

FINAL REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: GLOB2106cF

Product name: Revus Pro

Chemical active substances:

Propamocarb-HCl, 450 g/L

Mandipropamid, 75 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Globachem NV

Submission date: March 2023

MS Finalisation date: 06/03/2024

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Version history

When	What
March 2023	Initial dossier submission by applicant for approval of new product
July 2023	Dossier sent for evaluation
November 2023	zRMS evaluation of dRR
March 2024	Final version prepared by zRMS after Commenting period

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Evaluator comments:
The text highlighted in grey was provided by the evaluator.

6 Mammalian Toxicology (KCP 7)

6.1 Summary

Table 6.1-1: Information on GLOB2106cF*

Product name and code	GLOB2106cF/Revus Pro
Formulation type	Suspension concentrate [Code: SC]
Active substance(s) (incl. content)	Propamocarb-HCl: 450 g/L Mandipropamid: 75 g/L
Function	Fungicide
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 GLOB2106cF 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:

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Table 6.1-2: Justified proposals for classification and labelling for GLOB2106cF according to Regulation (EC) No 1272/2008


Hazard class(es), categories	Skin Sens. 1
Hazard pictograms or Code(s) for hazard pictogram(s)	
Signal word	Warning
Hazard statement(s)	H317 - May cause an allergic skin reaction.
Precautionary statement(s)	P261 - Avoid breathing dust/fume/ gas/mist/vapours/spray, P273, P272 - Contaminated work clothing should not be allowed out of the workplace, P280 - Wear protective gloves/ protective clothing/ eye protection/ face protection, P302+P352 - IF ON SKIN: Wash with plenty of water, P333+P313 - If skin irritation or rash occurs: Get medical advice/attention, P362+P364 - Take off contaminated clothing and wash it before reuse, P363, P391 P501 - Dispose of contents/ container to...
Additional labelling phrases	To avoid risks to man and the environment, comply with the instructions for use. [EUH401] Contains 1,2-benzisothiazol-3(2H)-one (CAS-number 2634-33-5). May produce an allergic reaction. [EUH208]

Table 6.1-3: Summary of risk assessment for operators, workers, residents and bystanders for GLOB2106cF

	Result	PPE / Risk mitigation measures
Operators	Acceptable	None (due to exposure assessment) Due to the toxicological properties of the product (Skin Sens. 1, H317), the operator should wear workwear and protective gloves during mixing, loading and handling the undiluted product.
Workers	Acceptable	None (Workwear)
Residents	Acceptable	None
Bystanders	Acceptable	None

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

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

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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, 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 a) a.s. 1 b) a.s. 2	Water L/ha min / max			Operator	Worker	Residents	Bystander
1	Seed, ware and starch potato (SOLTU)	F	Spraying, LCTM	3 ; 7	a) Propamocarb- HCl: 2.565 0.855 (per application) b) Mandipropamid: 0.4275 0.1425 (per application)	150 - 300	14	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	A	A	A	A

* 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

Noticed data gaps are:

- none

6.2 Toxicological Information on Active Substance(s)

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

Table 6.2-1: Information on active substance(s)

	Propamocarb	Mandipropamid
Common Name	Propamocarb (unless otherwise stated, the following data relate to the variant propamocarb hydrochloride)	Mandipropamid
CAS-No.	24579-73-5 (Propamocarb) 25606-41-1 (Propamocarb HCl)	374726-62-2
Classification and proposed labelling		

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	Propamocarb	Mandipropamid
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	Hazard classes (s), categories: Skin Sens. 1B Code(s) for hazard pictogram(s): GHS07 Signal word: Warning Hazard statement(s): H317 Precautionary statement(s): P102, P261, P272, P280, P302+P352, P333+P313, P321, P363, P501	Hazard classes (s), categories: none Code(s) for hazard pictogram(s): none Signal word: none Hazard statement(s): none Precautionary statement(s): none
Additional C&L proposal	-	-
Agreed EU endpoints		
AOEL systemic	0.29 mg/kg bw/d	0.17 mg/kg bw/d
Reference	EFSA Scientific Report (2006) 78, 1-80 SANCO/10057/2006 final, 25 April 2007	EFSA Scientific Report (2012) 10(11), 2935 SANCO/12991/2012 rev 4, 1 February 2013, (23 March 2018)
Conditions to take into account/critical areas of concern with regard to toxicology		
According to EFSA Conclusion for active substance	None	None

6.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for GLOB2106cF is given in the following tables. Full summaries of studies on the product that have not been previously considered within an EU peer review process are described in detail in Appendix 2.

Table 6.3-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for GLOB2106cF

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD ₅₀ oral	Study not necessary.	Yes	None	Theoretical calculations (see Part C)
LD ₅₀ dermal	Study not necessary.	Yes	None	Theoretical calculations (see Part C)
LC ₅₀ inhalation	Study not necessary.	Yes	None	Theoretical calculations (see Part C)
Skin irritation	Study not necessary.	Yes	None	Theoretical calculations (see Part C)
Eye irritation	Study not necessary.	Yes	None	Theoretical calculations (see Part C)

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Skin sensitisation	Study not necessary.	Yes	Skin Sens. 1, H317	Theoretical calculations (see Part C)
Supplementary studies for combinations of plant protection products	No data – not required			

Table 6.3-2: Additional toxicological information relevant for classification/labelling of GLOB2106cF

	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)	Propamocarb-HCl (43.8%)	Skin Sens. 1B, H317 (proposed)	None MSDS	Skin Sens. 1, H317
Toxicological properties of non-active substance(s) (relevant for classification of product)	None	None	None	None
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

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

6.5 Dermal Absorption (KCP 7.3)

A summary of the dermal absorption rates for the active substances in GLOB2106cF are presented in the following table.

