

FINAL REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: CHR/H/DIK 480 SL

Product name(s): Macamba 480 SL, Dikambin 480 SL

Chemical active substance(s):

Dicamba, 480 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Innvigo Sp. z o.o.

Submission date: May 2022

MS Finalisation date: 16/06/2023

Version history

When	What
01/2023	Dossier sent for evaluation
03/2023	Applicant update
04/2023	zRMS evaluation of dRR
06/2023	Final version prepared by zRMS after Commenting period

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Evaluator comments:

The text highlighted in grey was provided by the evaluator.

6 Mammalian Toxicology (KCP 7)

6.1 Summary

Table 6.1-1: Information on CHR/H/DIK 480 SL *

Product name and code	CHR/H/DIK 480 SL
Formulation type	SL
Active substance(s) (incl. content)	dicamba; 480 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/DIK 480 SL can be found in the confidential dRR Part C.

Justified proposals for classification and labelling

According to the criteria given in Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008, the following classification and labelling with regard to toxicological data is proposed for the preparation:

Table 6.1-2: Justified proposals for classification and labelling for CHR/H/DIK 480 SL according to Regulation (EC) No 1272/2008

Hazard class(es), categories:	Acute Tox. 4, H302 Skin Corr. 1B, H314 Eye Dam. 1, H318 STOT SE 3, H335
Hazard pictograms or Code(s) for hazard pictogram(s):	GHS05, GHS07
Signal word:	Warning Danger
Hazard statement(s):	Acute Tox. 4, H302 – Harmful if swallowed Skin Corr. 1B, H314 – Causes severe skin burns and eye damage Eye Dam. 1, H318 – Causes serious eye damage STOT SE 3, H335 – May cause respiratory irritation
Precautionary statement(s):	P261 – Avoid breathing dust, fume, gas, mist, vapours or spray. P264 – Wash contaminated skin thoroughly after handling. P280 – Wear protective gloves, protective clothing, eye protection and face protection. P301 + P312 – IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell. P304 + P340 – IF INHALED: Remove person to fresh air and keep comfortable for breathing P305 + P351 + P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313 – If eye irritation persists: Get medical advice/attention.
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]
	Contains: dimethylamine ... %

Table 6.1-3: Summary of risk assessment for operators, workers, bystanders and residents for CHR/H/DIK 480 SL

	Result	PPE / Risk mitigation measures
Operators	Acceptable	None Protective clothes, protective gloves and face/eye protection at the mixing/loading step due to hazard characterisation.
Workers	Acceptable	None (workwear)
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 resident exposure based on [Expo- sure 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
	Maize (BBCH 12-16)	F	Spraying, LCTM	1 ; 1	a) 0.288	200 - 300			A	A	A	A

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

*** e.g. LC: low crops, HC: high crop, TM: tractor-mounted, HH: hand-held

Explanation for column 10 “Acceptability of exposure assessment”

A	Exposure acceptable without PPE / risk mitigation measures
R	Further refinement and/or risk mitigation measures required
N	Exposure not acceptable/ Evaluation not possible

Data gaps

Noticed data gaps are:

- none

6.2 Toxicological Information on Active Substance(s)

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

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

	Dicamba
Common Name	Dicamba
CAS-No.	1918-00-9
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	<p>Hazard classes (s), categories: Acute Tox. 4, H302 Eye Dam. 1, H318</p> <p>Code(s) for hazard pictogram(s): GHS07, GHS05</p> <p>Signal word: Danger</p> <p>Hazard statement(s): H302 – Harmful if swallowed. H318 – Causes serious eye damage.</p> <p>Precautionary statement(s): P270 – Do not eat, drink or smoke when using this product.</p>

	Dicamba
	<p>P280 – Wear protective gloves/protective clothing/eye protection/face protection.</p> <p>P301 + P312 – IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.</p> <p>P305 + P351 + P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> <p>P310 – Immediately call a POISON CENTER or doctor/physician.</p>
Additional C&L proposal	-
AOEL systemic	0.3 mg/kg bw/d
AAOEL	None
Reference	EFSA Journal 2011;9(1):1965 SANCO/829/08-final rev. 2, 12 July 2016
EFSA Journal 2011;9(1):1965 for active substance	the operator and worker safety

