LC_{50} inhalation, rat (OECD 436)*	> 5.86 mg/L air	Yes	None	[redacted] 2020
Skin corrosion, RhET (OECD 431)	Non-corrosive	Supplementary	None	[redacted] 2020
Skin irritation, RhET (OECD 439)	Non-skin irritant	No		[redacted] 2020
Skin irritation, rabbit (OECD 404)*	Non-irritant	Yes		[redacted] 2020
Eye irritation, BCOP (OECD 437)	No category	No	None	[redacted] 2019

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
Eye irritation, RhCE (OECD 492)	No category	Supplementary		[redacted] 2020
Eye irritation, rabbit (OECD 405)*	Non-irritant	Yes		[redacted] 2020
Skin sensitisation, Keratinocyte-Based ARE-Nrf2 Luciferase Reporter Gene Test (OECD 442D)	Negative	Supplementary	None	[redacted] 2020
Skin sensitisation, human cell line activation test (hCLAT) (OECD 442E)	Positive	Supplementary		[redacted] 2020
Skin sensitisation, mouse (OECD 429, LLNA)*	Not sensitizing	Yes		[redacted] 2020
Supplementary studies for combinations of plant protection products	No data – not required	--	--	--

* The *in vivo* study has been generated to satisfy the regulatory requirements of the countries outside of the EU. The study is included in the dRR and the submission for completeness of information.

Table 6.3-2: Additional toxicological information relevant for classification/labelling of ADM.00900.I.1.C

	Substance (concentration in product, % w/w)	Classification of the substance (acc. to the criteria in Reg. 1272/2008)	Reference	Classification of product (acc. to the criteria in Reg. 1272/2008)
Toxicological properties of active substance (relevant for classification of product)	Chlorantraniliprole (18.5 - 19.1%)	None	Reg. 1272/2008 / EFSA conclusion	None
Toxicological properties of non-active substance (relevant for classification of product)	~~None~~	~~None~~	Reg. 1272/2008 / MSDSs*	~~None~~ Please refer to part C
	Confidential Please see part C			
Further toxicological information	No data – not required			

* Material safety data sheet provided by the applicant

6.4 Toxicological Evaluation of Groundwater Metabolites

All metabolite concentrations are predicted to stay below 0.1 µg/L – no groundwater assessment is required.

6.5 Dermal Absorption (KCP 7.3)

A summary of the dermal absorption values for the active substance in ADM.00900.I.1.C are presented in the following table.

Table 6.5-1: Dermal absorption values for active substance in ADM.00900.I.1.C

	Chlorantraniliprole	
	Value	Reference
Concentrate	10%	EFSA default value for water-based/dispersed or solid formulation types (EFSA Guidance on Dermal absorption, 2017)
Dilution	50%	

6.5.1 Justification for proposed values

No data on dermal absorption for Chlorantraniliprole in ADM.00900.I.1.C is considered required. Justifications for default values according to Guidance on Dermal Absorption (EFSA Journal 2017; 15(6):4873) are presented in the following table.

Table 6.5-2: Default dermal absorption rates for Chlorantraniliprole

	Value	Justification for value	Acceptability of justification
Concentrate	10%	Default value for SC concentrate formulation (EFSA Guidance on Dermal absorption, 2017)	Justification accepted. Endpoint can be used for current product
Dilution	50%		

6.6 Exposure Assessment of Plant Protection Product (KCP 7.2)

Reviewer comment:

The NDE calculations performed by the Applicant using EFSA Operator Model (75th quantile regression) are acceptable and zRMS agrees to the conclusions.
The risk assessment/calculated exposure for operators, workers and B&R are acceptable under conditions of intended uses. Reflecting cMS comments additional NDE calculations/assessments have been added in the revised RR

Table 6.6-1: Product information and toxicological reference values used for exposure assessment

Product name and code	Chlorantraniliprole 200 SC / ADM.00900.I.1.C
Formulation type	SC
Category	Insecticide
Active substance(s) (incl. content)	Chlorantraniliprole 200 g/L
AOEL systemic of a.s.	0.36 mg/kg bw/day (corrected by 13% for the limited oral absorption)
Inhalation absorption	100% (default assumption)
Oral absorption	13%
Dermal absorption	Concentrate: 10% Dilution: 50% *Default values (EFSA Guidance on Dermal absorption, 2017)*
Vapour pressure of a.s.	6.3×10^{-12} Pa at 20°C and 2.1×10^{-11} Pa at 25°C (calculated values)

6.6.1 Selection of critical uses and justification

The critical GAP used for the exposure assessment of the plant protection product is shown in Table 6.1-4. A list of all intended uses within the Central Zone is given in Part B, Section 0.

Justification

The critical GAP has been defined following evaluation of the individual GAPs for each crop and takes into account the maximum application rate applied in the minimum water volume as relevant for this zone.

6.6.2 Operator exposure

6.6.2.1 Estimation of operator exposure

A summary of the exposure models used for estimation of operator exposure to the active substance during application of Chlorantraniliprole 200 SC (product code ADM.00900.I.1.C) according to the critical uses is presented in Table 6.6-2. The outcome of the estimation is presented in Table 6.6-3 (longer term exposure). Detailed calculations are in Appendix 3.

As long as no harmonised approach on the setting of acute reference values for non-dietary human exposure is available, no acute exposure calculations are necessary.

Table 6.6-2: Exposure models for intended uses

Critical use(s)	• Head cabbage, cauliflower, broccoli (max. 0.14 L product/ha; min. 400 L water/ha) • Wine grapes, table grapes (max. 0.18 L product/ha; min. 400 L water/ha) • Corn (max. 0.14 L product/ha; min. 400 L water/ha) • Apple, pear, quince (max. 0.155 L product/ha; min. 500 L water/ha) • Potato (max. 0.06 L product/ha; min. 400 L water/ha)
Model	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 calculator version: 30/03/2015

Table 6.6-3: Estimated operator exposure (longer term exposure)

		Chlorantraniliprole	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Head cabbage, cauliflower, broccoli Vehicle-mounted downward-spraying, outdoor application			
Application rate		0.028 kg a.s/ha	
Spray application (AOEM; 75th percentile) Body weight: 60 kg			
	Work wear (arms, body and legs covered) M/L and A	0.013	3.49
Wine grapes, table grapes Vehicle-mounted upward-spraying, outdoor application			
Application rate		0.036 kg a.s/ha	
Spray application (AOEM; 75th percentile) Body weight: 60 kg			
	Work wear (arms, body and legs covered) M/L and A	0.017	4.64
Corn Vehicle-mounted downward-spraying, outdoor application			
Application rate		0.028 kg a.s/ha	
Spray application (AOEM; 75th percentile) Body weight: 60 kg			
	Work wear (arms, body and legs covered) M/L and A	0.013	3.49
Apple, pear, quince Vehicle-mounted upward-spraying, outdoor application			
Application rate		0.031 kg a.s/ha	
Spray application (AOEM; 75th percentile) Body weight: 60 kg			
	Work wear (arms, body and legs covered) M/L and A	0.015	4.07
Potato Vehicle-mounted downward-spraying, outdoor application			
Application rate		0.012 kg a.s/ha	
Spray application (AOEM; 75th percentile) Body weight: 60 kg			
	Work wear (arms, body and legs covered) M/L and A	0.006	1.77

zRMS: Reflecting cMSs comments where manual application is considered usual, the outcome of the estimated operator following manual application has been included in the table below.

Estimated operator exposure (longer term exposure) – Manual Application

		Chlorantraniliprole	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Hand held application to brassica vegetable			
Application rate		0.028 kg a.s./ha	
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	0.089	24.76
Knapsack application to brassica vegetable			
Application rate		0.028 kg a.s./ha	
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	0.104	28.86
Handheld application to grapes			
Application rate		0.036 kg a.s./ha	
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	0.0159	4.42
Knapsack application to grapes			
Application rate		0.036 kg a.s./ha	
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	0.0268	7.45
Handheld application to pome fruit			
Application rate		0.031 kg a.s./ha	
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	0.015	4.20
Knapsack application to pome fruit			
Application rate		0.031 kg a.s./ha	
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	0.0266	7.40
Handheld application to potatoes			
Application rate		0.012 kg a.s./ha	

Spray application (AOEM; 75th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	0.088	24.56
Knapsack application to potatoes			
Application rate		0.012 kg a.s./ha	
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	0.104	28.86

Results
It is concluded that the use of Chlorantraniliprole 200 SC (product code ADM.00900.I.1.C) is at an acceptable risk for the operator without additional PPE (Work wear with arms, body and legs covered).

6.6.2.2 Measurement of operator exposure

Since the operator exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses and consideration of the above mentioned personal protective equipment (PPE), a study to provide measurements of operator exposure was not necessary and was therefore not performed.

6.6.3 Worker exposure (KCP 7.2.3)

6.6.3.1 Estimation of worker exposure

Table 6.6-4 shows the exposure model(s) used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with Chlorantraniliprole 200 SC (product code ADM.00900.I.1.C) according to the critical use(s). Outcome of the estimation is presented in Table 6.6- (longer term exposure). Detailed calculations are in Appendix 3.

Table 6.6-4: Exposure models for intended uses

Critical use(s)	• Head cabbage, cauliflower, broccoli (max. 1 × 0.14 L product/ha; min. 400 L water/ha) • Wine grapes, table grapes (max. 1 × 0.18 L product/ha; min. 400 L water/ha) • Corn (max. 1 × 0.14 L product/ha; min. 400 L water/ha) • Apple, pear, quince (max. 1 × 0.155 L product/ha; min. 500 L water/ha) • Potato (max. 2 × 0.06 L product/ha with 7-day interval; min. 400 L water/ha)
Model	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 calculator version: 30/03/2015

Table 6.6-5: Estimated worker exposure (longer term exposure)

		Chlorantraniliprole	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Head cabbage, cauliflower, broccoli Reaching, picking Outdoor Work rate: 8 hours/day DT_{50}: 30 days DFR: 3 µg/cm²/kg a.s./ha			
Number of applications and application rate		1 × 0.028 kg a.s./ha	
Body weight: 60 kg	Potential	0.032	9.02

		Chlorantraniliprole	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
	Work wear (arms, body and legs covered) TC: 2500 cm^2/person/h	0.014	3.89
	Work wear and gloves (hands, arms, body and legs covered) TC: 580 cm^2/person/h	0.003	0.90
Grapes Hand harvesting Outdoor Work rate: 8 hours/day DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha			
Number of applications and application rate		1 × 0.036 kg a.s./ha	
Body weight: 60 kg	Potential	0.216	60.0
	Work wear (arms, body and legs covered) TC: 10100 cm^2/person/h	0.073	20.2
Corn Inspection, irrigation Outdoor Work rate: 2 hours/day DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha			
Number of applications and application rate		1 × 0.028 kg a.s./ha	
Body weight: 60 kg	Potential	0.018	4.86
	Work wear (arms, body and legs covered) TC: 1400 cm^2/person/h	0.002	0.54
Apple, pear, quince Searching, reaching, picking Outdoor Work rate: 8 hours/day DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha			
Number of applications and application rate		1 × 0.031 kg a.s./ha	
Body weight: 60 kg	Potential	0.140	38.8
	Work wear (arms, body and legs covered) TC: 4500 cm^2/person/h	0.028	7.75
	Work wear + gloves (hands, arms, body and legs covered) TC: 2250 cm^2/person/h	0.014	3.88
Potato Inspection, irrigation Outdoor Work rate: 2 hours/day DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha			
Number of applications and application rate		2 × 0.012 kg a.s./ha with 7-day interval	
Body weight: 60 kg	Potential	0.014	3.86

		Chlorantraniliprole	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
	Work wear (arms, body and legs covered) TC: 1400 cm^2/person/h	0.002	0.43

Results
It is concluded that, according to the EFSA-OPEX model, there is no unacceptable risk anticipated for the worker, when re-entering crops treated with Chlorantraniliprole 200 SC (product code ADM.00900.I.1.C) without additional PPE (Work wear with arms, body and legs covered).

As a standard rule, it should be mentioned on the label that treated crops should not be re-entered before spray deposits have completely dried.

6.6.3.2 Refinement of generic DFR value (KCP 7.2)

Since the worker exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses and considering above mentioned PPE level, exposure estimates using dislodgeable residue data are considered to be not necessary.

6.6.3.3 Measurement of worker exposure

Since the worker exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses and considering above mentioned PPE, a study to provide measurements of worker exposure was not necessary and was therefore not performed.

6.6.4 Resident and bystander exposure (KCP 7.2.2)

6.6.4.1 Estimation of resident and bystander exposure

The acute exposure assessment for bystanders covers the exposure that a resident could reasonably be expected to incur in a single day. Therefore, there is no need for a separate acute risk assessment for residents.

No bystander risk assessment is required for PPPs that do not have an acute AOEL. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure.

The estimation of resident exposure was performed according to the EFSA guidance on “the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products” (EFSA Journal 2014;12(10):3874).

Table 6.6- shows the exposure model used for estimation of resident and bystander exposure to Chlorantraniliprole. The outcome of the estimation is presented in (long term resident exposure). Detailed calculations are in Appendix 3.

Table 6.6-6: Exposure models for intended uses

Critical use(s)	• Head cabbage, cauliflower, broccoli (max. 1 × 0.14 L product/ha; min. 400 L water/ha) • Wine grapes, table grapes (max. 1 × 0.18 L product/ha; min. 400 L water/ha) • Corn (max. 1 × 0.14 L product/ha; min. 400 L water/ha) • Apple, pear, quince (max. 1 × 0.155 L product/ha; min. 500 L water/ha) • Potato (max. 2 × 0.06 L product/ha with 7-day interval; min. 400 L water/ha)

Model	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 calculator version: 30/03/2015

Table 6.6-7: Estimated resident exposure (long term exposure)

		Chlorantraniliprole	
Model data		**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Head cabbage, cauliflower, broccoli Vehicle-mounted downward spraying, outdoor application Buffer zone: 2 – 3 m Drift reduction technology: no DT_{50}: 30 days DFR: 3 µg/cm²/kg a.s./ha			
Number of applications and application rate		1 × 0.028 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.0009	0.26
	Vapour (75th perc.)	0.0011	0.30
	Deposits (75th perc.)	0.0002	0.06
	Re-entry (75th perc.)	0.0024	0.66
	Sum (mean)	**0.0036**	**1.01**
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.0002	0.06
	Vapour (75th perc.)	0.0002	0.06
	Deposits (75th perc.)	0.0000	0.03
	Re-entry (75th perc.)	0.0013	0.36
	Sum (mean)	**0.0015**	**0.40**
Grapes Vehicle-mounted upward-spraying, outdoor application Buffer zone: 5 m Drift reduction technology: no DT_{50}: 30 days DFR: 3 µg/cm²/kg a.s./ha			
Number of applications and application rate		1 × 0.036 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.0062	1.74
	Vapour (75th perc.)	0.0011	0.30
	Deposits (75th perc.)	0.0001	0.04
	Re-entry (75th perc.)	0.0030	0.84
	Sum (mean)	**0.0077**	**2.14**
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.0035	0.96
	Vapour (75th perc.)	0.0002	0.06
	Deposits (75th perc.)	0.0001	0.02
	Re-entry (75th perc.)	0.0017	0.47
	Sum (mean)	**0.0039**	**1.08**
Corn Vehicle-mounted downward spraying, outdoor application Buffer zone: 2 – 3 m Drift reduction technology: no DT_{50}: 30 days DFR: 3 µg/cm²/kg a.s./ha			
Number of applications and application rate		1 × 0.028 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.0009	0.26
	Vapour (75th perc.)	0.0011	0.30
	Deposits (75th perc.)	0.0002	0.06

		Chlorantraniliprole	
Model data		**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
	Re-entry (75th perc.)	0.0024	0.66
	Sum (mean)	**0.0036**	**1.01**
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.0002	0.06
	Vapour (75th perc.)	0.0002	0.06
	Deposits (75th perc.)	0.0000	0.03
	Re-entry (75th perc.)	0.0013	0.36
	Sum (mean)	**0.0015**	**0.40**
Apple, pear, quince Vehicle-mounted upward-spraying, outdoor application Buffer zone: 5 m Drift reduction technology: no DT_{50}: 30 days DFR: 3 µg/cm²/kg a.s./ha			
Number of applications and application rate		1 × 0.031 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.004	1.20
	Vapour (75th perc.)	0.001	0.30
	Deposits (75th perc.)	0.001	0.18
	Re-entry (75th perc.)	0.003	0.73
	Sum (mean)	**0.006**	**1.80**
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.002	0.66
	Vapour (75th perc.)	0.000	0.06
	Deposits (75th perc.)	0.000	0.08
	Re-entry (75th perc.)	0.001	0.40
	Sum (mean)	**0.003**	**0.88**
Potato Vehicle-mounted downward-spraying, outdoor application Buffer zone: 2 – 3 m Drift reduction technology: no DT_{50}: 30 days DFR: 3 µg/cm²/kg a.s./ha			
Number of applications and application rate		2 × 0.012 kg a.s./ha with 7-day interval	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.0004	0.11
	Vapour (75th perc.)	0.0011	0.30
	Deposits (75th perc.)	0.0002	0.05
	Re-entry (75th perc.)	0.0019	0.52
	Sum (mean)	**0.0029**	**0.81**
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.0001	0.03
	Vapour (75th perc.)	0.0002	0.06
	Deposits (75th perc.)	0.0001	0.02
	Re-entry (75th perc.)	0.0010	0.29
	Sum (mean)	**0.0012**	**0.32**

Results
It is concluded that there is no undue risk to both residents and bystander.

Estimated bystander exposure

Since no AAOEL value is set for Chlorantraniliprole, no acute non-dietary risk assessment was performed. Lack of scientific guidance or methodology is an acceptable reason for waiving according to Guidance of the European Commission[1]. The absence of such guidance on derivation of an appropriate reference dose ("AAOEL") was recognized by

- the European Food Safety Authority[2], and
- the European Commission Standing Committee[3].

Therefore, this waiver is presented in line with Guidance of the European Commission.

According to the EFSA-OPEX guidance, a bystander risk assessment is required for plant protection products that have an acute AOEL.

The chronic risk for bystanders however is covered by the chronic risk assessment for residents.

6.6.4.2 Measurement of resident and/or bystander exposure

Since the resident and/or bystander exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) for Chlorantraniliprole will not be exceeded under conditions of intended uses and considering above mentioned risk mitigation measures, a study to provide measurements of resident/bystander exposure was not necessary and was therefore not performed.

6.6.5 Combined exposure

Not relevant. The product contains only one active substance.

[1] Guidance Document for applicants on preparing dossiers for the approval of a chemical new active substance and for the renewal of approval of a chemical active substance according to Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013. SANCO/10181/2013, May 2013.
[2] Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. EFSA Journal 2014;12(10):3874)
[3] Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. SANTE-10832-2015.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	Vertebrate study Y/N	*Owner
KCP 7.1.1/01	[redacted]	2020	Acute oral toxicity study of Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C) in rats (acute toxic class method) Sponsor reference No.: 000103527 Study No: 401-1-01-23748 [redacted] GLP Unpublished	Y	ADM
KCP 7.1.2/01	[redacted]	2020	Acute dermal toxicity study of Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C) in rats (fixed dose procedure) Sponsor reference No.: 000103526 Study No: 403-1-01-23749 [redacted] GLP Unpublished	Y	ADM
KCP 7.1.3/01	[redacted]	2020	Acute inhalation toxicity study of Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C) in rats (acute toxic class method) Sponsor reference No.: 000103525 Study No: 405-1-01-23750 [redacted] GLP Unpublished	Y	ADM
KCP 7.1.4/01	[redacted]	2020	*In vitro* skin corrosion test of Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C) using reconstructed human epidermis tissues Sponsor reference No.: 000103534 Study No: 616-1-06-23741 [redacted] GLP Unpublished	N	ADM
KCP 7.1.4/02	[redacted]	2020	*In vitro* skin irritation test of Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C) using reconstructed human epidermis tissues	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
			Sponsor reference No.: 000103532 Study No: 618-1-06-23742 [redacted] GLP Unpublished		
KCP 7.1.4/03	[redacted]	2020	Acute dermal irritation study of Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C) in rabbits Sponsor reference No.: 000103524 Study No: 406-1-01-23751 [redacted] GLP Unpublished	Y	ADM
KCP 7.1.5/01	[redacted]	2019	*In vitro* eye irritation test of Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C) using bovine corneal opacity and permeability test Sponsor reference No.: 000103531 Study No: 530-1-01-23746 [redacted] GLP Unpublished	N	ADM
KCP 7.1.5/02	[redacted]	2020	*In vitro* eye irritation test of Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C) using reconstructed human cornea-like epithelium (RhCE) Sponsor reference No.: 000103533 Study No: 630-1-01-23747 [redacted] GLP Unpublished	N	ADM
KCP 7.1.5/03	[redacted]	2020	Acute eye irritation study of Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C) in rabbits Sponsor reference No.: 000103523 Study No: 407-1-01-23752 [redacted] GLP Unpublished	Y	ADM
KCP 7.1.6/01	[redacted]	2020	*In Vitro* Skin Sensitisation: Keratinocyte-Based ARE-Nrf2 Luciferase Reporter Gene Test of Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C). Sponsor reference No.: 000103529	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**
			Study No: 628-1-06-23744 [redacted] GLP Unpublished		
KCP 7.1.6/02	[redacted]	2020	*In Vitro* Skin Sensitisation: human Cell Line Activation Test (hCLAT) of Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C). Sponsor reference No.: 000103528 Study No: 629-1-06-23745 [redacted] GLP Unpublished	N	ADM
KCP 7.1.6/03	[redacted]	2020	Skin sensitisation study of Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C) by Local Lymph Node Assay in mice Sponsor reference No.: 000103522 Study No: 409-1-01-23753 [redacted] GLP Unpublished	Y	ADM

* ADM = proprietary of ADAMA Agricultural Solutions and all affiliates.