Table 6.5-1: Dermal absorption rates for active substances in GLOB2106cF

Propamocarb-HCl		
	Value	Reference
Concentrate	10%	Default value
Dilution 1 (1:79)	1.2%	Hassler, S., 2023
Dilution 2 (1:263)	5.1%	

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Mandipropamid		
	Value	Reference
Concentrate	10%	Default value
Dilution	50%	Default value

6.5.1 Justification for proposed values – Propamocarb-HCl

Proposed dermal absorption rates for Mandipropamid are the default values in line with the current EFSA guidance document on dermal absorption (EFSA Journal 2017; 15(6):4873).

Table 6.5-2: Default dermal absorption rates for Mandipropamid

	Value	Justification for value	Acceptability of justification
Concentrate	10%	Default value	Yes
Dilution	50%	Default value	Yes

Proposed dermal absorption rates for Propamocarb-HCl are based on dermal absorption studies on GLOB2106cF. Two different dilutions were tested for Propamocarb-HCl, i.e. 1.7 g Propamocarb-HCl/L and 0.302–5.7 g Propamocarb-HCl/L. The low dose level reflects the highest diluted spray solution of 1.9 L product in 500 L (worst-case) water/ha, the higher dose level reflects the lowest diluted spray solution of 1.9 L product in 150 L water/ha.

The study results are summarized in the following table. Full summaries of studies on the dermal absorption of Propamocarb-HCl/GLOB2106cF that have not previously been evaluated within an EU peer review process are described in detail in Appendix 2.

Table 6.5-13: Summary of the results of submitted dermal absorption studies for Propamocarb-HCl

Test	Concentration	Spray dilution 1 (1:79)	Spray dilution 2 (1:263)	Formulation in study	Acceptability of study	Justification provided on representativity of study formulation for current product	Acceptability of justification	Reference *
In vitro (human)	Not relevant / Not tested – default value of 10% used as worst-case	1.2%	5.1%	GLOB2106cF	Yes	Not required	Justification accepted. Endpoint can be used for current product	Hassler S., 2023

* indicates that a study was reviewed at EU level

6.5.2 Justification for proposed values – Mandipropamid

No data on dermal absorption for Mandipropamid in GLOB2106cF is available. Justifications for default

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values according to Guidance on Dermal Absorption (EFSA Journal 2017; 15(6):4873) are presented in the following table.

Table 6.5-24: Default dermal absorption rates for Mandipropamid

	Value	Justification for value	Acceptability of justification
Concentrate	10%	Default value	Yes
Dilution	50%	Default value	Yes

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	GLOB2106cF/Revus Pro	
Formulation type	SC	
Category	Fungicide	
Container size(s), short description	0.1-20 L, HDPE, opening 42-63 mm	
Active substance(s) (incl. content)	Propamocarb-HCl 450 g/L	Mandipropamid 75 g/L
AOEL systemic	0.29 mg/kg bw/d	0.17 mg/kg bw/d
Inhalation absorption	100%	100%
Oral absorption	100%	100%
Dermal absorption	Concentrate: 10% Dilution 1: 1.2% (Dilution rate 1:79) Dilution 2: 5.1% (Dilution rate 1:263) (Based on product GLOB2106cF)	Concentrate: 10% Dilution: 50% (Default)

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 within the zone is given in Part B, Section 0.

Justification

The critical gap used for the exposure assessment is selected based on the highest application rate and the minimum interval between applications (worst-case).

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6.6.2 Operator exposure (KCP 7.2.1)

Comments of zRMS:	<p>Acceptable. The Applicant performed operator exposure calculations using the EFSA OPEX calculator version 1.0.0 in accordance with the EFSA guidance (2022).</p> <p>The calculation results confirmed that operator exposure is acceptable (55.6% of the AOEL for propamocarb-HCl and 34.1% of the AOEL for mandipropamid) if the product is used as intended (vehicle mounted for low vegetables) and the operator is wearing a workwear.</p> <p>However, due to the toxicological properties of the product (Skin Sens. 1, H317), the operator should wear workwear and protective gloves during mixing, loading and handling the undiluted product.</p> <p>zRMS re-calculated operator exposure using the available updated OPEX version 1.0.1 and a water volume range of 150-300 L/ha instead of 150-500 L/ha. The appropriate change in the report was included in Appendix 3. According to the calculation results, the operator exposure has not been changed.</p>
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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 GLOB2106cF according to the critical use(s) is presented in Table 6.6-2.

The outcome of the estimation is presented in the tables below (longer term exposure). Detailed calculations are in Appendix 3.

Table 6.6-2: Exposure models for intended uses

Critical use(s)	Potatoes (max. 3 x 1.9 L product/ha) A worst case water volume range of 500 150-300 L/ha is used.
Model(s)	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: 1.0.0

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

		Propamocarb-HCl	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to low crops-vegetables			
Application rate		3 x 0.855 kg a.s./ha	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	0.2	55.6

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

		Mandipropamid	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to low crops-vegetables			
Application rate		3 x 0.1425 kg a.s./ha	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	0.06	34.1

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)

Comments of zRMS:	<p>Acceptable. The Applicant performed operator exposure calculations using the EFSA OPEX calculator version 1.0.0 in accordance with the EFSA guidance (2022).</p> <p>The calculation results confirmed that worker exposure is acceptable (10.6% of AOEL for propamocarb-HCl and 15.1% of AOEL for mandipropamid) when worker is wearing a workwear.</p> <p>As a standard rule, treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried.</p> <p>zRMS re-calculated worker exposure using the available updated OPEX version 1.0.1 and a water volume range of 150-300 L/ha instead of 150-500 L/ha. The appropriate change in the report was included in Appendix 3. According to the calculation results, the worker exposure has not been changed.</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 GLOB2106cF according to the critical use(s). Outcome of the estimation is presented in the tables below (longer term exposure). Detailed calculations are in Appendix 3.

