FINAL REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: CHR/H/ETO 500 SC

Product name(s): BITT 500 SC, BETRON 500 SC, ETONAL 500 SC

Chemical active substance(s):

Ethofumesate, 500 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Innvigo Sp. z o.o.

Submission date: June 2021

MS Finalisation date: 14/01/2022

Version history

When	What
06/2021	Dossier sent for evaluation to Merit Mark (PL)
11/2021	zRMS finalised evaluation
01/2022	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)

In the following document, data for active substance ethofumesate was described during its renewal process in 2016. Where reference to active substance data in the current risk assessment has been made, it was based on the data presented by Bayer.
In June 14th, 2018r Kemiron Koncentrat 500SC product has been renewed in Poland thus according to the art. 59 reg. 1107/2009, data protection for mentioned data expired 30 months from date of first renewal of authorisation of product containing that active substance (in this case December, 14th 2020).
Considering analogous arguments (art. 59 reg 1107/2009) – data protection of studies presented by UPL for renewal of product Bettix Combi 500 SC (renewal of authorisation granted in Poland 14.02.2019 r.) expires August 14th, 2021.
Taking into account that some data was presented by others Notifiers, Applicant would like to emphasise that unprotected Bayer's endpoints and input parameters accepted during renewal of active substance, should be treated as an equivalent matching data in cases where any of endpoints might be protected.

6.1 Summary

Table 6.1-1: Information on CHR/H/ETO 500 SC *

Product name and code	CHR/H/ETO 500 SC
Formulation type	Suspension concentrate [Code: e.g. SC]
Active substance(s) (incl. content)	ethofumesate; 500 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/ETO 500 SC 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/ETO 500 SC according to Regulation (EC) No 1272/2008

Hazard class(es), categories:	none
Hazard pictograms or Code(s) for hazard pictogram(s):	None
Signal word:	None
Hazard statement(s):	None
Precautionary statement(s):	~~P 305 + P351 + P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing~~ ~~P310 – Immediately call a Poison center/doctor/…~~ ~~Other section of the label:~~ ~~P201: Obtain special instructions before use.~~ ~~P264: Wash hands thoroughly after handling.~~ ~~P270: Do no eat, drink or smoke when using this product.~~ ~~P362+364: Take off contaminated clothing and wash before reuse.~~ ~~P405: Store locked up.~~ ~~P403 + P233: Store in a well-ventilated place. Keep container tightly closed.~~ ~~P501: Dispose of contents/container to…~~ ~~P330 – Rinse mouth.~~ ~~And P280 as follows:~~ ~~Section "First Aid"~~ ~~P301+P310, P331, P330~~ ~~P332 + P313~~ ~~P304+P340~~ ~~P301 + P312~~ ~~P308 + P313~~ ~~For polish version: see the label~~
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401] Contains 1,2-benzoizotiazol-3(2H)-onMay produce an allergic reaction. [EUH 280]

Table 6.1-3: Summary of risk assessment for operators, workers, bystanders and residents for CHR/ETO 500 SC

	Result	PPE / Risk mitigation measures
Operators	Acceptable	None
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. safener/synergist (L/ha))** **critical gap for operator, worker, bystander or resident exposure based on [Exposure model]**	**Acceptability of exposure assessment**			
			Method / Kind **(incl. application technique *****)**	**Max. number (min. interval between applications)** **a) per use** **b) per crop/ season**	**Max. application rate kg as/ha** **a) a.s. 1** **b) a.s. 2**	**Water L/ha** **min / max**			**Operator**	**Worker**	**Bystander**	**Residents**
1	Sugar Beet	F	Spraying, LCTM	~~2 ; 5~~ a) 2 (5) b) 2 (5)	0.5~~00~~	200-300						
2	Sugar beet	F	Spraying, LCTM	~~3:5~~ a) 3 (5) b) 3 (5)	0.3~~30~~	200-300						

* 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)

	Ethofumesate
Common Name	Ethofumesate
CAS-No.	26225-79-6
Classification and proposed labelling	
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	~~Hazard classes (s), categories: Aquatic Acute 1, Aquatic Chronic 1~~ ~~Code(s) for hazard pictogram(s): GHS09~~ ~~Signal word: Warning~~ ~~Hazard statement(s): H400, H410~~ ~~Precautionary statement(s):~~ None for human health
Additional C&L	Please insert proposal for additional C&L if no (sufficient) harmonized

	Ethofumesate
proposal	classification is available
Agreed EU endpoints	
AOEL systemic	2.5 mg/kg bw/d
Reference	EFSA Journal 2016;14(1):4374
Conditions to take into account/critical areas of concern with regard to toxicology	
EFSA Journal 2016;14(1):4374 for active substance	**Ethofumesate SC 500** Operators: Use: herbicide in beets, tractor mounted equipment, application rate max. 1 kg a.s./ha Exposure estimates (model): % of AOEL UK POEM Without PPE: 11 PPE (gloves and coverall): 2 German model Without PPE: 1.5 PPE (gloves and coverall): < 1 Workers: EUROPOEM II: 1% of AOEL (no gloves) Bystanders and residents: Martin et al., 2008: Bystander adult: 0.15% of AOEL Bystander child: 0.12% of AOEL Resident adult: 0.02% of AOEL Resident child: 0.05% of AOEL

6.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for CHR/H/ETO 500 SC 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/ETO 500 SC

Type of test, species, model system (Guideline)	**Result**	**Acceptability**	**Classification (acc. to the criteria in Reg. 1272/2008)**	**Reference**
LD_{50} oral, rat (calculated method)	> 2000 mg/kg bw	Yes	None	~~, 2019~~ Toxicological classification of product CHR/H/ETO based on calculation method taking into consideration health hazards of constituent substances; Chemirol Sp. z o.o., 2021
LD_{50} dermal, rat (calculated method)	> 2000 mg/kg bw	Yes	None	~~, 2019~~ Toxicological classification of product CHR/H/ETO based on

				calculation method taking into consideration health hazards of constituent substances; Chemirol Sp. z o.o., 2021
LC_{50} inhalation, rat (calculated method)	> 20 mg/L air	Yes	None	~~-~~, ~~2019~~ Toxicological classification of product CHR/H/ETO based on calculation method taking into consideration health hazards of constituent substances; Chemirol Sp. z o.o., 2021
Skin irritation (calculated method)	Non-irritant	Yes	None	~~-~~, ~~2019~~ Toxicological classification of product CHR/H/ETO based on calculation method taking into consideration health hazards of constituent substances; Chemirol Sp. z o.o., 2021
Skin corrosive (calculated method)	Non corrosive	Yes		~~-~~, ~~2019~~ Toxicological classification of product CHR/H/ETO based on calculation method taking into consideration health hazards of constituent substances; Chemirol Sp. z o.o., 2021
Eye irritation (calculated method)	Non-irritant	Yes	None	~~-~~, ~~2019~~ Toxicological classification of product