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

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

List of data submitted by the applicant and not relied on

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

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

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

Appendix 2 Detailed evaluation of the studies relied upon

A 2.1 Statement on bridging possibilities.

Comments of zRMS:	Bridging is not applicable. Hazard classification via the application of bridging principles is not possible since data on a similar mixture are not available. *In vivo* studies has been provided using currently registered product (ADM.0900.I.1.C).

A 2.2 Acute oral toxicity (KCP 7.1.1)

Comments of zRMS:	Acute Oral toxicity study [redacted] 2020 has been reviewed for compliance with the current guidelines, resulting from scientific progress. There is no deviation from studies protocol. The OECD 423 procedure implements the 3R rules thus study is in line with the suggestions of point 5 of Regulation 284/2013. Results of the study and conclusions are adequate for risk assessment and classification purpose. Study accepted

Reference	KCP 7.1.1/01
Report	Acute oral toxicity study of Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C) in rats (acute toxic class method) [redacted] 2020 Study No: 401-1-01-23748
Guideline(s)	OECD 423
Deviations	No
GLP	Yes
Acceptability	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test material (Lot/Batch No.)	Chlorantraniliprole 200 SC (product code : ADM.0900.I.1.C) (Batch 3188-220519-01)
Species	Rat, RccHan:WIST
No. of animals (group size)	6 rats/female
Dose(s)	2000 mg/kg body weight
Exposure	Gavage
Vehicle/Dilution	None, as supplied (18.9 %, 206 g/L)
Post exposure observation period	14 days
Remarks	None

Results and discussions

Table A 1: Results of acute oral toxicity study in rats of Chlorantraniliprole 200 SC

Dose (mg/kg bw)	Toxicological results *	Duration of signs	Time of death	LD_{50} (mg/kg bw) (14 days)
Female rats				
2000	0/0/6	n.a	Scheduled sacrifice	> 2000

* Number of animals which died/number of animals with clinical signs/number of animals used

Table A 2: Summary of findings of acute oral toxicity study in rats of Chlorantraniliprole 200 SC

Mortality	No mortality occurred.
Clinical signs	No clinical signs of toxicity were observed.
Body weight	Body weight gain was considered to be normal.
Macroscopic examination	The necropsies performed at the end of the study revealed no apparent findings.

Conclusion

Based on results of this study, the acute oral LD_{50} of Chlorantraniliprole 200 SC (product code: ADM.0090.I.1.C) is higher than 2000 mg/kg bw in rats.
Thus, no classification is required according to CLP Regulation (EC) No. 1272/2008.

A 2.3 Acute percutaneous (dermal) toxicity (KCP 7.1.2)

Comments of zRMS:	Acute percutaneous study [redacted] 2020 has been reviewed for compliance with the current guidelines, resulting from scientific progress. OECD 402 procedure is still valid and acceptable. Results of the study and conclusions are adequate for risk assessment and classification purpose. Study accepted.

Reference	KCP 7.1.2/01
Report	Acute dermal toxicity study of Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C) in rats (fixed dose procedure) [redacted] 2020 Study No: 403-1-01-23749
Guideline(s)	OECD 402
Deviations	No
GLP	Yes
Acceptability	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test material (Lot/Batch No.)	Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C) (Batch 3188-220519-01)
Species	Rat, RccHan: Wistar
No. of animals (group size)	3 rats/female
Dose(s)	2000 mg/kg bw
Exposure	24 hours (dermal, semi-occlusive)
Vehicle/Dilution	None
Post exposure observation period	14 days
Remarks	None

Results and discussions

Table A 3: Results of acute dermal toxicity study in rats of Chlorantraniliprole 200 SC

Dose (mg/kg bw)	Toxicological results *	Duration of signs	Time of death	LD_{50} (mg/kg bw) (14 days)
2000	0/0/3	n.a	Scheduled sacrifice	> 2000

* Number of animals which died/number of animals with clinical signs/number of animals used

Table A 4: Summary of findings of acute dermal toxicity study in rats of Chlorantraniliprole 200 SC

Mortality	No mortality occurred.
Clinical signs	No clinical signs of toxicity were observed.
Body weight	Body weight gain was considered to be normal.
Macroscopic examination	The necropsies performed at the end of the study revealed no apparent findings.

Conclusion

Based on results of this study, the acute dermal LD_{50} of Chlorantraniliprole 200 SC (product code: ADM.00900.I.1.C) is higher than 2000 mg/kg bw in rats.
Thus, no classification is required according to CLP Regulation (EC) No. 1272/2008.

A 2.4 Acute inhalation toxicity (KCP 7.1.3)

Comments of zRMS:	Study has been reviewed for compliance with the current guidelines In an acute inhalation toxicity study [redacted] 2020 [redacted] rats were exposed to an aerosol of the product in a dynamic flow-past, nose only inhalation exposure system. The test item aerosol was generated using a nebuliser and the breathing zone concentration, measured gravimetrically, was 5.86 mg product code: ADM.0900.I.1.C/L air. The mass median aerodynamic diameter (MMAD) of the aerosolized ADM.0900.I.1.C was determined to be 3.42 µm with an average geometric standard deviation (GSD) of 1.61. The 4-h acute inhalation median lethal concentration (LC_{50}) of: ADM.0900.I.1.C in in male and female [redacted] rats was found to be greater than the gravimetric concentration of 5.86 mg/L air. Results of the study and conclusions are adequate for risk assessment and classification purpose. Study accepted.

Reference	KCP 7.1.3/01
Report	Acute inhalation toxicity study of Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C) in rats (acute toxic class method) [redacted] 2020 Study No: 405-1-01-23750
Guideline(s)	OECD 436
Deviations	No
GLP	Yes
Acceptability	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test material (Lot/Batch No.)	Chlorantraniliprole 200 SC (product code : ADM.0900.I.1.C) (Batch 3188-220519-01)
Species	Rat, Wistar (RccHan: WIST)
No. of animals (group size)	6 rats (3 rats/sex)
Concentration(s)	5 mg/L air
Exposure	4 hours (nose only)
Vehicle/Dilution	None, as supplied (18.9 %, 206 g/L)
Post exposure observation period	14 days
Remarks	None

Results and discussions

Table A 5: Concentration(s) and exposure conditions

Target conc. (mg/L air)	Nominal conc. (mg/L air)	MMAD * (µm)	GSD ** (µm)
5	9.706	3.42	1.61

* MMAD = Mass Median Aerodynamic Diameter (mean)
** GSD = Geometric Standard Deviation (mean)

Table A 6: Results of acute inhalation toxicity study in rats of Chlorantraniliprole 200 SC

Estimated gravimetric concentration (mg/L air)	Toxicological results *	Duration of signs	Time of death	LC_{50} (mg/L air) (14 days)
Male rats				
5.86	0/ 0 /3	n.a	Scheduled sacrifice	>5.86
Female rats				
5.86	0/ 0 /3	n.a	Scheduled sacrifice	>5.86

* Number of animals which died/number of animals with clinical signs/number of animals used

Table A 7: Summary of findings of acute inhalation toxicity study in rats of Chlorantraniliprole 200 SC

Mortality	No mortality occurred.
Clinical signs	No clinical signs of toxicity were observed.
Body weight	A decrease in the mean body weight was observed on day 1, whereas an increase in the body weight was observed on day 3, 7, and 14 in both sexes of rats, when compared with day 0 mean body weight.
Macroscopic examination	The necropsies performed at the end of the study revealed no apparent findings.

Conclusion

Under conditions of this study, the 4-h acute inhalation median lethal concentration (LC_{50}) of Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C) in male and female Wistar rats was found to be greater than the achieved gravimetric breathing zone concentration of 5.86 mg/L air.
Thus, no classification is required according to CLP Regulation (EC) No. 1272/2008.

A 2.5 Skin irritation (KCP 7.1.4)

Comments of zRMS:	Study [redacted] 2020 based on RhE has been reviewed for compliance with the current guidelines, resulting from scientific progress. However, study outcome is reliable but for this ongoing registration process zRMS decided to conclude hazard assessment taking into account results of available *in vivo* study, therefore study [redacted] 2020 has been considered as supplementary to *in vivo* studies outcome.

A 2.5.1 Study 1

Reference	KCP 7.1.4/01
Report	*In vitro* skin corrosion test of Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C) using reconstructed human epidermis tissues [redacted] 2020 Study No: 616-1-06-23741
Guideline(s)	OECD Test Guideline 431 (2019)
Deviations	No
GLP	Yes
Acceptability	Supplementary ~~Yes~~
Duplication (if vertebrate study)	n.a

Materials and methods

Test material (Lot/Batch No.)	Chlorantraniliprole 200 SC (Product Code: ADM.0900.I.1.C); (Batch Batch 3188-220519-01)

Test system	Reconstructed human epidermis (SkinEthic™ RHE)
No. of replicates	6-well plates - Three replicates were used per exposure for the test item, positive control and negative control
Exposure	40 µL/0.5 cm^2 of Chlorantraniliprole 200 SC (Product Code: ADM.0900.I.1.C)
Vehicle/Dilution	None
Positive control	40 µL/0.5 cm^2 of 8N KOH
Negative control	40 µL/0.5 cm^2 of sterile distilled water
Remarks	None

The RhE test method is based on the premise that corrosive chemicals are able to penetrate the stratum corneum by diffusion or erosion and are cytotoxic to the cells in the underlying layers. Cell viability is measured by enzymatic conversion of the vital dye MTT [3-(4,5- Dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide, Thiazolyl blue tetrazolium bromide], into a blue formazan salt that is quantitatively measured after extraction from tissues.
Corrosive chemicals are identified by their ability to decrease cell viability below defined threshold levels.

Experimental procedures

Pre-Tests

Prior to the main experiment, preliminary tests, i.e. a colour interference test, direct MTT reduction test, and mesh compatibility were performed to select appropriate adapted controls and use of nylon mesh on the apical surface of each tissue.

Main Study

Pre-incubation

Upon receipt, the RhE tissues were cleaned, using Kim wipes, to remove any basal agarose and then transferred to 6-well plates containing 1 mL fresh maintenance medium. Tissues were pre-incubated overnight at 37 ± 1 °C in 5 ± 1% CO_2 in a humidified incubator.

Treatment

Tissues were exposed to Chlorantraniliprole 200 SC (Product Code: ADM.0900.I.1.C) or a negative control (sterile distilled water) for 3 minutes and 60 minutes. The positive control (8N KOH) was exposed for 60 minutes. Three replicates were used per exposure for the test item, positive control and negative control.
For the treatment of negative control tissues, 40 µL/0.5 cm^2 of sterile distilled water was applied for 3 minutes at room temperature and 60 minutes at 37 ± 1 °C in 5±1% CO_2 in a humidified incubator. For the treatment of Chlorantraniliprole 200 SC, 40 µL/0.5 cm^2 of Chlorantraniliprole 200 SC was applied on tissues and uniformly spread across the tissue surface by applying nylon mesh. For the treatment of positive control tissues, 40 µL/0.5 cm^2 of 8N KOH was applied for the exposure period of 60 minutes at 37±1 °C in 5±1% CO_2 in a humidified incubator. For treatment of positive and negative control nylon mesh was used.

Adapted Controls for MTT reducer

For the correction of OD, due to non-specific MTT reduction (by the positive control), additional adapted controls (i.e., two freeze killed tissues each) were maintained for both the negative and positive control. The negative and positive control tissues were treated for 60 minutes at 37 ± 1 °C in 5 ± 1% CO_2 in a humidified incubator.
Killed tissues were prepared by incubating the viable tissues at -80 ± 5 °C for 48 hours. For the treatment of negative control tissues, 40 µL/0.5 cm^2 each of sterile distilled water was applied for 60 minutes exposure time. For the treatment of freeze-killed positive control tissues, 40 µL/0.5 cm^2 of 8N KOH was applied for 60 minutes exposure time. Nylon mesh was used for uniform spreading of liquid materials.

Rinsing and Drying

After exposure, tissues were rinsed and dried with cotton buds. Any residual test item was initially removed by knocking the treated insert on a beaker or by holding upside down with forceps. Treated tissues were rinsed 20 times in a constant stream of 1 mL DPBS at a 5–8 cm distance from the insert to remove all residual test item from the epidermal surface. Mesh (applied on negative, treatment group and positive control treated tissues only) was removed by washing all tissues. The bottom of tissue inserts were dried on sterile absorbent paper (Kim wipes) for 1-2 seconds. The surface of the stratum corneum was gently swept using both ends of a cotton tip (5-6 turns per end). After washing, inserts were transferred to holding plates containing 300 µL maintenance medium

Assay Acceptance Criteria

Before assay data were evaluated, data were evaluated to meet the acceptance criteria for a valid assay. The following acceptance criteria were used to determine a valid assay:

- **Negative control (NC) acceptance criteria**: The NC data of mean optical density were within the OECD Guideline 431 range, i.e., ≥ 0.8 and ≤ 3.0 for each exposure time.
- **Positive control (PC) acceptance criteria**: Mean viability of tissues exposed for 60 minutes with the positive control (8N KOH), expressed as % of the negative control were < 15%.
- **Variation**: In the range of 20-100% viability and for OD's ≥ 0.3, difference in viability between tissue replicates was not > 30%.

Assay Evaluation Criteria

Once criteria for a valid assay had been met and the assay responses evaluated, the criteria necessary to classify the test item as corrosive or non-corrosive were as detailed for the prediction model for SkinEthic™ RhE:

Viability measured after exposure time points (3 and 60 minutes)	**Prediction to be considered**
STEP 1 : SkinEthic™ RhE	
< 50% after 3 min exposure	Corrosive
≥ 50% after 3 min exposure and < 15% after 60 min exposure	Corrosive
≥ 50% after 3 min exposure and ≥ 15% after 60 min exposure	Non-corrosive
STEP 2 for SkinEthic™ RhE for Test Item/mixtures identified as Corrosive in step 1	
< 18 % after 3 min exposure	Optional Sub-category 1A *
≥ 18 % after 3 min exposure	A combination of optional Sub-categories 1B-and-1C

Analysis

Data from individual tissue replicates i.e., OD values were processed further to calculate mean, standard deviation and percentage cell viability, in addition to the evaluation of classification. Data of percent coefficient of variation between tissue replicates were determined for each exposure time.

Results and discussions

Main Study

The mean percent viability of tissues treated with Chlorantraniliprole 200 SC, negative control and positive control are summarised below:

Table A 8: Corrosion results for Chlorantraniliprole 200 SC

Treatment	Viability	
	3 Minutes Exposure	60 Minutes Exposure
Negative control (Sterile distilled water)	100%	100%
Chlorantraniliprole 200 SC (Product Code :ADM .0900.I.1.C)	108.89%	102.72%
Positive control (8N KOH)	-	0.38%

Key: - = Not applicable.

All Optical Density (OD) values (corrected OD) for negative control replicates were between 1.999 and 2.431, against a guideline requirement of ≥ 0.8 and ≤ 3.0 (the acceptance criteria for SkinEthic™ RHE model). The positive control showed 0.38 % cell viability, against a guideline requirement of <15%, when compared with that of the concurrent negative control, demonstrating the efficiency of the SkinEthic™ RHE model.
All criteria for a valid study were met.

From results of this study, under the specified experimental conditions, Chlorantraniliprole 200 SC was concluded to be non-corrosive in the *in vitro* skin corrosion test, using reconstructed human epidermis (RhE) tissues.

Based on results of this study, Chlorantraniliprole 200 SC (Product Code: ADM.0900.I.1.C) is classified as non-corrosive as per the "United Nations Globally Harmonized System of Classification and Labelling of Chemicals.

Conclusion

From results of this study, it was concluded that Chlorantraniliprole 200 SC (Product Code: ADM.00900.I.1.C) is not corrosive to skin.

Comments of zRMS:	Regarding *in vitro* study [redacted] 2020 zRMS reviewer draws attention to the following information available in GD OECD 439 revision 14 June 2021 INITIAL CONSIDERATIONS AND LIMITATIONS Subsection 8: p.2 (..) data indicates a lack of applicability of the RhE based *in vitro* skin irritation test for agrochemical formulations (47). (..). See also: Kolle S.N, van Ravenzwaay B. and Landsiedel R. (2017). Regulatory accepted but out of domain: *In vitro* skin irritation tests for agrochemical formulations. Regul. Toxicol. Pharmacol 89, 125-130. Therefore study outcome is not accepted. Thus, taking into account mentioned above information zRMS decided to conclude assessment for Skin irritation hazard category for the ADM.00900.I.1.C taking into account outcome of the *in vivo* study [redacted] 2020 *Acute dermal irritation study of Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C) in rabbits*.

A 2.5.2 Study 2

Reference	KCP 7.1.4/02
Report	*In vitro* skin irritation test of Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C) using reconstructed human epidermis tissues [redacted] 2020 Study No: 618-1-06-23742
Guideline(s)	OECD Test Guideline 439 (2019)
Deviations	No
GLP	Yes
Acceptability	~~Yes~~ No
Duplication (if vertebrate study)	n.a

Materials and methods

Test material (Lot/Batch No.)	Chlorantraniliprole 200 SC (Product Code: ADM.0900.I.1.C); (Batch Batch 3188-220519-01)
Test system	Reconstructed human epidermis (SkinEthic™ RHE)
No. of replicates	6-well plates - Three replicates were used for the test item, positive control and negative control
Exposure	16 µL/0.5 cm^2 of test item
Vehicle/Dilution	None
Positive control	16 µL/0.5 cm^2 of 5% sodium dodecyl sulfate (5% aq.)
Negative control	16 µL/0.5 cm^2 of sterile Dulbecco's phosphate buffered saline (DPBS)
Remarks	None

The RhE test method is based on the premise that irritant chemicals are able to penetrate the stratum corneum and damage the underlying layers of keratinocytes and other skin cells. Cell viability is measured by enzymatic conversion of the vital dye MTT [3-(4, 5-Dimethylthiazol-2- yl)-2, 5-diphenyltetrazolium bromide, Thiazolyl blue tetrazolium bromide], into a blue formazan salt that is quantitatively measured after extraction from tissues.
Irritant chemicals are identified by their ability to decrease cell viability below defined threshold levels.

Experimental procedures

Pre-Tests

Prior to the main experiment, preliminary tests such as colour interference test, mesh compatibility test and direct MTT reduction tests were performed to select the appropriate adapted controls.

Main Study

Pre-incubation

Upon receipt, the RhE tissues were cleaned to remove basal agarose using Kim wipes and then transferred to 6-well plates containing 1 mL fresh growth medium. Tissues were pre-incubated overnight, at 37±1 °C in 5±1% CO_2 in a 95% humidified incubator.

Treatment

Tissues were exposed to test item, negative and positive control for 42 minutes. Three replicates were used for the test item, positive control and negative control.
For the treatment of test item, negative control tissues and positive control tissues, 16 µL/0.5 cm^2 of test item, 16 µL/0.5 cm^2 of sterile Dulbecco's phosphate buffered saline (DPBS) and 16 µL/0.5 cm^2 of 5% sodium dodecyl sulfate (5% aq.) were applied for 42 minutes at room temperature, respectively.

Rinsing and Drying

After exposure, tissues were rinsed and then dried with cotton buds. The test item was removed by rinsing 25 times in a constant soft stream of 1 mL DPBS from 5–8 cm distance from the insert to remove the entire test item from the epidermal surface. Mesh (applied on test item treated tissues, negative and positive control tissues) was removed during washing all tissues. The bottom of the tissue inserts were dried on a sterile absorbent paper (Kim wipes) for 1–2 seconds. The surface of the stratum corneum was gently swept up using both ends of a cotton tip (5–6 turns per end). After washing, inserts were transferred to holding plates containing 300 µL maintenance medium.

Post-Incubation

After washing and drying, tissues were incubated in 6-well plate containing 2 mL growth medium at 37±1°C in 5±1% CO_2 in a humidified incubator for 42 hours.

Assay Acceptance Criteria

- **Negative control (NC) acceptance criteria**: The NC data meet the acceptance criteria if the mean OD value of the 3 tissues is ≥ 1.2 at 570 ± 30 nm according to the historical database. The standard deviation value is considered as valid if it is ≤ 18%.
- **Positive control (PC) acceptance criteria**: The PC data meet the acceptance criteria if the mean viability, expressed as % of the NC, is < 40 % and the Standard Deviation value is ≤ 18 %.
- **Batch acceptance criteria**: All test item data from one batch is considered as valid if both the negative and the positive controls data fulfill the above criteria requirement.