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Table 6.6-5: Exposure models for intended uses

Critical use(s)	Potatoes (max. 3 x 1.9 L product/ha) A worst-case water volume range of 500 150-300 L/ha is used.
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: 1.0.0

The only relevant re-entry activity for workers on potato fields is “inspection, irrigation (all)”.

Table 6.6-6: Estimated worker exposure (longer term exposure) for Propamocarb-HCl

		Propamocarb-HCl	
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Inspection, irrigation (all) Outdoor Work rate: 2 hours/day DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		3 x 0.855 kg a.s./ha	
Body weight: 60 kg	Potential TC: 12500 cm ² /person/h	0.3	94.7
	Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h	0.03	10.6
	Work wear (arms, body and legs covered) and gloves TC: 1250 cm ² /person/h	0.03	9.5

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Table 6.6-7: Estimated worker exposure (longer term exposure) for Mandipropamid

		Mandipropamid	
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Inspection, irrigation (all) Outdoor Work rate: 2 hours/day DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		3 x 0.1425 kg a.s./ha	
Body weight: 60 kg	Potential TC: 12500 cm ² /person/h	0.2	135
	Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h	0.03	15.1
	Work wear (arms, body and legs covered) and gloves TC: 1250 cm ² /person/h	0.02	13.5

6.6.3.2 Refinement of generic DFR value (KCP 7.2)

Not required.

6.6.3.3 Measurement of worker exposure

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

6.6.4 Resident and bystander exposure (KCP 7.2.2)

Comments of zRMS:	<p>Acceptable. The Applicant performed resident exposure calculations using the EFSA OPEX calculator version 1.0.0 in accordance with the EFSA guidance (2022).</p> <p>The calculation results confirmed that resident exposure (both for child and adult) is acceptable (below the AOEL) considering all pathways of exposure – drift, vapour, deposit and re-entry.</p> <p>The AAOEL values for propamocarb-HCl and mandipropamid are not specified, therefore it is assumed that the bystander exposure estimation is covered by the calculated resident exposure to both substances.</p> <p>zRMS re-calculated resident exposure using the available updated OPEX version 1.0.1 and a water volume range of 150-300 L/ha instead of 150-500 L/ha. The appropriate change in the report was included in Appendix 3. According to the calculation results, the resident exposure has not been changed.</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.

No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure.

Table 6.6-8 shows the exposure model(s) used for estimation of resident and bystander exposure to Propamocarb-HCl and Mandipropamid. The outcome of the estimation is presented in Table 6.6-9 and Table 6.6-10 (longer term resident exposure). Detailed calculations are in Appendix 3.

Table 6.6-8: Exposure models for intended uses

Critical use(s)	Potatoes (max. 3 x 1.9 L product/ha) A worst case water volume range of 500-1500 L/ha is used.
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: 1.0.0

Table 6.6-9: Estimated resident exposure (longer term exposure) for Propamocarb-HCl

		Propamocarb-HCl	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to low crops Buffer zone: 2-3 m Drift reduction technology: no DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		3 x 0.855 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.008	2.7
	Vapour (75 th perc.)	0.0008	0.3
	Deposits (75 th perc.)	0.005	1.7
	Re-entry (75 th perc.)	0.04	12.8
	Sum (mean)	0.04	13.2
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.002	0.6
	Vapour (75 th perc.)	0.0003	0.09
	Deposits (75 th perc.)	0.001	0.5
	Re-entry (75 th perc.)	0.02	7.1
	Sum (mean)	0.02	6.4

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Table 6.6-10: Estimated resident exposure (longer term exposure) for Mandipropamid

		Mandipropamid	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to low crops Buffer zone: 2-3 m Drift reduction technology: no DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		3 x 0.1425 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.01	7.6
	Vapour (75 th perc.)	0.0008	0.5
	Deposits (75 th perc.)	0.003	1.7
	Re-entry (75 th perc.)	0.03	18.2
	Sum (mean)	0.03	20.4
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.003	1.8
	Vapour (75 th perc.)	0.0003	0.2
	Deposits (75 th perc.)	0.001	0.7
	Re-entry (75 th perc.)	0.02	10.1
	Sum (mean)	0.02	9.6

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 Propamocarb-HCl and Mandipropamid 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

The product is a mixture of two active substances.

6.6.5.1 Exposure assessment of Propamocarb-HCl and Mandipropamid in GLOB2106cF

Comments of zRMS:	The combined exposure calculations for operator, workers and residents conducted by the Applicant and presented in Table 6.6-11 are acceptable. The Hazard Index is <1, therefore combined exposure to both active substances, propamocarb-HCl and mandipropamid in GLOB2106cF is not expected to pose a risk for operators and workers and residents. The exposure assessment of residents also covers the bystander exposure, therefore
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	the combined exposure of bystanders is also not expected.
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Note: The combined toxicological effect of these active substances has not been investigated with regard to repeated dose toxicity.

