REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: ASA-01

Product name(s): **VIARES**

Chemical active substance:

Acetamiprid, 300 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: XXXX

Submission date: March 2024

Evaluation date: May 2025

MS Finalisation date: December 2025

Version history

When	What
March 2024	Version submitted by the applicant
May 2025	Version evaluated by zRMS PL
December 2025	Final version by zRMS

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6 Mammalian Toxicology (KCP 7)

6.1 Summary

Table 6.1-1: Information on ASA-01 *

Product name and code	ASA-01
Formulation type	Suspension concentrate [Code: SC]
Active substance(s) (incl. content)	Acetamiprid; 300 g/L
Function	insecticide
Product already evaluated as the 'representative formulation' during the approval of the active substance(s)	No
Product previously evaluated in another MS according to Uniform Principles	No

* Information on the detailed composition of ASA-01 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 ASA-01 according to Regulation (EC) No 1272/2008

Hazard class(es), categories	Skin Sens. 1; H317 Acute Tox. 4, H302 Repr. 2, H361d
Hazard pictograms or Code(s) for hazard pictogram(s)	 GHS07 GHS08
Signal word	Warning
Hazard statement(s)	H302 - Harmful if swallowed H317 - May cause an allergic skin reaction H361d - Suspected of damaging the unborn child.
Precautionary statement(s)	~~P201 - Obtain special instructions before use.~~ P202 - Do not handle until all safety precautions have been read and understood. ~~P260 - Do not breathe dust/fume/gas/mist/vapours/ spray.~~ P261 - Avoid breathing spray. P263 - Avoid contact during pregnancy and while nursing. P264 - Wash hands thoroughly after handling. P270 - Do not eat, drink or smoke when using this product. P272 - Contaminated work clothing should not be allowed out of the workplace. P280 - Wear protective gloves/ protective clothing P301 + P312, P330 - IF SWALLOWED: Rinse mouth. Call a POISON CENTRE or doctor if you feel unwell. P302 + P352 - IF ON SKIN: Wash with plenty of water P308 + P313 - IF exposed or concerned: Get medical advice/ attention. P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention P362 + P364 - Take off contaminated clothing and wash it before reuse. P405 - Store locked up P501 - Dispose of contents/ container to … … in accordance with local/ regional/national regulation
Additional labelling phrases	EUH401 - To avoid risks to man and the environment, comply with the instructions for use. 2-methyl-4-isothiazolin-3-one, 1,2-Benzisothiazol-3(2H)-one, reaction mass of 5-chloro-2- methyl-2*H*-isothiazol-3-one and 2-methyl-2*H*-isothiazol-3-one

Table 6.1-3: Summary of risk assessment for operators, workers, residents and bystanders for ASA-01

	Result	PPE / Risk mitigation measures
Operators	Acceptable	Workwear. Recomended: Gloves during M&L and A.
Workers	Acceptable	Workwear. Recomended: Gloves during field activities.
Residents	Acceptable	None
Bystanders	Acceptable	None

No unacceptable risk for operators, workers, residents and bystanders was identified when the product is used as intended and provided that the PPE/ risk mitigation measures stated in Table 6.1-3 are applied.

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))** **critical gap for operator, worker, resident or bystander exposure based on [Exposure model]**	**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 (per use)** **acetamiprid**	**Water L/ha** **min / max**			**Operator**	**Worker**	**Residents**	**Bystander**
1	*Field crops:* Winter oilseed rape (BBCH 50-60)	F	Spraying, LCTM	a) 1 b) 1	0.03 kg as/ha	200-400 L/ha	-	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032				
3	*Orchards:* Apple (BBCH 57-75)	F	Spraying, HCTM	a) 1 b) 2 (7-10 days)	0.027 kg as/ha	500-750 L/ha	-					

* 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

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

Data gaps should be listed in the summary to give an overview (especially for cMS).

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(s)

	Acetamiprid
Common Name	Acetamiprid
CAS-No.	135410-20-7
Classification and proposed labelling	
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	Harmonised C&L (ATP18) *Hazard classes (s), categories:* Acute Tox. 3 Aquatic Acute 1 Aquatic Chronic 1 Repr. 2 *Code(s) for hazard pictogram(s):* GHS06 GHS08 GHS09 *Signal word:* Danger *Hazard statement(s):* H301 (ATE = 140 mg/kg bw) H361d H400 (M=10) H410 (M=10)
Additional C&L proposal	-
Agreed EU endpoints	
AOEL systemic	0.025 mg/kg bw/d
AAOEL	0.025 mg/kg bw/d
Reference	EFSA Journal 2016;14(11):4610
Conditions to take into account/critical areas of concern with regard to toxicology	
Peer review of the pesticide risk assessment of the active substance Acetamiprid: EFSA Journal 2016;14(11):4610	None

6.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for ASA-01 is given in the following tables.
No new studies have been provided with this application.

Table 6.3-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for ASA-01

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
Oral acute toxicity	Estimation based on composition of the product	YES	Acute Tox. 4, H302	dRR Part C
Dermal acute toxicity	Estimation based on composition of the product	YES	None	dRR Part C
Inhalation acute toxicity	Estimation based on composition of the product	YES	None	dRR Part C
Skin irritation	Estimation based on composition of the product	YES	None	dRR Part C
Eye irritation	Estimation based on composition of the product	YES	None	dRR Part C
Skin sensitisation	Estimation based on composition of the product	YES	Skin Sens. 1 H317	dRR Part C
Reproductive toxicity	Estimation based on composition of the product	YES	Repr. 2, H361d	dRR Part C
Supplementary studies for combinations of plant protection products	-	-	-	-

Table 6.3-2: Additional toxicological information relevant for classification/labelling of ASA-01

	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(s) (relevant for classification of product)	Acetamiprid (ca. 27% (w/w))	Acute Tox. 3, H301 *(oral: ATE = 140 mg/kg bw)* Repr. 2, H361d *(>3%)*	Reg. 1272/2008	Acute Tox. 4, H302 Repr. 2, H361d
Toxicological properties of non-active substance(s) (relevant for classification of product)	-	-	-	-
Further toxicological information	No data – not required	-	-	-

* Please use concentration range or concentration limit (e.g. 1-10% or > 1%) as provided in MSDS.
** Material safety data sheet by the applicant

6.4 Toxicological Evaluation of Groundwater Metabolites

PEC_{gw} simulations for acetamiprid and metabolites: IM-1-2, IM-1-4, IC-0 and IM-1-5 for all scenarios showed that they do not exceed the trigger value of 0.1 µg/L. For more details, please refer to dRR Part B Section 8.

