

# FINAL REGISTRATION REPORT

## **Part B**

### **Section 6**

#### **Mammalian Toxicology**

Detailed summary of the risk assessment

Product code: Acetamipryd 200 SL

Product name(s): -

Chemical active substance:

acetamiprid, 200 g/L

Central Zone

Zonal Rapporteur Member State: Poland

#### **CORE ASSESSMENT**

(authorization)

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

Submission date: March 2024

MS Finalisation date: 03.2025; 08.2025; 02.2026

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## Version history

When	What
03.2025	ZRM's evaluated dRR submitted by Applicant
08.2025	The final Registration Report after the reporting period
01.2026	Update on Ministry request
02.2026	ZRMs update

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## 6 Mammalian Toxicology (KCP 7)

### 6.1 Summary

**Table 6.1-1: Information on Acetamipryd 200 SL \***



Product name and code	Acetamipryd 200 SL
Formulation type	Soluble liquid [Code: SL]
Active substance(s) (incl. content)	acetamiprid; 200 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 Acetamipryd 200 SL 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 Acetamipryd 200 SL according to Regulation (EC) No 1272/2008**

Hazard class(es), categories	Acute Tox. 4, H302 Eye Irrit. 2, H319 Skin Sens. 1, H317 Repr. 2, H361d
Hazard pictograms or Code(s) for hazard pictogram(s)	  GHS07 GHS08
Signal word	Warning
Hazard statement(s)	H302 - Harmful if swallowed. H319 - Causes serious eye irritation. H317 - May cause an allergic skin reaction. H361d - Suspected of damaging the unborn child.
Precautionary statement(s)	<b>Warning section of the label (first page):</b> P202 - Do not handle until all safety precautions have been read and understood. P280 - Wear protective gloves and eye/face protection. <del>protective clothing.</del> P301 + P312 - IF SWALLOWED: Call a POISON CENTRE or doctor if you feel unwell. P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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	<p>P302+P352 - IF ON SKIN: Wash with plenty of water.</p> <p>Other section of the label:</p> <p>P270 - Do not eat, drink or smoke when using this product.</p> <p>P264 - Wash hands thoroughly after handling.</p> <p>And P280 as follows:</p> <p>Operator:</p> <p>„Stosować rękawice ochronne, ochronę oczu oraz odzież roboczą (kombinezon) w trakcie przygotowywania cieczy roboczej oraz w trakcie wykonywania zabiegu.”</p> <p>“Wear protective gloves, eye protection and work wear (coverall) during mixing/loading and application”.</p> <p>Section First Aid:</p> <p>P301 + P312 - IF SWALLOWED: Call a POISON CENTRE or doctor if you feel unwell.</p> <p>P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> <p>P302+P352 - IF ON SKIN: Wash with plenty of water.</p> <p>P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.</p> <p>P308 + P313 - IF exposed or concerned: Get medical advice/ attention.</p>
Additional labelling phrases	EUH401 - To avoid risks to man and the environment, comply with the instructions for use.

**Table 6.1-3: Summary of risk assessment for operators, workers, residents and bystanders for Acetamipryd 200 SL**

	Result	PPE / Risk mitigation measures
Operators	Acceptable	<p>Exposure:</p> <p>Workwear.</p> <p>Recommended: additionally gloves during mixing/loading</p> <p>Classification:</p> <p>Protective gloves and eye/face protection</p>
Workers	Acceptable	<p>None.</p> <p>Recommended: Workwear and gloves during field activities</p>
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.

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**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, F <sub>n</sub> , F <sub>pn</sub> G, G <sub>n</sub> , G <sub>pn</sub> 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 g or kg as/ha (per use)  acetamiprid	Water L/ha  min / max			Operator	Worker	Residents	Bystander
1	Field crops: <b>Winter oilseed rape</b> (BBCH 50-60) spring, post emergence	F	Spraying, LCTM	a) 1 b) 1	50 g as/ha	200-400 L/ha	14 d	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				
4	Low vegetables: <b>Potato</b> (BBCH 35-75) spring, post emergence	F	Spraying, LCTM	a) 1 b) 1	24 g as/ha	200-400 L/ha	3 d					
5	Orchards: <b>Apple</b> (BBCH 71-84) spring, post emergence	F	Spraying, HCTM	a) 1 b) 2 (7 days)	25 g as/ha	500-900 L/ha	14 d					
41	Low vegetables: <b>Tomato</b> (BBCH 20-89)	G	Spraying, LCTMHH	a) 1 b) 1	60 g as/ha	300-750 L/ha	3 d					
47	High ornamentals: <b>Forest and ornamental nurseries plants Restockings,afforestations and forest trees' seed plantations; Christmas trees grown on plantations</b> (BBCH 11-69)	F	Spraying, HCTM	a) 1 b) 1	38 g as/ha	200-400 L/ha	-					
12	Field crops: <b>Spring oilseed rape, Turnip rape</b> (BBCH 59-71) Spring, post emergence)	F	Spraying, LCTM	a) 1 b) 1	60 g as/ha	200-400 L/ha	50 d					

\* 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

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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
<b>Classification and proposed labelling</b>	
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	<p><u>Harmonised C&amp;L (ATP18)</u>  <i>Hazard classes (s), categories:</i>            Acute Tox. 3            Aquatic Acute 1            Aquatic Chronic 1            Repr. 2</p> <p><i>Code(s) for hazard pictogram(s):</i>            GHS06            GHS08            GHS09</p> <p><i>Signal word:</i>            Danger</p> <p><i>Hazard statement(s):</i>            H301 (ATE = 140 mg/kg bw)            H361d            H400 (M=10)            H410 (M=10)</p>
Additional C&L proposal	-
<b>Agreed EU endpoints</b>	
AOEL systemic	0.025 mg/kg bw/d
AAOEL	0.025 mg/kg bw/d
Reference	EFSA Journal 2016;14(11):4610 SANTE/10502/2017 Rev 4, 13 December 2017

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	Acetamiprid
<b>Conditions to take into account/critical areas of concern with regard to toxicology</b>	
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 Acetamipryd 200 SL is given in the following tables.

