FINAL REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: SHA 6100 A

Product name(s): ALIVE

Chemical active substance:

Propaquizafop, 100 g/L

Central

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: SHARDA Cropchem España S.L.

Submission date: October 2020

MS Finalisation date: 03/2021; 03/2022

Version history

When	What
March 2021	ZRMS evaluated the dRR
March 2022	The Final Registration Report

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6 Mammalian Toxicology (KCP 7)

6.1 Summary

Table 6.1-1: Information on SHA 6100 A / ALIVE *

Product name and code	SHA 6100 A / ALIVE
Formulation type	Emulsifiable concentrate [Code: EC]
Active substance(s) (incl. content)	Propaquizafop; 100 g/L
Function	Herbicide
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 SHA 6100 A / ALIVE 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 SHA 6100 A / ALIVE according to Regulation (EC) No 1272/2008

Hazard class(es), categories	Acute Tox. 4 (oral), Eye Damage Category 1, Skin sensitisation, Category 1, Aspiration toxicity, Category 1
Hazard pictograms or Code(s) for hazard pictogram(s)	GHS05, GHS07, GHS08
Signal word	Danger
Hazard statement(s)	H302, H304, H317, H318
Precautionary statement(s)	P280, P301 + P310 + P331, P302 + P352, P305 + P351 + P338, P501
Additional labelling phrases	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]
	Repeated exposure may cause skin dryness or cracking. [EUH066]

Table 6.1-3: Summary of risk assessment for operators, workers, residents and bystanders for SHA 6100 A / ALIVE

	Crops	Result	PPE / Risk mitigation measures
Operators	Sugar beet, winter oilseed rape, potato, onion, bean, green peas, peas for dry seeds, cabbage,	Acceptable	Work wear (arms, body and legs covered) M/L and A + gloves M/L

	Crops	Result	PPE / Risk mitigation measures
	carrot, parsley, strawberry, osr, spring oilseed rape, opium poppy, common flax, linen flax, broccoli, brussels sprouts, broad beans, faba bean, field peas, white lupine, yellow lupine, narrow-leaved lupine, root celery, parsnip, swede, garlic, shallot, fodder beet, beetroot, jerusalem artichokes, horseradish, black radish, daikon, radish, salsify, white turnip, black turnip, alfalfa, yellow alfalfa, black medic, red clover, white clover, crimson clover, common sainfoin, vetch, little white bird's-foot, lentil, white melilot, yellow melilot, grass pea		
Workers	Sugar beet, winter oilseed rape, potato, carrot, parsley, osr, spring oilseed rape, opium poppy, common flax, linen flax, root celery, parsnip, swede, fodder beet, beet-root, jerusalem artichokes, horseradish, black radish, daikon, radish, salsify, white turnip, black turnip, alfalfa, yellow alfalfa,	Acceptable	Work wear (arms, body and legs covered)

	Crops	Result	PPE / Risk mitigation measures
	black medic, red clover, white clover, crimson clover, common sainfoin, vetch, little white bird's-foot, white melilot, yellow melilot		
	Onion, bean, green peas, peas for dry seeds, cabbage, broccoli, brussels sprouts, broad beans, faba bean, field peas, white lupine, yellow lupine, narrow-leaved lupine, garlic, shallot, lentil, grass pea, strawberry		Work wear (arms, body and legs covered) and gloves
Residents	Sugar beet, winter oilseed rape, potato, onion, bean, green peas, peas for dry seeds, cabbage, carrot, parsley, strawberry, osr, spring oilseed rape, opium poppy, common flax, linen flax, broccoli, brussels sprouts, broad beans, faba bean, field peas, white lupine, yellow lupine, narrow-leaved lupine, root celery, parsnip, swede, garlic, shallot, fodder beet, beetroot, jerusalem artichokes, horseradish, black radish, daikon, radish, salsify, white turnip, black turnip, alfalfa, yellow alfalfa,	Acceptable	None
Bystanders		Acceptable	None

	Crops	Result	PPE / Risk mitigation measures
	black medic, red clover, white clover, crimson clover, common sainfoin, vetch, little white bird's-foot, lentil, white melilot, yellow melilot, grass pea		

No unacceptable risk for residents and bystanders was identified when the product is used as intended. No specific PPE is necessary.

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

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

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

1	2	3	4	5	6	7	8	9	10			
Use-No.*	**Crops and situation (e.g. growth stage of crop)**	**F, Fn, Fpn G, Gn, Gpn or I ******	**Application**		**Application rate**		**PHI (d)**	**Remarks:** **(e.g. safener/synergist (L/ha))** **critical gap for operator, worker, resident or bystander exposure based on [Exposure model]**	**Acceptability of exposure assessment**			
			Method / Kind **(incl. application technique *****)**	**Max. number (min. interval between applications)** **a) per use** **b) per crop/ season**	**Max. application rate kg as/ha** **a) a.s. 1** **b) a.s. 2**	**Water L/ha** **min / max**			**Operator**	**Worker**	**Residents**	**Bystander**
1	Sugar beet (BBCH 13-16* BBCH 12-35**)	F	Spraying, LCTM	a)1 b)1	a) 0.125 - 0.150	200-300	28	*weeds grow stage **crop grow stage Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874				
2	Winter oilseed rape (BBCH 13-16* BBCH 12-30**)	F	Spraying, LCTM	a)1 b)1	a) 0.125 - 0.150	200-300	42	*weeds grow stage **crop grow stage Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874				
3	Potato (BBCH 13-16*	F	Spraying, LCTM	a)1 b)1	a) 0.125 - 0.150	200-300	40	*weeds grow stage **crop grow stage				

1	2	3	4	5	6	7	8	9	10
	BBCH 10-35**)							Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874	
4	Onion (BBCH 13-16* BBCH 11-12** BBCH 09-53***)	F	Spraying, LCTM	a)1 b)1	a) 0.125 - 0.150	200-300	30	*weeds grow stage **crop grow stage *** grow stage crop for seeds Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874	
5	Bean (BBCH 13-16* min. BBCH 13**)	F	Spraying, LCTM	a)1 b)1	a) 0.125 - 0.150	200-300	45	*weeds grow stage **crop grow stage Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874	
6	Green peas, peas for dry seeds (BBCH 13-16* min. BBCH 12**)	F	Spraying, LCTM	a)1 b)1	a) 0.125 - 0.150	200-300	45	*weeds grow stage **crop grow stage Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874	
7	Cabbage (BBCH 13-16* min. BBCH 13**)	F	Spraying, LCTM	a)1 b)1	a) 0.125 - 0.150	200-300	28	*weeds grow stage **crop grow stage Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874	
8	Carrot, parsley (BBCH 13-16* min. BBCH 12**)	F	Spraying, LCTM	a)1 b)1	a) 0.125 - 0.150	200-300	28	*weeds grow stage **crop grow stage Guidance on the assessment of	

1	2	3	4	5	6	7	8	9	10
								exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874	
9	Strawberry (BBCH 13-16* BBCH 91-92**)	F	Spraying, LCTM	a)1 b)1	a) 0.125 - 0.150	200-300	NA	*weeds grow stage **crop grow stage Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874	
10	Osr (Post emergence BBCH 12-39)	F	Spraying, LCTM	a)1 b)1	a) 0.12	200-400	90	Weeds max BBCH 20 Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874	
11	Spring oilseed rape (BBCH 13-16* BBCH 12-30**)	F	Spraying, LCTM	a)1 b)1	a) 0.125 - 0.150	200-300	90	*weeds grow stage **crop grow stage Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874	
12	Opium poppy, common flax, linen flax, broccoli, brussels sprouts, broad beans, faba bean, field peas, white lupine, yellow lupine, narrow-leaved lupine (BBCH 13-16* BBCH 13**)	F	Spraying, LCTM	a)1 b)1	a) 0.125 - 0.150	200-300	Poppy, common flax: 90 Broccoli, brussels sprouts: 28 Broad beans, faba bean, field peas, white lupine, yellow lupine, narrow-leaved lupine: 45	*weeds grow stage **crop grow stage Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874	