6.5 Dermal Absorption (KCP 7.3)

A summary of the dermal absorption rates for the active substances in ASA-01 are presented in the following table.

Table 6.5-1: Dermal absorption rates for active substances in ASA-01

	acetamiprid	
	Value	**Reference**
Concentrate	0.91 %	New study reported in Appendix 2 / Study No.: AG-G1145
Dilution (1:20 000)	7.2 %	

6.5.1 Justification for proposed values - acetamiprid

Proposed dermal absorption rates for acetamiprid are based on dermal absorption studies on a formulation identical to ASA-01. The study results are summarised in the following table. Full summaries of studies on the dermal absorption of acetamiprid that have not previously been evaluated within an EU peer review process are described in detail in Appendix 2.

Table 6.5-2: Summary of the results of submitted dermal absorption studies for acetamiprid

Test	**Concentrate**	**Spray dilution (1:20 000)**	**Formulation in study**	**Acceptability of study**	**Justification provided on representativity of study formulation for current product**	**Acceptability of justification**	**Reference***
In vitro (human skin)	0.91 %	7.2 %	ASA-01	Acceptable	Not required	-	XXXX, 2023 / Study No.: AG-G1145

6.6 Exposure Assessment of Plant Protection Product (KCP 7.2)

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

Product name and code	ASA-01
Formulation type	SC
Category	Insecticide
Active substance(s) (incl. content)	**Acetamiprid** 300 g/L
AOEL systemic	0.025 mg/kg bw/d
AAOEL	0.025 mg/kg bw/d
Inhalation absorption	100%
Oral absorption	100%
Dermal absorption	Concentrate: 0.91 % Dilution: 7.2% (0.015 g/L) Based on product (ASA-01)

6.6.1 Selection of critical use(s) 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 is given in Part B, Section 0.

Justification

The critical GAP was selected on a worst-case assumption.

6.6.2 Operator exposure (KCP 7.2.1)

6.6.2.1 Estimation of operator exposure

A summary of the exposure models used for estimation of operator exposure to the active substances during application of ASA-01 according to the critical uses is presented in Table 6.6-2. The outcome of the estimation is presented in

Table 6.6-3 (acute exposure) and Table 6.6-4 (longer term exposure). Detailed calculations are in Appendix 3.

Table 6.6-2: Exposure models for intended uses

Critical uses	Oilseed rape (max. 0.1 L product/ha) Apple (max. 0.09 L product/ha)
Model	**AOEM EFSA model** (Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032) OPEX version: 1.0.1

Table 6.6-3: Estimated operator exposure (acute exposure)

acetamiprid			
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AAOEL**
Oilseed rape Field crops/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/95th percentile Crop density: Normal			
Application rate		1x0.03 kg a.s./ha	
Spray application (AOEM**;** 95th percentile) Body weight: 60 kg *OPEX version: 1.0.1*	Potential exposure	0.002	73
	M/L: Workwear App: Workwear	0.001	39
Apple (pome fruits) Orchards/Outdoor/ Upward spraying/Vehicle-mounted/Drift reduction: 0 %/95th percentile Crop density: Normal			
Application rate		2x 0.027 kg a.s./ha	
Spray application (AOEM**;** 95th percentile) Body weight: 60 kg *OPEX version: 1.0.1*	Potential exposure	0.03	102
	M/L: Workwear App: Workwear	0.007	26.5

Table 6.6-4: Estimated operator exposure (longer term exposure)

acetamiprid			
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Oilseed rape Field crops/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/75th percentile Crop density: Normal			
Application rate		1x 0.03 kg a.s./ha	
Spray application (AOEM; 75th percentile) Body weight: 60 kg *OPEX version: 1.0.1*	Potential exposure	0.003	11.5
	M/L: Workwear App: Workwear	0.002	7.9
Apple (pome fruits) Orchards/Outdoor/Upward spraying/Vehicle-mounted/Drift reduction: 0 %/75th percentile Crop density: Normal			
Application rate		2x 0.027 kg a.s./ha	
Spray application (AOEM; 75th percentile) Body weight: 60 kg *OPEX version: 1.0.1*	Potential exposure	0.004	21.9
	M/L: Workwear App: Workwear	0.002	9.7

Conclusion

Performed calculations indicate an acceptable exposure risk for an operator using work wear (arms, body and legs covered) even without RPE/PPE, when the product ASA-01 is used according to GAP table. However, it's recommended for operator to wear also protective gloves during mixing/loading and during application.

zRMS:
The acute and longer term exposures to acetamiprid (an active substance of formulation ASA-01 (product VIARES) of operator not wearing PPE, but wearing a work clothing (long sleeved shirt, long trousers) and applying formulation ASA-01 in line with GAP on oilseed rape at dose of max. 0.1 L product/ha (0.03 kg a.s./ha) using tractor-mounted/trailed sprayer (downward spraying, or on apples (pome fruits) at dose of max. 0.09 L product/ha) (0.027 kg a.s./ha) using tractor-mounted/trailed sprayer (upward spraying) calculated with the EFSA AOEM 2022 are below AAOEL and below AOEL (both 0.025 mg/kg bw/d), therefore it is concluded that operator is not at risk when applying ASA-01 (product VIARES) according to its intended use on oilseed rape or apples.

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 6.6-5 shows the exposure model used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with ASA-01 according to the critical uses. Outcome of the estimation is presented in Table 6.6-6. Detailed calculations are in Appendix 3.