**Table 6.3-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for Acetamipryd 200 SL**

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	accepted	Acute Tox. 4, H302	dRR Part C
Dermal acute toxicity	Estimation based on composition of the product	accepted	None	dRR Part C
Inhalation acute toxicity	Estimation based on composition of the product	accepted	None	dRR Part C
Skin irritation	Estimation based on composition of the product	accepted	None	dRR Part C
Eye irritation	Estimation based on composition of the product	accepted	Eye Irrit. 2, H319	dRR Part C
Skin sensitisation	Estimation based on composition of the product	accepted	Skin Sens. 1, H317	dRR Part C
Reproductive toxicity	Estimation based on composition of the product	accepted	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 Acetamipryd 200 SL**

	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 (> 17% (w/w))	H302 H361d	Reg. 1272/2008 (ATP18)	H302 H361d
Toxicological	co-formulant 1	H319	Reg.	H319

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	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)
properties of non-active substance(s) (relevant for classification of product)	referred in Confidential information (dRR Part C)		1272/2008 (CLP00)	
Toxicological properties of non-active substance(s) (relevant for classification of product)	co-formulant 3 referred in Confidential information (dRR Part C)	H302 H319 H317	Reg. 1272/2008 (ATP21)	H302 H319 H317
Further toxicological information	-	-	-	-

## 6.4 Toxicological Evaluation of Groundwater Metabolites

Comments of ZRMs:	<p>- According to Appendix to EFSA, 2016. Conclusion on the peer review of the pesticide risk assessment of the active substance acetamiprid. EFSA Journal 2016;14(11):4610 the metabolite IM-1-5 has to be classified regarding acute oral toxicity: Acute Tox. 3, H302 (rat: LD50: 141 mg/kg and 132 mg/kg bw in males and females, respectively). The results of <i>in vitro</i> studies (Ames and mouse lymphoma assay) showed that IM-1-5 is not mutagenic.</p> <p>- The parent substance (acetamiprid) is classified regarding reproductive toxicity (Repr. 2, H361d). According to Sanco/221/2000 – rev.11, 21 October 2021, for parent active substances that are classified for reproductive toxicity (any category), it must be shown by an appropriate test or convincing other evidence that the metabolite does not qualify for the same classification.</p> <p>Conclusions:</p> <p>Considering the data presented above, IM-1-5 is a <b>toxicologically relevant groundwater metabolite</b> of acetamiprid. The maximum PEC<sub>gw</sub> of IM-1-5 exceeds permissible concentration and amounts to 0.122248 µg/L µg/L. Product field uses that result in an IM-1-5 concentration in the groundwater exceeding 0.1 µg/L cannot be accepted due to unacceptable risk for consumers.</p> <p><b>zRMS comments: February 2026</b></p> <p>New PEC gw were provided by the Applicant based on corrected doses. Acc. the ZRMs conclusions in the dRR, sec. B8, estimated values of PEC<sub>gw</sub> for metabolite IM-1-5 are below the concentration threshold of 0.1 µg/L for all scenarios and crops, except scenario Thiva. This scenario is not relevant for Poland.</p>
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The metabolite IM-1-5 is predicted to occur in groundwater at concentrations above 0.1 µg/L (see Part B, Section 8). Assessment of the relevance of this metabolite according to the stepwise procedure of the EC guidance document SANCO/221/2000 – rev.10 is therefore required. For more details, please refer to dRR Part B Section 10.

At the request of the Polish Ministry of Agriculture and Rural Development and the evaluator, the PEC<sub>gw</sub>

calculations for uses for which IM-1-5 PEC<sub>gw</sub> value was above 0.1 µg/L (orchards BBCH 51 - apple, pear, Chinese pear, plum, peach, nectarine, apricot, sour cherry, sweet cherry, walnut, hazelnut, common osier and purple willow) was performed again (details in dRR/RR Part B Section 8).

PEC<sub>gw</sub> values for IM-1-5 are below the trigger value of 0.1 µg/L indicating there is no unacceptable risk of groundwater contamination in case of every year application except of scenario Thiva for which further PEC<sub>gw</sub> modelling or other risk mitigations at national level is needed. However, Thiva scenario is not relevant for Poland and it can be concluded that there is no unacceptable risk for consumers.

## 6.5 Dermal Absorption (KCP 7.3)

A summary of the dermal absorption rates for the active substances in Acetamipryd 200 SL are presented in the following table.

**Table 6.5-1: Dermal absorption rates for active substances in Acetamipryd 200 SL**

acetamiprid		
	Value	Reference
Concentrate	1.2 %	New study reported in Appendix 2 / Study No.: AG-G0065
Dilution (1:16 667)	8.7 %	New study reported in Appendix 2 / Study No.: AG-G0065

### 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 Acetamipryd 200 SL. 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	Concen- trate	Spray di- lution (1:16 667)	Formulation in study	Acceptability of study	Justification provided on representa- tivity of study formulation for current product	Acceptability of justifica- tion	Reference*
<i>In vitro</i> (human skin)	1.2 %	8.7 %	Acetamipryd 200 SL	accepted	Not required		Yogeesha S., 2022 / Study No.: AG- G0065

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## 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	Acetamipryd 200 SL
Formulation type	SL
Category	Insecticide
Active substance(s) (incl. content)	<b>acetamiprid</b> 200 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: 1.2 % Dilution: 8.7% (0.012 g/L) Based on product (Acetamipryd 200 SL)