6.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for CHR/H/DIK 480 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/DIK 480 SL

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD ₅₀ oral (calucation method)	873.36 mg/kg bw	Yes	Acute Tox. 4, H302	K. Žero, 2022
LD ₅₀ dermal (calucation method)	>2000 mg/kg bw*	Yes	None	K. Žero, 2022
LC ₅₀ inhalation (calucation method)	76.92 mg/L air	Yes	None	K. Žero, 2022
Skin irritation (calucation method)	Irritant	Yes	Skin Corr. 1B, H314	K. Žero, 2022
Eye irritation (calucation method)	Irritant	Yes	Eye Dam. 1, H318	K. Žero, 2022
Skin sensitisation (calucation method)	Non-sensitising	Yes	None	K. Žero, 2022
Supplementary studies for combinations of plant protection products	No data – not required			

* The product CHR/H/DIK 480 SL does not contain ingredients classified as dermal toxic, therefore the formulation will not be classified as Acute Tox. 4, H312 as well.

Table 6.3-2: Additional toxicological information relevant for classification/labelling of CHR/H/DIK 480 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)	Dicamba (CAS: 1918-00-9, 40 - 43 % (w/w))	Acute Tox. 4, H302 Eye Dam. 1, H318	Annex VI of Reg. 1272/2008	Acute Tox. 4, H302 Eye Dam. 1, H318
Toxicological properties of non-active substance(s) (relevant for classification of product)	Dimethylamine 60 % (CAS:124- 40-3, ≥ 5 % (w/w))	Acute Tox. 4, H302, Acute Tox. 4, H332, Skin Corr. 1B, H314, Eye Dam. 1, H318, STOT SE 3, H335,	Annex VI of Reg. 1272/2008 and co-formulant MSDS	Acute Tox. 4, H302, Skin Corr. 1B, H314, Eye Dam. 1, H318, STOT SE 3, H335,
Further toxicological information	No data – not required			

* Please use concentration range or concentration limit (e.g. 1-10 % or > 1 %) as provided in MSDS.

** Material safety data sheet by the applicant

6.4 Toxicological Evaluation of Groundwater Metabolites

zRMS comments: Acceptable. See also dRR B10.

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

6.5 Dermal Absorption (KCP 7.3)

A summary of the dermal absorption rates for the active substances in CHR/H/DIK 480 SL are presented in the following table.

Table 6.5-1: Dermal absorption rates for active substances in CHR/H/DIK 480 SL

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

6.5.1 Justification for proposed values - dicamba

No data on dermal absorption for dicamba in CHR/H/DIK 480 SL 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 dicamba

	Value	Justification for value	Acceptability of justification
Concentrate	10 %	EFSA Journal 2017;15(6):4873	Yes
Dilution	50 %	EFSA Journal 2017;15(6):4873	Yes

6.6 Exposure Assessment of Plant Protection Product (KCP 7.2)

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

Product name and code	CHR/H/DIK 480 SL
Formulation type	SL
Category	Herbicide
Active substance(s) (incl. content)	Dicamba 480 g/L
AOEL systemic	0.3 mg/kg bw/d
AAOEL	None
Inhalation absorption	100 %
Oral absorption	100 %
Dermal absorption	Concentrate: 10 % Dilution: 50 % (Default for water-based formulation)

6.6.1 Selection of critical use(s) and justification

The critical GAP used for the exposure assessment of the plant protection product is shown in Table 6.1-4. A list of all intended uses within the zone/ EU is given in Part B, Section 0.

6.6.2 Operator exposure (KCP 7.2.1)

zRMS comments:	<p>The operator exposure calculations for the proposed use of CHR/H/DIK 480 SL conducted by the Applicant using EFSA model are acceptable.</p> <p>The AAOEL value for dicamba is not determined, therefore an acute risk assessment is not required.</p> <p>The potential longer term exposure to CHR/H/DIK 480 SL applied to maize is within acceptable limit (43.84% of AOEL).</p> <p>However, taking also into consideration the classification of the product, protective clothes, protective gloves and face/eye protection should be used during the mixing/loading step.</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/DIK 480 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)	Cereals Culture(s) (max. 0.6 L product/ha)
Model(s)	EFSA Model (2014), calculator version: 30/03/2015

