FINAL REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: CHR/H/FETEC-PART B 110 EC

Product name(s): Fenoxinn Max 110 EC, Herbos Max 110 EC

Chemical active substance:

Fenoxaprop-P-ethyl, 110 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Innvigo Sp. z o.o.

Submission date: February 2023

MS Finalisation date: 06/03/2024

Version history

When	What
05/2023	Dossier sent for evaluation
11/2023	zRMS evaluation of dRR
March 2024	Final version prepared by zRMS after Commenting period

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

6 Mammalian Toxicology (KCP 7)

6.1 Summary

Table 6.1-1: Information on CHR/H/FETEC-PART B 110 EC

Product name and code	CHR/H/FETEC-PART B 110 EC (Fenoxinn Max 110 EC, Herbos Max 110 EC)
Formulation type	EC
Active substance(s) (incl. content)	Fenoxaprop-P-ethyl, 110 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/FETEC-PART B 110 EC 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/FETEC-PART B 110 EC according to Regulation (EC) No 1272/2008

Hazard class(es), categories:	Asp. Tox. 1, Skin Irrit. 2, Skin Sens. 1, Eye Dam. 1, STOT RE 2
Hazard pictograms or Code(s) for hazard pictogram(s):	GHS05, GHS07, GHS08
Signal word:	Danger
Hazard statement(s):	H304: May be fatal if swallowed and enters airways. H318: Causes serious eye damage. H317: May cause an allergic skin reaction. H315: Causes skin irritation. H373: May cause damage to organs (kidneys) through prolonged or repeated exposure
Precautionary statement(s):	<u>WARNING SECTION OF THE LABEL (first page):</u> P260 – Do not breathe spray. P301 +310: IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. P331: Do NOT induce vomiting. P280 – Wear protective gloves, eye protection/face protection. P302 + P352 – IF ON SKIN: Wash with plenty of water P305 + P351 + P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. <u>Other sections of the label:</u> P264 – Wash face, hands and contaminated skin thoroughly after handling. P362: Take off contaminated clothing and wash before reuse. P363: Wash contaminated clothing before reuse. P272: Contaminated work clothing should not be allowed out of the workplace. P405: Store locked up. P501: Dispose of contents/container to … And P280 as follows: Operator: “Wear protective gloves, eye/face protection and work wear during mixing/loading, and protective gloves and work wear during application.” *„Stosować rękawice ochronne, ochronę oczu/twarzy oraz odzież roboczą w trakcie przygotowywania cieczy użytkowej oraz rękawice ochronne i odzież roboczą w czasie wykonywania zabiegu.”* Worker: “Wear protective gloves and work wear (long trousers, long-sleeve shirt) during inspection.” *„Stosować rękawice ochronne oraz odzież roboczą (długie spodnie, koszula z długim rękawem) podczas wchodzenia na teren poddany opryskowi”.* <u>Section First Aid:</u> P301 +310: IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. P331: Do NOT induce vomiting. P302 + P352 – IF ON SKIN: Wash with plenty of water. P333+P313: If skin irritation or rash occurs: Get medical advice/attention. P305 + 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 or doctor/physician.
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]
	Hazardous ingredients that must be listed on the label: Cloquintocet-mexyl; Hydrocarbons, C10-C13, aromatics,<1% naphthalene; Benzenesulfonic acid,

	C10-13-(linear)alkyl derivs., calcium salt

Table 6.1-3: Summary of risk assessment for operators, workers, bystanders and residents for CHR/H/FETEC-PART B 110 EC

	Result	PPE / Risk mitigation measures
Operators	Acceptable	Exposure: Protective clothing during mixing/loading and gloves during mixing/loading and application. Classification: protective gloves, eye/face protection during mixing/loading.
Workers	Acceptable	Based on exposure estimation: Work wear – arms, body and legs covered. Recommendation: protective gloves and work wear when inspecting treated area.
Bystanders	Acceptable	None
Residents	Acceptable	None

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

A summary of the critical uses and the overall conclusion regarding exposure for operators, workers and 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	Winter wheat (TRZAW), Winter triticale (TTLWI) Winter barley (HORVW) (BBCH 20-31)	F	Spray, medium sprayer	a) 1 b) 1	a) 0.077 b) 0.077	200 - 400	n/a					
2	Spring wheat (TRZAS), Spring barley (HORVS) (BBCH 20-31)	F	Spray, medium sprayer	a) 1 b) 1	a) 0.077 b) 0.077	200 - 400	n/a					
3	Winter wheat (TRZAW), Winter triticale (TTLWI) Winter barley (HORVW) (BBCH 20-31)	F	Spray, medium sprayer	a) 1 b) 1	a) 0.055 kg a.s./ha + 0.0125 kg a.s/ha Tristar 50 SG/Trimax 50 SG/Triben Super 50 SG b) 0.055 kg a.s./ha + 0.0125 kg a.s/ha Tristar 50 SG/Trimax 50 SG/Triben Super 50 SG	200 - 400	n/a					
4	Spring wheat (TRZAS), Spring barley (HORVS) (BBCH 20-31)	F	Spray, medium sprayer	a) 1 b) 1	a) 0.055 kg a.s./ha + 0.0125 kg a.s/ha Tristar 50 SG/Trimax 50 SG/Triben Super 50 SG b) 0.055 kg a.s./ha + 0.0125 kg a.s/ha Tristar 50 SG/Trimax 50 SG/Triben Super 50 SG	200 - 400	n/a					

1	2	3	4	5	6	7	8	9	10
5	Winter wheat (TRZAW), Winter triticale (TTLWI) Winter barley (HORVW) (BBCH 20-31)	F	Spray, medium sprayer	a) 1 b) 1	a) 0.055 kg a.s./ha + 0.08 kg a.s/ha Galaper 200 EC/ Fluroherb 200 EC/ Herbistar 200 EC b) 0.055 kg a.s./ha + 0.08 kg a.s/ha Galaper 200 EC/ Fluroherb 200 EC/ Herbistar 200 EC	200 - 400	n/a		
6	Spring wheat (TRZAS), Spring barley (HORVS) (BBCH 20-31)	F	Spray, medium sprayer	a) 1 b) 1	a) 0.055 kg a.s./ha + 0.08 kg a.s/ha Galaper 200 EC/ Fluroherb 200 EC/ Herbistar 200 EC b) 0.055 kg a.s./ha + 0.08 kg a.s/ha Galaper 200 EC/ Fluroherb 200 EC/ Herbistar 200 EC	200-400	n/a		

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

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

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

Explanation for column 10 "Acceptability of exposure assessment"

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

Points 1 and 2, 3 and 4, 5 and 6 are considered together in further calculations.
The risk assessment for the combinations of CHR/H/FETEC-PART B 110 EC with Galaper 200 EC/ Fluroherb 200 EC/ Herbistar 200 EC or with Tristar 50 SG/Trimax 50 SG/Triben Super 50 SG is covered by the risk assessment of these plant protection products used separately and it is included in these products registration dossiers.

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) regarding toxicology

	Fenoxaprop-P-ethyl
Common Name	Fenoxaprop-P-ethyl
CAS-No.	71283-80-2
Classification and proposed labelling	
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	Hazard classes (s), categories: Skin Sens. 1, H317 STOT RE 2, H373 (kidneys) Code(s) for hazard pictogram(s): Signal word: Warning Hazard statement(s): H317 – May cause an allergic skin reaction. H373 – May cause damage to organs through prolonged or repeated exposure. Precautionary statement(s): P260 – Do not breathe dust/fume/gas/mist/vapours/spray. P280 – Wear protective gloves/protective clothing/eye protection/face protection. P302 + P352 – IF ON SKIN: Wash with plenty of water. P314 – Get medical advice/attention if you feel unwell. P362 + P364 – Take off contaminated clothing and wash it before reuse.
Additional C&L proposal	N/A
Agreed EU endpoints	
AOEL systemic	0.014 mg/kg bw/d
Reference	EFSA Scientific Report (2007) 121, 1-76
Conditions to take into account/critical areas of concern with regard to toxicology	
EFSA Scientific Report (2007) 121, 1-76	The operator/worker/bystander exposure assessment for the safener mefenpyr-diethyl and the risk assessment for the formulation (fenoxaprop-P-ethyl + mefenpyr-diethyl) could not be concluded and are to be considered at Member State level.