Table 6.6-5: Exposure models for intended uses

Critical uses	Oilseed rape (max. 0.1 L product/ha) Apple (max. 0.09 L product/ha)
Model	**AOEM EFSA model** (Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032) OPEX version: 1.0.1

Table 6.6-6: Estimated worker exposure

acetamiprid			
Model data	**Level of PPE**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Field crops Oilseed rape (oilseeds) Inspection, irrigation / Outdoor Work rate: 2 hours/day Interval: NA Body weight: 60 kg TC (potential): 12500 cm²/h TC (workwear (arms, body and legs covered)): 1400 cm²/h			

TC (workwear (arms, body and legs covered) and gloves): 1250 cm²/h			
Application rate		1x 0.03 kg a.s./ha	
Body weight: 60 kg EFSA model AOEM *OPEX version: 1.0.1*	Potential TC: 12500 cm^2/person/h	0.003	10.8
	Work wear (arms, body and legs covered) TC: 1400 cm^2/person/h	0.0003	1.2
	Work wear (arms, body and legs covered) and gloves TC: 1250 cm^2/person/h	0.0003	1.1
Orchards Apple (pome fruits) Outdoor Searching, reaching, picking / Outdoor Work rate: 8 hours/day Interval: 7 days Body weight: 60 kg TC (potential): 12500 cm²/h TC (workwear (arms, body and legs covered)): 3500 cm²/h TC (workwear (arms, body and legs covered) and gloves): 1250 cm²/h			
Application rate		2x 0.027 kg a.s./ha	
Body weight: 60 kg EFSA model AOEM *OPEX version: 1.0.1*	Potential TC: 12500 cm2/person/h	0.02	71.9
	Work wear (arms, body and legs covered) TC: 3500 cm2/person/h	0.005	20.1
	Work wear (arms, body and legs covered) and gloves TC: 1250 cm2/person/h	0.002	7.2

Conclusion

The results of the exposure estimations performed by AOEM EFSA models show that the use of ASA-01 according to the list of intended uses presented in GAP Table, causes no health risk for the worker assuming the workwear (arms, body and legs covered) and no gloves are used.
However, it's recommended for worker to wear also protective gloves during field activities.
As a standard rule, it should be mentioned on the label that treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried.

zRMS:
The potential exposure to acetamiprid (an active substance of formulation ASA-01 product VIARES) of worker) entering for 2 hours for inspection/irrigation a field of oilseed rape treated with this product at at dose of max. 0.1 L product/ha (0.03 kg a.s./ha) using tractor-mounted/trailed sprayer (downward spraying) calculated with the EFSA AOEM 2022 is below AOEL of acetamiprid, thus does not pose a systemic health risk.
The potential exposure to acetamiprid (an active substance of formulation ASA-01 product VIARES) of worker) entering for 8 hours for searching, reaching, picking an orchard (pome trees) treated with this product at dose of max. 0.09L product/ha (0.027 kg a.s./ha) using tractor-mounted/trailed sprayer (upward spraying) calculated with the EFSA AOEM 2022 is below AOEL of acetamiprid, thus does not pose a systemic health risk. Wearing a work wear (arms, body and legs covered) and protective gloves further reduce exposure and health risk of worker.

6.6.3.2 Refinement of generic DFR value (KCP 7.2)

Not relevant.

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 mention 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.

Table 6.6-7 shows the exposure model used for estimation of resident and bystander exposure to acetamiprid. The outcome of the estimation is presented in Table 6.6-9 (longer term resident exposure) and Table 6.6-8 (acute bystander exposure). Detailed calculations are in Appendix 3.

Table 6.6-7: Exposure models for intended uses

Critical use	Apple (max. 0.09 L product/ha)
Model	**AOEM EFSA model** (Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032) OPEX version: 1.0.1

Table 6.6-8: Estimated resident exposure (longer term exposure)

acetamiprid			
Model data		**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Apple (pome fruits) Season: Early season Buffer zone: 5 m Drift reduction technology: 0 % Interval between treatments: 7 days Minimum volume of water: 500 L			
Number of applications and application rate		2x 0.027 kg a.s./ha	
Resident child Body weight: 10 kg *OPEX version: 1.0.1*	Drift (75th perc.)	0.0005	2.2
	Vapour (75th perc.)	0.0008	3.2
	Deposits (75th perc.)	0.0003	1
	Re-entry (75th perc.)	0.0006	2.4
	Sum (mean)	**0.002**	**7.3**
Resident adult Body weight: 60 kg *OPEX version: 1.0.1*	Drift (75th perc.)	0.0003	1.2
	Vapour (75th perc.)	0.0003	1.1
	Deposits (75th perc.)	7e-05	0.3

	Re-entry (75th perc.)	0.0003	1.3
	Sum (mean)	**0.0008**	**3.1**

Table 6.6-9: Estimated bystander exposure (acute exposure)

acetamiprid			
Model data		**Total absorbed dose (mg/kg bw/day)**	**% of systemic AAOEL**
Apple (pome fruits) Season: Early season Buffer zone: 5 m Drift reduction technology: 0 % Interval between treatments: 7 days Minimum volume of water: 500 L			
Application rate		2x 0.027 kg a.s./ha	
Bystander child Body weight: 10 kg *OPEX version: 30/03/2015*	Drift (95th perc.)	0.0012526	5.01
	Vapour (95th perc.)	0.0010700	4.28
	Deposits (95th perc.)	0.0006206	2.48
	Re-entry (95th perc.)	0.0006071	2.43
Bystander adult Body weight: 60 kg *OPEX version: 30/03/2015*	Drift (95th perc.)	0.0006894	2.76
	Vapour (95th perc.)	0.0002300	0.92
	Deposits (95th perc.)	0.0001729	0.69
	Re-entry (95th perc.)	0.0003373	1.35
Bystander child Body weight: 10 kg *OPEX version: 1.0.1*	Drift (95th perc.)	0.001	5
	Vapour (95th perc.)	0.0008	3.2
	Deposits (95th perc.)	0.0006	2.5
	Re-entry (95th perc.)	0.0006	2.4
Bystander adult Body weight: 60 kg *OPEX version: 1.0.1*	Drift (95th perc.)	0.0007	2.8
	Vapour (95th perc.)	0.0003	1.1
	Deposits (95th perc.)	0.0002	0.7
	Re-entry (95th perc.)	0.0003	1.3

Conclusion

The exposure of bystander and resident (children and adult) to acetamiprid contained in the formulation ASA-01 causes no risk to human health if the product is used in accordance with the intended uses listed in the GAP Table.

zRMS:
The exposure estimation of residents (adult and child) to acetamiprid (an active substance of formulation ASA-01, product VIARES) applied on an orchard (pome trees at dose of max. 0.09L product/ha (0.027 kg a.s./ha) being a critical application using tractor-mounted/trailed sprayer (upward calculated with the EFSA AOEM 2022 demonstrates that such a exposure in all cases is well below AOEL, therefore the application of formulation ASA-01, product VIARES) does not pose an unacceptable risk to the health of adult and child residents for its intended use within good agricultural practice.