Table 6.6-3: Estimated operator exposure

		Dicamba	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to low crops Application rate: 0.288 kg a.s./ha			
EFSA Model () Body weight: 60 kg	no PPE* (potential exposure)	0.1315208	43.84
	Work wear during mix/loading and application	0.0834994	27.83
	Work wear during mix/loading and application + gloves during mix/loading	0.0207364	6.91

* no PPE: Operator wearing T-shirt and shorts

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)

zRMS comments:	<p>The worker exposure calculations for the proposed use of CHR/H/DIK 480 SL conducted by the Applicant using EFSA model are acceptable.</p> <p>The potential exposure for workers is within acceptable limit (60% of AOEL), however the use of workwear (arms, body and legs covered) is always recommended for workers.</p> <p>As a standard rule, crops treated by CHR/H/DIK 480 SL should not be re-entered before spray deposit on leaf surfaces has completely dried.</p>
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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/DIK 480 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 6.6-4: Exposure models for intended uses

Critical use(s)	Cereals Culture(s) (max. 1 x 0.6 L product/ha)
Model	EFSA Model (2014), calculator version: 30/03/2015

Table 6.6-5: Estimated worker exposure

		Dicamba	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Number of applications and application rate:		0.288 kg a.s./ha	
2 hours/day ⁽¹⁾ , TC: 12500 cm ² /person/h ⁽²⁾ Body weight: 60 kg	no PPE ⁽³⁾	0.1800000	60
	With no PPE ⁽⁴⁾ -- Work wear - arms, body and legs covered	0.0201600	6.72

(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 in accordance with the EFSA model. TC: Transfer coefficient

(3) no PPE: Worker wearing long sleeved shirt, long trousers ("permeable") but no gloves potential exposure

(4) with PPE: type of PPE/ see 'Instructions for use'

6.6.4.2 Refinement of generic DFR value (KCP 7.2)

Not required.

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)

zRMS comment	<p>The resident exposure calculations for the proposed use of CHR/H/DIK 480 SL conducted by the Applicant using EFSA model are acceptable.</p> <p>As no AAOEL value was established for active substance dicamba, bystander's exposure is covered by resident's exposure.</p> <p>The resident/bystander exposure (both for children and adults) calculated for dicamba is within the acceptable limit, when the CHR/H/DIK 480 SL formulation is used in maize (all pathways: 4.64% of AOEL for adults and 10.93% of AOEL for children).</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 dicamba. Outcome of the estimation is presented in Table 6.6-7. Detailed calculations are in Appendix 3. The lack of AAOEL value for dicamba the calculations for bystander exposure are covered by resident exposure.

Table 6.6-6: Exposure models for intended uses

Critical use(s)	Cereals Culture(s) (max. 1 x 0.6 L product/ha)
Model	EFSA Model (2014), calculator version: 30/03/2015

Table 6.6-7: Estimated bystander and resident exposure

Model data	Dicamba	
	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to low crops Application rate: 0.288 kg as/ha		
Resident/Bystanders (adult) Body weight: 60 kg	0.0139106	4.64
Resident/Bystanders Body weight: 10 kg	0.0328031	10.93
Residents/ Bystander (adult) Body weight: 60 kg	0.0139106	4.64
Residents/ Bystander (children) Body weight: 10 kg	0.0328031	10.93

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 dicamba 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.

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	K. Žero	2022	Toxicological classification of product CHR/H/DIK 480 SL based on calculation method taking into consideration health hazards of constituent substances. Chemirol Sp. z o.o. Non GLP Unpublished	N	Chemirol Sp. z o.o

A 2.2 Acute oral toxicity (KCP 7.1.1)

Reference:	KCP 7
Report	Toxicological classification of product CHR/H/DIK 480 SL based on calculation method taking into consideration health hazards of constituent substances., K. Žero, 2022,
Guideline(s):	Legal basis: REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.
Deviations:	No
GLP:	No
Acceptability:	Yes
Duplication (if vertebrate study)	No