				CHR/H/ETO based on calculation method taking into consideration health hazards of constituent substances; Chemirol Sp. z o.o., 2021
Eye corrosive (calculated method)	Non corrosive	Yes	None	~~, 2019~~ Toxicological classification of product CHR/H/ETO based on calculation method taking into consideration health hazards of constituent substances; Chemirol Sp. z o.o., 2021
Skin sensitisation (calculated method)	Non-sensitising		None	~~, 2019~~ Toxicological classification of product CHR/H/ETO based on calculation method taking into consideration health hazards of constituent substances; Chemirol Sp. z o.o., 2021
Specific target organ toxicity (calculated method)	Non triggering	Yes	None	~~, 2019~~ Toxicological classification of product CHR/H/ETO based on calculation method taking into consideration health hazards of constituent substances; Chemirol Sp. z o.o., 2021
Carcinogenicity (calculated method)	Non carcinogenicity	Yes	None	~~, 2019~~ Toxicological

				classification of product CHR/H/ETO based on calculation method taking into consideration health hazards of constituent substances; Chemirol Sp. z o.o., 2021
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/ETO 500 SC

	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)	NR	NR	NR	NR
Toxicological properties of non-active substance(s) (relevant for classification of product)	NR	NR	NR	NR
Further toxicological information	NR	NR	NR	NR

* Please use concentration range or concentration limit (e.g. 1-10 % or > 1 %) as provided in MSDS.
** Material safety data sheet by the applicant

6.4 Toxicological Evaluation of Groundwater Metabolites

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

6.5 Dermal Absorption (KCP 7.3)

A summary of the dermal absorption rates for the active substances in CHR/H/ETO 500 SC are presented in the following table.

Table 6.5-1: Dermal absorption rates for active substances in CHR/H/ETO 500 SC

	Ethofumesate	
	Value	**Reference**
Concentrate	10 % Default value	EFSA Journal 2017;15(6):4873
Dilution	50 %	EFSA Journal

	Ethofumesate	
	Value	**Reference**
(dilution factor)	Default value	2017;15(6):4873

6.5.1 Justification for proposed values - ethofumesate

No data on dermal absorption for ethofumesate in CHR/H/ETO 500 SC 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 ethofumesate

	Value	Justification for value	Acceptability of justification
Concentrate	10 % Default value	EFSA Journal 2017;15(6):4873	Yes
Dilution	50 % Default value	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/ETO 500 SC
Formulation type	SC
Category	Herbicide
Container size(s), short description	0.1L - 20L HDPE/PA 0.1 - 20L HDPE/F 0.1-20L HDPE/EvOH
Active substance(s) (incl. content)	**Ethofumesate** 500 g/L
AOEL systemic	2.5 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(s) 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 zone is given in Part B, Section 0.

6.6.2 Operator exposure (KCP 7.2.1)

Comments of zRMS:	The operator exposure calculations for the proposed uses of formulation CHR/H/ETO 500 SC containing Ethofumesate (500 g/L) conducted by the Applicant using the EFSA calculator and presented in Table 6.6-3 are accepted. At the applications 2 x 0.50 kg a.s./ha and 3 x 0.3 kg a.s./ha in sugar beet the predicted potential exposure of unprotected operator to Ethofumesate contained in the formulation CHR/H/ETO 500 SC is within acceptable limit (8.20% of AOEL at the application 2 x 0.50 kg a.s./ha and 5.44% of AOEL at the application 3 x 0.30 kg a.s./ha). However, according to good agricultural practices, gloves are generally recommended when handling the concentrated product and contaminated surfaces.

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/ETO 500 SC according to the critical use(s) is presented in Table 6.6-2 ~~**Błąd! Nie można odnaleźć źródła odwołania.**~~. Outcome of the estimation is presented in Table 6.6-23. Detailed calculations are in Appendix 3.

Table 6.6-2: Exposure models for intended uses

Critical use(s)	Sugar beet (2x 0.5 kg/ha or 3x 0.3 kg/ha)
Model	EFSA MODEL Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014; 12(10):3874 calculator version: 30/03/2015

Table 6.6-~~2~~3: Estimated operator exposure (acute exposure)

Ethofumesate			
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: 2 x .0.5 kg a.s./ha			
EFSA Model (Sugarbeet)	no PPE	**0.2049984**	**8.20%**
Ethofumesate			
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: 3 x 0.3 kg a.s./ha			
EFSA Model (Sugarbeet)	no PPE	**0.1358942**	**5.44%**

6.6.2.2 Measurement of operator exposure

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

6.6.3 Worker exposure (KCP 7.2.3)

Comments of zRMS:	The worker exposure calculations for the proposed uses of formulation CHR/H/ETO 500 SC containing Ethofumesate (500 g/L) conducted by the Applicant using the EFSA calculator and presented in Table 6.6-5 are accepted. At the applications 2 x 0.50 kg a.s./ha and 3 x 0.3 kg a.s./ha in sugar beet the predicted potential exposure of unprotected worker to Ethofumesate contained in the formulation CHR/H/ETO 500 SC is within acceptable limit (23.64% of AOEL at the application 2 x 0.50 kg a.s./ha and 20.13% of AOEL at the application 3 x 0.30 kg a.s./ha). The use of work wear further reduces worker exposure to 2.65% of AOEL at the application 2 x 0.50 kg a.s./ha and 2.26% of AOEL at the application 3 x 0.30 kg a.s./ha, therefore taking also into consideration the hygienic rules it is recommended for worker inspecting treated area to wear proper work wear - arms, body and legs covered. As a standard rule, crops treated by formulation CHR/H/ETO 500 SC containing Ethofumesate (500 g/L) should not be re-entered before spray deposit on leaf surfaces has completely dried.

6.6.3.1 Estimation of worker exposure

Table 6.6-34 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/F/PROTIO~~ CHR/H/ETO 500 SC according to the critical use(s). Outcome of the estimation is presented below in Table 6.6-5 (~~acute and longer term~~ total systemic exposure). Detailed calculations are in Appendix 3.