The exposure estimation of bystanders (adult and child) to acetamiprid (an active substance of formulation ASA-01, product VIARES) applied on an orchard (pome trees at dose of max. 0.09L product/ha (0.027 kg

a.s./ha) being a critical application using tractor-mounted/trailed sprayer (upward calculated with the EFSA AOEM 2022 demonstrates that such a exposure in all cases is well below AAOEL, therefore the application of formulation ASA-01, product VIARES) does not pose an unacceptable risk to the health of adult and child bystanders for its intended use within good agricultural practice.

Summing up an application of a formulation ASA-01 (product VIARES) on orchard (pome trees) at dose of max. 0.09L product/ha (0.027 kg a.s./ha) (upward spraying) or on oilseed rape at dose of max. 0.1 L product/ha (0.03 kg a.s./ha) (downward spraying) does not pose an unacceptable health risk for residents and bystanders

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 acetamiprid 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.

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

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

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
KCP 7.3/01	XXXX	2023	*IN VITRO* PERCUTANEOUS DERMAL ABSORPTION STUDY OF ACETAMIPRID, FORMULATED AS ASA-01, THROUGH HUMAN SKIN STUDY No.: AG- G1145 XXXX GLP Unpublished	N	XXXX

* XXXX

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	Verte-brate study Y/N	Owner

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

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

Appendix 2 Detailed evaluation of the studies relied upon

A 2.1 Statement on bridging possibilities

Not relevant.

A 2.2 Acute oral toxicity (KCP 7.1.1)

Comments of Evaluator:	The product require classification as Acute Tox. 4, H302. See part C

No studies submitted with this application. Classification based on composition of the product.

According to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 *on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006* classification of ASA-01 for toxicological part was based on ingredients of the mixture (Additivity formula) and concentration limits. The CLP calculation method is an alternative method based on the concentration addition of all adverse substances in a mixture. The additivity approach is often accepted as a worst-case estimation of chemical interaction.

The acute oral toxicity of product was estimated to be between 300 and 2000 mg/kg. According to Regulation (EC) No. 1272/2008 product is classified as **Acute Tox. 4, H302 (Oral)**. For more details, please refer to dRR Part C.

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

Comments of Evaluator:	The formulation ASA-01 (product VIARES) does not require classification for acute dermal toxicity. See part C.

No studies submitted with this application. Classification based on composition of the product.

According to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 *on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006* classification of ASA-01 for toxicological part was based on ingredients of the mixture (Additivity formula) and concentration limits. The CLP calculation method is an alternative method based on the concentration addition of all adverse substances in a mixture. The additivity approach is often accepted as a worst-case estimation of chemical interaction.

The formulation does not contain ingredients classified for acute dermal toxicity. According to Regulation (EC) No. 1272/2008 no classification is required. For more details, please refer to dRR Part C.

A 2.4 Acute inhalation toxicity (KCP 7.1.3)

Comments of Evaluator:	The formulation ASA-01 (product VIARES) does not require classification for acute inhalation toxicity. See part C.

No studies submitted with this application. Classification based on composition of the product.

According to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 *on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006* classification of ASA-01 for toxicological part was based on ingredients of the mixture (Additivity formula) and concentration limits. The CLP calculation method is an alternative method based on the concentration addition of all adverse substances in a mixture. The additivity approach is often accepted as a worst-case estimation of chemical interaction.

The formulation does not contain ingredients classified for acute inhalation toxicity. According to Regulation (EC) No. 1272/2008 no classification is required. For more details, please refer to dRR Part C.

A 2.5 Skin irritation (KCP 7.1.4)

Comments of Evaluator:	The formulation ASA-01 (product VIARES) does not require classification for skin irritation . See part C.

No studies submitted with this application. Classification based on composition of the product.

According to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 *on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006* classification of ASA-01 for toxicological part was based on ingredients of the mixture (Additivity formula) and concentration limits. The CLP calculation method is an alternative method based on the concentration addition of all adverse substances in a mixture. The additivity approach is often accepted as a worst-case estimation of chemical interaction.

According to Regulation (EC) No. 1272/2008 no classification regarding skin corrosion/irritation is required. For more details, please refer to dRR Part C.

A 2.6 Eye irritation (KCP 7.1.5)

Comments of Evaluator:	The formulation ASA-01 (product VIARES) does not require classification for eye irritation . See part C.

No studies submitted with this application. Classification based on composition of the product.

According to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 *on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006* classification of ASA-01 for toxicological part was based on ingredients of the mixture (Additivity formula) and concentration limits. The CLP calculation method is an alternative method based on the concentration addition of all adverse substances in a mixture. The additivity approach is often accepted as a worst-case estimation of chemical interaction.

According to Regulation (EC) No. 1272/2008 no classification regarding eye damage/itrritation is required. For more details, please refer to dRR Part C.

A 2.7 Skin sensitisation (KCP 7.1.6)

Comments of Evaluator:	The formulation ASA-01 (product VIARES) require classification for skin sensitisation as Skin Sens. 1; H317. See part C.

No studies submitted with this application. Classification based on composition of the product.

According to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 *on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006* classification of ASA-01 for toxicological part was based on ingredients of the mixture (Additivity formula) and concentration limits. The CLP calculation method is an alternative method based on the concentration addition of all adverse substances in a mixture. The additivity approach is often accepted as a worst-case estimation of chemical interaction.