At the first tier, combined exposure is calculated as the sum of the component exposures without regard to the mode of action or mechanism/target of toxicity. Initially, the individual Hazard Quotients (HQ) are calculated for all active substances in the PPP by assessing the exposure according to appropriate models and dividing the individual exposure levels by the respective systemic AOEL. This is equivalent to the predicted exposure as % of systemic AOEL from the tables above converted to decimal. The Hazard Index (HI) is the sum of the individual HQs.

Table 6.6-11: Risk assessment from combined exposure (longer term exposure)

Application scenario	Active ingredient	Estimated exposure / AAOEL (HQ)
Operators – tractor mounted – no PPE	Propamocarb-HCl	0.556
	Mandipropamid	0.341
	Cumulative risk operators (HI)	0.896
Workers – inspection, irrigation	Propamocarb-HCl	0.106
	Mandipropamid	0.151
	Cumulative risk workers (HI)	0.3
Resident - child	Propamocarb-HCl	
	Drift	0.027
	Vapour	0.03
	Deposits	0.017
	Re-entry	0.128
	Sum of all pathways	0.132
	Mandipropamid	
	Drift	0.076
	Vapour	0.005
	Deposits	0.017
	Re-entry	0.182
	Sum of all pathways	0.204
	Cumulative risk resident – child (HI)	
	Drift	0.1
	Vapour	0.007
	Deposits	0.03
	Re-entry	0.3
	Sum of all pathways	0.3
Resident – adult	Propamocarb-HCl	

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Application scenario	Active ingredient	Estimated exposure / AAOEL (HQ)
	Drift	0.006
	Vapour	0.0009
	Deposits	0.005
	Re-entry	0.071
	Sum of all pathways	0.064
	Mandipropamid	
	Drift	0.018
	Vapour	0.002
	Deposits	0.007
	Re-entry	0.101
	Sum of all pathways	0.096
	Cumulative risk resident – adult (HI)	
	Drift	0.02
	Vapour	0.003
	Deposits	0.01
	Re-entry	0.2
	Sum of all pathways	0.2

The Hazard Index is < 1. Thus, combined exposure to all active substances in GLOB2106cF is not expected to present a risk for operators, workers, residents and bystanders. No further refinement of the assessment is required.

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Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 7.3	Hassler S.	2023	Propamocarb-HCl – In vitro percutaneous penetration of [¹⁴ C]Propamocarb-HCl formulated as GLOB2106cF through human skin membranes 20220226 Innovative Environmental Services GLP Unpublished	N	Globachem NV

Appendix 2 Detailed evaluation of the studies relied upon

A 2.1 Statement on bridging possibilities

Not necessary.

Comments of zRMS:	Acceptable
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A 2.2 Acute oral toxicity (KCP 7.1.1)

Comments of zRMS:	Acceptable. The toxicological assessment of the GLPB2106cF formulation was carried out using the calculation method in accordance with CLP, based on the composition of the formulation and taking into account the classification of each component of the mixture. One of the co-formulants of GLOB2106cF contains components classified as Acute Tox 4, H302, whose final concentrations in the formulation are far below the generic cut-off value for Acute Toxicity, Category 4 (1%), according to Table 1.1 in Annex I to the CLP Regulation. Therefore, there is no need to classify the GLPB2106cF formulation in this hazard class. Details available in Doc. C.
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No tests were performed on GLOB2106cF in the interest of animal welfare. The assessments have been conducted according to Regulation (EC) 1107/2009 (amended by Commission Regulation (EU) No 286/2011).

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

Comments of zRMS:	Acceptable. The toxicological assessment of the GLPB2106cF formulation was carried out using the calculation method in accordance with CLP, based on the composition of the formulation and taking into account the classification of each component of the mixture. None of the co-formulants of GLOB2106cF is classified as dermal toxic, therefore there is no need to classify this formulation in this hazard class. Details available in Doc. C.
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No tests were performed on GLOB2106cF in the interest of animal welfare. The assessments have been conducted according to Regulation (EC) 1107/2009 (amended by Commission Regulation (EU) No 286/2011).

A 2.4 Acute inhalation toxicity (KCP 7.1.3)

Comments of zRMS:	Acceptable. The toxicological assessment of the GLPB2106cF formulation was
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	carried out using the calculation method in accordance with CLP, based on the composition of the formulation and taking into account the classification of each component of the mixture. None of the co-formulants of GLOB2106cF is classified as inhalation toxic, therefore there is no need to classify this formulation in this hazard class. Details available in Doc. C.
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No tests were performed on GLOB2106cF in the interest of animal welfare. The assessments have been conducted according to Regulation (EC) 1107/2009 (amended by Commission Regulation (EU) No 286/2011).

A 2.5 Skin irritation (KCP 7.1.4)

Comments of zRMS:	Acceptable. The toxicological assessment of the GLPB2106cF formulation was carried out using the calculation method in accordance with CLP, based on the composition of the formulation and taking into account the classification of each component of the mixture. One of the co-formulants of GLOB2106cF is classified as Skin Irrit. 2, H315, but its concentration in the formulation is below the trigger value of 10%, according to the CLP Regulation, therefore there is no need to classify the GLPB2106cF formulation in this hazard class. Details available in Doc. C.
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No tests were performed on GLOB2106cF in the interest of animal welfare. The assessments have been conducted according to Regulation (EC) 1107/2009 (amended by Commission Regulation (EU) No 286/2011).