Assay Evaluation Criteria

The OD values obtained with test item was used to calculate the percentage of viability normalised to NC, which is set to 100%. The cut-off value of percentage cell viability distinguishing irritant from non-classified test item and the statistical procedure(s) used to evaluate the results and identify irritant chemicals should be clearly defined, documented, and proven to be appropriate the cut-off values for the prediction of irritation are given below:

- The test is considered to be irritant to skin in accordance with UN GHS Category 2, if the tissue viability after exposure and post-treatment incubation is less than or equal (≤) to 50%.
- The test item is considered as non-irritant to skin in accordance with UN GHS No Category, if the

tissue viability after exposure and post-treatment incubation is more than (>) 50%.

Analysis

For controls and test item, data from individual tissue replicates (e.g., OD values and calculated percentage cell viability for each test item, including classification were reported in tabular form. In addition, mean and ranges of viability, standard deviation and CVs between tissue replicates for controls and test item were reported.

Results and discussions

Main Study

The mean percent viability of the Chlorantraniliprole 200 SC treated tissues, and the control tissues, is tabulated below:

Table A 9: Skin irritation results for Chlorantraniliprole 200 SC

Treatment	**Mean Percent Viability**
	42±1 Minutes Exposure
Negative control (Dulbecco's Phosphate Buffered Saline (DPBS))	100
Chlorantraniliprole 200 SC (ADM.0900.I.1.C)	86.9
Positive control (Sodium dodecyl sulfate (5% aq.))	1.2

The negative and positive controls met the acceptance range for the OECD guideline and the efficiency of the test system was demonstrated. All criteria for a valid study were met as described in the study plan.

Based on results of this study, Chlorantraniliprole 200 SC (ADM.0900.I.1.C) is classified under "No Category (Non Irritant)", as per the "United Nations Globally Harmonized System of Classification and Labelling of Chemicals".

Conclusion

Based on the results of this study, Chlorantraniliprole 200 SC (ADM.0900.I.1.C) is not an irritant to the skin. Therefore, no classification is required for Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C) according to CLP Regulation (EC) No. 1272/2008.

Comments of zRMS:	Acute dermal irritation study [redacted] 2020 has been reviewed for compliance with the current guidelines, resulting from scientific progress. OECD 404 procedure is still valid and acceptable. Results of the study and conclusions are adequate for risk assessment and classification purpose. Study accepted.

A 2.5.3 Study 3

Reference	KCP 7.1.4/03
Report	Acute dermal irritation study of Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C) in rabbits; [redacted] 2020 Study No: 406-1-01-23751
Guideline(s)	OECD 404
Deviations	No
GLP	Yes
Acceptability	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test material (Lot/Batch No.)	Chlorantraniliprole 200 SC (product code : ADM.0900.I.1.C) (Batch 3188-220519-01)
Species	Rabbit, New Zealand White
No. of animals (group size)	3 males
Initial test using one animal	No
Exposure	0.5 mL (4 hours, semi-occlusive)
Vehicle/Dilution	None
Post exposure observation period	72 hours
Remarks	None

Results and discussions

Table A 10: Skin irritation of Chlorantraniliprole 200 SC

Animal No.		Scores after treatment *				Mean scores (24-72 h)	Reversible (day)
		1 h	24 h	48 h	72 h		
1	Erythema Oedema	1 1	0 0	0 0	0 0	0.00 0.00	n.r.
2	Erythema Oedema	1 0	0 0	0 0	0 0	0.00 0.00	n.r.
3	Erythema Oedema	1 0	0 0	0 0	0 0	0.00 0.00	n.r.

* scores in the range of 0 to 4 (according to Draize et al)
n.r. not relevant

Clinical signs:	No clinical signs of toxicity were observed.

The classification of irritancy was obtained by adding the average erythema and edema scores for the 30-60 minutes, 24, 48 and 72-hours scoring intervals and dividing by the number of evaluation intervals.

The resulting Primary Dermal Irritation Index (PDII) was classified as follows:

PDII	Classification
0	Non-irritating
> 0 – 2.0	Slightly irritating
2.1 – 5.0	Moderately irritating
> 5.0	Severely irritating

According to CLP Regulation (EC) No. 1272/2008, an irritant Category 2 classification is required when:

- Mean value of ≥ 2,3 - ≤ 4,0 for erythema/ eschar or for oedema in at least 2 of 3 tested animals from gradings at 24, 48 and 72 hours after patch removal or, if reactions are delayed, from grades on 3 consecutive days after the onset of skin reactions; or
- Inflammation that persists to the end of the observation period normally 14 days in at least 2 animals, particularly taking into account alopecia (limited area), hyperkeratosis, hyperplasia, and scaling; or
- In some cases where there is pronounced variability of response among animals, with very definite positive effects related to chemical exposure in a single animal but less than the criteria above.

Conclusion

The mean scores for erythema (0.00) and oedema (0.00), observed at 24, 48, and 72-h post-patch removal, indicate that Chlorantraniliprole 200 SC is a non- irritant under the described experimental conditions.
In conclusion, Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C) showed no signs of skin irritation to rabbit skin.
Under the experimental conditions, no classification is required for Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C) according to CLP Regulation (EC) No. 1272/2008.

A 2.6 Eye irritation (KCP 7.1.5)

Comments of zRMS:	Regarding *in vitro* study [redacted] 2019, (Bovine corneal opacity and permeability assay for identifying test item inducing serious eye damage and test item not requiring classification – OECD 437), zRMS reviewer draws attention to the following information available in the paper: Kolle S.N., van Cott A., van Ravenzwaay B. and Landsiedel R. (2017): *Lacking applicability of in vitro eye irritation methods to identify seriously eye irritating agrochemical formulations: Results of bovine cornea opacity and permeability assay, isolated chicken eye test and the EpiOcular™ ET-50 method to classify according to UN GHS.* Regulatory Toxicology and Pharmacology 85 (2017) 33-47. Therefore study outcome is not accepted. Thus, taking into account mentioned above information zRMS decided to conclude assessment in this hazard category for the product based on *in vivo* study: *Acute eye irritation study of Chlorantraniliprole 200 SC* (product code: ADM.0900.I.1.C) in rabbits; [redacted] 2020.

A 2.6.1 Study 1

Reference:	KCP 7.1.5/01
Report	*In vitro* eye irritation test of Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C) using bovine corneal opacity and permeability test [redacted] 2019; Study No: 530-1-01-23746
Guideline(s):	OECD Test Guideline 437
Deviations:	No
GLP:	Yes
Acceptability:	~~Yes~~ No
Duplication (if vertebrate study)	n.a

Materials and methods

Test material (Lot/Batch No.)	Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C) (Batch 3188-220519-01)
Test system	Bovine cornea, prepared from eyes of freshly slaughtered animals
Number of replicates	3 corneas per test group (test item, positive control, negative control)
Exposure	750 µL of chlorantraniliprole 200 SC (undiluted)
Vehicle/Dilution	none
Positive control	750 µL dimethylformamide (undiluted)
Negative control	750 µL normal saline
Remarks	None

The Bovine Corneal Opacity and Permeability (BCOP) test method measures the ability of the test item to induce opacity and increase permeability in an isolated bovine cornea. This test method can identify chemicals inducing serious eye damage (Category 1) and those which do not require classification (No Category), according to United Nations Globally Harmonized System of Classification and Labelling of Chemicals (UN GHS).

Experimental procedures

Selected corneas were mounted on the corneal holders with the endothelial side against the O-ring of the

posterior half of the holder. The anterior half of the holder was then placed on the top of the cornea and fixed in place. Both chambers were then filled to excess with pre-warmed phenol red free Eagle's Minimum Essential Medium (EMEM) (the posterior chamber filled first to allow the cornea to return to its natural concave position), ensuring no bubbles were present within the holders. The device was then equilibrated at 32 ± 1°C for at least one hour to allow the corneas to equilibrate with the medium and achieve normal metabolic activity, to the extent possible.
Following equilibration, the medium was removed from both chambers and fresh pre-warmed phenol red free EMEM added to both chambers. A baseline opacity reading was then taken for each cornea.

Treatment

Corneas having an opacity value <7 opacity units for the opacitometer were used in the study. Three corneas were tested in each group, as follows:

Group 1 Negative Control	750 µL normal saline
Group 2 Positive Control	750 µL dimethylformamide (undiluted)
Group 3 Test Item	750 µL of chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C) (undiluted)

Application Procedure

- Initially, pH of the test item was determined at Jai Research Foundation and was found to be 7.45 ± 0.03.
- Liquids were tested undiluted.
- For each isolated eye, a volume of 750 µL was introduced into the anterior chamber through the dosing holes on the top surface of the chamber. The anterior compartment was then plugged.
- Post-test-item application, the holders were turned to a horizontal position and slightly rotated to ensure uniform covering of the test item over the cornea.
- Corneas were exposed for approximately 10 minutes ± 30 seconds at 32 ± 1 °C.
- At the end of exposure period, the test item, positive control and negative control were removed from their respective anterior chamber and the corneal epithelium washed until no visual evidence of test item, positive control or negative control was observed using EMEM (containing phenol red).

Post Exposure Incubation

- Once the medium was free from any visible test item, the corneas were given a final rinse with EMEM (without phenol red).
- Media in the anterior and the posterior chamber was removed and fresh EMEM (without phenol red) was filled. The compartments were plugged, and post treatment opacity of each cornea recorded.
- Once the medium was free of test item, the corneas were given a final rinse with EMEM (without phenol red).
- The anterior chamber was then refilled with fresh EMEM without phenol red.
- After rinsing, the corneas were incubated for an additional period of approximately 2 hours ± 10 minutes at 32 ± 1ºC.

The following formula was used to determine the *in vitro* irritation score (IVIS)

IVIS = mean opacity value + (15 x mean permeability OD_{490} value)

Decision Criteria

The IVIS cut-off values for identifying test item as inducing serious eye damage (UN GHS Category 1) and test item not requiring classification for eye irritation or serious eye damage (UN GHS No Category) are given below:

IVIS	UN GHS
≤ 3	No Category
> 3; ≤ 55	No prediction can be made
> 55	Category 1

Acceptance Criteria

The following acceptance criteria should be satisfied for the assays to be considered valid:

Negative control (NC) acceptance criteria: The negative or solvent/vehicle control responses should result in opacity and permeability values that are less than the established upper limits for background opacity and permeability values for bovine corneas treated with the respective negative or solvent/vehicle control.
Positive control (PC) acceptance criteria: The mean In-Vitro Irritancy Score (IVIS) of positive control treated corneas should be within the range of two standard deviations of the mean of the historical control data.

Results and discussion

Corneal Opacity

The mean final opacity values for Chlorantraniliprole 200 SC treated eyes (2.63) shows an observable increase in comparison to the control group (0.30). An observable marked increase in the final mean opacity was observed in corneas treated with the positive control, N,N-dimethylformamide (76.12).

Corneal Permeability

The mean final corneal permeability values for Chlorantraniliprole 200 SC treated eyes (0.020) shows no observable increase in comparison to the control group (0.041). An observable marked increase in the mean final corneal permeability was observed in corneas treated with the positive control, N,N-dimethylformamide (1.606).

In vitro Irritancy Score (IVIS)

The mean *In-Vitro* Irritancy Score (IVIS) of normal saline (control) and N,N-dimethylformamide (positive control) treated corneas were found to be 0.91 and 100.21, respectively.
The mean IVIS score for the corneas treated with Chlorantraniliprole 200 SC was found to be 2.93.

Table A 11: Ocular irritancy of Chlorantraniliprole 200 SC

Treatment	Mean Corneal Opacity	Mean Corneal Permeability	*In Vitro* Irritancy Score (IVIS)
Negative control (Saline)	0.30	0.041	0.91
Positive control (DMF)	76.12	1.647	100.21
Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C)	2.63	0.061	2.93

Validity of the Test

The mean *In-Vitro* Irritancy Score (IVIS) of dimethylformamide (positive control) treated corneas were found to be 100.21 which is within the range of two standard deviation of the mean of the historical control data, confirming the reliability of the test procedure.
The opacity and permeability values of the negative control (saline) treated corneas (0.30 and 0.041, respectively) were less than the established upper limits for background values, confirming the reliability of the test procedure

Conclusion

The mean IVIS score for corneas treated with Chlorantraniliprole 200 SC was found to be 2.93. Based on the mean IVIS cut-off values (OECD Test Guideline 437), no classification is required for Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C).

Comments of zRMS:	Study [redacted] 2020 based on in vitro RhCE metod has been reviewed for compliance with the current guidelines, resulting from scientific progress. However, study outcome is reliable but for this ongoing registration process zRMS decided to conclude hazard assessment taking into account results of available *in vivo* study, therefore study [redacted] 2020 has been considered as supplementary to *in vivo* studies outcome.

A 2.6.2 Study 2

Reference:	KCP 7.1.5/02
Report	*In vitro* eye irritation test of Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C) using reconstructed human cornea-like epithelium (RhCE) [redacted] 2020 Study No: 630-1-01-23747
Guideline(s):	OECD Test Guideline 492 (2019)
Deviations:	No
GLP:	Yes
Acceptability:	~~Yes~~ Supplementary
Duplication (if vertebrate study)	n.a

Materials and methods

Test material (Lot/Batch No.)	Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C) (Batch 3188-220519-01)
Test system	Reconstructed human cornea epithelium (RhCE)
Number of replicates	Two tissues tested in each group (test item, positive control, negative control)
Exposure	10 µL DPBS + 30 µL Chlorantraniliprole 200 SC (Product Code: ADM.0900.I.1.C)
Vehicle/Dilution	DPBS
Positive control	10 µL DPBS + 30 µL methyl acetate (undiluted)
Negative control	30 µL DPBS
Remarks	None

The reconstructed human cornea-like epithelium (RhCE) test method measures the ability of a test chemical to induce cytotoxicity in a RhCE tissue construct, as measured by the MTT assay.
This test method can identify chemicals which do not require classification (No Category), according to United Nations Globally Harmonized System of Classification and Labelling of Chemicals (UN GHS).

Experimental procedures

Pre-tests

Test item which directly reduce MTT or which are strongly coloured may interfere with the measurement of Formazan dye, leading to a false estimate of tissue viability, i.e., under-prediction of eye irritation. Prior to main experiment, a pre-test was performed to determine the need for appropriate adapted controls.

Application of the Test and Control Substances

The tissue surface was moistened with DPBS before application of test item, to mimic the wet conditions of human eye. Tissues were exposed to test item, negative and positive control for 30 minutes. Two tissues were tested in each group, as follows:

Negative control	30 µL DPBS
Positive control	10 µL DPBS + 30 µL methyl acetate (undiluted)
Chlorantraniliprole 200 SC (Product Code: ADM.0900.I.1.C)	10 µL DPBS + 30 µL Chlorantraniliprole 200 SC (Product Code: ADM.0900.I.1.C)

Rinsing and Post-Incubation

At the end of this exposure period, residual test item or control substances was removed from the tissue surface by rinsing the tissues with DPBS. After rinsing, the tissues were transferred to wells containing 750 µL of fresh maintenance medium, and tissues was immerged with 750 µL of fresh maintenance medium pre-warmed at room temperature. Tissues were verified for the presence of air bubbles below tissues and were immersed for 30 ± 2 minutes at 37 ± 2 °C, 5 ± 1% CO_2 with saturated humidity. At the end of the post-exposure immersion, each tissue was removed from the maintenance medium and the medium was discarded. The bottom of the insert was dried by gently tapping on a dry absorbent paper and blotting the surface with a cotton swab.

Acceptance and Evaluation Criteria

The following acceptance criteria were used to determine a valid assay:

- **Negative control (NC) acceptance criteria**: The NC data met the acceptance criteria, where the mean OD value was > 1.0 and < 2.5.
- **Positive control (PC) acceptance criteria**: Mean viability of the tissue replicates exposed with the positive control, expressed as % of the negative control was: 30-minute exposure (Liquid): below 30% of control viability
- **Variation**: Difference of viability between the two relating tissues of a single set was < 20% in the same run (for all groups). The same applies also to the killed controls and the colorant controls which are calculated as percent values related to the viability of the relating negative control.

Decision Criteria

% Viability	No Category	No prediction can be made
For Liquid Test Item	Mean tissue viability > 60%	Mean tissue viability ≤ 60%

Results and discussion

Main Study

The mean percent viability of the Chlorantraniliprole 200 SC treated tissues, and the control tissues, is tabulated below:

Table A 12: Mean viability score obtained with Chlorantraniliprole 200 SC

Treatment	Mean Percent Viability
Negative control (DPBS)	100.00
Positive control (methyl acetate)	14.01
Chlorantraniliprole 200 SC	70.01

Although there was a reduction in the percent cell viability observed in Chlorantraniliprole 200 SC treated tissues, when compared with that of the concurrent negative control, the mean viability score of 70.01% is above the established tissue viability cut- off value of 60%.
Adaptive controls were not included in the main test since the test item did not show direct MTT reduction or colour interference in the pre-tests.
Therefore, based on results of this study, Chlorantraniliprole 200 SC is classified as "No category", as per the "United Nations Globally Harmonized System of Classification and Labelling of Chemicals".

Validity of the Test

- Negative control OD values were found to be within the range of > 1.0 to < 2.5
- Mean tissue viability values for positive control was found < 30%
- Variation within the replicates was acceptable (< 20%)

Therefore, the experiment is considered valid.

Conclusion

Based on the mean viability score of 70.01%, determined under the specified experimental conditions using SkinEthic^{TM} HCE RhCE, Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C) is considered as not irritating to eyes.
Therefore, no classification is required for Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C) according to CLP Regulation (EC) No. 1272/2008.

Comments of zRMS:	Study ([redacted] 2020) has been reviewed for compliance with the current guidelines resulting from scientific progress (OECD 405 rev 2017). Updated TG mainly focused on the use of analgesics and anesthetics without impacting the basic concept and structure of the TG ICCVAM. TG concluded that the use of topical anesthetics and systemic analgesics could avoid most or all pain and distress without affecting the outcome of the test, and recommended that these substances should always be used. In the discussed study ([redacted] 2020) topical anesthetics has been used. One hour before the application of the test item, 0.01 mg/kg of buprenorphine was administered subcutaneously in order to achieve a therapeutic level of systemic analgesia. Approximately 5 minutes prior to the application of the test item, 1–2 drops of an ocular anaesthetic (proparacaine hydrochloride ophthalmic 0.5% solution) were administered in both the treated and the control eye of the animal. To prevent pain and distress after the application of the test item the animal was treated with the 0.05 mg/kg sc of buprenorphine and meloxicam. Study implements 3R rules and humane endpoints minimizing pain and distress of animals. In the mentioned study degree of eye irritation/serious eye damage were evaluated by scoring lesions of conjunctiva, cornea, and iris, at specific intervals. Duration of the study was sufficient to evaluate the reversibility or irreversibility of the effects. Results of the study and conclusions are adequate for risk assessment and classification purpose. Study accepted.

A 2.6.3 Study 3

Reference	KCP 7.1.5/03
Report	Acute eye irritation study of Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C) in rabbits [redacted] 2020;n Study No: 407-1-01-23752
Guideline(s)	OECD 405
Deviations	No
GLP	Yes
Acceptability	Yes
Duplication (if vertebrate study)	No

Materials and methods

~~**Test material (Lot/Batch No.)**~~	~~Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C) (Batch 3188-220519-01)~~
~~**Test system**~~	~~Reconstructed human cornea epithelium (RhCE)~~
~~**Number of replicates**~~	~~Two tissues tested in each group (test item, positive control, negative control)~~
~~**Exposure**~~	~~10 µL DPBS + 30 µL Chlorantraniliprole 200 SC (Product Code: ADM.0900.I.1.C)~~
~~**Vehicle/Dilution**~~	~~DPBS~~
~~**Positive control**~~	~~10 µL DPBS + 30 µL methyl acetate (undiluted)~~
~~**Negative control**~~	~~30 µL DPBS~~
~~**Remarks**~~	~~None~~

Test material (Lot/Batch No.)	Chlorantraniliprole 200 SC (product code : ADM.0900.I.1.C) (Batch 3188-220519-01)

Species	Rabbit, New Zealand White
No. of animals (group size)	3 females
Initial test using one animal	No
Exposure	0.1 mL (single instillation in conjunctival sac of right eye)
Irrigation (time point)	No
Vehicle/Dilution	None
Post exposure observation period	72 hours
Remarks	None

Results and discussions

Table A 13: Eye irritation of Chlorantraniliprole 200 SC

Animal No.		Scores after treatment *				Mean scores (24-72 h)	Reversible (day)
		1 h	24 h	48 h	72 h		
1	Corneal opacity	0	0	0	0	0.00	Day 2
	Iritis	0	0	0	0	0.00	
	Redness conjunctivae	1	1	0	0	0.33	
	Chemosis conjunctivae	0	0	0	0	0.00	
2	Corneal opacity	0	0	0	0	0.00	Day 2
	Iritis	0	0	0	0	0.00	
	Redness conjunctivae	1	1	0	0	0.33	
	Chemosis conjunctivae	0	0	0	0	0.00	
3	Corneal opacity	0	0	0	0	0.00	Day 2
	Iritis	0	0	0	0	0.00	
	Redness conjunctivae	1	1	0	0	0.33	
	Chemosis conjunctivae	0	0	0	0	0.00	

* scores in the range of 0 to 4 for cornea opacity and chemosis, 0 to 3 for redness of conjunctivae and 0 to 2 for iritis (according to Draize *et al*.)

