FINAL REGISTRATION REPORT

Part B

Section 9

Ecotoxicology

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(s):

Fenoxaprop-P-ethyl, 110 g/L

Central Zone

Zonal Rapporteur Member State: POLAND

CORE ASSESSMENT

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
10/2023	Applicant update
11/2023	zRMS evaluation of dRR
March 2024	Final version prepared by zRMS after Commenting period

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

9 Ecotoxicology (KCP 10)

9.1 Critical GAP and overall conclusions

Table 9.1-1: Table of critical GAPs

1	2	3	4	5	6	7	8	9	15	11	12	13	14	15							
Use-No. (e)	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha (f)	ZRMs Conclusion						
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			BIRDS	MAMMALS	AQUATIC OR	BEES	NTA	SOIL ORGANISMS	NTP
Zonal uses (field or outdoor uses, certain types of protected crops)																					
1	PL	Winter wheat (TRZAW), Winter triticale (TTLWI) Winter barley (HORVW)	F	monocotyledonous weeds	Spray, medium sprayer	spring BBCH 20-31	a)1 b)1	n/a	a) 0.7 l/ha b) 0.7 l/ha	a) 0.077 kg a.s./ha b) 0.077 kg a.s./ha	200-400	n/a									
2	PL	Spring wheat (TRZAS), Spring barley (HORVS)	F	monocotyledonous weeds	Spray, medium sprayer	spring BBCH 20-31	a)1 b)1	n/a	a) 0.7 l/ha b) 0.7 l/ha	a) 0.077 kg a.s./ha b) 0.077 kg a.s./ha	200-400	n/a									
3	PL	Winter wheat (TRZAW), Winter triticale (TTLWI) Winter barley (HORVW)	F	monocotyledonous and dicotyledonous weeds	Spray, medium sprayer	spring BBCH 20-31	a)1 b)1	n/a	a) 0.5 l/ha +25 g/ha Tristar 50 SG/Trimax 50 SG/Triben Super 50 SG b) 0.5 l/ha +25 g/ha Tristar 50 SG/Trimax 50 SG/Triben	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 +	200-400	n/a									

1	2	3	4	5	6	7	8	9	15	11	12	13	14	15							
Use-No. (e)	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha (f)	ZRMs Conclusion						
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			BIRDS	MAMMALS	AQUATIC OR	BEES	NTA	SOIL ORGANISMS	NTP
Zonal uses (field or outdoor uses, certain types of protected crops)																					
									Super 50 SG	0.0125 kg a.s/ha Tristar 50 SG/Trimax 50 SG/Triben Super 50 SG											
4	PL	Spring wheat (TRZAS), Spring barley (HORVS)	F	monocotyledonous and dicotyledonous weeds	Spray, medium sprayer	spring BBCH 20-31	a)1 b)1	n/a	a) 0.5 l/ha +25 g/ha Tristar 50 SG/Trimax 50 SG/Triben Super 50 SG b) 0.5 l/ha +25 g/ha Tristar 50 SG/Trimax 50 SG/Triben Super 50 SG	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										
5	PL	Winter wheat (TRZAW), Winter triticale (TTLWI) Winter barley (HORVW)	F	monocotyledonous and dicotyledonous weeds	Spray, medium sprayer	spring BBCH 20-31	a)1 b)1	n/a	a) 0.5 l/ha + 0.4 l/ha Galaper 200 EC/ Fluroherb 200 EC/ Herbistar 200 EC b) 0.5 l/ha +	a) 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										

1	2	3	4	5	6	7	8	9	15	11	12	13	14	15							
Use-No. (e)	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha (f)	ZRMs Conclusion						
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			BIRDS	MAMMALS	AQUATIC OR	BEES	NTA	SOIL ORGANISMS	NTP
Zonal uses (field or outdoor uses, certain types of protected crops)																					
									80.4 l/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											
6	PL	Spring wheat (TRZAS), Spring barley (HORVS)	F	monocotyledonous and dicotyledonous weeds	Spray, medium sprayer	spring BBCH 20-31	a)1 b)1	n/a	a) 0.5 l/ha + 0.4 l/ha Galaper 200 EC/ Fluroherb 200 EC/ Herbistar 200 EC b) 0.5 l/ha + 0.4 l/ha Galaper 200 EC/ Fluroherb 200 EC/ Herbistar 200 EC	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									
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)																					

1	2	3	4	5	6	7	8	9	15	11	12	13	14	15							
Use-No. (e)	**Member state(s)**	**Crop and/ or situation** (crop destination / purpose of crop)	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha (f)	ZRMs Conclusion						
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			BIRDS	MAMMALS	AQUATIC OR	BEES	NTA	SOIL ORGANISMS	NTP
Zonal uses (field or outdoor uses, certain types of protected crops)																					
7																					
8																					
Minor uses according to Article 51 (zonal uses)																					
9																					
10																					
Minor uses according to Article 51 (interzonal uses)																					
11																					
12																					

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.

* 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

Explanation for column 15 – 21 “Conclusion”

A	Acceptable, Safe use

R	Further refinement and/or risk mitigation measures required
C	To be confirmed by cMS
N	No safe use

Remarks table:

(1) Numeration necessary to allow references
(2) Use official codes/nomenclatures of EU
(3) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(4) 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
(5) Scientific names and EPPO-Codes of target pests/diseases/ weeds or when relevant the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named
(6) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(7) Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(8) The maximum number of application possible under practical conditions of use must be provided
(9) Minimum interval (in days) between applications of the same product.
(10) For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products
(11) The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
(12) If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
(13) PHI - minimum pre-harvest interval
(14) Remarks may include: Extent of use/economic importance/restrictions

9.1.1 Overall conclusions

9.1.1.1 Effects on birds (KCP 10.1.1), Effects on terrestrial vertebrates other than birds (KCP 10.1.2), Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

Overall, acceptable acute and reproductive risk to birds and mammals may be concluded for application of CHR/H/FETEC-PART B 110 EC to cereals according to the intended uses.

9.1.1.2 Effects on aquatic organisms (KCP 10.2)

Overall, acceptable risk to aquatic organisms may be concluded for application of CHR/H/FETEC-PART B 110 EC to cereals according to the intended uses.

9.1.1.3 Effects on bees (KCP 10.3.1)

Overall, acceptable acute and reproductive risk to bees may be concluded for application of CHR/H/FETEC-PART B 110 EC to cereals according to the intended uses.

9.1.1.4 Effects on arthropods other than bees (KCP 10.3.2)

Overall, acceptable acute and reproductive risk to arthropods other than bees may be concluded for application of CHR/H/FETEC-PART B 110 EC to cereals according to the intended uses.

9.1.1.5 Effects on non-target soil meso- and macrofauna (KCP 10.4), Effects on soil microbial activity (KCP 10.5)

Overall, acceptable acute and reproductive risk to earthworms and other non-target soil organisms (meso- and macrofauna) may be concluded for application of CHR/H/FETEC-PART B 110 EC to cereals according to the intended uses.

9.1.1.6 Effects on non-target terrestrial plants (KCP 10.6)

Based on the predicted rates of CHR/H/FETEC-PART B 110 EC in off-field areas, the TER values describing the risk for non-target plants following exposure to CHR/H/FETEC-PART B 110 EC according to the GAP of the formulation CHR/H/FETEC-PART B 110 EC achieve the acceptability criteria TER ≥ 5 with no need for risk mitigation measures.

9.1.1.7 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)

Not required.

9.1.2 Grouping of intended uses for risk assessment

The following table documents the grouping of the intended uses to support application of the risk envelope approach (according to SANCO/11244/2011).

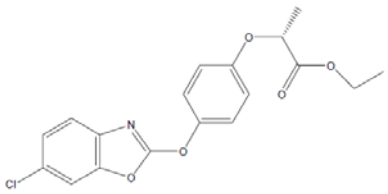
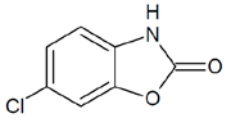
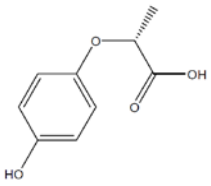
Table 9.1-2: Critical use pattern of CHR/H/FETEC-PART B 110 EC grouped according to crop, application rate, number of applications, timing criterion

Grouping according to criterion			
Group	**Intended uses**	**relevant use parameters for grouping**	**relevant parameter or value for sorting**
1	Winter cereals BBCH 20-31 0.7 l [product]/ha	crop, application rate, number of applications, timing,	crop, application rate, number of applications, timing,
2	Spring cereals BBCH 20-31 0.7 l [product]/ha	crop, application rate, number of applications, timing,	crop, application rate, number of applications, timing,

9.1.3 Consideration of metabolites

A list of metabolites found in environmental compartments is provided below. The need for conducting a metabolite-specific risk assessment in the context of the evaluation of CHR/H/FETEC-PART B 110 EC is indicated in the table.

Table 9.1-3 Metabolites of Fenoxaprop-P-ethyl

Metabolite	Molar mass	Chemical structure	Maximum observed occurence in compartements	Exposue assessment required due to
Fenoxaprop-P (AE F088406)	333.74		Water and sediment 97.2 %	PEC soil, PECgw, PECsw/sed
Chlorobenzoxazolone (AE F05014)	169.57		Soil: 19.1% Water and Sediment: 8%	PEC_{gw}, PEC_{soil}, $PEC_{sw/sed}$
HOPP-acid (AE F096918)	182.19		Water and Sediment: 26.3%	$PEC_{sw/sed}$

9.2 Effects on birds (KCP 10.1.1)

zRMS Comments:

The toxicity data for acute and long-term risk were agreed at the EU level.
For acute risk assessment, the short-term dietary LDD_{50} = 401 mg/kg bw/d should be taken into account.
The proposed use pattern of formulation was taken into consideration.

The acute risk was re-calculated by the evaluator.

Intended use	**Cereals**
Active substance/product	Fenoxapop-P-ethyl
Application rate (g/ha)	1 ×77 g a.s./ha
Acute toxicity (mg/kg bw)	401
TER criterion	10

Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening step	Small omnivorous bird	158.8	1	12.23	32.8

Fenoxaprop-P. The screening step assessment of the acute and long-term risk for birds, respectively, confirmed an acceptable risk for formulation proposed use pattern.

The risk for birds via drinking water is acceptable.
The risk for earthworm-eating and fish-eating birds is also acceptable.

The risk to birds following application of Fenoxinn Max 110 EC/Herbos Max 110 EC in accordance with the proposed use is acceptable.

9.2.1 Toxicity data

Avian toxicity studies have been carried out with fenoxaprop-P-ethyl and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.
Effects on birds of CHR/H/FETEC-PART B 110 EC were not evaluated as part of the EU assessment of fenoxaprop-P-ethyl. However, the provision of further data on the CHR/H/FETEC-PART B 110 EC is not considered essential, because studies from Annex I inclusion can be used.
The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process. Justifications are provided below.

Table 9.2-1: Endpoints and effect values relevant for the risk assessment for birds

Species	Substance	Exposure System	Results	Reference
Japanese Quail	Fenoxaprop-P-ethyl	Acute	LD_{50} ~ 2000 mg/kg bw	EFSA Scientific Report (2007) 121, 1-76
Japanese Quail	Fenoxaprop-P-ethyl	Short-term	LDD_{50} > 401 mg/kg bw/d	EFSA Scientific Report (2007) 121, 1-76
Bobwhite Quail	Fenoxaprop-P-ethyl	Long-term	NOEL = 30.8 mg/kg bw/d (reproduction / offspring effects on xxx)	EFSA Scientific Report (2007) 121, 1-76

9.2.2 Risk assessment for spray applications

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).

Birds and mammals risk assessment were performed using worst case scenario application in winter and spring cereals 1 x 77 g a.s./ha per season which is the risk envelope for other uses of CHR/H/FETEC-PART B 110 EC according to the GAP presented in table 9.1.-1.

9.2.2.1 First-tier assessment (screening/generic focal species)

The results of the acute and reproductive first-tier risk assessments are summarised in the following tables.

Table 9.2-2: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of CHR/H/FETEC-PART B 110 EC in cereals

Intended use	**Cereals**				
Active substance/product	Fenoxapop-P-ethyl				
Application rate (g/ha)	1 ×77 g a.s./ha				
~~**Acute toxicity (mg/kg bw)**~~	~~2000~~				
~~**TER criterion**~~	~~10~~				
~~**Crop scenario Growth stage**~~	~~**Indicator/generic focal species**~~	~~**SV_{90}**~~	~~**MAF_{90}**~~	~~**DDD_{90} (mg/kg bw/d)**~~	~~**TER_a**~~

~~Screening step~~	~~Small omnivorous bird~~	~~158.8~~	~~1~~	~~12.23~~	~~163.6~~
Reprod. toxicity (mg/kg bw/d)	30.8				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Screening step	Small omnivorous bird	64.8	0.53	4.99	11.6

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

9.2.2.2 Higher-tier risk assessment

Not required – all of TER values exceed triggered value 5.

9.2.2.3 Drinking water exposure

When necessary, the assessment of the risk for birds due to uptake of contaminated drinking water is conducted for a small granivorous bird with a body weight of 15.3 g (*Carduelis cannabina*) and a drinking water uptake rate of 0.46 L/kg bw/d (*cf.* Appendix K of EFSA/2009/1438).

Leaf scenario

Since CHR/H/FETEC-PART B 110 EC is not a product for spray applications / not intended to be applied on leafy vegetables forming heads or crop plants with comparable water collecting structures at principal growth stage 4 or later, the leaf scenario does not have to be considered.

Puddle scenario

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/kg).

With a K(f)oc of 6000, fenoxaprop-P-ethyl belongs to the group of less/more sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group also covers the risk for birds from all other intended uses in spring cereals and winter cereals (see 9.1.2).

Effective application rate (g/ha)	=	77		
Acute toxicity (mg/kg bw)	=	2000	quotient =	0.0385
Reprod. toxicity (mg/kg bw/d)	=	30.8	quotient =	2.5

PEC_{puddle}: concentration in puddles; DW: drinking water; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

9.2.2.4 Effects of secondary poisoning

The log P_{ow} of fenoxaprop-P-ethyl amounts to 4.58 and thus exceeds the trigger value of 3. A risk assessment for effects due to secondary poisoning is required.