According to Regulation (EC) No. 1272/2008 no classification regarding skin sensitization is required. For more details, please refer to dRR Part C.

A 2.8 Reproductive toxicity

Comments of Evaluator:	The formulation ASA-01 (product VIARES) requires classification for reproductive toxicity as **Repr. 2, H361d**. See part C.

No studies submitted with this application. Classification based on composition of the product.

According to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 *on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006* classification of ASA-01 for toxicological part was based on ingredients of the mixture (Additivity formula) and concentration limits. The CLP calculation method is an alternative method based on the concentration addition of all adverse substances in a mixture. The additivity approach is often accepted as a worst-case estimation of chemical interaction.

According to Regulation (EC) No. 1272/2008 the product is classified as **Repr. 2, H361d**. For more details, please refer to dRR Part C.

A 2.9 Supplementary studies for combinations of plant protection products (KCP 7.1.7)

Not relevant. No new/additional supplementary studies were submitted with this application.

A 2.10 Data on co-formulants (KCP 7.4)

A 2.10.1 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 2.10.2 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 2.11 Studies on dermal absorption (KCP 7.3)

A 2.11.1 Study 1 – Acetamiprid in ASA-01

Dermal absorption, *in vitro* using human skin

Comments of Evaluator:	The study performed on formulation ASA-01 according to relevant OECD method and in GLP conditions is acceptable. The concentrate (300 g of acetamiprid /L) and one in-use spray dilution (0.015 g of acetamiprid /L) of the product were tested. The final dermal absorption rates were derived according to EFSA Guidance on Dermal Absorption (EFSA Journal 2017;15(6):4873) using for calculation of the dermal absorption of each substance a formula: mean value for a given concentrate or dilution + ks, where k is multiplication factor and s is the sample standard deviation. Thus, the dermal penetration estimates to be used for risk assessment due to exposure to acetamiprid is 0.91%, % for the concentrated formulation (300 g Zoxamide/L) and 7.2 % for the spray dilution (0.015 g of acetamiprid /L) based on the EFSA guidance criteria.

Reference	KCP 7.3/01
Report	*IN VITRO* PERCUTANEOUS DERMAL ABSORPTION STUDY OF ACETAMIPRID, FORMULATED AS ASA-01, THROUGH HUMAN SKIN, XXXX, 2023, STUDY No.: AG-G1145
Guideline(s)	Yes, OECD guideline for the testing of chemicals: Guideline No. 428; Skin Absorption: in vitro method (April 2004) Which provides references to below guideline documents and formats; OECD guideline notes on dermal absorption, series on testing and assessment no. 156, ENV/JM/MONO (2011) 36; Guideline on dermal absorption EFSA Journal 2017;15(6):4873.
Deviations	No
GLP	Yes
Acceptability	Yes
Duplication (if vertebrate study)	No

Materials and methods

The objective of this study was to generate skin absorption data of acetamiprid, formulated as ASA-01 provided by sponsor using ‘In vitro Franz cell Diffusion’ method. The study was designed to examine the In vitro percutaneous absorption of acetamiprid through human abdominal skin of acetamiprid at two target concentrations: the maximal concentration of 300 g/L of acetamiprid when handling the undiluted formulation (concentrate) and the concentration recommended for use in the field 0.015 g/L of acetamiprid (field dilution). The test item was in contact with the skin was 8 hours, followed by a 16 hour post exposure time.

The extent of percutaneous absorption was determined by analysing compound related radioactivity over 24 hours. Mass balance was determined analysing the amount of ^{14}C material (acetamiprid) in the receptor fluid, residues remaining in/on the skin membranes and in the stratum corneum, as well as in the receptor and donor compartment rinse and skin wash. The study was performed using flow-through diffusion cells (7 in-line cells were used for study).

Test material	Name (Lot/Batch No.)	ASA-01 / 20221111P
	Test preparation	Radioformulation ^{14}C- Acetamiprid
	Specific activity	10.297 MBq/mg
	Radiochemical purity	99.66%
Product	Name (Lot/Batch No.)	ASA-01 / 20221111P
	Company code	ASA-01
	Concentration a.s.	29.94%
	Formulation type	SC
Blank product	Name (Lot/Batch No.)	Placebo ASA-01 / 20221111BS
	Concentration a.s.	-

Test System Information

Section of non-viable human skin derived from abdomen was obtained from consented four adult donors (female), through XXXX, who have signed an IRB validated donor consent form that specifically stated the intended uses in compliance with all legal and ethical regulations. The procured skin was transported and stored at -20°C until use. Upon thawing, the subcutaneous fat was removed and the skin was cut to a target thickness of ca.0.2-0.4 mm (i.e. split thickness skin membrane).

Donor No.	Lot Number	Specifications	Donor No.	Lot Number	Specifications
H-1	SKIN102422A	Gender: Female, Age: 59 Location: Abdomen Diabetic: No	H-3	SKIN092022A	Gender: Female, Age: 39 Location: Abdomen Diabetic: No
H-2	SKIN102622A	Gender: Female, Age: 61 Location: Abdomen Diabetic: No	H-4	SKIN091422C	Gender: Female, Age: 34 Location: Abdomen Diabetic: No

Experimental Design

Acetamiprid, formulated as ASA-01 was separately applied to the skin membranes according to the design below. The exposure time was 8 h and receptor fluid samples were collected from 0-24 h.

Test Group	Group Size	Species	Total Concentration	Mean Dose Applied (Active Ingredient)
A	4	human	299.44 g/L	2994.37 µg/cm^2
B	4	human	0.015 g/L	0.15 µg/cm^2

Experiment Method

- Frozen skin samples were allowed to thaw at room temperature (25 ± 1°C) and extra fat layer was removed. The skin thickness was measured and then placed in Ringer solution for a minimum of 30 min.
- The skin membranes were mounted on In-Line Franz diffusion cells with an average exposed skin area of 0.64 cm^2 and receptor fluid pump rate was 1.8 mL/hour.
- After mounting the skin on franz cells, the skin membranes were hydrated for about 20 hours prior to start the exposure.