### 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)

Comments of zRMS:	<p>The estimations of operator exposure to acetamiprid contained in the product Acetamiprid 200 SL performed by the Applicant are accepted. For this active substance, AOEL and AAOEL values have been established, which means that operator protection takes into account the effects of both long-term and acute exposure.</p> <p>According to the estimation results, the use of Acetamiprid 200 SL <b>causes acceptable health risk for operator</b> taking into account the following risk mitigation measures:</p> <p>Field use:</p> <ol style="list-style-type: none"> <li>1. Field crops (downward spraying, vehicle-mounted): <b>workwear</b> (m&amp;l, appl.);</li> <li>2. Low vegetables (downward spraying):             <ol style="list-style-type: none"> <li>a. vehicle-mounted: safe for <b>unprotected</b> operator;</li> </ol> </li> <li>3. Orchards (upward spraying, vehicle-mounted): <b>workwear</b> (m&amp;l, appl.);</li> <li>4. High ornamentals (upward spraying):             <ol style="list-style-type: none"> <li>a. vehicle-mounted: <b>workwear</b> (m&amp;l, appl.);</li> <li>b. manual-hand held and knapsack: <b>workwear</b> (m&amp;l, appl.)</li> </ol> </li> </ol> <p>Greenhouse use:</p>
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	<p>1. Low vegetables (downward spraying, manual-hand held and knapsack): <b>work-wear</b> (m&amp;l, appl.)</p> <p>Taking into account the results of exposure assessment and the classification of the product, the following sentence regarding the use of PPE is recommended by the evaluator to be placed on the label:</p> <p>„Stosować rękawice ochronne, ochronę oczu oraz odzież roboczą (kombinezon) w trakcie przygotowywania cieczy roboczej oraz w trakcie wykonywania zabiegu.”</p> <p>“Wear protective gloves, eye protection and work wear (coverall) during mixing/loading and application”.</p>
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### 6.6.2.2 Estimation of operator exposure

A summary of the exposure models used for estimation of operator exposure to the active substances during application of Acetamipryd 200 SL 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. 0.25 L product/ha) Potato (max. 0.12 L product/ha) Apple (max. 2x 0.125 L product/ha) Tomato (max. 0.3 L product/ha) Forest and ornamental nurseries plants Restockings, afforestations and forest trees' seed plantations; Christmas trees grown on plantations ( <i>High ornamentals</i> ) (max. 0.19 L product/ha) Spring oilseed rape, Turnip rape (max. 0.3 L/product/ha)
Models	<b>AOEM EFSA model</b> (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)

**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		1 x 0.05 kg a.s./ha	
<b>Spray application</b> (AOEM; 95 <sup>th</sup> percentile) Body weight: 60 kg	Potential exposure	0.03	135
	M/L: Workwear App: Workwear	0.02	71.1
Potato Low vegetables/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/95th percentile			

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Crop density: Normal			
Application rate		1 x 0.024 kg a.s./ha	
<b>Spray application</b> (AOEM; 95 <sup>th</sup> percentile) Body weight: 60 kg	Potential exposure	0.02	80.2
	M/L: Workwear App: Workwear	0.01	42.3
Apple Orchards/Outdoor/Upward spraying/Vehicle-mounted/Drift reduction: 0 %/95th percentile Crop density: Normal			
Application rate		2 x 0.025 kg a.s./ha	
<b>Spray application</b> (AOEM; 95 <sup>th</sup> percentile) Body weight: 60 kg	Potential exposure	0.03	116
	M/L: Workwear App: Workwear	0.008	30.2
Tomato Low vegetables/Indoor/Downward spraying/Manual-hand held/Drift reduction: 0 %/95th percentile Crop density: Normal			
Application rate		1 x 0.06 kg a.s./ha	
<b>Spray application</b> (AOEM; 95 <sup>th</sup> percentile) Body weight: 60 kg	Potential exposure	0.05	200
	M/L: Workwear App: Workwear	0.009	36.8
Tomato Low vegetables/Indoor/Downward spraying/Manual-knapsack/Drift reduction: 0 %/95th percentile Crop density: Normal			
Application rate		1 x 0.06 kg a.s./ha	
<b>Spray application</b> (AOEM; 95 <sup>th</sup> percentile) Body weight: 60 kg	Potential exposure	0.05	218
	M/L: Workwear App: Workwear	0.01	56.3
Forest and ornamental nurseries plants Restockings, afforestations and forest trees' seed plantations; Christmas trees grown on plantations High ornamentals/Outdoor/Upward spraying/Vehicle-mounted/Drift reduction: 0 %/95th percentile Crop density: Normal			
Application rate		1 x 0.038 kg a.s./ha	
<b>Spray application</b> (AOEM; 95 <sup>th</sup> percentile) Body weight: 60 kg	Potential exposure	0.04	173
	M/L: Workwear App: Workwear	0.01	44.3
Forest and ornamental nurseries plants Restockings, afforestations and forest trees' seed plantations; Christmas trees grown on plantations High ornamentals/Outdoor/Upward spraying/Manual-hand held/Drift reduction: 0 %/95th percentile Crop density: Normal			
Application rate		1 x 0.038 kg a.s./ha	
<b>Spray application</b> (AOEM; 95 <sup>th</sup> percentile) Body weight: 60 kg	Potential exposure	0.3	1045
	M/L: Workwear	0.009	35.8

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	App: Workwear		
Forest and ornamental nurseries plants Restockings, afforestations and forest trees' seed plantations; Christmas trees grown on plantations High ornamentals/Outdoor/Upward spraying/Manual-knapsack/Drift reduction: 0 %/95th percentile Crop density: Normal			
Application rate		1 x 0.038 kg a.s./ha	
<b>Spray application</b> (AOEM; 95 <sup>th</sup> percentile) Body weight: 60 kg	Potential exposure	0.3	1031
	M/L: Workwear App: Workwear	0.01	41.3
Spring oilseed rape, Turnip rape Field crops/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0%/95th percentile Crop density: Normal			
Application rate		1 x 0.060 kg a.s./ha	
<b>Spray application</b> (AOEM; 95 <sup>th</sup> percentile) Body weight: 60 kg	Potential exposure	0.04	154
	M/L: Workwear App: Workwear	0.02	80.9