Clinical signs:	No sign of systemic toxicity, including clinical observation and body weight, was observed in any rabbit, throughout the experimental period.
Eye examinations	At 1 and 24-h post-TIA, treated eyes of all rabbits revealed conjunctival redness [some blood vessels definitely hyperaemic (injected); score of 1]. At 48-h post-TIA, treated eyes of all rabbits recovered completely and appeared normal for the remainder of the experimental period. Conjunctival chemosis, corneal opacity and iritis were not observed in any rabbit, throughout the experimental period. Examination with fluorescein dye and cobalt blue filter revealed no (area) corneal epithelium damage in any rabbit at 24 h post TIA.

Conjunctival redness was evident at an interval of 1 and 24 h in all rabbits, which resolved by 48 h post-TIA in all rabbits. The rabbit mean eye irritation score, at 24, 48, and 72-h post-TIA observation, was 0.00, 0.00, 0.00 for corneal opacity, 0.00, 0.00, 0.00 for iris effects, 0.33, 0.33, 0.33 for conjunctival redness, and 0.00, 0.00, 0.00 for conjunctival chemosis for rabbit N° 1, 2, and 3, respectively. An examination with fluorescein dye and cobalt blue filter [corneal epithelium damage showing as green fluorescein staining] revealed no (area) corneal epithelium damage in any rabbit at 24-h post-TIA

According to CLP Regulation (EC) No. 1272/2008, a category 2 for reversible eye effects, is required if, when applied to the eye of an animal, a substance produces:

- at least in 2 of 3 tested animals, a positive response of:
    - corneal opacity ≥ 1 and/or
    - iritis ≥ 1, and/or
    - conjunctival redness ≥ 2 and/or

- conjunctival oedema (chemosis) ≥ 2

- calculated as the mean scores following grading at 24, 48 and 72 hours after installation of the test material, and which fully reverses within an observation period of 21 days.

Conclusion

Based on results of this study, there were no signs of eye irritation after ocular application of Chlorantraniliprole 200 SC. The main eye irritation scores (at 24, 48 and 72 h) were corneal opacity (0), iritis (0), chemosis (0) and conjunctival redness (0.33).
Under the experimental conditions, no classification is required for Chlorantraniliprole 200 SC (product code: ADM.00900.I.1.C) according to CLP Regulation (EC) No. 1272/2008.

A 2.7 Skin sensitisation (KCP 7.1.6)

Reviewer general comment regarding skin sensitisation assessment:
There are three studies (2 *in vitro* and 1 *in vivo*) has been submitted to elucidate skin sensitisation potential of the product ADM.0900.I.1.C. *In vitro* studies gave contradictory results, negative ([redacted] 2020) and positive ([redacted] 2020). *In vivo* study ([redacted] 2020) LLNA test was clearly negative, thus considering WoE two out three studies were negative, available results supports conclusion that skin sensitization classification is not warrant.

Comments of zRMS:	Study [redacted] 2020 based on on in vitro Keratinocyte-Based ARE-Nrf2 Luciferase method has been reviewed for compliance with the current guidelines, resulting from scientific progress. Due to fact that *In vitro* studies gave contradictory results, negative ([redacted] 2020) and positive ([redacted] 2020) for this ongoing registration process zRMS decided to conclude hazard assessment taking into account results of available *in vivo* study, therefore study [redacted] 2020 has been considered as supplementary to *in vivo* studies outcome.

A 2.7.1 Study 1

Reference	KCP 7.1.6/01
Report	*In Vitro* Skin Sensitisation: Keratinocyte-Based ARE-Nrf2 Luciferase Reporter Gene Test of Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C). [redacted] 2020 Study No: 628-1-06-23744
Guideline(s)	OECD 442D
Deviations	No
GLP	Yes
Acceptability	~~Yes~~ Supplementary
Duplication (if vertebrate study)	n.a

Materials and methods

Test material (Lot/Batch No.)	Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C) (Batch 3188-220519-01)
Test system	Genetically modified HaCaT cell line (KeratinoSens™)
Number of replicates	Two independent repetitions, each containing three replicates of each concentration
Exposure	Chlorantraniliprole 200 SC : 0.98µM to 2000µM
Vehicle/Dilution	Distilled water
Positive control	Trans-cinnamaldehyde: final concentration of positive control ranging from 4 to 64 µM
Negative control	DMSO
Remarks	None

Experimental procedures

Experimental Design

For each test article and positive control, one experiment consisting of at least two independent repetitions, each containing three replicates of each concentration, was performed. Each independent repetition was performed on a different day with fresh stock solutions of chemicals and independently harvested cells.

Preparation of Cell Culture for Treatment (Day -1)

One day prior to testing, cells were harvested and distributed into 96-well plates at a cell density of 10,000 cells/well, as follows:
After cells attained 80–90% confluency, they were washed twice with DPBS containing 0.05% of EDTA. To each flask 2–3 mL of 0.05% Trypsin-EDTA was added and flasks were incubated at 37 ± 1 °C (usually 5–10 minutes). After cells were detached completely, they were re-suspended in DMEM with 9.1% FBS without geneticin. Cell count was taken and cell density was adjusted to 8 × 104 cells/mL. 125 µL of this culture (containing approx. 10,000 cells) was then dispensed into each well of the 96-well plates, leaving one cell empty (to assess background values). Plates were incubated for 24 hours in 5 ± 1 % CO2 at 37 ± 1 °C.
Note: Four plates were seeded for Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C) i.e., three 96-well white assay plates (for luciferase assay) and one 96-well flat-bottom transparent plate (for cytotoxicity, MTT assay).

Preparation of Control and Test Item

The test item and control substances were prepared on the day of testing (day 1).

Control Preparation

Positive control: Trans-cinnamaldehyde was dissolved in DMSO to achieve concentration of 200 mM. This solution was further diluted to final concentration of 6.4 mM by adding 32 µL of 200 mM solution to 968 µL of DMSO.
Negative control: Distilled water was used as negative (solvent) control.

Test Item Preparation

A quantity of 528.09 mg of Chlorantraniliprole 200 SC was dissolved in 1 mL distilled water to attain the stock solution concentration of 200 mM.
Serial dilutions were made using distilled water to obtain 12 stock concentrations (0.098 mM to 200 mM).

Application of Test and Control Items (Day 1)

The 96-well microtiter master plate (100X Master Plate) contained Chlorantraniliprole 200 SC in rows A and a positive and negative control in row H. At least one well per plate was left empty (no cells and no treatment) to assess background values:

For Test Item Row (Row A)
100 µL of distilled water was added in column 1–11 of rows A. Then 100 µL of 200 mM of stock solution of test item was added in column 11 & 12 of corresponding rows. Serial dilutions were prepared by transferring 100 µL from column 11 to column 10 and was continued until column 1.

For Control Row (Row H)
100 µL of distilled water was added in column 1–6 and column 12. 100 µL of DMSO was added in column 7–10. In column 10 and 11, 100 µL of 6.4 mM stock solution of trans-cinnamaldehyde was added. Serial dilutions were prepared by transferring 100 µL from column 10 to column 9 (until column 7). Column 1–6 served as negative control (distilled water), column 7–11 served as positive control and column 12 served as a no-cell blank

Test Item Exposure Procedure (Day 2)
After 24 ± 2 hours of incubation, medium from all the 4 plates (three plates for luciferase assay and one for cytotoxicity, MTT assay) was aspirated and discarded. It was replaced with 150 µL of DMEM containing 1% FBS without geneticin. The 25-fold dilution of the 100X master plate (prepared as described above in Section 4.5) was performed into a fresh plate (10 µL test solution
+ 230 µL of DMEM with 1% FBS without geneticin + 10 µL DMSO). The resulting 4X plate was further distributed to assay plates: 50 µL of this stock solutions were added to three white assay plates and one

cytotoxicity plate already containing 150 µL of culture medium. Final test concentrations used for the exposure were 0.98, 1.95, 3.91, 7.81, 15.63, 31.25, 62.5, 125, 250, 500, 1000, and 2000 µM for both the experiments. Plates were then covered with petri-seal and incubated for 48 ± 2 hours in 5 ± 1 % CO_2 at 37 ± 1 °C.

Assay Acceptance Criteria
An assay is considered acceptable if it met the following criteria:
The luciferase activity induction obtained with the positive control, trans-cinnamaldehyde, should be statistically significant above the threshold of 1.5 (e.g., using a t-test) in at least one of the tested concentrations (from 4 to 64 µM)

- I_{max} and $EC_{1.5}$ for trans-cinnamaldehyde was calculated.
- (i) $EC_{1.5}$ value should be within two standard deviations of the historical mean of the testing facility (e.g. between 7 µM and 30 µM based on the validation dataset)
- (ii) Average gene induction in three replicates for trans-cinnamaldehyde at 64 µM should be between 2 and 8. If the latter criterion is not fulfilled, the dose-response of trans- cinnamaldehyde should be carefully checked, and tests may be accepted only if there is a clear dose-response with increasing gene induction at increasing dose for the positive control.
- Average coefficient of variation in the 3×6 solvent control wells (DW) for each repetition should be below 20%. If variability is higher, results are discarded.

Note: If the data for one well is > 25% lower or higher the average of other five wells, this well can be considered an outlier and removed from the analysis.

Assay Evaluation Criteria
A KeratinoSens™ prediction was considered positive if all the following conditions were met in 2 of 2 or in the same 2 of 3 repetitions. If these conditions were not met the KeratinoSens™ prediction should be considered negative.

- The I_{max} is higher than (>) 1.5- fold and statistically significantly different as compared to the solvent (negative) control (as determined by a two-tailed, unpaired Student's T-test).
- The cellular viability is higher than (>) 70% at the lowest concentration with induction of luciferase activity above 1.5-fold (i.e., at the $EC_{1.5}$ concentration).
- The $EC_{1.5}$ value is less than (<) 1000 µM (or < 200 µg/mL for test item with no defined MW).
- There is an apparent overall dose response for luciferase induction (or a biphasic response).

If in a given repetition, all of the three first conditions were met but a clear dose-response for the luciferase induction cannot be observed, then the result of that repetition should be considered inconclusive and further testing may be required. In addition, a negative result obtained with concentrations < 1000 µM (or < 200 µg/mL for test item with no defined MW) should also be considered as inconclusive.
In rare cases, test items which induced luciferase activity very close to cytotoxic levels, can be positive in some repetitions at non-cytotoxic levels (i.e., $EC_{1.5}$ determining concentration below (<) the IC_{30}), and in other repetitions only at cytotoxic levels (i.e., $EC_{1.5}$ determining concentration above (>) the IC_{30}). Such test items should be retested with a narrower dose- response analysis using a lower dilution factor (e.g., 1.33 or √2 (=1.41) fold dilution between wells), to determine if induction has occurred at cytotoxic levels or not.

Results and discussions

Negative Control
The coefficient of variation observed for the negative control, during experiment 2 and 3 for Chlorantraniliprole 200 SC was 16.28% and 12.78%, respectively, which was below 20%. Since variation amongst the replicates was less than 20%, results of this run were considered as valid.
In experiment-03 plate 1, for the six wells, the variability in the negative control was 52.86%, but this was considered to be due to one well. Since the data from this well was > 25% the average of the other five wells, it was considered as an outlier. After removal of the outlier, the variation in the negative control was 12.78%, which was within the acceptable range.

Positive Control
Luciferase activity induction obtained with the positive control, trans-cinnamaldehyde, was found to be >1.5 (the threshold value) at concentrations of 8 µM, 16 µM, 32 µM, and 64 µM in both repetitions. The induction for positive control at concentrations of 8, 16, 32 µM and 64 µM was found to be 1.72, 2.79, 2.65 µM and 3.92 µM in experiment 1 and 1.56, 1.68, 2.06 and 3.51 µM in experiment 3, respectively. The $EC_{1.5}$ for positive control was 5.16 µM in experiment 1 and 7.19 in experiment 3.
The average gene induction for positive control at 64 µM was found to be 3.92 and 3.51 for experiment 1 and 3, respectively (which was within the guideline acceptable limit of 2 and 8). A clear dose response, with increasing gene induction at increasing dose, was observed for trans- cinnamaldehyde in experiment 1 and experiment 3.

Luciferase Activity
The maximal average fold induction of luciferase activity (I_{max}) following treatment with Chlorantraniliprole 200 SC was 1.00, which is less than the 1.5-fold increase required for a positive result. The $EC_{1.5}$ mean values, representing the concentration where induction of luciferase activity is above the 1.5 fold threshold (i.e 50% enhanced luciferase activity), for Chlorantraniliprole 200 SC were >2000 µM and there was no dose dependent increase in luciferase induction.

Cytotoxicity Assessment
Toxicity was observed, as cellular viability below 70%, at concentrations of 125 µM to 2000 µM. Cellular viability was 51.66, 39.71, 29.06, 7.63, 0.76% at the tested concentrations of 125, 250, 500, 1000, and 2000 µM respectively.

Interpretation
For Chlorantraniliprole 200 SC, three experiments were conducted and out of these, two valid experiments (experiments 1 and 3) were considered for the final evaluation. The reason for conducting the repeat experiments was due to the failure of the positive controls to meet the acceptance criteria in experiment 2. The mean results are summarised below:

Table A 14: Skin sensitization of Chlorantraniliprole 200 SC

Test Item Name	Luciferase gene induction		Cellular viability		KeratinoSens™ Prediction
	I_{max}	$EC_{1.5}$	IC_{50}	IC_{30}	
Chlorantraniliprole 200 SC	1.00	>2000 µM	155.47 µM	91.01 µM	Non-Sensitiser
Positive Control (trans- Cinnamaldehyde)	3.72	6.09	-	-	Sensitiser

Results of this KeratinoSens assay indicate that Chlorantraniliprole 200 SC met all the evaluation criteria to predict that it is a non-sensitiser. The negative and positive controls met the acceptance criteria and were correctly identified as the non-sensitiser and sensitiser, respectively. This showed the suitability of the test system and procedures used in the test facility.

Conclusion

From results of this KeratinoSens assay, under the specified experimental conditions, Chlorantraniliprole 200 SC is predicted to be a non-sensitiser to skin.

A 2.7.2 Study 2

Comments of zRMS:	Study [redacted] 2020 based on in vitro Human Cell Line Activation Test (hCLAT) method has been reviewed for compliance with the current guidelines, resulting from scientific progress. Due to fact that In vitro studies gave contradictory results, negative ([redacted] 2020) and positive ([redacted] 2020) for this ongoing registration process zRMS decided to conclude hazard assessment taking into account results of available *in vivo* study, therefore [redacted] 2020 has been considered as supplementary to *in vivo* studies outcome.

Reference	KCP 7.1.6/02
Report	*In Vitro* Skin Sensitisation: Human Cell Line Activation Test (hCLAT) of Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C). [redacted] 2020 Study No: 629-1-06-23745
Guideline(s)	OECD 442E
Deviations	No
GLP	Yes
Acceptability	~~Yes~~ Supplementary
Duplication (if vertebrate study)	n.a

Materials and methods

Test material (Lot/Batch No.)	Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C) (Batch 3188-220519-01)
Test system	THP-1. a human monocytic leukemia cell line. procured from American Type Culture Collection (ATCC)
Number of replicates	Two independent experiments, each containing a single replicate for each concentration of the test item and control
Exposure	Eight different concentrations i.e., 938 µg/mL, 1126 µg/mL, 1351 µg/mL, 1621 µg/mL,. 1945 µg/mL, 2334 µg/mL, 2801 µg/mL and 3361 µg/mL of th test item
Vehicle/Dilution	Saline
Positive control	2, 4-Dinitrochlorobenzene at a single concentration of 4.0 µg/mL in DMSO
Negative control	Medium Control: Complete medium Saline Control: Saline diluted to 2% in complete medium. which was tested at a final concentration of 1% in the plate. DMSO Control: DMSO diluted to 0.4% in complete medium. which was tested at a final concentration of 0.2% in the plate.
Remarks	None

Experimental procedures

Dose Range Finding Assay (DRF)

Dose Range Finding assays were performed to determine the CV75 value, being the test item concentration that resulted in 75% cell viability (CV) compared to the solvent/vehicle control. The mean of two CV75 values was used to determine the concentrations for CD86/CD54 expression measurement.

Test Item Preparation

A total of four independent DRF experiments were conducted for the test item with concentrations ranging

from 1.95 µg/mL to 1000 µg/mL (for experiments 1 and 2) and 9.77 µg/mL to 5000 µg/mL (for experiments-3 and 4).

Application of Test Item and Controls

The working solutions of test item and controls were mixed in a 1:1 (v/v) ratio with the cell suspensions prepared in the 96-well flat-bottom plate. The treated plates were incubated for 23 h and 45 min at 37 ± 1 °C under 5 ± 1% CO_2. Plates were sealed prior to incubation with the test item to avoid evaporation of test item and cross-contamination between wells by test item.
In each experiment of the DRF assay, two wells of untreated cells were also included on the day of treatment. These samples were incubated along with those of the test item and controls and were processed the following day, i.e., one well was stained with PI and the other well was kept unstained, following the PI staining procedure. These samples were used for adjusting the voltages of FSC, SSC and PI channels, prior to acquisition of test item and control samples.

Propidium Iodide (PI) Staining

Propidium iodide staining was conducted to determine cell viability of the treated and control samples. After 23 h and 45 min of exposure, cells were transferred into 96-well V-bottom plate and were collected by centrifugation (250 x g, 4 °C, 5 min). The supernatants were discarded, and the remaining cells were resuspended with 200 µL of staining buffer. Cells were washed twice with 200 µL of staining buffer. Finally, cells were resuspended in 200 µL of P1-staining buffer (final concentration of PI = 0.625 µg/mL). The resulting samples were analysed on flow cytometer.

Experimental Design

Four dose range finding assays were performed with varied ranges of concentrations for the determination of CV75 value of the test item. The test item was tested at ten concentrations ranging from 1.95 µg/mL to 1000 µg/mL in the first set of DRF (experiments-1 and 2) and 9.77 µg/mL to 5000 µg/mL in the second set of DRF (experiments-3 and 4).
Based on the results of the DRF assay (experiments-3 and 4), CV75 value of the test item was determined and concentrations were selected for CD86/CD54 expression measurement.
Additional DRF experiments had to be conducted as the highest concentration in the first set of DRF assays (i.e., experiments-1 and 2) of 1000 µg/mL was found to be non-toxic, hence a new set of experiments was conducted to determine the maximum non-toxic concentration. The final concentration in the plate did not exceeded 5000 µg/mL for the stably dispersed test item.

CD86/CDS4 Expression Measurement

Test Item Preparation

Eight different concentrations ie., 938 µg/mL 1126 µg/mL, 1351 µg/mL, 1621 µg/mL, 1945 µg/mL, 2334 µg/mL, 2801 µg/mL and 3361 µg/mL of the test item were selected as the final concentrations to be tested in CD86/CD54 Expression Measurement.

Application of Test Item and Controls

The working solutions of test item and controls prepared (500 µL) were mixed with 500 µL of suspended cells (1 x 10^6 cells) in a 1:1 ratio in a 24-well plate and incubated for 23 h and 30 min at 37 ± 1 °C under 5 ± 1% CO_2. Plates were sealed prior to incubation with the test item to avoid evaporation of volatile test item and cross-contamination between wells by the test item.
In each experiment of CD86/CD54 expression measurement, three wells of untreated cells (one was kept unstained, one was stained with PI and the other was stained with only antibodies (i.e., IgG1, CD86 and CD54)), two wells of DNCB-treated cells (one well was stained with only PI and the other well was stained with only appropriate antibodies i.e., IgG1, CD86 and CD54) were included on the day of treatment.
These samples were incubated along with those of the test item and controls and were processed the following day, following the procedure of cell staining. These samples were used for adjusting voltages of FSC, SSC, PI and FITC acquisition channels, prior to acquisition of test item and control samples.

Cell Staining

Cell staining was performed to determine CD86 and CD54 expression levels and cell viability of the treated and control samples on flow cytometer. After 23 h and 30 min of exposure, cells were transferred from 24-well plates into sample tubes and were collected by centrifugation (250 x g, 4 °C, 5 min). Cells were then washed twice with 1 ml of staining buffer. After washing, cells were blocked with 600 µpL of blocking solution (staining buffer containing 0.01% (w/v) globulin) and incubated for 15 min on ice. After blocking, cells were split in three aliquots of 180 µL into a 96-well V-bottom plate.
The three groups of cells were centrifuged and the cell pellets were stained with 50 µL of FITC-labelled anti-CD86, anti-CD54 and mouse IgG1 (isotype) antibodies respectively, and incubated for 30 min on ice. The antibodies were used by diluting 6:50 (v/v, for CD86) and 3:50 (v/v, for CD54 and IgG1) with staining buffer. After incubation, cells were centrifuged (250 x g, 4 °C, 5 min) and were washed with 150 µL of staining buffer three times. Finally, cells were resuspended in 200 µL of PI-staining buffer (final concentration of PI = 0.625 µg/mL). The resulting samples were analysed on flow cytometer.

Experimental Design

Two independent experiments of CD86/CD54 expression measurement were performed for the test item, wherein the test item was tested at eight concentrations ranging from 938 µg/mL to 3361 µg/mL. Each independent experiment contained a single replicate for each concentration of the test item and control to derive a prediction.