Table 6.6-~~3~~4: Exposure models for intended uses

Critical use(s)	Sugar beet (2x 0.5 kg/ha or 3x 0.3 kg/ha)
Model	EFSA MODEL Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014; 12(10):3874 calculator version: 30/03/2015

Table 6.6-45: Estimated worker exposure

		Ethofumesate	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Number of applications and application rate:		2 x 0.5 kg as/ha	
Sugar beet 8 hours/day (1), 2h inspection and irrigation TC: 2500 12500 cm^2/person/h (2) (Total potential exposure), 1400 cm^2/person/h (arms, body and legs covered) Body weight: 60 kg	no PPE (3)	0.5909058	**23.64**
	with PPE (4) Work wear - arms, body and legs covered	0.0661815	2.65
Number of applications and application rate:		3 x 0.3 kg as/ha	
Sugar beet 8 hours/day (1), 2h inspection and irrigation TC: 2500 12500 cm^2/person/h (2) (Total potential exposure), 1400 cm^2/person/h (arms, body and legs covered) Body weight: 60 kg	no PPE (3)	0.5033624	**20.13**
	with PPE (4) Work wear - arms, body and legs covered	0.0563766	2.26

6.6.3.2 Refinement of generic DFR value (KCP 7.2)

Not required.

6.6.3.3 Measurement of worker exposure

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

6.6.4 Resident and bystander exposure (KCP 7.2.2)

Comments of zRMS:	The resident/bystander exposure calculations for the proposed uses of formulation CHR/H/ETO 500 SC containing Ethofumesate (500 g/L) conducted by the Applicant using the EFSA calculator and presented in Tables 6.6-6 were completed by Evaluator. <u>Resident exposure</u> The application 2 x 0.50 kg a.s./ha in sugar beet

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)	0.3357250	0.0107000	0.0765058	0.7977229	0.8876892
Total systemic exposure per kg body weight (mg/kg	0.0335725	0.0010700	0.0076506	0.0797723	0.0887689
% of RVNAS	1.34%	0.04%	0.31%	3.19%	3.55%

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.4820000	0.0138000	0.1932498	2.6590763	2.5044412
Total systemic exposure per kg body weight (mg/kg	0.0080333	0.0002300	0.0032208	0.0443179	0.0417407
% of RVNAS	0.32%	0.01%	0.13%	1.77%	1.67%

The application 3 x 0.30 kg a.s./ha in sugar beet

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)	0.2014350	0.0107000	0.0651713	0.6795392	0.7111890
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0201435	0.0010700	0.0065171	0.0679539	0.0711189
% of RVNAS	0.81%	0.04%	0.26%	2.72%	2.84%

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.2892000	0.0138000	0.1646196	2.2651306	2.0777799
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0048200	0.0002300	0.0027437	0.0377522	0.0346297
% of RVNAS	0.19%	0.01%	0.11%	1.51%	1.39%

The predicted total systemic exposure to a child and adult resident from spray drift, vapour, surface deposits, entry into treated crops and sum of all pathways calculated for the proposed uses of the formulation CHR/H/ETO 500 SC containing Ethofumesate (500 g/L) are within acceptable limits. Therefore the use of the formulation CHR/H/ETO 500 SC does not cause unacceptable health risk for child and adult resident.

Bystander exposure

According to EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA Journal 2014;12(10):3874): "No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure."

6.6.4.1 Estimation of resident and bystander exposure

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

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

Table 6.6-56 shows the exposure model(s) used for estimation of resident and bystander exposure to ethofumesate. The outcome of the estimation is presented below in Table 6.6.-7 (longer term resident exposure) ~~and (acute bystander exposure).~~ Detailed calculations are in Appendix 3.

Table 6.6-~~56~~: Exposure models for intended uses

Critical use(s)	Sugarbeets (2x 0.5 kg as/ha or 3 x 0.3 kg as/ha)
Model	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 calculator version: 30/03/2015

Table 6.6-~~6~~7: Estimated bystander and resident exposure

	Ethofumesate	
Model data	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Tractor mounted boom spray application outdoors to low crops		
Application rate:	2 x 0.5 kg a.s./ha	
~~Bystanders (adult) Drift rate: 2.77 % (1 m) Body weight: 60 kg~~	~~0.0417407~~	~~1.67~~
~~Bystanders (children) Drift rate: 2.77 % (1 m) Body weight:10 kg~~	~~0.0887589~~	~~3.55~~
Residents (adult) Drift rate: 2.77 % (1 m) Body weight: 60 kg	0.0417407 All pathways (mean)	1.67 All pathways (mean)
Residents (children) Drift rate: 2.77 % (1 m) Body weight:10 kg	0.0887589 All pathways (mean)	3.55 All pathways (mean)
Application rate:	3 x 0.3 kg a.s./ha	
~~Bystanders (adult) Drift rate: 2.77 % (1 m) Body weight: 60 kg~~	~~0.0346297~~	~~1.39~~
~~Bystanders (children) Drift rate: 2.77 % (1 m) Body weight:10 kg~~	~~0.0711189~~	~~2.84~~
Residents (adult) Drift rate: 2.77 % (1 m) Body weight: 60 kg	0.0346297 All pathways (mean)	1.39 All pathways (mean)
Residents (children) Drift rate: 2.77 % (1 m) Body weight:10 kg	0.0711189 All pathways (mean)	2.84 All pathways (mean)

6.6.5 Combined exposure

Not relevant. The product contains only one active substance.

Appendix 1 Lists of data considered in support of the evaluation

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	-	2021	Toxicological classification of product CHR/H/ETO 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.

Appendix 2 Detailed evaluation of the studies relied upon

A 1.1 Statement on bridging possibilities

A 1.2 Acute oral toxicity (KCP 7.1.1)

Comments of zRMS:	A prediction of acute oral toxicity of CHR/H/ETO 500 SC based on calculation method as specified in the Regulation (EC) No 1272/2008 (CLP) is acceptable. Acute oral toxicity was determined taking into consideration valid data available on each of the component in the mixture, which allows classification of the product according to CLP. The synergistic effects between any of the components are not expected. The calculated ATEmix is significantly higher than 2 000 mg/kg b.w., therefore no classification is required for acute oral toxicity.

Reference: 7.1.1

Report Toxicological classification of product CHR/H/ETO based on calculation method taking into consideration health hazards of constituent substances; 2021; according to Part C, appendix 2

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/ETO are known, the acute oral toxicity test is not necessary.

Materials and methods

We use the summation method using the formula:

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

Where:

- Ci - concentration of ingredient i (% w/w or % v/v)
- i – the individual ingredient from 1 to n
- n – the number of ingredients
- ATEi - Acute Toxicity Estimate of ingredient i.