A 2.6 Eye irritation (KCP 7.1.5)

Comments of zRMS:	Acceptable. The toxicological assessment of the GLPB2106cF formulation was carried out using the calculation method in accordance with CLP, based on the composition of the formulation and taking into account the classification of each component of the mixture. The GLOB2106cF formulation contain one component classified as Eye Dam. 1 (H318) and one classified as Eye Irrit. 2 (H319). The final concentrations both components are below the generic cut-off value for Serious damage to eyes/eye irritation (1%), according to Table 1.1 in Annex I to the CLP Regulation. Therefore, there is no need to classify the GLPB2106cF formulation in this hazard class. Details available in Doc. C.
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No tests were performed on GLOB2106cF in the interest of animal welfare. The assessments have been conducted according to Regulation (EC) 1107/2009 (amended by Commission Regulation (EU) No 286/2011).

A 2.7 Skin sensitisation (KCP 7.1.6)

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Comments of zRMS:	<p>Acceptable. The toxicological assessment of the GLPB2106cF formulation was carried out using the calculation method in accordance with CLP, based on the composition of the formulation and taking into account the classification of each component of the mixture.</p> <p>The active substance Propamocarb-HCl (43.8%) is classified as Skin Sens. 1 (H317), therefore the GLPB2106cF formulation should be classified as Skin Sens. 1, H317 - <i>May cause an allergic skin reaction</i>.</p> <p>Details available in Doc. C.</p>
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No tests were performed on GLOB2106cF in the interest of animal welfare. The assessments have been conducted according to Regulation (EC) 1107/2009 (amended by Commission Regulation (EU) No 286/2011).

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

Not required.

A 2.9 Data on co-formulants (KCP 7.4)

A 2.9.1 Material safety data sheet for each co-formulant

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

A 2.9.2 Available toxicological data for each co-formulant

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

A 2.10 Studies on dermal absorption (KCP 7.3)

A 2.10.1 Study 1 – Active substance 1 in product code/name

Comparative dermal absorption, in vitro using rat and human skin

Comments of zRMS:	<p>Study accepted, also dermal absorption values accepted for risk assessment.</p> <p>Dermal absorption results include data from tape strips 3-10 as $t_{0.5}$ absorption is <75% (61% for dilution 1 and 64% for dilution 2). According to the EFSA Guidance on dermal absorption (2017), absorption should be calculated as follows:</p> <p>Absorption = receptor fluid + receptor chamber washes + skin sample (excluding tape strips 1 and 2).</p> <p>Taking into account the variability between replicates, the mean standard deviation</p>
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	corrected by the multiplication factor should be added to the mean absorption. Dilution 1 (number of replicates: n=9, Multiplication factor: k=0.77): $0.86\% + 0.45 \times 0.77 = 1.2\%$ Dilution 2 (number of replicates: n=10, Multiplication factor: k=0.72): $3.47\% + 2.25 \times 0.72 = 5.1\%$ Dermal absorption values finally used in risk assessment: Dilution 1 (High dose) – 1.2% Dilution 2 (Low dose) – 5.1%
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Reference	KCP 7.3
Report	Propamocarb-HCl – In vitro percutaneous penetration of [¹⁴ C]Propamocarb-HCl formulated as GLOB2106cF through human skin membranes, Hassler S., 2022, 20220226
Guideline(s)	Yes, OECD 428, EC No 440/2008, Method B.45
Deviations	No
GLP	Yes
Acceptability	Yes/No/Supplementary
Duplication (if vertebrate study)	/

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Materials and methods

Test material [14C]-Labeled Test Item	Name (Lot/Batch No.)	[14C]Propamocarb-HCl (13154GXR003-2)
	Test preparation	Radioformulation
	Specific activity	1694 MBq/mmol
	Radiochemical purity	98.5%
Product Unlabeled Test Item used for dilution of the radiolabeled test item and for analytical purposes.	Name (Lot/Batch No.)	Propamocarb-HCl tech concentrate solution in water
	Company code	2507-2526
	Concentration a.s.	69.42 % (w/w) Propamocarb-HCl content 26.56 % (w/w) Water content
	Formulation type	-
Blank product Formulation delivered by the sponsor	Name (Lot/Batch No.)	Blank Formulation GLOB2106cF (BRN 3878)
	Concentration a.s.	Propamocarb-HCl 0 g/L Mandipropamid 0 g/L
	Formulation type	SC

Test system		
Diffusion cell	Cell type	dynamic
	(if dynamic) Flow rate	3 mL/h
	Exposed skin area	1 cm ²
	Cover	semi-occlusive
Membrane	Skin type	dermatomed
	Skin thickness range	400 µm
	Skin donors age	53-86
	Skin donors sex	m+f
	Location	abdomen
	Source	ex vivo
	Integrity test	y, T2O
Receptor	Receptor medium	phosphate physiological buffered saline
	Solubility in receptor medium	y, 0.0562 mg/mL
Sample Time	Exposure time	6 h
	Observation time	24 h
Sampling	Sample intervals	1-2 h
Washing		post exposure + post observation At 6 and 24 h 3 times with cotton swabs and mild shower gel solution (1% in water)
Final Procedure	Tape stripping	y
	TS1-2 analysed separately	y
Remarks: -		

Tested doses	Spray dilution 1 – 1:79	Spray dilution 2 – 1:263
Target concentration [mg/ml]	5.7	1.7
Area dose [µg/cm ²]	57	17
Total dose [µg/cell]	56.7	17
Specific activity [kBq/ml]	1912	571
No. of donors	5	5
No of cells used/valid cells	9	10