Assay Acceptance Criteria

Before assay data were evaluated, data were evaluated to meet the acceptance criteria for a valid assay. The following acceptance criteria were used to determine a valid assay:

i. The cell viabilities of medium and solvent/vehicle controls should be higher than 90%.
ii. In the solvent/vehicle control. RFI values of both CD86 and CD54 should not exceed the positive criteria (CD86 RFI ≥l50% and CD54 RFI ≥200%).
iii. For both medium and solvent/vehicle controls, the MFI ratio of both CD86 and CD54 to isotpe control should be >105%
iv. In the positive control (DNCB). RFI values of both CD86 and CD54 should meet the positive criteria (CD86 RFI ≥l50% and CD54 RFI ≥200%) and cell viability should be more than 50%.
v. For the test item, the cell viability should be more than 50% in at least four tested concentrations in each run.

Note: Negative results are acceptable only for test item exhibiting a cell viability of less than 90% at the highest concentration tested (i.e. 1.2 x CV75 according to the serial dilution scheme). If the cell viability at 1.2 x CV75 is equal or above 90% the negative result should be discarded. In such a case it is recommended to try to refine the dose selection by repeating the CV75 determination. It will be noted that when 5000 µg/mL in saline (or medium or other solvents/vehicles), 1000 µg/mL in DMSO or the highest soluble concentration is used as the maximal test concentration of a test item, a negative result is acceptable even if the cell viability is above 90%.

Assay Evaluation Criteria/Prediction Model

Once criteria for a valid assay had been met, responses observed in the assay were evaluated. For CD86/CD54 expression measurement, test item is tested in at least two independent runs to derive a single prediction (**Positive** or **Negative**). An hCLAT prediction is considered as **Positive** if at least one of the following conditions is met in 2 of 2 or in at least 2 of 3 independent runs, otherwise the hCLAT prediction is considered as **Negative**:

i. The RFI of CD86 is equal to or greater than 150% in at least one tested concentration (with cell viability ≥50%);
ii. The RFI of CD54 is equal to or greater than 200% in at least one tested concentration (with cell viability ≥50%)

Based on the results obtained, if the first two runs are both positive for CD86 and/or are both positive for CD54, the hCLAT prediction is considered **Positive** and a third run does not need to be conducted. Similarly, if the first two runs are negative for both markers, the hCLAT prediction is considered **Negative**, without the need for a third run. If however, the first two runs are not concordant for at least one of the markers (CD54 or CD86), a third run is needed and the final prediction will be based on the majority result of the three individual runs (i.e. 2 out of 3). In this respect, it will be noted that if two independent runs are conducted and one is only positive for CD86 (referred to as P_1) and the other is only positive for CD54 (referred to as P_2), a third run is required. If this third run is negative for both markers (referred to as N), the hCLAT prediction is considered **Negative**. On the other hand, if the third run is positive for either marker (P_1 or P_2) or for both markers (referred to as P_{12}), the hCLAT prediction is considered **Positive**.

Results and discussions

Dose Range Finding (DRF) assay

In the first set of DRF (concentration range: 1.95 µg/mL - 1000 µg/mL), no significant cell death (i.e., <75% cell viability) was observed at any tested concentration. Thus, CV75 could not be calculated on the basis of results of the first set of DRF experiments.
Therefore, another set of DRF experiments was conducted with a different set of concentrations ranging from 9.77 µg/mL - 5000 µg/mL. In the second set of DRF (concentration range: 9.77 µg/mL - 5000 µg/mL), a significant cytotoxicity (i.e., <75% cell viability) was observed at the concentration of 5000 µg/mL.
The concentrations, resulting in the cellular viability directly above and below 75%, i.e., 2500 µg/mL and 5000 µg/mL respectively, in both experiments, were selected for calculation of CV75 value of the test item. On the basis of results obtained in DRF-experiments 3 and 4, the CV75 value of the test item was found to be 2801 µg/mL.

CD86/CD54 Expression Measurement (Expression Study)

The test item produced a positive response for CD54 marker (i.e., RFI CD54 ≥200%. with cell viability ≥50%) in 5/8 and 6/8 tested concentrations m the experiment-l and 2 respectively. A negative response of CD86 marker (i.e., RFI CD86 <150%) was observed in both experiments.
Based on results of experiment-l and 2, the prediction obtained for the test item was P_2. The cell viability of the test item was found to be >50% in 5/8 and in 6/8 tested concentrations in both experiments, which met the assay acceptance criteria (i.e., cell viability in 4/8 tested concentrations should be >50%). Based on the calculated RFI CD54 values, EC200 value of the test item was reported as <938 µg/mL. The EC150 value could not be calculated for the test item because of the negative CD86 response (i.e., RFI CD86 <150%) observed in both experiments, and was thus reported as ">3361 µg/mL" (i.e., the highest tested concentration of the test item in CD86/CD54 expression measurement).

The RFI values of positive control, i.e., 2,4-Dinitrochlorobenzene were found to be 392.55% and 324.23% for the CD86 marker and 1101.60% and 948.00% for CD54 marker, in experiments-1 and 2 respectively, which met the assay acceptance criteria (RFI CD86 ≥150%, RFI CD54 ≥200%). The cell viability of the positive control was found to be >50% in both experiments.
The observed values of the negative (solvent) control were within the acceptable ranges of the test guideline.

All criteria for a valid study were met, as described in the study plan.

Results of CV75, EC150 and EC200

The mean values from all experiments and assay predictions for the test item are as mentioned below:

Table A 15: Skin sensitization of Chlorantraniliprole 200 SC

Observed CV75 (in µg/mL)	Observed EC150 for CD86 (in µg/mL)^	Observed EC200 for CD54 (in µg/mL)*	Expt. 1 Prediction	Expt. 3 Prediction	Final Prediction
2801	>3361	<938	Positive (P_2)	Positive (P_2)	Positive

Key: ^ = A negative response of CD86 marker (i.e., RFI CD86 <150) was observed at all tested concentrations in the experiments-1 and 2 of CD86/CD54 expression measurement. Hence, EC150 value was reported as ">3361 µg/mL" (i.e., highest tested concentration of test item in CD86/CD54 expression measurement).
* = Lowest tested concentration of the test item in CD86/CD54 expression measurement.

The CV75 value of the test item was found to be 2801 µg/mL. In experiment-1, a positive response of CD54 marker (i.e., RFI CD54 ≥200%, cell viability ≥50%) was observed in 5/8 tested concentrations, while in experiment-2, 6/8 tested concentrations were positive. In both experiments, the RFI CD54 value at the lowest tested concentration was above the positive criteria (i.e., RFI CD54 ≥200%), hence EC200 value cannot be calculated by linear interpolation. For calculation by log-linear extrapolation, two such concentrations were required, where the difference in RFI CD54 values was >10%.
In the case of the test item, two such concentrations, where the difference in RFI CD54 values was >10%, were not obtained hence the EC200 value could not even be calculated by log-linear extrapolation. Thus, EC200 value of the test item was reported as <938 µg/mL (i.e., the lowest tested concentration of the test item in CD86/CD54 expression measurement).
A negative response of CD86 marker (i.e., RFI CD86 <150%) was observed at all tested concentrations in the experiments-1 and 2. Hence, EC150 value for the test item could not be determined and was reported as >3361 µg/mL" (i.e., highest tested concentration of test item in CD86/CD54 expression measurement).

Interpretation

In the experiments-l and 2, a positive response was obtained for CD54 and a negative response was obtained for CD86. Based on the results obtained in the experiments-1 and 2, the prediction obtained for the test item was P_2. The final prediction for the test item was "positive".
Results of the present study indicate that Chlorantraniliprole 200 SC (Product code: ADM.0900.I.1.C) met all the evaluation criteria to conclude as 'positive" in the hCLAT assay.
The negative (solvent) and the positive controls met the specified acceptance criteria for controls. This showed the suitability of the test system and procedures used in this test facility

Conclusion

From results of this hCLAT assay, under the specified experimental conditions, Chlorantraniliprole 200 SC (Product code: ADM.0900.I.1.C) was concluded as "positive" in an *in vitro* skin sensitisation assay.

A 2.7.3 Study 3

Comments of zRMS:	Skin sensitisation study [redacted] 2020 has been reviewed for compliance with the current guidelines, resulting from scientific progress. There is no deviation from studies protocol, the OECD 429 procedure is valid and acceptable. Study is in line with the suggestions of point 5 of Regulation 284/2013 and Annex VII to REACH REG (EC) No 1907/2006. Results of the study and conclusions are adequate for risk assessment and classification purpose. Study accepted.

Reference	KCP 7.1.6/03
Report	Skin sensitisation study of Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C) by Local Lymph Node Assay in mice [redacted] 2020 Study No: 409-1-01-23753
Guideline(s)	OECD 429
Deviations	No
GLP	Yes
Acceptability	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test material (Lot/Batch No.)	Chlorantraniliprole 200 SC (Product Code :ADM.0900.I.1.C) (Batch 3188-220519-01)
Species	Mice, *Mus musculus* (CBA/J)
No. of animals (group size)	6 (2 mice/group) for preliminary assay 25 (5 mice/group) for main study females
Range finding	Yes, preliminary test with test substance concentrations of 25%, 50% and 100%.
Exposure (concentration(s), no. of applications)	10% (v/v), 50% (v/v) and 100% of test item applied for three consecutive days (days 0, 1 and 2)
Vehicle	1% Pluronic® L92
Pretreatment prior to topical application	No
Reliability check	Yes
Remarks	Positive control substance: Hexyl Cinnamaldehyde (HCA)

Results and discussions

Table A 16: Results of skin sensitisation study of Chlorantraniliprole 200 SC

Dose concentration (%)	No. of mice used	Group Mean DPM	Stimulation index (SI)
Test vehicle control group 1% L92	5	1122.60 ± 420.73	1
Positive control 25% (v/v) HCA	5	4582.20** ± 674.92	4.08
10% (v/v) Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C)	5	1335.80 ± 295.76	1.19
50% (v/v) Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C)	5	1635.40 ± 652.32	1.46
100% Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C)	5	2595.80** ± 1835.56	2.31

Note : Values are mean with standard deviation.
Key : HCA = α-Hexylcinnamaldehyde
DPM = Disintegrations per minute

Stimulation Index = Mean DPM of test group divided by mean DPM of solvent/vehicle control group
** = Significantly higher than control ($p \leq 0.01$)

Clinical signs:	No treatment related clinical sign was observed in mice from the vehicle control, positive control, and treated groups at 10% (v/v) and 50% (v/v) in 1% L92, and 100% Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C). No erythema was observed in any treated mouse at 10% (v/v) and 50% (v/v) in 1% L92 and 100% Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C) on day 0 to day 5. Very slight erythema was observed in the group treated with 25% HCA (during days 1 to 5) in all mice (5/5 mouse).

Stimulation Index (SI) values calculated for groups treated with Chlorantraniliprole 200 SC were found to be 1.19, 1.46, and 2.31 at the dose concentrations of 10% (v/v), 50% (v/v) in 1% L92 and 100% Chlorantraniliprole 200 SC, respectively and 4.08 for the 25% HCA treated positive control group.
Since the SI obtained for Chlorantraniliprole 200 SC at all tested concentrations showed a less than three-fold increase over the control value, the EC_3 value was not calculated.

Conclusion

The SI obtained for Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C) at the tested concentrations 10% (v/v), 50% (v/v) in 1% L92 and 100% Chlorantraniliprole 200 SC showed a less than three-fold increase over the control value. Therefore, Chlorantraniliprole 200 SC did not demonstrate sensitisation potential in the local lymph node assay.
The SI of 4.08 obtained for the concurrent positive control, α-Hexylcinnamaldehyde, showed greater than a three-fold increase over the control value indicating a positive response in agreement with the historical control for this known weak sensitiser. This confirmed the reliability of this test procedure.
Under the experimental conditions, no classification is required for Chlorantraniliprole 200 SC (product code: ADM.0900.I.1.C) according to Regulation (EC) No. 1272/2008.

A 2.8 Supplementary studies for combinations of plant protection products (KCP 7.1.7)

Not relevant.

A 2.9 Data on co-formulants (KCP 7.4)

A 2.9.1 Material safety data sheet for each co-formulant

Information regarding material safety data sheets of the co-formulants can be found in the confidential dossier of this submission (Registration Report - Part C).

A 2.9.2 Available toxicological data for each co-formulant

Available toxicological data for each co-formulant can be found in the confidential dossier of this submission (Registration Report - Part C).

A 2.10 Studies on dermal absorption (KCP 7.3)

No study available. Default values of 10% and 50% were used for the concentrate and in use dilution respectively.

A 2.11 Other/Special Studies

Not relevant.

Appendix 3 Exposure calculations

A 3.1 Operator exposure calculations (KCP 7.2.1.1)

Table A 17: Input parameters considered for the estimation of operator exposure in head cabbage, cauliflower, broccoli

Substance name	Chlorantraniliprole	
Product name	Chlorantraniliprole 200 SC	
Reference value non acutely toxic active substance (RVNAS)	0,36	mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)		mg/kg bw/day
Crop type	Brassica vegetables	
Substance properties		
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Miniumum volume water for application (liquids)	400	L/ha
Maximum application rate of active substance	0,028	kg a.s. /ha
50% Dissipation Time DT50	30	days
Initial Dislodgeable Foliar Residue	3	µg/cm2 of foliage/kg a.s. applied/ha
Dermal absorption of product	10,00%	
Dermal absorption of in-use dilution	50,00%	
Oral absorption of active substance	13,00%	
Inhalation absorption of active substance	100,00%	
Vapour pressure of active substance	low volatile substances having a vapour pressure of <5*10-3Pa	
Scenario		
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Buffer strip	2-3	m
Number of applications	1	
Interval between multiple applications	365	days
Season (upward spraying orchards only)	not relevant	

Table A 18: Estimation of longer term operator exposure towards Chlorantraniliprole in head cabbage, cauliflower, broccoli according to EFSA guidance

Operator exposure for Chlorantraniliprole 200 SC outdoor spray applications

Application rate of active substance	0,028 kg a.s./ha	*i_AppRate*	
Assumed area treated	50 ha/day	*d_AreaTreated*	
Amount of active substance applied	1,4 kg a.s./day	*i_AmoutAS*	
Dermal absorption of the product	10,00%	*i_AbsorpProduct*	
Dermal absorption of in-use dilution	50,00%	*i_AbsorInuse*	
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		
Indoor or Outdoor application	Outdoor		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		
Season	not relevant		

OutdoorSoluble concentrates, emulsifiable concentrate, etc.Downward sprayingVehicle-mounted

	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75th centile	95th centile		
Mixing and loading	Hands	6293	23126	AOEM	
	Body	4519	79421	AOEM	
	Head	73	398	AOEM	
	Protected hands (gloves)	43	277	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	32	205	AOEM	
	Protected head (hood and face shield)	1	23	AOEM	
	Inhalation	4	29	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

	Exposure values	µg exposure/day applied		Reference	Comment
		75th centile	95th centile		
Application	Hands	208	2932	AOEM	
	Body	116	599	AOEM	
	Head	5	17	AOEM	
	Protected hands (gloves)	51	3466	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	3	8	AOEM	
	Inhalation	1	4	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE
Longer term		
Total systemic exposure from mixing, loading and application (mg a.s./day)	1,2584039	0,7532405
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0209734	0,0125540
% of RVNAS	5,83%	3,49%

Table A 17 B Input parameters considered for the estimation of operator exposure in head cabbage, cauliflower, broccoli (Manual Hand held)

Substance name	Chlorantraniliprole	
Product name	Chlorantraniliprole 200 SC	
Reference value non acutely toxic active substance (RVNAS)	0.36	mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)		mg/kg bw/day
Crop type	Brassica vegetables	
Substance properties		
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Miniumum volume water for application (liquids)	400	L/ha
Maximum application rate of active substance	0.028	kg a.s. /ha
50% Dissipation Time DT50	30	days
Initial Dislodgeable Foliar Residue	3	µg/cm2 of foliage/kg a.s. applied/ha
Dermal absorption of product	10.00%	
Dermal absorption of in-use dilution	50.00%	
Oral absorption of active substance	13.00%	
Inhalation absorption of active substance	100.00%	
Vapour pressure of active substance	low volatile substances having a vapour pressure of <5*10-3Pa	
Scenario		
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Buffer strip	2-3	m
Number of applications	1	
Interval between multiple applications	365	days
Season (upward spraying orchards only)	not relevant	

Table A 18B: Estimation of longer term operator exposure towards Chlorantraniliprole in head cabbage, cauliflower, broccoli according to EFSA guidance (Manual Handheld)

Operator exposure for Chlorantraniliprole 200 SC outdoor spray applications

Application rate of active substance	0.028	kg a.s./ha	*i_AppRate*
Assumed area treated	4	ha/day	*d_AreaTreated*
Amount of active substance applied	0.112	kg a.s./day	*i_AmountAS*
Dermal absorption of the product	10.00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	50.00%		*i_Absoinuse*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		
Indoor or Outdoor application	Outdoor		
Application method	Downward spraying		
Application equipment	Manual-Hand held		
Season	not relevant		

OutdoorSoluble concentrates, emulsifiable concentrate, etc.Downward sprayingManual-Hand held

	Exposure values	µg exposure/day mixed and loaded 75th centile	95th centile	Reference	Comment
Mixing and loading	Hands	900	3236	AOEM	
	Body	766	38129	AOEM	
	Head	6	32	AOEM	
	Protected hands (gloves)	8	22	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	3	16	AOEM	
	Protected head (hood and face shield)	0	2	AOEM	
	Inhalation	2	27	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear – arms, body and legs covered		incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

	Exposure values	µg exposure/day applied 75th centile	95th centile	Reference	Comment
Application	Hands	1544	4213	AOEM	
	Body	88868	137007	AOEM	
	Head	12	85	AOEM	
	Protected hands (gloves)	5	22	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	8903	62630	AOEM	
	Inhalation	26	26	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear – arms, body and legs covered		incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying	

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	45.4071064	5.3483887	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.7567851	0.0891398	
% of RVNAS	210.22%	24.76%	

Table A 17 C Input parameters considered for the estimation of operator exposure in head cabbage, cauliflower, broccoli (Manual Knapsack)

Substance name	Chlorantraniliprole	
Product name	Chlorantraniliprole 200 SC	
Reference value non acutely toxic active substance (RVNAS)	0.36	mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)		mg/kg bw/day
Crop type	Brassica vegetables	
Substance properties		
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Miniumum volume water for application (liquids)	400	L/ha
Maximum application rate of active substance	0.028	kg a.s. /ha
50% Dissipation Time DT50	30	days
Initial Dislodgeable Foliar Residue	3	µg/cm2 of foliage/kg a.s. applied/ha
Dermal absorption of product	10.00%	
Dermal absorption of in-use dilution	50.00%	
Oral absorption of active substance	13.00%	
Inhalation absorption of active substance	100.00%	
Vapour pressure of active substance	low volatile substances having a vapour pressure of <5*10-3Pa	
Scenario		
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Manual-Knapsack	
Buffer strip	2-3	m
Number of applications	1	
Interval between multiple applications	365	days
Season (upward spraying orchards only)	not relevant	

Table A 18C: Estimation of longer term operator exposure towards Chlorantraniliprole in head cabbage, cauliflower, broccoli according to EFSA guidance (Manual Knapsack)

Operator exposure for Chlorantraniliprole 200 SC outdoor spray applications

Application rate of active substance	0.028	kg a.s./ha	*i_AppRate*
Assumed area treated	1	ha/day	*d_AreaTreated*
Amount of active substance applied	0.028	kg a.s./day	*i_AmountAS*
Dermal absorption of the product	10.00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	50.00%		*i_Absorbuse*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		
Indoor or Outdoor application	Outdoor		
Application method	Downward spraying		
Application equipment	Manual-Knapsack		
Season	not relevant		

Mixing and loading

Exposure values	µg exposure/day mixed and loaded 75th centile	95th centile	Reference	Comment
Hands	9495	25482	AOEM	
Body	803	2787	AOEM	
Head	5	11	AOEM	
Protected hands (gloves)	18	164	AOEM	
Protected body (workwear or protective garment and sturdy footwear)	25	103	AOEM	
Protected head (hood and face shield)	5	11	AOEM	
Inhalation	25	26	AOEM	
Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
Gloves	No			
Clothing	Work wear - arms, body and legs covered		incl. in AOEM model	
Head and respiratory PPE	None		1	1
Water soluble bag	No		1	

Application

Exposure values	µg exposure/day applied 75th centile	95th centile	Reference	Comment
Hands	1544	4213	AOEM	
Body	88868	137007	AOEM	
Head	12	85	AOEM	
Protected hands (gloves)	5	22	AOEM	
Protected body (workwear or protective garment and sturdy footwear)	8903	62630	AOEM	
Inhalation	26	26	AOEM	
Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
Gloves	No			
Clothing	Work wear - arms, body and legs covered		incl. in AOEM model	
Head and respiratory PPE	None		1	1
Closed cab	No		vehicle mounted upward spraying	

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	46.2933000	6.2330000	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.7715550	0.1038833	
% of RVNAS	214.32%	28.86%	

Table A 19: Input parameters considered for the estimation of operator exposure in grapes