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 bodyweight)	$0 < \text{Category } 1 \leq 5$ $5 < \text{Category } 2 \leq 50$ $50 < \text{Category } 3 \leq 300$ $300 < \text{Category } 4 \leq 2\,000$	0,5 5 100 500
Dermal (mg/kg bodyweight)	$0 < \text{Category } 1 \leq 50$ $50 < \text{Category } 2 \leq 200$ $200 < \text{Category } 3 \leq 1\,000$ $1\,000 < \text{Category } 4 \leq 2\,000$	5 50 300 1\,100
Gases (ppmV)	$0 < \text{Category } 1 \leq 100$ $100 < \text{Category } 2 \leq 500$ $500 < \text{Category } 3 \leq 2\,500$ $2\,500 < \text{Category } 4 \leq 20\,000$	10 100 700 4\,500

Vapours (mg/l)	$0 < \text{Category 1} \leq 0,5$ $0,5 < \text{Category 2} \leq 2,0$ $2,0 < \text{Category 3} \leq 10,0$ $10,0 < \text{Category 4} \leq 20,0$	0,05 0,5 3 11
Dust/mist (mg/l)	$0 < \text{Category 1} \leq 0,05$ $0,05 < \text{Category 2} \leq 0,5$ $0,5 < \text{Category 3} \leq 1,0$ $1,0 < \text{Category 4} \leq 5,0$	0,005 0,05 0,5 1,5

Only two ingredients are relevant in this class of hazard:

- 42.26 % (Acute Tox. 4, H302)

- 14.14 % (Acute Tox. 4, H302)

$$ATE_{mix} = \frac{100}{\sum_{i=1}^n \frac{C_i}{ATE_{mix}}} = \frac{100}{\frac{42.26}{500} + \frac{14.14}{500}} = \frac{100}{0.1145} = 873.36 \frac{mg}{kg \text{ b.w.}}$$

Conclusion

According to the table 3.1.2, a result (873.36 mg/kg bw) **classifies** the whole formulation as **Acute Tox. 4, H302..**

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

zRMS comments:	Acceptable. The formulation CHR/H/DIK 480 SL does not need to be classified as dermal toxic.
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The product CHR/H/DIK 480 SL does not contain ingredients classified as dermal toxic, therefore the formulation will not be classified as Acute Tox. 4, H312 as well.

A 2.4 Acute inhalation toxicity (KCP 7.1.3)

zRMS comments:	The Applicant performed the toxicological assessment of the formulation CHR/H/DIK 480 SL using the calculation method in accordance with CLP based on the composition of the formulation and taking into account the classification of each component of the mixture. The calculations provided by Applicant are acceptable. According to the calculation result the formulation does not to be classified as Acute Tox. 4 (H332).
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Reference: KCP 7

Report Toxicological classification of product CHR/H/DIK 480 SL based on calculation method taking into consideration health hazards of constituent substances., K. Žero, 2022,

Guideline(s): Legal basis: REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Deviations: No

GLP: No

Acceptability: Yes

Duplication No
 (if vertebrate study)

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:

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 bodyweight)	$0 < \text{Category 1} \leq 5$ $5 < \text{Category 2} \leq 50$ $50 < \text{Category 3} \leq 300$ $300 < \text{Category 4} \leq 2\,000$	0,5 5 100 500
Dermal (mg/kg bodyweight)	$0 < \text{Category 1} \leq 50$ $50 < \text{Category 2} \leq 200$ $200 < \text{Category 3} \leq 1\,000$ $1\,000 < \text{Category 4} \leq 2\,000$	5 50 300 1\,100
Gases (ppmV)	$0 < \text{Category 1} \leq 100$ $100 < \text{Category 2} \leq 500$ $500 < \text{Category 3} \leq 2\,500$ $2\,500 < \text{Category 4} \leq 20\,000$	10 100 700 4\,500
Vapours (mg/l)	$0 < \text{Category 1} \leq 0,5$ $0,5 < \text{Category 2} \leq 2,0$ $2,0 < \text{Category 3} \leq 10,0$ $10,0 < \text{Category 4} \leq 20,0$	0,05 0,5 3 11
Dust/mist (mg/l)	$0 < \text{Category 1} \leq 0,05$ $0,05 < \text{Category 2} \leq 0,5$ $0,5 < \text{Category 3} \leq 1,0$ $1,0 < \text{Category 4} \leq 5,0$	0,005 0,05 0,5 1,5

Only one ingredient is relevant in this class of hazard:

- 14.14% (Acute Tox. 4, H332)

$$ATE_{mix} = \frac{100}{\sum_{i=1}^n \frac{C_i}{ATE_{mix}}} = \frac{100}{\frac{14.14}{11}} = \frac{100}{1.3} = 76.92 \frac{mg}{L}$$

Conclusion

According to the table 3.1.2, a result (76.92 mg/L) does not classify the whole formulation as Acute Tox. 4, H332.