We use the table:
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-	0 < Category 1 ≤ 5	0,5

weight)	5 < Category 2 ≤ 50 50 < Category 3 ≤ 300 300 < Category 4 ≤ 2 000	5 100 500
Dermal (mg/kg body weight)	0 < Category 1 ≤ 50 50 < Category 2 ≤ 200 200 < Category 3 ≤ 1 000 1 000 < Category 4 ≤ 2 000	5 50 300 1 100
Gases (ppmV)	0 < Category 1 ≤ 100 100 < Category 2 ≤ 500 500 < Category 3 ≤ 2 500 2 500 < Category 4 ≤ 20 000	10 100 700 4 500
Vapours (mg/l)	0 < Category 1 ≤ 0,5 0,5 < Category 2 ≤ 2,0 2,0 < Category 3 ≤ 10,0 10,0 < Category 4 ≤ 20,0	0,05 0,5 3 11
Dust/mist (mg/l)	0< Category 1 ≤ 0,05 0,05 < Category 2 ≤ 0,5 0,5 < Category 3 ≤ 1,0 1,0 < Category 4 ≤ 5,0	0,005 0,05 0,5 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.

Ingredients C_2, C_3, C_4, E_2 and F_1 are classified in this class of hazard:

- C_2 – 0.0036% (Acute Tox. 4, H302, LD50 = 500 mg/kg)
- C_3 – $1.8 \cdot 10^{-5}$% (Acute Tox. 3, H301, LD50 = 100 mg/kg)
- C_4 – $1.8 \cdot 10^{-5}$% (Acute Tox. 3, H301, LD50 = 100 mg/kg)
- E_2 – 0.094% (Acute Tox. 4, H302, LD50 = 500 mg/kg)
- F_1 – 0.045% (Acute Tox. 4, H302, LD50 = 1193 mg/kg)

LD_{50} for the ingredient F_1 were taken to the calculations (according to MSDS manufactures). For the rest of ingredients the estimated value according to Table 3.1.2 was used.

$$ATE_{mix} = \frac{100}{\sum_{i=1}^{n} ATE_i} = \frac{100}{\frac{0.0036}{500} + \frac{1.8 \cdot 10^{-5}}{100} + \frac{1.8 \cdot 10^{-5}}{100} + \frac{0.094}{500} + \frac{0.045}{1193}} = 428\,669$$

Results and discussions

According to the table 3.1.2, the result (428 669 mg/kg bw) is significantly higher than generic concentration level (2 000 mg/kg b.w.). Therefore the formulation is not classified as Acute Tox. 4, H302.

Conclusion

According to the table 3.1.2, the result (428 669 mg/kg bw) is significantly higher than generic concentration level (2 000 mg/kg b.w.). Therefore the formulation is not classified as Acute Tox. 4, H302.

A 1.3 Acute percutaneous (dermal) toxicity (KCP 7.1.2)

Comments of zRMS:	A prediction of acute dermal toxicity of CHR/H/ETO 500 SC based on calculation method as specified in the Regulation (EC) No 1272/2008 (CLP) is acceptable. Acute dermal toxicity was determined taking into consideration valid data available on each of the component in the mixture, which allows classification of the product according to CLP. The synergistic effects between any of the components

	are not expected. The calculated ATEmix is significantly higher than 2 000 mg/kg b.w., therefore no classification is required for acute dermal toxicity.

~~A 1.3.1~~ Study 1

Reference: 7.1.2

Report: Toxicological classification of product CHR/H/ETO based on calculation method taking into consideration health hazards of constituent substances; ~~2019~~ 2021; according to Part C, appendix 2

According to point 7.1.~~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."

Only ingredient D_1 is classified in this hazard class.

- C_3 – $1.8 \cdot 10^{-5}$% (Acute Tox. 3, H311, LD50 = 300 mg/kg)
- C_4 – $1.8 \cdot 10^{-5}$% (Acute Tox. 2, H310, LD50 = 50 mg/kg)

LD_{50} is not known. Therefore the estimated values were used to the calculation.

$$ATE_{mix} = \frac{100}{\sum_{i=1}^{n} \frac{C_i}{ATE_{mix}}} = \frac{100}{\frac{1.8 \times 10^{-5}}{300} + \frac{1.8 \times 10^{-5}}{50}} \approx 240\,000\,000$$

Results and discussions

According to the table 3.1.2, the result is significantly higher than generic concentration level (2000 mg/kg bw). Therefore the formulation is not classified in this class of hazard.

Conclusion

According to the table 3.1.2, the result is significantly higher than generic concentration level (2000 mg/kg bw). Therefore the formulation is not classified in this class of hazard.

A 1.4 Acute inhalation toxicity (KCP 7.1.3)

Comments of zRMS:	A prediction of acute inhalation toxicity of CHR/H/ETO 500 SC based on calculation method as specified in the Regulation (EC) No 1272/2008 (CLP) is acceptable. Acute inhalation toxicity was determined taking into consideration valid data available on each of the component in the mixture, which allows classification of the product according to CLP. The synergistic effects between any of the components are not expected. The calculated ATEmix is significantly higher than 20.0 mg/L, therefore no classification is required for acute inhalation toxicity.

~~A 1.4.1~~ Study 1

Reference: 7.1.3

Report: Toxicological classification of product CHR/H/ETO based on calculation method taking into consideration health hazards of constituent substances; ~~2019~~ 2021; according to Part C, appendix 2

According to point 7.1.~~1~~3 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 ihalation 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 inhalation 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."

Ingredients C_3 and C_4 at the concentration of $1.8 \cdot 10^{-5}$ % each, are classified in this hazard class.

- C_3 – $1.8 \cdot 10^{-5}$% (Acute Tox. 2, H330, LD50 = 0.5 mg/L)
- C_4 – $1.8 \cdot 10^{-5}$% (Acute Tox. 2, H330, LD50 = 0.5 mg/L)

LD_{50} is not known. Therefore the estimated values were used to the calculation.

$$ATE_{mix} = \frac{100}{\sum_{i=1}^{n} \frac{C_i}{ATE_{mix}}} = \frac{100}{2 \times \frac{1.8 \times 10^{-5}}{0.5}} = 1\,388\,889$$

Results and discussions

According to the table 3.1.2, the result (~1 400 000 mg/L > 20.0 mg/L) is significantly higher than generic concentration level. Therefore the formulation is not classified in this class of hazard.

Conclusion

According to the table 3.1.2, the result (~1 400 000 mg/L > 20.0 mg/L) is significantly higher than generic concentration level. Therefore the formulation is not classified in this class of hazard.

A 1.5 Skin irritation (KCP 7.1.4)

Comments of zRMS:	A prediction of skin irritancy of CHR/H/ETO 500 SC based on calculation method as specified in the Regulation (EC) No 1272/2008 (CLP) is acceptable. Skin irritancy was determined taking into consideration valid data available on each of the component in the mixture, which allows classification of the product according to CLP. The synergistic effects between any of the components are not expected. The calculated sum of all ingredients of a mixture classified as skin corrosive and irritant is significantly lower than generic concentration level (10%), therefore no classification is required for skin irritation.