1	2	3	4	5	6	7	8	9	10
13	Root celery, parsnip, swede (BBCH 13-16* BBCH 12**)	F	Spraying, LCTM	a)1 b)1	a) 0.125 - 0.150	200-300	28	*weeds grow stage **crop grow stage Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874	
14	Garlic, shallot (BBCH 13-16* BBCH 11-12**)	F	Spraying, LCTM	a)1 b)1	a) 0.125 - 0.150	200-300	30	*weeds grow stage **crop grow stage Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874	
15	Fodder beet, beetroot (BBCH 13-16* BBCH 12-35**)	F	Spraying, LCTM	a)1 b)1	a) 0.125 - 0.150	200-300	28	*weeds grow stage **crop grow stage Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874	
16	Jerusalem artichokes, horseradish, black radish, daikon, radish, salsify, white turnip, black turnip (BBCH 13-16* min. BBCH 12**)	F	Spraying, LCTM	a)1 b)1	a) 0.125 - 0.150	200-300	28	*weeds grow stage **crop grow stage Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874	
17	Alfalfa, yellow alfalfa, black medic, red clover, white clover, crimson clover, common sainfoin, vetch, little white bird's-foot, lentil, white melilot, yellow melilot, grass pea (BBCH 13-16* min. BBCH 13**)	F	Spraying, LCTM	a)1 b)1	a) 0.125 - 0.150	200-300	45	*weeds grow stage **crop grow stage Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874	

* 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

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)

	Propaquizafop
Common Name	Propaquizafop
CAS-No.	111479-05-1
Classification and proposed labelling	
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	Hazard classes (s), categories: Skin Sens. 1 Code(s) for hazard pictogram(s): GHS07 Signal word: Warning Hazard statement(s): H317 Precautionary statement(s): P261, P272, P280, P302 + P352, P333 + P313, P321, P363, P501
Additional C&L proposal	-
Agreed EU endpoints	
AOEL systemic	0.04 mg/kg bw/d
Reference	EFSA Scientific Report (2008) 204, 1-171
Conditions to take into account/critical areas of concern with regard to toxicology	
According to Review report for Propaquizafop (SANCO/131/08 final – 26 May 2009)	The operator and worker safety and ensure that conditions of use prescribe the application of adequate personal protective equipment.

6.3 Toxicological Evaluation of Plant Protection Product

The assessment of all acute toxicological properties of Propaquizafop 10% EC is derived from the classification of the active compound and co-formulants.

Justification for the proposed classification according the Regulation (EC) No 1272/2008:

Full details of the calculation methodology, co-formulants and their volumes in the product can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

Classification for Propaquizafop 10% EC was calculated based on classification of active ingredient and co-formulants. Based on those calculations for formulation, Propaquizafop 10% EC is classified as: Acute

Tox. 4 (oral), Eye Damage Category 1, Skin sensitisation, Category 1, Aspiration toxicity, Category 1.

Table 6.3-1: Additional toxicological information relevant for classification/labelling of SHA 6100 A / ALIVE

	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)	Propaquizafop (10% (w/w))	H317	Reg. 1272/2008	H317
Toxicological properties of non-active substance(s) (relevant for classification of product)	co-formulant 1 (10-50% (w/w))*	H302 H318	Reg. 1272/2008	H302 H318
Toxicological properties of non-active substance(s) (relevant for classification of product)	co-formulant 2 (5-10% (w/w))*	H319	Reg. 1272/2008	None
Toxicological properties of non-active substance(s) (relevant for classification of product)	co-formulant 3 (10-50% (w/w))*	H304	Reg. 1272/2008	H304
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 SHA 6100 A / ALIVE are presented in the following table.

Table 6.5-1: Dermal absorption rates for active substances in SHA 6100 A / ALIVE

	Propaquizafop	
	Value	**Reference**
Concentrate	25%	EFSA Journal 2017;15(6):4873
Dilution	70%	EFSA Journal 2017;15(6):4873

6.5.1 Justification for proposed values - Propaquizafop

No data on dermal absorption for Propaquizafop in SHA 6100 A / ALIVE is available. Justifications for default values according to Guidance on Dermal Absorption (EFSA Journal 2017;15(6):4873) are presented in the following table.

Table 6.5-2: Default dermal absorption rates for Propaquizafop

	Value	Justification for value	Acceptability of justification
Concentrate	25%	EFSA Journal 2017;15(6):4873	Acceptable
Dilution	70%	EFSA Journal 2017;15(6):4873	Acceptable

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	SHA 6100 A / ALIVE
Formulation type	EC
Category	Herbicide
Active substance(s) (incl. content)	**Propaquizafop** 100 g/L
AOEL systemic	0.04 mg/kg bw/d
Inhalation absorption	100%
Oral absorption	100%
Dermal absorption	Concentrate: 25% Dilution: 70% (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 current critical GAPs are taking into account the maximal exposure for the operator/worker/bystander/resident/consumer.

6.6.2 Operator exposure (KCP 7.2.1)

6.6.2.1 Estimation of operator exposure

A summary of the exposure models used for estimation of operator exposure to the active substances during application of SHA 6100 A / ALIVE according to the critical use(s) is presented in Table 6.6-2. The outcome of the estimation is presented in Table 6.6-3 (longer term exposure). Detailed calculations are in Appendix 3.

Table 6.6-2: Exposure models for intended uses

Critical use(s)	Sugar beet, winter oilseed rape, potato, onion, bean, green peas, peas for dry seeds, cabbage, carrot, parsley, strawberry, spring oilseed rape, opium poppy, common flax, linen flax, broccoli, brussels sprouts, broad beans, faba bean, field peas, white lupine, yellow lupine, narrow-leaved lupine, root celery, parsnip, swede, garlic, shallot, fodder beet,beetroot, jerusalem artichokes, horseradish, black radish, daikon, radish, salsify, white turnip, black turnip, alfalfa, yellow alfalfa, black medic, red clover, white clover, crimson clover, common sainfoin, vetch, little white bird's-foot, lentil, white melilot, yellow melilot, grass pea (max. 1.5 L product/ha) Osr (max. 1.2 L product/ha)
Model(s)	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 calculator version: 30/03/2015

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

		Propaquizafop	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Tractor mounted boom spray application outdoors to low crops (sugar beet, winter oilseed rape, potato, onion, bean, green peas, peas for dry seeds, cabbage, carrot, parsley, strawberry, spring oilseed rape, opium poppy, common flax, linen flax, broccoli, brussels sprouts, broad beans, faba bean, field peas, white lupine, yellow lupine, narrow-leaved lupine, root celery, parsnip, swede, garlic, shallot, fodder beet, beetroot, jerusalem artichokes, horseradish, black radish, daikon, radish, salsify, white turnip, black turnip, alfalfa, yellow alfalfa, black medic, red clover, white clover, crimson clover, common sainfoin, vetch, little white bird's-foot, lentil, white melilot, yellow melilot, grass pea)			
Application rate		0.15 kg a.s./ha	
Spray application (AOEM**;** 95th percentile) Body weight: 60 kg	Potential exposure	0.1791	**448**
	Work wear (arms, body and legs covered) M/L and A + gloves M/L	0.0164	**41**
Tractor mounted boom spray application outdoors to low crops (osr)			
Application rate		0.12 kg a.s./ha	
Spray application (AOEM**;** 95th percentile) Body weight: 60 kg	Potential exposure	0.1507	**377**
	Work wear (arms, body and legs covered) M/L and A + gloves M/L	0.0132	**33**

According to the EFSA AOEM Model, it can be concluded that the risk for the operator is acceptable with use of personal protective equipment.
Implication for labelling: P280: Wear protective gloves, protective clothing.