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Results and discussions

Table A 1: In-vitro dermal penetration of active substance 1 formulated as product code/name through human skin - Recovery data

Dose group	Spray dilution 1 (Spray dilution 1:79)		Spray dilution 2 (Spray dilution 1:263)	
	Mean	S.D.	Mean	S.D.
Target concentration [mg/mL]	5.7		1.7	
Target dose [$\mu\text{g}/\text{cm}^2$]	57		17	
Mean actual applied dose [$\mu\text{g}/\text{cm}^2$]	56.7		17	
	Recovery [%]		Recovery [%]	
	Mean	S.D.	Mean	S.D.
Dislodgeable dose				
Skin washing after 6 and 24 h	98.77	2.13	95.34	2.93
Donor chamber wash	0.06	0.08	0.17	0.18
Dose associated to skin				
Tape strips: 1 st sample, strips 1 + 2	0.55	0.98	0.68	0.31
Tape strips: 2 nd sample; strips 3 - 10	0.22	0.35	1.38	1.22
Skin preparation	0.04	0.05	0.09	0.08
Absorbed dose				
Receptor fluid	0.59	0.49	1.98	1.77
Receptor chamber wash	0.01	0.01	0.02	0.01
Total recovery¹				
Absorption essentially complete at end of study (>75% absorption within half the study duration) [%Absorption at $t_{0.5}$]	No		No	
If no: Absorption estimates = absorbed dose + skin preparation + tape strips sample 2) ²	0.86	0.45	3.47	2.25
If yes: Absorption estimates = absorbed dose + skin preparation	-	-	-	-
Absorption estimate normalised ³	0.86		3.47	
Relevant absorption estimate ⁴	1.208		5.092	
Absorption estimates used for risk assessment⁵	1.2		5.1	

¹ Values may not calculate exactly due to rounding of figures

² In accordance with the EFSA Guidance on Dermal Absorption (EFSA Journal 2017; 15(6):4873) the radioactivity in the second tape-strip pool (3rd to nth tape strip) is considered potentially absorbable if less than 75% of the absorption occurred in the first half of the study (see Table 7.6.2-1) Finally, the skin preparation is also considered potentially absorbable.

³ According to the EFSA Guidance on Dermal Absorption, cells with insufficient recovery (< 95%) can be corrected by normalisation of absorption estimate to 100% recovery; explanation should be included.

⁴ In accordance with the EFSA Guidance on Dermal Absorption, the standard deviation corrected for the number of replicates was added to the mean% dermal penetration.

⁵ Relevant absorption estimate was rounded to the required number of significant figures.

N/A: not applicable

Conclusion/endpoint:

The dermal penetration of Propamocarb-HCl formulated as GLOB2106cF through human dermatomed skin was determined in vitro. The amount of applied dose penetrating within 24 hours was determined to be 0.86

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± 0.45 (mean \pm standard deviation corrected for the number of replicates) and 3.47 ± 2.25 (mean \pm standard deviation corrected for the number of replicates) for the 1:79 and 1:263 spray dilution, respectively. The dermal penetration estimates to be used for risk assessment were set at 1.2% and 5.1% for the 1:79 and 1:263 spray dilution, respectively, based on the EFSA guidance criteria.

A 2.11 Other/Special Studies

None

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Appendix 3 Exposure calculations

Table A 3-1: Information on product and active substances

Product name	GLOB2106cF
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.
Product category	Other
Name of active substance	Propamocarb-hcl
Concentration of active substance [g a.s./l or kg]	450
AOEL [mg/kg bw/day]	0.29
AAOEL [mg/kg bw]	
Inhalation absorption [%]	100
Oral absorption [%]	100
Dermal absorption [%] (concentrate)	10
Dermal absorption [%] (dilution) 5.7 [g a.s./l or kg]	1.2
Dermal absorption [%] (dilution) 1.7 [g a.s./l or kg]	5.1
Name of active substance	Mandipropamid
Concentration of active substance [g a.s./l or kg]	75
AOEL [mg/kg bw/day]	0.17
AAOEL [mg/kg bw]	
Inhalation absorption [%]	100
Oral absorption [%]	100
Dermal absorption [%] (concentrate)	10

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Table A 3-2: Assessed uses





Use	Crops	Max. application rate of the product [l or kg/ha]	Unit	Max. no. of applications	Interval between multiple applications [days]	Min. volume water [l/ha]	Max. volume water [l/ha]	Indoor/outdoor	Application method	Type of cultivation	Application technique	Buffer strip [m]	Drift reduction [%]
Use 1	Low vegetables	1.9	l/ha	3	7	150	500	Outdoor	Downward spraying	Normal	Vehicle-mounted	2-3	0

Use	Crops	Max. application rate of the product [l or kg/ha]	Unit	Max. no. of applications	Interval between multiple applications [days]	Min. volume water [l/ha]	Max. volume water [l/ha]	Indoor/outdoor	Application method	Type of cultivation	Application technique	Buffer strip [m]	Drift reduction [%]
Use 1	Low vegetables	1.9	l/ha	3	7	150	300	Outdoor	Downward spraying	Normal	Vehicle-mounted	2-3	0

A 3.1 Operator exposure calculations (KCP 7.2.1.1)

A 3.1.1 Calculations for Propamocarb-HCl, Mandipropamid and combined exposure according to EFSA guidance (including input parameters)