Risk assessment for earthworm-eating birds via secondary poisoning

According to EFSA/2009/1438, the risk for vermivorous birds is assessed for a bird of 100 g body weight with a daily food consumption of 104.6 g. Bioaccumulation in earthworms is estimated based on measured/predicted concentrations in soil/porewater / is based on experimental data.
To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group also covers the risk for birds from all other intended uses in spring and winter cereals (see 9.1.2).

Table 9.2-3: Assessment of the risk for earthworm-eating birds due to exposure to fenoxaprop-P-ethyl via bioaccumulation in earthworms (secondary poisoning) for the intended use in cereals.

Parameter	Fenoxaprop-P-ethyl	comments
PEC_{soil} (twa = 21 d) (mg/kg soil)	0.0033	
log P_{ow} / P_{ow}	4.58 / 38018.93	
Koc	6000	Mean (n = 1)
foc	0.02	Default
BCF_{worm}	3.81	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw})$ $= (0.84 + 0.012 \times P_{ow}) / foc \times Koc$
PEC_{worm}	0.01257	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	0.0132	$DDD = PEC_{worm} \times 1.05$
NOEL (mg/kg bw/d)	30.8	
TER_{lt}	2333.33 (>5)	

TER values shown in bold fall below the relevant trigger.

According to EFSA/2009/1438, the risk for piscivorous birds is assessed for a bird of 1000 g body weight with a daily food consumption of 159 g. Bioaccumulation in fish is estimated based on predicted concentrations in surface.

Table 9.2-4: Assessment of the risk for fish-eating birds due to exposure to fenoxaprop-P-ethyl via bioaccumulation in fish (secondary poisoning) for the intended use in cereals

Parameter	Fenoxaprop-P-ethyl	comments
PEC_{sw} (twa = 21 d) (mg/L)	0.0002	step 2

Parameter	Fenoxaprop-P-ethyl	comments
BCF_{fish}	338	
BMF	-	biomagnification factor (relevant for BCF ≥ 2000)
PEC_{fish}	0.0676	$PEC_{fish} = PEC_{water} \times BCF_{fish}$
Daily dietary dose (mg/kg bw/d)	0.0107	$DDD = PEC_{fish} \times 0.159$
NOEL (mg/kg bw/d)	30.8	
TER_{lt}	2878.5 (>5)	

TER values shown in bold fall below the relevant trigger.

9.2.2.5 Biomagnification in terrestrial food chains

Not relevant.

9.2.3 Risk assessment for baits, pellets, granules, prills or treated seed

Not relevant.

9.2.4 Overall conclusions

Overall, acceptable acute and reproductive risk to birds may be concluded for application of CHR/H/FETEC 110 EC – PART B to cereals according to the intended uses.

CHR/H/FETEC 110 EC – PART B presents no unacceptable risk to birds resulting from exposure via drinking water. Since the log Pow value of fenoxaprop-P-ethyl is above the trigger of 3, the evaluation of the risk of secondary poisoning was necessary. Nevertheless, TER values was above relevant trigger value 5.

9.3 Effects on terrestrial vertebrates other than birds (KCP 10.1.2)

zRMS Comments:	The used endpoints for acute and long-term risk were agreed at the EU level. The proposed use was taken into consideration. **Fenoxaprop-P**. The screening step and first tier assessment of the acute and long-term risk for mammals respectively, confirmed an acceptable risk for formulation proposed use. The NOAEL of 10 mg/kg bw/d was used in long-term risk assessment; this value was agreed at the EU and zonal level. The risk for mammals via drinking water is acceptable.

	The risk for earthworm-eating and fish-eating mammals is also acceptable. The risk to mammals following application of Fenoxinn Max 110 EC/Herbos Max 110 EC in accordance with the proposed use is acceptable.

9.3.1 Toxicity data

Mammalian toxicity studies have been carried out with fenoxaprop-P-ethyl and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

However, the provision of further data on the CHR/H/FETEC-PART B 110 EC is not considered essential, because the selection of studies and endpoints for the risk assessment is in line with / deviates from the results of the EU review process. Justifications are provided below.

Table 9.3-1: Endpoints and effect values relevant for the risk assessment for mammals

Species	Substance	Exposure System	Results	Reference
Rat	Fenoxaprop-P-ethyl	Acute oral	LD_{50} > 3150 mg/kg bw	EFSA Scientific Report (2007) 121, 1-76
Rat	Fenoxaprop-P-ethyl	Short term	NOAEL = 2 mg/kg bw/d	EFSA Scientific Report (2007) 121, 1-76
Rat	Fenoxaprop-P-ethyl	Long term	NOAEL = 1.6 mg/kg bw/d	EFSA Scientific Report (2007) 121, 1-76

9.3.1.1 Justification for new endpoints

Not required.

9.3.2 Risk assessment for spray applications

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Mammals and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).
To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group cereals also covers the risk for mammals from all other intended uses in groups.

9.3.2.1 First-tier assessment (screening/generic focal species)

The results of the acute and reproductive screening and first-tier risk assessments are summarised in the following tables.

Table 9.3-2: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of CHR/H/FETEC-PART B 110 EC in cereals

Intended use **Active substance/product** **Application rate (g/ha)**	Cereals Fenoxapop-P-ethyl 1 ×77 g a.s./ha				
Acute toxicity (mg/kg bw) **TER criterion**	3150 10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening step	Small herbivorous mammal	118.4	1	9.12	345.5
Reprod. toxicity (mg/kg bw/d) **TER criterion**	10 5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Screening step	Small herbivorous mammal	48.3	0.53	1.97	5.07

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

9.3.2.2 Higher-tier risk assessment

No further risk refinement is required.

9.3.2.3 Drinking water exposure

When necessary, the assessment of the risk for mammals due to uptake of contaminated drinking water is conducted for a small omnivorous mammal with a body weight of 21.7 g (*Apodemus sylvaticus*) and a drinking water uptake rate of 0.24 L/kg bw/d (*cf.* Appendix K of EFSA/2009/1438).

Puddle scenario

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/kg).

With a K(f)oc of 6000, fenoxaprop-P-ethyl belongs to the group of more sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group cereals also covers the risk for mammals from all other intended uses in groups.

Effective application rate (g/ha)	=	77		
Acute toxicity (mg/kg bw)	=	3150	quotient	= 0.0244
Reprod. toxicity (mg/kg bw/d)	=	10	quotient	= 7.7

9.3.2.4 Effects of secondary poisoning

The log P_{ow} of fenoxaprop-P-ethyl amounts to 4.58 and thus exceeds the trigger value of 3. A risk assessment for effects due to secondary poisoning is required.

Risk assessment for earthworm-eating mammals via secondary poisoning

According to EFSA/2009/1438, the risk for vermivorous mammals is assessed for a small mammal of 10 g body weight with a daily food consumption of 12.8 g. Bioaccumulation in earthworms is estimated based on measured/predicted concentrations in soil/porewater / is based on experimental data.
To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group cereals also covers the risk for mammals from all other intended uses in groups.

Table 9.3-3: Assessment of the risk for earthworm-eating mammals due to exposure to fenoxaprop-P-ethyl via bioaccumulation in earthworms (secondary poisoning) for the intended use in cereals.

Parameter	fenoxaprop-P-ethyl	comments
PEC_{soil} (twa = 21 d) (mg/kg soil)	0.0033	
log P_{ow} / P_{ow}	4.58 / 38018.93	
Koc	6000	Mean (n = 1)
foc	0.02	Default
BCF_{worm}	3.81	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw})$ $= (0.84 + 0.012 \times P_{ow}) / foc \times Koc$
PEC_{worm}	0.01257	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	0.0161	$DDD = PEC_{worm} \times 1.28$
NOEL (mg/kg bw/d)	10	
TER_{lt}	621.12 (>5)	

TER values shown in bold fall below the relevant trigger.

Risk assessment for fish-eating mammals via secondary poisoning

According to EFSA/2009/1438, the risk for piscivorous mammals is assessed for a mammal of 3000 g body weight with a daily food consumption of 425 g. Bioaccumulation in fish is estimated based on predicted concentrations in surface water / is based on the regulatory acceptable concentration for aquatic organisms as a limit value for admissible concentrations of fenoxaprop-P-ethyl in water.

Table 9.3-4: Assessment of the risk for fish-eating mammals due to exposure to fenoxaprop-P-ethyl via bioaccumulation in fish (secondary poisoning) for the intended use in cereals

Parameter	**Fenoxaprop-P-ethyl**	**comments**
PEC_{sw} (twa = 21 d) (mg/L)	0.0002	Step 1
BCF_{fish}	338	
BMF	-	biomagnification factor (relevant for BCF ≥ 2000)
PEC_{fish}	0.0676	$PEC_{fish} = PEC_{water} \times BCF_{fish}$
Daily dietary dose (mg/kg bw/d)	0.0096	$DDD = PEC_{fish} \times 0.142$
NOEL (mg/kg bw/d)	10	
TER_{lt}	1041.66 (>5)	

TER values shown in bold fall below the relevant trigger.

9.3.2.5 Biomagnification in terrestrial food chains

Not relevant.

9.3.3 Risk assessment for baits, pellets, granules, prills or treated seed

Not relevant.

9.3.4 Overall conclusions

Overall, acceptable acute and reproductive risk to mammals may be concluded for application of CHR/H/FETEC 110 EC – PART B to cereals according to the intended uses.

CHR/H/FETEC 110 EC – PART B presents no unacceptable risk to mammals resulting from exposure via drinking water. Since the log Pow value of fenoxaprop-P-ethyl is above the trigger of 3, the evaluation of the risk of secondary poisoning was necessary. Nevertheless, TER values was above relevant trigger value 5.

9.4 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

Not required.

9.5 Effects on aquatic organisms (KCP 10.2)

zRMS Comments:	New studies were submitted and evaluated in Appendix 2. New endpoints for formulation Fenoxinn Max 110 EC/Herbos Max 110 EC were used in the risk assessment for aquatic organisms. The application pattern proposed in GAP table was taken into consideration: **Fenoxaprop-P**. The endpoints agreed at the EU level were taken into consideration in risk assessment. No mitigation measures were proposed as PECsw values assessed in Step 3 (please refer to Part B8) were sufficient. **Metabolites of Fenoxaprop-P.** The metabolites Chlorobenzoxazolone and HOPP-acid were taken into consideration. The submitted risk assessment is based on Step 1 and Step 2 PECsw i PECsed values was sufficient. The risk assessment for metabolites was accepted. The metabolites pose an acceptable risk. **Formulation Fenoxinn Max 110 EC/Herbos Max 110.** The submitted risk assessment for formulation was accepted. No additional mitigation measure is required.

9.5.1 Toxicity data

Studies on the toxicity to aquatic organisms have been carried out with fenoxaprop-P-ethyl and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on aquatic organisms of CHR/H/FETEC-PART B 110 EC were not evaluated as part of the EU assessment of fenoxaprop-P-ethyl. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process. Justifications are provided below.

Table 9.5-1: Endpoints and effect values relevant for the risk assessment for aquatic organisms – Fenoxaprop-Pethyl and relevant metabolites

Species	Substance	Exposure System	Results	Reference
Lepomis macrochirus	Fenoxaprop-Pethyl	96 h	LC_{50} = 0.19 mg a.s./L $_{mm}$	EFSA Scientific Report (2007) 121, 1-76
Oncorhynchus mykiss	Fenoxaprop-Pethyl	91d	NOEC = 0.036 mg a.s./L $_{mm}$	EFSA Scientific Report (2007) 121, 1-76
Oncorhynchus mykiss	AE F088406	96h	EC_{50} >72.2	EFSA Scientific Report (2007) 121, 1-76
Oncorhynchus mykiss	AE F088406	28d	NOEC ≥ 3.2 nom	EFSA Scientific Report (2007) 121, 1-76
Oncorhynchus mykiss	AE F054014	96h	EC_{50} > 9.22mm	EFSA Scientific Report (2007) 121, 1-76
Oncorhynchus mykiss	AE F096918	96h	EC_{50} = 353 nom	EFSA Scientific Report (2007) 121, 1-76
Oncorhynchus mykiss	AE F096918	28d	EC_{50} ≥ 32 nom	EFSA Scientific Report (2007) 121, 1-76
Daphnia magna	Fenoxaprop-Pethyl	48 h, s	EC_{50} >1.06 mg a.s./L $_{mm}$	EFSA Scientific Report (2007) 121, 1-76
Daphnia magna	Fenoxaprop-Pethyl	21 d, ss	NOEC = 0.22 mg a.s./L $_{mm}$	EFSA Scientific Report (2007) 121, 1-76
Daphnia magna	AE F088406	48h	EC_{50} = 126	EFSA Scientific Report (2007) 121, 1-76
Daphnia magna	AE F088406	21d	NOEC = 1.0	EFSA Scientific Report (2007) 121, 1-76
Daphnia magna	AE F054014	48h	EC_{50} = 6.6	EFSA Scientific Report (2007) 121,

Species	Substance	Exposure System	Results	Reference
				1-76
Daphnia magna	AE F096918	48h	EC_{50} > 200	EFSA Scientific Report (2007) 121, 1-76
Daphnia magna	AE F096918	21d	NOEC = 3.2	EFSA Scientific Report (2007) 121, 1-76
Chironomus riparius	Fenoxaprop-Pethyl	28 d, spiked sediment	NOEC = 0.2 mg a.s./L $_{nom}$	EFSA Scientific Report (2007) 121, 1-76
Scenedesmus subspicatus	Fenoxaprop-Pethyl	72 h, s	E_rC_{50} = 0.66 mg a.s./L $_{mm}$ E_bC_{50} = 0.54 mg a.s./L $_{mm}$	EFSA Scientific Report (2007) 121, 1-76
Pseudokirchneriella subcapitata	AE F088406	72 h	E_bC_{50} = 35	EFSA Scientific Report (2007) 121, 1-76
Pseudokirchneriella subcapitata	AE F054014	72 h	E_bC_{50} = 8 E_rC_{50} = 9.9	EFSA Scientific Report (2007) 121, 1-76
Pseudokirchneriella subcapitata	AE F096918	72 h	E_bC_{50} = 9.6 E_rC_{50} = 53.4	EFSA Scientific Report (2007) 121, 1-76
Lemna gibba	Fenoxaprop-Pethyl	14 d, ss	$E_yC_{50} \geq 2.76$ mg a.s./L $_{mm}$	EFSA Scientific Report (2007) 121, 1-76
Higher-tier studies (micro- or mesocosm studies)				

s: static; ss: semi-static; f: flow-through; nom: based on nominal concentrations; mm: based on mean measured concentrations; im: based on initial measured concentrations

Table 9.5-2: Endpoints and effect values relevant for the risk assessment for aquatic organisms – CHR/H/FETEC-PART B 110 EC

Species	Substance	Exposure System	Results	Reference
Daphnia magna	CHR/H/FETEC-	48 h	EC_{50} = 6.328 mg/L $_{nom}$	Szlauer, S.