6.6.2.2 Measurement of operator exposure

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

6.6.3 Worker exposure (KCP 7.2.3)

6.6.3.1 Estimation of worker exposure

Table 6.6-4 shows the exposure model(s) used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with SHA 6100 A / ALIVE according to the critical use(s). Outcome of the estimation is presented in Table 6.6-5 (longer term exposure). Detailed calculations are in Appendix 3.

Table 6.6-4: Exposure models for intended uses

Critical use(s)	Sugar beet, winter oilseed rape, potato, onion, bean, green peas, peas for dry seeds, cabbage, carrot, parsley, strawberry, spring oilseed rape, opium poppy, common flax, linen flax, broccoli, brussels sprouts, broad beans, faba bean, field peas, white lupine, yellow lupine, narrow-leaved lupine, root celery, parsnip, swede, garlic, shallot, fodder beet, beetroot, jerusalem artichokes, horseradish, black radish, daikon, radish, salsify, white turnip, black turnip, alfalfa, yellow alfalfa, black medic, red clover, white clover, crimson clover, common sainfoin, vetch, little white bird's-foot, lentil, white melilot, yellow melilot, grass pea (max. 1 x 1.5 L product/ha) Osr (max. 1 x 1.2 L product/ha)
Model	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 calculator version: 30/03/2015

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

		Propaquizafop	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Sugar beet, winter oilseed rape, potato, carrot, parsley, spring oilseed rape, opium poppy, common flax, linen flax, root celery, parsnip, swede, fodder beet, beetroot, jerusalem artichokes, horseradish, black radish, daikon, radish, salsify, white turnip, black turnip, alfalfa, yellow alfalfa, black medic, red clover, white clover, crimson clover, common sainfoin, vetch, little white bird's-foot, white melilot, yellow melilot			
Inspection, irrigation Outdoor Work rate: 2 hours/day, DT_{50}: 30 days DFR: 3 µg/cm²/kg a.s./ha Interval between treatments: 365 days			
Number of applications and application rate		1 x 0.15 kg a.s./ha	
Body weight: 60 kg	Potential TC: 12500 cm²/person/h	0.1313	**328**
	Work wear (arms, body and legs covered) TC: 1400 cm²/person/h	0.0147	**37**
	Work wear (arms, body and legs covered) and gloves TC: not available for this assessment	–	–
Onion, bean, green peas, peas for dry seeds, cabbage, broccoli, brussels sprouts, broad beans, faba bean, field peas, white lupine, yellow lupine, narrow-leaved lupine, garlic, shallot, lentil, grass pea			
Reaching, picking Outdoor Work rate: 8 hours/day, DT_{50}: 30 days DFR: 3 µg/cm²/kg a.s./ha Interval between treatments: 365 days			
Number of applications and application rate		1 x 0.15 kg a.s./ha	
Body weight: 60 kg	Potential	0.2436	**609**

	TC: 5800 cm^2/person/h		
	Work wear (arms, body and legs covered) TC: 2500 cm^2/person/h	0.1050	**263**
	Work wear (arms, body and legs covered) and gloves TC: 580 cm^2/person/h	0.0244	**61**
Strawberry			
Reaching, picking Outdoor Work rate: 8 hours/day, DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha Interval between treatments: 365 days			
Number of applications and application rate		1 x 0.15 kg a.s./ha	
Body weight: 60 kg	Potential TC: 5800 cm^2/person/h	0.2436	**609**
	Work wear (arms, body and legs covered) TC: 3000 cm^2/person/h	0.1260	**315**
	Work wear (arms, body and legs covered) and gloves TC: 750 cm^2/person/h	0.0315	**79**
Osr			
Inspection, irrigation Outdoor Work rate: 2 hours/day, DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha Interval between treatments: 365 days			
Number of applications and application rate		1 x 0.12 kg a.s./ha	
Body weight: 60 kg	Potential TC: 12500 cm^2/person/h	0.1050	**263**
	Work wear (arms, body and legs covered) TC: 1400 cm^2/person/h	0.0118	**29**
	Work wear (arms, body and legs covered) and gloves TC: not available for this assessment	–	–

According to the EFSA AOEM Model, it can be concluded there is no unacceptable risk anticipated for the worker for maintenance activities for re-entering: sugar beet, winter oilseed rape, potato, carrot, parsley, spring oilseed rape, opium poppy, common flax, linen flax, root celery, parsnip, swede, fodder beet, beetroot, jerusalem artichokes, horseradish, black radish, daikon, radish, salsify, white turnip, black turnip, alfalfa, yellow alfalfa, black medic, red clover, white clover, crimson clover, common sainfoin, vetch, little white bird's-foot, white melilot, yellow melilot and osr, treated with ALIVE, even without suitable protective clothing.

Implication for labelling: None

According to the EFSA AOEM Model, it can be concluded there is no unacceptable risk anticipated for the worker wearing adequate work clothing and personal protective equipment (gloves) for maintenance activities for re-entering: onion, bean, green peas, peas for dry seeds, cabbage, broccoli, brussels sprouts, broad beans, faba bean, field peas, white lupine, yellow lupine, narrow-leaved lupine, garlic, shallot, lentil, grass pea and strawberry treated with ALIVE.

Implication for labelling: P280: Wear protective gloves, protective clothing.

6.6.3.2 Refinement of generic DFR value (KCP 7.2)

Not required.
If no DFR data for the specific compound are available, a conservative default value for the DFR may be taken as 3 μg/cm^2 (30 mg a.s./m^2).

6.6.3.3 Measurement of worker exposure

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

6.6.4 Resident and bystander exposure (KCP 7.2.2)

6.6.4.1 Estimation of resident and bystander exposure

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

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 6.6-6 shows the exposure model(s) used for estimation of resident and bystander exposure to Propaquizafop. The outcome of the estimation is presented in Table 6.6-7 (longer term resident exposure). Detailed calculations are in Appendix 3.

Table 6.6-6: Exposure models for intended uses

Critical use(s)	Sugar beet, winter oilseed rape, potato, onion, bean, green peas, peas for dry seeds, cabbage, carrot, parsley, strawberry, spring oilseed rape, opium poppy, common flax, linen flax, broccoli, brussels sprouts, broad beans, faba bean, field peas, white lupine, yellow lupine, narrow-leaved lupine, root celery, parsnip, swede, garlic, shallot, fodder beet,beetroot, jerusalem artichokes, horseradish, black radish, daikon, radish, salsify, white turnip, black turnip, alfalfa, yellow alfalfa, black

	medic, red clover, white clover, crimson clover, common sainfoin, vetch, little white bird's-foot, lentil, white melilot, yellow melilot, grass pea (max. 1 x 1.5 L product/ha) Osr (max. 1 x 1.2 L product/ha)
Model	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 calculator version: 30/03/2015