**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		1 x 0.05 kg a.s./ha	
<b>Spray application</b> (AOEM; 75 <sup>th</sup> percentile) Body weight: 60 kg	Potential exposure	0.005	21.4
	M/L: Workwear App: Workwear	0.004	14.5
Potato Low vegetables/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/75th percentile Crop density: Normal			
Application rate		1 x 0.024 kg a.s./ha	
<b>Spray application</b> (AOEM; 75 <sup>th</sup> percentile) Body weight: 60 kg	Potential exposure	0.003	12.6
	M/L: Workwear App: Workwear	0.002	8.8
Apple Orchards/Outdoor/Upward spraying/Vehicle-mounted/Drift reduction: 0 %/75th percentile Crop density: Normal			
Application rate		2 x 0.025 kg a.s./ha	

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<b>Spray application</b> (AOEM; 75 <sup>th</sup> percentile) Body weight: 60 kg	Potential exposure	0.006	24.6
	M/L: Workwear App: Workwear	0.003	10.9
Tomato Low vegetables/Indoor/Downward spraying/Manual-hand held/Drift reduction: 0 %/75th percentile Crop density: Normal			
Application rate		1 x 0.06 kg a.s./ha	
<b>Spray application</b> (AOEM; 75 <sup>th</sup> percentile) Body weight: 60 kg	Potential exposure	0.03	110
	M/L: Workwear App: Workwear	0.003	12.9
Tomato Low vegetables/Indoor/Downward spraying/Manual-knapsack/Drift reduction: 0 %/75th percentile Crop density: Normal			
Application rate		1 x 0.06 kg a.s./ha	
<b>Spray application</b> (AOEM; 75 <sup>th</sup> percentile) Body weight: 60 kg	Potential exposure	0.03	119
	M/L: Workwear App: Workwear	0.005	21.6
Forest and ornamental nurseries plants Restockings, afforestations and forest trees' seed plantations; Christmas trees grown on plantations High ornamentals/Outdoor/Upward spraying/Vehicle-mounted/Drift reduction: 0 %/75th percentile Crop density: Normal			
Application rate		1 x 0.038 kg a.s./ha	
<b>Spray application</b> (AOEM; 75 <sup>th</sup> percentile) Body weight: 60 kg	Potential exposure	0.009	35.9
	M/L: Workwear App: Workwear	0.004	15.1
Forest and ornamental nurseries plants Restockings, afforestations and forest trees' seed plantations; Christmas trees grown on plantations High ornamentals/Outdoor/Upward spraying/Manual-hand held/Drift reduction: 0 %/75th percentile Crop density: Normal			
Application rate		1 x 0.038 kg a.s./ha	
<b>Spray application</b> (AOEM; 75 <sup>th</sup> percentile) Body weight: 60 kg	Potential exposure	0.07	272
	M/L: Workwear App: Workwear	0.003	12.8
Forest and ornamental nurseries plants Restockings, afforestations and forest trees' seed plantations; Christmas trees grown on plantations High ornamentals/Outdoor/Upward spraying/Manual-knapsack/Drift reduction: 0 %/75th percentile Crop density: Normal			
Application rate		1 x 0.038 kg a.s./ha	
<b>Spray application</b> (AOEM; 75 <sup>th</sup> percentile) Body weight: 60 kg	Potential exposure	0.06	224
	M/L: Workwear App: Workwear	0.004	17.6
<b>Spring oilseed rape, Turnip rape</b>			

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Field crops/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0%/75th percentile Crop density: Normal			
Application rate		1 x 0.060 kg a.s./ha	
Spray application (AOEM; 95 <sup>th</sup> percentile) Body weight: 60 kg	Potential exposure	0.006	24.4
	M/L: Workwear App: Workwear	0.004	16.5

### 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 Acetamipryd 200 SL is used according to GAP table. However, it's recommended for operator to wear also protective gloves during mixing/loading and during application.

#### 6.6.2.3 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)

Comments of zRMS:	<p>The estimations of worker exposure to acetamiprid contained in the product Acetamiprid 200 SL performed by the Applicant are accepted.</p> <p>According to the estimation results, the use of Acetamiprid 200 SL <b>causes acceptable health risk for an unprotected worker</b>. However, considering the hygienic rules, work wear and protective gloves are recommended when working on treated areas.</p>
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### 6.6.3.1 Estimation of worker exposure

Table 6.6-5 shows the exposure model(s) used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with Acetamipryd 200 SL according to the critical use(s). Outcome of the estimation is presented in Table 6.6-6 (acute exposure) and **Błąd! Nie można odnaleźć źródła odwołania.** (longer term exposure). Detailed calculations are in Appendix 3.

**Table 6.6-5: Exposure models for intended uses**

Critical uses	Oilseed rape (max. 0.25 L product/ha) Potato (max. 0.12 L product/ha) Apple (max. 2x 0.125 L product/ha) Tomato (max. 0.3 L product/ha) Forest and ornamental nurseries plants Restockings, afforestations and forest trees' seed plantations; Christmas trees grown on plantations ( <i>High ornamentals</i> ) (max. 0.19 L product/ha) <b>Spring oilseed rape, Turnip rape (max. 0.3 L/product/ha)</b>
Models	<b>AOEM EFSA model</b> (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)

**Table 6.6-6: Estimated worker exposure**

acetamiprid				
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Re-entry restriction (days)
Oilseed rape ( <i>Field crops</i> ) Inspection, irrigation / Outdoor Work rate: 2 hours/day Interval: NA Body weight: 60 kg TC (potential): 12500 cm <sup>2</sup> /h TC (workwear (arms, body and legs covered)): 1400 cm <sup>2</sup> /h TC (workwear (arms, body and legs covered) and gloves): 1250 cm <sup>2</sup> /h TC (gloves): NA cm <sup>2</sup> /h				
Application rate		1x 0.05 kg a.s./ha		
Body weight: 60 kg	Potential	0.005	21.8	0
	Workwear	0.0006	2.4	0
	Workwear and gloves	0.0005	2.2	0
Potato ( <i>Low vegetables</i> ) Reaching, picking (all except Brassica) / Outdoor Work rate: 8 hours/day Interval: NA Body weight: 60 kg TC (potential): 5800 cm <sup>2</sup> /h TC (workwear (arms, body and legs covered)): 2500 cm <sup>2</sup> /h TC (workwear (arms, body and legs covered) and gloves): 580 cm <sup>2</sup> /h TC (gloves): NA cm <sup>2</sup> /h				
Application rate		1x 0.024 kg a.s./ha		
	Potential	0.005	19.4	0