~~A 1.5.1~~ Study 1

Reference:	7.1.4
Report	Toxicological classification of product CHR/H/ETO based on calculation method taking into consideration health hazards of constituent substances; ~~2019~~ 2021; according to Part C, appendix 2

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

Table 3.2.3
Generic concentration limits of ingredients classified for skin corrosive/irritant hazard (Category 1 or 2) that trigger classification of the mixture as corrosive/irritant to skin.

Sum of ingredients classified as:	Concentration triggering classification of a mixture as:	
	Skin Corrosive	Skin Irritant
	Category 1 (see note below)	Category 2
Skin Corrosive Categories 1A, 1B, 1C	≥ 5 %	≥ 1 % but < 5 %
Skin irritant Category 2		≥ 10 %
10 × Skin Corrosive Category 1A, 1B, 1C) + Skin irritant Category 2		≥ 10 %

Note
The sum of all ingredients of a mixture classified as Skin Corrosive Category 1A, 1B or 1C respectively, shall each be ≥ 5 % respectively in order to classify the mixture as either Skin Corrosive Category 1A, 1B or 1C. If the sum of the Skin Corrosive Category 1A ingredients is < 5 % but the sum of Category 1A+1B ingredients is ≥ 5 %, the mixture shall be classified as Skin Corrosive Category 1B. Similarly, if the sum of Skin Corrosive Category 1A+1B ingredients is < 5 % but the sum of Category 1A+1B+1C ingredients is ≥ 5 % the mixture shall be classified as Skin Corrosive Category 1C.

Ingredients classified as irritant to skin and corrosive to skin are taking into account – C_3, C_4, E_1, E_2, F_1 and F_2.

- C_3 – $1.8 \cdot 10^{-5}$ % (Skin Corr. 1, H314)
- C_4 – $1.8 \cdot 10^{-5}$ % (Skin Corr. 1, H314)
- E_1 – 1.69% (Skin Irrit. 2, H315)
- E_2 – 0.094% (Skin Irrit. 2, H315)
- F_1 – 0.045% (Skin Irrit. 2, H315)

We use the summation method, consisting in adding up the percentages of all ingredients classified in the each class.
The total amount of ingredients classified as H315 is ~~29.54~~ 1.83%.

$$10 \times \sum (C_{SkinCorr.}) + \sum C_{SkinIrrit.} = 10 \times (3.6 \times 10^{-5})\% + 1.69\% + 0.094\% + 0.045\% = 1.83\%$$

Conclusion:
According to the table 3.2.3, the result (1.83%) is significantly ~~higher~~ lower than generic concentration level (10%). Therefore the formulation is not classified as Skin Irrit. 2, H315.

~~A 1.5.2~~ Study 2

Reference: 7.1.4

Report Toxicological classification of product CHR/H/ETO based on calculation

method taking into consideration health hazards of constituent substances; ~~2019~~ 2021; according to Part C, appendix 2

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

Table 3.2.3
Generic concentration limits of ingredients classified for skin corrosive/irritant hazard (Category 1 or 2) that trigger classification of the mixture as corrosive/irritant to skin.

Sum of ingredients classified as:	Concentration triggering classification of a mixture as:	
	Skin Corrosive	Skin Irritant
	Category 1 (see note below)	Category 2
Skin Corrosive Categories 1A, 1B, 1C	≥ 5 %	≥ 1 % but < 5 %
Skin irritant Category 2		≥ 10 %
10 × Skin Corrosive Category 1A, 1B, 1C) + Skin irritant Category 2		≥ 10 %

Note
The sum of all ingredients of a mixture classified as Skin Corrosive Category 1A, 1B or 1C respectively, shall each be ≥ 5 % respectively in order to classify the mixture as either Skin Corrosive Category 1A, 1B or 1C. If the sum of the Skin Corrosive Category 1A ingredients is < 5 % but the sum of Category 1A+1B ingredients is ≥ 5 %, the mixture shall be classified as Skin Corrosive Category 1B. Similarly, if the sum of Skin Corrosive Category 1A+1B ingredients is < 5 % but the sum of Category 1A+1B+1C ingredients is ≥ 5 % the mixture shall be classified as Skin Corrosive Category 1C.

Ingredients C_3 and C_4 are classified in this hazard class.

- C_3 – $1.8 \cdot 10^{-5}$ % (Skin Corr. 1, H314)
- C_4 – $1.8 \cdot 10^{-5}$ % (Skin Corr. 1, H314)

We use the summation method, consisting in adding up the percentages of all ingredients classified in the each class.
The total amount of ingredients classified as H314 is 3.6×10^{-5}%.

$$\sum C_{SkinCorr.} = 2 \times 1.8 \times 10^{-5} = 3.6 \times 10^{-5}\%$$

Conclusion:
According to the table 3.2.3, the result is significantly lower than generic concentration level (1%). Therefore the formulation is no classified as Skin Corr. 1, H314.

A 1.6 Eye irritation (KCP 7.1.5)

Comments of zRMS:	A prediction of eye irritancy of CHR/H/ETO 500 SC based on calculation method as specified in the Regulation (EC) No 1272/2008 (CLP) is acceptable. Eye irritancy was determined taking into consideration valid data available on each of the component in the mixture, which allows classification of the product according to

	CLP. The synergistic effects between any of the components are not expected. The calculated sum of all ingredients of a mixture classified as eye irritant is significantly lower than generic concentration level (10%), therefore no classification is required for eye irritation

~~A 1.6.1~~ Study 1

Reference:	7.1.5
Report	Toxicological classification of product CHR/H/ETO based on calculation method taking into consideration health hazards of constituent substances; ~~2019~~ 2021; according to Part C, appendix 2

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."

Due to the fact, that all components of the formulation CHR/H/ETO are known, eye corrosion 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 of a mixture classified as Skin corrosive Category 1 and/ or eye Category 1 or 2 for effects on the eye that trigger classification of the mixture for effects on the eye (Category 1 or 2).

Sum of ingredients classified as:	Concentration triggering classification of a mixture as:	
	Irreversible Eye Effects	Reversible Eye Effects
	Category 1	Category 2
Eye Effects Category 1 or Skin Corrosive Category 1A, 1B, 1C	≥ 3 %	≥ 1 % but < 3 %
Eye Effects Category 2		≥ 10 %
(10 × Eye Effects Category 1) + Eye effects Category 2		≥ 10 %
Skin Corrosive Category 1A, 1B, 1C + Eye effects Category 1	≥ 3 %	≥ 1 % but < 3 %
10 × (Skin Corrosive Category 1A, 1B, 1C + Eye Effects Category 1) + Eye Effects Category 2		≥ 10 %

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

Ingredients classified as corrosive to eyes and skin are taking into account – C_1, C_2, C_3, C_4, E_2, F_1.

