

**FINAL REGISTRATION REPORT**

**Part B**

**Section 6**

**Mammalian Toxicology**

Detailed summary of the risk assessment

Product code: CHR/H/IMA 40 SL

Product name(s):

Mazzam 40 SL, Zemax 40 SL

Chemical active substance:

Imazamox, 40 g/L

Central Zone

Zonal Rapporteur Member State: Poland

Co-Rapporteur Member State: Hungary, Romania, Slovakia

**CORE ASSESSMENT**

(authorization)

Applicant: Innvigo Sp. z o.o.

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## Version history

When	What
January 2023	Dossier sent for evaluation
September 2023	Applicant update
April 2024	zRMS evaluation of dRR
July 2024	Final version prepared by zRMS after Commenting period

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zRMS comments:

The text highlighted in grey was provided by the zRMS.

## 6 Mammalian Toxicology (KCP 7)

Considering winter oilseed rape magnitude of residue studies we are obliged to rely upon following studies taking account that according to Regulation (EC) No 1107/2009 Article 59 Data protection: The period of data protection is 30 months starting at the date of renewal in accordance to art. 43 in that Member State. Renewal of the product in Poland was in 20.11.2017 (R-45/2017), therefore data protection is over, and other applicants can refer to studies performed during inclusion and extensions of uses of the product Clentiga 262.5 SC.

### 6.1 Summary

**Table 6.1-1: Information on CHR/H/IMA 40 SL \***

Product name and code	CHR/H/IMA 40 SL/Mazzam/Zemax
Formulation type	Soluble concentration (SL)
Active substance(s) (incl. content)	imazamox; 40 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 CHR/H/IMA 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 CHR/H/IMA 40 SL according to Regulation (EC) No 1272/2008**

Hazard class(es), categories:	Skin irrit. 2 <del>H315</del> ; Skin Sens. 1A <del>H317</del> ; Eye Irrit. 2 <del>H319</del> ; Repr. 2 <del>H361d</del>
Hazard pictograms or Code(s) for hazard pictogram(s):	GHS07, GHS08
Signal word:	Warning
Hazard statement(s):	H315 – causes skin irritation; H317 – may cause an allergic skin reaction; H319 – causes serious eye irritation; <del>H361d - Suspected of damaging the unborn child.</del>
Precautionary statement(s):	<p><b>WARNING SECTION OF THE LABEL (first page):</b>  P201 – Obtain special instructions before use.  P280 - Wear protective gloves/<del>protective clothing</del>/eye protection/face protection.  <del>P281 – Use personal protective equipment as required.</del>  P302+352 - IF ON SKIN: Wash with plenty of soap and water.  P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  P308 + P313 - IF exposed or concerned: Get medical advice/attention.  <del>P321 – Specific treatment (see ... on this label)</del>  <del>P332+P313 – If skin irritation occurs: Get medical advice/attention</del>  <del>P362 – Take off contaminated clothing and wash before reuse.</del>  <del>P363 – Wash contaminated clothing before reuse.</del></p> <p><b>Other sections of the label:</b>  P202 – Do not handle until all safety precautions have been read and understood.  P261 - Avoid breathing <del>dust/fume/ gas/mist/vapours/spray</del>.  P264 – Wash hands thoroughly after handling.  <del>P362 + P364 - Take off contaminated clothing and wash it before reuse</del>  P272 - Contaminated work clothing should not be allowed out of the workplace.  P405 - Store locked up.  P501 - Dispose of contents/container to ...</p> <p>And P280 as follows:</p> <p><b>OPERATOR:</b>  <i>„Stosować rękawice ochronne, ochronę oczu lub twarzy oraz odzież roboczą (kombinezon), w trakcie przygotowywania cieczy użytkowej oraz rękawice ochronne i odzież roboczą w trakcie wykonywania zabiegu.”</i>  “Wear protective gloves, eye/face protection and work wear during mixing/loading and <del>protective gloves and work wear</del> during application.”</p> <p><b>Section “First Aid”</b>  <del>P308 + P313 - IF exposed or concerned: Get medical advice/attention.</del>  P305 + P351 + P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  <del>P310: Immediately call a POISON CENTER/doctor</del>  P337 + P313 - If eye irritation persists: Get medical advice/attention.  P302+352 - IF ON SKIN: Wash with plenty of soap and water.  P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention.</p>
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

**Table 6.1-3: Summary of risk assessment for operators, workers, bystanders and residents for CHR/H/IMA 40 SL**

	Result	PPE / Risk mitigation measures
Operators	Acceptable	Exposure: None Classification: eye/face protection, protective gloves (M&L)
Workers	Acceptable	None
Bystanders	Acceptable	None
Residents	Acceptable	None

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

A summary of the critical uses and the overall conclusion regarding exposure for operators, workers and bystanders/residents 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. safen- er/synergist (L/ha))  critical gap for operator, worker, bystander or resi- dent exposure based on [Exposure model]	Acceptability of exposure as- sessment				
			Method / Kind (incl. applica- tion technique ***	Max. number (min. interval between applications) a) per use b) per crop/ season	Max. applica- tion rate kg as/ha a) a.s. 1 b) a.s. 2	Water L/ha min / max			Operator	Worker	Bystander	Residents	
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	Peas (BBCH 10-19)	F	Spraying, LCTM	1 ; 1	a) 0.024-0.048	200 - 400	N/A						
2	Soya	F	Spraying, LCTM	1 ; 1	a) 0.032-0.048	200 - 400							
Minor uses according to Article 51 (field uses)													
5	Beans	F	Spraying, LCTM	1 ; 1	a) 0.024-0.048	200-400	N/A	*only for dry seeds use					
6	Broad bean	F	Spraying, LCTM	1 ; 1	a) 0.032-0.048	200-400	N/A	*only for dry seeds use					
7	Lentils	F	Spraying, LCTM	1 ; 1	a) 0.032-0.048	200-400	N/A	*only for dry seeds use					
8	Lupine	F	Spraying, LCTM	1 ; 1	a) 0.032-0.048	200-400	N/A	*only for dry seeds use					
9	Linseeds	F	Spraying, LCTM	1 ; 1	a) 0.024-0.048	200-400	N/A	*only for seeds use					
10	Spring oilseed rape	F	Spraying, LCTM	1 ; 1	a) 0.032-0.048	200-400	N/A	*only for seeds use					
11	Breadseed poppy	F	Spraying, LCTM	1 ; 1	a) 0.032-0.048	200-400	N/A	*only for seeds use					
12	Sesame	F	Spraying, LCTM	1 ; 1	a) 0.032-0.048	200-400	N/A	*only for seeds					

1	2	3	4	5	6	7	8	9	10
								use	
13	Mustard	F	Spraying, LCTM	1 ; 1	a) 0.024-0.048	200-400	N/A	*only for seeds use	
14	Sunflower	F	Spraying, LCTM	1 ; 1	a) 0.032-0.048	200-400	N/A	*only for seeds use	
15	Soy	F	Spraying, LCTM	1 ; 1	a) 0.032-0.048	200-400	N/A	*only for seeds use	
16	Safflower	F	Spraying, LCTM	1 ; 1	a) 0.032-0.048	200-400	N/A	*only for seeds use	
17	Borage	F	Spraying, LCTM	1 ; 1	a) 0.024-0.048	200-400	N/A	*only for seeds use	
18	Pumpkin	F	Spraying, LCTM	1 ; 1	a) 0.032-0.048	200-400	N/A	*only for seeds use	
19	Hemp	F	Spraying, LCTM	1 ; 1	a) 0.032-0.048	200-400	N/A	*only for seeds use	
20	Castor beans	F	Spraying, LCTM	1 ; 1	a) 0.032-0.048	200-400	N/A	*only for seeds use	
21	Cotton	F	Spraying, LCTM	1 ; 1	a) 0.024-0.048	200-400	N/A	*only for seeds use	
22	Tobacco <i>Nicotiana tabacum</i> (NIOTA)	F	Spraying, LCTM	1 ; 1	a) 0.015-0.048	200-400	N/A		
23	Coniferous / deciduous forest nurse- ries, Ornamental shrubs	F	Spraying, LCTM	1 ; 1	a) 0.015-0.048	200-400	N/A		
24	<i>Salix vimi- nalis</i> (SAXVI)  Wicker (1SAXG)	F	Spraying, LCTM	1 ; 1	a) 0.015-0.048	200-400	N/A		
25	<i>Ornamental</i>	F	Spraying, LCTM	1 ; 1	a) 0.015-0.048	200-400	N/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:

## 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)**

	Active substance - imazamox	
Common Name	Imazamox	
CAS-No.	114311-32-9	
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	<p>Hazard classes (s), categories:  <b>Repr. 2, H361d</b>  Aquatic Acute 1;  Aquatic Chronic 1</p> <p>Code(s) for hazard pictogram(s): GHS09</p> <p>Signal word: Very toxic to aquatic life; Very toxic to aquatic life with long lasting effects</p> <p>Hazard statement(s): H400, H410  Precautionary statement(s): P273, P391, P501</p>	
Additional C&L proposal	None	
AOEL systemic	2.25 mg/kg bw/d	
Reference	EFSA Journal 2016;14(4):4432	
Review Report/EFSA Conclusion for active substance	Operators	Use: Sunflower, Soybean, Alfalfa (field), tractor mounted boom sprayer, application rate 50g a.s./ha Exposure estimates (model): % of AOEL UK POEM Without PPE: 27.1 PPE (gloves during all phases): 2.6 German model Without PPE: 2.1 PPE (gloves and coverall): 0.8
	Workers	2 hours/day scouting and irrigation in Sunflower, Soybean, Alfalfa EuroPOEM II: % of AOEL Without PPE: 0.8
	Bystanders/Residents	Bystanders: < <b>0.1</b> % of AOEL (EUROPOEM II) Residents: < <b>0.1</b> % of AOEL (Martin et al.2008)

## 6.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for CHR/H/IMA 40 SL 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 CHR/H/IMA 40 SL**

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD <sub>50</sub> oral, rat (Calculation method)	Non determined – no relevant ingredient	yes	None	Žero K., 2022
LD <sub>50</sub> dermal, rat (Calculation method)	Non determined – no relevant ingredient	yes	None	Žero K., 2022
LC <sub>50</sub> inhalation, rat (Calculation method)	Non determined – no relevant ingredient	yes	None	Žero K., 2022
Skin irritation (Calculation method)	Irritant	yes	Skin Irrit. 2, H315	Žero K., 2022
Eye irritation (Calculation method)	Irritant	yes	Eye Irrit. 2, H319	Žero K., 2022
Skin sensitisation	Sensitising	yes	Skin Sens. 1A, H317	Žero K., 2022
Supplementary studies for combinations of plant protection products	No data – not required			

**Table 6.3-2: Additional toxicological information relevant for classification/labelling of CHR/H/IMA 40 SL**

	Substance (Concentration in product, % w/w)	Classification of the substance (acc. to the criteria in Reg. 1272/2008)	Reference	Classification of product (acc. to the criteria in Reg. 1272/2008)
Toxicological properties of active substance(s) (relevant for classification of product)	Imazamox (3.72% w/w)	Hazard statement(s) H400 – very toxic to aquatic life H410 – very toxic to aquatic life with long lasting effects	Reg. 1272/2008	None
Toxicological properties of active substance(s) (relevant for classification of product)	2-methylisothiazol-3(2H)-one	Hazard statement H317 – may cause an allergic reaction of skin	Reg. 1272/2008	Skin Sens. 1A – H317

\* 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

The following data on metabolites with the potential to reach the groundwater in concentrations above 0.1 µg/L and requiring relevance assessment were submitted. Note that the relevance assessment of the metabolites is reported in Part B.10; the submitted toxicological studies are summarized in this document.

Not relevant.

#### 6.4.1 CL312622

<p>zRMS Comments:</p>	<p>The PECgw value for metabolite submitted by the applicant is in accordance with PELMO 6.6.4, Hamburg modeling results. The maximum PECgw value for CL 312622 is above the trigger value of 0.1</p> <ul style="list-style-type: none"> <li>According to EFSA Scientific Report (EFSA Journal, 2016;14(4):4432), the metabolite CL 312622 is considered relevant because it cannot be excluded that it shares the developmental toxicity potential of imazamox. It leads to the critical area of concern. Available information, including toxicity studies, indicate that the metabolite has no pesticidal activity, it is of low acute oral toxicity to rats (&gt;5000 mg/kg b.w.) and it is not genotoxic in standard <i>in vitro</i> test battery (Ames test, Gene mutation assay (HPRT), In vitro /Micronucleus tests).</li> <li>Taking into account concerns presented above, the QSAR analysis was provided by the Applicant (2023, Cotterill J.V. and Jones S., In Silico Assessment of Reproductive and Developmental Toxicity of a Metabolite of Imazamox Fera Project Number: FR02225-20).</li> </ul> <p><u>Summary of the assessment of the results of QSAR analysis:</u></p> <ul style="list-style-type: none"> <li>The concerns: the suitability of the model for predicting the assessed toxic effects and the fact that the <i>in silico</i> analysis submitted for the assessment did not show any structural alerts for the parent substance (imazamox), which has demonstrated teratogenic effect.</li> </ul> <p>The following data were analysed and taken into account:</p> <ul style="list-style-type: none"> <li>no structural alerts for the metabolite CL 312622;</li> <li>comparison results of the chemical structure of imazapyr (substance without reproductive toxicity) and metabolite CL 312622 (presence of an additional carboxyl group, reducing the toxicity of the compound);</li> <li>predicted NOAEL values for tested compounds;</li> <li>projected PECgw values (below 0.75 µg/L) giving a predicted exposure to the metabolite in the worst case scenario (child, 5 kg) amounts to 0.0483 µg/L (0.002 % ADI for the parent substance);</li> </ul> <p><b>Conclusions:</b></p> <p>Toxicological data presented above indicate that the metabolite CL 312622 can be considered toxicologically non-relevant and the risk resulting from consumer exposure to this metabolite is very low.</p>
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An overview of the results of the accepted toxicological studies for groundwater metabolite CL 312622 is given in the following table. Full summaries of studies on the metabolite that have not previously been considered within an EU peer review process are described in detail in Appendix 2 (A 2.11 Other/Special Studies).