Species	Substance	Exposure System	Results	Reference
	PART B 110 EC			Study code: EMI/4/536/2020 S.Szlauer, Study code: EMI/5/536/2020, Amendment No.1
Raphidocelis subcapitata	CHR/H/FETEC-PART B 110 EC	72 h	E_rC_{50} = 0.826 mg/L $_{nom}$ E_yC_{50} = 0.445 mg/L $_{nom}$	Domagał, J., Study code: 0038/0111/E
Lemna gibba	CHR/H/FETEC-PART B 110 EC	7 d	E_rC_{50} = 22.89 mg/L $_{nom}$ E_yC_{50} = 11.480 mg/L $_{nom}$	Kubisiak, K. Study code: 0038/0112/E
Navicula pelliculosa	CHR/H/FETEC-PART B 110 EC	72 h	E_rC_{50} = 1.646 mg/L $_{nom}$ E_yC_{50} = 1.040 mg/L $_{nom}$	Woźniak, A. Study code: 0038/0110/E
Higher-tier studies (micro- or mesocosm studies)				

s: static; ss: semi-static; f: flow-through; nom: based on nominal concentrations; mm: based on mean measured concentrations

9.5.1.1 Justification for new endpoints

9.5.2 Risk assessment

The evaluation of the risk for aquatic and sediment-dwelling organisms was performed in accordance with the recommendations of the “Guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters in the context of Regulation (EC) No 1107/2009”, as provided by the Commission Services (SANTE-2015-00080, 15 January 2015).
The relevant global maximum FOCUS Step 1, 2 and 3 PEC_{SW} for risk assessments covering the proposed use pattern and the resulting PEC/RAC ratios are presented in the table below. In the following table, the ratios between predicted environmental concentrations in surface water bodies (PEC_{SW}, PEC_{SED}) and regulatory acceptable concentrations (RAC) for aquatic organisms are given per intended use for each FOCUS scenario and each organism group.

Table 9.5-3: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Fenoxaprop-P-ethyl for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/H/FETEC-PART B 110 EC in winter cereals.

Group		**Fish acute**	**Fish prolonged**	**Inverte b. acute**	**Inverteb. prolonge d**	**Algae**	**Sed. dwell. prolonged**	**Highe r plants**
Test species		***Lepomis macrochiru s***	***Oncorhynch us mykiss***	***Daphnia magna***	***Daphnia magna***	***Scenedesmu s subspicatus***	***Chironomu s riparius***	***Lemn a gibba***
Endpoin t (µg/L)		LC_{50} 190	NOEC 36	EC_{50} 1060	NOEC 220	E_rC_{50} 660	NOEC 200	EC50 ≥2760
AF		100	10	100	10	10	10	10
RAC (µg/L)		1.9	3.6	10.6	22	66	20	≥276
FOCUS Scenario	**PEC sw-max (µg/L)**							
Step 1								
	3.56	**1.8737**	0.9889	0.3358	0.1618	0.0539	0.1780	0.0129
Step 2								
N-Europe	0.71	0.3737	0.1972	0.0670	0.0323	0.0108	0.0355	0.0026
Step 3								
D1/ditch	0.4940	0.2600	0.1372	0.0466	0.0225	0.0075	0.0247	0.0018
D1/stream	0.4319	0.2273	0.1200	0.0407	0.0196	0.0065	0.0216	0.0016
D2/ditch	0.4903	0.2581	0.1362	0.0463	0.0223	0.0074	0.0245	0.0018
D2/stream	0.3886	0.2045	0.1079	0.0367	0.0177	0.0059	0.0194	0.0014
D3/ditch	0.4865	0.2561	0.1351	0.0459	0.0221	0.0074	0.0243	0.0018
D4/pond	0.01687	0.0089	0.0047	0.0016	0.0008	0.0003	0.0008	0.0001
D4/stream	0.4001	0.2106	0.1111	0.0377	0.0182	0.0061	0.0200	0.0014

Group		Fish acute	Fish prolonged	Inverte b. acute	Inverteb. prolonge d	Algae	Sed. dwell. prolonged	Highe r plants
D5/pond	0.0168 8	0.0089	0.0047	0.0016	0.0008	0.0003	0.0008	0.0001
D5/strea m	0.4553	0.2396	0.1265	0.0430	0.0207	0.0069	0.0228	0.0016
D6/ditch	0.4793	0.2523	0.1331	0.0452	0.0218	0.0073	0.0240	0.0017
R1/pond	0.0168 7	0.0089	0.0047	0.0016	0.0008	0.0003	0.0008	0.0001
R1/strea m	0.3208	0.1688	0.0891	0.0303	0.0146	0.0049	0.0160	0.0012
R3/strea m	0.4501	0.2369	0.1250	0.0425	0.0205	0.0068	0.0225	0.0016
R4/strea m	0.3182	0.1675	0.0884	0.0300	0.0145	0.0048	0.0159	0.0012

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

For the intended uses (winter cereals), calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for *Lepomis macrochirus* as characterised by an LC_{50} for species of 190 µg/L in connection with an assessment factor of 100) in all FOCUS Steps 1-3 scenarios. Therefore, no further assessment is necessary.

Table 9.5-4: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Fenoxaprop-P for each organism group based on FOCUS Steps 1, 2 calculations for the use of CHR/H/FETEC-PART B 110 EC in winter cereals.

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchneriella subcapitata***
Endpoint		EC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}
(µg/L)		72200	3200	126000	1000	35000
AF		100	10	100	10	10
RAC (µg/L)		722	320	1260	100	3500

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**
FOCUS Scenario	**PEC $_{sw-max}$ (µg/L)**					
Step 1						
	~~17.95~~ 32.39	~~0.0249~~ 0.04486	~~0.0561~~ 0.10122	~~0.0142~~ 0.02571	~~0.1795~~ 0.3239	~~0.0051~~ 0.00925
Step 2						
N-Europe	~~0.63~~ 2.33	~~0.0009~~ 0.00323	~~0.0020~~ 0.00728	~~0.0005~~ 0.00185	~~0.0063~~ 0.0233	~~0.0002~~ 0.00067

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

For the intended uses (winter cereals), calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for *Daphnia magna* as characterised by an NOEC for species of 1000 µg/L in connection with an assessment factor of 10) in all FOCUS Steps 1-3 scenarios. Therefore, no further assessment is necessary.

Table 9.5-5: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Chlorobenzoxazolone for each organism group based on FOCUS Steps 1, 2 calculations for the use of CHR/H/FETEC-PART B 110 EC in winter cereals.

Group		**Fish acute**	**Inverteb. acute**	**Algae**
Test species		***Oncorhynchus mykiss***	***Daphnia magna***	***Pseudokirchneriella subcapitata***
Endpoint (µg/L)		EC50 92200	EC50 6600	ErC50 9900
AF		100	100	10
RAC (µg/L)		922	66	990
FOCUS Scenario	**PEC $_{sw-max}$ (µg/L)**			
Step 1				
	2.21	0.0024	0.0335	0.0022
Step 2				
N-Europe	0.25	0.0003	0.0038	0.0003

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

For the intended uses (winter cereals), calculated PEC/RAC ratios did indicate an acceptable risk for the

most sensitive group of aquatic organisms (risk for *Daphnia magna* as characterised by an NOEC for species of 6600 µg/L in connection with an assessment factor of 100) in all FOCUS Steps 1-3 scenarios. Therefore, no further assessment is necessary.

Table 9.5-6: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for HOPP-acid for each organism group based on FOCUS Steps 1, 2 calculations for the use of CHR/H/FETEC-PART B 110 EC in winter cereals.

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchneriella subcapitata***
Endpoint (µg/L)		EC50 353000	NOEC 32000	EC50 200000	NOEC 3200	ErC50 53400
AF		100	10	100	10	10
RAC (µg/L)		35300	3200	2000	320	5340
FOCUS Scenario	**PEC $_{sw-max}$ (µg/L)**					
Step 1						
	3.37	9.5E-05	1.1E-03	1.7E-03	1.1E-02	6.3E-04
Step 2						
N-Europe	0.09	2.5E-06	2.8E-05	4.5E-05	2.8E-04	1.7E-05

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

For the intended uses (winter cereals), calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for *Daphnia magna* as characterised by an NOEC for species of 3200 µg/L in connection with an assessment factor of 10) in all FOCUS Steps 1-3 scenarios. Therefore, no further assessment is necessary.

Table 9.5-7: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Fenoxaprop-P-ethyl for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/H/FETEC 110 EC in spring cereals.

Group		**Fish acute**	**Fish prolonged**	**Inverte b. acute**	**Inverteb. prolonge d**	**Algae**	**Sed. dwell. prolonged**	**Highe r plants**
Test species		***Lepomis macrochiru s***	***Oncorhynch us mykiss***	***Daphnia magna***	***Daphnia magna***	***Scenedesmu s subspicatus***	***Chironomu s riparius***	***Lemn a gibba***
Endpoin t (µg/L)		LC_{50} 190	NOEC 36	EC_{50} 1060	NOEC 220	E_rC_{50} 660	NOEC 200	EC50 ≥2760
AF		100	10	100	10	10	10	10
RAC (µg/L)		1.9	3.6	10.6	22	66	20	276
FOCUS Scenario	**PEC sw-max (µg/L)**							
Step 1								
	3.56	1.8737	0.9889	0.3358	0.1618	0.0539	0.1780	0.0129
Step 2								
N-Europe	0.71	0.3737	0.1972	0.0670	0.0323	0.0108	0.0355	0.0026
Step 3								
D1/ditch	0.4916	0.2587	0.1366	0.0464	0.0223	0.0074	0.0246	0.0018
D1/stream	0.4038	0.2125	0.1122	0.0381	0.0184	0.0061	0.0202	0.0015
D3/ditch	0.4880	0.2568	0.1356	0.0460	0.0222	0.0074	0.0244	0.0018
D4/pond	0.01687	0.0089	0.0047	0.0016	0.0008	0.0003	0.0008	0.0001
D4/stream	0.3992	0.2101	0.1109	0.0377	0.0181	0.0060	0.0200	0.0014
D5/pond	0.01687	0.0089	0.0047	0.0016	0.0008	0.0003	0.0008	0.0001
D5/stream	0.3876	0.20	0.11	0.04	0.02	0.01	0.02	0.001

Group		**Fish acute**	**Fish prolonged**	**Inverte b. acute**	**Inverteb. prolonge d**	**Algae**	**Sed. dwell. prolonged**	**Highe r plants**
R4/strea m	0.3211	0.17	0.09	0.03	0.01	0.00	0.02	0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

For the intended uses (spring cereals), calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for *Lepomis macrochirus* as characterised by an LC_{50} for species of 190 µg/L in connection with an assessment factor of 10) in all FOCUS Steps 1-3 scenarios. Therefore, no further assessment is necessary.

Table 9.5-8: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Fenoxaprop-P for each organism group based on FOCUS Steps 1, 2 calculations for the use of CHR/H/FETEC-PART B 110 EC in spring cereals.

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchneriella subcapitata***
Endpoint		EC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}
(µg/L)		72200	3200	126000	1000	35000
AF		100	10	100	10	10
RAC (µg/L)		722	320	1260	100	3500
FOCUS Scenario	**PEC $_{sw-max}$ (µg/L)**					
Step 1						
	~~17.95~~ 32.39	~~0.0249~~ 0.04486	~~0.0561~~ 0.10122	~~0.0142~~ 0.02571	~~0.1795~~ 0.3239	~~0.0051~~ 0.00925
Step 2						
N-Europe	~~0.63~~ 2.33	~~0.0009~~ 0.00323	~~0.0020~~ 0.00728	~~0.0005~~ 0.00185	~~0.0063~~ 0.0233	~~0.0002~~ 0.00067

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

For the intended uses (spring cereals), calculated PEC/RAC ratios did indicate an acceptable risk for the

most sensitive group of aquatic organisms (risk for *Daphnia magna* as characterised by an NOEC for species of 1000 µg/L in connection with an assessment factor of 10) in all FOCUS Steps 1-3 scenarios. Therefore, no further assessment is necessary.

Table 9.5-9: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Chlorobenzoxazolone for each organism group based on FOCUS Steps 1, 2 calculations for the use of CHR/H/FETEC-PART B 110 EC in spring cereals.

Group		**Fish acute**	**Inverteb. acute**	**Algae**
Test species		***Oncorhynchus mykiss***	***Daphnia magna***	***Pseudokirchneriella subcapitata***
Endpoint (µg/L)		EC50 92200	EC50 6600	ErC50 9900
AF		100	100	10
RAC (µg/L)		922	66	990
FOCUS Scenario	**PEC $_{sw-max}$ (µg/L)**			
Step 1				
	2.21	0.0024	0.0335	0.0022
Step 2				
N-Europe	0.25	0.0003	0.0038	0.0003

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

For the intended uses (spring cereals), calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for *Daphnia magna* as characterised by an NOEC for species of 6600 µg/L in connection with an assessment factor of 100) in all FOCUS Steps 1-3 scenarios. Therefore, no further assessment is necessary.

Table 9.5-10: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for HOPP-acid for each organism group based on FOCUS Steps 1, 2 calculations for the use of CHR/H/FETEC-PART B 110 EC in spring cereals.

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchneriella subcapitata***
Endpoint (µg/L)		EC50 353000	NOEC 32000	EC50 200000	NOEC 3200	ErC50 53400

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**
AF		100	10	100	10	10
RAC (µg/L)		35300	3200	2000	320	5340
FOCUS Scenario	**PEC $_{sw-max}$ (µg/L)**					
Step 1						
	3.37	9.5E-05	1.1E-03	1.7E-03	1.1E-02	6.3E-04
Step 2						
N-Europe	0.09	2.5E-06	2.8E-05	4.5E-05	2.8E-04	1.7E-05

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

For the intended uses (spring cereals), calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for *Daphnia magna* as characterised by an NOEC for species of 3200 µg/L in connection with an assessment factor of 10) in all FOCUS Steps 1-3 scenarios. Therefore, no further assessment is necessary.