Substance name	Chlorantraniliprole	
Product name	Chlorantraniliprole 200 SC	
Reference value non acutely toxic active substance (RVNAS)	0,36	mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)		mg/kg bw/day
Crop type	Grapes	
Substance properties		
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Miniumum volume water for application (liquids)	400	L/ha
Maximum application rate of active substance	0,036	kg a.s. /ha
50% Dissipation Time DT50	30	days
Initial Dislodgeable Foliar Residue	3	µg/cm2 of foliage/kg a.s. applied/ha
Dermal absorption of product	10,00%	
Dermal absorption of in-use dilution	50,00%	
Oral absorption of active substance	13,00%	
Inhalation absorption of active substance	100,00%	
Vapour pressure of active substance	low volatile substances having a vapour pressure of <5*10-3Pa	
Scenario		
Indoor or Outdoor application	Outdoor	
Application method	Upward spraying	
Application equipment	Vehicle-mounted	
Buffer strip	5	m
Number of applications	1	
Interval between multiple applications	365	days
Season (upward spraying orchards only)	not relevant	

Table A 20: Estimation of longer term operator exposure towards Chlorantraniliprole in grapes according to EFSA guidance

Operator exposure for Chlorantraniliprole 200 SC outdoor spray applications

Application rate of active substance	0,036	kg a.s./ha	*i_AppRate*
Assumed area treated	10	ha/day	*d_AreaTreated*
Amount of active substance applied	0,36	kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	10,00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	50,00%		*i_AbsorInuse*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		
Indoor or Outdoor application	Outdoor		
Application method	Upward spraying		
Application equipment	Vehicle-mounted		
Season	not relevant		

OutdoorSoluble concentrates, emulsifiable concentrate, etc.Upward sprayingVehicle-mounted

	Exposure values	µg exposure/day mixed and loaded 75th centile	95th centile	Reference	Comment
Mixing and loading	Hands	2212	8032	AOEM	
	Body	1740	53527	AOEM	
	Head	19	102	AOEM	
	Protected hands (gloves)	18	71	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	10	53	AOEM	
	Protected head (hood and face shield)	0	6	AOEM	
	Inhalation	3	28	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

	Exposure values	µg exposure/day applied 75th centile	95th centile	Reference	Comment
Application	Hands	1020	2245	AOEM	No data available for a drift reduction scenario
	Body	3172	18510	AOEM	
	Head	417	2559	AOEM	
	Protected hands (gloves)	13	331	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	41	81	AOEM	
	Inhalation	36	30	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE
Longer term		
Total systemic exposure from mixing, loading and application (mg a.s./day)	2,7400323	1,0016231
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0456672	0,0166937
% of RVNAS	12,69%	4,64%

Table A 21: Input parameters considered for the estimation of operator exposure in corn

Substance name	Chlorantraniliprole	
Product name	Chlorantraniliprole 200 SC	
Reference value non acutely toxic active substance (RVNAS)	0,36	mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)		mg/kg bw/day
Crop type	Cereals	
Substance properties		
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Miniumum volume water for application (liquids)	400	L/ha
Maximum application rate of active substance	0,028	kg a.s. /ha
50% Dissipation Time DT50	30	days
Initial Dislodgeable Foliar Residue	3	µg/cm2 of foliage/kg a.s. applied/ha
Dermal absorption of product	10,00%	
Dermal absorption of in-use dilution	50,00%	
Oral absorption of active substance	13,00%	
Inhalation absorption of active substance	100,00%	
Vapour pressure of active substance	low volatile substances having a vapour pressure of <5*10-3Pa	
Scenario		
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Buffer strip	2-3	m
Number of applications	1	
Interval between multiple applications	365	days
Season (upward spraying orchards only)	not relevant	

Table A 19B: Input parameters considered for the estimation of operator exposure in grapes (Manual Handheld)

Substance name	Chlorantraniliprole	
Product name	Chlorantraniliprole 200 SC	
Reference value non acutely toxic active substance (RVNAS)	0.36	mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)		mg/kg bw/day
Crop type	Grapes	
Substance properties		
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Miniumum volume water for application (liquids)	400	L/ha
Maximum application rate of active substance	0.036	kg a.s. /ha
50% Dissipation Time DT50	30	days
Initial Dislodgeable Foliar Residue	3	µg/cm2 of foliage/kg a.s. applied/ha
Dermal absorption of product	10.00%	
Dermal absorption of in-use dilution	50.00%	
Oral absorption of active substance	13.00%	
Inhalation absorption of active substance	100.00%	
Vapour pressure of active substance	low volatile substances having a vapour pressure of <5*10-3Pa	
Scenario		
Indoor or Outdoor application	Outdoor	
Application method	Upward spraying	
Application equipment	Manual-Hand held	
Buffer strip	5	m
Number of applications	1	
Interval between multiple applications	365	days
Season (upward spraying orchards only)	not relevant	

Table A 20B: Estimation of longer term operator exposure towards Chlorantraniliprole in grapes according to EFSA guidance (Manual Handheld)

Operator exposure for Chlorantraniliprole 200 SC outdoor spray applications

Application rate of active substance	0.036	kg a.s./ha	*i_AppRate*
Assumed area treated	4	ha/day	*d_AreaTreated*
Amount of active substance applied	0.144	kg a.s./day	*i_AmountAS*
Dermal absorption of the product	10.00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	50.00%		*i_Absoinuse*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		
Indoor or Outdoor application	Outdoor		
Application method	Upward spraying		
Application equipment	Manual-Hand held		
Season	not relevant		

Outdoor|Soluble concentrates, emulsifiable concentrate, etc.|Upward spraying|Manual-Hand held

Mixing and loading

Exposure values	µg exposure/day mixed and loaded 75th centile	95th centile	Reference	Comment
Hands	1093	3935	AOEM	
Body	914	41017	AOEM	
Head	7	41	AOEM	
Protected hands (gloves)	10	29	AOEM	
Protected body (workwear or protective garment and sturdy footwear)	4	21	AOEM	
Protected head (hood and face shield)	0	2	AOEM	
Inhalation	2	27	AOEM	
Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
Gloves	No			
Clothing	Work wear - arms, body and legs covered		incl. in AOEM model	
Head and respiratory PPE	None		1	1
Water soluble bag	No		1	

Application

Exposure values	µg exposure/day applied 75th centile	95th centile	Reference	Comment
Hands	538	1998	AOEM	No data available for a drift reduction scenario
Body	45381	175534	AOEM	
Head	82	436	AOEM	
Protected hands (gloves)	3	18	AOEM	
Protected body (workwear or protective garment and sturdy footwear)	1033	1938	AOEM	
Inhalation	16	57	AOEM	
Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
Gloves	No			
Clothing	Work wear - arms, body and legs covered		incl. in AOEM model	
Head and respiratory PPE	None		1	1
Closed cab	No		vehicle mounted upward spraying	

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	23.2201122	0.9550740	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.3870019	0.0159179	
% of RVNAS	107.50%	4.42%	

Table A 19C: Input parameters considered for the estimation of operator exposure in grapes (Manual Knapsack)

Substance name	Chlorantraniliprole	
Product name	Chlorantraniliprole 200 SC	
Reference value non acutely toxic active substance (RVNAS)	0.36	mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)		mg/kg bw/day
Crop type	Grapes	
Substance properties		
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Miniumum volume water for application (liquids)	400	L/ha
Maximum application rate of active substance	0.036	kg a.s. /ha
50% Dissipation Time DT50	30	days
Initial Dislodgeable Foliar Residue	3	µg/cm2 of foliage/kg a.s. applied/ha
Dermal absorption of product	10.00%	
Dermal absorption of in-use dilution	50.00%	
Oral absorption of active substance	13.00%	
Inhalation absorption of active substance	100.00%	
Vapour pressure of active substance	low volatile substances having a vapour pressure of <5*10-3Pa	
Scenario		
Indoor or Outdoor application	Outdoor	
Application method	Upward spraying	
Application equipment	Manual-Knapsack	
Buffer strip	5	m
Number of applications	1	
Interval between multiple applications	365	days
Season (upward spraying orchards only)	not relevant	

Table A 20C: Estimation of longer term operator exposure towards Chlorantraniliprole in grapes according to EFSA guidance (Manual Knapsack)

Operator exposure for Chlorantraniliprole 200 SC outdoor spray applications

Application rate of active substance	0.036	kg a.s./ha	*i_AppRate*
Assumed area treated	1	ha/day	*d_AreaTreated*
Amount of active substance applied	0.036	kg a.s./day	*i_AmountAS*
Dermal absorption of the product	10.00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	50.00%		*i_Absorbuse*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		
Indoor or Outdoor application	Outdoor		
Application method	Upward spraying		
Application equipment	Manual-Knapsack		
Season	not relevant		

OutdoorSoluble concentrates, emulsifiable concentrate, etcUpward sprayingManual-Knapsack

	Exposure values	µg exposure/day mixed and loaded 75th centile	95th centile	Reference	Comment
Mixing and loading	Hands	9495	25482	AOEM	
	Body	803	2787	AOEM	
	Head	5	11	AOEM	
	Protected hands (gloves)	18	164	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	25	103	AOEM	
	Protected head (hood and face shield)	5	11	AOEM	
	Inhalation	25	26	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear – arms, body and legs covered		incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

	Exposure values	µg exposure/day applied 75th centile	95th centile	Reference	Comment
Application	Hands	169	692	AOEM	No data available for a drift reduction scenario
	Body	36529	173271	AOEM	
	Head	52	277	AOEM	
	Protected hands (gloves)	1	4	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	1033	1938	AOEM	
	Inhalation	5	25	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear – arms, body and legs covered		incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying	

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	19.4356658	1.6097041	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.3239278	0.0268284	
% of RVNAS	89.98%	7.45%	

Table A 22: Estimation of longer term operator exposure towards Chlorantraniliprole in corn according to EFSA guidance

Operator exposure for Chlorantraniliprole 200 SC outdoor spray applications

Application rate of active substance	0,028 kg a.s./ha		*i_AppRate*
Assumed area treated	50 ha/day		*d_AreaTreated*
Amount of active substance applied	1,4 kg a.s./day		*i_AmoutAS*
Dermal absorption of the product	10,00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	50,00%		*i_AbsorInuse*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		
Indoor or Outdoor application	Outdoor		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		
Season	not relevant		

OutdoorSoluble concentrates, emulsifiable concentrate, etc.Downward sprayingVehicle-mounted

	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75th centile	95th centile		
Mixing and loading	Hands	6293	23126	AOEM	
	Body	4519	79421	AOEM	
	Head	73	398	AOEM	
	Protected hands (gloves)	43	277	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	32	205	AOEM	
	Protected head (hood and face shield)	1	23	AOEM	
	Inhalation	4	29	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

	Exposure values	µg exposure/day applied		Reference	Comment
		75th centile	95th centile		
Application	Hands	208	2932	AOEM	
	Body	116	599	AOEM	
	Head	5	17	AOEM	
	Protected hands (gloves)	51	3466	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	3	8	AOEM	
	Inhalation	1	4	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE
Longer term		
Total systemic exposure from mixing, loading and application (mg a.s./day)	1,2584039	0,7532405
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0209734	0,0125540
% of RVNAS	5,83%	3,49%

Table A 23: Input parameters considered for the estimation of operator exposure in apple, pear and quince

Substance name	Chlorantraniliprole	
Product name	Chlorantraniliprole 200 SC	
Reference value non acutely toxic active substance (RVNAS)	0,36	mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)		mg/kg bw/day
Crop type	Pome fruit	
Substance properties		
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Miniumum volume water for application (liquids)	500	L/ha
Maximum application rate of active substance	0,031	kg a.s. /ha
50% Dissipation Time DT50	30	days
Initial Dislodgeable Foliar Residue	3	µg/cm2 of foliage/kg a.s. applied/ha
Dermal absorption of product	10,00%	
Dermal absorption of in-use dilution	50,00%	
Oral absorption of active substance	13,00%	
Inhalation absorption of active substance	100,00%	
Vapour pressure of active substance	low volatile substances having a vapour pressure of <5*10-3Pa	
Scenario		
Indoor or Outdoor application	Outdoor	
Application method	Upward spraying	
Application equipment	Vehicle-mounted	
Buffer strip	5	m
Number of applications	1	
Interval between multiple applications	365	days
Season (upward spraying orchards only)	not relevant	

Table A 24: Estimation of longer term operator exposure towards Chlorantraniliprole in apple, pear and quince according to EFSA guidance

Operator exposure for Chlorantraniliprole 200 SC outdoor spray applications

Application rate of active substance	0,031 kg a.s./ha		*i_AppRate*
Assumed area treated	10 ha/day		*d_AreaTreated*
Amount of active substance applied	0,31 kg a.s./day		*i_AmoutAS*
Dermal absorption of the product	10,00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	50,00%		*i_AbsorInuse*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		
Indoor or Outdoor application	Outdoor		
Application method	Upward spraying		
Application equipment	Vehicle-mounted		
Season	not relevant		

Outdoor/Soluble concentrates, emulsifiable concentrate, etc./Upward spraying/Vehicle-mounted

	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75th centile	95th centile		
Mixing and loading	Hands	1971	7149	AOEM	
	Body	1566	51252	AOEM	
	Head	16	88	AOEM	
	Protected hands (gloves)	16	61	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	8	45	AOEM	
	Protected head (hood and face shield)	0	5	AOEM	
	Inhalation	3	28	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

	Exposure values	µg exposure/day applied		Reference	Comment
		75th centile	95th centile		
Application	Hands	893	1933	AOEM	No data available for a drift reduction scenario
	Body	2732	15939	AOEM	
	Head	359	2203	AOEM	
	Protected hands (gloves)	11	285	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	36	70	AOEM	
	Inhalation	33	26	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE
Longer term		
Total systemic exposure from mixing, loading and application (mg a.s./day)	2,3827767	0,8790233
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0397129	0,0146504
% of RVNAS	11,03%	4,07%

Table A 23 B: Input parameters considered for the estimation of operator exposure in apple, pear and quince (Manuel Handheld)

Substance name	Chlorantraniliprole	
Product name	Chlorantraniliprole 200 SC	
Reference value non acutely toxic active substance (RVNAS)	0.36	mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)		mg/kg bw/day
Crop type	Pome fruit	
Substance properties		
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Miniumum volume water for application (liquids)	500	L/ha
Maximum application rate of active substance	0.031	kg a.s. /ha
50% Dissipation Time DT50	30	days
Initial Dislodgeable Foliar Residue	3	µg/cm2 of foliage/kg a.s. applied/ha
Dermal absorption of product	10.00%	
Dermal absorption of in-use dilution	50.00%	
Oral absorption of active substance	13.00%	
Inhalation absorption of active substance	100.00%	
Vapour pressure of active substance	low volatile substances having a vapour pressure of <5*10-3Pa	
Scenario		
Indoor or Outdoor application	Outdoor	
Application method	Upward spraying	
Application equipment	Manual-Hand held	
Buffer strip	5	m
Number of applications	1	
Interval between multiple applications	365	days
Season (upward spraying orchards only)	not relevant	

Table A 24B : Estimation of longer term operator exposure towards Chlorantraniliprole in apple, pear and quince according to EFSA guidance (Manuel Handheld)

Operator exposure for Chlorantraniliprole 200 SC outdoor spray applications

Application rate of active substance	0.031	kg a.s./ha	*i_AppRate*
Assumed area treated	4	ha/day	*d_AreaTreated*
Amount of active substance applied	0.124	kg a.s./day	*i_AmountAS*
Dermal absorption of the product	10.00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	50.00%		*i_AbsorInuse*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		
Indoor or Outdoor application	Outdoor		
Application method	Upward spraying		
Application equipment	Manual-Hand held		
Season	not relevant		

	Exposure values	µg exposure/day mixed and loaded 75th centile	95th centile	Reference	Comment
Mixing and loading	Hands	974	3503	AOEM	
	Body	822	39274	AOEM	
	Head	6	35	AOEM	
	Protected hands (gloves)	9	25	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	4	18	AOEM	
	Protected head (hood and face shield)	0	2	AOEM	
	Inhalation	2	27	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

	Exposure values	µg exposure/day applied 75th centile	95th centile	Reference	Comment
Application	Hands	475	1782	AOEM	No data available for a drift reduction scenario
	Body	44331	175289	AOEM	
	Head	78	415	AOEM	
	Protected hands (gloves)	3	15	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	1033	1938	AOEM	
	Inhalation	14	53	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying	

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	22.6385960	0.9075209	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.3773099	0.0151253	
% of RVNAS	104.81%	4.20%	

Table A 23 C: Input parameters considered for the estimation of operator exposure in apple, pear and quince (Manuel Knapsack)

Substance name	Chlorantraniliprole	
Product name	Chlorantraniliprole 200 SC	
Reference value non acutely toxic active substance (RVNAS)	0.36	mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)		mg/kg bw/day
Crop type	Pome fruit	
Substance properties		
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Miniumum volume water for application (liquids)	500	L/ha
Maximum application rate of active substance	0.031	kg a.s. /ha
50% Dissipation Time DT50	30	days
Initial Dislodgeable Foliar Residue	3	µg/cm2 of foliage/kg a.s. applied/ha
Dermal absorption of product	10.00%	
Dermal absorption of in-use dilution	50.00%	
Oral absorption of active substance	13.00%	
Inhalation absorption of active substance	100.00%	
Vapour pressure of active substance	low volatile substances having a vapour pressure of <5*10-3Pa	
Scenario		
Indoor or Outdoor application	Outdoor	
Application method	Upward spraying	
Application equipment	Manual-Knapsack	
Buffer strip	5	m
Number of applications	1	
Interval between multiple applications	365	days
Season (upward spraying orchards only)	not relevant	

Table A 24C : Estimation of longer term operator exposure towards Chlorantraniliprole in apple, pear and quince according to EFSA guidance (Manuel Knapsack)

Operator exposure for Chlorantraniliprole 200 SC outdoor spray applications

Application rate of active substance	0.031 kg a.s./ha	*i_AppRate*
Assumed area treated	1 ha/day	*d_AreaTreated*
Amount of active substance applied	0.031 kg a.s./day	*i_AmountAS*
Dermal absorption of the product	10.00%	*i_AbsorpProduct*
Dermal absorption of in-use dilution	50.00%	*i_AbsorpInuse*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Indoor or Outdoor application	Outdoor	
Application method	Upward spraying	
Application equipment	Manual-Knapsack	
Season	not relevant	

OutdoorSoluble concentrates, emulsifiable concentrate, etc.Upward sprayingManual-Knapsack

Mixing and loading

Exposure values	µg exposure/day mixed and loaded 75th centile	95th centile	Reference	Comment
Hands	9495	25482	AOEM	
Body	803	2787	AOEM	
Head	5	11	AOEM	
Protected hands (gloves)	18	164	AOEM	
Protected body (workwear or protective garment and sturdy footwear)	25	103	AOEM	
Protected head (hood and face shield)	5	11	AOEM	
Inhalation	25	26	AOEM	
Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
Gloves	No			
Clothing	Work wear – arms, body and legs covered		incl. in AOEM model	
Head and respiratory PPE	None		1	1
Water soluble bag	No		1	

Application

Exposure values	µg exposure/day applied 75th centile	95th centile	Reference	Comment
Hands	149	617	AOEM	
Body	35684	173029	AOEM	
Head	50	264	AOEM	
Protected hands (gloves)	1	4	AOEM	No data available for a drift reduction scenario
Protected body (workwear or protective garment and sturdy footwear)	1033	1938	AOEM	
Inhalation	5	23	AOEM	
Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
Gloves	No			
Clothing	Work wear – arms, body and legs covered		incl. in AOEM model	
Head and respiratory PPE	None		1	1
Closed cab	No		vehicle mounted upward spraying	

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	19.0014056	1.5979600	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.3166901	0.0266327	
% of RVNAS	87.97%	7.40%	

Table A 25: Input parameters considered for the estimation of operator exposure in potato

Substance name	Chlorantraniliprole	
Product name	Chlorantraniliprole 200 SC	
Reference value non acutely toxic active substance (RVNAS)	0,36	mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)		mg/kg bw/day
Crop type	Root and tuber vegetables	
Substance properties		
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Miniumum volume water for application (liquids)	400	L/ha
Maximum application rate of active substance	0,012	kg a.s. /ha
50% Dissipation Time DT50	30	days
Initial Dislodgeable Foliar Residue	3	µg/cm2 of foliage/kg a.s. applied/ha
Dermal absorption of product	10,00%	
Dermal absorption of in-use dilution	50,00%	
Oral absorption of active substance	13,00%	
Inhalation absorption of active substance	100,00%	
Vapour pressure of active substance	low volatile substances having a vapour pressure of <5*10-3Pa	
Scenario		
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Buffer strip	2-3	m
Number of applications	2	
Interval between multiple applications	7	days
Season (upward spraying orchards only)	not relevant	

Table A 26: Estimation of longer term operator exposure towards Chlorantraniliprole in potato according to EFSA guidance

Operator exposure for Chlorantraniliprole 200 SC outdoor spray applications

Application rate of active substance	0,012	kg a.s./ha	*i_AppRate*
Assumed area treated	50	ha/day	*d_AreaTreated*
Amount of active substance applied	0,6	kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	10,00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	50,00%		*i_AbsorInuse*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		
Indoor or Outdoor application	Outdoor		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		
Season	not relevant		