**Table 6.4-1: Summary of the results of toxicity studies for CL 312622**

Type of test, species (Guideline)	Result	Acceptability	Reference*
Acute oral LD50	> 5000 mg/kg bw (males and females)		(1995b) DocID ID-470-001
Microbial Mutagenicity Assay (Ames)	+S9a:Negative -S9b:Negative (at dose levels of 312.5, 625, 1250, 2500 and 5000 µg/plate)		Mulligan, E. (1995a) DocID ID-470-005
In vitro /Micronucleus test	+S9a:Negative -S9b:Negative (at dose lev- els/concentrations of 4.5, 8.9, 17.9, 35.8, 71.6, 143.2, 286.4, 572.8P, 1145.5, and 2291.0 µg/mL)		Bohnenberger, S. (2013a) DocID 2013/1113583
Gene mutation assay (HPRT)	+S9a:Negative -S9b:Negative (at dose lev- els/concentrations of 218.8, 437.5, 875.0, 1750.0 and 3500.0 µg/mL and 500.0, 1000.0 2000.0 and 3500.0 µg/mL (-S9 only))		Kapp, M.J. and Landsiedel, R. (2013) DocID 2013/1235040
QSAR	On balance, the weight of evidence obtained in this study suggests that the Metabolite is unlikely to be a Reproductive toxicant (there were no Reproduc- tive Toxicity structural alerts (from either Derek Nexus or the OECD QSAR Toolbox for any of the test compounds). The test compounds were all pre- dicted to be non-Estrogen and non- Androgen Receptor bind- er in the VEGA models. There is no evidence to suggest that the Metabo- lite is likely to be Devel- opmental Toxicant (there were no Developmental Toxici- ty structural alerts from either Derek Nexus or the OECD QSAR Toolbox) and a high NOEL/LOEL es-	Accepted	J.V.Cotterill, S. Jones, Study code: FR02225-20

Type of test, species (Guideline)	Result	Acceptability	Reference*
	<p>imate of 998 mg/kg/day was obtained. However, it should be noted that there were no structural alerts for Developmental Toxicity for Imazamox either, which is known to be teratogenic in rabbits (but not in rats). Unfortunately, there were no reliable estimates obtained using QSAR models for Developmental Toxicity for any of the test compounds to add to the weight of evidence. The Developmental toxicity NOEL/LOEL estimate for the Metabolite (998 mg/kg/day) however, was higher than that of Imazamox (325 mg/kg/day; Reprotox GHS classification Repr2, H361d, suspected of damaging the unborn child) and similar to that of Imazapyr (956 mg/kg/day; no Reprotox GHS classification). This indicates that the Metabolite is of less toxicological concern (for Developmental Toxicity) than Imazamox.</p>		

## 6.5 Dermal Absorption (KCP 7.3)

A summary of the dermal absorption rates for the active substances in CHR/H/IMA are presented in the following table.

**Table 6.5-1: Dermal absorption rates for active substances in CHR/H/IMA 40 SL**

	Imazamox	
	Value	Reference
Concentrate	10 % 50%	EFSA Journal 2017;15(6):4873
Dilution	50 %	EFSA Journal 2017;15(6):4873

### 6.5.1 Justification for proposed values - imazamox

No data on dermal absorption for imazamox in CHR/H/IMA 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 imazamox**

	Value	Justification for value	Acceptability of justification
Concentrate	<del>10 %</del> 50%	<p>A default dermal absorption value of 10% may be applied for concentrated products that are liquid formulated.</p> <p>A default dermal absorption value of 50% may be applied for concentrated products that are water-based/dispersed or solid-formulated, because nominal content of <b>penoxulam imazamox</b> in CHR/H/IMA 40 SL is 40 g/L and therefore this active substance should be treated like dilution</p>	Accepted
Dilution	50 %	A default dermal absorption value of 50% may be applied for liquid-formulated.	Accepted

## 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	CHR/H/IMA 40 SL
Formulation type	SL
Category	Herbicide
Container size(s), short description	<p>HDPE: Bottles/Jars: 180 – 2000 mL Containers/Cannisters: 3000 – 22000 mL</p> <p>HDPE/PA, HDPE/PA COEX: Bottles: 320 – 1100 mL and 5000 -5500 mL Containers/Cannisters: 5000 – 10000 mL</p> <p>HDPE/F: Bottles: 310 – 1200 mL and 5950 mL Cannisters: 5950 mL</p> <p>HDPE/EvOH: Bottles/Containers/Cannisters: 500-20000 mL</p>
Active substance(s)	<b>Imazamox</b>

(incl. content)	40 g/L
AOEL systemic	2.25 mg/kg bw/d
Inhalation absorption	100 %
Oral absorption	100 %
Dermal absorption	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 Central and Southern Zone is given in Part B, Section 0.

#### Justification

No new endpoint were established

### 6.6.2 Operator exposure (KCP 7.2.1)

Comments of zRMS:	<p>The estimations of operator exposure to imazamox contained in the formulation CHR/H/IMA 40 SL (based on AOEM) performed by the Applicant are correct.</p> <p>Conclusions:</p> <p>According to the estimation based on AOEM, the use of CHR/H/IMA 40 SL containing imazamox (40 g/L) <b>causes acceptable health risk for unprotected operator</b>. The potential exposure to the active substance for all proposed crop types is significantly below the AOEL. However, taking into account the classification of the product, eye/face shield, protective gloves and protective clothing during M&amp;L is mandatory.</p> <p>Thus, the following sentence regarding the use of PPE is recommended by the evaluator to be placed on the label:</p> <p><i>„Stosować rękawice ochronne, ochronę oczu lub twarzy oraz odzież roboczą (kombonezon) w trakcie przygotowywania cieczy roboczej oraz rękawice ochronne i odzież roboczą w czasie wykonywania zabiegu”</i></p> <p>“Wear protective gloves, eye/face protection and work wear during mixing/loading and protective gloves and work wear during application”.</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 CHR/H/IMA 40 SL according to the critical use(s) is presented in Table 6.6-2. Outcome of the estimation is presented in Table 6.6-3. Detailed calculations are in Appendix 3.

**Table 6.6-2: Exposure models for intended uses**

Critical use(s)	Legume vegetables (max. 1.2 L product/ha)
Model(s)	EFSA Model (AOEM) ver. 30.03.2015

Critical use(s)	Oilseeds (max. 1.2 L product/ha)
Model(s)	EFSA Model (AOEM) ver. 30.03.2015)
Critical use(s)	Leaf vegetables and fresh herbs (max. 1.2 L product/ha)
Model(s)	EFSA Model (AOEM) ver. 30.03.2015)
Critical use(s)	Ornamentals (max. 1.2 L product/ha)
Model(s)	EFSA Model (AOEM) ver. 30.03.2015)

**Table 6.6-3: Estimated operator exposure**

**Legume vegetables**

Vegetable					
		Imazamox		Imazamox	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to low crops Application rate: 0.048 kg a.s./ha					
EFSA Model (AOEM) Body weight: 60 kg Concentration of a.s. in spray dilution: 0.24 g a.s./L	no PPE*	1.9140685	1.42%	0.1402644	6.23
	+ type of PPE (e.g. Gloves mixing/loading)	0.3123234	0.23%	-	-

**Oilseeds**

		Imazamox		Imazamox	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to low crops Application rate: 0.048 kg a.s./ha					
EFSA Model (AOEM) Body weight: 60 kg Concentration of a.s. in spray dilution: 0.24 g a.s./L	no PPE*	1.9140685	1.42%	0.1402644	6.23
	+ type of PPE (e.g. Gloves mixing/loading)	0.3123234	0.23%	-	-

**Leaf vegetables and fresh herbs**

Leafy Vegetables and Fresh Herbs					
		Imazamox		Imazamox	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to low crops					



Application rate: 0.048 kg a.s./ha					
<b>EFSA Model (AOEM)</b>	no PPE*	1.9140685	1.42%	0.1402644	6.23
Body weight: 60 kg Concentration of a.s. in spray dilution: 0.24 g a.s./L	+ type of PPE (e.g. Gloves mixing/loading)	0.3123234	0.23%	-	-

### Ornamentals

		Imazamox		Imazamox	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to low crops Application rate: 0.048 kg a.s./ha					
<b>EFSA Model (AOEM)</b>	no PPE*	1.4237548	1.05%	0.0564941	2.51
Body weight: 60 kg Concentration of a.s. in spray dilution: 0.24 g a.s./L	+ type of PPE (e.g. Gloves mixing/loading)	0.9381478	0.69%	-	-

\* no PPE: Operator wearing T-shirt and shorts

\*\* no PPE: Operator wearing long sleeved shirt, long trousers (“permeable”) but no gloves

### 6.6.3 Measurement of operator exposure

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

### 6.6.4 Worker exposure (KCP 7.2.3)

Comments of zRMS:	<p>The estimations of worker exposure to the active substance contained in CHR/H/IMA 40 SL performed by the Applicant are accepted. According to the estimation results (AOEM), the use of CHR/H/IMA 40 SL containing imazamox (40 g/kg) <b>causes acceptable health risk for an unprotected worker</b> assuming 2 h working day in the case of inspection, irrigation (oilseeds) and 8 hour working day for searching, reaching and picking (legumes vegetables, leaf vegetables), as well as cutting, sorting, bundling, carrying (ornamentals). The results of exposure estimations to the active substance are significantly below the AOEL value for izamazox for all intended uses.</p> <p>According to current requirements of Polish Authorities, if a PPP is anticipated to be used only once per season EUROPOEM II should be used to estimate worker exposure to-</p>
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	wards an active substance of such formulation. Therefore, the exposure data has been recalculated based on EUROPOEM II and the results are as follows:	
		Exposure (mg a.s./day)
	% of systemic AOEL	
	Ornamentals (worst scenario, TC: 0.5 m <sup>2</sup> /h) Work duration: 8 h	
	Work wear, no PPE	2.88
	Work wear and protective gloves	0.576
<p>According to the estimation results (EUROPOEM II), the use of CHR/H/IMA 40 SL containing imazamox (40 g/kg) <b>causes acceptable health risk for unprotected worker</b> during 8 hour working day (searching, reaching and picking). The exposure to the active substance is below the AOEL value.</p> <p><u>Conclusions:</u></p> <p>According to the estimations results, the use of CHR/H/IMA 40 SL <b>does not cause unacceptable health risk for a worker wearing work wear (no PPE)</b> according to EFSA model and EUROPOEM II.</p> <p>Bearing in minds the hygienic rules and the classification of the product (especially H317, including the risk to most sensitive individuals and no dose-effect relationship in case of sensitization), the following sentence regarding the use of PPE <u>is recommended</u> by the evaluator to be placed in the section of precautions for the workers:</p> <p>„Stosować rękawice ochronne oraz odzież roboczą podczas zbiorów.”</p> <p>“Wear protective gloves and protective clothing during harvesting.”</p>		

#### 6.6.4.1 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 CHR/H/IMA 40 SL according to the critical use(s). Outcome of the estimation is presented in Table 6.6-5. Detailed calculations are in Appendix 3.

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

Critical use(s)	Legume vegetables (max. 1.2 L product/ha)
Model(s)	EFSA Model (AOEM) ver. 30.03.2015
Critical use(s)	Oilseeds (max. 1.2 L product/ha)
Model(s)	EFSA Model (AOEM) ver. 30.03.2015)
Critical use(s)	Leaf vegetables and fresh herbs (max. 1.2 L product/ha)
Model(s)	EFSA Model (AOEM) ver. 30.03.2015)
Critical use(s)	Ornamentals (max. 1.2 L product/ha)
Model(s)	EFSA Model (AOEM) ver. 30.03.2015)

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

Legume vegetables

		Imazamox	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Number of applications and application rate:		1 x 0.048 kg a.s./ha	
28 hours/day <sup>(1)</sup> , TC: 14000 cm <sup>2</sup> /person/h <sup>(2)</sup> Body weight: 60 kg	no PPE <sup>(3)</sup>	3.3408	2.47%
	with PPE <sup>(4)</sup>	1.4400	1.07%

#### Oilseeds

		Imazamox	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Number of applications and application rate:		1 x 0.048 kg a.s./ha	
2 hours/day <sup>(1)</sup> , TC: 14000 cm <sup>2</sup> /person/h <sup>(2)</sup> Body weight: 60 kg	no PPE <sup>(3)</sup>	1.8000	1.33%
	with PPE <sup>(4)</sup>	0.2016	0.15%

#### Leaf vegetables and fresh herbs

		Imazamox	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Number of applications and application rate:		1 x 0.048 kg a.s./ha	
28 hours/day <sup>(1)</sup> , TC: 14000 cm <sup>2</sup> /person/h <sup>(2)</sup> Body weight: 60 kg	no PPE <sup>(3)</sup>	1.8000 0.055680	1.33% 2.47
	with PPE <sup>(4)</sup>	0.2016	0.15%

#### Ornaments

		Imazamox	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Number of applications and application rate:		1 x 0.048 kg a.s./ha	
28 hours/day <sup>(1)</sup> , TC: 14000 cm <sup>2</sup> /person/h <sup>(2)</sup> Body weight: 60 kg	no PPE <sup>(3)</sup>	8.0640	5.97%
	with PPE <sup>(4)</sup>	2.8800	2.13%

- (1) e.g. 8 h/day for professional applications for harvesting, pruning, tying, thinning or weeding activities etc. or 2 h/day for professional applications for maintenance, inspection or irrigation activities etc.
- (2) e.g. EUROPOEM II, 2002, Post-Application Exposure of Workers to Pesticides in Agriculture or US-EPA policy paper [EPA, Science Advisory Council for Exposure; Agricultural Transfer Coefficients, Policy # 3.]. TC: Transfer coefficient
- (3) no PPE: Worker wearing long sleeved shirt, long trousers ("permeable") but no gloves
- (4) with PPE: type of PPE / see 'Instructions for use'

#### 6.6.4.2 Refinement of generic DFR value (KCP 7.2)

Not relevant

#### 6.6.4.3 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.

#### 6.6.5 Bystander and resident exposure (KCP 7.2.2)

Comments of zRMS:	<p>The results of bystander and resident exposure estimations to imazamox (40 g/L) contained in the formulation CHR/H/IMA 40 SL presented by the applicant are accepted.</p> <p>The reference values acutely toxic active substance (RVAAS) for imazamox is not allocated. Consequently, it is assumed that the estimation of bystander exposure is covered by the calculation of resident exposure towards imazamox.</p> <p><b>Summary and conclusions:</b></p> <p>The estimations performed according to AOEM indicate that the systemic exposure to imazamox (40 g/L), contained in the formulation CHR/H/IMA 40 SL does not exceed the values of AOEL for the active substance.</p> <p>The <b>incidental short-time exposure of bystander and resident (children and adult)</b> to imazamox contained in the formulation CHR/H/IMA 40 SL <b>causes no risk</b> to human health if the product is used in accordance to the intended uses listed in the GAP Table.</p>
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##### 6.6.5.1 Estimation of bystander and resident exposure

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

**Table 6.6-7: Exposure models for intended uses**

Critical use(s)	Legume vegetables (max. 1.2 L product/ha)
Model(s)	EFSA Model (AOEM) ver. 30.03.2015
Critical use(s)	Oilseeds (max. 1.2 L product/ha)
Model(s)	EFSA Model (AOEM) ver. 30.03.2015)
Critical use(s)	Leaf vegetables and fresh herbs (max. 1.2 L product/ha)
Model(s)	EFSA Model (AOEM) ver. 30.03.2015)
Critical use(s)	Ornamentals (max. 1.2 L product/ha)
Model(s)	EFSA Model (AOEM) ver. 30.03.2015)

**Table 6.6-8: Estimated bystander and resident exposure**

Legume vegetables

	Imazamox		Imazamox	
Model data	Total absorbed dose (mg/kg/day)	Total absorbed dose (mg/kg/day)	Total absorbed dose (mg/kg/day)	Total absorbed dose (mg/kg/day)
Tractor mounted boom spray application outdoors to low crops				
Bystanders (adult) Drift rate: 5.60 % (2-3 m) Body weight: 60 kg	Covered by resident value	Covered by resident value	Covered by resident value	Covered by resident value
Bystanders (children) Drift rate: 5.60 % (2-3 m) Body weight: 10 kg	Covered by resident value	Covered by resident value	Covered by resident value	Covered by resident value
Residents (adult) Drift rate: 5.60 % (2-3 m) Body weight: 60 kg	0.0462720	0.03%	0.0025101	0.11
Residents (children) Drift rate: 5.60 % (2-3 m) Body weight: 10 kg	0.0322296	0.14%	0.0063589	0.28