9.5.2.1 Risk assessment for formulation to aquatic organisms

Table 9.5-4: **Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolites of CHR/H/FETEC-PART B 110 EC for each organism group based on Drift Calculator SWASH MODEL ver 5.3 calculations for the use of CHR/H/FETEC-PART B 110 EC in cereals.**

Intended use	Cereals
Formulation	CHR/H/FETEC-PART B 110 EC
Application rate (g[prod]/ha)	1 x 726.6
Entry into surface water via spray drift (Drift calculator from SWASH)	
Buffer zone (m)	**PECsw [µg prod/L]**
1	4.6681
Entry into surface water via spray drift (Drift calculator from SWASH)	
Buffer zone (m)	**RAC/PEC ratio** *Daphnia magna* EC_{50} = 6328 µg/L RAC = 63.28 (AF=100)

1	0.07377
Buffer zone (m)	**RAC/PEC ratio** *Raphidocelis subcapitata* EC_{50} = 826 µg/L RAC= 82.6 (AF = 10)
1	0.05651
Buffer zone (m)	**RAC/PEC ratio** *Navicula pelliculosa* EC_{50} = 1646 µg/L RAC = 164.6 (AF = 10)
1	0.02836
Buffer zone (m)	**RAC/PEC ratio** *Lemna gibba* EC_{50} = 22 890 µg/L RAC = 2289 (AF = 10)
1	0.00204

9.5.3 Overall conclusions

Overall, acceptable risk may be concluded following intended uses of CHR/H/FETEC-PARTB 110 EC. The TER values describing the risk for aquatic organisms following exposure to CHR/H/FETEC-PARTB 110 EC according to the GAP of the formulation CHR/H/FETEC-PARTB 110 EC achieve the acceptability criteria with 1 m buffer zone.

9.6 Effects on bees (KCP 10.3.1)

zRMS Comments:	The submitted risk assessment is based on SANCO guidance (2002). The EU agreed endpoints for active substance were used in risk assessment. New studies for acute and chronic toxicity were submitted and accepted. The acute risk assessment performed in accordance with the SANCO guidance presented by the Applicant was accepted. The hazard quotients are below the trigger value, indicating that the active substance and formulation pose an acceptable acute and chronic risk to bees. Therefore, an acceptable risk to bees is expected from the application of Fenoxinn Max 110 EC/Herbos Max 110 EC in accordance with proposed use pattern.

9.6.1 Toxicity data

Studies on the toxicity to bees have been carried out with fenoxaprop-P-ethyl its relevant metabolites. Full

details of these studies are provided in the respective EU DAR and related documents.

Effects on bees of CHR/H/FETEC-PART B 110 EC were not evaluated as part of the EU assessment of Fenoxaprop-P-ethyl. New data submitted with this application are listed and summarised in Appendix 2.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process. Justifications are provided below.

Table 9.6-1: Endpoints and effect values relevant for the risk assessment for bees

Species	Substance	Exposure System	Results	Reference
Apis mellifera	Fenoxaprop-P-ethyl	Oral	LD_{50} >199 µg/bee	EFSA Scientific Report (2007) 121, 1-76
Apis mellifera	Fenoxaprop-P-ethyl	Contact	LD_{50} > 200 µg/bee	EFSA Scientific Report (2007) 121, 1-76
Apis mellifera	CHR/H/FETEC-PART B 110 EC	Oral	LD_{50} > 200 µg/bee	M. Grzesica, Study code: EMI/4/538/2020
Apis mellifera	CHR/H/FETEC-PART B 110 EC	Contact	LD_{50} > 200 µg/bee	M. Grzesica, Study code: EMI/4/539/2020
Apis mellifera	CHR/H/FETEC-PART B 110 EC	Larval Toxicity	LD_{50} > 82.134 µg test item./larva	Woźniak A., Study code: 0038/0114/E
Apis mellifera	CHR/H/FETEC-PART B 110 EC	Chronic Oral	$LD_{50} \geq$ 39.39 µg t.i./bee/day	M. Grzesica, Study code: EMI/4/551/2020
Higher-tier studies (tunnel test, field studies)				
Not required				

9.6.1.1 Justification for new endpoints

No new endpoints were established – it is not required.

9.6.2 Risk assessment

The evaluation of the risk for bees was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services

(SANCO/10329/2002 rev.2 (final), October 17, 2002).

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the cereals (BBCH 20-31) also covers the risk for bees from all other intended uses.

9.6.2.1 Hazard quotients for bees

Table 9.6-2: First-tier assessment of the risk for bees due to the use of CHR/H/FETEC-PART B 110 EC in cereals.

Intended use	Cereals		
Active substance	Fenoxaprop-P-ethyl		
Application rate (g/ha)	1 × 77 g/ha		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	>199 µg/bee	77g/ha	0.37
Contact toxicity	>200 µg/bee		0.385
Product	CHR/H/FETEC-PART B 110 EC		
Application rate (g/ha)	1 × 726.6 g/ha		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	>200 µg/bee	726.6 g/ha	3.63
Contact toxicity	>200 µg/bee		3.63

Q_{HO}, Q_{HC}: Hazard quotients for oral and contact exposure. Q_H values shown in bold breach the relevant trigger.

9.6.2.2 Higher-tier risk assessment for bees (tunnel test, field studies)

Not relevant.

9.6.3 Effects on bumble bees

Not relevant.

9.6.4 Effects on solitary bees

Not relevant.

9.6.5 Overall conclusions

Overall, acceptable acute and reproductive risk to bees may be concluded for application of CHR/H/FETEC– PART B 110 EC to cereals according to the intended uses.
All hazard quotients (HQ) are considerably less than 50, indicating that CHR/H/FETEC– PART B 110 EC applied at the maximum use rate in cereals poses low risk to bees.

9.7 Effects on arthropods other than bees (KCP 10.3.2)

zRMS Comments:	The submitted risk assessment based on the "Guidance Document on Terrestrial Ecotoxicology" (2002) was accepted. New studies for formulation were submitted. The laboratory study 2D and aged-residue extended laboratory study were evaluated and accepted for the risk assessment. **In field risk**. The hazard quotients are below the trigger value (HQ ≤ 1) for most species. Only for *Coccinella septempunctata* the HQ > 1. Considering the extended study with *Coccinella septempunctata,* it is expected the potential recovery for this species, indicating that the active substance poses an acceptable risk to arthropods other than bees. **Off-field risk**. The hazard quotients are below the trigger value (HQ ≤ 1) for all species indicating that the active substance poses an acceptable risk to arthropods other than bees. The risk to arthropods other than bees is acceptable if the Fenoxinn Max 110 EC/Herbos Max 110 EC is applied in accordance with proposed use pattern.

9.7.1 Toxicity data

Studies on the toxicity to non-target arthropods have been carried out with fenoxaprop-P-ethyl its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on non-target arthropods of CHR/H/FETEC-PART B 110 EC were not evaluated as part of the EU assessment of Fenoxaprop-P-ethyl. New data submitted with this application are listed and summarised in Appendix 2.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process. Justifications are provided below.

Table 9.7-1: Endpoints and effect values relevant for the risk assessment for non-target arthropods

Species	Substance	Exposure System	Results	Reference
Typhlodromus pyri (protonymphs)	CHR/H/FETEC-PART B 110 EC	Extended laboratory test glass plates (2D)	LR_{50} > 706.4 mL/ha which is equivalent to 733.24 g prod/ha ER_{50} > 706.4 mL/ha which is equivalent to 733.24 g prod/ha	Kulec-Płoszczyca, E. Study code: B-111-22
Aphidius rhopalosiphi (adults)	CHR/H/FETEC-PART B 110 EC	Laboratory test glass plates (2D)	LR_{50} ≥700 ml/ha which is equivalent to 726.74 g prod/ha ER_{50} ≥700 ml/ha which is equivalent to 726.74 g prod/ha	Woźniak, A., Study code: 0038/0113/E
Coccinella septempunctata	CHR/H/FETEC-PART B 110 EC	Extended laboratory test glass plates (2D)	LR_{50} = 442.4 mL/ha which is equivalent to 459.2 g prod/ha	Kulec-Płoszczyca, E. Study code: B-112-22
Chrysoperla carnea	CHR/H/FETEC-PART B 110 EC	Extended laboratory test glass plates (2D)	LR_{50} > 706.4 mL/ha which is equivalent to 733.24 g prod/ha ER_{50} > 706.4 mL/ha which is equivalent to 733.24 g prod/ha	Kulec-Płoszczyca, E. Study code: B-113-22
Field or semi-field tests				
Aged-residue study Coccinella septempunctata	CHR/H/FETEC-PART B 110 EC	Aged-residue Extended Laboratory Tests	The effects of both fresh and aged foliar residues of CHR/H/FETEC-Part B 110 EC on the ladybird beetle, Coccinella septempunctata, were evaluated under extended laboratory conditions. When	Ch. Van Staden, Study code: CHR-23-01, 2023

Species	Substance	Exposure System	Results	Reference
			applied at a rate equivalent to 0.7 L test item/ha, freshly dried residues (0-day-old) of CHR/H/FETEC-Part B 110 EC and the subsequent bioassay evaluating 14-day-old field-aged foliar residues of CHR/H/FETEC-Part B 110 EC, showed no unacceptable effects on either the survival or the subsequent reproductive capacity of the ladybirds.	

9.7.2 Risk assessment

The evaluation of the risk for non-target arthropods was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002), and in consideration of the recommendations of the guidance document ESCORT 2.

9.7.2.1 Risk assessment for in-field exposure

To achieve a concise risk assessment, the risk envelope approach is applied.

Table 9.7-2: Higher tier assessment of the in-field risk for non-target arthropods due to the use of CHR/H/FETEC-PART B 110 EC in cereals

Intended use	Cereals		
Active substance/product	CHR/H/FETEC-PART B 110 EC		
Application rate (g/ha)	1 × 726.6 g/ha		
MAF	1		
Test species Higher Tier	**LR_{50} (lab.) (g [prod]/ha)**	**$PER_{in\text{-}field}$ (g/ha)**	**$HQ_{in\text{-}field}$ criterion: HQ ≤ 1**

Typhlodromus pyri	733.24	726.6	0.99
Aphidius rhopalosiphi	726.74		0.99
Coccinella septempunctata	459.2		**1.58**
Chrysoperla carnea	733.24		0.99
Additional study			
Coccinella septempunctata – aged residue study	~~The study is ongoing~~ The effects of both fresh and aged foliar residues of CHR/H/FETEC-Part B 110 EC on the ladybird beetle, Coccinella septempunctata, were evaluated under extended laboratory conditions. When applied at a rate equivalent to 0.7 L test item/ha, freshly dried residues (0-day-old) of CHR/H/FETEC-Part B 110 EC and the subsequent bioassay evaluating 14-day-old field-aged foliar residues of CHR/H/FETEC-Part B 110 EC, showed no unacceptable effects on either the survival or the subsequent reproductive capacity of the ladybirds.		

MAF: Multiple application factor; PER: Predicted environmental rate; HQ: Hazard quotient; DALT: Days after last treatment. Criteria values shown in bold breach the relevant trigger.

* If an LR_{50} or ER_{50} from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

9.7.2.2 Risk assessment for off-field exposure

To achieve a concise risk assessment, the risk envelope approach is applied.

Table 9.7-3: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of CHR/H/FETEC-PART B 110 EC in cereals

Intended use	Cereals
Active substance/product	Fenoxaprop-P-ethyl
Application rate (g/ha)	1 × 726.6 g/ha
MAF	1
vdf	1 (Tier II)

Test species Tier II	**LR_{50} (lab.) (g[prod]/ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (g/ha)**	**CF**	**$HQ_{off\text{-}field}$ criterion: HQ ≤ 1**
Typhlodromus pyri	733.24	0.0277	20.12	5	0.137
Aphidius rhopalosiphi	726.74				0.138

Coccinella septempunctata	459.2				0.219
Chrysoperla carnea	733.24				0.137

MAF: Multiple application factor; vdf: Vegetation distribution factor; (corr.) PER: (corrected) Predicted environmental rate; CF: Correction factor; HQ: Hazard quotient. Criteria values shown in bold breach the relevant trigger.

* If an LR_{50} or ER_{50} from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

9.7.2.3 Additional higher-tier risk assessment

~~Not relevant~~.

According to GLP aged residue study provided on the most sensitive species from laboratory studies – C. septempunctata the effects of freshly-dried and field-aged foliar residues of CHR/H/FETEC – PART B 110 EC on the predatory mite *Coccinella septempunctata* were evaluated in a series of extended laboratory tests. When applied to dwarf French beans plants at a rate equivalent to 0.7L test item/ha, fresh-dried and 14-day field-aged residues resulted in no unacceptable effects on either the survival or the subsequent reproductive capacity of the mites, (i.e. < 50% corrected mortality and < 50% reduction in reproduction, relative to the control).

The results of the mortality assessments are summarised below.

Bioassay initiated	Treatment	Test-item rate (L/ha)	% pre-imaginal mortality [a)]	Corrected % pre-imaginal mortality [b)]
0 DAT	Control	-	2.5	-
	CHR/H/FETEC-Part B 110 EC	0.7	7.5	5.1
	Toxic reference	-	97.5*	97.4
14 DAT	Control	-	7.5	-
	CHR/H/FETEC-Part B 110 EC	0.7	5.0	-2.7

a) For each bioassay, pre-imaginal mortality in the test item treatment, and the toxic reference in the 0 DAT bioassay, was compared to the control using Fisher's exact binomial test (one sided, > control, $\alpha = 0.05$). An asterisk (*) indicates where differences were significant.

b) Corrected mortalities were calculated using Abbott's formula. A positive value indicates an increase in mortality, a negative value indicates a decrease, relative to the control.

The results of the reproduction assessments are summarised below.

Bioassay initiated	Treatment	Test-item rate (L/ha)	Mean no. eggs/♀/ day	Mean % egg viability	Mean no. viable eggs/♀/ day
0 DAT	Control	-	26.2	56.7	14.9
	CHR/H/FETEC-Part B 110 EC	0.7	18.7	46.4	8.7
14 DAT	Control	-	11.9	53.1	6.3
	CHR/H/FETEC-Part B 110 EC	0.7	10.2	39.3	4.0

In the 0 and 14 DAT bioassays, the mean numbers of viable eggs produced in the test item treatment rate was > 2.0 eggs/female/day. This threshold is currently viewed as being indicative of no harmful treatment effect.

9.7.2.4 Risk mitigation measures

No risk mitigation needed.