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

		Propaquizafop	
Model data		**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Sugar beet, winter oilseed rape, potato, onion, bean, green peas, peas for dry seeds, cabbage, carrot, parsley, strawberry, spring oilseed rape, opium poppy, common flax, linen flax, broccoli, brussels sprouts, broad beans, faba bean, field peas, white lupine, yellow lupine, narrow-leaved lupine, root celery, parsnip, swede, garlic, shallot, fodder beet, beetroot, jerusalem artichokes, horseradish, black radish, daikon, radish, salsify, white turnip, black turnip, lentil, grass pea			
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: 365 days			
Number of applications and application rate		1 x 0.15 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.0140939	35.23
	Vapour (75th perc.)	0.0010700	2.68
	Deposits (75th perc.)	0.0016506	4.13
	Re-entry (75th perc.)	0.0177188	44.30
	Sum (mean)	0.0241680	60.42
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.0033735	8.43
	Vapour (75th perc.)	0.0002300	0.58
	Deposits (75th perc.)	0.0007154	1.79
	Re-entry (75th perc.)	0.0098438	24.61
	Sum (mean)	0.0102050	25.51
Osr			
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: 365 days			
Number of applications and application rate		1 x 0.12 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.0112751	28.19
	Vapour (75th perc.)	0.0010700	2.68
	Deposits (75th perc.)	0.0013205	3.30
	Re-entry (75th perc.)	0.0141750	35.44

	Sum (mean)	0.0195484	48.87
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.0026988	6.75
	Vapour (75th perc.)	0.0002300	0.58
	Deposits (75th perc.)	0.0005723	1.43
	Re-entry (75th perc.)	0.0078750	19.69
	Sum (mean)	0.0082100	20.52
Alfalfa, yellow alfalfa, black medic, red clover, white clover, crimson clover, common sainfoin, vetch, little white bird's-foot, white melilot, yellow melilot			
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/cm²/kg a.s./ha Interval between treatments: 365 days			
Number of applications and application rate		1 x 0.15 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.0140939	35.23
	Vapour (75th perc.)	0.0010700	2.68
	Deposits (75th perc.)	0.0016506	4.13
	Re-entry (75th perc.)	0.0043406	10.85
	Sum (mean)	0.0134527	33.63
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.0033735	8.43
	Vapour (75th perc.)	0.0002300	0.58
	Deposits (75th perc.)	0.0007154	1.79
	Re-entry (75th perc.)	0.0015969	3.99
	Sum (mean)	0.0039531	9.88

According to the EFSA AOEM Model, it can be concluded that there is no undue risk to any resident exposure to ALIVE.
Implication for labelling: None

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 Propaquizafop will not be exceeded under conditions of intended uses and considering above mentioned risk mitigation measures, a study to provide measurements of resident/bystander exposure was not necessary and was therefore not performed.

6.6.5 Combined exposure

Not relevant. The product contains only one active substance.

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

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

List of data submitted by the applicant and relied on

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

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

No additional study submitted.

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

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

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
			Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished		

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

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

Appendix 2 Detailed evaluation of the studies relied upon

A 2.1 Statement on bridging possibilities

Not relevant.

A 2.2 Acute oral toxicity (KCP 7.1.1)

Comments of zRMS:	**The acute oral toxicity of Propaquizafop 10% EC was estimated 1378.17 mg/kg.** **Therefore, according to the Regulation EC No. 1272/2008, Propaquizafop 10% EC is classified as Acute Toxicity Category 4 (oral) (H302) with pictogram GHS07 and signal word "Warning".**

The classification of Propaquizafop 10% EC was performed by calculation. The assessment of all acute toxicological properties of Propaquizafop 10% EC is derived from the classification of the active compound and co-formulants as shown below. For obvious confidentiality reasons, the names and percentages of co-formulants are disclosed in Part C:

Formulant	% of formulation	Acute Oral Toxicity	Acute Dermal Toxicity	Acute Inhalation Toxicity	Dermal Irritation	Ocular Irritation	Sensitising potential
Propaquizafop (98,64%) (CAS no. 111479-05-1)	**9,84**	5000 mg/kg	2000 mg/kg	*	Not Irritating[1)]	Not Irritating[1)]	Skin Sens. 1A H317
Coformulant 1	**xxx**	500 mg/kg[2)] H302	>2000 mg/kg	*	Not Irritating[1)]	Eye Dam. 1, H318	Not sensitising[1)]
Coformulant 2	**xxx**	>2000 mg/kg	>2000 mg/kg	*	Not Irritating[1)]	Not Irritating[1)]	Not sensitising[1)]
Coformulant 3	**xxx**	>5000 mg/kg	>2000 mg/kg	*	Not Irritating[1)]	Eye Irrit. 2, H319	Not sensitising[1)]
Coformulant 4	**xxx**	>5000 mg/kg	>2000 mg/kg	*	Not Irritating[1)]	Not Irritating[1)]	Not sensitising[1)]

* No Information / but in their MSDS are not classified acutely inhalation toxic

1) As co-formulant is not classified

2) According to the Regulation (EC) n°1272/2008, Oral: ATE = 500 mg/kg is used for the calculation for co-formulant classified as Acute Tox. 4: H302

According to Regulation (EC) No 1272/2008 classification of mixtures based on ingredients of the mixture is determined by calculation from the ATE values:

$$\frac{100}{ATE_{mix}} = \sum_{r} \frac{C_i}{ATE_i}$$

or

$$\frac{100 - (\sum C_{unknown} if > 10\%)}{ATE_{mix}} = \sum_{r} \frac{C_i}{ATE_i}$$

where:
C_i = concentration of ingredient i (% w/w or % v/v)
i = the individual ingredient from 1 to n
n = the number of ingredients
ATE_i = Acute Toxicity Estimate of ingredient i.

The acute oral toxicity classification for Propaquizafop 10% EC is calculated:

$$ATE_{mix} = \frac{100}{\sum_r \frac{C_i}{ATE_i}}$$

$$ATE_{mix} = \frac{100}{\frac{xxx}{500}} = 1378.17\ mg/kg\ bw$$

Details of the co-formulants and their classification and the calculation methodology that was used to assess the acute oral toxicity of Propaquizafop 10% EC can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

Conclusion
The acute oral toxicity of Propaquizafop 10% EC was estimated to be < 2000 mg/kg.

Therefore, according to the Regulation EC No. 1272/2008, Propaquizafop 10% EC is classified as Acute Toxicity Category 4 (oral) (H302) with pictogram GHS07 and signal word "Warning".

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

Comments of zRMS:	**According to the Regulation EC No. 1272/2008, Propaquizafop 10% EC is not classified. No signal word or hazard statement is required for this hazard.**

There is no co-formulant in the Propaquizafop 10% EC recipe classified as danger through dermal contact.

According to the Regulation EC No. 1272/2008, Propaquizafop 10% EC is **not classified**. No signal word or hazard statement is required for this hazard.

A 2.4 Acute inhalation toxicity (KCP 7.1.3)

Comments of zRMS:	**According to the Regulation EC No. 1272/2008, Propaquizafop 10% EC is not classified. No signal word or hazard statement is required for this hazard**.

There is no co-formulant in the Propaquizafop 10% EC recipe classified as danger through inhalation.

According to the Regulation EC No. 1272/2008, Propaquizafop 10% EC is **not classified**. No signal word or hazard statement is required for this hazard.

A 2.5 Skin irritation (KCP 7.1.4)

Comments of zRMS:	**According to the Regulation EC No. 1272/2008, Propaquizafop 10% EC is not classified. No signal word or hazard statement is required for this hazard.**

There is no co-formulant in the Propaquizafop 10% EC recipe classified as danger through skin contact.

According to the Regulation EC No. 1272/2008, Propaquizafop 10% EC is **not classified**. No signal word or hazard statement is required for this hazard.

A 2.6 Eye irritation (KCP 7.1.5)

Comments of zRMS:	**According to the Regulation EC No. 1272/2008, Propaquizafop 10% EC is classified as Eye Damage Category 1 (H318) with pictogram GHS05 and signal word "Danger**

The product contains > 3% of co-formulants considered as eye damage (classified as: Eye Dam. 1; H318) and < 10% of co-formulants considered as eye irritation (classified as: Eye Irrit. 2, H319). Under the GHS classification system this component does trigger value of the classification according to Regulation (EC) no. 1272/2008.