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Body weight: 60 kg	Workwear	0.002	8.4	0
	Workwear and gloves	0.0005	1.9	0
Apple ( <i>Orchards</i> ) Searching, reaching, picking / Outdoor Work rate: 8 hours/day Interval: 7 days Body weight: 60 kg TC (potential): 12500 cm <sup>2</sup> /h TC (workwear (arms, body and legs covered)): 3500 cm <sup>2</sup> /h TC (workwear (arms, body and legs covered) and gloves): 1250 cm <sup>2</sup> /h TC (gloves): NA cm <sup>2</sup> /h				
Application rate		2x 0.025 kg a.s./ha		
Body weight: 60 kg	Potential	0.02	80.5	0
	Workwear	0.006	22.5	0
	Workwear and gloves	0.002	8	0
Tomato ( <i>Low vegetables</i> ) Reaching, picking (all except Brassica) / Harvesting, including cutting and bundling / Indoor Work rate: 8 hours/day Interval: 7 days Body weight: 60 kg TC (potential): 5800 cm <sup>2</sup> /h TC (workwear (arms, body and legs covered)): 2500 cm <sup>2</sup> /h TC (workwear (arms, body and legs covered) and gloves): 580 cm <sup>2</sup> /h TC (gloves): NA cm <sup>2</sup> /h TSF: 0.1 mg a.s./h / kg a.s./ha				
Application rate		1x 0.06 kg a.s./ha		
Body weight: 60 kg	Potential	0.01	52.3	0
	Workwear	0.006	24.7	0
	Workwear and gloves	0.002	8.7	0
Forest and ornamental nurseries plants Restockings, afforestations and forest trees' seed plantations; Christmas trees grown on plantations ( <i>High ornamentals</i> ) Cutting, sorting, bundling, carrying / Outdoor Work rate: 8 hours/day Interval: 7 days Body weight: 60 kg TC (potential): 14000 cm <sup>2</sup> /h TC (workwear (arms, body and legs covered)): 5000 cm <sup>2</sup> /h TC (workwear (arms, body and legs covered) and gloves): 1400 cm <sup>2</sup> /h TC (gloves): NA cm <sup>2</sup> /h				
Application rate		1x 0.038 kg a.s./ha		
Body weight: 60 kg	Potential	0.02	74.1	0
	Workwear	0.007	26.4	0
	Workwear and gloves	0.002	7.4	0
Spring oilseed rape, Turnip rape ( <i>Field crops</i> ) Inspection, irrigation / Outdoor Work rate: 2 hours/day Interval: NA				

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Application rate		1x 0.06 kg a.s./ha		
Body weight: 60 kg	Potential TC: 12500 cm <sup>2</sup> /h/person	0.007	26.1	0
	Workwear TC: 1400 cm <sup>2</sup> /h/person	0.0007	2.9	0
	Workwear and gloves TC: 1250 cm <sup>2</sup> /h/person	0.0007	2.6	0

### Conclusion

The results of the performed exposure calculations show that the use of Acetamipryd 200 SL according to the list of intended uses presented in GAP Table, causes no health risk for the worker even in case of potential exposure. However, it's recommended for worker to wear workwear (arms, body and legs covered) and 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.

#### 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)

Comments of zRMS:	<p>The AAOEL value for acetamiprid has been established. Consequently, the exposure estimations of bystander and resident were calculated separately.</p> <p>The results of exposure estimations demonstrate that the use of Acemapride 200SL, according to the list of intended uses presented in the GAP Table and anticipating the introduction of buffer zones presented (2-3m and 5m for downward and upward spraying, respectively), <b>causes acceptable health risk for bystander and resident (adult and child).</b></p>
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##### 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.

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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

Spring oilseed rape, Turnip rape ( <i>Field crops</i> ) Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: N/A Minimum volume of water: 200 l DFR: 3 µg/cm <sup>2</sup> foliage per kg a.s./ha DT50: 30 days			
Number of applications and application rate		1x 0.06 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 <sup>th</sup> perc.)	0.0007	2.8
	Vapour (75 <sup>th</sup> perc.)	0.0008	3.2
	Deposits (75 <sup>th</sup> perc.)	0.0001	0.5
	Re-entry (75 <sup>th</sup> perc.)	0.0009	3.5
	Sum (mean)	0.002	7.9
Resident adult Body weight: 60 kg	Drift (75 <sup>th</sup> perc.)	0.0002	0.7
	Vapour (75 <sup>th</sup> perc.)	0.0003	1.1
	Deposits (75 <sup>th</sup> perc.)	4e-05	0.1
	Re-entry (75 <sup>th</sup> perc.)	0.0005	2
	Sum (mean)	0.0008	3.1

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 uses	Apple (max. 2x 0.125 L product/ha) Forest and ornamental nurseries plants Restockings, afforestations and forest trees' seed plantations; Christmas trees grown on plantations ( <i>High ornamentals</i> ) (max. 0.19 L product/ha) Spring oilseed rape, Turnip rape (max. 0.3 L/product/ha)
Models	<b>AOEM EFSA model</b> (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)