9.7.3 Overall conclusions

Overall, acceptable acute and reproductive risk to non-target arthropods may be concluded for application of CHR/H/FETEC– PART B 110 EC to cereals according to the intended uses.
The aged residues study for *Coccinella septempunctata* is ongoing.
All hazard quotients (HQ off-field) are considerably less than 1, indicating that CHR/H/FETEC– PART B 110 EC applied at the maximum use rate in cereals poses low risk to non-target arthropods.

9.8 Effects on non-target soil meso- and macrofauna (KCP 10.4)

zRMS Comments:	The submitted information and justification were accepted. New studies were submitted and accepted. The endpoints for active substance and its metabolites were agreed at the EU level. The max PECs values for active substance and its metabolites were used for risk assessment. **Fenoxaprop-P**. The TER values for active substance, its metabolites and formulation is above the trigger values of 10 and 5 for acute and chronic risk assessment, respectively. The risk is acceptable. An acceptable risk to non-target soil organisms meso- and macrofauna is expected if the application of the Fenoxinn Max 110 EC/Herbos Max 110 EC is in accordance with proposed use pattern.

9.8.1 Toxicity data

Studies on the toxicity to earthworms and other non-target soil organisms (meso- and macrofauna) have been carried out with fenoxaprop-P-ethyl and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on on earthworms and other non-target soil organisms (meso- and macrofauna) of CHR/H/FETEC-PART B 110 EC were not evaluated as part of the EU assessment of Fenoxaprop-P-ethyl. New data submitted with this application are listed and summarised in Appendix 2.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process. Justifications are provided below.

Table 9.8-1: Endpoints and effect values relevant for the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna)

Species	Substance	Exposure System	Results	Reference
Eisenia fetida	Fenoxaprop-P-ethyl	14 d Acute	$LC_{50,corr*}$ > 500 mg/kg dw soil	EFSA Scientific Report (2007) 121, 1-76
Eisenia fetida	Fenoxaprop-P	Acute	$LC_{50,\ corr*}$ > 500 mg a.s/kg d.w. soil	EFSA Scientific Report (2007) 121, 1-76
Eisenia fetida	Chlorobenzoxalone	Acute	280 < LC_{50} > 500 mg a.s/kg d.w. soil	EFSA Scientific Report (2007) 121, 1-76
Eisenia fetida	CHR/H/FETEC-PART B 110 EC	56 d Chronic 10 % peat content	$NOEC_{reproduction}$* = 50 mg product /kg soil EC_{10}* = 130.3 mg product /kg soil	Wróbel, A., Study code: G-02-22
Folsomia candida	CHR/H/FETEC-PART B 110 EC	28d Chronic 5% peat content	$NOEC_{reproduction}$* = 28 mg product /kg soil EC_{10}* = 24.7 mg test item /kg soil	Pieczka, P., Study code: G-01-22
Hypoaspis aculeifer	CHR/H/FETEC-PART B 110 EC	14 d Chronic 5 % peat content	$NOEC_{reproduction}$* = 90 mg product /kg soil EC_{10}* = 124.11 mg test item /kg soil	Wróbel, A., Study code: G-03-22
Field studies				
Not required				
Litter bag test				
Not required				

* Corrected value derived by dividing the endpoint by a factor of 2 in accordance with the EPPO earthworm scheme 2002.

9.8.2 Risk assessment

The evaluation of the risk for earthworms and other non-target soil organisms (meso- and macrofauna) was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

9.8.2.1 First-tier risk assessment

The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, Table 8.7-3. According to the assessment of environmental-fate data, multi-annual accumulation in soil does not need to be considered for fenoxaprop-P-ethyl.
To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group cereals also covers the risk for earthworms and other non-target soil organisms (meso- and macrofauna) from all other intended uses (see 9.1.2).

Table 9.8-2: First-tier assessment of the acute and chronic risk for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use of CHR/H/FETEC-PART B 110 EC in cereals.

Intended use			
Acute effects on earthworms ***Eisenia foetida***			
Product/active substance	**LC_{50}** **(mg/kg dw)**	**PEC_{soil}** **(mg/kg dw)**	**TER_a** **(criterion TER ≥ 10)**
Not required			
Chronic effects on earthworms *Eisenia foetida*			
Product/active substance	**NOEC** **(mg/kg dw)**	**PEC_{soil}** **(mg/kg dw)**	**TER_{lt}** **(criterion TER ≥ 5)**
CHR/H/FETEC-PART B 110 EC	50	0.77504	64.513
Chronic effects on other soil macro- and mesofauna *Folsomia candida*			
Product/active substance	**EC_{10}** **(mg/kg dw)**	**PEC_{soil}** **(mg/kg dw)**	**TER_{lt}** **(criterion TER ≥ 5)**
CHR/H/FETEC-PART B 110 EC	24.7	0.77504	31.87
Chronic effects on other soil macro- and mesofauna *Hypoaspis aculifer*			

Product/active substance	**NOEC** (mg/kg dw)	**PEC_{soil}** (mg/kg dw)	**TER_{lt}** (criterion TER ≥ 5)
CHR/H/FETEC-PART B 110 EC	90	0.77504	116.12

TER values shown in bold fall below the relevant trigger.

9.8.2.2 Higher-tier risk assessment

Not relevant.

9.8.3 Overall conclusions

Overall, acceptable acute and reproductive risk to earthworms and other non-target soil organisms (meso- and macrofauna) may be concluded for application of CHR/H/FETEC– PART B 110 EC to cereals according to the intended uses.
All TER values are considerably more than 5, indicating that CHR/H/FETEC– PART B 110 EC applied at the maximum use rate in cereals poses low risk to earthworms and other non-target soil organisms (meso- and macrofauna).

9.9 Effects on soil microbial activity (KCP 10.5)

zRMS Comments:	The submitted information and data were accepted. The endpoints for active substance and its metabolites were agreed at the EU level. New study was submitted and accepted. An acceptable risk to soil microorganisms is expected if the Fenoxinn Max 110 EC/Herbos Max 110 EC formulation is applied in accordance with proposed use pattern.

9.9.1 Toxicity data

Studies on effects soil microorganisms have been carried out with fenoxaprop-P-ethyl. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on soil microorganisms of CHR/H/FETEC-PART B 110 EC were not evaluated as part of the EU assessment of fenoxaprop-P-ethyl. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process. Justifications are provided below.

Table 9.9-1: Endpoints and effect values relevant for the risk assessment for soil microorganisms

Endpoint	Substance	Exposure System	Results	Reference
N-mineralisation	Fenoxaprop-P-ethyl	56 d	< 22 % effect at day 0 - 56 at 0.133 mg a.s./kg d.w.soil (100 mg a.s/ha)	EFSA Scientific Report (2007) 121, 1-76
N-mineralisation	CHR/H/FETEC-PART B 110 EC	28 d aerobic soil type	CHR/H/FETEC-PARTB 110 EC at the concentrations defined as PEC – 4.83 mg of the test item/kg dry weight of soil (0.51 mg of fenoxaprop-P-ethyl and 0.36 mg of cloquintocet mexyl /kg dry weight of soil) and upper PEC (5xPEC) – 24.15 mg of the test item/kg of soil (2.55 mg of fenoxaprop-P-ethyl and 1.83 mg of cloquintocet mexyl /kg dry weight of soil) can be evaluated as having no long-term influence on nitrogen transformation in soils.	Dec, W., Study code: EMI/4/547/2020

9.9.2 Risk assessment

The evaluation of the risk for soil microorganisms was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, Table 8.7-3 and were already used in the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna) (see 9.8).
To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the cereals (BBCH 20-31) also covers the risk for the soil microorganisms from all other intended uses (see 9.1.2)

Table 9.9-2: Assessment of the risk for effects on soil micro-organisms due to the use of CHR/H/FETEC-PART B 110 EC in cereals

Intended use			
N-mineralisation			
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**Risk acceptable?**
Fenoxaprop-P-ethyl	0.133 (at 56 d)	0.0821	yes
CHR/H/FETEC-PART B 110 EC	4.83 (at 28 d)	0.77504	yes

9.9.3 Overall conclusions

The Predicted Environmental Concentrations of the formulation CHR/H/FETEC-PART B 110 EC and its active substance Fenoxaprop-P-ethyl in soil are below the concentrations at which no unacceptable effects (< 25%) regarding the soil microbial activity were observed after 56 days or more of exposure, indicating that the proposed use of CHR/H/FETEC-PART B 110 EC poses an acceptable risk to soil microorganisms.

9.10 Effects on non-target terrestrial plants (KCP 10.6)

zRMS Comments:	The new studies were submitted and accepted. Toxicity effects of Fenoxinn Max 110 EC/Herbos Max 110 EC formulation were assessed. The effect on vegetative vigour and seedling emergence were tested. The ER_{10} ER_{50} and NOER values for seedling emergence and vegetative vigour for tested maximum application rate of 0.706 L formulation/ha (equivalent to ~ 77 g a.s./ha) for all tested plant species (Table 9.10-1) were calculated. Density of formulation of 1.038 g/L were used in recalculations. The ER_{50} was determined for visual phytotoxicity effects, basis on the results after 21 days of the experiment. An acceptable risk to non-target terrestrial plants is expected if the application of the Fenoxinn Max 110 EC/Herbos Max 110 EC is in accordance with proposed use pattern. No mitigation measure is required.

9.10.1 Toxicity data

Studies on the toxicity to non-target terrestrial plants have been carried out with fenoxaprop-P-ethyl and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on non-target terrestrial plants of CHR/H/FETEC-PART B 110 EC were not evaluated as part of the EU assessment of fenoxaprop-P-ethyl. New data submitted with this application are listed in Appendix 1 summarised in Appendix 2.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process. Justifications are provided below.

Table 9.10-1: Endpoints and effect values relevant for the risk assessment for non-target terrestrial plants

Species	Substance	Exposure System	Results	Reference
Sunflower *Helianthus annuus*	CHR/H/FETEC-PARTB 110 EC	21 d Seedling emergence	ER_{50} > 706.0 ml prod/ha equal to ER_{50} > 732.83 g prod/ha	Wróbel, A. Study Code: G-05-22
Pea *Pisum sativum*				
Cabbage *Brassica oleracea var. capitata*				
Onion *Allium cepa*				
Perennial ryegrass *Lolium perenne*				
Oats *Avena sativa*				
Sunflower *Helianthus annuus*	CHR/H/FETEC-PARTB 110 EC	21 d Vegetative vigour	ER_{50} > 706.0 ml prod/ha equal to ER_{50} > 732.83 g prod/ha	Pieczka, P. Study code: G-04-22
Pea *Pisum sativum*				
Cabbage *Brassica oleracea var. capitata*				

Species	Substance	Exposure System	Results	Reference
Onion *Allium cepa*				
Perennial ryegrass *Lolium perenne*				
Oats *Avena sativa*			ER_{50} > 177.4 ml prod/ha equal to ER_{50} > 184.14 g prod/ha	

m: monocotyledonous; d: dicotyledonous

9.10.2 Risk assessment

9.10.2.1 Tier-1 risk assessment (based screening data)

Not relevant.

9.10.2.2 Tier-2 risk assessment (based on dose-response data)

The risk assessment is based on the "Guidance Document on Terrestrial Ecotoxicology", (SANCO/10329/2002 rev.2 final, 2002). It is restricted to off-field situations, as non-target plants are non-crop plants located outside the treated area.

Table 9.10-2: Assessment of the risk for non-target plants due to the use of CHR/H/FETEC-PARTB 110 EC in cereals

Intended use	Cereals
Active substance/product	CHR/H/FETEC-PARTB 110 EC
Application rate (g/ha)	1 × 726.6
MAF	1

Test species	**ER_{50} (g/ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (g/ha)**	**TER criterion: TER ≥ 5**
On the basis of seedling emergence studies				
Sunflower *Helianthus annuus*	732.83	0.0277	20.127	36.41

Pea *Pisum sativum*	732.83	0.0277	20.127	36.41
Cabbage *Brassica oleracea var. capitata*	732.83	0.0277	20.127	36.41
Onion *Allium cepa*	732.83	0.0277	20.127	36.41
Perennial ryegrass *Lolium perenne*	732.83	0.0277	20.127	36.41
Oats *Avena sativa*	732.83	0.0277	20.127	36.41
On the basis of seedling vegetative vigour studies				
Sunflower *Helianthus annuus*	732.83	0.0277	20.127	36.41
Pea *Pisum sativum*	732.83	0.0277	20.127	36.41
Cabbage *Brassica oleracea var. capitata*	732.83	0.0277	20.127	36.41
Onion *Allium cepa*	732.83	0.0277	20.127	36.41
Perennial ryegrass *Lolium perenne*	732.83	0.0277	20.127	36.41
Oats *Avena sativa*	184.14	0.0277	20.127	9.15

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio.
TER values shown in bold fall below the relevant trigger.

9.10.2.3 Higher-tier risk assessment

Not relevant.

9.10.2.4 Risk mitigation measures

No risk mitigation needed.

9.10.3 Overall conclusions

Based on the predicted rates of CHR/H/FETEC-PART B 110 EC in off-field areas, the TER values

describing the risk for non-target plants following exposure to CHR/H/FETEC-PARTB 110 EC according to the GAP of the formulation CHR/H/FETEC-PART B 110 EC achieve the acceptability criteria TER ≥ 5 with no need for risk mitigation measures.

9.11 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)

Not relevant.

9.12 Monitoring data (KCP 10.8)

Not relevant.

9.13 Classification and Labelling

zRMS Comments:	The proposed classification and labelling was accepted. The P273 was crossed-out as it is not relevant for plant protection products.

Having considered studies, the following ecotoxicological classification and labelling of CHR/H/FETEC-PART B 110 EC is proposed:

Classification:
Aquatic Acute 1, H400
Aquatic Chronic 2, H411

Hazard statement:
H400 – Very toxic to aquatic life.
H411 – Toxic to aquatic life with long lasting effects.

Labelling:
Aquatic Chronic 1, H410
H410 – Very toxic to aquatic life with long lasting effects.

Pictogram:

GHS09

Signal word:
WARNING

Precautionary statement:

~~P273: Avoid release to the environment.~~
P391: Collect spillage.
P501: Dispose of contents/container in accordance with local regulation.
EUH401: To avoid risks to man and the environment, comply with the instructions for use.

According to *EFSA Scientific Report (2007) 121, 1-76* fenoxaprop-P-ethyl is considered not to be readily biodegradable.