6.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for CHR/H/FETEC-PART B 110 EC 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/FETEC-PART B 110 EC

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD_{50} oral (calculation method – alternative method)	> 2000 mg/kg bw	Yes.	None	Żero, K. (2022)
LD_{50} dermal (calculation method – alternative method)	> 2000 mg/kg bw	Yes.	None	Żero, K. (2022)
LC_{50} inhalation (calculation method – alternative method)	> 20 mg/L air	Yes.	None	Żero, K. (2022)
Skin irritation (calculation method – alternative method)	Irritant	Yes.	**Skin Irrit. 2, H315**	Żero, K. (2022)
Eye irritation (calculation method – alternative method)	Corrosive	Yes.	**Eye Dam. 1, H318**	Żero, K. (2022)
Skin sensitisation (calculation method – alternative method)	Sensitising	Yes.	**Skin Sens. 1, H317**	Żero, K. (2022)
Supplementary studies for combinations of plant protection products	No data – not required			
Aspiration Toxicity (calculation method – alternative method)	Classified	Yes.	**Asp. Tox. 1, H304**	Żero, K. (2022)
Specific target organ toxicity - repeated exposure (calculation method – alternative method)	Classified	Yes.	**STOT RE 2, H373**	Żero, K. (2022)

Table 6.3-2: Additional toxicological information relevant for classification/labelling of CHR/H/FETEC-PART B 110 EC

	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)	Fenoxaprop-P-ethyl (≥ 10% (w/w))	Skin Sens. 1, H317 (criteria ≥ 1 %) STOT RE 2, H373 (criteria ≥ 10 %)	Annex IV of Reg. 1272/2008	Skin Sens. 1, H317 STOT RE 2, H373
Toxicological properties of non-active substance(s)	Benzenesulfonic acid, C10-13-(linear)alkyl	Eye Dam. 1, H318 (criteria ≥ 3 %)	MSDS	Eye Dam. 1, H318

	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)
(relevant for classification of product)	derivs., calcium salt (≥ 3% (w/w))*	Skin Irrit. 2, H315 (criteria ≥ 10 %)		
Further toxicological information	No data – not required			

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

6.4 Toxicological Evaluation of Groundwater Metabolites

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

6.5 Dermal Absorption (KCP 7.3)

A summary of the dermal absorption rates for the active substances in CHR/H/FETEC-PART B 110 EC are presented in the following table.

Table 6.5-1: Dermal absorption rates for active substances in CHR/H/FETEC-PART B 110 EC

	Fenoxaprop-P-ethyl	
	Value	**Reference**
Concentrate	25 %	Default value from Guidance on Dermal Absorption (EFSA Journal 2017;15(6):4873)
Dilution	70 %	Default value from Guidance on Dermal Absorption (EFSA Journal 2017;15(6):4873)

6.5.1 Justification for proposed values – fenoxaprop-P-ethyl

No data on dermal absorption for fenoxaprop-P-ethyl in CHR/H/FETEC-PART B 110 EC 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 CHRH/FETEC-PART B 110 EC

	Value	Justification for value	Acceptability of justification
Concentrate	25 %	Value of 25% for concentrated product is proposed by Dermal Absorption Guidance (EFSA Journal 2017;15(6):4873)	Accepted
Dilution	70 %	Value of 70% for diluted product is proposed by Dermal Absorption Guidance (EFSA Journal 2017;15(6):4873)	Accepted

6.6 Exposure Assessment of Plant Protection Product (KCP 7.2)

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

Product name and code	CHR/H/FETEC-PART B 110 EC
Formulation type	EC
Category	Herbicide
Container size(s), short description	0.12 L to 10 L HDPE/PA 0.12 L to 10 L HDPE/F 0.1 L to 20 L HDPE/EvOH
Active substance(s) (incl. content)	**fenoxaprop-P-ethyl** 110 g/L
AOEL systemic	0.014 mg/kg bw/d
Inhalation absorption	100 %
Oral absorption	100 %
Dermal absorption	Concentrate: 25 % Dilution: 70 %

6.6.1 Selection of critical use(s) and justification

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

6.6.2 Operator exposure (KCP 7.2.1)

Comments of zRMS:	The estimations of operator exposure to Fenoxaprop-P-ethyl contained in CHR/H/FETEC 110 EC (based on AOEM model) performed by the Applicant are accepted. Conclusions:

	According to the results of estimations, the use of CHR/H/FETEC 110 EC containing Fenoxaprop-P-ethyl (110 g/L) using vehicle-mounted downward spraying (outdoors), **causes unacceptable health risk for unprotected operator wearing work wear (with long sleeved and long trousers) regardless the use presented in the GAP Table.** However, **the use of appropriate PPE**, i.e. gloves during mixing/loading and application and work wear during mixing/loading lowers the potential exposure **to the acceptable level** (46.85% and 34.78% of the systemic AOEL for the active substance for the application at the dose of 0.077 kg a.s./ha and 0.055 kg a.s./ha, respectively). The use of CHR/H/FETEC 110 EC containing Fenoxaprop-P-ethyl (110 g/L) in the combination with: - Galaper 200 EC/ Fluroherb 200 EC/ Herbistar 200 EC containing Fluroxypyr or - Tristar 50 SG/Trimax 50 SG/Triben Super 50 SG containing Tribenuron-methyl is **acceptable** assuming **the same mitigation measures are undertaken** (gloves during mixing/loading and application and protective cloth during mixing/loading). Taking into account the results of exposure estimations and the classification of the product, the use of protective gloves, face/eye protection and work wear during mixing/loading and protective gloves and work wear during application is necessary. Thus, the following sentence regarding the use of PPE is recommended by the evaluator to be placed in the label: „*Stosować rękawice ochronne, ochronę oczu/twarzy oraz odzież roboczą w trakcie przygotowywania cieczy użytkowej oraz rękawice ochronne i odzież roboczą w czasie wykonywania zabiegu.*" "Wear protective gloves, eye/face protection and work wear during mixing/loading, and protective gloves and work wear during application."

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/FETEC-PART B 110 EC and its combinations with Galaper 200 EC/ Fluroherb 200 EC/ Herbistar 200 EC or Tristar 50 SG/Trimax 50 SG/Triben Super 50 SG products according to the critical use(s) is presented in Table 6.6.2-1. Outcome of the estimations are presented in Tables 6.6.2-2 – 6.6.2.4. Detailed calculations are in Appendix 3.

Table 6.6.2-1: Exposure models for intended uses

Critical use(s)	Cereals (max. 1 x 0.7 L product/ha)
Model(s)	EFSA model ver. 30 mar 2015 [Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products, European Food Safety Authority (EFSA), Parma, Italy, *EFSA Journal 2014;12(10):3874*]
Critical use(s)	Cereals (max. 1 x 0.5 L product/ha + 25 g/ha Tristar 50 SG/Trimax 50 SG/Triben Super 50 SG)
Model(s)	EFSA model ver. 30 mar 2015 [Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products, European Food Safety Authority (EFSA), Parma, Italy, *EFSA Journal 2014;12(10):3874*]
Critical use(s)	Cereals (max. 1 x 0.5 L product/ha + 0.4 l/ha Galaper 200 EC/ Fluroherb 200 EC/ Herbistar 200 EC)

Model(s)	EFSA model ver. 30 mar 2015 [Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products, European Food Safety Authority (EFSA), Parma, Italy, *EFSA Journal 2014;12(10):3874*]

Table 6.6.2-2: Estimated operator exposure – fenoxaprop-P-ethyl

		Fenoxaprop-P-ethyl	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Vehicle-mounted downward spraying outdoors Application rate: 0.077 kg a.s./ha			
EFSA exposure model Application volume 1 x 0.7 L/ha Body weight: 60 kg	no PPE	**0.1069907**	**764.22%**
	+ type of PPE (gloves during mixing/loading and application)	**0.0445729**	**318.38%**
	+ type of PPE (clothing during mixing and loading)	0.0065596	46.85%

Table 6.6.2-3: Estimated operator exposure – fenoxaprop-P-ethyl + Tristar 50 SG/Trimax 50 SG/Triben Super 50 SG

		Fenoxaprop-P-ethyl	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Vehicle-mounted downward spraying outdoors Application rate: 0.055 kg a.s./ha			
EFSA exposure model Application volume 1 x 0.5 L/ha Body weight: 60 kg	no PPE	**0.0826087**	**590.06%**
	+ type of PPE (gloves during mixing/loading and application)	**0.0348914**	**249.22%**
	+ type of PPE (clothing during mixing and loading)	0.0048693	34.78%
		Tribenuron-methyl	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Vehicle-mounted downward spraying outdoors Application rate: 0.0125 kg a.s./ha			
EFSA exposure model Application volume 1 x 0.25 L/ha Body weight: 60 kg	no PPE	0.0047873	9.57%

Table 6.6.2-4: Estimated operator exposure – fenoxaprop-P-ethyl + Galaper 200 EC/ Fluro-herb 200 EC/ Herbistar 200 EC

		Fenoxaprop-P-ethyl	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Vehicle-mounted downward spraying outdoors Application rate: 0.055 kg a.s./ha			
EFSA exposure model Application volume 1 x 0.5 L/ha Body weight: 60 kg	no PPE	**0.0826087**	**590.06%**
	+ type of PPE (gloves during mixing/loading and application)	**0.0348914**	**249.22%**
	+ type of PPE (clothing during mixing/loading)	0.0048693	34.78%
		Fluroxypyr	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Vehicle-mounted downward spraying outdoors Application rate: 0.08 kg a.s./ha			
EFSA exposure model Application volume 1 x 0.4 L/ha Body weight: 60 kg	no PPE	0.1101864	13.77%