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Mixing/loading Application		Propamocarb-hcl (% AOEL)	Mandipropamid (% AOEL)	Combined (hazard index)
 	 	Normal & vehicle-mounted		
		89.9	52	1.42
		55.6	34.1	0.896

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Low vegetables/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/75th percentile Crop density: Normal			
Propamocarb-hcl	Number of applications and application rate: 3 x 0.855 kg a.s./ha Dermal absorption (concentrate): 10 % Dermal absorption (in-use dilution): 5.1 %		
	M/L: Workwear App: Workwear	0.2	55.6
Mandipropamid	Number of applications and application rate: 3 x 0.1425 kg a.s./ha Dermal absorption (concentrate): 10 % Dermal absorption (in-use dilution): 50 %		
	M/L: Workwear App: Workwear	0.06	34.1
Combined exposure			Hazard index
M/L: Workwear App: Workwear			0.9

Propamocarb-HCl , Input Data

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Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	Name of active substance	Propamocarb-hcl
Concentration of active substance [g a.s./l or kg]	450	Crops	Low vegetables
Area treated [ha/day]	50	Application method	Downward spraying
Dermal absorption [%] (concentrate)	10	Application technique	Vehicle-mounted
Dermal absorption [%] (dilution)	5.1	Indoor/outdoor	Outdoor
Oral absorption [%]	100	Drift reduction [%]	0
Inhalation absorption [%]	100	Type of cultivation	Normal
Body weight (kg)	60		
AOEL [mg/kg bw/day]	0.29		
AAOEL [mg/kg bw]			

Propamocarb-HCl , Per body part - Short term exposure

Activity	Systemic exposure per body part	With workwear	With workwear + PPE/RPE
Mixing and loading (µg/kg bw per day)	Hand protection	None	None
	Hands exposure	150	150
	Body protection	Workwear	Workwear
	Body exposure	0.9	0.9
	Head protection	None	None
	Head exposure	4.5	4.5
	Inhalation protection	None	None
	Inhalation exposure	0.2	0.2
Application (µg/kg bw per day)	Hand protection	None	None
	Hands exposure	5.4	5.4

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Activity	Systemic exposure per body part	With workwear	With workwear + PPE/RPE
	<i>Body protection</i>	<i>Workwear</i>	<i>Workwear</i>
	Body exposure	0.08	0.08
	<i>Head protection</i>	<i>None</i>	<i>None</i>
	Head exposure	0.1	0.1
	<i>Inhalation protection</i>	<i>None</i>	<i>None</i>
	Inhalation exposure	0.1	0.1
Total	Total systemic exposure [mg/kg bw per day]	0.2	0.2
	% of AOEL	55.6	55.6

Mandipropamid , Input Data

Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	Name of active substance	Mandipropamid
Concentration of active substance [g a.s./l or kg]	75	Crops	Low vegetables
Area treated [ha/day]	50	Application method	Downward spraying
Dermal absorption [%] (concentrate)	10	Application technique	Vehicle-mounted
Dermal absorption [%] (dilution)	50	Indoor/outdoor	Outdoor
Oral absorption [%]	100	Drift reduction [%]	0
Inhalation absorption [%]	100	Type of cultivation	Normal
Body weight (kg)	60		
AOEL [mg/kg bw/day]	0.17		
AAOEL [mg/kg bw]			

Mandipropamid , Per body part - Short term exposure

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Activity	Systemic exposure per body part	With workwear	With workwear + PPE/RPE
Mixing and loading (µg/kg bw per day)	<i>Hand protection</i>	<i>None</i>	<i>None</i>
	Hands exposure	47.6	47.6
	<i>Body protection</i>	<i>Workwear</i>	<i>Workwear</i>
	Body exposure	0.3	0.3
	<i>Head protection</i>	<i>None</i>	<i>None</i>
	Head exposure	0.7	0.7
	<i>Inhalation protection</i>	<i>None</i>	<i>None</i>
	Inhalation exposure	0.1	0.1
Application (µg/kg bw per day)	<i>Hand protection</i>	<i>None</i>	<i>None</i>
	Hands exposure	8.8	8.8
	<i>Body protection</i>	<i>Workwear</i>	<i>Workwear</i>
	Body exposure	0.1	0.1
	<i>Head protection</i>	<i>None</i>	<i>None</i>
	Head exposure	0.2	0.2
	<i>Inhalation protection</i>	<i>None</i>	<i>None</i>
	Inhalation exposure	0.05	0.05
Total	Total systemic exposure [mg/kg bw per day]	0.06	0.06
	% of AOEL	34.1	34.1

A 3.2 Worker exposure calculations (KCP 7.2.3.1)

A 3.2.1 Calculations for Propamocarb-HCl, Mandipropamid and combined exposure according to EFSA guidance (including input parameters) – Inspection, irrigation

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Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL	Re-entry restriction [days]
Inspection, irrigation (All) / Outdoor Work rate: 2 hours/day Interval: 7 days 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			
Propamocarb-hcl Number of applications & application rate: 3 x 0.855 kg a.s./ha Dermal absorption: 10 % DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days			
Potential	0.3	94.7	0
Workwear	0.03	10.6	0
Workwear and gloves	0.03	9.5	0
Hands covered, no workwear			
Mandipropamid Number of applications & application rate: 3 x 0.1425 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days			
Potential	0.2	135	13
Workwear	0.03	15.1	0
Workwear and gloves	0.02	13.5	0
Hands covered, no workwear			
Combined		Hazard index	
potential		2.3	36
Workwear		0.3	0
Workwear and gloves		0.2	0
Hands covered, no workwear			0