The hazard statement of H410 for the labelling results from the provisions of the Guidance on the Application of the CLP Criteria Version 5.0 – July 2017 (See Table 4.1, page 552 of Guidance).

SP 1: Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe3: Cereals - To protect aquatic organisms respect 1 m non-spray buffer zone to surface water bodies.

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 10.1.1	Żero, K.	**2022**	**Fenoxaprop-P-ethyl - TER Calculations for Terrestial Verterbrates** Chemirol GLP No Unpublished	N	Chemirol
KCP 10.1.2	Żero, K.	**2022**	**Fenoxaprop-P-ethyl - TER Calculations for Terrestial Verterbrates** Chemirol GLP No Unpublished	N	Chemirol
KCP 10.2/01	Szlauer, S.	~~2020~~ 2022	CHR/H/FETEC-PARTB 110 EC *Daphnia* sp., Acute Immobilisation Test Ecomelius Institute Sp. z o. o. Kalinowa 2, Zaborze 43-520 Chybie, Poland Study Code: EMI/4/538/2020 GLP Unpublished	N	Chemirol
KCP 10.2/01 - 1	Szlauer, S.	2023	Amendment No. 1 to the FINAL REPORT Daphnia sp., Acute Immobilisation Test Ecomelius Institute Sp. z o. o. Kalinowa 2, Zaborze 43-520 Chybie, Poland Study Code: EMI/4/538/2020	N	Chemirol

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
			GLP Unpublished		
KCP 10.2/02	Domagała, J.	2022	Freshwater algae (*Raphidocelis subcapitata*) growth inhibition test of the test item CHR/H/FETEC-PART B 110 EC according to OECD 201 guideline SORBOLAB Research Laboratory LLC, Zaniemyska Street 11, 61-029 Poznań, Poland Study Code: 0038/0111/E GLP Unpublished	N	Chemirol
KCP 10.2/03	Woźniak, A.	2022	Freshwater alga (*Navicula pelliculosa*) growth inhibition test of the test item CHR/H/FETEC-PART B 110 EC according to OECD 201 guideline SORBOLAB Research Laboratory LLC, Zaniemyska Street 11, 61-029 Poznań, Poland Study Code: 0038/0111/E GLP Unpublished	N	Chemirol
KCP 10.2/04	Kubisiak, K.	2022	*Lemna gibba* growth inhibition test of the test item CHR/H/FETEC-PART B 110 EC according to OECD guideline 221 SORBOLAB Research Laboratory LLC, Zaniemyska Street 11, 61-029 Poznań, Poland Study Code: 0038/0112/E GLP Unpublished	N	Chemirol

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 10.3.1/01	Grzesica, M.	2020	CHR/H/FETEC-PARTB 110 EC Honeybees (*Apis mellifera* L.), Acute Oral Toxicity Test Ecomelius Institute Sp. z o. o. Kalinowa 2, Zaborze 43-520 Chybie, Poland Study Code: EMI/4/538/2020 GLP Unpublished	N	Chemirol
KCP 10.3.1/02	Grzesica, M.	2020	CHR/H/FETEC-PARTB 110 EC Honeybees (*Apis mellifera* L.), Acute Contact Toxicity Test Ecomelius Institute Sp. z o. o. Kalinowa 2, Zaborze 43-520 Chybie, Poland Study Code: EMI/4/539/2020 GLP Unpublished	N	Chemirol
KCP 10.3.1/03	Woźniak, A.	2022	Honey bee larval toxicity test following repeated exposure of the test item CHR/H/FETEC-PART B 110 EC according to OECD GD 239 ENV/JM/MONO(2016)34 SORBOLAB Research Laboratory LLC, Zaniemyska Street 11, 61-029 Poznań, Poland Study Code: 0038/0114/E GLP Unplublished	N	Chemirol
KCP 10.3.1/04	Grzesica, M.	2020	CHR/H/FETEC-PARTB 110 EC Honeybees (Apis mellifera L.), Chronic Oral Toxicity Test Ecomelius Institute Sp. z o. o. Kalinowa 2, Zaborze 43-520 Chybie, Poland Study Code: EMI/4/551/2020 GLP Unpublished	N	Chemirol

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 10.3.2/01	Kulec-Płoszczyca, E.	2022	An extended laboratory test for evaluating the effects of CHR/H/FETEC – PART B 110 EC on the predatory mite, *Typhlodromus pyri* (Sch.) Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna Ecotoxicology Research Group Doświadczalna 27, 43 – 200 Pszczyna, Poland Study Code: B-111-22 GLP Unpublished	N	Chemirol
KCP 10.3.2/02	Woźniak, A.	2022	Extended laboratory test to evaluate effects on *Aphidius rhophalosiphi* (DeStephani-Perez) of the test item CHR/H/FETEC-PART B 110 EC; SORBOLAB Research Laboratory LLC; Zaniemyska Street 11; 61-029 Poznań, Poland Study Code: 0038/0113/E GLP Unpublished	N	Chemirol
KCP 10.3.2/03	Kulec-Płoszczyca, E.	2022	An extended laboratory test for evaluating effects of CHR/H/FETEC - PART B 110 EC on the green lacewing, *Chrysoperla carnea* (Sch.) Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna Ecotoxicology Research Group Doświadczalna 27, 43 – 200 Pszczyna, Poland Study Code: B-113-22 GLP Unpublished	N	Chemirol

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 10.3.2/04	Kulec-Płoszczyca, E.	2022	An extended laboratory test for evaluating effects of CHR/H/FETEC - PART B 110 EC on the ladybird beetle, *Coccinella septempunctata* (L.) Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna Ecotoxicology Research Group Doświadczalna 27, 43 – 200 Pszczyna, Poland Study Code: B-112-22 GLP Unpublished	N	Chemirol
KCP 10.3.2/05	Ch. Van Staden	2023	CHR/H/FETEC-Part B 110 EC – A Series of Aged-Residue Extended Laboratory Tests to Determine Effects on the Ladybird Beetle, Coccinella septempunctata (Coleoptera: Coccinellidae) CHR-23-01 Mambo-Tox A Division of Cawood Scientific Ltd. 2 Venture Road, University Science Park, Southampton SO16 7NP, UK GLP Unpublished	N	Chemirol
KCP 10.4.1/01	Pieczka, P.	2022	CHR/H/FETEC-PART B 110 EC Earthworm reproduction test (*Eisenia andrei*) Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna Ecotoxicology Research Group Doświadczalna 27, 43 – 200 Pszczyna, Poland Study Code: G-01-22 GLP Unpublished	N	Chemirol
KCP 10.4.1/02	Wróbel, A.	2022	CHR/H/FETEC- PARTB 110 EC Collembolan (*Folsomia candida*) Reproduction Test	N	Chemirol

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
			Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna Ecotoxicology Research Group Doświadczalna 27, 43 – 200 Pszczyna, Poland Study Code: G-02-22 GLP Unpublished		
KCP 10.4.1/03	Wróbel, A.	2022	CHR/H/FETEC- PARTB 110 EC Predatory mite (*Hypoaspis (Geolaelaps) aculeifer*) reproduction test in soil Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna Ecotoxicology Research Group Doświadczalna 27, 43 – 200 Pszczyna, Poland Study Code: G-03-22 GLP Unpublished	N	Chemirol
KCP 10.5.1/01	Dec, W.	2020	CHR/H/FETEC- PARTB 110 EC Soil Microorganisms: Nitrogen Transformation Test Ecomelius Institute Sp. z o. o. Kalinowa 2, Zaborze 43-520 Chybie, Poland Study Code: EMI/4/547/2020 GLP Unpublished	N	Chemirol
KCP 10.6.1/01	Wróbel, A.	2022	CHR/H/FETEC-PART B 110 EC Terrestial Plant Test: Vegetative Vigour TestTerrestial Plant Test: Seedling Emergence and Seedling Growth Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna Ecotoxicology Research Group Doświadczalna 27, 43 – 200 Pszczyna, Poland	N	Chemirol

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
			Study Code: G-05-22 GLP Unpublished		
KCP 10.6.1/02	Pieczka, P.	2022	CHR/H/FETEC-PART B 110 EC Terrestial Plant Test: Vegetative Vigour Test Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna Ecotoxicology Research Group Doświadczalna 27, 43 – 200 Pszczyna, Poland Study Code: G- 04-22 GLP Unpublished	N	Chemirol

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

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 10.2/01	Christ M.T. & Ruff D.F.	1999g	Effect to Anabaena flos-aquae (Blue-Green Alga) in a Growth Inhibition Test Fenoxaprop-P-ethyl Technical 88.1% w/w Code: AE F046360 00 1C97 0002 Generated by: AgrEvo USA Company AgrEvo Research Center Ecotoxicology Department 703 NOR-AM Road PO Box	N	BCS

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
			538 Pikeville, NC 27863 Report No: BM98W518 GLP / GEP: yes Unpublished		
KCP 10.2/02	Christ M.T. & Ruff D.F.	1997b	Toxicity to Duckweed (*Lemna gibba*), in a Static Renewal System; Fenoxaprop-Pethyl Technical 88.1% w/w Code AE F046360 00 1C97 0002 Generated by: AgrEvo USA Company; Research Center; Ecotoxicology Department; 703 NOR-AM Road; PO Box 538; Pikeville, NC 27863 Report No: BM97W502 GLP / GEP: yes Unpublished	N	BCS
KCP 10.2/03	Christ M.T. & Ruff D.F.	1999h	Effect on *Pseudokirchneriella subcapitata* (green algae) in a Growth Inhibition Test AE F054014 Technical 99.7% w/w: Code AE F054014 00 1C99 0004 Generated by: AgrEvo USA Company; Research Center; Ecotoxicology Department; 703 NOR-AM Road; PO Box 538; Pikeville, NC 27863 Report No: BM98W523 GLP / GEP: yes Unpublished	N	BCS
KCP 10.2/04	Ebeling M., Nguyen D., Gosch H.	2002a	Fenoxaprop-P *Daphnia magna* - Chronic Toxicity and Reproduction Test under semi-static conditions; code AE F088406 00 1C97 0001Generated by: Bayer CropScience GmbH; Ecotoxicology, D-65926 Frankfurt	N	BCS

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
			Report No: CE02/057 GLP / GEP: yes unpublished		
KCP 10.2/05 (KCP 10.6/01)	Ebert E.	2005	Tier 2 summaries of additional ecotoxicological studies 1st addendum to document C029144 (A II, S6, P8) and C029145 (A III, S6, P10) Refined risk assessments for aquatic organisms and non target plants According to the prevailing EU guidance documents Code: AE F046360 Generated by: Bayer CropScience, Frankfurt, DEU Document No: C046104 GLP / GEP: No Unpublished	N	BCS
KCP 10.2/06	xxxxxxxx	1987	Hoe 046360, active ingredient technical (Code: Hoe 046360 0H ZC96 0002) – Testing for acute oral toxicity in the male and female Japanese quail (*Coturnix coturnix japonica*) xxxxxxxxxxxxxxxxxxxxxxx Document No: A36978 GLP Yes Unpublished	Y	BCS
KCP 10.2/07	xxxxxxxx	1986a	Hoe 046360, active ingredient (Code: Hoe 046360 0H ZC96 0002) – Testing for acute oral toxicity in the male and female bobwhite quail (*Colinus virginianus*) xxxxxxxxxxxxx Document No: A36429 GLP Yes Unpublished	Y	BCS

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 10.2/08	Ebert E., Leist K.-H.	1986b	Hoe 046360, active ingredient (Code: Hoe 046360 0H ZC96 0002) – Testing for acute oral toxicity in the male and female mallard duck (*Anas platyrhynchos*) xxxxxxxxxxxxxxxxxxx Document No: A36428 GLP Yes Unpublished	Y	BCS
KCP 10.2/09	xxxxxxxxx	1986c	Hoe 046360, active ingredient technical (Code: Hoe 046360 0H ZC96 0002) – Testing for acute oral toxicity in the male and female partridge (*Perdix perdix*) xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx Document No: A36679 GLP Yes Unpublished	Y	BCS
KCP 10.2/10	xxxxxxxxxxxxxx	1986d	Hoe 046360, active ingredient technical (Code: Hoe 046360 0H ZC96 0002) - 8- day dietary LC_{50} test in the Japanesenquail (*Coturnix coturnix japonica*) xxxxxxxxxxxxxxxxxxxxxxxxxxxx Document No: A36733 GLP Yes Unpublished	Y	BCS
KCP 10.2/11	xxxxxxxxx	1986e	Hoe 046360, active ingredient technical (Code: Hoe 046360 0H ZC96 0002) - 8- day dietary LC_{50} test in the mallard duck (*Anas platyrhynchos*) xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx Document No: A36430	Y	BCS

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
			GLP Yes Unpublished		
KCP 10.2/12	xxxxxxx	2001	Bobwhite quail dietary reproduction range finding study Fenoxaprop-P-ethyl, Code: AE F046360 00 1D96 0001 xxxxxxxxxxxxxxx Document No: C017041 GLP Yes Unpublished	Y	BCS
KCP 10.2/13	xxxxxxxxx	1986c	The Effect of Hoe 046360 - substance, technical Identification code Hoe 046360 OH ZC96 0002 to *Salmo gairdneri* (Rainbow trout) in a dynamic acute toxicity Test (Sg349/b, method OECD) xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx Report No: OEK86/080E GLP / GEP: yes Unpublished	Y	BCS
KCP 10.2/14	Fischer R.	1986a	The Effect of Hoe 046360 - substance, technical Identification code Hoe 046360 OH ZC96 0002 to *Scenedesmus subspicatus* CHODAT (Green alga) in a Growth Inhibition Test (5s39/d + 5s39/e, method OECD Generated by: Hoechst Company; Ecological Laboratory, D-6230 Frankfurt, Germany Report No: OEK86/043E GLP / GEP: yes Unpublished	N	BCS