6.6.3 Measurement of operator exposure

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

6.6.4 Worker exposure (KCP 7.2.3)

Comments of zRMS:	The estimations of worker exposure to Fenoxaprop-P-ethyl contained in CHR/H/FETEC 110 EC (based on AOEM model) performed by the Applicant are accepted. Conclusions: According to the results of estimations, the use of CHR/H/FETEC 110 EC containing Fenoxaprop-P-ethyl (110 g/L), **causes unacceptable health risk for unprotected worker regardless the use presented in the GAP Table.** However, **the use of appropriate PPE**, i.e. work wear (arms, body and legs covered) lowers the potential exposure **to the acceptable level** (53.90% and 38.50% of the systemic AOEL for the active substance for the application at the dose of 0.077 kg a.s./ha and 0.055 kg a.s./ha, respectively). The use of CHR/H/FETEC 110 EC containing Fenoxaprop-P-ethyl (110 g/L) in the combination with:

	- Galaper 200 EC/ Fluroherb 200 EC/ Herbistar 200 EC containing Fluroxypyr or - Tristar 50 SG/Trimax 50 SG/Triben Super 50 SG containing Tribenuron-methyl is **acceptable** for the worker assuming **the same mitigation measures are undertaken** (work wear: arms, body and legs covered). The sensitization potential of CHR/H/FETEC 110 EC is expected when using undiluted product. However, bearing in minds the risk for the most sensitive individuals and no dose-effect relationship in case of sensitization, the protective gloves and work wear is recommended for the worker during field inspection. Thus, the following sentence regarding the use of PPE is recommended by the evaluator to be placed in the label in the section for the worker: *„Stosować rękawice ochronne oraz odzież roboczą (długie spodnie, koszula z długim rękawem) podczas wchodzenia na teren poddany opryskowi”*. “Wear protective gloves and work wear (long trousers, long-sleeve shirt) during inspection.”

6.6.4.1 Estimation of worker exposure

Table 6.6.4-1 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/FETEC-PART B 110 EC and its combinations with Galaper 200 EC/ Fluroherb 200 EC/ Herbistar 200 EC or Tristar 50 SG/Trimax 50 SG/Triben Super 50 SG products according to the critical use(s). Outcome of the estimations are presented in Tables 6.6.4-2 to 6.6.4.4. Detailed calculations are in Appendix 3.

Table 6.6.4-1: Exposure models for intended uses

Critical use(s)	Cereals (max. 1 x 0.7 L product/ha)
Model(s)	EFSA model ver. 30 mar 2015 [Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products, European Food Safety Authority (EFSA), Parma, Italy, *EFSA Journal 2014;12(10):3874*]
Critical use(s)	Cereals (max. 1 x 0.5 L product/ha + 25 g/ha Tristar 50 SG/Trimax 50 SG/Triben Super 50 SG)
Model(s)	EFSA model ver. 30 mar 2015 [Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products, European Food Safety Authority (EFSA), Parma, Italy, *EFSA Journal 2014;12(10):3874*]
Critical use(s)	Cereals (max. 1 x 0.5 L product/ha + 0.4 l/ha Galaper 200 EC/ Fluroherb 200 EC/ Herbistar 200 EC)
Model(s)	EFSA model ver. 30 mar 2015 [Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products, European Food Safety Authority (EFSA), Parma, Italy, *EFSA Journal 2014;12(10):3874*]

Table 6.6.4-2: Estimated worker exposure - fenoxaprop-P-ethyl

		fenoxaprop-P-ethyl	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Number of applications and application rate:		1 x 0.0077 kg a.s./ha	
8 hours/day [(1)], TC: 23,000 cm^2/person/h [(2)] Body weight: 60 kg	no PPE [(3)]	**0.0673750**	**481.25%**
	with PPE (workwear[(4)]	0.0075460	53.90%

Table 6.6.4-3: Estimated worker exposure - fenoxaprop-P-ethyl + Tristar 50 SG/Trimax 50 SG/Triben Super 50 SG

		fenoxaprop-P-ethyl		**tribenuron-methyl**	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Number of applications and application rate:		1 x 0.055 kg a.s./ha		1 x 0.0125 kg a.s./ha	
8 hours/day[(1)], TC: 23,000 cm^2/person/h [(2)] Body weight: 60 kg	no PPE[(3)]	**0.0481250**	**343.75%**	0.0078125	15.63%
	with PPE[(4)]	0.0053900	38.50%	0.0008750	1.75%

Table 6.6.4-4: Estimated worker exposure - fenoxaprop-P-ethyl + Galaper 200 EC/ Fluroherb 200 EC/ Herbistar 200 EC

		fenoxaprop-P-ethyl		Fluroksypyr	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Number of applications and application rate:		1 x 0.055 kg a.s./ha		1 x 0.08 kg a.s./ha	
8 hours/day(1), TC: 23,000 cm^2/person/h (2) Body weight: 60 kg	no PPE(3)	**0.0481250**	**343.75%**	0.0700000	8.75%
	with PPE(4)	0.0053900	38.50%	0.0078400	0.98%

Conclusion
According to the calculations of the worker exposure with the EFSA exposure model, no undue risk is predicted for all uses supported in the EU central zone and applied with vehicle mounted sprayers. Further personal protective equipment is not necessary as the maximum estimated exposure of workers wearing work wear covering arms, body and legs and even for workers without PPE (potential exposure) is below the AOEL for Fenoxaprop-P-ethyl and for its combinations with Galaper 200 EC/ Fluroherb 200 EC/ Herbistar 200 EC or Tristar 50 SG/Trimax 50 SG/Triben Super 50 SG products.

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)

Comments of zRMS:	The AAOEL value for the Fenoxaprop-P-ethyl is not allocated. Consequently, it is assumed that the estimation of bystander exposure is covered by the calculation of resident exposure towards the active substance. The estimations performed by the Applicant (based on AOEM model) are acceptable. **Summary and conclusions of bystander and resident exposure to CHR/H/FETEC 110 EC:** The systemic exposure to Fenoxaprop-P-ethyl (110 g/L) contained in the formulation CHR/H/FETEC 110 EC does not exceed the value of AOEL for this active substance regardless the use presened in the GAP Table, including combined used with either Galaper 200 EC/ Fluroherb 200 EC/ Herbistar 200 EC containing Fluroxypyr or Tristar 50 SG/Trimax 50 SG/Triben Super 50 SG containing Tribenuron-methyl.

	The **incidental short-time exposure of bystander and resident (children and adult**) to Fenoxaprop-P-ethyl (110 g/L) contained in the formulation CHR/H/FETEC 110 EC **causes no risk** to human health if the product is used in accordance to the intended uses listed in the GAP Table.

6.6.5.1 Estimation of bystander and resident exposure

Table 6.6.5-1 shows the exposure model(s) used for estimation of bystander and resident exposure to Fenoxaprop-P-ethyl and its combinations with Galaper 200 EC/ Fluroherb 200 EC/ Herbistar 200 EC or Tristar 50 SG/Trimax 50 SG/Triben Super 50 SG products. Outcome of the estimations are presented in Table 6.6.5-2 to 6.6.5-4. Detailed calculations are in Appendix 3.

Table 6.6.5-1: Exposure models for intended uses

Critical use(s)	Cereals (max. 1 x 0.7 L product/ha)
Model(s)	EFSA model ver. 30 mar 2015 [Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products, European Food Safety Authority (EFSA), Parma, Italy, *EFSA Journal 2014;12(10):3874*]
Critical use(s)	Cereals (max. 1 x 0.5 L product/ha + 25 g/ha Tristar 50 SG/Trimax 50 SG/Triben Super 50 SG)
Model(s)	EFSA model ver. 30 mar 2015 [Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products, European Food Safety Authority (EFSA), Parma, Italy, *EFSA Journal 2014;12(10):3874*]
Critical use(s)	Cereals (max. 1 x 0.5 L product/ha + 0.4 l/ha Galaper 200 EC/ Fluroherb 200 EC/ Herbistar 200 EC)
Model(s)	EFSA model ver. 30 mar 2015 [Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products, European Food Safety Authority (EFSA), Parma, Italy, *EFSA Journal 2014;12(10):3874*]

Table 6.6.5-2: Estimated bystander and resident exposure – fenoxaprop-P-ethyl

	Fenoxaprop-P-ethyl	
Model data	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Vehicle-mounted downward spraying outdoors Application rate: 1 x 0.0077 kg a.s./ha		
Bystanders (adult) Buffer strip: 2-3 m Body weight: 60 kg	0.00535	**38.22**
Bystanders (children)	0.0129	**92.34**

Buffer strip: 2-3 m Body weight: 10 kg		
Residents (adult) Buffer strip: 2-3 m Body weight: 60 kg	0.00535	**38.22**
Residents (children) Buffer strip 2-3 m Body weight: 10kg	0.0129	**92.34**