#### Oilseeds

	Imazamox		Imazamox	
Model data	Total absorbed dose (mg/kg/day)	% of systemic AOEL	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to low crops				
Bystanders (adult) Drift rate: 5.60 % (2-3 m) Body weight: 60 kg	Covered by resident value	Covered by resident value	Covered by resident value	Covered by resident value
Bystanders (children) Drift rate: 5.60 % (2-3 m) Body weight: 10 kg	Covered by resident value	Covered by resident value	Covered by resident value	Covered by resident value
Residents (adult) Drift rate: 5.60 % (2-3 m) Body weight: 60 kg	0.0462720	0.03%	0.0025101	0.11
Residents (children) Drift rate: 5.60 % (2-3 m) Body weight: 10 kg	0.0322296	0.14%	0.0063589	0.28

#### Leaf vegetables and fresh herbs

	Imazamox		Imazamox	
Model data	Total absorbed dose (mg/kg/day)	% of systemic AOEL	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to low crops				

Bystanders (adult) Drift rate: 5.60 % (2-3 m) Body weight: 60 kg	Covered by resident value	Covered by resident value	Covered by resident value	Covered by resident value
Bystanders (children) Drift rate: 5.60 % (2-3 m) Body weight: 10 kg	Covered by resident value	Covered by resident value	Covered by resident value	Covered by resident value
Residents (adult) Drift rate: 5.60 % (2-3 m) Body weight: 60 kg	0.0462720	0.03%	0.0025101	0.11
Residents (children) Drift rate: 5.60 % (2-3 m) Body weight: 10 kg	0.0322296	0.14%	0.0063589	0.28

#### Ornamentals

	Imazamox		Imazamox	
Model data	Total absorbed dose (mg/kg/day)	% of systemic AOEL	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to low crops				
Bystanders (adult) Drift rate: 5.60 % (2-3 m) Body weight: 60 kg	Covered by resident value	Covered by resident value	Covered by resident value	Covered by resident value
Bystanders (children) Drift rate: 5.60 % (2-3 m) Body weight: 10 kg	Covered by resident value	Covered by resident value	Covered by resident value	Covered by resident value
Residents (adult) Drift rate: 5.60 % (2-3 m) Body weight: 60 kg	0.1191840	0.09%	0.0025101	0.11
Residents (children) Drift rate: 5.60 % (2-3 m) Body weight: 10 kg	0.0730848	0.32%	0.0063589	0.28

### 6.6.5.2 Measurement of bystander and/or resident exposure

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

### 6.6.6 Combined exposure

Not relevant. The product contains only one active substance.

From a scientific point of view it is regarded necessary to take into account potential combination effects. However, the evaluation of cumulative or synergistic effects as requested by Art. 4 (3b) of Regulation

(EC) No. 1107/2009 should only be performed when harmonised “scientific methods accepted by the Authority to assess such effects are available.”

## Appendix 1 Lists of data considered in support of the evaluation

### List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 7.1.1 KCP 7.1.2 KCP 7.1.3 KCP 7.1.4 KCP 7.1.5 KCP 7.1.6 KCP 7.1.7 KCP 7.1.8	Žero K.	2022	Toxicological classification of product CHR/H/IMA 40 SL based on calculation method taking into consideration health hazards of constituent substances PUH Chemirol Sp. z o. o. Non-GLP Unpublished	N	Chemirol
KCP. 7/01	J.V. Cotterill S. Jones	2023	IN SILICO ASSESSMENT OF REPRODUCTIVE AND DEVELOPMENTAL TOXICITY OF A METABOLITE OF IMAZAMOX FR02225-20 Fera Science Ltd., Sand Hutton, York, YO41 1LZ, UK GLP Unpublished	N	Chemirol

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

Considering winter oilseed rape magnitude of residue studies we are obliged to rely upon following studies taking account that according to Regulation (EC) No 1107/2009 Article 59 Data protection: The period of data protection is 30 months starting at the date of renewal in accordance to art. 43 in that Member State. Renewal of the product in Poland was in 20.11.2017 (R-45/2017), therefore data protection is over, and other applicants can refer to studies performed during inclusion and extensions of uses of the product Clentiga 262.5 SC.



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
KCA 7.1	-	1995	Oral LD50 study in Albino Rats with AC 312,622 A95-92 GLP Unpublished	Y	BASF
KCA 7.1	Mulligan E.	1995	Microbial mutagenicity plate incorporation assay of CL 312,622 American Cyanamid Co.; Princeton NJ; United States of America ID-470-005 Yes unpublished	N	BASF
KCA 7.1	Bohnenberger S.,	2013	In vitro micronucleus test in Chinese hamster V79 cells with Reg.No. 4110542 (metabolite of BAS 720 H, Imazamox) 2013/1113583 Harlan Cytotest Cell Research GmbH, Rossdorf, Germany Fed.Rep. GLP Unpublished	N	BASF
KCA 7.1	Kapp M., D.,Landsiedel R.,	2013	Reg.No. 4110542 (metabolite of BAS 720 H, Imazamox) - In vitro gene mutation test in CHO cells (HPRT locus assay) 2013/1235040 BASF SE, Ludwigshafen/Rhein, Germany, Fed.Rep GLP Unpublished	N	BASF

## Appendix 2 Detailed evaluation of the studies relied upon

### A 2.1 Statement on bridging possibilities

Not required

### A 2.2 Acute oral toxicity (KCP 7.1.1)

Comments of zRMS:	<b>Conclusion:</b> Taking into account the composition of the product, the formulation CHR/H/IMA 40 SL <b>does not require classification in regards to oral acute toxicity.</b>
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Reference:	KCP 7.1.1
Report	Žero K., Toxicological classification of product CHR/H/IMA 40 SL based on calculation method taking into consideration health hazards of constituent sub-stances, 2022
Guideline(s):	Regulation (EC) No. 1272/2008
Deviations:	-
GLP:	No
Acceptability:	Yes
Duplication (if vertebrate study)	No

According to point 7.1.1 of Part A of Annex to the Commission Regulation (EU) No 284/2013 as regards the data requirements for plant protection products:

” A test for acute oral toxicity shall be carried out, unless the applicant can justify an alternative approach under Regulation (EC) No 1272/2008. In the latter case, acute oral toxicity of all components shall be provided or reliably predicted with a validated method. Consideration shall be given to the possible effects of components on the toxic potential of the total mixture.”

The complete composition of the formulation with the classification of individual ingredients is available in part C.

Due to the fact, that all components of the formulation CHR/H/IMA 40 SL are known, the acute oral toxicity test is not necessary.

### Materials and methods

Each type of hazard is considered separately, taking into account the sum of the components posing a hazard. We use the summation method using the formula:

$$ATE_{mix} = \frac{100}{\sum_{i=1}^n \frac{C_i}{ATE_i}}$$

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<sub>i</sub> - Acute Toxicity Estimate of ingredient i.

Table 3.1.2 Conversion from experimentally obtained acute toxicity range values (or acute toxicity hazard categories) to acute toxicity point estimates for classification for the respective routes of exposure

Exposure routes	Classification Category or experimentally obtained acute toxicity range estimate	Converted acute toxicity point estimate (see Note 1)
Oral (mg/kg body-weight)	0 < Category 1 ≤ 5	0,5
	5 < Category 2 ≤ 50	5
	50 < Category 3 ≤ 300	100
	300 < Category 4 ≤ 2 000	500
Dermal (mg/kg body-weight)	0 < Category 1 ≤ 50	5
	50 < Category 2 ≤ 200	50
	200 < Category 3 ≤ 1 000	300
	1 000 < Category 4 ≤ 2 000	1 100
Gases (ppmV)	0 < Category 1 ≤ 100	10
	100 < Category 2 ≤ 500	100
	500 < Category 3 ≤ 2 500	700
	2 500 < Category 4 ≤ 20 000	4 500
Vapours (mg/l)	0 < Category 1 ≤ 0,5	0,05
	0,5 < Category 2 ≤ 2,0	0,5
	2,0 < Category 3 ≤ 10,0	3
	10,0 < Category 4 ≤ 20,0	11
Dust/mist (mg/l)	0 < Category 1 ≤ 0,05	0,005
	0,05 < Category 2 ≤ 0,5	0,05
	0,5 < Category 3 ≤ 1,0	0,5
	1,0 < Category 4 ≤ 5,0	1,5

**Note 1**

These values are designed to be used in the calculation of the ATE for classification of a mixture based on its components and do not represent test results.

Three ingredients are classified in this class of hazard:

- ☐ 0.0045 % (Acute Tox. 4, H302)
- ☐ 0.0045% (Acute Tox. 3, H301)
- ☐ 0.00005 % (Acute Tox. 3, H301)

## Results and discussions

According to Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of sub-stances and mixtures (v. 5.0, July, 2017) the 'relevant ingredients' of a mixture for this class of hazard are those which are present in concentrations of 0.1% for ingredients classified as acute toxic at category 1-3 or 1% for ingredients classified as acute toxic at category 4.

None of the ingredients classified in this hazard class is relevant. Therefore the whole formulation is not classified as toxic by ingestion.

## Conclusions

Due to the fact the formulation does not contain an ingredient classified as acute toxic in a concentration higher than 0.1%, the product is not classified as toxic by ingestion.

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

Comments of zRMS:	Conclusion:
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	Taking into account the composition of the product, the formulation CHR/H/IMA 40 SL <b>does not require classification in regards to dermal acute toxicity.</b>
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### A 2.3.1 Study 1

Reference:	KCP 7.1.2
Report	Žero K., Toxicological classification of product CHR/H/IMA 40 SL based on calculation method taking into consideration health hazards of constituent sub-stances, 2022
Guideline(s):	Regulation (EC) No. 1272/2008
Deviations:	-
GLP:	No
Acceptability:	Yes
Duplication (if vertebrate study)	No

According to point 7.1.2 of Part A of Annex to the Commission Regulation (EU) No 284/2013 as regards the data requirements for plant protection products:

”A test for dermal toxicity shall be carried out on a case by case basis, unless the applicant can justify an alternative approach under Regulation (EC) No 1272/2008. In the latter case, acute dermal toxicity of all components shall be provided or reliably predicted with a validated method. Consideration shall be given to the possible effects of components on the toxic potential of the total mixture. Findings of severe skin irritation or corrosion in the dermal study may be used instead of performing a specific irritation study.”

The complete composition of the formulation with the classification of individual ingredients is available in part C.

Due to the fact, that all components of the formulation CHR/H/IMA 40 SL are known, the acute dermal toxicity test is not necessary.

#### Materials and methods

Only one ingredient is classified in this class of hazard.

☐ 0.0045 % (Acute Tox. 3, H311)

#### Results and discussions

According to Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of sub-stances and mixtures (v. 5.0, July, 2017) the ‘relevant ingredients’ of a mixture for this class of hazard are those which are present in concentrations of 0.1% for ingredients classified as acute toxic at category 1-3 or 1% for ingredients classified as acute toxic at category 4.

None of the ingredients classified in this hazard class is relevant. Therefore the whole formulation is not classified as toxic by contact.

#### Conclusions

Due to the fact the formulation does not contain an ingredient classified as acute toxic in a concentration higher than 0.1%, the product is not classified as toxic by contact.

## A 2.4 Acute inhalation toxicity (KCP 7.1.3)

### A 2.4.1 Study 1

Comments of zRMS:	<u>Conclusion:</u> Taking into account the composition of the product, the formulation CHR/H/IMA 40 SL <b>does not require classification in regards to inhalation toxicity.</b>
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Reference:	KCP 7.1.3
Report	Žero K., Toxicological classification of product CHR/H/IMA 40 SL based on calculation method taking into consideration health hazards of constituent substances, 2022
Guideline(s):	Regulation (EC) No. 1272/2008
Deviations:	-
GLP:	No
Acceptability:	Yes
Duplication (if vertebrate study)	No

Inhalation study on CHR/H/IZOXACYC 250 SC is not required according to point 7.1.3 of Part A of Annex to the Commission Regulation (EU) No 284/2013 as regards the data requirements for plant protection products the inhalation test must be carried out since the preparation is:

- a gas or liquefied gas,
- a smoke generating formulation or fumigant,
- used with fogging equipment,
- a vapor releasing preparation,
- an aerosol,
- a powder containing a significant proportion of particles of diameter  $< 50 \mu\text{m}$  ( $> 1\%$  on a weight basis),
- to be applied from aircraft in cases where inhalation exposure is relevant,
- contains an active substance with a vapor pressure  $> 1 \times 10^{-2}$  Pa and is to be used in enclosed spaces such as warehouses or glasshouses,
- to be applied in a manner which generates a significant proportion of particles or droplets of diameter  $< 50 \mu\text{m}$  ( $> 1\%$  on a weight basis).

### Materials and methods

Three ingredients are classified in this class of hazard:

- ☐ 0.0045 % (Acute Tox. 2, H330)
- ☐ 0.0045% (Acute Tox. 2, H330)
- ☐ 0.00005 % (Acute Tox. 2, H330)

According to Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures (v. 5.0, July, 2017) the ‘relevant ingredients’ of a mixture for this class of hazard are those

which are present in concentrations of 0.1% for ingredients classified as acute toxic at category 1-3 or 1% for ingredients classified as acute toxic at category 4.

None of the ingredients classified in this hazard class is relevant. Therefore the whole formulation is not classified as toxic by inhalation.

### Conclusions

Due to the fact the formulation does not contain an ingredient classified as acute toxic in a concentration higher than 0.1%, the product is not classified as toxic by inhalation.

## A 2.5 Skin irritation (KCP 7.1.4)

Comments of zRMS:	<u>Conclusion:</u> Acc. to the Regulation 1272/2008 and data presented in part C of dRR, the sum of the concentrations of the relevant ingredients is above generic concentration limit that triggers classification of the mixture in regards to the skin irritation. ( $\geq 10\%$ ) Taking into account the composition of the product, the formulation CHR/H/IMA 40 SL <b>requires classification in regards to skin irritation (Skin Irrit. 2, H315).</b>
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### A 2.5.1

#### Study 1

Reference:	KCP 7.1.4
Report	Žero K., Toxicological classification of product CHR/H/IMA 40 SL based on calculation method taking into consideration health hazards of constituent substances, 2022
Guideline(s):	Regulation (EC) No. 1272/2008
Deviations:	-
GLP:	No
Acceptability:	Yes
Duplication (if vertebrate study)	No

According to point 7.1.4 of Part A of Annex to the Commission Regulation (EU) No 284/2013 as regards the data requirements for plant protection products:

” The skin irritancy of the plant protection product shall be reported based on the tiered approach, unless the applicant can justify an alternative approach under Regulation (EC) No 1272/2008. In the latter case, skin irritation properties of all components shall be provided or reliably predicted with a validated method. Consideration shall be given to the possible effects of components on the irritant potential of the total mixture.”

The complete composition of the formulation with the classification of individual ingredients is available in part C.

Due to the fact, that all components of the formulation CHR/H/IMA 40 SL are known, skin corrosive test is not necessary.