- C_1 – 0.0036% (Eye Dam. 1, H318)
- C_2 – 0.0036% (Eye Dam. 1, H318)
- C_3 – $1.8 \cdot 10^{-5}$ % (Skin Corr. 1, H314)
- C_4 – $1.8 \cdot 10^{-5}$ % (Eye Dam. 1, H318)
- E_2 – 0.094% (Eye Dam. 1, H318)
- F_1 – 0.045% (Eye Dam. 1, H318)

$$\sum C_{EyeDam.} + C_{SkinCorr.} = 0.0036\% + 0.0036\% + 1.8 \cdot 10^{-5}\,\% + 1.8 \cdot 10^{-5}\,\% + 0.094\% + 0.045\% = 0.15\%$$

Conclusion:

The sum of the concentration (0.15%) is significantly lower than generic concentration level (1%). Therefore the whole formulation is not classified as Eye Dam. 1.

~~A 1.6.2~~ Study 2

Reference: 7.1.5

Report: Toxicological classification of product CHR/H/ETO based on calculation method taking into consideration health hazards of constituent substances; ~~2019~~ 2021; according to Part C, appendix 2

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."

Due to the fact, that all components of the formulation CHR/H/ETO are known, eye corrosion 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 of a mixture classified as Skin corrosive Category 1 and/ or eye Category 1 or 2 for effects on the eye that trigger classification of the mixture for effects on the eye (Category 1 or 2).

Sum of ingredients classified as:	Concentration triggering classification of a mixture as:	
	Irreversible Eye Effects	Reversible Eye Effects
	Category 1	Category 2
Eye Effects Category 1 or Skin Corrosive Category 1A, 1B, 1C	≥ 3 %	≥ 1 % but < 3 %
Eye Effects Category 2		≥ 10 %
(10 × Eye Effects Category 1) + Eye effects Category 2		≥ 10 %
Skin Corrosive Category 1A, 1B, 1C + Eye effects Category 1	≥ 3 %	≥ 1 % but < 3 %
10 × (Skin Corrosive Category 1A, 1B, 1C + Eye Effects Category 1) + Eye Effects Category 2		≥ 10 %

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

Ingredients classified as irritant to eyes, corrosive to eyes and skin are taking into account – C_1, C_2, C_3, C_4, E_1, E_2, F_1 and F_2.

- C_1 – 0.0036% (Eye Dam. 1, H318)
- C_2 – 0.0036% (Eye Dam. 1, H318)
- C_3 – $1.8 \cdot 10^{-5}$ % (Skin Corr. 1, H314)
- C_4 – $1.8 \cdot 10^{-5}$ % (Eye Dam. 1, H318)
- E_1 – 1.69% (Eye Irrit. 2, H319)
- E_2 – 0.094% (Eye Dam. 1, H318)
- F_1 – 0.045% (Eye Dam. 1, H318)

$$10 \times \sum (C_{EyeDam.} + C_{SkinCorr.}) + \sum C_{EyeIrrit.}$$
$$= 10 \times (0.0036\% + 0.0036\% + 1.8 \cdot 10^{-5}\% + 1.8 \cdot 10^{-5}\% + 0.094\% + 0.045\%) + 1.69\% = 3.2\%$$

Conclusion:

The sum of the concentration (3.2%) is significantly lower than generic concentration level (10%). Therefore the whole formulation is not classified as Eye Irrit. 2, H319.

A 1.7 Skin sensitisation (KCP 7.1.6)

Comments of zRMS:	A prediction of skin sensitisation of CHR/H/ETO 500 SC based on approach as specified in the Regulation (EC) No 1272/2008 (CLP) is acceptable. Skin sensitisation was determined taking into consideration valid data available on each of the component in the mixture, which allows classification of the product according to CLP. The concentration triggering classification (0.1%) is not exceeded by any ingredient, therefore the formulation is not classified as skin sensitiser.

~~A 1.7.1~~ Study 1

Reference: 7.1.~~5~~6

Report: Toxicological classification of product CHR/H/ETO based on calculation method taking into consideration health hazards of constituent substances; ~~2019~~ 2021; according to Part C, appendix 2

According to point 7.1.~~5~~6 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 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."

Due to the fact, that all components of the formulation CHR/H/ETO are known, ~~eye corrosion~~ skin sensitisation test is not necessary.

Materials and methods

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

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	≥ 1,0 %	-	-
Skin Sensitiser Category 1A	≥ 0,1 %	-	-
Skin Sensitiser Category 1B	≥ 1,0 %		
Respiratory Sensitiser Category 1	-	≥ 1,0 %	≥ 0,2 %
Respiratory Sensitiser Category 1A	-	≥ 0,1 %	≥ 0,1 %
Respiratory Sensitiser Category 1B		≥ 1,0 %	≥ 0,2 %

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

Ingredients C_3, C_4 and F_1 is classified in this hazard class.

- C_3 – $1.8 \cdot 10^{-5}$ % (Skin Sens. 1A, H317)
- C_4 – $1.8 \cdot 10^{-5}$ % (Skin Sens. 1A, H317)
- F_1 – 0.045% (Skin Sens. 1B, H317)

Conclusion:

The concentration triggering classification is not exceeded by any ingredient. Therefore the formulation is not classified as Skin Sens. 1, H317.

A 1.8 Supplementary studies for combinations of plant protection products (KCP 7.1.7)

Not required

A 1.9 Data on co-formulants (KCP 7.4)

~~A 1.9.1~~ 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 1.9.2~~ 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 1.10 Studies on dermal absorption (KCP 7.3)

Comments of zRMS:	According to the Guidance on Dermal Absorption EFSA (EFSA Journal 2017;15(6):4873) following default values were set for formulation CHR/H/ETO 500 SC: 10% (concentrate) and 50% (dilution).

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 ~~25~~10% may be applied for concentrated products that are ~~organic solvent formulated or in other types of formulations~~ water-based/dispersed or solid-formulated (including suspension concentrate (SC) formulation type).
A default dermal absorption value of ~~70~~50% may be applied for (in use) dilutions ~~of organic solvent formulated or in other types of formulation~~ water-based/dispersed or solid-formulated (including suspension concentrate (SC) formulation type).

A 1.11 Other/Special Studies

~~A 2.11.1~~ A 1.11.1. Specific target organ toxicity

Comments of zRMS:	A prediction of specific target organ toxicity of CHR/H/ETO 500 SC based on approach as specified in the Regulation (EC) No 1272/2008 (CLP) is acceptable. The specific target organ toxicity was determined taking into consideration valid data available on each of the component in the mixture, which allows classification of the product according to CLP. The concentration of one ingredient with classification of STOT RE1, H372 is much lower than a concentration triggering classification of formulation CHR/H/ETO 500 SC (1%), therefore the formulation is not classified for specific target organ toxicity.