Table 6.6.5-3: Estimated bystander and resident exposure - fenoxaprop-P-ethyl + Tristar 50 SG/Trimax 50 SG/Triben Super 50 SG

	Fenoxaprop-P-ethyl		**Tribenuron-methyl**	
Model data	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Vehicle-mounted downward spraying outdoors				
Application rate:	1 x 0.055 kg a.s./ha		1 x 0.0125 kg a.s./ha	
Bystanders (adult) Buffer strip: 2-3 m Body weight: 60 kg	0.0038875	**27.77**	0.0008238	**1.65**
Bystanders (children) Buffer strip: 2-3 m Body weight: 10 kg	0.0095393	**68.14**	0.0024473	**4.89**
Residents (adult) Buffer strip: 2-3 m Body weight: 60 kg	0.0038875	**27.77**	0.0008238	**1.65**
Residents (children) Buffer strip: 2-3 m Body weight:10 kg	0.0095393	**68.14**	0.0024473	**4.89**

Table 6.6.5-4: Estimated bystander and resident exposure - fenoxaprop-P-ethyl + Galaper 200 EC/ Fluroherb 200 EC/ Herbistar 200 EC

	Fenoxaprop-P-ethyl		**Fluroxypyr**	
Model data	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Vehicle-mounted downward spraying outdoors				
Application rate:	1 x 0.055 kg a.s./ha		1 x 0.08 kg a.s./ha	
Bystanders (adult) Buffer strip: 2-3 m Body weight: 60 kg	0.0038875	**27.77**	0.0055500	**0.69**
Bystanders (children) Buffer strip: 2-3 m	0.0095393	**68.14**	0.0133889	**1.67**

Body weight: 10 kg				
Residents (adult) Buffer strip: 2-3 m Body weight: 60 kg	0.0038875	**27.77**	0.0055500	**0.69**
Residents (children) Buffer strip: 2-3 m Body weight:10 kg	0.0095393	**68.14**	0.0133889	**1.67**

Conclusion
According to the EFSA model calculations it can be concluded that there is no undue risk to any resident (adult or child) after exposure to CHR/H/FETEC-PART B 110 EC applied to cereals and combinations of CHR/H/FETEC-PART B 110 EC with Galaper 200 EC/ Fluroherb 200 EC/ Herbistar 200 EC or Tristar 50 SG/Trimax 50 SG/Triben Super 50 SG products. As no AAOEL value was established for active substance fenoxaprop-P-ethyl, tribenuron-methyl and fluroxypyr, bystander's exposure is covered by resident's exposure. Hence no risk mitigation measures are necessary.

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 fenoxaprop-P-ethyl and for combination of fenoxaprop-P-ethyl with Galaper 200 EC/ Fluroherb 200 EC/ Herbistar 200 EC or Tristar 50 SG/Trimax 50 SG/Triben Super 50 SG products 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

The product may be used as a mixture of two active substances in two different agents.

Comments of zRMS:	**Summary and conclusions:** The estimations performed according to AOEM indicate that the concurernt systemic exposure to: - Fenoxaprop-P-ethyl (110 g/L) contained in CHR/H/FETEC 110 EC and Fluroxypyr (200 g/L) contained in Galaper 200 EC/ Fluroherb 200 EC/ Herbistar 200 EC - Tribenuron-methyl (50 g/L) contained in Tristar 50 SG/Trimax 50 SG/Triben Super 50 SG **does not cause unaceptable risk for the health of operators, workers, bystanders and residents (adults and children)** beacause the HI values remian always below 1 assuming the uses presented in the GAP Table. Warning: A detailed analysis of exposure to formulations Galaper 200 EC/ Fluroherb 200 EC/ Herbistar 200 EC and Tristar 50 SG/Trimax 50 SG/Triben Super 50 SG were not the subject of ongoing assessment.

6.6.6.1 Exposure Assessment of fenoxaprop-P-ethyl and tribenuron-methyl in Tristar 50 SG/Trimax 50 SG/Triben Super 50 SG

Note: The combined toxicological effect of these active substances has not been investigated with regard to repeated dose toxicity.

At the first tier, combined exposure is calculated as the sum of the component exposures without regard to the mode of action or mechanism/target of toxicity. Initially, the individual Hazard Quotients (HQ) are calculated for all active substances in the PPP by assessing the exposure according to appropriate models and dividing the individual exposure levels by the respective systemic AOEL. This is equivalent to the predicted exposure as % of systemic AOEL from Tables 6.6.2-3, 6.6.4-3 and 6.6.5-3 converted to decimal. The Hazard Index (HI) is the sum of the individual HQs.

Table 6.6.6-1: Acute risk assessment from combined exposure

Application scenario	Active Ingredient	Estimated exposure / AOEL (HQ)
Operators	Fenoxaprop-P-ethyl	0.3478
	Tribenuron-methyl	0.0957
	Cumulative risk Operators (HI)	**0.4435**
Workers	Fenoxaprop-P-ethyl	0.385
	Tribenuron-methyl	0.0175
	Cumulative risk Workers (HI)	**0.4025**
Bystander	As no AAOEL value was established for active substance fenoxaprop-P-ethyl, tribenuron-methyl and fluroxypyr, bystander's exposure is covered by resident's exposure. Hence no risk mitigation measures are necessary.	
Resident - Adult	Fenoxaprop-P-ethyl	0.2777
	Tribenuron-methyl	0.0165
	Cumulative risk Resident – Adult (HI)	**0.30**
Resident - Child	Fenoxaprop-P-ethyl	0.6814
	Tribenuron-methyl	0.0489
	Cumulative risk Resident – Child (HI)	**0.73**

The Hazard Index is < 1. Thus combined exposure to all active substances in CHR/H/FETEC-PART B 110 EC is not expected to present a risk for operators, workers, bystanders and residents. No further refinement of the assessment is required.

6.6.6.2 Exposure Assessment of fenoxaprop-P-ethyl and fluroxypyr in Galaper 200 EC/ Fluroherb 200 EC/ Herbistar 200 EC

Note: The combined toxicological effect of these active substances has not been investigated with regard to repeated dose toxicity.

At the first tier, combined exposure is calculated as the sum of the component exposures without regard to the mode of action or mechanism/target of toxicity. Initially, the individual Hazard Quotients (HQ) are calculated for all active substances in the PPP by assessing the exposure according to appropriate models and dividing the individual exposure levels by the respective systemic AOEL. This is equivalent to the predicted exposure as % of systemic AOEL from Tables 6.6.2-4, 6.6.4-4 and 6.6.5-4 converted to decimal. The Hazard Index (HI) is the sum of the individual HQs.

Table 6.6.6-2: Acute risk assessment from combined exposure

Application scenario	Active Ingredient	Estimated exposure / AOEL (HQ)
Operators	Fenoxaprop-P-ethyl	0.3478
	Fluroksypyr	0.1377
	Cumulative risk Operators (HI)	**0.4855**
Workers	Fenoxaprop-P-ethyl	0.3850
	Fluroksypyr	0.0098
	Cumulative risk Workers (HI)	**0.3948**
Bystander	As no AAOEL value was established for active substance fenoxaprop-P-ethyl, tribenuron-methyl and fluroxypyr, bystander's exposure is covered by resident's exposure. Hence no risk mitigation measures are necessary.	
Resident - Adult	Fenoxaprop-P-ethyl	0.2777
	Fluroksypyr	0.0069
	Cumulative risk Resident – Adult (HI)	**0.2846**
Resident - Child	Fenoxaprop-P-ethyl	0.6814
	Fluroksypyr	0.0167
	Cumulative risk Resident – Child (HI)	**0.6981**

The Hazard Index is < 1. Thus combined exposure to all active substances in CHR/H/FETEC-PART B 110 EC is not expected to present a risk for operators, workers, bystanders and residents. No further refinement of the assessment is required.

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	Verte-brate study Y/N	Owner
KCP 7.1.1 – 7.1.6	Żero, K.	2022	Toxicological classification of product CHR/H/FETEC-PART B 110 EC based on calculation method taking into consideration health hazards of constituent substances. non GLP Unpublished	N	Chemirol

Appendix 2 Detailed evaluation of the studies relied upon

A 2.1 Statement on bridging possibilities

Not required.

A 2.2 Acute oral toxicity (KCP 7.1.1)

Comments of zRMS:	Taking into account the composition of the product (one ingredient classified as Acute Tox. 4, H302) and the provisions of the Regulation EC No. 1272/2008, the formulation CHR/H/FETEC 110 EC **does not require classification in regards to oral acute toxicity.**

Reference:	KCP 7.1.1
Report	Toxicological classification of product CHR/H/FETEC-PART B 110 EC based on calculation method taking into consideration health hazards of constituent substances; K. Żero; 2022
Guideline(s):	Regulation (EC) No. 1272/2008
Deviations:	-
GLP:	No
Acceptability:	

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/FETEC-PART B 110 EC 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
- ATE_i - 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 bodyweight)	0 < Category 1 ≤ 5 5 < Category 2 ≤ 50 50 < Category 3 ≤ 300 300 < Category 4 ≤ 2 000	0,5 5 100 500
Dermal (mg/kg bodyweight)	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.