## Materials and methods

For consideration of corrosive and irritant properties the following table applies:

Table 3.2.3

**Generic concentration limits of ingredients classified as skin corrosion (Category 1, 1A, 1B or 1C)/skin irritation (Category 2) that trigger classification of the mixture as skin corrosion/skin irritation where the additivity approach applies**

Sum of ingredients classified as:	Concentration triggering classification of a mixture as:	
	Skin corrosion	Skin irritation
	Category 1 (see note below)	Category 2
Skin corrosion Sub-Category 1A, 1B, 1C or Category 1	$\geq 5 \%$	$\geq 1 \%$ but $< 5 \%$
Skin irritation Category 2		$\geq 10 \%$
$(10 \times \text{Skin corrosion Sub-Category 1A, 1B, 1C or Category 1}) + \text{Skin irritation Category 2}$		$\geq 10 \%$

Five ingredients are relevant in this class of hazard.

- ☐ 0.93 % (Skin Corr. 1B, H314)
- ☐ 0.11 % (Skin Corr. 1A, H314)
- ☐ 0.0045 % (Skin Corr. 1B, H314)
- ☐ 0.00005% (Skin Corr. 1B, H314)
- ☐ 0.0045 % (Skin Irrit. 2, H315)

We use the summation method, consisting in adding up the percentages of all ingredients classified in the each class.

$$10 (\Sigma C_{SkinCorr.}) + \Sigma C_{SkinCorr.} = 10 \times (0.93 \% + 0.11 \% + 0.0045\% + 0.00005\%) + 0.0045 \% = 10.45\%$$

## Results

The concentrations sum of relevant ingredients (10.45 %) is higher than generic concentration level (10%). Therefore the formulation is classified as irritating to skin (**Skin Irrit. 2, H315**).

## Conclusion

According to the calculation method, CHR/H/IMA 40 SL is a skin irritant (Skin Irrit. 2, H317). Thus, classification is required according to Regulation (EC) No. 1272/2008.

### A 2.6 Eye irritation (KCP 7.1.5)

Comments of zRMS:	<b>Conclusion:</b> Acc. to the Regulation 1272/2008 and data presented in part C of dRR, the sum of the concentrations of the relevant ingredients is above the generic concentration limit that triggers classification of the mixture in regards to the eye irritation. ( $\geq 1\%$ ) Taking into account the composition of the product, the formulation CHR/H/IMA 40 SL <b>requires classification in regards to eye irritation (Eye Irrit. 2, H319).</b>
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#### A 2.6.1 Study 1

Reference:	KCP 7.1.5
Report	Žero K., Toxicological classification of product CHR/H/IMA 40 SL based on calculation method taking into consideration health hazards of constituent substances, 2022
Guideline(s):	Regulation (EC) No. 1272/2008
Deviations:	-
GLP:	No
Acceptability:	Yes
Duplication (if vertebrate study)	No

According to point 7.1.5 of Part A of Annex to the Commission Regulation (EU) No 284/2013 as regards the data requirements for plant protection products:

” Eye irritation tests shall be provided, unless it is likely that severe effects on the eyes may be produced or the applicant can justify an alternative approach under Regulation (EC) No 1272/2008. In the latter case, eye irritation properties of all components shall be provided or reliably predicted with a validated method. Consideration shall be given to the possible effects of components on the irritant potential of the total mixture.”

The complete composition of the formulation with the classification of individual ingredients is available in part C.

Due to the fact, that all components of the formulation CHR/H/IZOXACYP 250 SC are known, eye irritation test is not necessary.

## Materials and methods

For consideration of corrosive and irritant properties the following table applies:



Table 3.3.3

Generic concentration limits of ingredients classified as skin corrosion (Category 1, 1A, 1B or 1C) and/or serious eye damage (Category 1) or eye irritation (Category 2) that trigger classification of the mixture as serious eye damage/eye irritation where the additivity approach applies

Sum of ingredients classified as:	Concentration triggering classification of a mixture as:	
	Serious eye damage	Eye irritation
	Category 1	Category 2
Skin corrosion Sub-Category 1A, 1B, 1C or Category 1 + Serious eye damage (Category 1) (*)	$\geq 3 \%$	$\geq 1 \%$ but $< 3 \%$
Eye irritation (Category 2)		$\geq 10 \%$
$10 \times$ (Skin corrosion Sub-Category 1A, 1B, 1C or Skin corrosion Category 1 + Serious eye damage (Category 1)) + Eye irritation (Category 2)		$\geq 10 \%$

Five ingredients are classified as corrosive to eye or to skin.

- ☐ 0.93% (Eye Dam. 1, H318, Skin Corr. 1B, H314)
- ☐ 0.11% (Skin Corr. 1A, H314)
- ☐ 0.0045% (Eye Dam. 1, H318)
- ☐ 0.0045% (Eye Dam. 1, H318, Skin Corr. 1B, H314)
- ☐ 0.00005 % (Eye Dam. 1, H318, Skin Corr. 1B, H314)

We use the summation method, consisting in adding up the percentages of all ingredients classified in the each class.  
 $\Sigma C_{SkinCorr.} + \Sigma C_{EyeDam} = 0.93 \% + 0.11 \% + 0.0045\% + 0.0045\% + 0.00005\% = 1.05 \%$

## Results and discussions

The concentrations sum of ingredients classified as skin or eye corrosive (1.05 %) is lower than a generic concentration limit (3%). Therefore the whole formulation is not classified as corrosive to eyes. However, result is higher than generic concentration limit triggering eye irritation classification (1%). Therefore whole product will be classified as **Eye Irrit. 2, H319**.

## Conclusion

According to the calculation method, CHR/H/IZOXACYP 250 SC is an eye irritant (Eye Irrit 2., H319). Thus, classification is required according to Regulation (EC) No. 1272/2008.

### A 2.7 Skin sensitisation (KCP 7.1.6)

Comments of zRMS:	<p><u>Conclusion:</u></p> <p>Acc. to the Regulation 1272/2008 and data presented in part C of dRR, the sum of the concentrations of the relevant ingredients is above the specific concentration limit that triggers classification of the mixture in regards to the skin sensitization (</p>
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	$\geq 0,0015 \%$ ). Taking into account the composition of the product, the formulation CHR/H/IMA 40 SL <b>requires classification in regards to skin sensitization (Skin Sens. 1, H317).</b>
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### A 2.7.1 Study 1

Reference:	KCP 7.1.6
Report	Žero K., Toxicological classification of product CHR/H/IMA 40 SL based on calculation method taking into consideration health hazards of constituent substances, 2022
Guideline(s):	Regulation (EC) No. 1272/2008
Deviations:	-
GLP:	No
Acceptability:	Yes
Duplication (if vertebrate study)	No

According to point 7.1.6 of Part A of Annex to the Commission Regulation (EU) No 284/2013 as regards the data requirements for plant protection products:

”The skin sensitisation test shall be carried out unless the active substances or co-formulants are known to have sensitising properties or the applicant can justify an alternative approach under Regulation (EC) No 1272/2008. In the latter case, skin sensitisation properties of all components shall be provided or reliably predicted with a validated method. Consideration shall be given to the possible effects of components on the sensitising potential of the total mixture.”

The complete composition of the formulation with the classification of individual ingredients is available in part C.

Due to the fact, that all components of the formulation CHR/H/IMA 40 SL are known, the skin sensitisation test is not necessary.

### Materials and methods

We use the table:

Table 3.4.5

Generic concentration limits of ingredients of a mixture classified as either skin sensitisers or respiratory sensitisers that trigger classification of the mixture

Ingredient classified as:	Concentration triggering classification of a mixture as:		
	Skin Sensitiser	Respiratory Sensitiser	
	All physical states	Solid/Liquid	Gas
Skin Sensitiser Category 1	$\geq 1,0 \%$	-	-
Sensitiser Category 1A	$\geq 0,1 \%$	-	-
Skin Sensitiser Category 1B	$\geq 1,0 \%$		
Respiratory Sensitiser	-	$\geq 1,0 \%$	$\geq 0,2 \%$

Category 1			
Respiratory Category 1A	Sensitiser	-	$\geq 0,1 \%$
Respiratory Category 1B	Sensitiser		$\geq 1,0 \%$
			$\geq 0,2 \%$

Three ingredients are relevant:

- ☐ 0.0045 % (Skin Sens. 1, H317) SCL:  $\geq 0.05 \%$
- ☐ 0.0045 % (Skin Sens. 1A, H317) SCL:  $\geq 0.0015 \%$
- ☐ 0.00005 % (Skin Sens. 1A, H317)

## Results and discussions

The concentration of one of the ingredients classified as Skin Sens. 1A, H317 is higher than specific concentration level (SCL  $\geq 0,0015 \%$ ). Therefore whole formulation will be classified as skin sensitizer (**Skin Sens. 1A, H317**).

## Conclusion

According to the calculation method, CHR/H/IMA 40 SL is a skin sensitizer (Skin Sens. 1A, H317). Thus, classification is required according to Regulation (EC) No. 1272/2008.

## A 2.8 Specific target organ toxicity (KCP 7.1.7)

Comments of zRMS:	<b>Conclusion:</b> Taking into account the composition of the product, the formulation CHR/H/IMA 40 SL <b>does not require classification in regards to specific target organ toxicity.</b>
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### A 2.8.1

### Study 1

Reference:	KCP 7.1.7
Report	Žero K., Toxicological classification of product CHR/H/IMA 40 SL based on calculation method taking into consideration health hazards of constituent substances, 2022
Guideline(s):	Regulation (EC) No. 1272/2008
Deviations:	-
GLP:	No
Acceptability:	Yes
Duplication (if vertebrate study)	No

For consideration of specific target organ toxicity the following table applies:

Table 3.8.3

Generic concentration limits of ingredients of a mixture classified as a specific target organ toxicant that trigger classification of the mixture as Category 1 or 2.

Ingredient classified as:	Generic concentration limits triggering classification of the mixture as:	
	Category 1	Category 2
Category 1 Specific Target Organ Toxicant	Concentration $\geq 10\%$	$1,0\% \leq \text{concentration} < 10\%$
Category 2 Specific Target Organ Toxicant		Concentration $\geq 10\%$ [(Note 1)]

Note 1

If a Category 2 specific target organ toxicant is present in the mixture as an ingredient at a concentration  $\geq 1,0\%$  a SDS shall be available for the mixture upon request.

We also took into account the point 3.8.3.4.5.: “Care shall be exercised when extrapolating toxicity of a mixture that contains Category 3 ingredient(s). A generic concentration limit of 20 % is appropriate; however, it shall be recognised that this concentration limit may be higher or lower depending on the Category 3 ingredient(s) and that some effects such as respiratory tract irritation may not occur below a certain concentration while other effects such as narcotic effects may occur below this 20 % value. Expert judgement shall be exercised.”

### Specific target organ toxicity - single exposure (STOT SE3, H335)

Two ingredient are classified as STOT SE 3.

- ☐ 0.93 % (STOT SE 3, H335) SCL:  $\geq 5\%$
- ☐ 0.00005% (STOT SE 3, H335) SCL:  $\geq 0.5\%$

The concentrations of ingredients classified as STOT SE 3, H335 are significantly lower than specific concentrations triggering classification. According to point 3.8.3.4.5. CLP Regulation the formulation is not classified as STOT SE 3, H335.

## 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)

Comments of zRMS:	According to the Guidance on Dermal Absorption EFSA Journal 2017;15(6):4873 and SANTE/2018/10591 rev.1 24 October 2018 , the default value of dermal absorption of the active substances contained in CHR/H/IMA 40 SL amounts to 50% for both, the concentrate and the dilution.
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For the dermal absorption of the active substances the Applicant refers to Guidance on Dermal Absorption1 EFSA, EFSA Journal 2017;15(6):4873.

Based on an evaluation of agreed dermal absorption values for a range of concentrated pesticide formula-

tions and their dilutions, the following default values are recommended (see opinion section 4.1.1.for details).

A default dermal absorption value of 10% may be applied for concentrated products that are water-based/dispersed or solid-formulated.

A default dermal absorption value of 50% may be applied for (in use) dilutions water-based/dispersed or solid-formulated.

## A 2.11 Other/Special Studies (KCP 7.1.8)

Comments of zRMS:	<u>Conclusion:</u> Acc. to the Regulation 1272/2008 and data presented in part C of dRR, the concentrations of the relevant ingredients is above generic concentration limit that triggers the classification of the mixture in regards to the reproduction toxicity ( $\geq 3\%$ ) Taking into account the composition of the product, the formulation CHR/H/IMA 40 SL <b>requires classification in regards to reproduction toxicity (Repr. 2, H361d).</b>
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### A 2.11.1 Study 1 – reproduction toxicity, H361d

Reference:	KCP 7.1.8
Report	Žero K., Toxicological classification of product CHR/H/IMA 40 SL based on calculation method taking into consideration health hazards of constituent substances, 2022
Guideline(s):	Regulation (EC) No. 1272/2008
Deviations:	-
GLP:	No
Acceptability:	Yes
Duplication (if vertebrate study)	No

For consideration of carcinogenicity the following table applies:

Table 3.7.2

**Generic concentration limits of ingredients of a mixture classified as reproduction toxicants or for effects on or via lactation that trigger classification of the mixture**

Ingredient classified as:	Generic concentration limits triggering classification of a mixture as:			
	Category 1A reproductive toxicant	Category 1B reproductive toxicant	Category 2 reproductive toxicant	Additional category for effects on or via lactation
Category 1A reproductive toxicant	≥ 0,3 % [Note 1]			
Category 1B reproductive toxicant		≥ 0,3 % [Note 1]		
Category 2 reproductive toxicant			≥ 3,0 % [Note 1]	
Additional category for effects on or via lactation				≥ 0,3 % [Note 1]

**Note**

The concentration limits in the table above apply to solids and liquids (w/w units) as well as gases (v/v units).

**Note 1**

If a Category 1 or Category 2 reproductive toxicant or a substance classified for effects on or via lactation is present in the mixture as an ingredient at a concentration above 0,1 %, a SDS shall be available for the mixture upon re-quest.

Two ingredients are classified as toxic to reproduction:

- ☐ 3.77 % (Repr. 2, H361d)
- ☐ 0.00005 % (Repr. 2, H361f)

The sum of the concentration of the classified as Repr. 2, H361d ingredients is higher than concentration triggering classification (3%). Therefore the formulation is classified as toxic for reproduction (Repr. 2, H361d).

**A 2.11.1**

**Study 2 – QSAR**

<b>Reference:</b>	KCP 7/01
<b>Report</b>	J.V. Cotterill, S. Jones., IN SILICO ASSESSMENT OF REPRODUCTIVE AND DEVELOPMENTAL TOXICITY OF A METABOLITE OF IMAZAMOX, Study code: FR02225-20, 2023,
<b>Guideline(s):</b>	Expert System DEREK Nexus (Version 6.2.1), OECD (Q)SAR Application Toolbox (Version 4.5) and two QSAR platforms VEGA (v.1.2) and T.E.S.T. (v.5.1.1)
<b>Deviations:</b>	-
<b>GLP:</b>	No
<b>Acceptability:</b>	Yes

Duplication No  
(if vertebrate study)

The current study was conducted to assess the potential Reproductive and Developmental Toxicity of a metabolite of Imazamox, namely (2-[(4RS)-4-isopropyl-4-methyl-5-oxo-4,5-dihydro-1 H-imidazol-2-yl]pyridine-3,5-dicarboxylic acid; CL 312622) “Metabolite”, using in silico methods. As a point of toxicological reference, a parallel assessment was also performed on Imazamox (which has a Reprotox GHS classification; Repr 2, H361d, suspected of damaging the unborn child) and a third structurally similar compound Imazapyr (which has no Reprotox GHS classification). The toxicological assessments were performed using the in-silico Expert System DEREK Nexus (Version 6.2.1), OECD (Q)SAR Application Toolbox (Version 4.5) and two QSAR platforms VEGA (v.1.2) and T.E.S.T. (v.5.1.1). The main toxicological estimates (excluding those of low reliability, which were not considered in the weight of evidence) are detailed in Table 1.