- The diffusion chamber and skin were maintained at a constant target temperature of 32 ± 1°C and humidity in the range of 38-61%.
- After ~ 20 hours of hydration, tritium water of 200 µL (17.2 kBq/mL) was loaded on each skin membrane then flow through receptor fluid samples were collected every hour up to 3 hours (0-1, 1-2, 2-3 hours).
- Remaining tritium water was removed from the cells and washed 3 times with 0.5 mL of Milli-Q® water and then the skin was dried with cotton swab. Membrane was kept overnight to allow wash out of the tritiated water from membrane.
- Solubility of Acetamiprid in the receptor fluid was confirmed to be 10 times higher than the concentration of Acetamiprid obtained in the receptor fluid of 24 hours cumulative samples at the end of the study.
- Test item dose formulation was prepared using both the radiolabel ([^{14}C]-Acetamiprid) and non-labelled test item to achieve the application concentration of 37 kBq (1 µCi) over 1 cm^2 area of skin application.
- The homogeneity of test item in the dose formulation was determined by analysing random aliquots in triplicate by LSC prior to application to skin membranes.
- Prior to dose application, the skin surface was dried, and the skin membrane was allowed to equilibrate with receptor fluid for at least 10 min.
- For the application rate of 10 µL/cm^2 (liquid formulations), an aliquot of 6.7 µL of dose formulations (concentrate and field dilution dose formulations) were applied topically to the skin membranes.
- Aliquots of receptor medium were collected automatically by the instrument at 0-1 h, 1-2 h, subsequently at 2 h intervals until 24 h post application,
- At the last sampling time point, the receptor medium was drawn out of the receptor chamber completely.
- After 8 h application, unabsorbed test item was removed from the application site using a mild soap solution (3%) followed by three rinses with water. The skin was dried with cotton swab.
- Next, donor chamber was removed from the skin surface and wiped at the bottom with a cotton swab soaked in the solvent followed by a dry cotton swab. The skin was wiped using two (1.wet cotton and 2.dry cotton swabs) cotton swabs.
- Each diffusion cell was dismantled to analyze the amount of test item in the different compartments. Receptor and donor compartments were washed with ethanol.
- Each skin membrane was tape striped 15 times using stripping technique with the help of tape stripping.
- Skin was removed and digested in tissue solubilizer (1.5 M KOH solution with 20% aqueous ethanol for 24 hrs).
- The mass balance of the test item was determined by collecting receptor fluid samples, skin wash and cotton swabs receptor compartment wash, donor compartment wash, tape strips, and digested skin.

Samples Collected for Mass Balance Evaluation

Twenty-four hours post application, the mass balance of the test item was determined by collecting receptor fluid, skin wash, receptor compartment wash, donor compartment wash, tape strips, and digested skin.

- Receptor fluid samples were collected during the following intervals for 0-1 h,
- 1-2 h, subsequently at 2 h intervals until 24 h post application with the help of PermeGear ILC07 automated system.

- Skin wash: After an exposure period of 8 hours, the unabsorbed test substance was removed from the application site using a mild soap solution (i.e. 3% Dove in water) followed by water wash and drying with cotton swabs.
- 24 hours after application, the diffusion cells were dismantled. Receptor and donor compartments were washed with ethanol.
- Each skin membrane was tape stripped 15 times using adhesive tapes. Tape strips were collected individually for further analysis by LSC.
- Skin membranes were digested in tissue solubilizer (1.5 M KOH solution with 20% aqueous ethanol for 24 hours).

HPLC Analysis of Acetamiprid

Instrument : Shimadzu Prominence LC-20AD liquid chromatograph
Column : Inertsil ODS 3V, [250 mm × 4.6 mm I.D, 5µm]
Column Oven : 30°C
Mobile Phase A : 0.01 M ammonium acetate in Milli-Q® Water
Mobile Phase B : Acetonitrile
Mobile Phase Gradient :

Time (minutes)	Solvent A (%)	Solvent B (%)
0.01	92.5	7.5
8.0	75.0	25
12.0	60.0	40
19.0	10.0	90
20.0	5.0	95
21.0	92.5	7.5
30.0	92.5	7.5

Flow Rate : 1.0 mL/min
Scint Flow : Active Counting Mode (ACM)
Run Time : 30 mins
Detector : Photo diode array at 265 nm equipped with a radiochemical detector (B-RAM, model: 5C)

Results and discussions

Parameters	Concentrate Dose Formulation (A)		Field Dilution Dose Formulation (B)	
Concentration measured	299.44 ± 2.07		0.015 ± 0.0001	
Dose (µg/cm^2)	2994.37 ± 20.67		0.15 ± 0.001	
Replicate	8		8	
Penetration into the receptor fluid after 24h	µg/cm^2	µg/cm^2	% of dose	% of dose
	9.9933 ± 0.8569	0.39 ± 0.03	3.20 ± 0.50	3.20 ± 0.50
Maximal flux [µg/cm^{2}h]	0.4785 ± 0.0568		0.0002 ± 0.0001	
Lag time [h]	0.45 ± 0.13		0.36 ± 0.25	
Absorbed dose [% of dose][a]	0.55 ± 0.05		4.63 ± 0.24	
Potentially absorbed dose [% of applied dose][b,c]	0.85 ± 0.06 (**0.91**)[d]		6.95 ± 0.28 (**7.2**)[d]	

Group	Concentrate Dose (A)	Field Dilution (B)
Number of skin donor /replicates	4/8	4/8
75% absorbed in RF in first half of study	No	No
Lower limit of confidence of $t_{0.5}$	57.96 ± 2.62%	59.56 ± 3.14%