Only one ingredient is relevant in this class of hazard.

- 0.497 % (Acute Tox. 4, H302)

Estimated values of LD_{50} were taken.

$$ATE_{mix} = \frac{100}{\sum_{i=1}^{n} \frac{C_i}{ATE_i}} = \frac{100}{\frac{0.497}{500}} = \frac{100}{0.001} = 100\,000 \frac{\text{mg}}{\text{kg bw}}$$

According to the table 3.1.2, the result (100 000 mg/ kg bw > > 2 000 mg/kg bw) is higher than generic concentration level. Therefore the formulation is not classified this this hazard class.

Conclusion

According to calculation method, the result 100 000 mg/kg bw is significantly higher than result triggering classification. Therefore the formulation is not classified as Acute Tox. 4, H302.

According to point 7.1.1 of part A of Annex Regulation No 284/2014, it is possible to waive from performing acute oral toxicity tests.

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

Comments of zRMS:	Taking into account the composition of the product (one ingredient classified as Acute Tox. 4, H312) and the provisions of the Regulation EC No. 1272/2008, the formulation CHR/H/FETEC 110 EC **does not require classification in regards to dermal acute toxicity.**

Reference:	KCP 7.1.2
Report	Toxicological classification of product CHR/H/FETEC-PART B 110 EC based on calculation method taking into consideration health hazards of constituent substances; K. Żero; 2022
Guideline(s):	Regulation (EC) No. 1272/2008
Deviations:	-
GLP:	No
Acceptability:	

According to point 7.1.2 of Part A of Annex to the Commission Regulation (EU) No 284/2013 as regards the data requirements for plant protection products:
”A test for dermal toxicity shall be carried out on a case by case basis, unless the applicant can justify an alternative approach under Regulation (EC) No 1272/2008. In the latter case, acute dermal toxicity of all components shall be provided or reliably predicted with a validated method. Consideration shall be given to the possible effects of components on the toxic potential of the total mixture.
Findings of severe skin irritation or corrosion in the dermal study may be used instead of performing a specific irritation study.”

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

Due to the fact, that all components of the formulation CHR/H/FETEC-PART B 110 EC are known, the acute dermal 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
- ATE_i - 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 bodyweight)	0 < Category 1 ≤ 5	0,5
	5 < Category 2 ≤ 50	5
	50 < Category 3 ≤ 300	100
	300 < Category 4 ≤ 2 000	500
Dermal (mg/kg bodyweight)	0 < Category 1 ≤ 50	5
	50 < Category 2 ≤ 200	50
	200 < Category 3 ≤ 1 000	300
	1 000 < Category 4 ≤ 2 000	1 100
Gases (ppmV)	0 < Category 1 ≤ 100	10
	100 < Category 2 ≤ 500	100
	500 < Category 3 ≤ 2 500	700
	2 500 < Category 4 ≤ 20 000	4 500
Vapours (mg/l)	0 < Category 1 ≤ 0,5	0,05
	0,5 < Category 2 ≤ 2,0	0,5
	2,0 < Category 3 ≤ 10,0	3
	10,0 < Category 4 ≤ 20,0	11
Dust/mist (mg/l)	0< Category 1 ≤ 0,05	0,005
	0,05 < Category 2 ≤ 0,5	0,05
	0,5 < Category 3 ≤ 1,0	0,5
	1,0 < Category 4 ≤ 5,0	1,5

Note 1 These values are designed to be used in the calculation of the ATE for classification of a mixture based on its components and do not represent test results.

Only one ingredient is relevant in this class of hazard.

- 4.86 % (Acute Tox. 4, H312)

Estimated values of LD_{50} were taken.

$$ATE_{mix} = \frac{100}{\sum_{i=1}^{n} \frac{C_i}{ATE_i}} = \frac{100}{\frac{4.86}{1100}} = \frac{100}{0.0044} = 22\,727 \frac{\text{mg}}{\text{kg bw}}$$

According to the table 3.1.2, the result (22 727 mg/ kg bw > > 2 000 mg/kg bw) is higher than generic concentration level. Therefore the formulation is not classified this this hazard class.

Conclusion

According to calculation method, the result 22 727 mg/kg bw is significantly higher than result triggering classification. Therefore the formulation is not classified as Acute Tox. 4, H312.

According to point 7.1.2 of part A of Annex Regulation No 284/2014, it is possible to waive from performing acute oral toxicity tests.

A 2.4 Acute inhalation toxicity (KCP 7.1.3)

Comments of zRMS:	Taking into account the composition of the product (two ingredients classified as Acute Tox. 4, H332) and the provisions of the Regulation EC No. 1272/2008, the formulation CHR/H/FETEC 110 EC **does not require classification in regards to inhalation acute toxicity**.

Reference:	KCP 7.1.3
Report	Toxicological classification of product CHR/H/FETEC-PART B 110 EC based on calculation method taking into consideration health hazards of constituent substances; K. Żero; 2022
Guideline(s):	Regulation (EC) No. 1272/2008
Deviations:	-
GLP:	No
Acceptability:	

Inhalation study on CHR/H/FETEC-PART B 110 EC is not required according to point 7.1.3 of Part A of Annex to the Commission Regulation (EU) No 284/2013 as regards the data requirements for plant protection products the inhalation test must be carried out since the preparation is:

- a gas or liquefied gas,
- a smoke generating formulation or fumigant,
- used with fogging equipment,
- a vapor releasing preparation,
- an aerosol,
- a powder containing a significant proportion of particles of diameter <50 µm (> 1% on a weight basis),
- to be applied from aircraft in cases where inhalation exposure is relevant,
- contains an active substance with a vapor pressure > 1x10-2 Pa and is to be used in enclosed spaces such as warehouses or glasshouses,
- to be applied in a manner which generates a significant proportion of particles or droplets of diameter < 50 µm (> 1% on a weight basis).

The active substances and the other co-formulants are not classified as acute inhalation toxic, it can be assumed that entire formulation is not classified in this class. According to point 7.1.3 of part A of Annex Regulation No 284/2014, it is possible to waive from acute inhalation toxicity test.

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

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
- ATE_i - 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 bodyweight)	0 < Category 1 ≤ 5 5 < Category 2 ≤ 50 50 < Category 3 ≤ 300 300 < Category 4 ≤ 2 000	0,5 5 100 500
Dermal (mg/kg bodyweight)	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.

Two ingredients are relevant in this class of hazard.

- 5.35 % (Acute Tox. 4, H332)
- 4.86 % (Acute Tox. 4, H332)

Estimated values of LD_{50} were taken.

$$ATE_{mix} = \frac{100}{\sum_{i=1}^{n} \frac{C_i}{ATE_i}} = \frac{100}{\frac{5.35}{11} + \frac{4.86}{11}} = \frac{100}{0.486 + 0.442} = \frac{100}{0.93} = 107.52 \ \frac{\text{mg}}{\text{l}}$$

According to the table 3.1.2, the result (107.52 mg/l > > 20 mg/l) is higher than generic concentration level. Therefore the formulation is not classified this this hazard class.

Conclusion

According to calculation method, the result 107.52 mg/kg bw is significantly higher than a result triggering classification. Therefore the formulation is not classified as Acute Tox. 4, H332.

According to point 7.1.3 of part A of Annex Regulation No 284/2014, it is possible to waive from performing acute oral toxicity tests.

A 2.5 Skin irritation (KCP 7.1.4)

Comments of zRMS:	Taking into account the composition of the product (two ingredients classified as Skin Irrit. 2, H315 with total concentration of 12.9% of the product) and the provisions of the Regulation EC No. 1272/2008, the formulation CHR/H/FETEC 110 EC **requires classification in regards to skin irritation as Skin Irrit. 2, H315.**

Reference:	KCP 7.1.4
Report	Toxicological classification of product CHR/H/FETEC-PART B 110 EC based on calculation method taking into consideration health hazards of constituent substances; K. Żero; 2022
Guideline(s):	Regulation (EC) No. 1272/2008
Deviations:	-
GLP:	No
Acceptability:	Yes

Materials and methods

According to point 7.1.4 of Part A of Annex to the Commission Regulation (EU) No 284/2013 as regards the data requirements for plant protection products:
" The skin irritancy of the plant protection product shall be reported based on the tiered approach, unless the applicant can justify an alternative approach under Regulation (EC) No 1272/2008. In the latter case, skin irritation properties of all components shall be provided or reliably predicted with a validated method. Consideration shall be given to the possible effects of components on the irritant potential of the total mixture."
The complete composition of the formulation with the classification of individual ingredients is available in part C.
Due to the fact, that all components of the formulation CHR/H/FETEC-PART B 110 EC are known, skin corrosive test is not necessary.