~~**A 2.11.2 Study 1**~~

Reference: 7.1.~~1~~7

Report: Toxicological classification of product CHR/H/ETO based on calculation method taking into consideration health hazards of constituent substances;

~~2019~~ 2021; according to Part C, appendix 2

According to point 3.8.3 of Regulation (EC) No 1272/2008 as regards the data requirements for plant protection products:
" Mixtures are classified using the same criteria as for substances, or alternatively as described below. As with substances, mixtures shall be classified for specific target organ toxicity following single exposure. Where there is no reliable evidence or test data for the specific mixture itself, and the bridging principles cannot be used to enable classification, then classification of the mixture is based on the classification of the ingredient substances. In this case, the mixture shall be classified as a specific target organ toxicant (specific organ specified), following single exposure, when at least one ingredient has been classified as a Category 1 or Category 2 specific target organ toxicant and is present at or above the appropriate generic concentration limit as mentioned in Table 3.8.3 for Category 1 and 2 respectively"

Due to the fact, that all components of the formulation CHR/H/ETO are known, ~~eye corrosion~~ specific target organ toxicity test is not necessary.

Materials and methods

For consideration of specific target organ properties 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 ≥ 10 %	1,0 % ≤ concentration < 10 %
Category 2 Specific Target Organ Toxicant		Concentration ≥ 10 % [(Note 1)]

Note 1
If a Category 2 specific target organ toxicant is present in the mixture as an ingredient at a concentration ≥ 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."

Results and discussions

We consider an ingredient B_2 at a concentration of 0.0036%. According to the point 3.8.3.4.5 CLP Regulation, the content of this ingredient is lower than a concentration triggering classification (1%). Therefore the formulation is not classified as STOT RE1, H372.

~~A 2.11.2~~ **A 1.11.2.~~ Study 2~~ Carcinogenicity**

Comments of zRMS:	A prediction of carcinogenicity of CHR/H/ETO 500 SC based on approach as specified in the Regulation (EC) No 1272/2008 (CLP) is acceptable. The carcinogenisity was determined taking into consideration valid data available on each of

	the component in the mixture, which allows classification of the product according to CLP. The concentration of one ingredient with classification of Carc. 1A, H350 is much lower than a concentration triggering classification of formulation CHR/H/ETO 500 SC (0.1%), therefore the formulation is not classified for carcinogenicity.

Reference: 7.1.~~1~~7

Report: Toxicological classification of product CHR/H/ETO based on calculation method taking into consideration health hazards of constituent substances; ~~2019~~ 2021; according to Part C, appendix 2

~~According to point 3.8.3 of Regulation (EC) No 1272/2008 as regards the data requirements for plant protection products:~~
~~" Mixtures are classified using the same criteria as for substances, or alternatively as described below. As with substances, mixtures shall be classified for specific target organ toxicity following single exposure. Where there is no reliable evidence or test data for the specific mixture itself, and the bridging principles cannot be used to enable classification, then classification of the mixture is based on the classification of the ingredient substances. In this case, the mixture shall be classified as a specific target organ toxicant (specific organ specified), following single exposure, when at least one ingredient has been classified as a Category 1 or Category 2 specific target organ toxicant and is present at or above the appropriate generic concentration limit as mentioned in Table 3.8.3 for Category 1 and 2 respectively"~~

Due to the fact, that all components of the formulation CHR/H/ETO are known, ~~eye corrosion~~ test on carcinogenicity is not necessary.

Materials and methods

Table 3.6.2
Generic concentration limits of ingredients of a mixture classified as carcinogen that trigger classification of the mixture

Ingredient classified as:	Generic concentration limits triggering classification of a mixture as:		
	Category 1 carcinogen		Category 2 carcinogen
	Category 1A	Category 1B	
Category 1A carcinogen	≥ 0,1 %	-	-
Category 1B carcinogen	-	≥ 0,1 %	
Category 2 carcinogen	-	-	≥ 1,0 % [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 2 carcinogen is present in the mixture as an ingredient at a concentration ≥ 0,1 % a SDS shall be available for the mixture upon request.

Results and discussions

Only ingredient B_2 (Carc. 1A, H350) at the concentration of 0.0036% is relevant. The content of the ingredient classified in this hazard class is lower than concentration triggering classification (0.1%). Therefore according to table 3.6.2 the result is no classification.

Appendix 3 Exposure calculations

A 3.1 Operator exposure calculations (KCP 7.2.1.1)

~~A 3.1.1~~ Calculations for ethofumesate

Operator exposure for outdoor spray applications

Application rate of active substance	0.5	kg a.s./ha	*i_AppRate*
Assumed area treated	50	ha/day	*d_AreaTreated*
Amount of active substance applied	25	kg a.s./day	*i_AmoutAS*
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

	Exposure values	µg exposure/day mixed and loaded 75th centile	95th centile	Reference	Comment
Mixing and loading	Hands	57881	218196	AOEM	
	Body	34276	183491	AOEM	
	Head	1297	7114	AOEM	
	Protected hands (gloves)	280	4952	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	412	3656	AOEM	
	Protected head (hood and face shield)	21	403	AOEM	
	Inhalation	10	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	

	Exposure values	µg exposure/day applied 75th centile	95th centile	Reference	Comment
Application	Hands	3708	24212	AOEM	
	Body	2073	10688	AOEM	
	Head	98	296	AOEM	
	Protected hands (gloves)	243	4851	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	57	139	AOEM	
	Inhalation	5	19	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)	12.2999012	12.2999012	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.2049984	0.2049984	
% of RVNAS	8.20%	8.20%	
Acute			
Total systemic exposure from mixing, loading and application (mg a.s./day)	58.5271358	58.5271358	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.9754523	0.9754523	
% of RVAAS	#DZIEL/0!	#DZIEL/0!	