**Table 1. Main predicted toxicological end-points and alerts**

Approach	Compound	Toxicological Alerts and possible activity
Derek Nexus	Imazamox	No alerts fired for Developmental/Reproductive Toxicity endpoints
	Metabolite	No alerts fired for Developmental/Reproductive Toxicity endpoints
	Imazapyr	No alerts fired for Developmental/Reproductive Toxicity endpoints
T.E.S.T.	Imazamox	No reliable estimates obtained
	Metabolite	No reliable estimates obtained
	Imazapyr	No reliable estimates obtained
VEGA	Imazamox	Non-ER binder and Non-AR binder No reliable Developmental Toxicity estimates
	Metabolite	Non-ER binder and Non-AR binder No reliable Developmental Toxicity estimates
	Imazapyr	Non-ER binder and Non-AR binder No reliable Developmental Toxicity estimates
OECD QSAR Toolbox	Imazamox	Developmental Toxicity NOEL/LOEL = 325 mg/kg/day Profilers: not known precedent in DART scheme and Non-ER binder
	Metabolite	Developmental Toxicity NOEL/LOEL = 998 mg/kg/day Profilers: not known precedent in DART scheme and Non-ER binder
	Imazapyr	Developmental Toxicity NOEL/LOEL = 956 mg/kg/day Profilers: not known precedent in DART scheme and Non-ER binder

DEREK Nexus There were no alerts any of the test compounds for any of the Developmental/Reproductive Toxicity endpoints

T.E.S.T. No reliable estimates were obtained for Developmental Toxicity for any of the test compounds

VEGA No reliable estimates were obtained for Developmental Toxicity for any of the test compounds. All three test compounds were predicted to be Non-Estrogen Receptor binders and Non-Androgen Receptor binders (good reliability).

OECD Toolbox The Developmental toxicity NOEL/LOEL estimate for the Metabolite (998 mg/kg/day) was higher than that of Imazamox (325 mg/kg/day) and similar to that of Imazapyr (956 mg/kg/day). There were no DART scheme alerts or Estrogen Receptor binding alerts. Experimental data for Imazamox (NOEL of 300 mg/kg/day in the rabbit) was available in the Toolbox; the similarity to the estimated value of 325 mg/kg/day provides confidence in the Read-across approach taken.

#### Overall conclusion

On balance, the weight of evidence obtained in this study suggests that the Metabolite is unlikely to be a Reproductive toxicant (there were no Reproductive Toxicity structural alerts (from either Derek Nexus or the OECD QSAR Toolbox for any of the test compounds). The test compounds were all predicted to be non-Estrogen and non-Androgen Receptor binder in the VEGA models. There is no evidence to suggest that the Metabolite is likely to be Developmental Toxicant (there were no Developmental Toxicity structural alerts from either Derek Nexus or the OECD QSAR Toolbox) and a high NOEL/LOEL estimate of 998 mg/kg/day was obtained. However, it should be noted that there were no structural alerts for Developmental Toxicity for Imazamox either, which is known to be teratogenic in rabbits (but not in rats). Unfortunately, there were no reliable estimates obtained using QSAR models for Developmental Toxicity for any of the test compounds to add to the weight of evidence. The Developmental toxicity NOEL/LOEL estimate for the Metabolite (998 mg/kg/day) however, was higher than that of Imazamox (325 mg/kg/day; Reprotox GHS classification Repr2, H361d, suspected of damaging the unborn child) and similar to that of Imazapyr (956 mg/kg/day; no Reprotox GHS classification). This indicates that the Metabolite is of less toxicological concern (for Developmental Toxicity) than Imazamox.



## Appendix 3 Exposure calculations

### A 3.1 Operator exposure calculations (KCP 7.2.1.1)

#### A 3.1.1 Calculations for imazamox

Table A1: Estimation of operator exposure towards imazamox with PPE at mixing and loading using EFSA Model ver. 30.03.3015 for legume vegetables

Operator exposure for CHR/H/IMA 40 SL outdoor spray applications					
Application rate of active substance	0.048 kg a.s./ha		<i>i_AppRate</i>		
Assumed area treated	50 ha/day		<i>d_AreaTreated</i>		
Amount of active substance applied	2.4 kg a.s./day		<i>i_AmountAS</i>		
Dermal absorption of the product	10.00%		<i>i_AbsorpProduct</i>		
Dermal absorption of in-use dilution	50.00%		<i>i_AbsorInuse</i>		
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				
Indoor or Outdoor application	Outdoor				
Application method	Downward spraying				
Application equipment	Vehicle-mounted				
Season	not relevant				

  

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	9529	35187	AOEM	
	Body	6601	92884	AOEM	
	Head	125	683	AOEM	
	Protected hands (gloves)	61	475	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	52	351	AOEM	
	Protected head (hood and face shield)	2	39	AOEM	
	Inhalation	5	29	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

  

Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	356	4351	AOEM	
	Body	199	1026	AOEM	
	Head	9	28	AOEM	
	Protected hands (gloves)	68	3691	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	5	13	AOEM	
	Inhalation	2	5	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

<b>1. Total</b>			
	Without RPE/PPE	With RPE/PPE	
<b>Longer term</b>			
Total systemic exposure from mixing, loading and application (mg a.s./day)	1.9140685	0.3123234	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0319011	0.0052054	
% of RVNAS	1.42%	0.23%	
<b>Acute</b>			
Total systemic exposure from mixing, loading and application (mg a.s./day)	15.6123594	2.8879305	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.2602060	0.0481322	
% of RVAAS	11.56%	2.14%	

**Table A2: Estimation of operator exposure towards imazamox with PPE at mixing and loading using EFSA Model ver. 30.03.3015 for oilseeds**

**Table A3: Leaf vegetables and fresh herbs; operator with PPE at mixing loading**

Application rate of active substance		0.048 kg a.s./ha	<i>i_AppRate</i>		
Assumed area treated		50 ha/day	<i>d_AreaTreated</i>		
Amount of active substance applied		2.4 kg a.s./day	<i>i_AmountAS</i>		
Dermal absorption of the product		10.00%	<i>i_AbsorpProduct</i>		
Dermal absorption of in-use dilution		50.00%	<i>i_AbsorInuse</i>		
Formulation type		Soluble concentrates, emulsifiable concentrate, etc.			
Indoor or Outdoor application		Outdoor			
Application method		Downward spraying			
Application equipment		Vehicle-mounted			
Season		not relevant			
Outdoor/Soluble concentrates, emulsifiable concentrate, etc. Downward spraying/Vehicle-mounted					
Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	9529	35187	AOEM	
	Body	6601	92884	AOEM	
	Head	125	683	AOEM	
	Protected hands (gloves)	61	475	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	52	351	AOEM	
	Protected head (hood and face shield)	2	39	AOEM	
	Inhalation	5	29	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	
Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	356	4351	AOEM	
	Body	199	1026	AOEM	
	Head	9	28	AOEM	
	Protected hands (gloves)	68	3691	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	5	13	AOEM	
	Inhalation	2	5	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	
	Gloves	No			
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	1.9140685	0.3123234	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0319011	0.0052054	
% of RVNAS	1.42%	0.23%	
Acute			
Total systemic exposure from mixing, loading and application (mg a.s./day)	15.6123594	2.8879305	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.2602060	0.0481322	
% of RVAAS	11.56%	2.14%	

Table A4: Ornamentals; operator with PPE at mixing loading

Application rate of active substance		0.048 kg a.s./ha		i_AppRate	
Assumed area treated		10 ha/day		d_AreaTreated	
Amount of active substance applied		0.48 kg a.s./day		i_AmountAS	
Dermal absorption of the product		10.00%		i_AbsorpProduct	
Dermal absorption of in-use dilution		50.00%		i_AbsorInuse	
Formulation type		Soluble concentrates, emulsifiable concentrate, etc.			
Indoor or Outdoor application		Outdoor			
Application method		Downward spraying			
Application equipment		Vehicle-mounted			
Season		not relevant			
OutdoorSoluble concentrates, emulsifiable concentrate, etc. Downward sprayingVehicle-mounted					
Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	2760	10049	AOEM	
	Body	2129	58193	AOEM	
	Head	25	137	AOEM	
	Protected hands (gloves)	21	95	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	12	70	AOEM	
	Protected head (hood and face shield)	0	8	AOEM	
	Inhalation	3	28	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	
Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	778	2190	AOEM	This scenario assumes that small area equipment is used
	Body	1067	1352	AOEM	
	Head	6	75	AOEM	
	Protected hands (gloves)	15	20	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	13	16	AOEM	
	Inhalation	4	27	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	1.4237548	0.9381478	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0237292	0.0156358	
% of RVNAS	1.05%	0.69%	
Acute			
Total systemic exposure from mixing, loading and application (mg a.s./day)	8.7009417	1.8932510	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.1450157	0.0315542	
% of RVAAS	6.45%	1.40%	

**Table A1: Estimation of operator exposure towards imazamox without PPE for legume vegetables**

**Operator exposure for outdoor spray applications**

Operator exposure for outdoor spray applications		0.048 kg a.s./ha	i_AppRate		
Application rate of active substance		50 ha/day	d_AreaTreated		
Assumed area treated		2.4 kg a.s./day	i_AmountAS		
Amount of active substance applied		50.00%	i_AbsorpProduct		
Dermal absorption of the product		50.00%	i_AbsorInuse		
Dermal absorption of in-use dilution					
Formulation type		Soluble concentrates, emulsifiable concentrate, etc.			
Indoor or Outdoor application		Outdoor			
Application method		Downward spraying			
Application equipment		Vehicle-mounted			
Season		not relevant			
		OutdoorSoluble concentrates, emulsifiable concentrate, etc. Downward sprayingVehicle-mounted			
Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	9529	35187	AOEM	
	Body	6601	92884	AOEM	
	Head	125	683	AOEM	
	Protected hands (gloves)	61	475	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	52	351	AOEM	
	Protected head (hood and face shield)	2	39	AOEM	
	Inhalation	5	29	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
Water soluble bag	No		1		
Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	356	4351	AOEM	
	Body	199	1026	AOEM	
	Head	9	28	AOEM	
	Protected hands (gloves)	68	3691	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	5	13	AOEM	
	Inhalation	2	5	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

**1. Total**

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	8.4158621	8.4158621	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.1402644	0.1402644	
% of RVNAS	6.23%	6.23%	

**Table A2: Estimation of operator exposure towards imazamox without PPE for oilseeds**

**Operator exposure for outdoor spray applications**

Operator exposure for outdoor spray applications					
Application rate of active substance		0.048 kg a.s./ha		i_AppRate	
Assumed area treated		50 ha/day		d_AreaTreated	
Amount of active substance applied		2.4 kg a.s./day		i_AmountAS	
Dermal absorption of the product		50.00%		i_AbsorpProduct	
Dermal absorption of in-use dilution		50.00%		i_AbsorInuse	
Formulation type		Soluble concentrates, emulsifiable concentrate, etc.			
Indoor or Outdoor application		Outdoor			
Application method		Downward spraying			
Application equipment		Vehicle-mounted			
Season		not relevant			
Outdoor/Soluble concentrates, emulsifiable concentrate, etc. Downward spraying/Vehicle-mounted					
Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	9529	35187	AOEM	
	Body	6601	92884	AOEM	
	Head	125	683	AOEM	
	Protected hands (gloves)	61	475	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	52	351	AOEM	
	Protected head (hood and face shield)	2	39	AOEM	
	Inhalation	5	29	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
Water soluble bag	No		1		
Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	356	4351	AOEM	
	Body	199	1026	AOEM	
	Head	9	28	AOEM	
	Protected hands (gloves)	68	3691	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	5	13	AOEM	
	Inhalation	2	5	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	
	Gloves	No			
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

**1. Total**

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	8.4158621	8.4158621	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.1402644	0.1402644	
% of RVNAS	6.23%	6.23%	

**Table A3: Leaf vegetables and fresh herbs; operator without PPE**

**Operator exposure for outdoor spray applications**

Operator: Exposure for: Outdoor spray applications					
Application rate of active substance		0.048 kg a.s./ha	i_AppRate		
Assumed area treated		50 ha/day	d_AreaTreated		
Amount of active substance applied		2.4 kg a.s./day	i_AmountAS		
Dermal absorption of the product		50.00%	i_AbsorpProduct		
Dermal absorption of in-use dilution		50.00%	i_AbsorInuse		
Formulation type		Soluble concentrates, emulsifiable concentrate, etc.			
Indoor or Outdoor application		Outdoor			
Application method		Downward spraying			
Application equipment		Vehicle-mounted			
Season		not relevant			
Outdoor/Soluble concentrates, emulsifiable concentrate, etc. Downward spraying/Vehicle-mounted					
Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	9529	35187	AOEM	
	Body	6601	92884	AOEM	
	Head	125	683	AOEM	
	Protected hands (gloves)	61	475	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	52	351	AOEM	
	Protected head (hood and face shield)	2	39	AOEM	
	Inhalation	5	29	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	
Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	356	4351	AOEM	
	Body	199	1026	AOEM	
	Head	9	28	AOEM	
	Protected hands (gloves)	68	3691	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	5	13	AOEM	
	Inhalation	2	5	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	
	Gloves	No			
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

**1. Total**

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	8.4158621	8.4158621	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.1402644	0.1402644	
% of RVNAS	6.23%	6.23%	

**Table A4: Ornamentals; operator without PPE**

**Operator exposure for outdoor spray applications**

Application rate of active substance	0.048 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated	10 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied	0.48 kg a.s./day	<i>i_AmountAS</i>
Dermal absorption of the product	50.00%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	50.00%	<i>i_AbsorInuse</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Season	not relevant	

*Outdoor: Soluble concentrates, emulsifiable concentrate, etc. Downward spraying: vehicle-mounted*