OutdoorSoluble concentrates, emulsifiable concentrate, etc.Downward sprayingVehicle-mounted

	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75th centile	95th centile		
Mixing and loading	Hands	3278	11956	AOEM	
	Body	2491	62091	AOEM	
	Head	31	171	AOEM	
	Protected hands (gloves)	25	119	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	15	88	AOEM	
	Protected head (hood and face shield)	0	10	AOEM	
	Inhalation	3	28	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

	Exposure values	µg exposure/day applied		Reference	Comment
		75th centile	95th centile		
Application	Hands	89	1576	AOEM	
	Body	50	257	AOEM	
	Head	2	7	AOEM	
	Protected hands (gloves)	32	3140	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	1	3	AOEM	
	Inhalation	1	2	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE
Longer term		
Total systemic exposure from mixing, loading and application (mg a.s./day)	0,6545278	0,3827349
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0109088	0,0063789
% of RVNAS	3,03%	1,77%

Table A 25B: Input parameters considered for the estimation of operator exposure in potato (Manual Handheld)

Substance name	Chlorantraniliprole	
Product name	Chlorantraniliprole 200 SC	
Reference value non acutely toxic active substance (RVNAS)	0.36	mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)		mg/kg bw/day
Crop type	Root and tuber vegetables	
Substance properties		
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Miniumum volume water for application (liquids)	400	L/ha
Maximum application rate of active substance	0.012	kg a.s. /ha
50% Dissipation Time DT50	30	days
Initial Dislodgeable Foliar Residue	3	µg/cm2 of foliage/kg a.s. applied/ha
Dermal absorption of product	10.00%	
Dermal absorption of in-use dilution	50.00%	
Oral absorption of active substance	100.00%	
Inhalation absorption of active substance	100.00%	
Vapour pressure of active substance	low volatile substances having a vapour pressure of <5*10-3Pa	
Scenario		
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Manual-Hand held	
Buffer strip	2-3	m
Number of applications	2	
Interval between multiple applications	7	days
Season (upward spraying orchards only)	not relevant	

Table A 26B: Estimation of longer term operator exposure towards Chlorantraniliprole in potato according to EFSA guidance (Manual Handheld)

Operator exposure for Chlorantraniliprole 200 SC outdoor spray applications

Application rate of active substance	0.012	kg a.s./ha	*i_AppRate*
Assumed area treated	4	ha/day	*d_AreaTreated*
Amount of active substance applied	0.048	kg a.s./day	*i_AmountAS*
Dermal absorption of the product	10.00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	50.00%		*i_Absoinuse*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		
Indoor or Outdoor application	Outdoor		
Application method	Downward spraying		
Application equipment	Manual-Hand held		
Season	not relevant		

OutdoorSoluble concentrates, emulsifiable concentrate, etc.Downward sprayingManual-Hand held

Mixing and loading

Exposure values	µg exposure/day mixed and loaded 75th centile	95th centile	Reference	Comment
Hands	469	1673	AOEM	
Body	422	29809	AOEM	
Head	2	14	AOEM	
Protected hands (gloves)	5	10	AOEM	
Protected body (workwear or protective garment and sturdy footwear)	2	7	AOEM	
Protected head (hood and face shield)	0	1	AOEM	
Inhalation	1	27	AOEM	
Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
Gloves	No			
Clothing	Work wear – arms, body and legs covered		incl. in AOEM model	
Head and respiratory PPE	None		1	1
Water soluble bag	No		1	

Application

Exposure values	µg exposure/day applied 75th centile	95th centile	Reference	Comment
Hands	1544	4213	AOEM	
Body	88868	137007	AOEM	
Head	12	85	AOEM	
Protected hands (gloves)	5	22	AOEM	
Protected body (workwear or protective garment and sturdy footwear)	8903	62630	AOEM	
Inhalation	26	26	AOEM	
Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
Gloves	No			
Clothing	Work wear – arms, body and legs covered		incl. in AOEM model	
Head and respiratory PPE	None		1	1
Closed cab	No		vehicle mounted upward spraying	

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	45.3288471	5.3043061	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.7554808	0.0884051	
% of RVNAS	209.86%	24.56%	

Table A 25C: Input parameters considered for the estimation of operator exposure in potato (Manual Knapsack)

Substance name	Chlorantraniliprole	
Product name	Chlorantraniliprole 200 SC	
Reference value non acutely toxic active substance (RVNAS)	0.36	mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)		mg/kg bw/day
Crop type	Root and tuber vegetables	
Substance properties		
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Miniumum volume water for application (liquids)	400	L/ha
Maximum application rate of active substance	0.012	kg a.s. /ha
50% Dissipation Time DT50	30	days
Initial Dislodgeable Foliar Residue	3	µg/cm2 of foliage/kg a.s. applied/ha
Dermal absorption of product	10.00%	
Dermal absorption of in-use dilution	50.00%	
Oral absorption of active substance	100.00%	
Inhalation absorption of active substance	100.00%	
Vapour pressure of active substance	low volatile substances having a vapour pressure of <5*10-3Pa	
Scenario		
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Manual-Knapsack	
Buffer strip	2-3	m
Number of applications	2	
Interval between multiple applications	7	days
Season (upward spraying orchards only)	not relevant	

Table A 26B: Estimation of longer term operator exposure towards Chlorantraniliprole in potato according to EFSA guidance (Manual Knaspack)

Operator exposure for Chlorantraniliprole 200 SC outdoor spray applications

Application rate of active substance	0.012	kg a.s./ha	*i_AppRate*
Assumed area treated	1	ha/day	*d_AreaTreated*
Amount of active substance applied	0.012	kg a.s./day	*i_AmountAS*
Dermal absorption of the product	10.00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	50.00%		*i_Absorbuse*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		
Indoor or Outdoor application	Outdoor		
Application method	Downward spraying		
Application equipment	Manual-Knapsack		
Season	not relevant		

	Exposure values	µg exposure/day mixed and loaded 75th centile	95th centile	Reference	Comment
Mixing and loading	Hands	9495	25482	AOEM	
	Body	803	2787	AOEM	
	Head	5	11	AOEM	
	Protected hands (gloves)	18	164	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	25	103	AOEM	
	Protected head (hood and face shield)	5	11	AOEM	
	Inhalation	25	26	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

	Exposure values	µg exposure/day applied 75th centile	95th centile	Reference	Comment
Application	Hands	1544	4213	AOEM	
	Body	88868	137007	AOEM	
	Head	12	85	AOEM	
	Protected hands (gloves)	5	22	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	8903	62630	AOEM	
	Inhalation	26	26	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying	

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	46.2933000	6.2330000	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.7715550	0.1038833	
% of RVNAS	214.32%	28.86%	

A 3.2 Worker exposure calculations (KCP 7.2.3.1)

Table A 27: Input parameters considered for the estimation of worker exposure in head cabbage, cauliflower, broccoli

Substance name	Chlorantraniliprole	
Product name	Chlorantraniliprole 200 SC	
Reference value non acutely toxic active substance (RVNAS)	0,36	mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)		mg/kg bw/day
Crop type	Brassica vegetables	
Substance properties		
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Miniumum volume water for application (liquids)	400	L/ha
Maximum application rate of active substance	0,028	kg a.s. /ha
50% Dissipation Time DT50	30	days
Initial Dislodgeable Foliar Residue	3	µg/cm2 of foliage/kg a.s. applied/ha
Dermal absorption of product	10,00%	
Dermal absorption of in-use dilution	50,00%	
Oral absorption of active substance	13,00%	
Inhalation absorption of active substance	100,00%	
Vapour pressure of active substance	low volatile substances having a vapour pressure of <5*10-3Pa	
Scenario		
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Buffer strip	2-3	m
Number of applications	1	
Interval between multiple applications	365	days
Season (upward spraying orchards only)	not relevant	

Table A 28: Estimation of worker exposure towards Chlorantraniliprole in head cabbage, cauliflower, broccoli according to EFSA guidance

Worker exposure from residues on foliage for Chlorantraniliprole 200 SC		
Crop type	Brassica vegetables	
Indoor or outdoor	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Worker's task	Reaching, picking	
Main body parts in contact with foliage	Hand and body	
Application rate of active substance	0,028	kg a.s./ha
Number of applications	1	
Interval between multiple applications	365	days
Half-life of active substance	30	days
Multiple application factor	1,0	
Dermal absorption of the product	10,00%	
Dermal absorption of the in-use dilution	50,00%	
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,084	µg a.s./cm^2
Working hours	8	hr
Dermal transfer coefficient - Total potential exposure	5800	cm^2/hr
Dermal transfer coefficient - arms, body and legs covered	2500	cm^2/hr
Dermal transfer coefficient - hands, arms, body and legs covered	580	cm^2/hr
Inhalation transfer coefficient for automated applications	NA	ha/hr*10^(-3)
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10^(-3)
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10^(-3)

1. Total

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	1,9488000	0,8400000	0,1948800
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0324800	0,0140000	0,0032480
% of RVNAS	9,02%	3,89%	0,90%

Table A 29: Input parameters considered for the estimation of worker exposure in grapes

Substance name	Chlorantraniliprole	
Product name	Chlorantraniliprole 200 SC	
Reference value non acutely toxic active substance (RVNAS)	0,36	mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)		mg/kg bw/day
Crop type	Grapes	
Substance properties		
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Miniumum volume water for application (liquids)	400	L/ha
Maximum application rate of active substance	0,036	kg a.s. /ha
50% Dissipation Time DT50	30	days
Initial Dislodgeable Foliar Residue	3	µg/cm2 of foliage/kg a.s. applied/ha
Dermal absorption of product	10,00%	
Dermal absorption of in-use dilution	50,00%	
Oral absorption of active substance	13,00%	
Inhalation absorption of active substance	100,00%	
Vapour pressure of active substance	low volatile substances having a vapour pressure of <5*10-3Pa	
Scenario		
Indoor or Outdoor application	Outdoor	
Application method	Upward spraying	
Application equipment	Vehicle-mounted	
Buffer strip	5	m
Number of applications	1	
Interval between multiple applications	365	days
Season (upward spraying orchards only)	not relevant	

Table A 30: Estimation of worker exposure towards Chlorantraniliprole in grapes according to EFSA guidance

Worker exposure from residues on foliage for Chlorantraniliprole 200 SC			
Crop type	Grapes		
Indoor or outdoor	Outdoor		
Application method	Upward spraying		
Application equipment	Vehicle-mounted		
Worker's task	Hand harvesting		
Main body parts in contact with foliage	Hand and body		
Application rate of active substance	0,036	kg a.s./ha	*i_AppRate*
Number of applications	1		*i_AppNo*
Interval between multiple applications	365	days	*i_AppInt*
Half-life of active substance	30	days	*d_HalflifeAS*
Multiple application factor	1,0		*d_MAF*
Dermal absorption of the product	10,00%		*i_AbsorpProduct*
Dermal absorption of the in-use dilution	50,00%		*i_AbsorpInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,108	µg a.s./cm^2	*d_DFR*
Working hours	8	hr	*d_WorkHr*
Dermal transfer coefficient - Total potential exposure	30000	cm^2/hr	*d_DermTcUCV*
Dermal transfer coefficient - arms, body and legs covered	10100	cm^2/hr	*d_DermTcCV1*
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment	cm^2/hr	*d_DermTcCV2*
Inhalation transfer coefficient for automated applications	NA	ha/hr*10^(-3)	*d_InhalTcAut*
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10^(-3)	*d_InhalTcCut*
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10^(-3)	*d_InhalTcSort*

1. Total

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	12,9600000	4,3632000	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0,2160000	0,0727200		
% of RVNAS	60,00%	20,20%		

Table A 31: Input parameters considered for the estimation of worker exposure in corn

Substance name	Chlorantraniliprole	
Product name	Chlorantraniliprole 200 SC	
Reference value non acutely toxic active substance (RVNAS)	0,36	mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)		mg/kg bw/day
Crop type	Cereals	
Substance properties		
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Miniumum volume water for application (liquids)	400	L/ha
Maximum application rate of active substance	0,028	kg a.s. /ha
50% Dissipation Time DT50	30	days
Initial Dislodgeable Foliar Residue	3	µg/cm2 of foliage/kg a.s. applied/ha
Dermal absorption of product	10,00%	
Dermal absorption of in-use dilution	50,00%	
Oral absorption of active substance	13,00%	
Inhalation absorption of active substance	100,00%	
Vapour pressure of active substance	low volatile substances having a vapour pressure of <5*10-3Pa	
Scenario		
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Buffer strip	2-3	m
Number of applications	1	
Interval between multiple applications	365	days
Season (upward spraying orchards only)	not relevant	

Table A 32: Estimation of worker exposure towards Chlorantraniliprole in corn according to EFSA guidance

Worker exposure from residues on foliage for Chlorantraniliprole 200 SC		
Crop type	Cereals	
Indoor or outdoor	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Worker's task	Inspection, irrigation	
Main body parts in contact with foliage	Hand and body	
Application rate of active substance	0,028	kg a.s./ha
Number of applications	1	
Interval between multiple applications	365	days
Half-life of active substance	30	days
Multiple application factor	1,0	
Dermal absorption of the product	10,00%	
Dermal absorption of the in-use dilution	50,00%	
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,084	µg a.s./cm^2
Working hours	2	hr
Dermal transfer coefficient - Total potential exposure	12500	cm^2/hr
Dermal transfer coefficient - arms, body and legs covered	1400	cm^2/hr
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment	cm^2/hr
Inhalation transfer coefficient for automated applications	NA	ha/hr*10^(-3)
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10^(-3)
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10^(-3)

1. Total

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	1,0500000	0,1176000	no TC available for this assessment
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0175000	0,0019600	
% of RVNAS	4,86%	0,54%	

Table A 33: Input parameters considered for the estimation of worker exposure in apple, pear and quince

Substance name	Chlorantraniliprole	
Product name	Chlorantraniliprole 200 SC	
Reference value non acutely toxic active substance (RVNAS)	0,36	mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)		mg/kg bw/day
Crop type	Pome fruit	
Substance properties		
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Miniumum volume water for application (liquids)	500	L/ha
Maximum application rate of active substance	0,031	kg a.s. /ha
50% Dissipation Time DT50	30	days
Initial Dislodgeable Foliar Residue	3	µg/cm2 of foliage/kg a.s. applied/ha
Dermal absorption of product	10,00%	
Dermal absorption of in-use dilution	50,00%	
Oral absorption of active substance	13,00%	
Inhalation absorption of active substance	100,00%	
Vapour pressure of active substance	low volatile substances having a vapour pressure of <5*10-3Pa	
Scenario		
Indoor or Outdoor application	Outdoor	
Application method	Upward spraying	
Application equipment	Vehicle-mounted	
Buffer strip	5	m
Number of applications	1	
Interval between multiple applications	365	days
Season (upward spraying orchards only)	not relevant	

Table A 34: Estimation of worker exposure towards Chlorantraniliprole in apple, pear and quince according to EFSA guidance

Worker exposure from residues on foliage for Chlorantraniliprole 200 SC		
Crop type	Pome fruit	
Indoor or outdoor	Outdoor	
Application method	Upward spraying	
Application equipment	Vehicle-mounted	
Worker's task	Searching, reaching, picking	
Main body parts in contact with foliage	Hand and body	
Application rate of active substance	0,031	kg a.s./ha
Number of applications	1	
Interval between multiple applications	365	days
Half-life of active substance	30	days
Multiple application factor	1,0	
Dermal absorption of the product	10,00%	
Dermal absorption of the in-use dilution	50,00%	
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,093	µg a.s./cm^2
Working hours	8	hr
Dermal transfer coefficient - Total potential exposure	22500	cm^2/hr
Dermal transfer coefficient - arms, body and legs covered	4500	cm^2/hr
Dermal transfer coefficient - hands, arms, body and legs covered	2250	cm^2/hr
Inhalation transfer coefficient for automated applications	NA	ha/hr*10^(-3)
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10^(-3)
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10^(-3)

1. Total

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	8,3700000	1,6740000	0,8370000
Total systemic exposure per kg body weight (mg/kg bw/day)	0,1395000	0,0279000	0,0139500
% of RVNAS	38,75%	7,75%	3,88%

Table A 35: Input parameters considered for the estimation of worker exposure in potato

Substance name	Chlorantraniliprole	
Product name	Chlorantraniliprole 200 SC	
Reference value non acutely toxic active substance (RVNAS)	0,36	mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)		mg/kg bw/day
Crop type	Root and tuber vegetables	
Substance properties		
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Miniumum volume water for application (liquids)	400	L/ha
Maximum application rate of active substance	0,012	kg a.s. /ha
50% Dissipation Time DT50	30	days
Initial Dislodgeable Foliar Residue	3	µg/cm2 of foliage/kg a.s. applied/ha
Dermal absorption of product	10,00%	
Dermal absorption of in-use dilution	50,00%	
Oral absorption of active substance	13,00%	
Inhalation absorption of active substance	100,00%	
Vapour pressure of active substance	low volatile substances having a vapour pressure of <5*10-3Pa	
Scenario		
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Buffer strip	2-3	m
Number of applications	2	
Interval between multiple applications	7	days
Season (upward spraying orchards only)	not relevant	

Table A 36: Estimation of worker exposure towards Chlorantraniliprole in potato according to EFSA guidance

Worker exposure from residues on foliage for Chlorantraniliprole 200 SC		
Crop type	Root and tuber vegetables	
Indoor or outdoor	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Worker's task	Inspection, irrigation	
Main body parts in contact with foliage	Hand and body	
Application rate of active substance	0,012	kg a.s./ha
Number of applications	2	
Interval between multiple applications	7	days
Half-life of active substance	30	days
Multiple application factor	1,9	
Dermal absorption of the product	10,00%	
Dermal absorption of the in-use dilution	50,00%	
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,036	µg a.s./cm^2
Working hours	2	hr
Dermal transfer coefficient - Total potential exposure	12500	cm^2/hr
Dermal transfer coefficient - arms, body and legs covered	1400	cm^2/hr
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment	cm^2/hr
Inhalation transfer coefficient for automated applications	NA	ha/hr*10^(-3)
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10^(-3)
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10^(-3)

1. Total

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	0,8328002	0,0932736	no TC available for this assessment
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0138800	0,0015546	
% of RVNAS	3,86%	0,43%	

A 3.3 Resident exposure calculations (KCP 7.2.2.1)

Table A 37: Input parameters considered for the estimation of resident exposure in head cabbage, cauliflower, broccoli

Substance name	Chlorantraniliprole	
Product name	Chlorantraniliprole 200 SC	
Reference value non acutely toxic active substance (RVNAS)	0,36	mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)		mg/kg bw/day
Crop type	Brassica vegetables	
Substance properties		
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Miniumum volume water for application (liquids)	400	L/ha
Maximum application rate of active substance	0,028	kg a.s. /ha
50% Dissipation Time DT50	30	days
Initial Dislodgeable Foliar Residue	3	µg/cm2 of foliage/kg a.s. applied/ha
Dermal absorption of product	10,00%	
Dermal absorption of in-use dilution	50,00%	
Oral absorption of active substance	13,00%	
Inhalation absorption of active substance	100,00%	
Vapour pressure of active substance	low volatile substances having a vapour pressure of <5*10-3Pa	
Scenario		
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Buffer strip	2-3	m
Number of applications	1	
Interval between multiple applications	365	days
Season (upward spraying orchards only)	not relevant	

Table A 38: Estimation of resident exposure towards Chlorantraniliprole in head cabbage, cauliflower, broccoli according to EFSA guidance

Resident exposure for Chlorantraniliprole 200 SC			
Croptype	Brassica vegetables		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		*i_AppEquip*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		*i_FormVal*
Buffer strip	2-3	m	*i_Buffer*
Application rate of the product	0,028	kg a.s./ha	*i_AppRate*
Concentration of active substance (in-use dilution for liquid applications)	0,07	g a.s./l	*d_ConcAS*
Dermal absorption of product	10,00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	50,00%		*i_AbsorpInuse*
Oral absorption	13,00%		*i_AbsorpOralInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,084	µg a.s./cm^2	*d_DFR*
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa	*i_Volat*
Concentration in air	0,001	mg/m^3	*d_AirCon*
Resident dermal spray drift exposure 75th percentile - adult	0,47	ml spray dilution/person	
Resident dermal spray drift exposure 75th percentile - child	0,327	ml spray dilution/person	
Resident inhal. spray drift exposure 75th percentile - adult	0,00010	ml spray dilution/person	
Resident inhal. spray drift exposure 75th percentile - child	0,00022	ml spray dilution/person	
Resident dermal spray drift exposure mean - adult	0,22318	ml spray dilution/person	
Resident dermal spray drift exposure mean - child	0,18	ml spray dilution/person	
Resident inhal. spray drift exposure mean - adult	0,00009	ml spray dilution/person	
Resident inhal. spray drift exposure mean - child	0,00017	ml spray dilution/person	
Exposure duration dermal	2	hours	*d_ReExpDur*
Exposure duration inhalation	24	hours	*d_ReExpDurInhal*
Exposure duration entry into treated crops	0,25	hours	*d_ExpDurTreatCrop*
Light clothing adjustment factor	18,0%		*d_ClothAF*
Breathing rate adult	0,23	m^3/day/kg	*d_BreathRAd*
Breathing rate child (1-3 year old)	1,07	m^3/day/kg	*d_BreathRCh*
Drift percentage on surface (75th percentile)	5,60%		
Drift percentage on surface (mean)	4,10%		
Turf transferable residues percentage	5,00%		*d_Turf*
Transfer coeff. of surface deposits-adult	7300	cm^2/hour	*d_ReTCAd*
Transfer coeff. of surface deposits-child (1-3 year old)	2600	cm^2/hour	*d_ReTCCh*
Saliva extraction percentage	50,00%		*d_SalExt*
Surface area of hands mouthed	20	cm^2	*d_AreaHM*
Frequency of hand to mouth activity	9,5	events/hour	*d_ReFreqHM*
Ingestion rate for mouthing of grass per day	25	cm^2	*d_MouthGrass*
Dislodgeable residues percentage transferability for object to mouth	20,00%		*d_DRP*
Transfer coefficient for entry into treated crops (75th percentile) - adı	7500	cm^2/h	*d_TcEntryAd*
Transfer coefficient for entry into treated crops (75th percentile) - chi	2250	cm^2/h	*d_TcEntryCh*
Transfer coefficient for entry into treated crops (mean) - adult	5980	cm^2/h	*d_TcEntryAd*
Transfer coefficient for entry into treated crops (mean) - child	1794	cm^2/h	*d_TcEntryCh*