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 %

Two ingredients are relevant in this class if hazard.

- 7.5 % (Skin Irrit. 2, H315)
- 5.4 % (Skin Irrit. 2, H315)

$$C_{Skin\ Irrit.} = 7.5\ \% + 5.4\ \% = 12.9\ \%$$

The result (12.9%) is higher than result triggering eye hazard classification (10 %).

Conclusion

According to calculation method, the result 12.9 % is significantly higher than a concentration triggering classification (10%). Therefore the formulation is classified as **Skin Irrit. 2, H315**.

A 2.6 Eye irritation (KCP 7.1.5)

Comments of zRMS:	Taking into account the composition of the product (two ingredients classified as Eye Dam. 1, H318 with total concentration of 12.9% of the product) and the provisions of the Regulation EC No. 1272/2008, the formulation CHR/H/FETEC 110 EC **requires classification in regards to corrosive effect to the eye as Eye Dam. 1, H318.**

Reference:	KCP 7.1.5
Report	Toxicological classification of product CHR/H/FETEC-PART B 110 EC based on calculation method taking into consideration health hazards of constituent sub-stances; Żero, K.; 2022
Guideline(s):	Regulation (EC) No. 1272/2008
Deviations:	-
GLP:	No
Acceptability:	

According to point 7.1.5 of Part A of Annex to the Commission Regulation (EU) No 284/2013 as regards the data requirements for plant protection products:
" Eye irritation tests shall be provided, unless it is likely that severe effects on the eyes may be produced or the applicant can justify an alternative approach under Regulation (EC) No 1272/2008. In the latter case, eye irritation properties of all components shall be provided or reliably predicted with a validated method. Consideration shall be given to the possible effects of components on the irritant potential of the total mixture."
The complete composition of the formulation with the classification of individual ingredients is available in part C.
Due to the fact, that all components of the formulation CHR/H/FETEC-PART B 110 EC are known, eye irritation test is not necessary.

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 %

Two ingredients are relevant in this class of hazard.

- 7.5 % (Eye Dam. 1, H318)
- 5.4 % (Eye Dam. 1, H318)

$$C_{Skin\ Corr} + C_{Eye\ Dam.} = 7.5\ \% + 5.4\ \% = 12.9\ \%$$

The result (12.9%) is higher than result triggering eye hazard classification (3%).

Conclusion

According to calculation method, the result 12.9 % is significantly higher than a concentration triggering classification (3%). Therefore the formulation is classified as **Eye Dam. 1, H318**.

A 2.7 Skin sensitisation (KCP 7.1.6)

Comments of zRMS:	Taking into account the composition of the product (two ingredients classified as Skin Sens. 1, H317 with total concentration of 16.35% of the product) and the provisions of the Regulation EC No. 1272/2008, the formulation CHR/H/FETEC 110 EC **requires classification in regards to skin sensitization as Skin Sens. 1, H317.**

Reference:	KCP 7.1.6
Report	Toxicological classification of product CHR/H/FETEC-PART B 110 EC based on calculation method taking into consideration health hazards of constituent sub-stances; Żero, K.; 2022
Guideline(s):	Regulation (EC) No. 1272/2008
Deviations:	-
GLP:	No
Acceptability:	

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

”The skin sensitisation test shall be carried out unless the active substances or co-formulants are known to have sensitising properties or the applicant can justify an alternative approach under Regulation (EC) No 1272/2008. In the latter case, skin sensitisation properties of all components shall be provided or reliably predicted with a validated method.
Consideration shall be given to the possible effects of components on the sensitising potential of the total mixture.” Due to the fact, that all components of the formulation CHR/H/FETEC-PART B 110 EC are known, skin sensitisation test is not necessary.

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

Materials and methods

We use the table:

Table 3.4.5
Generic concentration limits of ingredients of a mixture classified as either skin sensitisers or respiratory sensitisers that trigger classification of the mixture

Ingredient classified as:	Concentration triggering classification of a mixture as:		
	Skin Sensitiser	Respiratory Sensitiser	
	All physical states	Solid/Liquid	Gas
Skin Sensitiser Category 1	≥ 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 %

Two ingredients are relevant in this class of hazard.

- 11 % (Skin Sens. 1, H317)
- 5.35 % (Skin Sens. 1, H317)

Both relevant ingredients exceed the generic concentration limit which triggers product's sensitization classification (1%).

Conclusion

According to calculation method, the concentration of relevant ingredients is significantly higher than a concentration triggering classification (1%). Therefore the formulation is classified as **Skin Sens. 1, H317**.

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)

Not required.

A 2.11 Other/Special Studies

A 2.11.1 Specific target organ toxicity

Comments of zRMS:	Taking into account the composition of the product (two ingredients classified as STOT RE 2, H373 with total concentration exceeding 10% of the product) and the provisions of the Regulation EC No. 1272/2008, the formulation CHR/H/FETEC 110 EC **requires classification in regards to specific target toxicity as STOT RE 2, H373.**

Reference:	KCP 7.1.7
Report	Toxicological classification of product CHR/H/FETEC-PART B 110 EC based on calculation method taking into consideration health hazards of constituent sub-stances; Żero, K.; 2022
Guideline(s):	Regulation (EC) No. 1272/2008
Deviations:	-
GLP:	No
Acceptability:	

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".

Materials and Methods

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 ≥ 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."

Two ingredients are classified in this class of hazard. The concentration of one of the ingredients (10.9 %) is higher than concentration triggering STOT RE 2, H373 classification of whole formulation (10 %).

Conclusions
The concentration of one of the ingredients (11 %) is higher than concentration triggering STOT RE 2, H373 classification of whole formulation (10 %). Therefore the whole product will be classified as **STOT RE 2, H373**.

A 2.11.2 Aspiration Toxicity

Comments of zRMS:	Taking into account the composition of the product (one ingredient classified as Asp. Tox. 1, H304 at the concentration exceeding 10% of the product) and the provisions of the Regulation EC No. 1272/2008, the formulation CHR/H/FETEC 110 EC **requires classification in regards to specific target toxicity as Asp. Tox. 1, H304.**

Reference:	KCP 7.1.7
Report	Toxicological classification of product CHR/H/FETEC-PART B 110 EC based on calculation method taking into consideration health hazards of constituent sub-stances; Żero, K.; 2022
Guideline(s):	Regulation (EC) No. 1272/2008
Deviations:	-
GLP:	No
Acceptability:	

According to point 3.10.3.3 of Regulation (EC) No 1272/2008 as regards the data requirements for plant protection products:
"A mixture is classified as Category 1 when the sum of the concentrations of Category 1 ingredients is ≥ 10 % and the mixture has a kinematic viscosity ≤ 20,5 mm2/s, measured at 40 °C.".

Materials and Methods

CHR/H/FETEC-PART B 110 EC contains ingredient classified as Asp. Tox. 1, H304 at concentration higher than 10 % and has a kinematic viscosity 19.77 mm^2/s at 40 ºC.

Conclusions
The mixture meets the criteria that classify it as Asp. Tox. 1, H304. Therefore the formulation is classified as **Asp. Tox. 1, H304**.

Appendix 3 Exposure calculations

A 3.1 Operator exposure calculations (KCP 7.2.1.1)

A 3.1.1 Calculations for Fenoxaprop-P-ethyl using EFSA Model ver. 30.03.2015.

Operator exposure for outdoor spray applications

Application rate of active substance	0.077	kg a.s./ha	*i_AppRate*
Assumed area treated	50	ha/day	*d_AreaTreated*
Amount of active substance applied	3.85	kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	25.00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	70.00%		*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		

	Exposure values	µg exposure/day mixed and loaded 75th centile	95th centile	Reference	Comment
Mixing and loading	Hands	13711	50839	AOEM	
	Body	9202	106554	AOEM	
	Head	200	1096	AOEM	
	Protected hands (gloves)	83	763	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	79	563	AOEM	
	Protected head (hood and face shield)	3	62	AOEM	
	Inhalation	6	30	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 75th centile	95th centile	Reference	Comment
Application	Hands	571	6151	AOEM	
	Body	319	1646	AOEM	
	Head	15	46	AOEM	
	Protected hands (gloves)	88	3900	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	9	21	AOEM	
	Inhalation	2	6	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	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)	6.4194435	0.3935764	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.1069907	0.0065596	
% of RVNAS	764.22%	46.85%	

A 3.1.2 Calculations for Fenoxaprop-P-ethyl with combination of tribenuron-methyl or fluroxypyr using EFSA Model ver. 30.03.2015.