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

acetamiprid			
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Apple ( <i>Orchards</i> ) 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 0.025 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 <sup>th</sup> perc.)	0.0006	2.4
	Vapour (75 <sup>th</sup> perc.)	0.0008	3.2
	Deposits (75 <sup>th</sup> perc.)	0.0003	1.1
	Re-entry (75 <sup>th</sup> perc.)	0.0007	2.7
	<b>Sum (mean)</b>	0.002	7.8
Resident adult Body weight: 60 kg	Drift (75 <sup>th</sup> perc.)	0.0003	1.3
	Vapour (75 <sup>th</sup> perc.)	0.0003	1.1
	Deposits (75 <sup>th</sup> perc.)	8e-05	0.3
	Re-entry (75 <sup>th</sup> perc.)	0.0004	1.5
	<b>Sum (mean)</b>	0.0008	3.4
Forest and ornamental nurseries plants Restockings, afforestations and forest trees' seed plantations; Christmas trees grown on plantations ( <i>High ornamentals</i> ) Season: Not relevant Buffer zone: 5 m Drift reduction technology: 0 % Interval between treatments: 7 days Minimum volume of water: 200 l			
Number of applications and application rate		1x 0.038 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 <sup>th</sup> perc.)	0.002	9.2
	Vapour (75 <sup>th</sup> perc.)	0.0008	3.2
	Deposits (75 <sup>th</sup> perc.)	4e-05	0.2
	Re-entry (75 <sup>th</sup> perc.)	0.0006	2.2
	<b>Sum (mean)</b>	0.003	11.2
Resident adult Body weight: 60 kg	Drift (75 <sup>th</sup> perc.)	0.001	5.1
	Vapour (75 <sup>th</sup> perc.)	0.0003	1.1
	Deposits (75 <sup>th</sup> perc.)	1e-05	0.05
	Re-entry (75 <sup>th</sup> perc.)	0.0003	1.2
	<b>Sum (mean)</b>	0.001	5.5
Spring oilseed rape, Turnip rape ( <i>Field crops</i> )			

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Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: N/A Minimum volume of water: 200 l DFR: 3 µg/cm <sup>2</sup> foliage per kg a.s./ha DT50: 30 days			
Number of applications and application rate		1x 0.06 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 <sup>th</sup> perc.)	0.0007	2.8
	Vapour (75 <sup>th</sup> perc.)	0.0008	3.2
	Deposits (75 <sup>th</sup> perc.)	0.0001	0.5
	Re-entry (75 <sup>th</sup> perc.)	0.0009	3.5
	Sum (mean)	0.002	7.9
Resident adult Body weight: 60 kg	Drift (75 <sup>th</sup> perc.)	0.0002	0.7
	Vapour (75 <sup>th</sup> perc.)	0.0003	1.1
	Deposits (75 <sup>th</sup> perc.)	4e-05	0.1
	Re-entry (75 <sup>th</sup> perc.)	0.0005	2
	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 ( <i>Orchards</i> ) 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 0.025 kg a.s./ha	
Bystander child Body weight: 10 kg	Drift (95 <sup>th</sup> perc.)	0.001	5.6
	Vapour (95 <sup>th</sup> perc.)	0.0008	3.2
	Deposits (95 <sup>th</sup> perc.)	0.0006	2.6
	Re-entry (95 <sup>th</sup> perc.)	0.0007	2.7
Bystander adult Body weight: 60 kg	Drift (95 <sup>th</sup> perc.)	0.0008	3.1
	Vapour (95 <sup>th</sup> perc.)	0.0003	1.1
	Deposits (95 <sup>th</sup> perc.)	0.0002	0.8
	Re-entry (95 <sup>th</sup> perc.)	0.0004	1.5
Forest and ornamental nurseries plants Restockings, afforestations and forest trees' seed plantations; Christmas trees grown on plantations ( <i>High ornamentals</i> ) Season: Not relevant Buffer zone: 5 m			

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Drift reduction technology: 0 % Interval between treatments: 7 days Minimum volume of water: 200 l			
Application rate		1x 0.038 kg a.s./ha	
Bystander child Body weight: 10 kg	Drift (95th perc.)	0.005	21.2
	Vapour (95th perc.)	0.0008	3.2
	Deposits (95th perc.)	0.0001	0.4
	Re-entry (95th perc.)	0.0006	2.2
Bystander adult Body weight: 60 kg	Drift (95th perc.)	0.003	11.7
	Vapour (95th perc.)	0.0003	1.1
	Deposits (95th perc.)	3e-05	0.1
	Re-entry (95th perc.)	0.0003	1.2
Spring oilseed rape, Turnip rape ( <i>Field crops</i> ) Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: N/A Minimum volume of water: 200 l DFR: 3 µg/cm <sup>2</sup> foliage per kg a.s./ha DT50: 30 days			
Number of applications and application rate		1x 0.06 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 <sup>th</sup> perc.)	0.002	6.5
	Vapour (75 <sup>th</sup> perc.)	0.0008	3.2
	Deposits (75 <sup>th</sup> perc.)	0.0004	1.4
	Re-entry (75 <sup>th</sup> perc.)	0.0009	3.5
Resident adult Body weight: 60 kg	Drift (75 <sup>th</sup> perc.)	0.0004	1.7
	Vapour (75 <sup>th</sup> perc.)	0.0003	1.1
	Deposits (75 <sup>th</sup> perc.)	0.0001	0.4
	Re-entry (75 <sup>th</sup> perc.)	0.0005	2

## Conclusion

The exposure of bystander and resident (children and adult) to acetamiprid contained in the formulation Acetamipryd 200 SL causes no risk to human health if the product is used in accordance with the intended uses listed in the GAP Table.

### 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.

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### **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	Vertebrate study Y/N	Owner
KCP 7.3/01	Yogeesha S.	2022	<i>IN VITRO</i> PERCUTANEOUS DERMAL ABSORPTION STUDY OF ACETAMIPRID, FORMULATED AS ACETAMIPRYD 200 SL THROUGH HUMAN SKIN STUDY No.: AG- G0065 EUROFINS ADVINUS AGROSCIENCES SERVICES INDIA PRIVATE LIMITED GLP Unpublished	N	Pestila* ProAgri*