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Propamocarb-HCl , Input data

Indoor/outdoor	Outdoor	AOEL [mg/kg bw/day]	0.29
Re-entry activity	Inspection, irrigation (All)	Dermal transfer coefficient - Total potential exposure [cm²/h]	12500
Crops	Low vegetables	Dermal transfer coefficient - Arm, body and legs covered [cm²/h]	1400
Application method	Downward spraying	Dermal transfer coefficient - Hands, arm, body and legs covered [cm²/h]	1250
Application technique	Vehicle-mounted	Dermal transfer coefficient - Hands covered, no workwear [cm²/h]	
Max. application rate of the product [l or kg/ha]	1.9	DFR refined worker [µg/cm² foliage per kg a.s./ha]	3
Max. no. of applications	3	DT50 foliar worker [days]	30
Interval between multiple applications [days]	7	Inhalation task specific factor [ha/h*10⁻³]	0.01
Multiple application factor	2.57		
Body weight (kg)	60		
Name of active substance	Propamocarb-hcl		
Dermal absorption [%] (dilution)	5.1		
Inhalation absorption [%]	100		
Time [hours per day]	2		

Propamocarb-HCl , Exposure per body part

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Exposure route	Description	Potential	Workwear	Workwear and gloves	Gloves
Dermal	Systemic dermal exposure [mg a.s. per day]	16.5	1.8	1.6	NA
Inhalation	Systemic inhalation exposure [mg a.s. per day]				NA
Total	Total systemic exposure [mg a.s. per day]	16.5	1.8	1.6	NA
	Total systemic exposure [mg/kg bw per day]	0.3	0.03	0.03	NA
	% of AOEL	94.7	10.6	9.5	NA

Mandipropamid , Input data

Indoor/outdoor		Outdoor	AOEL [mg/kg bw/day]	0.17
Re-entry activity	Inspection, irrigation (All)		Dermal transfer coefficient - Total potential exposure [cm²/h]	12500
Crops	Low vegetables		Dermal transfer coefficient - Arm, body and legs covered [cm²/h]	1400
Application method	Downward spraying		Dermal transfer coefficient - Hands, arm, body and legs covered [cm²/h]	1250
Application technique	Vehicle-mounted		Dermal transfer coefficient - Hands covered, no workwear [cm²/h]	
Max. application rate of the product [l or kg/ha]	1.9		DFR refined worker [µg/cm² foliage per kg a.s./ha]	3
Max. no. of applications	3		DT50 foliar worker [days]	30
Interval between multiple applications [days]	7		Inhalation task specific factor [ha/h*10 ⁻³]	0.01
Multiple application factor	2.57			

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Body weight (kg)	60
Name of active substance	Mandipropamid
Dermal absorption [%] (dilution)	50
Inhalation absorption [%]	100
Time [hours per day]	2

Mandipropamid , Exposure per body part

Exposure route	Description	Potential	Workwear	Workwear and gloves	Gloves
Dermal	Systemic dermal exposure [mg a.s. per day]	13.7	1.5	1.4	NA
Inhalation	Systemic inhalation exposure [mg a.s. per day]				NA
Total	Total systemic exposure [mg a.s. per day]	13.7	1.5	1.4	NA
	Total systemic exposure [mg/kg bw per day]	0.2	0.03	0.02	NA
	% of AOEL	135	15.1	13.5	NA

A 3.3 Resident and bystander exposure calculations (KCP 7.2.2.1)

A 3.3.1 Calculations for Propamocarb-HCl, Mandipropamid and combined exposure according to EFSA guidance (including input parameters)

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Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: 7 days Minimum volume of water: 150 l			
Number of applications and application rate: 3 x 0.855 kg a.s./ha Dermal absorption: 10 % DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days			
Resident child Body weight: 10 kg	Drift (75th perc.)	0.008	2.7
	Vapour (75th perc.)	0.0008	0.3
	Deposits (75th perc.)	0.005	1.7
	Re-entry (75th perc.)	0.04	12.8
	Sum (mean)	0.04	13.2
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.002	0.6
	Vapour (75th perc.)	0.0003	0.09
	Deposits (75th perc.)	0.001	0.5
	Re-entry (75th perc.)	0.02	7.1
	Sum (mean)	0.02	6.4
Number of applications and application rate: 3 x 0.1425 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days			
Resident child Body weight: 10 kg	Drift (75th perc.)	0.01	7.6
	Vapour (75th perc.)	0.0008	0.5
	Deposits (75th perc.)	0.003	1.7
	Re-entry (75th perc.)	0.03	18.2
	Sum (mean)	0.03	20.4

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Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.003	1.8
	Vapour (75th perc.)	0.0003	0.2
	Deposits (75th perc.)	0.001	0.7
	Re-entry (75th perc.)	0.02	10.1
	Sum (mean)	0.02	9.6
Combined exposure			Hazard index
Resident child Body weight: 10 kg	Drift (75th perc.)		0.1
	Vapour (75th perc.)		0.007
	Deposits (75th perc.)		0.03
	Re-entry (75th perc.)		0.3
	Sum (mean)		0.3
Resident adult Body weight: 60 kg	Drift (75th perc.)		0.02
	Vapour (75th perc.)		0.003
	Deposits (75th perc.)		0.01
	Re-entry (75th perc.)		0.2
	Sum (mean)		0.2

A 3.4 Combined exposure calculations for Propamocarb-HCl and Mandipropamid

Please refer to point 6.6.5.1.

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)