Operator exposure for outdoor spray applications

Application rate of active substance	0.055 kg a.s./ha		*i_AppRate*
Assumed area treated	50 ha/day		*d_AreaTreated*
Amount of active substance applied	2.75 kg a.s./day		*i_AmoutAS*
Dermal absorption of the product	25.00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	70.00%		*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		

	Exposure values	µg exposure/day mixed and loaded 75th centile	95th centile	Reference	Comment
Mixing and loading	Hands	10582	39122	AOEM	
	Body	7264	96631	AOEM	
	Head	143	783	AOEM	
	Protected hands (gloves)	67	545	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	58	402	AOEM	
	Protected head (hood and face shield)	2	44	AOEM	
	Inhalation	5	29	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

	Exposure values	µg exposure/day applied 75th centile	95th centile	Reference	Comment
Application	Hands	408	4808	AOEM	
	Body	228	1176	AOEM	
	Head	11	33	AOEM	
	Protected hands (gloves)	73	3750	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	6	15	AOEM	
	Inhalation	2	5	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	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)	**4.9565196**	**0.2921565**	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	**0.0826087**	**0.0048693**	
% of RVNAS	**590.06%**	**34.78%**	

A 3.1.3 Calculations for tribenuron-methyl using EFSA Model ver. 30.03.2015.

Operator exposure for outdoor spray applications

Application rate of active substance	0.0125	kg a.s./ha	*i_AppRate*
Assumed area treated	50	ha/day	*d_AreaTreated*
Amount of active substance applied	0.625	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	Wettable granules, soluble granules		
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 75th centile	95th centile	Reference	Comment
Hands	913	4336	AOEM	
Body	888	14019	AOEM	
Head	4	56	AOEM	
Protected hands (gloves)	12	20	AOEM	
Protected body (workwear or protective garment and sturdy footwear)	12	39	AOEM	
Protected head (hood and face shield)	0	3	AOEM	
Inhalation	32	257	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 75th centile	95th centile	Reference	Comment
Hands	93	1624	AOEM	
Body	52	267	AOEM	
Head	2	7	AOEM	
Protected hands (gloves)	33	3155	AOEM	
Protected body (workwear or protective garment and sturdy footwear)	1	3	AOEM	
Inhalation	1	2	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)	0.2872358	0.2872358	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0047873	0.0047873	
% of RVNAS	9.57%	9.57%	

A 3.1.4 Calculations for fluroxypyr using EFSA Model ver. 30.03.2015.

Operator exposure for outdoor spray applications

Application rate of active substance	0.08	kg a.s./ha	*i_AppRate*
Assumed area treated	50	ha/day	*d_AreaTreated*
Amount of active substance applied	4	kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	25.00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	70.00%		*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		

	Exposure values	µg exposure/day mixed and loaded 75th centile	95th centile	Reference	Comment
Mixing and loading	Hands	14120	52375	AOEM	
	Body	9452	107744	AOEM	
	Head	208	1138	AOEM	
	Protected hands (gloves)	85	792	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	81	585	AOEM	
	Protected head (hood and face shield)	3	64	AOEM	
	Inhalation	6	30	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	593	6326	AOEM	
	Body	332	1710	AOEM	
	Head	16	47	AOEM	
	Protected hands (gloves)	90	3918	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	9	22	AOEM	
	Inhalation	2	6	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)	6.6111831	6.6111831
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.1101864	0.1101864
% of RVNAS	13.77%	13.77%

A 3.2 Worker exposure calculations (KCP 7.2.3.1)

A 3.2.1 Calculations for Fenoxaprop-P-ethyl using EFSA Model ver. 30.03.2015.

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	0.077	kg a.s./ha	*i_AppRate*
Number of applications	1		*i_AppNo*
Interval between multiple applications	365	days	*i_AppInt*
Half-life of active substance	30	days	*d_HalflifeAS*
Multiple application factor	1.0		*d_MAF*
Dermal absorption of the product	25.00%		*i_AbsorpProduct*
Dermal absorption of the in-use dilution	70.00%		*i_AbsorpInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.231	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)	4.0425000	0.4527600	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0673750	0.0075460		
% of RVNAS	481.25%	53.90%		

A 3.2.2 Calculations for Fenoxaprop-P-ethyl with combination of tribenuron-methyl or fluroxypyr using EFSA Model ver. 30.03.2015.

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	0.055	kg a.s./ha	*i_AppRate*
Number of applications	1		*i_AppNo*
Interval between multiple applications	365	days	*i_AppInt*
Half-life of active substance	30	days	*d_HalflifeAS*
Multiple application factor	1.0		*d_MAF*
Dermal absorption of the product	25.00%		*i_AbsorpProduct*
Dermal absorption of the in-use dilution	70.00%		*i_AbsorpInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.165	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)	2.8875000	0.3234000	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0481250	0.0053900		
% of RVNAS	343.75%	38.50%		

A 3.2.3 Calculations for tribenuron-methyl using EFSA Model ver. 30.03.2015.

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	0.0125	kg a.s./ha	*i_AppRate*
Number of applications	1		*i_AppNo*
Interval between multiple applications	365	days	*i_AppInt*
Half-life of active substance	30	days	*d_HalflifeAS*
Multiple application factor	1.0		*d_MAF*
Dermal absorption of the product	10.00%		*i_AbsorpProduct*
Dermal absorption of the in-use dilution	50.00%		*i_Absorpinuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.0375	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

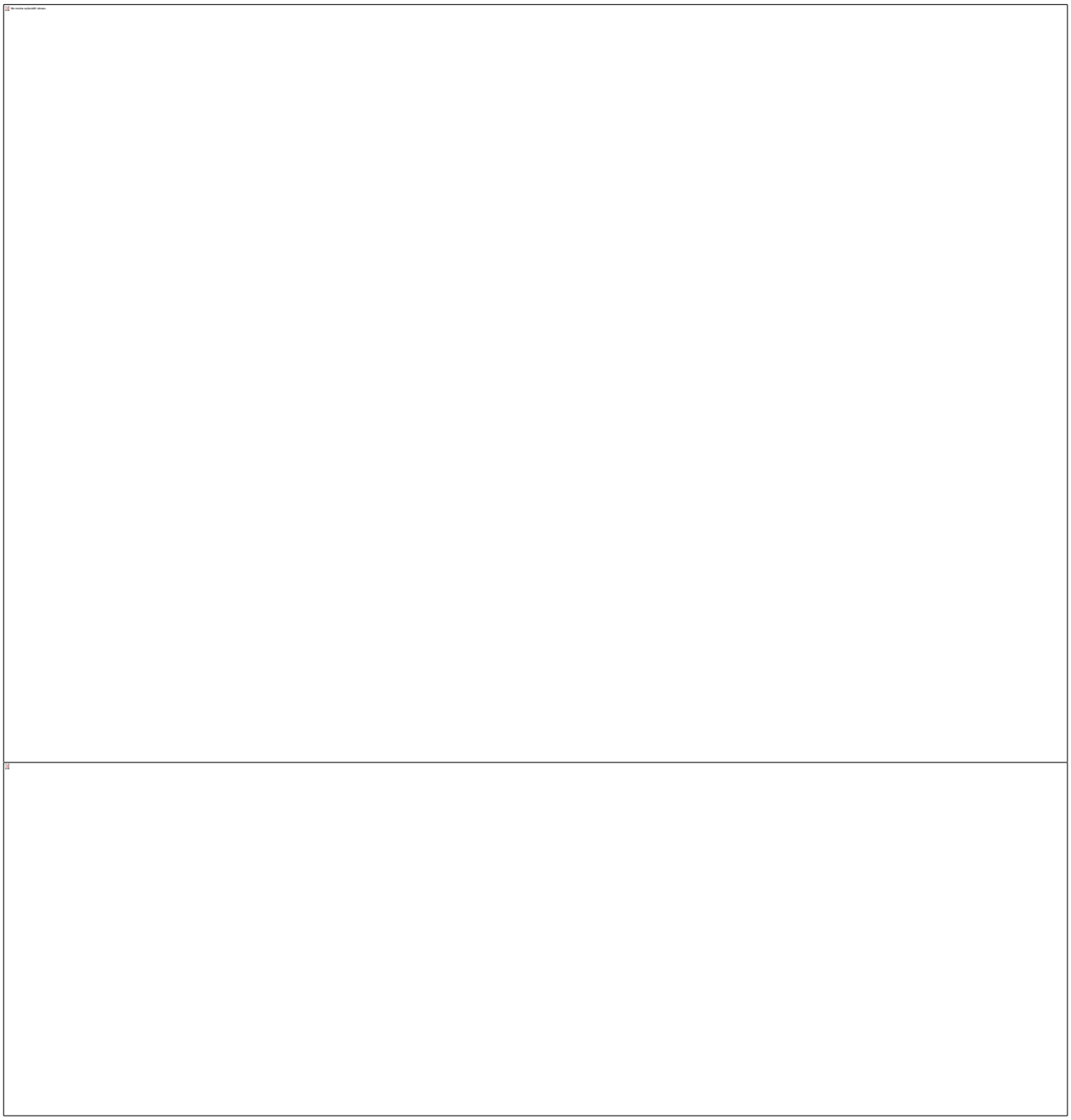
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	0.4687500	0.0525000	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0078125	0.0008750		
% of RVNAS	15.63%	1.75%		

A 3.2.4 Calculations for fluroxypyr using EFSA Model ver. 30.03.2015.