A 2.5 Skin irritation (KCP 7.1.4)

zRMS comments:	The Applicant performed the toxicological assessment of the formulation CHR/H/DIK 480 SL using the calculation method in accordance with CLP based on the composition
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	of the formulation and taking into account the classification of each component of the mixture. The calculations provided by Applicant are acceptable. According to the calculation result the formulation should be classified as Skin Corr. 1B (H314).
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Reference:	KCP 7
Report	Toxicological classification of product CHR/H/DIK 480 SL based on calculation method taking into consideration health hazards of constituent substances., K. Žero, 2022,
Guideline(s):	Legal basis: REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.
Deviations:	No
GLP:	No
Acceptability:	Yes
Duplication (if vertebrate study)	No

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		$\geq 10 \%$
($10 \times$ Skin corrosion Sub-Category 1A, 1B, 1C or Category 1) + Skin irritation Category 2		$\geq 10 \%$

Only one ingredient is relevant in this class of hazard:

- 14.14 % (Skin Corr. 1B, H314)

Conclusion

The concentration of relevant ingredient (14.14 %) is higher than concentration triggering the classification (5%). Therefore the whole formulation will be classified as **Skin Corr. 1B, H314** as well..

A 2.6 Eye irritation (KCP 7.1.5)

A 2.6.1 Study 1

zRMS comments:	The Applicant performed the toxicological assessment of the formulation CHR/H/DIK 480 SL using the calculation method in accordance with CLP based on the composition of the formulation and taking into account the classification of each component of the mixture. The calculations provided by Applicant are acceptable. According to the calculation result the formulation should be classified as Eye Dam. 1 (H318).
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Reference: KCP 7

Report Toxicological classification of product CHR/H/DIK 480 SL based on calculation method taking into consideration health hazards of constituent substances., K. Žero, 2022,

Guideline(s): Legal basis: REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Deviations: No

GLP: No

Acceptability: Yes

Duplication
(if vertebrate study) No

Materials and methods

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

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)		$\geq 10 \%$

Two ingredients are relevant in this class of hazard:

- 42.26 % (Eye Dam. 1, H318)
- 14.14 % (Skin Corr. 1, H314)

$$\sum C_{SkinCorr.} + \sum C_{EyeDam.} = 42.26 \% + 14.14 \% = 56.4 \%$$

Conclusion

As the result 56.4 % is higher than result triggering classification (3%) the whole formulation will be classified as corrosive to eyes (Eye Dam. 1, H318)..

A 2.7 Skin sensitisation (KCP 7.1.6)

A 2.7.1 Study 1

zRMS comments:	The Applicant performed the toxicological assessment of the formulation CHR/H/DIK 480 SL using the calculation method in accordance with CLP based on the composition of the formulation and taking into account the classification of each component of the mixture. The calculations provided by Applicant are acceptable. According to the calculation result the formulation does not to be classified as skin sensitiser.
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Reference:	KCP 7
Report	Toxicological classification of product CHR/H/DIK 480 SL based on calculation method taking into consideration health hazards of constituent substances., K. Žero, 2022,
Guideline(s):	Legal basis: REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.
Deviations:	No
GLP:	No
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

We use the table:

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

Skin sensitizing (Skin Sens. 1A, H317)

Only one ingredient is classified as sensitizing to skin:
- 0.000043 % (Skin Sens. 1A, H317)

The concentration of this compound is much lower than concentration triggering Skin Sens. 1, H317 classification. Therefore the whole formulation will not be classified as skin sensitizing.

Respiratory sensitizing (Resp. Sens. 1, H334)

Only one ingredient is classified as sensitizing to skin:
- 0.000043 % (Resp Sens. 1, H334)

The concentration of this compound is much lower than concentration triggering Resp. Sens. 1, H334 classification. Therefore the whole formulation will not be classified as respiratory tract sensitizing..