Conclusion
According to the Regulation EC No. 1272/2008, Propaquizafop 10% EC is classified as Eye Damage Category 1 (H318) with pictogram GHS05 and signal word "Danger".

A 2.7 Skin sensitisation (KCP 7.1.6)

Comments of zRMS:	**According to the Regulation EC No. 1272/2008, Propaquizafop 10% EC is classified as Skin sensitisation, Category 1 (H317) with pictogram GHS07 and signal word "Warning".**

The product contains > 1% of co-formulants considered as skin sensitiser (classified as: Skin Sens. 1; H317). Under the GHS classification system this component does trigger value of the classification according to Regulation (EC) no. 1272/2008.

Conclusion
According to the Regulation EC No. 1272/2008, Propaquizafop 10% EC is classified as Skin sensitisation, Category 1 (H317) with pictogram GHS07 and signal word "Warning".

Propaquizafop 10% EC contains a solvent which is classified as substance which may cause skin dryness or cracking. The concentration of this co-formulant is > 10% in the formulation, so does trigger a specific statement EUH066.
Therefore, EUH066 (Repeated exposure may cause skin dryness or cracking) is proposed.

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

No supplementary studies are necessary.

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)

According to the new EFSA guidance on dermal absorption (EFSA Journal 2017;15(6):4873 adopted: 24 May 2017) a default dermal absorption value 25 % (concentrate) and 70% (diluted) of may be applied for products that are organic solvent-based [(a)] or other [(b)]

[(a)]: Formulation types: emulsifiable concentrate (EC), emulsion, oil in water (EW), suspo-emulsion (SE), dispersible concentrate (DC), oil miscible liquids (OL/OF), oil-based suspension concentrates (OD), emulsion for seed treatment (ES), microemulsion (ME).

[(b)]: Formulation types: bait concentrate (CB), capsule suspension (CS), gel for direct application (GEL/GD), bait, ready for use (RB), mixture of capsule suspension and suspension concentrate (ZC), seed coated with a pesticide (PS), experimental solution of active substances in solvent (AI).

A 2.11 Other/Special Studies

No data submitted.

Appendix 3 Exposure calculations

A 3.1 Operator exposure calculations (KCP 7.2.1.1)

A 3.1.1 Calculations for Propaquizafop

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

Formulation type	EC		Crop type	Sugar beet, winter oilseed rape, potato, onion, bean, green peas, peas for dry seeds, cabbage, carrot, parsley, strawberry, spring oilseed rape, opium poppy, common flax, linen flax, broccoli, brussels sprouts, broad beans, faba bean, field peas, white lupine, yellow lupine, narrow-leaved lupine, root celery, parsnip, swede, garlic, shallot, fodder beet, beetroot, jerusalem artichokes, horseradish, black radish, daikon, radish, salsify, white turnip, black turnip, alfalfa, yellow alfalfa, black medic, red clover, white clover, crimson clover, common sainfoin, vetch, little white bird's-foot, lentil, white melilot, yellow melilot, grass pea
Application rate (AR)	0.15	kg a.s./ha	Application method	Downward spraying
Area treated per day (A)	50	ha	Application equipment	Vehicle-mounted
Dermal absorption (DA)	25	% (concentr.)	Indoor/outdoor	Outdoor
	70	% (dilution)	Closed cabin	No
Inhalation absorption (IA)	100	%	Drift reduction	No
Body weight (BW)	60	kg/person	Cultivation	Normal
AOEL	0.04	mg/kg bw/d	Water soluble bag	No

Table A 2: Estimation of longer term operator exposure towards Propaquizafop according to EFSA guidance

	Potential		**With work wear + PPE/RPE**	
Mixing and loading				
Hands			Protective gloves	
Specific exposure value	5727.2800697	µg/person	31.9477211	µg/person
Systemic exposure	**95.4546678**	**mg/kg bw/d**	**0.5324620**	**mg/kg bw/d**
Body			Work wear	
Specific exposure value	3676.0111715	µg/person	35.4452514	µg/person
Systemic exposure	**61.2668529**	**mg/kg bw/d**	**0.5907542**	**mg/kg bw/d**
Head			None	
Specific exposure value	97.2817271	µg/person	97.2817271	µg/person
Systemic exposure	**1.6213621**	**mg/kg bw/d**	**1.6213621**	**mg/kg bw/d**
Inhalation			None	
Specific exposure value	6.7424577	µg/person	6.7424577	µg/person

Systemic exposure	**0.1123743**	**mg/kg bw/d**	**0.1123743**	**mg/kg bw/d**
Application				
Hands			None	
Specific exposure value	778.6977445	µg/person	778.6977445	µg/person
Systemic exposure	**12.9782957**	**mg/kg bw/d**	**12.9782957**	**mg/kg bw/d**
Body			Work wear	
Specific exposure value	435.3965247	µg/person	11.9436614	µg/person
Systemic exposure	**7.2566087**	**mg/kg bw/d**	**0.1990610**	**mg/kg bw/d**
Head			None	
Specific exposure value	20.5783314	µg/person	20.5783314	µg/person
Systemic exposure	**0.3429722**	**mg/kg bw/d**	**0.3429722**	**mg/kg bw/d**
Inhalation			None	
Specific exposure value	2.8418233	µg/person	2.8418233	µg/person
Systemic exposure	**0.0473637**	**mg/kg bw/d**	**0.0473637**	**mg/kg bw/d**
Total				
Total systemic exposure	**0.1790805**	**mg/kg bw/d**	**0.0164246**	**mg/kg bw/d**
% of AOEL	**447.70**	**%**	**41.06**	**%**

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

Formulation type	EC		Crop type	Osr
Application rate (AR)	0.12	kg a.s./ha	Application method	Downward spraying
Area treated per day (A)	50	ha	Application equipment	Vehicle-mounted
Dermal absorption (DA)	25	% (concentr.)	Indoor/outdoor	Outdoor
	70	% (dilution)	Closed cabin	No
Inhalation absorption (IA)	100	%	Drift reduction	No
Body weight (BW)	60	kg/person	Cultivation	Normal
AOEL	0.04	mg/kg bw/d	Water soluble bag	No

Table A 4: Estimation of longer term operator exposure towards Propaquizafop according to EFSA guidance

	Potential		**With work wear + PPE/RPE**	
Mixing and loading				
Hands			Protective gloves	
Specific exposure value	4823.2990083	µg/person	27.6288682	µg/person
Systemic exposure	**80.3883168**	**mg/kg bw/d**	**0.4604811**	**mg/kg bw/d**
Body			Work wear	
Specific exposure value	3142.3594879	µg/person	29.0843882	µg/person
Systemic exposure	**52.3726581**	**mg/kg bw/d**	**0.4847398**	**mg/kg bw/d**
Head			None	
Specific exposure value	77.8253816	µg/person	77.8253816	µg/person
Systemic exposure	**1.2970897**	**mg/kg bw/d**	**1.2970897**	**mg/kg bw/d**
Inhalation			None	
Specific exposure value	6.3092511	µg/person	6.3092511	µg/person
Systemic exposure	**0.1051542**	**mg/kg bw/d**	**0.1051542**	**mg/kg bw/d**
Application				