	Exposure values	µg exposure/day mixed and loaded		Reference	Comment	
		75 <sup>th</sup> centile	95 <sup>th</sup> centile			
Mixing and loading	Hands	2760	10049	AOEM		
	Body	2129	58193	AOEM		
	Head	25	137	AOEM		
	Protected hands (gloves)	21	95	AOEM		
	Protected body (workwear or protective garment and sturdy footwear)	12	70	AOEM		
	Protected head (hood and face shield)	0	8	AOEM		
	Inhalation	3	28	AOEM		
	<b>Protective Equipment</b>	Select for inclusion		Penetration factor	Inhalation Protection factor	
	Gloves	No				
	Clothing	Potential exposure		Incl. in AOEM model		
Application	Head and respiratory PPE	None		1	1	
	Water soluble bag	No		1		
		Exposure values	µg exposure/day applied		Reference	Comment
			75 <sup>th</sup> centile	95 <sup>th</sup> centile		
		Hands	778	2190	AOEM	This scenario assumes that small area equipment is used
		Body	1067	1352	AOEM	
		Head	6	75	AOEM	
		Protected hands (gloves)	15	20	AOEM	
		Protected body (workwear or protective garment and sturdy footwear)	13	16	AOEM	
		Inhalation	4	27	AOEM	
<b>Protective Equipment</b>		Select for inclusion		Penetration factor	Inhalation Protection factor	
Gloves		No				
Clothing	Potential exposure		Incl. in AOEM model			
Head and respiratory PPE	None		1	1		
Closed cab	No		vehicle mounted upward spraying only			

**1. Total**

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	3.3896462	3.3896462	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0564941	0.0564941	
% of RVNAS	2.51%	2.51%	



## A 3.2 Worker exposure calculations (KCP 7.2.3.1)

### A 3.2.1 Calculations for imazamox

Table A5: Legume vegetables

Table 10: Legume vegetables		Legume vegetables		
Crop type		Outdoor		
Indoor or outdoor		Downward spraying		
Application method		Vehicle-mounted		
Application equipment		Reaching, picking		
Worker's task		Hand and body		
Main body parts in contact with foliage				
Application rate of active substance	0.048	kg a.s./ha	i_AppRate	
Number of applications	1		i_AppNo	
Interval between multiple applications	365	days	i_AppInt	
Half-life of active substance	30	days	d_HalfLifeAS	
Multiple application factor	1.0		d_MAF	
Dermal absorption of the product	10.00%		i_AbsorpProduct	
Dermal absorption of the in-use dilution	50.00%		i_Absorplnuse	
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.144	µg a.s./cm²	d_DFR	
Working hours	8	hr	d_WorkHr	
Dermal transfer coefficient - Total potential exposure	5800	cm²/hr	d_DermTcUCV	
Dermal transfer coefficient - arms, body and legs covered	2500	cm²/hr	d_DermTcCV1	
Dermal transfer coefficient - hands, arms, body and legs covered	580	cm²/hr	d_DermTcCV2	
Inhalation transfer coefficient for automated applications	NA	ha/hr*10^(-3)	d_InhalTcAut	
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10^(-3)	d_InhalTcCut	
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10^(-3)	d_InhalTcSort	
1. Total				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	3.3408000	1.4400000	0.3340800	
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0556800	0.0240000	0.0055680	
% of RVNAS	2.47%	1.07%	0.25%	
2. Details				
	Systemic exposure		Formula	Comments
	[mg a.s. /day]	[mg a.s./kg bw/day]		
Dermal - Potential	3.3408000	0.0556800	d_DermTcUCV*d_WorkHr*i_DFR*i_MAF/1000*i_Absorplnuse	
Dermal - Work wear - arms, body and legs covered	1.4400000	0.0240000	d_DermTcCV1*d_WorkHr*d_DFR*d_MAF/1000*i_Absorplnuse	
Dermal - Working wear and gloves	0.3340800	0.0055680	d_DermTcCV2*d_WorkHr*d_DFR*d_MAF/1000*i_Absorplnuse	
Inhalation				Na for outdoor activities

Worker exposure from residues on foliage for				
Crop type	Legume vegetables			
Indoor or outdoor	Outdoor			
Application method	Downward spraying			
Application equipment	Vehicle-mounted			
Worker's task	Reaching, picking			
Main body parts in contact with foliage	Hand and body			
Application rate of active substance	0.048	kg a.s./ha		i_AppRate
Number of applications	1			i_AppNo
Interval between multiple applications	365	days		i_AppInt
Half-life of active substance	30	days		d_HalfLifeAS
Multiple application factor	1.0			d_MAF
Dermal absorption of the product	50.00%			i_AbsorpProduct
Dermal absorption of the in-use dilution	50.00%			i_Absorplnuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.144	µg a.s./cm <sup>2</sup>		d_DFR
Working hours	8	hr		d_WorkHr
Dermal transfer coefficient - Total potential exposure	5800	cm <sup>2</sup> /hr		d_DermTcUCV
Dermal transfer coefficient - arms, body and legs covered	2500	cm <sup>2</sup> /hr		d_DermTcCV1
Dermal transfer coefficient - hands, arms, body and legs covered	580	cm <sup>2</sup> /hr		d_DermTcCV2
Inhalation transfer coefficient for automated applications	NA	ha/hr*10 <sup>^</sup> (-3)		d_InhalTcAut
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10 <sup>^</sup> (-3)		d_InhalTcCut
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10 <sup>^</sup> (-3)		d_InhalTcSort
<b>1. Total</b>				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	3.3408000	1.4400000	0.3340800	
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0556800	0.0240000	0.0055680	
% of RVNAS	2.47%	1.07%	0.25%	

Table A6: Oilseeds

Crop type	Oilseeds			
Indoor or outdoor	Outdoor			
Application method	Downward spraying			
Application equipment	Vehicle-mounted			
Worker's task	Inspection, irrigation			
Main body parts in contact with foliage	Hand and body			
Application rate of active substance	0.048	kg a.s./ha		i_AppRate
Number of applications	1			i_AppNo
Interval between multiple applications	365	days		i_AppInt
Half-life of active substance	30	days		d_HalfLifeAS
Multiple application factor	1.0			d_MAF
Dermal absorption of the product	10.00%			i_AbsorpProduct
Dermal absorption of the in-use dilution	50.00%			i_Absorplnuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.144	µg a.s./cm <sup>2</sup>		d_DFR
Working hours	2	hr		d_WorkHr
Dermal transfer coefficient - Total potential exposure	12500	cm <sup>2</sup> /hr		d_DermTcUCV
Dermal transfer coefficient - arms, body and legs covered	1400	cm <sup>2</sup> /hr		d_DermTcCV1
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment		cm <sup>2</sup> /hr	d_DermTcCV2
Inhalation transfer coefficient for automated applications	NA	ha/hr*10 <sup>^</sup> (-3)		d_InhalTcAut
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10 <sup>^</sup> (-3)		d_InhalTcCut
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10 <sup>^</sup> (-3)		d_InhalTcSort
<b>1. Total</b>				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	1.8000000	0.2016000	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0300000	0.0033600		
% of RVNAS	1.33%	0.15%		
<b>2. Details</b>				
	Systemic exposure		Formula	Comments
	[mg a.s. /day]	[mg a.s./kg bw/day]		
Dermal - Potential	1.8000000	0.0300000	d_DermTcUCV*d_WorkHr*i_DFR*i_MAF/1000*i_Absorplnuse	
Dermal - Work wear - arms, body and legs covered	0.2016000	0.0033600	d_DermTcCV1*d_WorkHr*d_DFR*d_MAF/1000*i_Absorplnuse	
Dermal - Working wear and gloves	no TC available for this assessment		d_DermTcCV2*d_WorkHr*d_DFR*d_MAF/1000*i_Absorplnuse	
Inhalation				Na for outdoor activities

Worker exposure from residues on foliage for			
Crop type	Oilseeds		
Indoor or outdoor	Outdoor		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		
Worker's task	Inspection, irrigation		
Main body parts in contact with foliage	Hand and body		
Application rate of active substance	0.048	kg a.s./ha	i_AppRate
Number of applications	1		i_AppNo
Interval between multiple applications	365	days	i_AppInt
Half-life of active substance	30	days	d_HalfLifeAS
Multiple application factor	1.0		d_MAF
Dermal absorption of the product	50.00%		i_AbsorpProduct
Dermal absorption of the in-use dilution	50.00%		i_Absorplnuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.144	µg a.s./cm <sup>2</sup>	d_DFR
Working hours	2	hr	d_WorkHr
Dermal transfer coefficient - Total potential exposure	12500	cm <sup>2</sup> /hr	d_DermTcUCV
Dermal transfer coefficient - arms, body and legs covered	1400	cm <sup>2</sup> /hr	d_DermTcCV1
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment		
Inhalation transfer coefficient for automated applications	NA	ha/hr*10 <sup>^</sup> (-3)	d_InhalTcAut
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10 <sup>^</sup> (-3)	d_InhalTcCut
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10 <sup>^</sup> (-3)	d_InhalTcSort

<b>1. Total</b>				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	1.8000000	0.2016000	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0300000	0.0033600		
% of RVNAS	1.33%	0.15%		

Table A7: Leaf vegetables and fresh herbs

Crop type	Leaf vegetables and fresh herbs		
Indoor or outdoor	Outdoor		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		
Worker's task	Reaching, picking		
Main body parts in contact with foliage	Hand and body		
Application rate of active substance	0.048	kg a.s./ha	i_AppRate
Number of applications	1		i_AppNo
Interval between multiple applications	365	days	i_AppInt
Half-life of active substance	30	days	d_HalfLifeAS
Multiple application factor	1.0		d_MAF
Dermal absorption of the product	10.00%		i_AbsorpProduct
Dermal absorption of the in-use dilution	50.00%		i_Absorplnuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.144	µg a.s./cm <sup>2</sup>	d_DFR
Working hours	8	hr	d_WorkHr
Dermal transfer coefficient - Total potential exposure	5800	cm <sup>2</sup> /hr	d_DermTcUCV
Dermal transfer coefficient - arms, body and legs covered	2500	cm <sup>2</sup> /hr	d_DermTcCV1
Dermal transfer coefficient - hands, arms, body and legs covered	580	cm <sup>2</sup> /hr	d_DermTcCV2
Inhalation transfer coefficient for automated applications	NA	ha/hr*10 <sup>^</sup> (-3)	d_InhalTcAut
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10 <sup>^</sup> (-3)	d_InhalTcCut
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10 <sup>^</sup> (-3)	d_InhalTcSort

<b>1. Total</b>				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	3.3408000	1.4400000	0.3340800	
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0556800	0.0240000	0.0055680	
% of RVNAS	2.47%	1.07%	0.25%	

<b>2. Details</b>				
	Systemic exposure		Formula	Comments
	[mg a.s. /day]	[mg a.s./kg bw/day]		
Dermal - Potential	3.3408000	0.0556800	$d\_DermTcUCV * d\_WorkHr * i\_DFR * i\_MAF / 1000 * i\_Absorplnuse$	
Dermal - Work wear - arms, body and legs covered	1.4400000	0.0240000	$d\_DermTcCV1 * d\_WorkHr * d\_DFR * d\_MAF / 1000 * i\_Absorplnuse$	
Dermal - Working wear and gloves	0.3340800	0.0055680	$d\_DermTcCV2 * d\_WorkHr * d\_DFR * d\_MAF / 1000 * i\_Absorplnuse$	
Inhalation				Na for outdoor activities

Worker exposure from residues on foliage for				
Crop type	Leaf vegetables and fresh herbs			
Indoor or outdoor	Outdoor			
Application method	Downward spraying			
Application equipment	Vehicle-mounted			
Worker's task	Reaching, picking			
Main body parts in contact with foliage	Hand and body			
Application rate of active substance	0.048	kg a.s./ha		<i>i_AppRate</i>
Number of applications	1			<i>i_AppNo</i>
Interval between multiple applications	365	days		<i>i_AppInt</i>
Half-life of active substance	30	days		<i>d_HalfLifeAS</i>
Multiple application factor	1.0			<i>d_MAF</i>
Dermal absorption of the product	50.00%			<i>i_AbsorpProduct</i>
Dermal absorption of the in-use dilution	50.00%			<i>i_Absorplnuse</i>
Dislodgeable foliar residue ( <i>i_AppRate</i> * <i>i_DFR</i> )	0.144	µg a.s./cm <sup>2</sup>		<i>d_DFR</i>
Working hours	8	hr		<i>d_WorkHr</i>
Dermal transfer coefficient - Total potential exposure	5800	cm <sup>2</sup> /hr		<i>d_DermTcUCV</i>
Dermal transfer coefficient - arms, body and legs covered	2500	cm <sup>2</sup> /hr		<i>d_DermTcCV1</i>
Dermal transfer coefficient - hands, arms, body and legs covered	580	cm <sup>2</sup> /hr		<i>d_DermTcCV2</i>
Inhalation transfer coefficient for automated applications	NA	ha/hr*10 <sup>^</sup> (-3)		<i>d_InhalTcAut</i>
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10 <sup>^</sup> (-3)		<i>d_InhalTcCut</i>
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10 <sup>^</sup> (-3)		<i>d_InhalTcSort</i>
<b>1. Total</b>				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	3.3408000	1.4400000	0.3340800	
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0556800	0.0240000	0.0055680	
% of RVNAS	2.47%	1.07%	0.25%	

Table A8: Ornamentals

Crop type	Ornamentals			
Indoor or outdoor	Outdoor			
Application method	Downward spraying			
Application equipment	Vehicle-mounted			
Worker's task	Cutting, sorting, bundling, carrying			
Main body parts in contact with foliage	Hand and body			
Application rate of active substance	0.048	kg a.s./ha		<i>i_AppRate</i>
Number of applications	1			<i>i_AppNo</i>
Interval between multiple applications	365	days		<i>i_AppInt</i>
Half-life of active substance	30	days		<i>d_HalfLifeAS</i>
Multiple application factor	1.0			<i>d_MAF</i>
Dermal absorption of the product	10.00%			<i>i_AbsorpProduct</i>
Dermal absorption of the in-use dilution	50.00%			<i>i_Absorplnuse</i>
Dislodgeable foliar residue ( <i>i_AppRate</i> * <i>i_DFR</i> )	0.144	µg a.s./cm <sup>2</sup>		<i>d_DFR</i>
Working hours	8	hr		<i>d_WorkHr</i>
Dermal transfer coefficient - Total potential exposure	14000	cm <sup>2</sup> /hr		<i>d_DermTcUCV</i>
Dermal transfer coefficient - arms, body and legs covered	5000	cm <sup>2</sup> /hr		<i>d_DermTcCV1</i>
Dermal transfer coefficient - hands, arms, body and legs covered	1400	cm <sup>2</sup> /hr		<i>d_DermTcCV2</i>
Inhalation transfer coefficient for automated applications	NA	ha/hr*10 <sup>^</sup> (-3)		<i>d_InhalTcAut</i>
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10 <sup>^</sup> (-3)		<i>d_InhalTcCut</i>
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10 <sup>^</sup> (-3)		<i>d_InhalTcSort</i>
<b>1. Total</b>				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	8.0640000	2.8800000	0.8064000	
Total systemic exposure per kg body weight (mg/kg bw/day)	0.1344000	0.0480000	0.0134400	
% of RVNAS	5.97%	2.13%	0.60%	
<b>2. Details</b>				
	Systemic exposure		Formula	Comments
	[mg a.s. /day]	[mg a.s./kg bw/day]		
Dermal - Potential	8.0640000	0.1344000	$d\_DermTcUCV * d\_WorkHr * i\_DFR * i\_MAF / 1000 * i\_Absorplnuse$	
Dermal - Work wear - arms, body and legs covered	2.8800000	0.0480000	$d\_DermTcCV1 * d\_WorkHr * d\_DFR * d\_MAF / 1000 * i\_Absorplnuse$	
Dermal - Working wear and gloves	0.8064000	0.0134400	$d\_DermTcCV2 * d\_WorkHr * d\_DFR * d\_MAF / 1000 * i\_Absorplnuse$	
Inhalation				Na for outdoor activities

Worker exposure from residues on foliage for				
Crop type	Ornamentals			
Indoor or outdoor	Outdoor			
Application method	Downward spraying			
Application equipment	Vehicle-mounted			
Worker's task	Cutting, sorting, bundling, carrying			
Main body parts in contact with foliage	Hand and body			
Application rate of active substance	0.048	kg a.s./ha		i_AppRate
Number of applications	1			i_AppNo
Interval between multiple applications	365	days		i_AppInt
Half-life of active substance	30	days		d_HalfLifeAS
Multiple application factor	1.0			d_MAF
Dermal absorption of the product	50.00%			i_AbsorpProduct
Dermal absorption of the in-use dilution	50.00%			i_Absorplnuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.144	µg a.s./cm <sup>2</sup>		d_DFR
Working hours	8	hr		d_WorkHr
Dermal transfer coefficient - Total potential exposure	14000	cm <sup>2</sup> /hr		d_DermTcUCV
Dermal transfer coefficient - arms, body and legs covered	5000	cm <sup>2</sup> /hr		d_DermTcCV1
Dermal transfer coefficient - hands, arms, body and legs covered	1400	cm <sup>2</sup> /hr		d_DermTcCV2
Inhalation transfer coefficient for automated applications	NA	ha/hr*10 <sup>^(-3)</sup>		d_InhalTcAut
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10 <sup>^(-3)</sup>		d_InhalTcCut
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10 <sup>^(-3)</sup>		d_InhalTcSort
<b>1. Total</b>				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	8.0640000	2.8800000	0.8064000	
Total systemic exposure per kg body weight (mg/kg bw/day)	0.1344000	0.0480000	0.0134400	
% of RVNAS	5.97%	2.13%	0.60%	

### A 3.3 Bystander and resident exposure calculations (KCP 7.2.2.1)

#### A 3.3.1 Calculations for imazamox

Notice: Bystander exposure values are covered by resident values shown in Tables A9-A12.