Maximal flux (µg/cm²h)	0.4785 ± 0.0568	0.0002 ± 0.0001
-	Percentage of dose (%, mean ± SD)	
Amount in RF	0.39 ± 0.03	3.20 ± 0.50
Amount in Receptor compartment wash	0.03 ± 0.01	0.14 ± 0.03
Amount in stripped skin	0.13 ± 0.03	1.28 ± 0.47
Amount in tape strips 1+2	0.08 ± 0.04	0.81 ± 0.28
Amount in tape strips 3-last	0.31 ± 0.07	2.32 ± 0.34
Amount in skin wash	99.10 ± 1.56	91.59 ± 1.14
Absorbed dose [a]	0.55 ± 0.05	4.63 ± 0.24
Potentially absorbed dose [b,c]	0.85 ± 0.06 (**0.91**)[d]	6.95 ± 0.28 (**7.2**)[d]
Total recovery	100.57 ± 1.64	101.29 ± 0.98

[a] The absorbed dose is defined as the amount in the receptor fluid, the receptor compartment wash and skin membrane, excluding tape strips
[b] The potentially absorbed dose is defined as the amount in the receptor fluid, the receptor compartment wash, the skin and *stratum corneum* (*except* for the first two tape strips)
[c] For risk assessment, in agreement with the EFSA Guidance on Dermal Absorption (2017), since less than 75% of the absorption in the receptor fluid occurred within half the study duration, it is considered appropriate to include all tape strips (except for the first 2 tape strips) in the calculations of the total absorption values (*i.e.* the potentially absorbed dose).
[d] Approach based on the EFSA Guidance on Dermal Absorption (mean + 0.84 × SD).

Conclusion/endpoint:

Acetamiprid in the test item ASA-01 was tested for the skin diffusion using franz cells automated diffusion system with human skin. Diffusion was quantified in terms of radioactive units (DPM).

A concentrated dose (299.44 g/L) was tested and the mean total recovery of radioactivity was found to be 100.57%, validating the results obtained. The absorption value for Acetamiprid was 0.85 ± 0.06%, after rounding and taking into account the correction for variability, the final value was calculated to be 0.91%, according to the EFSA Guidance on Dermal Absorption (2017).

In addition, a field dilution (0.015 g/L) was tested and the mean total recovery of radioactivity was found to be 101.29%, validating the results obtained. The absorption value for Acetamiprid was 6.95 ± 0.28%, after rounding and taking into account the correction for variability, the final value was calculated to be 7.2%, according to EFSA Guidance on Dermal Absorption (2017).

A 2.12 Other/Special Studies

No studies submitted with this application.

Appendix 3 Exposure calculations

A 3.1 Operator exposure calculations (KCP 7.2.1.1)

A 3.1.1 Calculations for acetamiprid

Table A 1: Input parameters considered for the estimation of operator exposure

Formulation type	SC		Crop type	Oilseeds
Application rate (AR)	0.03	kg a.s./ha	Application method	Downward spraying
Area treated per day (A)	50	ha	Application equipment	Vehicle-mounted
Dermal absorption (DA)	0.91	% (concentr.)	Indoor/outdoor	Outdoor
	7.2	% (dilution)	Closed cabin	No
Inhalation absorption (IA)	100	%	Drift reduction	No
Body weight (BW)	60	kg/person	Cultivation	Normal
AOEL	0.025	mg/kg bw/d	Water soluble bag	No
AAOEL	0.025	mg/kg bw/d	-	-

Table A 2: Estimation of operator exposure towards active substance according to EFSA guidance - AOEM EFSA model (OPEX version: 1.0.1)

Short term exposure			Acute exposure		
		Acetamiprid (% AOEL)			Acetamiprid (% AOEL)
Mixing/loading	Application	Normal & vehi-cle-mounted	Mixing/loading	Application	Normal & ve-hicle-mounted
		11.5			73
		7.9			39

Outdoor, normal, downward spraying, vehicle-mounted

Summary data - Short term exposure

Model data	Level of PPE	Total ab-sorbed dose [mg/kg bw per day]	% of sys-temic AOEL
Acetamiprid	Number of applications and application rate: 1 x 0.03 kg a.s./ha Dermal absorption (concentrate): 0.91 % Dermal absorption (in-use dilution): 7.2 %		
	M/L: Workwear App: Workwear	0.002	7.9

Summary data - Acute exposure

Model data	Level of PPE	Total absorbed dose [mg/kg bw]	% of systemic AAOEL
Field crops/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/95th percentile Crop density: Normal			
Acetamiprid	Number of applications and application rate: 1 x 0.03 kg a.s./ha Dermal absorption (concentrate): 0.91 % Dermal absorption (in-use dilution): 7.2 %		
	M/L: Workwear App: Workwear	0.01	39

Table A 3: Input parameters considered for the estimation of operator exposure

Formulation type	SC		Crop type	Pome fruits
Application rate (AR)	0.027	kg a.s./ha	Application method	Upward spraying
Area treated per day (A)	10	ha	Application equipment	Vehicle-mounted
Dermal absorption (DA)	0.91	% (concentr.)	Indoor/outdoor	Outdoor
	7.2	% (dilution)	Closed cabin	No
Inhalation absorption (IA)	100	%	Drift reduction	No
Body weight (BW)	60	kg/person	Cultivation	Normal
AOEL	0.025	mg/kg bw/d	Water soluble bag	No
AAOEL	0.025	mg/kg bw/d	-	-

Table A 4: Estimation of operator exposure towards active substance according to EFSA guidance - AOEM EFSA model (OPEX version: 1.0.1)

Short term exposure			Acute exposure		
		Acetamiprid (% AOEL)			Acetamiprid (% AOEL)
Mixing/loading	Application	Normal & vehicle-mounted	Mixing/loading	Application	Normal & vehicle-mounted
		**21.9**			**102**
		9.7			26.5

Outdoor, normal, downward spraying, vehicle-mounted

Summary data - Short term exposure

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Orchards/Outdoor/Upward spraying/Vehicle-mounted/Drift reduction: 0 %/75th percentile Crop density: Normal			
Acetamiprid	Number of applications and application rate: 2 x 0.027 kg a.s./ha Dermal absorption (concentrate): 0.91 % Dermal absorption (in-use dilution): 7.2 %		
	M/L: Workwear App: Workwear	0.002	9.7