Hands	622.9581956		None	
Specific exposure value	10.3826366	µg/person	622.9581956	µg/person
Systemic exposure		**mg/kg bw/d**	**10.3826366**	**mg/kg bw/d**
Body	348.3172198		Work wear	
Specific exposure value	5.8052870	µg/person	9.5549291	µg/person
Systemic exposure		**mg/kg bw/d**	**0.1592488**	**mg/kg bw/d**
Head	16.4626651		None	
Specific exposure value	0.2743778	µg/person	16.4626651	µg/person
Systemic exposure		**mg/kg bw/d**	**0.2743778**	**mg/kg bw/d**
Inhalation	2.5412369		None	
Specific exposure value	0.0423539	µg/person	2.5412369	µg/person
Systemic exposure		**mg/kg bw/d**	**0.0423539**	**mg/kg bw/d**
Total				
Total systemic exposure	**0.1506679**	**mg/kg bw/d**	**0.0132061**	**mg/kg bw/d**
% of AOEL	**376.67**	**%**	**33.02**	**%**

A 3.2 Worker exposure calculations (KCP 7.2.3.1)

A 3.2.1 Calculations for Propaquizafop

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

Intended use(s)	Sugar beet, winter oilseed rape, potato, carrot, parsley, spring oilseed rape, opium poppy, common flax, linen flax, root celery, parsnip, swede, fodder beet, beetroot, jerusalem artichokes, horse-radish, black radish, daikon, radish, salsify, white turnip, black turnip, alfalfa, yellow alfalfa, black medic, red clover, white clover, crim-son clover, common sain-foin, vetch, little white bird's-foot, white melilot, yellow melilot, inspection, irrigation, outdoor		Dislodgeable foliar residue (DFR)	3	µg/cm^2/kg a.s./ha
Application rate (AR)	0.15	kg a.s./ha	Dermal absorption (DA)	70	% (worst case)
Number of applications (NA)	1		Inhalation absorption (IA)	100	%
Interval between applications	365	days	Work rate per day (WR)	2	h/d
Half-life of active substance	30	days	TC dermal (potential)	12500	cm^2/h
Multiple application factor (MAF)	1.0		TC dermal (work wear)	1400	cm^2/h
Body weight (BW)	60	kg/person	TC dermal (work wear, gloves)	-	cm^2/h
AOEL	0.04	mg/kg bw/d	Task specific factor inhalation	-	ha/h x 10^{-3}

Table A 6: Estimation of longer term worker exposure towards Propaquizafop according to EFSA guidance

	Potential		**With work wear**		**With work wear and gloves**	
Worker (re-entry): Dermal exposure after application						
(DFR x TC x WR x AR x MAF x DA) / BW						
Systemic exposure	0.1312500	**mg/kg bw/d**	**0.0147000**	**mg/kg bw/d**	-	**mg/kg bw/d**
% of AOEL	**328.13**	**%**	**36.75**	**%**	-	**%**

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

Intended use(s)	Onion, bean, green peas, peas for dry seeds, cabbage, broccoli, brussels sprouts, broad beans, faba bean, field peas, white lupine, yellow lupine, narrow-leaved lupine, garlic, shallot, lentil, grass pea, reaching, picking outdoor		Dislodgeable foliar residue (DFR)	3	µg/cm^2/kg a.s./ha
Application rate (AR)	0.15	kg a.s./ha	Dermal absorption (DA)	70	% (worst case)
Number of applications (NA)	1		Inhalation absorption (IA)	100	%
Interval between applications	365	days	Work rate per day (WR)	8	h/d
Half-life of active substance	30	days	TC dermal (potential)	5800	cm^2/h
Multiple application factor (MAF)	1.0		TC dermal (work wear)	2500	cm^2/h
Body weight (BW)	60	kg/person	TC dermal (work wear, gloves)	580	cm^2/h
AOEL	0.04	mg/kg bw/d	Task specific factor inhalation	-	ha/h x 10^{-3}

Table A 8: Estimation of longer term worker exposure towards Propaquizafop according to EFSA guidance

	Potential		**With work wear**		**With work wear and gloves**	
Worker (re-entry): Dermal exposure after application						
(DFR x TC x WR x AR x MAF x DA) / BW						
Systemic exposure	0.2436000	**mg/kg bw/d**	**0.1050000**	**mg/kg bw/d**	**0.0243600**	**mg/kg bw/d**
% of AOEL	**609.00**	**%**	**262.50**	**%**	**60.90**	**%**

Table A 9: Input parameters considered for the estimation of worker exposure

Intended use(s)	Strawberry, reaching, picking, outdoor		Dislodgeable foliar residue (DFR)	3	µg/cm^2/kg a.s./ha
Application rate (AR)	0.15	kg a.s./ha	Dermal absorption (DA)	70	% (worst case)
Number of applications (NA)	1		Inhalation absorption (IA)	100	%
Interval between applications	365	days	Work rate per day (WR)	8	h/d
Half-life of active substance	30	days	TC dermal (potential)	5800	cm^2/h
Multiple application factor (MAF)	1.0		TC dermal (work wear)	3000	cm^2/h
Body weight (BW)	60	kg/person	TC dermal (work wear, gloves)	750	cm^2/h
AOEL	0.04	mg/kg bw/d	Task specific factor inhalation	-	ha/h x 10^{-3}

Table A 10: Estimation of longer term worker exposure towards Propaquizafop according to EFSA guidance

	Potential		**With work wear**		**With work wear and gloves**	
Worker (re-entry): Dermal exposure after application						
(DFR x TC x WR x AR x MAF x DA) / BW						
Systemic exposure	0.2436000	**mg/kg bw/d**	**0.1260000**	**mg/kg bw/d**	**0.0315000**	**mg/kg bw/d**
% of AOEL	**609.00**	**%**	**315.00**	**%**	**78.75**	**%**

Table A 11: Input parameters considered for the estimation of worker exposure

Intended use(s)	Osr, inspection, irrigation, outdoor		Dislodgeable foliar residue (DFR)	3	µg/cm²/kg a.s./ha
Application rate (AR)	0.12	kg a.s./ha	Dermal absorption (DA)	70	% (worst case)
Number of applications (NA)	1		Inhalation absorption (IA)	100	%
Interval between applications	365	days	Work rate per day (WR)	2	h/d
Half-life of active substance	30	days	TC dermal (potential)	12500	cm²/h
Multiple application factor (MAF)	1.0		TC dermal (work wear)	1400	cm²/h
Body weight (BW)	60	kg/person	TC dermal (work wear, gloves)	-	cm²/h
AOEL	0.04	mg/kg bw/d	Task specific factor inhalation	-	ha/h x 10^{-3}

Table A 11: Estimation of longer term worker exposure towards Propaquizafop according to EFSA guidance

	Potential		**With work wear**		**With work wear and gloves**	
Worker (re-entry): Dermal exposure after application						
(DFR x TC x WR x AR x MAF x DA) / BW						
Systemic exposure	0.1050000	**mg/kg bw/d**	**0.0117600**	**mg/kg bw/d**	-	**mg/kg bw/d**
% of AOEL	**262.50**	**%**	**29.40**	**%**	-	**%**

A 3.3 Resident and bystander exposure calculations (KCP 7.2.2.1)

A 3.3.1 Calculations for Propaquizafop

Table A 13: Input parameters considered for the estimation of longer term resident exposure

Intended use(s)	Sugar beet, winter oilseed rape, potato, onion, bean, green peas, peas for dry seeds, cabbage, carrot, parsley, strawberry, spring oilseed rape, opium poppy, common flax, linen flax, broccoli, brussels sprouts, broad beans, faba bean, field peas, white lupine, yellow lupine, narrow-leaved lupine, root celery, parsnip, swede, garlic, shallot, fodder beet, beetroot, jerusalem artichokes, horseradish, black radish, daikon, radish, salsify, white turnip, black turnip, lentil, grass pea, downward spraying	Drift reduction (DR)		%