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

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

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

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
KCA 6.4/01		2002b	IM-1-5: Acute oral toxicity study in rats; Report No. H220, Document No. RD-II 02424 GLP, not published	Y	Nippon Soda
KCA 6.4/02	Kanaguchi Y.	1997c	IM-1-5 - reverse mutation study on bacteria Odawara Research Center, Nippon Soda Co. Ltd., Report No. H145, Document No. RD-97101 GLP, not published	N	Nippon Soda
KCA 6.4/03	Riach, C.G.	2012a	IM-1-5: Bacterial Reverse Mutation Test in Salmonella typhimurium TA 1535, TA 100, TA 1537 and TA 98 and Escherichia coli WP2uvrA (OECD 471) Charles River, UK, Report No. 32827, Document No. RD-02354 GLP, not published	N	Nippon Soda
KCA 6.4/04	Riach, C.G.	2012b	IM-1-5: In vitro Mammalian Cell Gene Mutation Test in Mouse Lymphoma L5178Y Cells (OECD 476) Charles River, UK, Report No. 32830, Document No. RD-02372 Nippon-Soda Report No.: RD-02372 GLP, not published	N	Nippon Soda

The following tables are to be completed by MS

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**List of data submitted by the applicant and not relied on**

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

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

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

## 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:	Taking into account the composition of the product, the formulation Acetamiprid 200 SL requires classification in regards to acute oral toxicity ( <b>Acute Tox. 4, H302</b> ).
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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 Acetamipryd 200 SL 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 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:	Taking into account the composition of the product, the formulation Acetamiprid 200 SL does not require classification in regards to acute dermal toxicity.
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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 Acetamipryd 200 SL 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 is required. For more details, please refer to dRR Part C.

### A 2.4 Acute inhalation toxicity (KCP 7.1.3)

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Comments of Evaluator:	Taking into account the composition of the product, the formulation Acetamiprid 200 SL does not require classification in regards to acute inhalation toxicity.
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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 Acetamipryd 200 SL 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 is required. For more details, please refer to dRR Part C.

## A 2.5 Skin irritation (KCP 7.1.4)

Comments of Evaluator:	Taking into account the composition of the product, the formulation Acetamiprid 200 SL does not require classification in regards to skin irritation.
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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 Acetamipryd 200 SL 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 is required. For more details, please refer to dRR Part C.

## A 2.6 Eye irritation (KCP 7.1.5)

Comments of Evaluator:	Taking into account the composition of the product, the formulation Acetamiprid 200 SL requires classification in regards to eye irritation ( <b>Eye Irrit. 2, H319</b> ).
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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 Acetamipryd 200 SL 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.

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According to Regulation (EC) No. 1272/2008 product is classified as **Eye Irrit. 2, H319**. For more details, please refer to dRR Part C.

## A 2.7 Skin sensitisation (KCP 7.1.6)

Comments of Evaluator:	Taking into account the composition of the product, the formulation Acetamiprid 200 SL requires classification in regards to skin sensitisation ( <b>Skin Sens. 1, H317</b> ).
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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 Acetamipryd 200 SL 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 is classified as **Skin Sens. 1, H317**. For more details, please refer to dRR Part C.

## A 2.8 Reproductive toxicity

Comments of Evaluator:	Taking into account the composition of the product, the formulation Acetamiprid 200 SL requires classification in regards to reproductive toxicity ( <b>Repr. 2, H361d</b> ).
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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 Acetamipryd 200 SL 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 – Acetamidrid in Acetamipryd 200 SL**

#### **Dermal absorption, *in vitro* using human skin**

Comments of Evaluator:	The study (YOGESH S., 2022) is accepted. The values of dermal absorption of acetamidride containing in the product Acetamidride 200 SL amount to 1.2% for concentrate and 8.7% for spray dilution.
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Reference	KCP 7.3/01
Report	<i>IN VITRO</i> PERCUTANEOUS DERMAL ABSORPTION STUDY OF ACETAMIPRID, FORMULATED AS ACETAMIPRYD 200 SL THROUGH HUMAN SKIN, YOGESH S., 2022, STUDY No.: AG- G0065
Guideline(s)	Yes, OECD Guideline No. 428; Skin Absorption: <i>in vitro</i> method (April 2004); OECD Guideline 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 provide the data on *in vitro* percutaneous dermal absorption of acetamidrid following dermal application of Acetamipryd 200 SL using human abdominal skin. The diffusion properties such as flux rate, % of absorption, lag time were analysed using radiolabelled Acetamidrid by measuring the radioactive counts.

The test item was tested at two concentrations, one at concentrate dose (the concentrate represents the maximal concentration possible when handling the undiluted formulation) and another is field dilution

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(concentration recommended for use in the field). The concentrate dose was prepared using radiolabelled [ $^{14}\text{C}$ ]-Acetamiprid and non-radiolabelled test item (Acetamipryd 200 SL) and the field dilution was prepared by fortifying the radiolabelled [ $^{14}\text{C}$ ]-Acetamiprid in 16667 times diluted Acetamipryd 200 SL blank formulation. The concentrations of the prepared concentrate dose and field dilution were found to be 198.22 g/L (target concentration 200 g/L) and 0.0127 g/L (target concentration 0.012 g/L), respectively.

An aliquot of 6.7  $\mu\text{L}$  of concentrated and field dilution dose formulations at the rate of 10  $\mu\text{L}/\text{cm}^2$  were applied on 0.64  $\text{cm}^2$  area of skin membrane for 8 hours (a normal working hour in a day). Further, the absorption was observed 16 hours of post exposure. Receptor fluid samples were collected at different intervals and analysed for radioactivity in terms of DPM.

The radioactive residues remaining in/on the skin membranes and in the stratum corneum (16 h post exposure) were determined. The mass balance was achieved with the majority of the applied dose of Acetamiprid remained on the surface of the skin and considering the radioactivity in the receptor compartment rinse, donor compartment rinse and skin wash. The study was performed using flow-through diffusion cell apparatus.