Summary data - Acute exposure

Model data	Level of PPE	Total absorbed dose [mg/kg bw]	% of systemic AAOEL
Orchards/Outdoor/ Upward spraying/Vehicle-mounted/Drift reduction: 0 %/95th percentile Crop density: Normal			
Acetamiprid	Number of applications and application rate: 2 x 0.027 kg a.s./ha Dermal absorption (concentrate): 0.91 % Dermal absorption (in-use dilution): 7.2 %		
	M/L: Workwear App: Workwear	0.007	26.5

A 3.2 Worker exposure calculations (KCP 7.2.3.1)

A 3.2.1 Calculations for acetamiprid

Table A 5: Input parameters considered for the estimation of worker exposure

Intended use(s)	oilseeds, inspection/irrigation, outdoor		Dislodgeable foliar residue (DFR)	3	µg/cm²/kg a.s./ha
Application rate (AR)	0.03	kg a.s./ha	Dermal absorption (DA)	7.2	% (worst case)
Number of applications (NA)	1		Inhalation absorption (IA)	100	%
Interval between applications	NR	days	Work rate per day (WR)	2	h/d
Half-life of active substance	30	days	TC dermal (potential)	12500	cm²/h
Multiple application factor (MAF)	NR		TC dermal (work wear)	1400	cm²/h
Body weight (BW)	60	kg/person	TC dermal (work wear, gloves)	NA	cm²/h
AOEL	0.025	mg/kg bw/d	Task specific factor inhalation	NA	ha/h x 10^{-3}
AAOEL	0.025	mg/kg bw/d	-	-	-

Table A 6: Estimation of worker exposure towards acetamiprid according to EFSA guidance - AOEM EFSA model (OPEX version: 1.0.1)

Field crops Outdoor, normal

Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL	Re-entry restriction [days]
Inspection, irrigation / Outdoor Work rate: 2 hours/day Interval: NA Body weight: 60 kg TC (potential): 12500 cm²/h TC (workwear (arms, body and legs covered)): 1400 cm²/h TC (workwear (arms, body and legs covered) and gloves): 1250 cm²/h TC (gloves): NA cm²/h			
Acetamiprid	Number of applications & application rate: 1 x 0.03 kg a.s./ha Dermal absorption: 7.2 % DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days		
Potential	0.003	10.8	0
Workwear	0.0003	1.2	0
Workwear and gloves	0.0003	1.1	0

Table A 7: Input parameters considered for the estimation of worker exposure

Intended use(s)	pome fruits, searching/reaching/picking, outdoor		Dislodgeable foliar residue (DFR)	3	µg/cm²/kg a.s./ha
Application rate (AR)	0.027	kg a.s./ha	Dermal absorption (DA)	7.2	% (worst case)
Number of applications (NA)	2		Inhalation absorption (IA)	100	%
Interval between applications	7	days	Work rate per day (WR)	8	h/d
Half-life of active substance	30	days	TC dermal (potential)	22500	cm²/h
Multiple application factor (MAF)	1.9		TC dermal (work wear)	4500	cm²/h
Body weight (BW)	60	kg/person	TC dermal (work wear, gloves)	2250	cm²/h
AOEL	0.025	mg/kg bw/d	Task specific factor inhalation	NA	ha/h x 10^{-3}
AAOEL	0.025	mg/kg bw/d	-	-	-

Table A 8: Estimation of worker exposure towards acetamiprid according to EFSA guidance - AOEM EFSA model (OPEX version: 1.0.1)

Orchards Outdoor, normal

Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL	Re-entry restriction [days]
Searching, reaching, picking / Outdoor Work rate: 8 hours/day Interval: 7 days Body weight: 60 kg TC (potential): 12500 cm²/h TC (workwear (arms, body and legs covered)): 3500 cm²/h TC (workwear (arms, body and legs covered) and gloves): 1250 cm²/h TC (gloves): NA cm²/h			
Acetamiprid	Number of applications & application rate: 2 x 0.027 kg a.s./ha Dermal absorption: 7.2 % DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days		
Potential	0.02	71.9	0
Workwear	0.005	20.1	0
Workwear and gloves	0.002	7.2	0

A 3.3 Resident and bystander exposure calculations (KCP 7.2.2.1)

A 3.3.1 Calculations for acetamiprid

Table A 9 Estimation of longer term resident exposure towards acetamiprid according to EFSA guidance - AOEM EFSA model (OPEX version: 1.0.1)

Orchards Outdoor, early season

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Season: Early season Buffer zone: 5 m Drift reduction technology: 0 % Interval between treatments: 7 days Minimum volume of water: 500 l			

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Acetamiprid	Number of applications and application rate: 2 x 0.027 kg a.s./ha Dermal absorption: 7.2 % DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days		
Resident child Body weight: 10 kg	Drift (75th perc.)	0.0005	2.2
	Vapour (75th perc.)	0.0008	3.2
	Deposits (75th perc.)	0.0003	1
	Re-entry (75th perc.)	0.0006	2.4
	Sum (mean)	0.002	7.3
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.0003	1.2
	Vapour (75th perc.)	0.0003	1.1
	Deposits (75th perc.)	7e-05	0.3
	Re-entry (75th perc.)	0.0003	1.3
	Sum (mean)	0.0008	3.1

Table A 10: Estimation of longer term resident exposure towards acetamiprid according to EFSA guidance - AOEM EFSA model (OPEX version: 1.0.1)

Orchards Outdoor, early season

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AAOEL
	Season: Early season Buffer zone: 5 m Drift reduction technology: 0 % Interval between treatments: 7 days Minimum volume of water: 500 l		
Acetamiprid	Number of applications and application rate: 2 x 0.027 kg a.s./ha Dermal absorption: 7.2 % DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days		
Bystander child Body weight: 10 kg	Drift (95th perc.)	0.001	5
	Vapour (95th perc.)	0.0008	3.2
	Deposits (95th perc.)	0.0006	2.5
	Re-entry (95th perc.)	0.0006	2.4
Bystander adult Body weight: 60 kg	Drift (95th perc.)	0.0007	2.8
	Vapour (95th perc.)	0.0003	1.1
	Deposits (95th perc.)	0.0002	0.7
	Re-entry (95th perc.)	0.0003	1.3

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.