Application rate (AR)	0.15	kg a.s./ha	Transfer coefficient surface deposits (TC)	7300	cm^2/h (adult)
				2600	cm^2/h (child)
Minimum water volume (V)	200	L/ha	Drift on surface (D) - 75th perc.	5.60	%
Buffer strip	2-3	m	Drift on surface (D) - mean	4.10	%
Number of applications (NA)	1		Turf Transferable Residues (TTR)	5	%
Interval between applications	365	days	Exposure duration dermal (H_D)	2	h
Half-life of active substance	30	days	Exposure duration inhal. (H_I)	24	h
Multiple application factor (MAF)	1.0		Exposure duration entry into treated crops (H_E)	0.25	h
Body weight (BW)	60	kg/person (adults)	Airborne Concentration of Vapour (VC)	0.001	mg/m^3
	10	kg/person (children)			
Dermal absorption (DA)	70	% ('worst case')	Dislodgeable foliar residue (DFR)	3	$\mu g/cm^2$/kg a.s.
Inhalation absorption (IA)	100	%	Light clothing adjustment factor (CF)	18	%
Oral absorption (OA)	100	%	Saliva Extraction Factor (SE)	50	%
AOEL	0.04	mg/kg bw/d	Surface Area of Hands (SA)	20	cm^2
Spray drift dermal (SD) - 75th perc.	0.47	mL spray dilution (adult)	Frequency of Hand to Mouth (Freq)	20	events/h
	0.327	mL spray dilution (child)			
Spray drift inhal. (SI) - 75th perc.	0.00010	mL spray dilution (adult)	Dislodgeable residues object to mouth (DR_{OM})	20	%
	0.00022	mL spray dilution (child)			
Spray drift dermal (SD) - mean	0.22318	mL spray dilution (adult)	Ingestion Rate for Mouthing of Grass (IgR)	25	cm^2/d
	0.18	mL spray dilution (child)			
Spray drift inhal. (SD) - mean	0.00009	mL spray dilution (adult)	TC entry into treated crops - 75th perc.	7500	cm^2/h (adult)
	0.00017	mL spray dilution (child)		2250	cm^2/h (child)
Inhalation rate (IR)	16.57	m^3/d (adult)	TC entry into treated crops - mean:	5980	cm^2/h (adult)
	8.31	m^3/d (child)		1794	cm^2/h (child)

Table A 14: Estimation of longer term resident exposure towards Propaquizafop according to EFSA guidance

Adult			**Child**		
Spray drift (75th perc.)					
(SD x DA x (1- CF) + SI) x AR x MAF x V x DR/ BW					
Systemic exposure	**0.0033735**	**mg/kg bw/d**	**Systemic exposure**	**0.0140939**	**mg/kg bw/d**
% of AOEL:	**8.43**	**%**	**% of AOEL:**	**35.23**	**%**
Vapour (75th perc.)					
(VC x IR x IA) / BW					
Systemic exposure	**0.0002300**	**mg/kg bw/d**	**Systemic exposure**	**0.0010700**	**mg/kg bw/d**
% of AOEL:	**0.58**	**%**	**% of AOEL:**	**2.68**	**%**

Surface deposits (75th perc.)					
Dermal					
AR x MAF x D x TTR x TC x H_D x DA / BW					
Systemic exposure	**0.0007154**	**mg/kg bw/d**	**Systemic exposure**	**0.0015288**	**mg/kg bw/d**
Hand to mouth					
AR x MAF x D x TTR x SE x SA x Freq x H_D x OA / BW					
			Systemic exposure	**0.0000798**	**mg/kg bw/d**
Object to mouth					
AR x MAF x D x DR_{OM} x IgR x OA / BW					
			Systemic exposure	**0.0000420**	**mg/kg bw/d**
Total					
Systemic exposure	**0.0007154**	**mg/kg bw/d**	**Systemic exposure**	**0.0016506**	**mg/kg bw/d**
% of AOEL:	**1.79**	**%**	**% of AOEL:**	**4.13**	**%**
Entry into treated crops (75th perc.)					
Dermal					
AR x MAF x TC x H_D x DFR x DA / BW					
Systemic exposure	**0.0098438**	**mg/kg bw/d**	**Systemic exposure**	**0.0177188**	**mg/kg bw/d**
Hand to mouth					
AR x MAF x 100% x TTR x x SE x SA x Freq x H_D x OA / BW					
			Systemic exposure		**mg/kg bw/d**
Object to mouth					
AR x MAF x 100% x DR_{OM} x IgR x OA / BW					
			Systemic exposure		**mg/kg bw/d**
Total					
Systemic exposure	**0.0098438**	**mg/kg bw/d**	**Systemic exposure**	**0.0177188**	**mg/kg bw/d**
% of AOEL:	**24.61**	**%**	**% of AOEL:**	**44.30**	**%**
All pathways (mean)					
Systemic exposure		**0.0102050**	**mg/kg bw/d**	**Systemic exposure**	**0.0241680**	**mg/kg bw/d**
% of AOEL:	**25.51**	**%**	**% of AOEL:**	**60.42**	**%**

Table A 15: Input parameters considered for the estimation of longer term resident exposure

Intended use(s)	Osr, downward spraying		Drift reduction (DR)		%
Application rate (AR)	0.12	kg a.s./ha	Transfer coefficient surface deposits (TC)	7300	cm^2/h (adult)
				2600	cm^2/h (child)
Minimum water volume (V)	200	L/ha	Drift on surface (D) - 75th perc.	5.60	%
Buffer strip	2-3	m	Drift on surface (D) - mean	4.10	%
Number of applications (NA)	1		Turf Transferable Residues (TTR)	5	%
Interval between applications	365	days	Exposure duration dermal (H_D)	2	h
Half-life of active substance	30	days	Exposure duration inhal. (H_I)	24	h
Multiple application factor (MAF)	1.0		Exposure duration entry into treated crops (H_E)	0.25	h
Body weight (BW)	60	kg/person (adults)	Airborne Concentration of	0.001	mg/m^3

	10	kg/person (children)	Vapour (VC)		
Dermal absorption (DA)	70	% ('worst case')	Dislodgeable foliar residue (DFR)	3	µg/cm^2/kg a.s.
Inhalation absorption (IA)	100	%	Light clothing adjustment factor (CF)	18	%
Oral absorption (OA)	100	%	Saliva Extraction Factor (SE)	50	%
AOEL	0.04	mg/kg bw/d	Surface Area of Hands (SA)	20	cm^2
Spray drift dermal (SD) - 75th perc.	0.47	mL spray dilution (adult)	Frequency of Hand to Mouth (Freq)	20	events/h
	0.327	mL spray dilution (child)			
Spray drift inhal. (SI) - 75th perc.	0.00010	mL spray dilution (adult)	Dislodgeable residues object to mouth (DR_{OM})	20	%
	0.00022	mL spray dilution (child)			
Spray drift dermal (SD) - mean	0.22318	mL spray dilution (adult)	Ingestion Rate for Mouthing of Grass (IgR)	25	cm^2/d
	0.18	mL spray dilution (child)			
Spray drift inhal. (SD) - mean	0.00009	mL spray dilution (adult)	TC entry into treated crops - 75th perc.	7500	cm^2/h (adult)
	0.00017	mL spray dilution (child)		2250	cm^2/h (child)
Inhalation rate (IR)	16.57	m^3/d (adult)	TC entry into treated crops - mean:	5980	cm^2/h (adult)
	8.31	m^3/d (child)		1794	cm^2/h (child)

Table A 16: Estimation of longer term resident exposure towards Propaquizafop according to EFSA guidance