Operator exposure for outdoor spray applications

Application rate of active substance	0.3 kg a.s./ha		*i_AppRate*
Assumed area treated	50 ha/day		*d_AreaTreated*
Amount of active substance applied	15 kg a.s./day		*i_AmoutAS*
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		

Outdoor|Soluble concentrates, emulsifiable concentrate, etc.|Downward spraying|Vehicle-mounted

	Exposure values	µg exposure/day mixed and loaded 75th centile	95th centile	Reference	Comment
Mixing and loading	Hands	39062	146589	AOEM	
	Body	23935	158184	AOEM	
	Head	778	4268	AOEM	
	Protected hands (gloves)	201	2971	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	262	2194	AOEM	
	Protected head (hood and face shield)	12	242	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	

	Exposure values	µg exposure/day applied 75th centile	95th centile	Reference	Comment
Application	Hands	2225	16655	AOEM	
	Body	1244	6413	AOEM	
	Head	59	177	AOEM	
	Protected hands (gloves)	184	4571	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	34	84	AOEM	
	Inhalation	4	14	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)	8.1536503	8.1536503	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.1358942	0.1358942	
% of RVNAS	5.44%	5.44%	
Acute			
Total systemic exposure from mixing, loading and application (mg a.s./day)	42.5709701	42.5709701	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.7095162	0.7095162	
% of RVAAS	#DZIEL/0!	#DZIEL/0!	

A 3.2 Worker exposure calculations (KCP 7.2.3.1)

~~A 3.2.1~~ Calculations for ethofumesate

Worker exposure from residues on foliage for			
Crop type	Root and tuber vegetables		
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	0.5	kg a.s./ha	*i_AppRate*
Number of applications	2		*i_AppNo*
Interval between multiple applications	5	days	*i_AppInt*
Half-life of active substance	30	days	*d_HalflifeAS*
Multiple application factor	1.9		*d_MAF*
Dermal absorption of the product	10.00%		*i_AbsorpProduct*
Dermal absorption of the in-use dilution	50.00%		*i_AbsorpInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	1.5	µg a.s./cm^2	*d_DFR*
Working hours	2	hr	*d_WorkHr*
Dermal transfer coefficient - Total potential exposure	12500	cm^2/hr	*d_DermTcUCV*
Dermal transfer coefficient - arms, body and legs covered	1400	cm^2/hr	*d_DermTcCV1*
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment	cm^2/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)	35.4543510	3.9708873	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0.5909058	0.0661815		
% of RVNAS	23.64%	2.65%		

Worker exposure from residues on foliage for			
Crop type	Root and tuber vegetables		
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	0.3	kg a.s./ha	*i_AppRate*
Number of applications	3		*i_AppNo*
Interval between multiple applications	5	days	*i_AppInt*
Half-life of active substance	30	days	*d_HalflifeAS*
Multiple application factor	2.7		*d_MAF*
Dermal absorption of the product	10.00%		*i_AbsorpProduct*
Dermal absorption of the in-use dilution	50.00%		*i_AbsorpInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.9	µg a.s./cm^2	*d_DFR*
Working hours	2	hr	*d_WorkHr*
Dermal transfer coefficient - Total potential exposure	12500	cm^2/hr	*d_DermTcUCV*
Dermal transfer coefficient - arms, body and legs covered	1400	cm^2/hr	*d_DermTcCV1*
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment	cm^2/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)	30.2017415	3.3825950	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0.5033624	0.0563766		
% of RVNAS	20.13%	2.26%		

A 3.3 Bystander and resident exposure calculations (KCP 7.2.2.1)

~~A 3.3.1~~ Calculations for ethofumesate

Resident exposure for			
Croptype	Root and tuber 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	0.5	kg a.s./ha	*i_AppRate*
Concentration of active substance (in-use dilution for liquid applications)	2.5	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_AbsorpOralInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	1.5	µg a.s./cm^2	*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/m^3	*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	m^3/day/kg	*d_BreathRAd*
Breathing rate child (1-3 year old)	1.07	m^3/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	cm^2/hour	*d_ReTCAd*
Transfer coeff. of surface deposits-child (1-3 year old)	2600	cm^2/hour	*d_ReTCCh*
Saliva extraction percentage	50.00%		*d_SalExt*
Surface area of hands mouthed	20	cm^2	*d_AreaHM*
Frequency of hand to mouth activity	9.5	events/hour	*d_ReFreqHM*
Ingestion rate for mouthing of grass per day	25	cm^2	*d_MouthGrass*
Dislodgeable residues percentage transferability for object to mouth	20.00%		*d_DRP*
Transfer coefficient for entry into treated crops (75th percentile) - adı	7500	cm^2/h	*d_TcEntryAd*
Transfer coefficient for entry into treated crops (75th percentile) - chi	2250	cm^2/h	*d_TcEntryCh*
Transfer coefficient for entry into treated crops (mean) - adult	5980	cm^2/h	*d_TcEntryAd*
Transfer coefficient for entry into treated crops (mean) - child	1794	cm^2/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)	0.3357250	0.0107000	0.0765058	0.7977229	0.8876892
Total systemic exposure per kg body weight	0.0335725	0.0010700	0.0076506	0.0797723	0.0887689
% of RVNAS	1.34%	0.04%	0.31%	3.19%	3.55%

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.4820000	0.0138000	0.1932498	2.6590763	2.5044412
Total systemic exposure per kg body weight	0.0080333	0.0002300	0.0032208	0.0443179	0.0417407
% of RVNAS	0.32%	0.01%	0.13%	1.77%	1.67%

Resident exposure for				
Croptype	Root and tuber 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	0.3	kg a.s./ha		*i_AppRate*
Concentration of active substance (in-use dilution for liquid applications)	1.5	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_AbsorpOralInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.9	µg a.s./cm^2		*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/m^3		*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	m^3/day/kg		*d_BreathRAd*
Breathing rate child (1-3 year old)	1.07	m^3/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	cm^2/hour		*d_ReTCAd*
Transfer coeff. of surface deposits-child (1-3 year old)	2600	cm^2/hour		*d_ReTCCh*
Saliva extraction percentage	50.00%			*d_SalExt*
Surface area of hands mouthed	20	cm^2		*d_AreaHM*
Frequency of hand to mouth activity	9.5	events/hour		*d_ReFreqHM*
Ingestion rate for mouthing of grass per day	25	cm^2		*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	cm^2/h		*d_TcEntryAd*
Transfer coefficient for entry into treated crops (75th percentile) - chi	2250	cm^2/h		*d_TcEntryCh*
Transfer coefficient for entry into treated crops (mean) - adult	5980	cm^2/h		*d_TcEntryAd*
Transfer coefficient for entry into treated crops (mean) - child	1794	cm^2/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)	0.2014350	0.0107000	0.0651713	0.6795392	0.7111890
Total systemic exposure per kg body weight	0.0201435	0.0010700	0.0065171	0.0679539	0.0711189
% of RVNAS	0.81%	0.04%	0.26%	2.72%	2.84%

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.2892000	0.0138000	0.1646196	2.2651306	2.0777799
Total systemic exposure per kg body weight	0.0048200	0.0002300	0.0027437	0.0377522	0.0346297
% of RVNAS	0.19%	0.01%	0.11%	1.51%	1.39%

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)