Table A9: Legume vegetables

Croptype	Legume vegetables				
Application method	Downward spraying				
Application equipment	Vehicle-mounted				<i>i_AppEquip</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				<i>i_FormVal</i>
Buffer strip	2-3 m				<i>i_Buffer</i>
Application rate of the product	0.048 kg a.s./ha				<i>i_AppRate</i>
Concentration of active substance (in-use dilution for liquid applications)	0.24 g a.s./l				<i>d_ConcAS</i>
Dermal absorption of product	10.00%				<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	50.00%				<i>i_AbsorpInuse</i>
Oral absorption	100.00%				<i>i_AbsorpOrallnuse</i>
Dislodgeable foliar residue ( <i>i_AppRate</i> * <i>i_DFR</i> )	0.144 µg a.s./cm <sup>2</sup>				<i>d_DFR</i>
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10 <sup>-3</sup> Pa				<i>i_Volat</i>
Concentration in air	0.001 mg/m <sup>3</sup>				<i>d_AirCon</i>
Resident dermal spray drift exposure 75th percentile - adult	0.47 ml spray dilution/person				
Resident dermal spray drift exposure 75th percentile - child	0.327 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - adult	0.00010 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - child	0.00022 ml spray dilution/person				
Resident dermal spray drift exposure mean - adult	0.22318 ml spray dilution/person				
Resident dermal spray drift exposure mean - child	0.18 ml spray dilution/person				
Resident inhal. spray drift exposure mean - adult	0.00009 ml spray dilution/person				
Resident inhal. spray drift exposure mean - child	0.00017 ml spray dilution/person				
Exposure duration dermal	2 hours				<i>d_ReExpDur</i>
Exposure duration inhalation	24 hours				<i>d_ReExpDurInhal</i>
Exposure duration entry into treated crops	0.25 hours				<i>d_ExpDurTreatCrop</i>
Light clothing adjustment factor	18.0%				<i>d_ClothAF</i>
Breathing rate adult	0.23 m <sup>3</sup> /day/kg				<i>d_BreathRAAd</i>
Breathing rate child (1-3 year old)	1.07 m <sup>3</sup> /day/kg				<i>d_BreathRCh</i>
Drift percentage on surface (75th percentile)	5.60%				
Drift percentage on surface (mean)	4.10%				
Turf transferable residues percentage	5.00%				<i>d_Turf</i>
Transfer coeff. of surface deposits-adult	7300 cm <sup>2</sup> /hour				<i>d_ReTCAd</i>
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm <sup>2</sup> /hour				<i>d_ReTCCh</i>
Saliva extraction percentage	50.00%				<i>d_SalExt</i>
Surface area of hands mouthed	20 cm <sup>2</sup>				<i>d_AreaHM</i>
Frequency of hand to mouth activity	9.5 events/hour				<i>d_ReFreqHM</i>
Ingestion rate for mouthing of grass per day	25 cm <sup>2</sup>				<i>d_MouthGrass</i>
Dislodgeable residues percentage transferability for object to mouth	20.00%				<i>d_DRP</i>
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500 cm <sup>2</sup> /h				<i>d_TcEntryAd</i>
Transfer coefficient for entry into treated crops (75th percentile) - child	2250 cm <sup>2</sup> /h				<i>d_TcEntryCh</i>
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm <sup>2</sup> /h				<i>d_TcEntryAd</i>
Transfer coefficient for entry into treated crops (mean) - child	1794 cm <sup>2</sup> /h				<i>d_TcEntryCh</i>
<b>1. Total</b>					
<b>1.1 1-3 year old child</b>					
	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0322296	0.0107000	0.0038842	0.0405000	0.0635886
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0032230	0.0010700	0.0003884	0.0040500	0.0063589
% of RVNAS	0.14%	0.05%	0.02%	0.18%	0.28%
<b>1.2 Adult</b>					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0462720	0.0138000	0.0098112	0.1350000	0.1506057
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0007712	0.0002300	0.0001635	0.0022500	0.0025101
% of RVNAS	0.03%	0.01%	0.01%	0.10%	0.11%

Resident exposure for					
Croptype	Legume vegetables				
Application method	Downward spraying				
Application equipment	Vehicle-mounted				i_AppEquip
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				i_FormVal
Buffer strip	2-3 m				i_Buffer
Application rate of the product	0.048 kg a.s./ha				i_AppRate
Concentration of active substance (in-use dilution for liquid applications)	0.24 g a.s./l				d_ConcAS
Dermal absorption of product	50.00%				i_AbsorpProduct
Dermal absorption of in-use dilution	50.00%				i_AbsorpInuse
Oral absorption	100.00%				i_AbsorpOrallnuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.144 µg a.s./cm²				d_DFR
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa		Pa		i_Volat
Concentration in air	0.001 mg/m³				d_AirCon
Resident dermal spray drift exposure 75th percentile - adult	0.47 ml spray dilution/person				
Resident dermal spray drift exposure 75th percentile - child	0.327 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - adult	0.00010 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - child	0.00022 ml spray dilution/person				
Resident dermal spray drift exposure mean - adult	0.22318 ml spray dilution/person				
Resident dermal spray drift exposure mean - child	0.18 ml spray dilution/person				
Resident inhal. spray drift exposure mean - adult	0.00009 ml spray dilution/person				
Resident inhal. spray drift exposure mean - child	0.00017 ml spray dilution/person				
Exposure duration dermal	2 hours				d_ReExpDur
Exposure duration inhalation	24 hours				d_ReExpDurInhal
Exposure duration entry into treated crops	0.25 hours				d_ExpDurTreatCrop
Light clothing adjustment factor	18.0%				d_ClothAF
Breathing rate adult	0.23 m³/day/kg				d_BreathRAD
Breathing rate child (1-3 year old)	1.07 m³/day/kg				d_BreathRCh
Drift percentage on surface (75th percentile)	5.60%				
Drift percentage on surface (mean)	4.10%				
Turf transferable residues percentage	5.00%				d_Turf
Transfer coeff. of surface deposits-adult	7300 cm²/hour				d_ReTCAd
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm²/hour				d_ReTCCh
Saliva extraction percentage	50.00%				d_SolExt
Surface area of hands mouthed	20 cm²				d_AreaHM
Frequency of hand to mouth activity	9.5 events/hour				d_ReFreqHM
Ingestion rate for mouthing of grass per day	25 cm²				d_MouthGrass
Dislodgeable residues percentage transferability for object to mouth	20.00%				d_DRP
Transfer coefficient for entry into treated crops (75th percentile) - ad	7500 cm²/h				d_TcEntryAd
Transfer coefficient for entry into treated crops (75th percentile) - chi	2250 cm²/h				d_TcEntryCh
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm²/h				d_TcEntryAd
Transfer coefficient for entry into treated crops (mean) - child	1794 cm²/h				d_TcEntryCh
1. Total					
1.1 1-3 year old child					
Spray drift (75th percentile)		Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0322296	0.0107000	0.0038842	0.0405000	0.0635886
Total systemic exposure per kg body weight	0.0032230	0.0010700	0.0003884	0.0040500	0.0063589
% of RVNAS	0.14%	0.05%	0.02%	0.18%	0.28%
1.2 Adult					
Spray drift		Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0462720	0.0138000	0.0098112	0.1350000	0.1506057
Total systemic exposure per kg body weight	0.0007712	0.0002300	0.0001635	0.0022500	0.0025101
% of RVNAS	0.03%	0.01%	0.01%	0.10%	0.11%

Table A10: Oilseeds

Croptype	Oilseeds				
Application method	Downward spraying				
Application equipment	Vehicle-mounted				<i>i_AppEquip</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				<i>i_FormVal</i>
Buffer strip	2-3 m				<i>i_Buffer</i>
Application rate of the product	0.048 kg a.s./ha				<i>i_AppRate</i>
Concentration of active substance (in-use dilution for liquid applications)	0.24 g a.s./l				<i>d_ConcAS</i>
Dermal absorption of product	10.00%				<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	50.00%				<i>i_AbsorpInuse</i>
Oral absorption	100.00%				<i>i_AbsorpOrallinuse</i>
Dislodgeable foliar residue ( <i>i_AppRate</i> * <i>i_DFR</i> )	0.144 µg a.s./cm <sup>2</sup>				<i>d_DFR</i>
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10 <sup>-3</sup> Pa				<i>i_Volat</i>
Concentration in air	0.001 mg/m <sup>3</sup>				<i>d_AirCon</i>
Resident dermal spray drift exposure 75th percentile - adult	0.47 ml spray dilution/person				
Resident dermal spray drift exposure 75th percentile - child	0.327 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - adult	0.00010 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - child	0.00022 ml spray dilution/person				
Resident dermal spray drift exposure mean - adult	0.22318 ml spray dilution/person				
Resident dermal spray drift exposure mean - child	0.18 ml spray dilution/person				
Resident inhal. spray drift exposure mean - adult	0.00009 ml spray dilution/person				
Resident inhal. spray drift exposure mean - child	0.00017 ml spray dilution/person				
Exposure duration dermal	2 hours				<i>d_ReExpDur</i>
Exposure duration inhalation	24 hours				<i>d_ReExpDurInhal</i>
Exposure duration entry into treated crops	0.25 hours				<i>d_ExpDurTreatCrop</i>
Light clothing adjustment factor	18.0%				<i>d_ClothAF</i>
Breathing rate adult	0.23 m <sup>3</sup> /day/kg				<i>d_BreathRAAd</i>
Breathing rate child (1-3 year old)	1.07 m <sup>3</sup> /day/kg				<i>d_BreathRCh</i>
Drift percentage on surface (75th percentile)	5.60%				
Drift percentage on surface (mean)	4.10%				
Turf transferable residues percentage	5.00%				<i>d_Turf</i>
Transfer coeff. of surface deposits-adult	7300 cm <sup>2</sup> /hour				<i>d_ReTCAd</i>
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm <sup>2</sup> /hour				<i>d_ReTCCh</i>
Saliva extraction percentage	50.00%				<i>d_SalExt</i>
Surface area of hands mouthed	20 cm <sup>2</sup>				<i>d_AreaHM</i>
Frequency of hand to mouth activity	9.5 events/hour				<i>d_ReFreqHM</i>
Ingestion rate for mouthing of grass per day	25 cm <sup>2</sup>				<i>d_MouthGrass</i>
Dislodgeable residues percentage transferability for object to mouth	20.00%				<i>d_DRP</i>
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500 cm <sup>2</sup> /h				<i>d_TcEntryAd</i>
Transfer coefficient for entry into treated crops (75th percentile) - child	2250 cm <sup>2</sup> /h				<i>d_TcEntryCh</i>
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm <sup>2</sup> /h				<i>d_TcEntryAd</i>
Transfer coefficient for entry into treated crops (mean) - child	1794 cm <sup>2</sup> /h				<i>d_TcEntryCh</i>
<b>1. Total</b>					
<b>1.1 1-3 year old child</b>					
Spray drift (75th percentile)		Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0322296	0.0107000	0.0038842	0.0405000	0.0635886
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0032230	0.0010700	0.0003884	0.0040500	0.0063589
% of RVNAS	0.14%	0.05%	0.02%	0.18%	0.28%
<b>1.2 Adult</b>					
Spray drift		Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0462720	0.0138000	0.0098112	0.1350000	0.1506057
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0007712	0.0002300	0.0001635	0.0022500	0.0025101
% of RVNAS	0.03%	0.01%	0.01%	0.10%	0.11%