Adult			**Child**		
Spray drift (75th perc.)					
(SD x DA x (1- CF) + SI) x AR x MAF x V x DR/ BW					
Systemic exposure	**0.0026988**	**mg/kg bw/d**	**Systemic exposure**	**0.0112751**	**mg/kg bw/d**
% of AOEL:	**6.75**	**%**	**% of AOEL:**	**28.19**	**%**
Vapour (75th perc.)					
(VC x IR x IA) / BW					
Systemic exposure	**0.0002300**	**mg/kg bw/d**	**Systemic exposure**	**0.0010700**	**mg/kg bw/d**
% of AOEL:	**0.58**	**%**	**% of AOEL:**	**2.68**	**%**
Surface deposits (75th perc.)					
Dermal					
AR x MAF x D x TTR x TC x H_D x DA / BW					
Systemic exposure	**0.0005723**	**mg/kg bw/d**	**Systemic exposure**	**0.0012230**	**mg/kg bw/d**
Hand to mouth					
AR x MAF x D x TTR x SE x SA x Freq x H_D x OA / BW					
			Systemic exposure	**0.0000638**	**mg/kg bw/d**
Object to mouth					
AR x MAF x D x DR_{OM} x IgR x OA / BW					
			Systemic exposure	**0.0000336**	**mg/kg bw/d**
Total					
Systemic exposure	**0.0005723**	**mg/kg bw/d**	**Systemic exposure**	**0.0013205**	**mg/kg bw/d**

% of AOEL:	**1.43**	**%**	**% of AOEL:**	**3.30**	**%**
Entry into treated crops (75th perc.)					
Dermal					
AR x MAF x TC x H_D x DFR x DA / BW					
Systemic exposure	**0.0078750**	**mg/kg bw/d**	**Systemic exposure**	**0.0141750**	**mg/kg bw/d**
Hand to mouth					
AR x MAF x 100% x TTR x x SE x SA x Freq x H_D x OA / BW					
			Systemic exposure		**mg/kg bw/d**
Object to mouth					
AR x MAF x 100% x DR_{OM} x IgR x OA / BW					
			Systemic exposure		**mg/kg bw/d**
Total					
Systemic exposure	**0.0078750**	**mg/kg bw/d**	**Systemic exposure**	**0.0141750**	**mg/kg bw/d**
% of AOEL:	**19.69**	**%**	**% of AOEL:**	**35.44**	**%**
All pathways (mean)					
Systemic exposure			**0.0082100**	**mg/kg bw/d**	
Systemic exposure			**0.0195484**	**mg/kg bw/d**	
% of AOEL:	**20.52**	**%**	**% of AOEL:**	**48.87**	**%**

Table A 17: Input parameters considered for the estimation of longer term resident exposure

Intended use(s)	Alfalfa, yellow alfalfa, black medic, red clover, white clover, crimson clover, common sainfoin, vetch, little white bird's-foot, white melilot, yellow melilot, downward spraying		Drift reduction (DR)		%
Application rate (AR)	0.15	kg a.s./ha	Transfer coefficient surface deposits (TC)	7300	cm^2/h (adult)
				2600	cm^2/h (child)
Minimum water volume (V)	200	L/ha	Drift on surface (D) - 75th perc.	5.60	%
Buffer strip	2-3	m	Drift on surface (D) - mean	4.10	%
Number of applications (NA)	1		Turf Transferable Residues (TTR)	5	%
Interval between applications	365	days	Exposure duration dermal (H_D)	2	h
Half-life of active substance	30	days	Exposure duration inhal. (H_I)	24	h
Multiple application factor (MAF)	1.0		Exposure duration entry into treated crops (H_E)	0.25	h
Body weight (BW)	60	kg/person (adults)	Airborne Concentration of Vapour (VC)	0.001	mg/m^3
	10	kg/person (children)			
Dermal absorption (DA)	70	% ('worst case')	Dislodgeable foliar residue (DFR)	3	$\mu g/cm^2$/kg a.s.
Inhalation absorption (IA)	100	%	Light clothing adjustment factor (CF)	18	%
Oral absorption (OA)	100	%	Saliva Extraction Factor (SE)	50	%
AOEL	0.04	mg/kg bw/d	Surface Area of Hands (SA)	20	cm^2
Spray drift dermal (SD) - 75th perc.	0.47	mL spray dilution (adult)	Frequency of Hand to Mouth (Freq)	20	events/h
	0.327	mL spray dilution (child)			

Spray drift inhal. (SI) - 75th perc.	0.00010	mL spray dilution (adult)	Dislodgeable residues object to mouth (DR_{OM})	20	%
	0.00022	mL spray dilution (child)			
Spray drift dermal (SD) - mean	0.22318	mL spray dilution (adult)	Ingestion Rate for Mouthing of Grass (IgR)	25	cm^2/d
	0.18	mL spray dilution (child)			
Spray drift inhal. (SD) - mean	0.00009	mL spray dilution (adult)	TC entry into treated crops - 75th perc.	7500	cm^2/h (adult)
	0.00017	mL spray dilution (child)		2250	cm^2/h (child)
Inhalation rate (IR)	16.57	m^3/d (adult)	TC entry into treated crops - mean:	5980	cm^2/h (adult)
	8.31	m^3/d (child)		1794	cm^2/h (child)

Table A 18: Estimation of longer term resident exposure towards Propaquizafop according to EFSA guidance

Adult			**Child**		
Spray drift (75th perc.)					
(SD x DA x (1- CF) + SI) x AR x MAF x V x DR/ BW					
Systemic exposure	**0.0033735**	**mg/kg bw/d**	**Systemic exposure**	**0.0140939**	**mg/kg bw/d**
% of AOEL:	**8.43**	**%**	**% of AOEL:**	**35.23**	**%**
Vapour (75th perc.)					
(VC x IR x IA) / BW					
Systemic exposure	**0.0002300**	**mg/kg bw/d**	**Systemic exposure**	**0.0010700**	**mg/kg bw/d**
% of AOEL:	**0.58**	**%**	**% of AOEL:**	**2.68**	**%**
Surface deposits (75th perc.)					
Dermal					
AR x MAF x D x TTR x TC x H_D x DA / BW					
Systemic exposure	**0.0007154**	**mg/kg bw/d**	**Systemic exposure**	**0.0015288**	**mg/kg bw/d**
Hand to mouth					
AR x MAF x D x TTR x SE x SA x Freq x H_D x OA / BW					
			Systemic exposure	**0.0000798**	**mg/kg bw/d**
Object to mouth					
AR x MAF x D x DR_{OM} x IgR x OA / BW					
			Systemic exposure	**0.0000420**	**mg/kg bw/d**
Total					
Systemic exposure	**0.0007154**	**mg/kg bw/d**	**Systemic exposure**	**0.0016506**	**mg/kg bw/d**
% of AOEL:	**1.79**	**%**	**% of AOEL:**	**4.13**	**%**
Entry into treated crops (75th perc.)					
Dermal					
AR x MAF x TC x H_D x DFR x DA / BW					
Systemic exposure	**0.0015969**	**mg/kg bw/d**	**Systemic exposure**	**0.0043406**	**mg/kg bw/d**
Hand to mouth					
AR x MAF x 100% x TTR x x SE x SA x Freq x H_D x OA / BW					
			Systemic exposure		**mg/kg bw/d**
Object to mouth					

AR x MAF x 100% x DR_{OM} x IgR x OA / BW								
			Systemic exposure			**mg/kg bw/d**		
Total								
Systemic exposure	**0.0015969**	**mg/kg bw/d**	**Systemic exposure**		**0.0043406**	**mg/kg bw/d**		
% of AOEL:	**3.99**	**%**	**% of AOEL:**		**10.85**	**%**		
All pathways (mean)								
Systemic exposure			**0.0039531**	**mg/kg bw/d**	**Systemic exposure**		**0.0134527**	**mg/kg bw/d**
% of AOEL:	**9.88**	**%**	**% of AOEL:**			**33.63**	**%**	

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.