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

Not required

A 2.9 Data on co-formulants (KCP 7.4)

A 2.9.1 Material safety data sheet for each co- formulant

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

A 2.9.2 Available toxicological data for each co-formulant

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

A 2.10 Studies on dermal absorption (KCP 7.3)

zRMS comments:	Acceptable. The default values for dermal absorption were used for risk assessment in accordance with the EFSA Guidance on Dermal Absorption (2017) – 10% for concentrate and 50% for dilutions. The CHR/H/DIK 480 SL formulation is a soluble concentrate (SL), therefore the default values for water based/dispersed or solid formulation type were applied.
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For the dermal absorption of the active substance 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 formulations 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 organic solvent formulated or in other types of formulations.

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

A 2.11 Other/Special Studies

A 2.11.1 Study 1

zRMS comments:	The Applicant performed the toxicological assessment of the formulation CHR/H/DIK 480 SL using the calculation method in accordance with CLP based on the composition of the formulation and taking into account the classification of each component of the mixture. The calculations provided by Applicant are acceptable. According to the calculation result the formulation should be classified as STOT SE 3 (H335).
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Reference: KCP 7

Report Toxicological classification of product CHR/H/DIK 480 SL based on calculation method taking into consideration health hazards of constituent substances., K. Žero, 2022,

Guideline(s): Legal basis: REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Deviations: No

GLP: No
 Acceptability: Yes
 Duplication (if vertebrate study) No

Specific target organ toxicity

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.”

One ingredient is classified as STOT SE 3:

- 14.14 % (STOT SE 3, H335) SCL: STOT SE 3; H335: $C \geq 5\%$
- 0.000043 % (STOT SE 3, H335) SCL: STOT SE 3; H335: $0,5\% \leq C < 5\%$

The concentration of ingredient C exceeds its specific concentration level ($C \geq 5\%$) triggering the classification STOT SE 3, H335. Therefore whole formulation will be classified as **STOT SE 3, H335**.

A 2.11.2 Study 2

zRMS comments:	The Applicant performed the toxicological assessment of the formulation CHR/H/DIK 480 SL using the calculation method in accordance with CLP based on the composition of the formulation and taking into account the classification of each component of the mixture. The calculations provided by Applicant are acceptable. According to the calculation result the formulation does not to be classified as toxic for reproduction.
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Reference: KCP 7

Report: Toxicological classification of product CHR/H/DIK 480 SL based on calculation method taking into consideration health hazards of constituent substances., K. Žero, 2022,

Guideline(s): Legal basis: REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Deviations: No

GLP: No
Acceptability: Yes
Duplication (if vertebrate study) No

Toxicity for reproduction (Repr. 2, H361f)

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 request.

One ingredient is classified in this class of hazard:

- 0.000043 % (Repr. 2, H361f)

A concentration of this compound is lower than concentration triggering classification (3%). Therefore the formulation is not classified as toxic for reproduction.

Appendix 3 Exposure calculations

A 3.1 Operator exposure calculations (KCP 7.2.1.1)

A 3.1.1 Calculations for dicamba

Operator exposure for outdoor spray applications

Application rate of active substance	0.288 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated	50 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied	14.4 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 th centile	95 th centile		
	Hands	37853	142003	AOEM	
	Body	23258	156319	AOEM	
	Head	747	4098	AOEM	
	Protected hands (gloves)	195	2852	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	253	2106	AOEM	
	Protected head (hood and face shield)	12	232	AOEM	
	Inhalation	8	31	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 th centile	95 th centile		
	Hands	2136	16164	AOEM	
	Body	1194	6156	AOEM	
	Head	56	170	AOEM	
	Protected hands (gloves)	180	4549	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	33	80	AOEM	
	Inhalation	4	13	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)	7.8912503	7.8912503	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.1315208	0.1315208	
% of RVNAS	43.84%	43.84%	

- With work wear during mix/loading and application

Operator exposure for outdoor spray applications

Application rate of active substance	0.288 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated	50 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied	14.4 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	