Resident exposure for					
Croptype		Oilseeds			
Application method		Downward spraying			
Application equipment		Vehicle-mounted			i_AppEquip
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				i_FormVal
Buffer strip		2-3 m			i_Buffer
Application rate of the product		0.048 kg a.s./ha			i_AppRate
Concentration of active substance (in-use dilution for liquid applications)		0.24 g a.s./l			d_ConcAS
Dermal absorption of product		50.00%			i_AbsorpProduct
Dermal absorption of in-use dilution		50.00%			i_AbsorpInuse
Oral absorption		100.00%			i_AbsorpOralinuse
Dislodgeable foliar residue (i_AppRate*i_DFR)		0.144 µg a.s./cm²			d_DFR
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa			i_Volat
Concentration in air		0.001 mg/m³			d_AirCon
Resident dermal spray drift exposure 75th percentile - adult		0.47 ml spray dilution/person			
Resident dermal spray drift exposure 75th percentile - child		0.327 ml spray dilution/person			
Resident inhal. spray drift exposure 75th percentile - adult		0.00010 ml spray dilution/person			
Resident inhal. spray drift exposure 75th percentile - child		0.00022 ml spray dilution/person			
Resident dermal spray drift exposure mean - adult		0.22318 ml spray dilution/person			
Resident dermal spray drift exposure mean - child		0.18 ml spray dilution/person			
Resident inhal. spray drift exposure mean - adult		0.00009 ml spray dilution/person			
Resident inhal. spray drift exposure mean - child		0.00017 ml spray dilution/person			
Exposure duration dermal		2 hours			d_ReExpDur
Exposure duration inhalation		24 hours			d_ReExpDurInhal
Exposure duration entry into treated crops		0.25 hours			d_ExpDurTreatCrop
Light clothing adjustment factor		18.0%			d_ClothAF
Breathing rate adult		0.23 m³/day/kg			d_BreathRAAd
Breathing rate child (1-3 year old)		1.07 m³/day/kg			d_BreathRCh
Drift percentage on surface (75th percentile)		5.60%			
Drift percentage on surface (mean)		4.10%			
Turf transferable residues percentage		5.00%			d_Turf
Transfer coeff. of surface deposits-adult		7300 cm²/hour			d_ReTCAd
Transfer coeff. of surface deposits-child (1-3 year old)		2600 cm²/hour			d_ReTCCh
Saliva extraction percentage		50.00%			d_SalExt
Surface area of hands mouthed		20 cm²			d_AreaHM
Frequency of hand to mouth activity		9.5 events/hour			d_ReFreqHM
Ingestion rate for mouthing of grass per day		25 cm²			d_MouthGrass
Dislodgeable residues percentage transferability for object to mouth		20.00%			d_DRP
Transfer coefficient for entry into treated crops (75th percentile) - ad		7500 cm²/h			d_TcEntryAd
Transfer coefficient for entry into treated crops (75th percentile) - chi		2250 cm²/h			d_TcEntryCh
Transfer coefficient for entry into treated crops (mean) - adult		5980 cm²/h			d_TcEntryAd
Transfer coefficient for entry into treated crops (mean) - child		1794 cm²/h			d_TcEntryCh
1. Total					
1.1 1-3 year old child					
Spray drift (75th percentile)		Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0322296	0.0107000	0.0038842	0.0405000	0.0635886
Total systemic exposure per kg body weight (mg a.s./day/kg)	0.0032230	0.0010700	0.0003884	0.0040500	0.0063589
% of RVNAS	0.14%	0.05%	0.02%	0.18%	0.28%
1.2 Adult					
Spray drift		Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0462720	0.0138000	0.0098112	0.1350000	0.1506057
Total systemic exposure per kg body weight (mg a.s./day/kg)	0.0007712	0.0002300	0.0001635	0.0022500	0.0025101
% of RVNAS	0.03%	0.01%	0.01%	0.10%	0.11%

Table A11: Leaf vegetables and fresh herbs

Croptype	Leaf vegetables and fresh herbs				
Application method	Downward spraying				
Application equipment	Vehicle-mounted				
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				
Buffer strip	2-3 m				
Application rate of the product	0.048 kg a.s./ha				
Concentration of active substance (in-use dilution for liquid applications)	0.24 g a.s./l				
Dermal absorption of product	10.00%				
Dermal absorption of in-use dilution	50.00%				
Oral absorption	100.00%				
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.144 µg a.s./cm <sup>2</sup>				
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa Pa				
Concentration in air	0.001 mg/m <sup>3</sup>				
Resident dermal spray drift exposure 75th percentile - adult	0.47 ml spray dilution/person				
Resident dermal spray drift exposure 75th percentile - child	0.327 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - adult	0.00010 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - child	0.00022 ml spray dilution/person				
Resident dermal spray drift exposure mean - adult	0.22318 ml spray dilution/person				
Resident dermal spray drift exposure mean - child	0.18 ml spray dilution/person				
Resident inhal. spray drift exposure mean - adult	0.00009 ml spray dilution/person				
Resident inhal. spray drift exposure mean - child	0.00017 ml spray dilution/person				
Exposure duration dermal	2 hours				
Exposure duration inhalation	24 hours				
Exposure duration entry into treated crops	0.25 hours				
Light clothing adjustment factor	18.0%				
Breathing rate adult	0.23 m <sup>3</sup> /day/kg				
Breathing rate child (1-3 year old)	1.07 m <sup>3</sup> /day/kg				
Drift percentage on surface (75th percentile)	5.60%				
Drift percentage on surface (mean)	4.10%				
Turf transferable residues percentage	5.00%				
Transfer coeff. of surface deposits-adult	7300 cm <sup>2</sup> /hour				
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm <sup>2</sup> /hour				
Saliva extraction percentage	50.00%				
Surface area of hands mouthed	20 cm <sup>2</sup>				
Frequency of hand to mouth activity	9.5 events/hour				
Ingestion rate for mouthing of grass per day	25 cm <sup>2</sup>				
Dislodgeable residues percentage transferability for object to mouth	20.00%				
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500 cm <sup>2</sup> /h				
Transfer coefficient for entry into treated crops (75th percentile) - child	2250 cm <sup>2</sup> /h				
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm <sup>2</sup> /h				
Transfer coefficient for entry into treated crops (mean) - child	1794 cm <sup>2</sup> /h				
1. Total					
1.1 1-3 year old child					
Spray drift (75th percentile)		Vapour (75th percentile)		Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0322296	0.0107000	0.0038842	0.0405000	0.0635886
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0032230	0.0010700	0.0003884	0.0040500	0.0063589
% of RVNAS	0.14%	0.05%	0.02%	0.18%	0.28%
1.2 Adult					
Spray drift		Vapour		Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0462720	0.0138000	0.0098112	0.1350000	0.1506057
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0007712	0.0002300	0.0001635	0.0022500	0.0025101
% of RVNAS	0.03%	0.01%	0.01%	0.10%	0.11%

Resident exposure for					
Croptype	Leaf vegetables and fresh herbs				
Application method	Downward spraying				
Application equipment	Vehicle-mounted				
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				
Buffer strip	2-3 m				
Application rate of the product	0.048 kg a.s./ha				
Concentration of active substance (in-use dilution for liquid applications)	0.24 g a.s./l				
Dermal absorption of product	50.00%				
Dermal absorption of in-use dilution	50.00%				
Oral absorption	100.00%				
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.144 µg a.s./cm²				
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa				
Concentration in air	0.001 mg/m³				
Resident dermal spray drift exposure 75th percentile - adult	0.47 ml spray dilution/person				
Resident dermal spray drift exposure 75th percentile - child	0.327 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - adult	0.00010 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - child	0.00022 ml spray dilution/person				
Resident dermal spray drift exposure mean - adult	0.22318 ml spray dilution/person				
Resident dermal spray drift exposure mean - child	0.18 ml spray dilution/person				
Resident inhal. spray drift exposure mean - adult	0.00009 ml spray dilution/person				
Resident inhal. spray drift exposure mean - child	0.00017 ml spray dilution/person				
Exposure duration dermal	2 hours				
Exposure duration inhalation	24 hours				
Exposure duration entry into treated crops	0.25 hours				
Light clothing adjustment factor	18.0%				
Breathing rate adult	0.23 m³/day/kg				
Breathing rate child (1-3 year old)	1.07 m³/day/kg				
Drift percentage on surface (75th percentile)	5.60%				
Drift percentage on surface (mean)	4.10%				
Turf transferable residues percentage	5.00%				
Transfer coeff. of surface deposits-adult	7300 cm²/hour				
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm²/hour				
Saliva extraction percentage	50.00%				
Surface area of hands mouthed	20 cm²				
Frequency of hand to mouth activity	9.5 events/hour				
Ingestion rate for mouthing of grass per day	25 cm²				
Dislodgeable residues percentage transferability for object to mouth	20.00%				
Transfer coefficient for entry into treated crops (75th percentile) - ad	7500 cm²/h				
Transfer coefficient for entry into treated crops (75th percentile) - chi	2250 cm²/h				
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm²/h				
Transfer coefficient for entry into treated crops (mean) - child	1794 cm²/h				
1. Total					
1.1 1-3 year old child					
Spray drift (75th percentile)		Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0322296	0.0107000	0.0038842	0.0405000	0.0635886
Total systemic exposure per kg body weight	0.0032230	0.0010700	0.0003884	0.0040500	0.0063589
% of RVNAS	0.14%	0.05%	0.02%	0.18%	0.28%
1.2 Adult					
Spray drift		Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0462720	0.0138000	0.0098112	0.1350000	0.1506057
Total systemic exposure per kg body weight	0.0007712	0.0002300	0.0001635	0.0022500	0.0025101
% of RVNAS	0.03%	0.01%	0.01%	0.10%	0.11%

Table A12: Ornamentals

Croptype	Ornamentals				
Application method	Downward spraying				
Application equipment	Vehicle-mounted				<i>i_AppEquip</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				<i>i_FormVal</i>
Buffer strip	2-3 m				<i>i_Buffer</i>
Application rate of the product	0.048 kg a.s./ha				<i>i_AppRate</i>
Concentration of active substance (in-use dilution for liquid applications)	0.24 g a.s./l				<i>d_ConcAS</i>
Dermal absorption of product	10.00%				<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	50.00%				<i>i_AbsorpInuse</i>
Oral absorption	100.00%				<i>i_AbsorpOrallInuse</i>
Dislodgeable foliar residue ( <i>i_AppRate</i> * <i>i_DFR</i> )	0.144 µg a.s./cm <sup>2</sup>				<i>d_DFR</i>
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10 <sup>-3</sup> Pa				<i>i_Volat</i>
Concentration in air	0.001 mg/m <sup>3</sup>				<i>d_AirCon</i>
Resident dermal spray drift exposure 75th percentile - adult	0.47 ml spray dilution/person				
Resident dermal spray drift exposure 75th percentile - child	0.327 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - adult	0.00010 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - child	0.00022 ml spray dilution/person				
Resident dermal spray drift exposure mean - adult	0.22318 ml spray dilution/person				
Resident dermal spray drift exposure mean - child	0.18 ml spray dilution/person				
Resident inhal. spray drift exposure mean - adult	0.00009 ml spray dilution/person				
Resident inhal. spray drift exposure mean - child	0.00017 ml spray dilution/person				
Exposure duration dermal	2 hours				<i>d_ReExpDur</i>
Exposure duration inhalation	24 hours				<i>d_ReExpDurInhal</i>
Exposure duration entry into treated crops	0.25 hours				<i>d_ExpDurTreatCrop</i>
Light clothing adjustment factor	18.0%				<i>d_ClothAF</i>
Breathing rate adult	0.23 m <sup>3</sup> /day/kg				<i>d_BreathRAAd</i>
Breathing rate child (1-3 year old)	1.07 m <sup>3</sup> /day/kg				<i>d_BreathRCh</i>
Drift percentage on surface (75th percentile)	5.60%				
Drift percentage on surface (mean)	4.10%				
Turf transferable residues percentage	5.00%				<i>d_Turf</i>
Transfer coeff. of surface deposits-adult	7300 cm <sup>2</sup> /hour				<i>d_ReTCAd</i>
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm <sup>2</sup> /hour				<i>d_ReTCCh</i>
Saliva extraction percentage	50.00%				<i>d_SalExt</i>
Surface area of hands mouthed	20 cm <sup>2</sup>				<i>d_AreaHM</i>
Frequency of hand to mouth activity	9.5 events/hour				<i>d_ReFreqHM</i>
Ingestion rate for mouth of grass per day	25 cm <sup>2</sup>				<i>d_MouthGrass</i>
Dislodgeable residues percentage transferability for object to mouth	20.00%				<i>d_DRP</i>
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500 cm <sup>2</sup> /h				<i>d_TcEntryAd</i>
Transfer coefficient for entry into treated crops (75th percentile) - child	2250 cm <sup>2</sup> /h				<i>d_TcEntryCh</i>
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm <sup>2</sup> /h				<i>d_TcEntryAd</i>
Transfer coefficient for entry into treated crops (mean) - child	1794 cm <sup>2</sup> /h				<i>d_TcEntryCh</i>
<b>1. Total</b>					
<b>1.1 1-3 year old child</b>					
Spray drift (75th percentile)		Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0322296	0.0107000	0.0038842	0.0405000	0.0635886
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0032230	0.0010700	0.0003884	0.0040500	0.0063589
% of RVNAS	0.14%	0.05%	0.02%	0.18%	0.28%
<b>1.2 Adult</b>					
Spray drift		Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0462720	0.0138000	0.0098112	0.1350000	0.1506057
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0007712	0.0002300	0.0001635	0.0022500	0.0025101
% of RVNAS	0.03%	0.01%	0.01%	0.10%	0.11%

Resident exposure for					
Croptype	Ornamentals				
Application method	Downward spraying				
Application equipment	Vehicle-mounted			i_AppEquip	
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.			i_FormVal	
Buffer strip	2-3 m			i_Buffer	
Application rate of the product	0.048 kg a.s./ha			i_AppRate	
Concentration of active substance (in-use dilution for liquid applications)	0.24 g a.s./l			d_ConcAS	
Dermal absorption of product	50.00%			i_AbsorpProduct	
Dermal absorption of in-use dilution	50.00%			i_AbsorpInuse	
Oral absorption	100.00%			i_AbsorpOrallnuse	
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.144 µg a.s./cm²			d_DFR	
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa			Pa	i_Volat
Concentration in air	0.001 mg/m³				d_AirCon
Resident dermal spray drift exposure 75th percentile - adult	0.47 ml spray dilution/person				
Resident dermal spray drift exposure 75th percentile - child	0.327 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - adult	0.00010 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - child	0.00022 ml spray dilution/person				
Resident dermal spray drift exposure mean - adult	0.22318 ml spray dilution/person				
Resident dermal spray drift exposure mean - child	0.18 ml spray dilution/person				
Resident inhal. spray drift exposure mean - adult	0.00009 ml spray dilution/person				
Resident inhal. spray drift exposure mean - child	0.00017 ml spray dilution/person				
Exposure duration dermal	2 hours				d_ReExpDur
Exposure duration inhalation	24 hours				d_ReExpDurInhal
Exposure duration entry into treated crops	0.25 hours				d_ExpDurTreatCrop
Light clothing adjustment factor	18.0%				d_ClothAF
Breathing rate adult	0.23 m³/day/kg				d_BreathRAD
Breathing rate child (1-3 year old)	1.07 m³/day/kg				d_BreathRCh
Drift percentage on surface (75th percentile)	5.60%				
Drift percentage on surface (mean)	4.10%				
Turf transferable residues percentage	5.00%				d_Turf
Transfer coeff. of surface deposits-adult	7300 cm²/hour				d_ReTCAd
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm²/hour				d_ReTCCh
Saliva extraction percentage	50.00%				d_SolExt
Surface area of hands mouthed	20 cm²				d_AreaHM
Frequency of hand to mouth activity	9.5 events/hour				d_ReFreqHM
Ingestion rate for mouthing of grass per day	25 cm²				d_MouthGrass
Dislodgeable residues percentage transferability for object to mouth	20.00%				d_DRP
Transfer coefficient for entry into treated crops (75th percentile) - ad	7500 cm²/h				d_TcEntryAd
Transfer coefficient for entry into treated crops (75th percentile) - chi	2250 cm²/h				d_TcEntryCh
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm²/h				d_TcEntryAd
Transfer coefficient for entry into treated crops (mean) - child	1794 cm²/h				d_TcEntryCh
1. Total					
1.1 1-3 year old child					
Spray drift (75th percentile)		Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0322296	0.0107000	0.0038842	0.0405000	0.0635886
Total systemic exposure per kg body weight	0.0032230	0.0010700	0.0003884	0.0040500	0.0063589
% of RVNAS	0.14%	0.05%	0.02%	0.18%	0.28%
1.2 Adult					
Spray drift		Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0462720	0.0138000	0.0098112	0.1350000	0.1506057
Total systemic exposure per kg body weight	0.0007712	0.0002300	0.0001635	0.0022500	0.0025101
% of RVNAS	0.03%	0.01%	0.01%	0.10%	0.11%

## 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 required