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 10.2/15	xxxxxx	1989ap	The Effect of Fenoxaprop-P-ethyl - substance, technical (Identification code: Hoe 046360 OH ZC97 0002) to *Salmo gairdneri* (Rainbow trout) in a 21-day Prolonged Toxicity Test (method OECD) xxxxxxxxxxxxxxxxxxxxxxxxxx Report No: CE89/034 GLP / GEP: yes Unpublished	Y	BCS
KCP 10.2/16	xxxxxxxxxxxx	1986b	The Effect of Hoe 046360 - substance, technical Identification code . Hoe 046360 OH ZC96 0002 to *Salmo gairdneri* (Rainbow trout) in a Static Acute Toxicity Test (Sg347/a, method EPA) xxxxxxxxxxxxxxxxxxxxxxxxx Report No: OEK86/092E GLP / GEP: yes Unpublished	Y	BCS
KCP 10.2/17	xxxxxxxxx	1986d	Effect of Hoe 046360 - active ingredient technical (Code: Hoe 046360 OH ZC96 0002) on *Salmo gairdneri* (Rainbow trout) in a static-acute toxicity test (Study No. Sg348/a, BBA/EPA method) xxxxxxxxxxxxxxxxxxxx Report No: OEK86/073D GLP / GEP: yes Unpublished	Y	BCS
KCP 10.2/18	xxxxxxx	1986g	The Effect of Hoe 046360 - substance, technical Identification Code Hoe 046360 OH ZC96 0002 to *Lepomis macrochirus* (Bluegill sunfish) in a static-acute toxicity test (Lm16/a, method	Y	BCS

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
			EPA) xxxxxxxxxxxxxxxxxxxxx Report No: OEK86/003E GLP / GEP: yes Unpublished		
KCP 10.2/19	Fischer, R.	1986f	The Effect of Hoe 046360 - substance, technical, Identification Code Hoe 046360 OH ZC96 0002 to *Daphnia magna* (Waterflea) in a Static-Acute Toxicity Test (Dm610/a, method EPA) Generated by: Oekologisches Laboratorium, Pflanzenschutz Forschung Biologie, Hoechst AG, D-6230 Frankfurt, Germany Report No: OEK86/072E GLP / GEP: yes Unpublished	N	BCS
KCP 10.2/20	Fischer, R.	1989ao	The Effect of Fenoxaprop-P-ethyl - substance, technical (Identification code: Hoe 046360 OH ZC97 0002) to *Daphnia magna* (Water flea) in a 21-day Reproduction Test (method OECD) Generated by: Oekologisches Laboratorium, Pflanzenschutz Forschung Biologie, Hoechst AG, D-6230 Frankfurt am Main 80, Fed. Rep. of Germany Report No: CE89/033 GLP / GEP: yes Unpublished	N	BCS
KCP 10.2/21	xxxxxxx	1996j	Acute toxicity to rainbow trout (*Oncorhynchus mykiss*) Fenoxaprop-P, substance, technical Code: AE F088406 00 1C94 0001 xxxxxxxxxxxxxxxxxxxxxxxxxx	Y	BCS

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
			Report No: CE96/122 GLP / GEP: yes Unpublished		
KCP 10.2/22	Heusel R.	1993dy	Effect to *Daphnia magna* (water flea) in a Static-Acute Toxicity Test (method OECD) Fenoxaprop-P substance, technical (Hoe 088406 00 ZC93 0001) Generated by: Hoechst AG; GB C / Product Development Ecology, D-6230 Frankfurt Report No: Project No. CE92/002 GLP / GEP: yes Unpublished	N	BCS
KCP 10.2/23	Heusel R.	1993dx	Effect to *Selenastrum capricornutum* (green algae) in an algal assay bottle test (method EPA) Fenoxaprop-P substance, technical (Hoe 088406 00 ZC93 0001) Generated by: Hoechst AG; Ecobiology, D-65926 Frankfurt, Germany Report No: CE92/003 GLP / GEP: yes Unpublished	N	BCS
KCP 10.2/24	Heusel, R	1991bs	Effect to Selenastrum capricornutum (Green alga) in an Algal Assay Bottle Test (method EPA) Fenoxaprop-P-ethyl: substance, technical (Hoe 046360 00 ZC97 0002) Generated by: Hoechst Company; Ecological Laboratory, D-6230 Frankfurt, Germany Report No: CE90/093 GLP / GEP: yes	N	BCS

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
			Unpublished		
KCP 10.2/25	xxxxxx	1985a	Determination of tissue concentrations of Hoe 033171 in bobwhite quail after dietary administration xxxxxxxxxxxxxxxxxx Document No: A32063 GLP Yes Unpublished	Y	BCS
KCP 10.2/26	xxxxxx	1985b	Determination of tissue concentrations of Hoe 033171 in mallard duck after dietary Administration xxxxxxxxxxxxxxxxxxxxxxxxx Document No: A32064 GLP Yes Unpublished	Y	BCS
KCP 10.2/27	xxxxxx	1999a	Bioaccumulation and metabolism of 14CChlorophenyl AE F046360 in Bluegill Sunfish, *Lepomis macrochirus*, in a Flow-Through System xxxxxxxxxxxxxxxxxxx Report No: BM98E517 GLP / GEP: yes unpublished	Y	BCS
KCP 10.2/28	Reinhardt	1995	Respiration inhibition to activated sludge of Code: Hoe 046360 00 ZC97 0002 Generated by: Hoechst AG; Abteilung Umweltschutz Document No: A55598 GLP / GEP Yes Unpublished	N	BCS

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 10.2/29	xxxxxx	1986	The dietary toxicity (LC_{50}) of Hoe 046360, substance technical, in the bobwhite quail (Code: Hoe 046360 0H ZC96 0002) xxxxxxxxxxxxxxx Document No: A34917 GLP Yes unpublished	Y	BCS
KCP 10.2/30	xxxxxxx	1985	The effects of dietary inclusion of Hoe 033171, active ingredient technical on reproduction in the bobwhite quail; Code: Hoe 033171 0H ZD96 0001 xxxxxxxxxxxxx Document No: A31296 GLP Yes Unpublished	Y	BCS
KCP 10.2/31	xxxxxxxxxx	1985	The effects of dietary inclusion of Hoe 033171, active ingredient technical on reproduction in the mallard duck; Code: Hoe 033171 0H ZD96 0001 xxxxxxxxxxxxx Document No: A31342 GLP Yes Unpublished	Y	BCS
KCP 10.2/32	xxxxxxx	2004a	Rainbow trout (*Oncorhynchus mykiss*), Juvenile growth test (OECD 215), flowthrough study conditions, AE F096918; substance pure, code: AE F096918 00 1B99 0001 xxxxxxxxxxxxxxxxxx Report No: C045675 GLP / GEP: yes unpublished	Y	BCS

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 10.2/33	xxxxxx	2004a	Rainbow trout (*Oncorhynchus mykiss*), acute toxicity test, semi static exposure, AE F096918 substance pure, Code: AE F096918 00 1B99 0001 xxxxxxxxxx Report No: C043956 GLP / GEP: yes Unpublished	Y	BCS
KCP 10.2/34	Schäfers, C.	2004b	*Daphnia magna*, acute immobilization test (OECD 202), AE F096918; substance pure, Code: AE F096918 00 1B99 0001 Generated by: Fraunhofer – Institute for Molecular Biology and Applied Ecology, 57377 Schmallenberg, Germany Report No: C043957 GLP / GEP: yes Unpublished	N	BCS
KCP 10.2/35	Schäfers, C.	2004b	*Daphnia magna*, reproduction test (OECD 211), semi–static exposure, AE F096918; substance pure, code: AE F096918 00 1B99 0001 Generated by: Fraunhofer Institute for Molecular Biology and Applied Ecology, D-57377Schmalenberg, Germany Report No: C045676 GLP / GEP: yes unpublished	N	BCS
KCP 10.2/36	xxxxxx	2002	Bobwhite quail dietary reproduction study Fenoxaprop-P-ethyl, Code: AE F046360 00 1D96 0001	Y	BCS

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
			xxxxxxxxxxxxxx Document No: C027500 GLP Yes unpublished		
KCP 10.2/37	Sowig P.	2002u	Recalculation of biological endpoints from the study: The Effect of Hoe 046360 - substance, technical Identification code Hoe 046360 OH ZC96 0002 to *Scenedesmus subspicatus* CHODAT (Green alga) in a Growth Inhibition Test (5s39/d + 5s39/e, method OECD) Generated by: Bayer CropScience GmbH, Ecotoxicology, D-65926 Frankfurt am Main, Federal Republic of Germany Report No: OE 02/159 GLP / GEP: no Unpublished	N	BCS
KCP 10.2/38	xxxxxxxxx	2003a	Effects on survival and growth of juvenile rainbow trout (*Oncorhynchus mykiss*) in a 28 days flow-through study Fenoxaprop- P, substance, technical (code: AE F088406 00 1C97 0001) xxxxxxxxxx Report No: CE02/058 GLP / GEP: yes unpublished	Y	BCS
KCP 10.2/39	Sowig P., Weller O., Gosch H.,	1999ae	Algal growth inhibition – *Navicula pelliculosa* Fenoxaprop-P-ethyl substance, technical Code: AE F046360 00 1C97 0002 Generated by: Hoechst Schering AgrEvo GmbH; Ecobiology, D-65926 Frankfurt	N	BCS

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
			Report No: CE98/107 GLP / GEP: yes Unpublished		
KCP 10.2/40	xxxxxxxxxxxxx	1999s	The 96 hour acute toxicity to the rainbow trout, *Oncorhynchus mykiss*, in a flow through system; Fenoxaprop-P-ethyl, technical 88.1% w/w; Code: AE F046360 00 1C97 0002 xxxxxxxxxxxxxxxx Report No: BM98W520 GLP / GEP: yes Unpublished	Y	BCS
KCP 10.2/41	Stachura B.J. & Ruff D.F.	1998e	The 48 Hour Acute Toxicity to *Daphnia magna*, in a Static Renewal System Fenoxaprop-P-ethyl Technical 88.1% w/w Code: AE F046360 001 C97 0002 Generated by: AgrEvo USA Company Research Center Ecotoxicology Department 703 NOR-AM Road PO Box 538 Pikeville, NC 27863 Report No: BM98W514 GLP / GEP: yes Unpublished	N	BCS
KCP 10.2/40	xxxxxxxxxx	1999q	The 96 hour acute toxicity to the rainbow trout, *Oncorhynchus mykiss*, in a static renewal system; AE F054014, technical 99.7% w/w; code: AE F054014 00 1C99 0004 xxxxxxxxxxxxxxxxxxxx Report No: BM98W522	Y	BCS

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
			GLP / GEP: yes Unpublished		
KCP 10.2/41	xxxxxx	1999r	The 96-hours Acute Toxicity to the Bluegill Sunfish, *Lepomis macrochirus*, in a Flow Through System; Fenoxaprop-Pethyl Technical 88.1% w/w; Code: AE F046360 00 1C97 0002 xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx Report No: BM98W521 GLP / GEP: yes Unpublished	Y	BCS
KCP 10.2/42	xxxxxxxxxxxxxxx	1999t	Effects on Early Life Stages of Rainbow Trout, Oncorhynchus mykiss U.S.EPA 72-4 Fenoxaprop-P-ethyl Technical 88.1%w/w; Code: AE F046360 00 1C97 0002 xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx Report No: BM98W513 GLP / GEP: yes Unpublished	Y	BCS
KCP 10.2/43	Wenzel, A.	2004	Algal, (*Pseudokirchneriella subcapitata*), Growth inhibition test (OECD 201), static exposure (under consideration of proposal for updating OECD 201 of April 2004), AE F096918 substance pure, Code: AE F096918 00 1B99 0001 Generated by: Fraunhofer – Institute for Molecular Biology and Applied Ecology, 57377 Schmallenberg, Germany Report No: C043958	N	BCS

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
			GLP / GEP: yes Unpublished		
KCP 10.2/44	Young B.M. & Ruff D.F.	1999i	The 48 Hour Acute Toxicity to the Water Flea, *Daphnia Magna* in a Static renewal system; AE F054014, technical 99.7% w/w Code: AE F054014 00 1C99 0004 Generated by: AgrEvo USA Company; Research Center; Ecotoxicology Department; 703 NOR-AM Road; PO Box 538; Pikeville, NC 27863 Report No: BM98W524 GLP / GEP: yes Unpublished	N	BCS
KCP 10.2/45	Young B.M. & Ruff D.F.	1999h	Effect to *Skeletonema costatum* (Marine Diatom) in a Growth Inhibition Test Fenoxaprop-P-ethyl Technical 88.1% w/w Code: AE F046360 00 1C97 0002 Generated by: AgrEvo USA Company AgrEvo Research Center Ecotoxicology Department 703 NOR-AM Road PO Box 538 Pikeville, NC 27863 Report No: BM98W516 GLP / GEP: yes Unpublished	N	BCS
KCP 10.2/46	Ebert, E.	2004	Alga, (*Pseudokirchneriella subcapitata*), Growth Inhibition Test (OECD), static exposure, AE F046360 24 EW14 A717 Generated by: Fraunhofer Institute for Molecular Biology and Applied Ecology (IME) D-57377 Schmallenberg- Grafschaft; Germany Report No: C046105	N	BCS

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
			GLP / GEP: yes Unpublished		
KCP 10.3/01	Kleiner R.	2000	Toxicity to the honeybee *Apis mellifera* L. (laboratory) according to EPPO Guideline No. 170 (1992) Code: AE F046360 00 1D96 0001 Generated by: BioChem agrar Lab. f. biol. und chem. Analytik, DEU; Cunnersdorf Document No: C006598 GLP Yes Unpublished	N	BCS
KCP 10.4/01	Fischer R.	1988	The effect of Hoe 046360, substance, technical (Code: Hoe 046360 0H ZC97 0001) to *Eisenia fetida* (earthworm) in a 14 day artificial soil test (method OECD) Generated by: Hoechst AG; Pflanzenschutz Forschung Biologie Document No: A39888 GLP / GEP Yes Unpublished	N	BCS
KCP 10.4/02	Kuehner Ch.	1993	Testing for side-effects of Hoe 046360 24 EW14 A203on the staphylinid (Aleochara bilineata Gyll. Coleoptera, Staphylinidae) in the laboratory Generated by: GAB Biotechnologie GmbH; Document No: A51546 GLP Yes Unpublished	N	BCS

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 10.4/03	Kunze C.L.	2002	AE F054014; substance technical: Acute toxicity to earthworms (*Eisenia fetida*) Code: AE F054014 00 1C99 0004 Generated by: Bayer CropScience AG, DEU; Development - Environmental Biology, Monheim Document No: C027501 GLP / GEP Yes unpublished	N	BCS
KCP 10.4/04	Memmert, U.	2000a	Effects of Fenoxaprop-P-ethyl, substance technical; code: AE F046360 on the development of sediment-dwelling larvae of Chironomus riparius in a watersediment system. Generated by: RCC Ltd., Environmental Chemistry & Pharmanalytics Division, CH-4452 Itingen, Switzerland Report No: Study project No. 732194 GLP / GEP: yes Unpublished	N	BCS
KCP 10.4/05	Moll M., Groer M.	2001	Effects of AE F046360 24 EW14 A715 on the parasitoid *Aphidius rhopalosiphi* (*Hymenoptera, Braconidae)* in the laboratory -dose response test- Code: AE F046360 24 EW14 A715 Generated by: IBACON GmbH, Rossdorf, DEU; Document No: C011097 GLP Yes Unpublished	N	BCS