	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
Hands		37853	142003	AOEM	
Body		23258	156319	AOEM	
Head		747	4098	AOEM	
Protected hands (gloves)		195	2852	AOEM	
Protected body (workwear or protective garment and sturdy footwear)		253	2106	AOEM	
Protected head (hood and face shield)		12	232	AOEM	
Inhalation		8	31	AOEM	
Protective Equipment	Select for inclusion			Penetration factor	Inhalation Protection factor
Gloves	No				
Clothing	Work wear - arms, body and legs covered			Incl. in AOEM model	
Head and respiratory PPE	None			1	1
Water soluble bag	No			1	

	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
Hands		2136	16164	AOEM	
Body		1194	6156	AOEM	
Head		56	170	AOEM	
Protected hands (gloves)		180	4549	AOEM	
Protected body (workwear or protective garment and sturdy footwear)		33	80	AOEM	
Inhalation		4	13	AOEM	
Protective Equipment	Select for inclusion			Penetration factor	Inhalation Protection factor
Gloves	No				
Clothing	Work wear - arms, body and legs covered			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)	7.8912503	5.0099633	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.1315208	0.0834994	
% of RVNAS	43.84%	27.83%	

- With work wear during mix/loading and application + gloves during mix/loading

Operator exposure for outdoor spray applications

Application rate of active substance	0.288 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated	50 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied	14.4 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	

	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
Hands		37853	142003	AOEM	
Body		23258	156319	AOEM	
Head		747	4098	AOEM	
Protected hands (gloves)		195	2852	AOEM	
Protected body (workwear or protective garment and sturdy footwear)		253	2106	AOEM	
Protected head (hood and face shield)		12	232	AOEM	
Inhalation		8	31	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	

	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
Hands		2136	16164	AOEM	
Body		1194	6156	AOEM	
Head		56	170	AOEM	
Protected hands (gloves)		180	4549	AOEM	
Protected body (workwear or protective garment and sturdy footwear)		33	80	AOEM	
Inhalation		4	13	AOEM	
Protective Equipment		Select for inclusion		Penetration factor	Inhalation Protection factor
Gloves		No			
Clothing		Work wear - arms, body and legs covered		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)	7.8912503	1.2441855	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.1315208	0.0207364	
% of RVNAS	43.84%	6.91%	

A 3.2 Worker exposure calculations (KCP 7.2.3.1)

A 3.2.1 Calculations for dicamba

Worker exposure from residues on foliage for				
Crop type	Cereals			
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	0.288	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_AbsorpInuse</i>
Dislodgeable foliar residue (<i>i_AppRate</i> * <i>i_DFR</i>)	0.864	µg a.s./cm ²		<i>d_DFR</i>
Working hours	2	hr		<i>d_WorkHr</i>
Dermal transfer coefficient - Total potential exposure	12500	cm ² /hr		<i>d_DermTcUCV</i>
Dermal transfer coefficient - arms, body and legs covered	1400	cm ² /hr		<i>d_DermTcCV1</i>
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment			<i>d_DermTcCV2</i>
Inhalation transfer coefficient for automated applications	NA	ha/hr*10 [^] (-3)		<i>d_InhalTcAut</i>
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10 [^] (-3)		<i>d_InhalTcCut</i>
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10 [^] (-3)		<i>d_InhalTcSort</i>
1. Total				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	10.8000000	1.2096000	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0.1800000	0.0201600		
% of RVNAS	60.00%	6.72%		

A 3.3 Bystander and resident exposure calculations (KCP 7.2.2.1)

A 3.3.1 Calculations for dicamba

Resident exposure for					
Croptype			Cereals		
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			0.288 kg a.s./ha		i_AppRate
Concentration of active substance (in-use dilution for liquid applications)			1.44 g a.s./l		d_ConcAS
Dermal absorption of product			10.00%		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)			0.864 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_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) - ch			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)	0.1933776	0.0107000	0.0233050	0.2430000	0.3280314
Total systemic exposure per kg body weight (mg a.s./day/kg)	0.0193378	0.0010700	0.0023305	0.0243000	0.0328031
% of RVNAS	6.45%	0.36%	0.78%	8.10%	10.93%
1.2 Adult					
Spray drift		Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.2776320	0.0138000	0.0588672	0.8100000	0.8346343
Total systemic exposure per kg body weight (mg a.s./day/kg)	0.0046272	0.0002300	0.0009811	0.0135000	0.0139106
% of RVNAS	1.54%	0.08%	0.33%	4.50%	4.64%

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)