1. Total

1.1 1-3 year old child

	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0094003	0,0107000	0,0020680	0,0236250	0,0362289
Total systemic exposure per kg body weight	0,0009400	0,0010700	0,0002068	0,0023625	0,0036229
% of RVNAS	0,26%	0,30%	0,06%	0,66%	1,01%

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0134960	0,0138000	0,0057232	0,0787500	0,0871918
Total systemic exposure per kg body weight	0,0002249	0,0002300	0,0000954	0,0013125	0,0014532
% of RVNAS	0,06%	0,06%	0,03%	0,36%	0,40%

Table A 39: Input parameters considered for the estimation of resident exposure in grapes

Substance name	Chlorantraniliprole	
Product name	Chlorantraniliprole 200 SC	
Reference value non acutely toxic active substance (RVNAS)	0,36	mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)		mg/kg bw/day
Crop type	Grapes	
Substance properties		
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Miniumum volume water for application (liquids)	400	L/ha
Maximum application rate of active substance	0,036	kg a.s. /ha
50% Dissipation Time DT50	30	days
Initial Dislodgeable Foliar Residue	3	µg/cm2 of foliage/kg a.s. applied/ha
Dermal absorption of product	10,00%	
Dermal absorption of in-use dilution	50,00%	
Oral absorption of active substance	13,00%	
Inhalation absorption of active substance	100,00%	
Vapour pressure of active substance	low volatile substances having a vapour pressure of <5*10-3Pa	
Scenario		
Indoor or Outdoor application	Outdoor	
Application method	Upward spraying	
Application equipment	Vehicle-mounted	
Buffer strip	5	m
Number of applications	1	
Interval between multiple applications	365	days
Season (upward spraying orchards only)	not relevant	

Table A 40: Estimation of resident exposure towards Chlorantraniliprole in grapes according to EFSA guidance

Resident exposure for Chlorantraniliprole 200 SC				
Croptype	Grapes			
Application method	Upward spraying			
Application equipment	Vehicle-mounted			*i_AppEquip*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.			*i_FormVal*
Buffer strip	5	m		*i_Buffer*
Application rate of the product	0,036	kg a.s./ha		*i_AppRate*
Concentration of active substance (in-use dilution for liquid applications)	0,09	g a.s./l		*d_ConcAS*
Dermal absorption of product	10,00%			*i_AbsorpProduct*
Dermal absorption of in-use dilution	50,00%			*i_AbsorpInuse*
Oral absorption	13,00%			*i_AbsorpOralInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,108	µg a.s./cm^2		*d_DFR*
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa		*i_Volat*
Concentration in air	0,001	mg/m^3		*d_AirCon*
Resident dermal spray drift exposure 75th percentile - adult	5,63	ml spray dilution/person		
Resident dermal spray drift exposure 75th percentile - child	1,689	ml spray dilution/person		
Resident inhal. spray drift exposure 75th percentile - adult	0,00210	ml spray dilution/person		
Resident inhal. spray drift exposure 75th percentile - child	0,00164	ml spray dilution/person		
Resident dermal spray drift exposure mean - adult	3,68	ml spray dilution/person		
Resident dermal spray drift exposure mean - child	1,11	ml spray dilution/person		
Resident inhal. spray drift exposure mean - adult	0,00170	ml spray dilution/person		
Resident inhal. spray drift exposure mean - child	0,00133	ml spray dilution/person		
Exposure duration dermal	2	hours		*d_ReExpDur*
Exposure duration inhalation	24	hours		*d_ReExpDurInhal*
Exposure duration entry into treated crops	0,25	hours		*d_ExpDurTreatCrop*
Light clothing adjustment factor	18,0%			*d_ClothAF*
Breathing rate adult	0,23	m^3/day/kg		*d_BreathRAd*
Breathing rate child (1-3 year old)	1,07	m^3/day/kg		*d_BreathRCh*
Drift percentage on surface (75th percentile)	3,07%			
Drift percentage on surface (mean)	2,32%			
Turf transferable residues percentage	5,00%			*d_Turf*
Transfer coeff. of surface deposits-adult	7300	cm^2/hour		*d_ReTCAd*
Transfer coeff. of surface deposits-child (1-3 year old)	2600	cm^2/hour		*d_ReTCCh*
Saliva extraction percentage	50,00%			*d_SalExt*
Surface area of hands mouthed	20	cm^2		*d_AreaHM*
Frequency of hand to mouth activity	9,5	events/hour		*d_ReFreqHM*
Ingestion rate for mouthing of grass per day	25	cm^2		*d_MouthGrass*
Dislodgeable residues percentage transferability for object to mouth	20,00%			*d_DRP*
Transfer coefficient for entry into treated crops (75th percentile) - adı	7500	cm^2/h		*d_TcEntryAd*
Transfer coefficient for entry into treated crops (75th percentile) - chi	2250	cm^2/h		*d_TcEntryCh*
Transfer coefficient for entry into treated crops (mean) - adult	5980	cm^2/h		*d_TcEntryAd*
Transfer coefficient for entry into treated crops (mean) - child	1794	cm^2/h		*d_TcEntryCh*

1. Total

1.1 1-3 year old child

	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0624720	0,0107000	0,0014576	0,0303750	0,0770992
Total systemic exposure per kg body weight	0,0062472	0,0010700	0,0001458	0,0030375	0,0077099
% of RVNAS	1,74%	0,30%	0,04%	0,84%	2,14%

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,2079360	0,0138000	0,0040340	0,1012500	0,2335235
Total systemic exposure per kg body weight	0,0034656	0,0002300	0,0000672	0,0016875	0,0038921
% of RVNAS	0,96%	0,06%	0,02%	0,47%	1,08%

Table A 41: Input parameters considered for the estimation of resident exposure in corn

Substance name	Chlorantraniliprole	
Product name	Chlorantraniliprole 200 SC	
Reference value non acutely toxic active substance (RVNAS)	0,36	mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)		mg/kg bw/day
Crop type	Cereals	
Substance properties		
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Miniumum volume water for application (liquids)	400	L/ha
Maximum application rate of active substance	0,028	kg a.s. /ha
50% Dissipation Time DT50	30	days
Initial Dislodgeable Foliar Residue	3	µg/cm2 of foliage/kg a.s. applied/ha
Dermal absorption of product	10,00%	
Dermal absorption of in-use dilution	50,00%	
Oral absorption of active substance	13,00%	
Inhalation absorption of active substance	100,00%	
Vapour pressure of active substance	low volatile substances having a vapour pressure of <5*10-3Pa	
Scenario		
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Buffer strip	2-3	m
Number of applications	1	
Interval between multiple applications	365	days
Season (upward spraying orchards only)	not relevant	

Table A 42: Estimation of resident exposure towards Chlorantraniliprole in corn according to EFSA guidance

Resident exposure for Chlorantraniliprole 200 SC			
Croptype	Cereals		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		i_AppEquip
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		i_FormVal
Buffer strip	2-3	m	i_Buffer
Application rate of the product	0,028	kg a.s./ha	i_AppRate
Concentration of active substance (in-use dilution for liquid applications)	0,07	g a.s./l	d_ConcAS
Dermal absorption of product	10,00%		i_AbsorpProduct
Dermal absorption of in-use dilution	50,00%		i_AbsorpInuse
Oral absorption	13,00%		i_AbsorpOralInuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,084	µg a.s./cm^2	d_DFR
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa	i_Volat
Concentration in air	0,001	mg/m^3	d_AirCon
Resident dermal spray drift exposure 75th percentile - adult	0,47	ml spray dilution/person	
Resident dermal spray drift exposure 75th percentile - child	0,327	ml spray dilution/person	
Resident inhal. spray drift exposure 75th percentile - adult	0,00010	ml spray dilution/person	
Resident inhal. spray drift exposure 75th percentile - child	0,00022	ml spray dilution/person	
Resident dermal spray drift exposure mean - adult	0,22318	ml spray dilution/person	
Resident dermal spray drift exposure mean - child	0,18	ml spray dilution/person	
Resident inhal. spray drift exposure mean - adult	0,00009	ml spray dilution/person	
Resident inhal. spray drift exposure mean - child	0,00017	ml spray dilution/person	
Exposure duration dermal	2	hours	d_ReExpDur
Exposure duration inhalation	24	hours	d_ReExpDurInhal
Exposure duration entry into treated crops	0,25	hours	d_ExpDurTreatCrop
Light clothing adjustment factor	18,0%		d_ClothAF
Breathing rate adult	0,23	m^3/day/kg	d_BreathRAd
Breathing rate child (1-3 year old)	1,07	m^3/day/kg	d_BreathRCh
Drift percentage on surface (75th percentile)	5,60%		
Drift percentage on surface (mean)	4,10%		
Turf transferable residues percentage	5,00%		d_Turf
Transfer coeff. of surface deposits-adult	7300	cm^2/hour	d_ReTCAd
Transfer coeff. of surface deposits-child (1-3 year old)	2600	cm^2/hour	d_ReTCCh
Saliva extraction percentage	50,00%		d_SalExt
Surface area of hands mouthed	20	cm^2	d_AreaHM
Frequency of hand to mouth activity	9,5	events/hour	d_ReFreqHM
Ingestion rate for mouthing of grass per day	25	cm^2	d_MouthGrass
Dislodgeable residues percentage transferability for object to mouth	20,00%		d_DRP
Transfer coefficient for entry into treated crops (75th percentile) - adı	7500	cm^2/h	d_TcEntryAd
Transfer coefficient for entry into treated crops (75th percentile) - chi	2250	cm^2/h	d_TcEntryCh
Transfer coefficient for entry into treated crops (mean) - adult	5980	cm^2/h	d_TcEntryAd
Transfer coefficient for entry into treated crops (mean) - child	1794	cm^2/h	d_TcEntryCh

1. Total

1.1 1-3 year old child

	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0094003	0,0107000	0,0020680	0,0236250	0,0362289
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0009400	0,0010700	0,0002068	0,0023625	0,0036229
% of RVNAS	0,26%	0,30%	0,06%	0,66%	1,01%

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0134960	0,0138000	0,0057232	0,0787500	0,0871918
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0002249	0,0002300	0,0000954	0,0013125	0,0014532
% of RVNAS	0,06%	0,06%	0,03%	0,36%	0,40%

Table A 43: Input parameters considered for the estimation of resident exposure in apple, pear and quince

Substance name	Chlorantraniliprole	
Product name	Chlorantraniliprole 200 SC	
Reference value non acutely toxic active substance (RVNAS)	0,36	mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)		mg/kg bw/day
Crop type	Pome fruit	
Substance properties		
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Miniumum volume water for application (liquids)	500	L/ha
Maximum application rate of active substance	0,031	kg a.s. /ha
50% Dissipation Time DT50	30	days
Initial Dislodgeable Foliar Residue	3	µg/cm2 of foliage/kg a.s. applied/ha
Dermal absorption of product	10,00%	
Dermal absorption of in-use dilution	50,00%	
Oral absorption of active substance	13,00%	
Inhalation absorption of active substance	100,00%	
Vapour pressure of active substance	low volatile substances having a vapour pressure of <5*10-3Pa	
Scenario		
Indoor or Outdoor application	Outdoor	
Application method	Upward spraying	
Application equipment	Vehicle-mounted	
Buffer strip	5	m
Number of applications	1	
Interval between multiple applications	365	days
Season (upward spraying orchards only)	not relevant	

Table A 44: Estimation of resident exposure towards Chlorantraniliprole in in apple, pear and quince according to EFSA guidance

Resident exposure for Chlorantraniliprole 200 SC			
Croptype	Pome fruit		
Application method	Upward spraying		
Application equipment	Vehicle-mounted		*i_AppEquip*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		*i_FormVal*
Buffer strip	5	m	*i_Buffer*
Application rate of the product	0,031	kg a.s./ha	*i_AppRate*
Concentration of active substance (in-use dilution for liquid applications)	0,062	g a.s./l	*d_ConcAS*
Dermal absorption of product	10,00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	50,00%		*i_AbsorpInuse*
Oral absorption	13,00%		*i_AbsorpOralInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,093	µg a.s./cm^2	*d_DFR*
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa	*i_Volat*
Concentration in air	0,001	mg/m^3	*d_AirCon*
Resident dermal spray drift exposure 75th percentile - adult	5,63	ml spray dilution/person	
Resident dermal spray drift exposure 75th percentile - child	1,689	ml spray dilution/person	
Resident inhal. spray drift exposure 75th percentile - adult	0,00210	ml spray dilution/person	
Resident inhal. spray drift exposure 75th percentile - child	0,00164	ml spray dilution/person	
Resident dermal spray drift exposure mean - adult	3,68	ml spray dilution/person	
Resident dermal spray drift exposure mean - child	1,11	ml spray dilution/person	
Resident inhal. spray drift exposure mean - adult	0,00170	ml spray dilution/person	
Resident inhal. spray drift exposure mean - child	0,00133	ml spray dilution/person	
Exposure duration dermal	2	hours	*d_ReExpDur*
Exposure duration inhalation	24	hours	*d_ReExpDurInhal*
Exposure duration entry into treated crops	0,25	hours	*d_ExpDurTreatCrop*
Light clothing adjustment factor	18,0%		*d_ClothAF*
Breathing rate adult	0,23	m^3/day/kg	*d_BreathRAd*
Breathing rate child (1-3 year old)	1,07	m^3/day/kg	*d_BreathRCh*
Drift percentage on surface (75th percentile)	15,79%		
Drift percentage on surface (mean)	11,69%		
Turf transferable residues percentage	5,00%		*d_Turf*
Transfer coeff. of surface deposits-adult	7300	cm^2/hour	*d_ReTCAd*
Transfer coeff. of surface deposits-child (1-3 year old)	2600	cm^2/hour	*d_ReTCCh*
Saliva extraction percentage	50,00%		*d_SalExt*
Surface area of hands mouthed	20	cm^2	*d_AreaHM*
Frequency of hand to mouth activity	9,5	events/hour	*d_ReFreqHM*
Ingestion rate for mouthing of grass per day	25	cm^2	*d_MouthGrass*
Dislodgeable residues percentage transferability for object to mouth	20,00%		*d_DRP*
Transfer coefficient for entry into treated crops (75th percentile) - adı	7500	cm^2/h	*d_TcEntryAd*
Transfer coefficient for entry into treated crops (75th percentile) - chi	2250	cm^2/h	*d_TcEntryCh*
Transfer coefficient for entry into treated crops (mean) - adult	5980	cm^2/h	*d_TcEntryAd*
Transfer coefficient for entry into treated crops (mean) - child	1794	cm^2/h	*d_TcEntryCh*

1. Total

1.1 1-3 year old child

	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0430363	0,0107000	0,0064556	0,0261563	0,0646333
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0043036	0,0010700	0,0006456	0,0026156	0,0064633
% of RVNAS	1,20%	0,30%	0,18%	0,73%	1,80%

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,1432448	0,0138000	0,0178664	0,0871875	0,1901957
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0023874	0,0002300	0,0002978	0,0014531	0,0031699
% of RVNAS	0,66%	0,06%	0,08%	0,40%	0,88%

Table A 45: Input parameters considered for the estimation of resident exposure in potato

Substance name	Chlorantraniliprole	
Product name	Chlorantraniliprole 200 SC	
Reference value non acutely toxic active substance (RVNAS)	0,36	mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)		mg/kg bw/day
Crop type	Root and tuber vegetables	
Substance properties		
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Miniumum volume water for application (liquids)	400	L/ha
Maximum application rate of active substance	0,012	kg a.s. /ha
50% Dissipation Time DT50	30	days
Initial Dislodgeable Foliar Residue	3	µg/cm2 of foliage/kg a.s. applied/ha
Dermal absorption of product	10,00%	
Dermal absorption of in-use dilution	50,00%	
Oral absorption of active substance	13,00%	
Inhalation absorption of active substance	100,00%	
Vapour pressure of active substance	low volatile substances having a vapour pressure of <5*10-3Pa	
Scenario		
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Buffer strip	2-3	m
Number of applications	2	
Interval between multiple applications	7	days
Season (upward spraying orchards only)	not relevant	

Table A 46: Estimation of resident exposure towards Chlorantraniliprole in potato according to EFSA guidance

Resident exposure for Chlorantraniliprole 200 SC			
Croptype	Root and tuber vegetables		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		i_AppEquip
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		i_FormVal
Buffer strip	2-3	m	i_Buffer
Application rate of the product	0,012	kg a.s./ha	i_AppRate
Concentration of active substance (in-use dilution for liquid applications)	0,03	g a.s./l	d_ConcAS
Dermal absorption of product	10,00%		i_AbsorpProduct
Dermal absorption of in-use dilution	50,00%		i_AbsorpInuse
Oral absorption	13,00%		i_AbsorpOralInuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,036	µg a.s./cm^2	d_DFR
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa	i_Volat
Concentration in air	0,001	mg/m^3	d_AirCon
Resident dermal spray drift exposure 75th percentile - adult	0,47	ml spray dilution/person	
Resident dermal spray drift exposure 75th percentile - child	0,327	ml spray dilution/person	
Resident inhal. spray drift exposure 75th percentile - adult	0,00010	ml spray dilution/person	
Resident inhal. spray drift exposure 75th percentile - child	0,00022	ml spray dilution/person	
Resident dermal spray drift exposure mean - adult	0,22318	ml spray dilution/person	
Resident dermal spray drift exposure mean - child	0,18	ml spray dilution/person	
Resident inhal. spray drift exposure mean - adult	0,00009	ml spray dilution/person	
Resident inhal. spray drift exposure mean - child	0,00017	ml spray dilution/person	
Exposure duration dermal	2	hours	d_ReExpDur
Exposure duration inhalation	24	hours	d_ReExpDurInhal
Exposure duration entry into treated crops	0,25	hours	d_ExpDurTreatCrop
Light clothing adjustment factor	18,0%		d_ClothAF
Breathing rate adult	0,23	m^3/day/kg	d_BreathRAd
Breathing rate child (1-3 year old)	1,07	m^3/day/kg	d_BreathRCh
Drift percentage on surface (75th percentile)	5,60%		
Drift percentage on surface (mean)	4,10%		
Turf transferable residues percentage	5,00%		d_Turf
Transfer coeff. of surface deposits-adult	7300	cm^2/hour	d_ReTCAd
Transfer coeff. of surface deposits-child (1-3 year old)	2600	cm^2/hour	d_ReTCCh
Saliva extraction percentage	50,00%		d_SalExt
Surface area of hands mouthed	20	cm^2	d_AreaHM
Frequency of hand to mouth activity	9,5	events/hour	d_ReFreqHM
Ingestion rate for mouthing of grass per day	25	cm^2	d_MouthGrass
Dislodgeable residues percentage transferability for object to mouth	20,00%		d_DRP
Transfer coefficient for entry into treated crops (75th percentile) - adı	7500	cm^2/h	d_TcEntryAd
Transfer coefficient for entry into treated crops (75th percentile) - chi	2250	cm^2/h	d_TcEntryCh
Transfer coefficient for entry into treated crops (mean) - adult	5980	cm^2/h	d_TcEntryAd
Transfer coefficient for entry into treated crops (mean) - child	1794	cm^2/h	d_TcEntryCh

1. Total

1.1 1-3 year old child

	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0040287	0,0107000	0,0016402	0,0187380	0,0290604
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0004029	0,0010700	0,0001640	0,0018738	0,0029060
% of RVNAS	0,11%	0,30%	0,05%	0,52%	0,81%

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0057840	0,0138000	0,0045393	0,0624600	0,0696727
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0000964	0,0002300	0,0000757	0,0010410	0,0011612
% of RVNAS	0,03%	0,06%	0,02%	0,29%	0,32%

Appendix 4 Detailed evaluation of exposure and/or DFR studies relied upon (KCP 7.2, KCP 7.2.1.1, KCP 7.2.2.1, KCP 7.2.3.1)

Not relevant.