<b>Test material</b>	Name (Lot/Batch No.)	Acetamipryd 200 SL / 1/ACE/2022
	Test preparation	Radioformulation $^{14}\text{C}$ - Acetamiprid
	Specific activity	10.297 MBq/mg or 2314 MBq/mmol
	Radiochemical purity	99.55%
<b>Product</b>	Name (Lot/Batch No.)	Acetamipryd 200 SL / 1/ACE/2022
	Company code	Acetamipryd 200 SL
	Content of a.s.	197.2 g/L
	Formulation type	SL
<b>Blank product</b>	Name (Lot/Batch No.)	Acetamipryd 200 SL Placebo / 1/ACE/2022/PLACEBO
	Content of a.s.	-

### Test System Information

Section of non-viable human skin derived from abdomen was obtained from consented four adult donors (female), through Zen Bio laboratory, who have signed an IRB validated donor consent from that specifically stated the intended uses in compliance with all legal and ethical regulations. The procured skin was transported and stored at  $-20^{\circ}\text{C}$  until use. CoA of the skins are attached in the Appendix 2. 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	SKIN010622A	Gender: Female, Age: 50 Location: Abdomen Diabetic: No	H-3	SKIN020222A	Gender: Female, Age: 33 Location: Abdomen Diabetic: No
H-2	SKIN011122B	Gender: Female, Age: 66 Location: Abdomen Diabetic: No	H-4	SKIN041322B	Gender: Female, Age: 44 Location: Abdomen Diabetic: No

### Experimental Design

Acetamiprid, formulated as Acetamipryd 200 SL 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
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				(Active Ingredient)
A	4	human	198.22 g/L	1982.16 µg/cm <sup>2</sup>
B	4	human	0.0127 g/L	0.127 µg/cm <sup>2</sup>

## Experiment Method

- Frozen skin samples were allowed to thaw at room temperature ( $25 \pm 1^\circ\text{C}$ ) 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  $0.64\text{ cm}^2$  and receptor volume of  $0.1 - 5\text{ mL}$  and receptor fluid rate was  $1.8\text{ mL/hr}$ .
- After mounting the skin on franz cells, the skin membranes were hydrated for about 20 hours prior to start of exposure.
- The diffusion chamber and skin were maintained at a constant target temperature of  $32 \pm 1^\circ\text{C}$  and humidity in the range of 39-64%.
- After ~ 20 hours of hydration, tritium water of  $200\text{ }\mu\text{L}$  ( $17.2\text{ kBq/mL}$ ) 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  $0.5\text{ mL}$  of sterile 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 ( $^{14}\text{C}$ -Acetamiprid) and non-labelled test item to achieve the application concentration of  $37\text{ kBq}$  ( $1\text{ }\mu\text{Ci}$ ) over  $1\text{ cm}^2$  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  $10\text{ }\mu\text{L/cm}^2$  (liquid formulation), an aliquot of  $6.7\text{ }\mu\text{L}$  of dose formulation A and B was 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 analyse 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 ( $1.5\text{ M KOH}$  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.

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### 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 : 0.1 M ammonium acetate (pH 5.0)  
Mobile Phase B : Acetonitrile

Mobile Phase Gradient :	<b>Time (minutes)</b>	<b>Solvent A (%)</b>	<b>Solvent B (%)</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	198.22 ± 0.08 g/L		0.0127 ± 0.0001 g/L	
Dose (µg/cm <sup>2</sup> )	1982.16 ± 0.77		0.127 ± 0.0007	
Replicate	8		8	
Penetration into the receptor fluid after 24h	µg/cm <sup>2</sup>	% of dose	µg/cm <sup>2</sup>	% of dose
	15.8679 ± 0.6055	0.80 ± 0.03	0.0071 ± 0.0004	5.76 ± 0.34
Maximal flux [µg/cm <sup>2</sup> h]	0.6636 ± 0.0692		0.0004 ± 0.0001	

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<b>Lag time [h]</b>	$0.47 \pm 0.16$	$0.48 \pm 0.14$
<b>Absorbed dose [% of dose]<sup>a</sup></b>	$0.88 \pm 0.03$	$6.29 \pm 0.31$
<b>Potentially absorbed dose [% of applied dose]<sup>b,c</sup></b>	$1.14 \pm 0.03$ ( <b>1.2</b> ) <sup>d</sup>	$8.47 \pm 0.33$ ( <b>8.7</b> ) <sup>d</sup>

<sup>a</sup> The absorbed dose is defined as the amount in the receptor fluid, the receptor compartment wash and skin membrane, excluding tape strips

<sup>b</sup> 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)

<sup>c</sup> 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).

<sup>d</sup> Approach based on the EFSA Guidance on Dermal Absorption (mean + 0.84 × SD).

### Conclusion/endpoint:

Acetamiprid in the test item Acetamipryd 200 SL, was tested for the skin diffusion using Franz cells automated diffusion system using human skin. Diffusion was quantified in terms of radioactive unit (DPM). Concentrated dose (198.22 g/L) was tested, and the mean total recovery of the radioactivity was found to be 100.15%, validating the results obtained. The absorption value for Acetamiprid was  $1.14 \pm 0.03\%$ , rounding value, taking into account the correction for variability, is **1.2%**, calculated according to EFSA Guidance on Dermal Absorption (2017).

Field dilution (0.0127 g/L) was tested, and the mean total recovery of the radioactivity was found to be 99.95%, validating the results obtained. The absorption value for Acetamiprid was  $8.47 \pm 0.33\%$ , rounding value, taking into account the correction for variability, is **8.7%**, calculated according to EFSA Guidance on Dermal Absorption (2017).

## A 2.12 Other/Special Studies

No studies submitted with this application.

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## Appendix 3 Exposure calculations

### A 3.1 Operator, worker, resident and bystander exposure calculations (KCP 7.2.1.1, KCP 7.2.3.1, KCP 7.2.2.1)



Acetamipryd 200  
SL\_20240726.docx



Acetamipryd 200 SL\_20240726\_12h02\_opex1.0.2.zip

**OPEX version: 1.1.2 - additional exposure calculations - Spring oilseed rape, Turnip rape (Part B0, Appendix 1 ALL intended uses - use no. 12)**



Acetamipryd 200 SL\_20250721\_12h13\_opex1.1.2.zip



GENERAL\_Acetamip  
ryd 200 SL\_20250721

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#### **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.