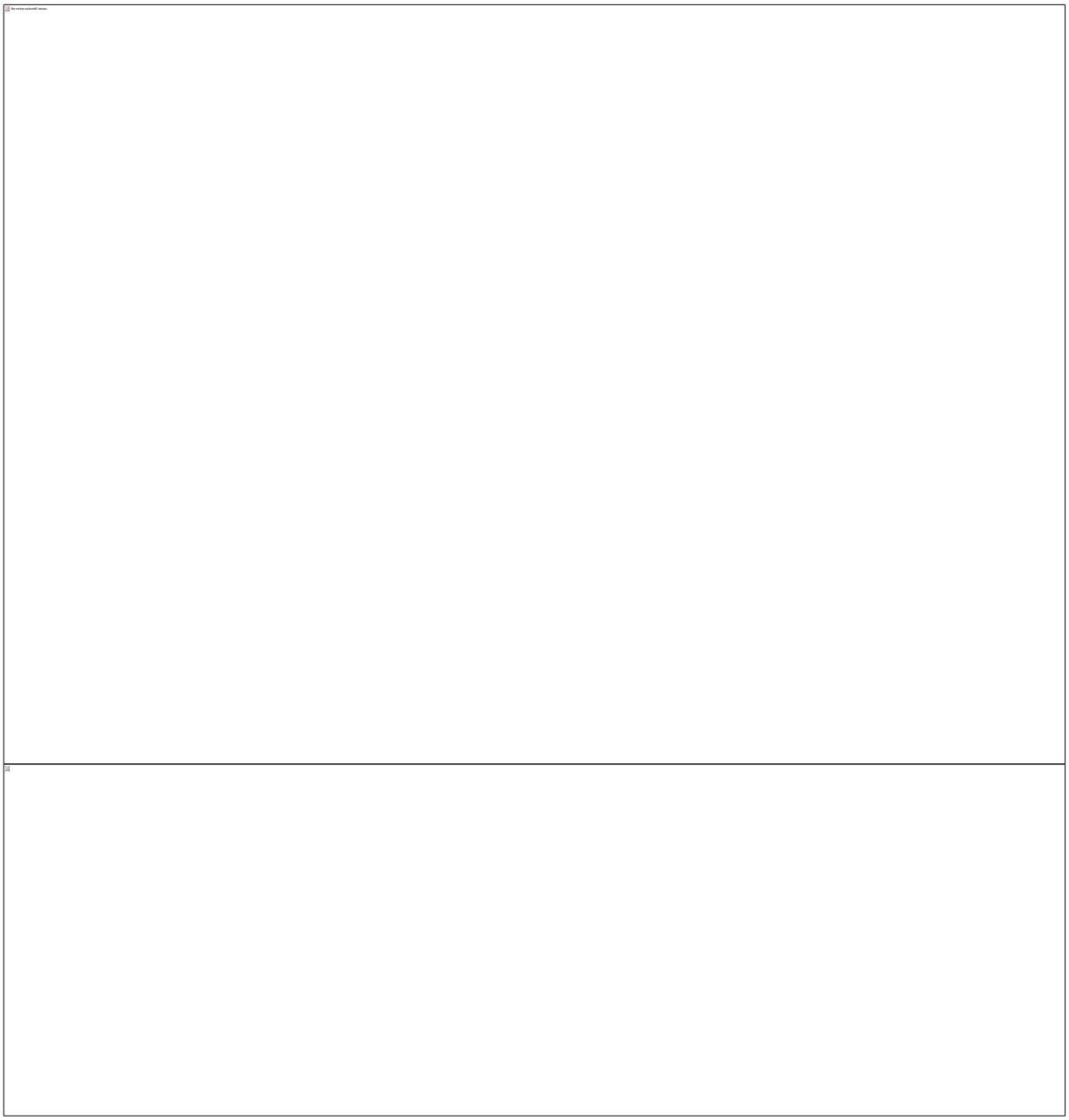
A 3.3 Bystander and resident exposure calculations (KCP 7.2.2.1)

A 3.3.1 Calculations for Fenoxaprop-P-ethyl using EFSA Model ver. 30.03.2015.

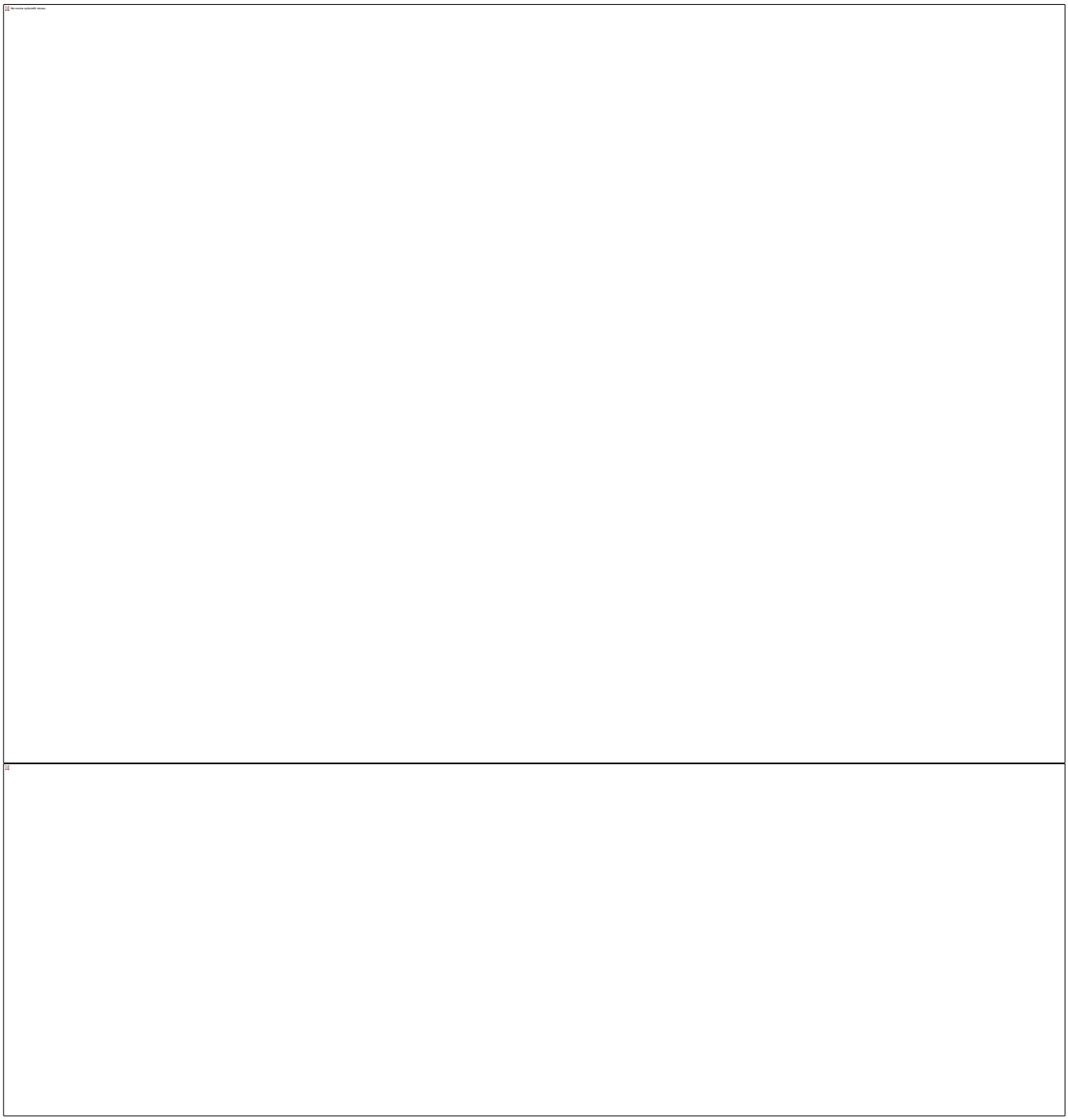
A 3.3.2 Calculations for Fenoxaprop-P-ethyl with combination of tribenuron-methyl or fluroxypyr using EFSA Model ver. 30.03.2015.



A 3.3.3 Calculations for tribenuron-methyl using EFSA Model ver. 30.03.2015.



A 3.3.4 Calculations for fluroxypyr using EFSA Model ver. 30.03.2015.



A 3.4 Combined exposure calculations

Please refer to point 6.6.6.1. and 6.6.6.2.

Appendix 4 Detailed evaluation of exposure and/or DFR studies relied upon (KCP 7.2, KCP 7.2.1.1, KCP 7.2.2.1, KCP 7.2.3.1)

Not required.