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 10.4/06	Petto R.	1992	Effects of Hoe 046360 24 EW14 A203 on the reproduction of Aleochara bilineata Gyll. (Coleoptera, Staphylinidae) in laboratory Generated by: Res.Consult.Comp., DEU; Document No: A47601 GLP Yes Unpublished	N	BCS
KCP 10.4/07	Petto R., Klepka S.	1995	Effects of Hoe 046360 24 EW14 A203 on Pardosa amentata (Clerck) (Araneae, Lycosidae) in laboratory Generated by: Res.Consult.Comp., DEU; Document No: A54209 GLP Yes Unpublished	N	BCS
KCP 10.4/08	Pietrzik J.	1992	Determination of the side-effects of Hoe 046360 24 EW14 A203 on the ground beetle (*Poecilus cupreus* L.) in the laboratory Generated by: GAB Biotechnologie GmbH; Document No: A48217 GLP Yes Unpublished	N	BCS
KCP 10.4/09	Sowig P.	2002	Acute toxicity to earthworms (*Eisenia fetida*) Fenoxaprop-P substance, technical Code: AE F088406 00 1C97 0001 Generated by: Bayer CropScience GmbH, DEU; Ecotoxicology, Frankfurt Document No: C024170 GLP / GEP Yes Unpublished	N	BCS

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 10.5/01	McMurray A.	2002	Microflora respiration and nitrogen transformation according to OECD guideline numbers 216 and 217 Fenoxaprop-P-ethyl technical substance Code: AE F046360 00 1D96 0001 Generated by: Aventis CropScience GmbH, DEU; Ecotoxicology, Frankfurt Document No: C020914 GLP / GEP Yes unpublished	N	BCS

List of data submitted by the applicant and not relied on

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

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

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

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

Appendix 2 Detailed evaluation of the new studies

A 2.1 KCP 10.1 Effects on birds and other terrestrial vertebrates

A 2.1.1 KCP 10.1.1 Effects on birds

No additional studies were performed.

A 2.1.1.1 KCP 10.1.1.1 Acute oral toxicity

No additional studies were performed.

A 2.1.2 KCP 10.1.2 Effects on terrestrial vertebrates other than birds

No additional studies were performed.

A 2.1.2.1 KCP 10.1.2.1 Acute oral toxicity to mammals

No additional studies were performed.
All available data summarised in Section 6 (Mammalian Toxicology).

A 2.1.2.2 KCP 10.1.2.2 Higher tier data on mammals

No additional studies were performed.

A 2.1.3 KCP 10.1.3 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians)

No additional studies were performed.

A 2.2 KCP 10.2 Effects on aquatic organisms

A 2.2.1 KCP 10.2.1 Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes

A 2.2.1.1 Study 1

Comments of zRMS:	The study was not accepted as wrong endpoints were presented.

	Instead of LCx should be ECx derived.

Reference:	KCP 10.2/01
Report	CHR/H/FETEC-PART B 110 EC *Daphnia* sp., Acute Immobilisation Test; Szlauer, S.; Ecomelius Institute Sp. z o. o.; Kalinowa 2, Zaborze; Poland; STUDY CODE: EMI/4/536/2020, 2020
Guideline(s):	According to OECD Guideline No 202/EU test method C.2.
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test Item:	CHR/H/FETEC-PART B 110 EC batch no.: 2020012 Active substance concentration: Fenoxaprop-P-ethyl: 110.1 g/L Cloquintocet mexyl: 54.8 g/L
Test Species:	*Daphnia magna* was used in the study. The original source of the test system: Toxkit ephippia, Microbiotest, Kleimoer 15, 9030 Gent, Begium.
Test Design:	Semi-static test Exposure duration: 48 hours
Endpoints:	LC_{10}/48h; LC_{20}/48h; LC_{50}/48h; LOEC/48h; NOEC/48h
Test Concentrations:	9 test item concentrations: 0.48, 0.86, 1.55, 2.80, 5.04, 9.07, 16.33, 29.40, 52.92 mg/L
Test Conditions:	Temperature: measured temperature between 20.4 – 20.9°C Light condition: 16-hour light and 8-hour dark cycle; the measured average light intensity: 1481.37 lux

The impact of CHR/H/FETEC-PARTB 110 EC on *Daphnia magna* was investigated during a 48-hour toxicity study. Five daphnids in four replicates were exposed to the test item solutions.
Preliminary experiment (non-GLP) were performed in order to determine test item concentrations for the main experiment. In the preliminary experiment, 5 concentrations were used: 0.86, 2.8, 9.07, 29.40 and

95.26 mg/L. Concentrations were chosen based upon known toxicity data of the fenoxaprop-P-ethyl. Based on the results of the preliminary experiment, 9 concentrations for the main experiment plus control were selected. Chosen concentrations were: 0.48, 0.86, 1.55, 2.80, 5.04, 9.07, 16.33, 29.40, 52.92 mg/L (separation factor 1.8).
In relation to chemical determinations, samples of all test item concentrations and control were collected at the beginning of the experiment, after 24 hours of exposure in spent and fresh concentrations and at the end of the treatment. Active substance – fenoxaprop-P-ethyl and the safener – cloquintocet mexyl concentrations were determined using a validated liquid chromatography method with mass spectroscopy.
Number of immobilized daphnids at 24 and 48 hours after the beginning of the test and any abnormal behavior or appearance were reported.

Results

Immobilisation of *Daphnia magna* exposed to the test item, CHR/H/FETEC-PART B 110 EC, was investigated during a 48-hour static test. After 24 hours of exposure, in the test item concentrations R1 (0.48 mg/L), R2 (0.86 mg/L), R3 (1.55 mg/L), R4 (2.80 mg/L) and R5 (5.04 mg/L) daphnids had normal behavior and appearance similar to control group. In the test item concentration R6 (9.07 mg/L), daphnids were swimming slower and had normal appearance. In the test item concentrations R7 (16.33 mg/L), R8 (29.40 mg/L) and R9 (52.92 mg/L), daphnids were lying at the bottom, additionally in the test item concentrations R8 (29.40 mg/L) and R9 (52.92 mg/L), daphnids were white.
After 48 hours of exposure, in the test item concentrations R1 (0.48 mg/L), R2 (0.86 mg/L), R3 (1.55 mg/L) and R4 (2.80 mg/L) daphnids had normal behavior and appearance similar to control group. In the test item concentration R5 (5.04 mg/L) immobilized daphnids were trapped at the surface. In the test item concentrations R6 (9.07 mg/L) and R7 (16.33 mg/L), daphnids were lying at the bottom and were white.

Table 1. Observations and number of immobilized daphnids after 24 and 48 hours

Test item concentrations		After 24 h		After 48 h	
Nominal test item concentration [mg/L]	Test vessel	Number of immobilized organisms (x/5)	Behaviour and appearance	Number of immobilized organisms (x/5)	Behaviour and appearance
Control	K/A	0/5	Normal behaviour and appearance	0/5	Normal behaviour and appearance
	K/B	0/5		0/5	
	K/C	0/5		0/5	
	K/D	0/5		0/5	
R1 [0.48]	R1/A	0/5	Normal behaviour and appearance	0/5	Normal behaviour and appearance
	R1/B	0/5		0/5	
	R1/C	0/5		0/5	
	R1/D	0/5		0/5	
R2 [0.86]	R2/A	0/5	Normal behaviour and appearance	0/5	Normal behaviour and appearance
	R2/B	0/5		0/5	
	R2/C	0/5		0/5	
	R2/D	0/5		0/5	
R3 [1.55]	R3/A	0/5	Normal behaviour and appearance	0/5	Normal behaviour and appearance
	R3/B	0/5		0/5	
	R3/C	0/5		0/5	
	R3/D	0/5		0/5	
R4 [2.80]	R4/A	0/5	Normal behaviour and appearance	1/5	Normal behaviour and appearance
	R4/B	0/5		1/5	
	R4/C	0/5		0/5	
	R4/D	0/5		0/5	
R5 [5.04]	R5/A	0/5	Normal behaviour and appearance	1/5	Immobilised ones trapped at the surface
	R5/B	0/5		2/5	
	R5/C	0/5		0/5	
	R5/D	0/5		0/5	
R6 [9.07]	R6/A	2/5	Slower swimming, normal appearance	5/5	Lying at the bottom, white colour
	R6/B	1/5		5/5	
	R6/C	1/5		4/5	
	R6/D	2/5		5/5	
R7 [16.33]	R7/A	4/5	Lying at the bottom	5/5	Lying at the bottom, white colour
	R7/B	3/5		5/5	
	R7/C	5/5		5/5	
	R7/D	5/5		5/5	

Test item concentrations		After 24 h		After 48 h	
Nominal test item concentration [mg/L]	Test vessel	Number of immobilized organisms (x/5)	Behaviour and appearance	Number of immobilized organisms (x/5)	Behaviour and appearance
R8 [29.40]	R8/A	5/5	Lying at the bottom, white colour	5/5	Lying at the bottom, white colour
	R8/B	5/5		5/5	
	R8/C	5/5		5/5	
	R8/D	5/5		5/5	
R9 [52.92]	R9/A	5/5	Lying at the bottom, white colour	5/5	Lying at the bottom, white colour
	R9/B	5/5		5/5	
	R9/C	5/5		5/5	
	R9/D	5/5		5/5	

Table 2. Endpoint values based on the nominal test item concentrations [mg/L]

Endpoint value [mg/L]		After 24 h	After 48 h
LC_{10}	Test item	7.014 (4.508 – 6.681)	3.815 (2.547 – 4.677)
	Fenoxaprop-P-ethyl	0.746 (0.479 – 0.710)	0.406 (0.271 – 0.497)
	Cloquintocet mexyl	0.371 (0.239 – 0.353)	0.202 (0.135 – 0.247)
LC_{20}	Test item	8.691 (6.315 – 10.271)	4.667 (3.463 – 5.490)
	Fenoxaprop-P-ethyl	0.924 (0.671 – 1.092)	0.496 (0.368 – 0.584)
	Cloquintocet mexyl	0.460 (0.334 – 0.543)	0.247 (0.183 – 0.290)
LC_{50}	Test item	12.014 (10.133 – 13.729)	6.328 (5.346 – 7.203)
	Fenoxaprop-P-ethyl	1.277 (1.077 – 1.459)	0.673 (0.568 – 0.766)
	Cloquintocet mexyl	0.636 (0.536 – 0.726)	0.335 (0.283 – 0.381)
LOEC	Test item	9.070	2.800
	Fenoxaprop-P-ethyl	0.964	0.298
	Cloquintocet mexyl	0.480	0.148
NOEC	Test item	5.040	1.550
	Fenoxaprop-P-ethyl	0.536	0.165
	Cloquintocet mexyl	0.267	0.082

Table 8. The effects on immobility in *Daphnia magna*

Concentration [mg/L]	Total number of daphnids	After 24 h		After 48 h	
		Immobile	% immobility	Immobile	% immobility
Control	20	0	0	0	0
R1 [0.48]	20	0	0	0	0
R2 [0.86]	20	0	0	0	0
R3 [1.55]	20	0	0	0	0
R4 [2.80]	20	0	0	2	10
R5 [5.04]	20	0	0	3	15
R6 [9.07]	20	6	30	19	95
R7 [16.33]	20	17	85	20	100
R8 [29.40]	20	20	100	20	100
R9 [52.92]	20	20	100	20	100

VALIDITY CRITERIA

For the test to be valid, the following performance criteria specified in OECD Guideline No. 202 (2004) were met for both experimental parts:

• In the control 0% of daphnids were immobilized (criterium: not more than 10%);

• The concentration of dissolved oxygen in the test and control vessels was ≥ 3 mg/L at the end of the test.

Table 9. Calculations made on the basis of the nominal test item concentrations [mg/L] at the end of the experiment, with 95% confidence limit.

Endpoint value [mg/L]		After 48 h
LC_{10}	Test item	3.815 (2.547 – 4.677)
	Fenoxaprop-P-ethyl	0.406 (0.271 – 0.497)
	Cloquintocet mexyl	0.202 (0.135 – 0.247)
LC_{20}	Test item	4.667 (3.463 – 5.490)
	Fenoxaprop-P-ethyl	0.496 (0.368 – 0.584)
	Cloquintocet mexyl	0.247 (0.183 – 0.290)
LC_{50}	Test item	6.328 (5.346 – 7.203)
	Fenoxaprop-P-ethyl	0.673 (0.568 – 0.766)
	Cloquintocet mexyl	0.335 (0.283 – 0.381)
LOEC	Test item	2.800
	Fenoxaprop-P-ethyl	0.298
	Cloquintocet mexyl	0.148
NOEC	Test item	1.550
	Fenoxaprop-P-ethyl	0.165
	Cloquintocet mexyl	0.082

Comments of zRMS:	The study is acceptable for risk assessment. The study was conducted according to OECD guideline 202. The validity criteria were met. The study was conducted in a static system. Chemical analysis of active substances on the last day of the experiment (after 48 hours) showed that the measured concentration of active substances is not within the acceptable range of 80-120%. Since the Study Plan did not specify whether the test should be conducted as static or semi-static, according to OECD Guideline No. 202, “the test may be carried out using semi-static renewal or flow-through system when the concentration of the test substance is not stable”, it was decided to repeat the test in a semi-static system, with the medium exchange after 24 hours from the start of the test. The formulation was the test item. The following endpoints were derived: 48h EC_{50} = 6.328 mg formulation/L NOEC = 1.550 mg formulation/L (< EC_{10})

Reference: KCP 10.2/01-01

Report	Amendment No. 1 to the FINAL REPORT Daphnia sp., Acute Immobilisation Test; Szlauer, S.; Ecomelius Institute Sp. z o. o.; Kalinowa 2, Zaborze; Poland; STUDY CODE: EMI/4/536/2020, 2020
Guideline(s):	According to OECD Guideline No 202/EU test method C.2.
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test Item:	CHR/H/FETEC-PART B 110 EC batch no.: 2020012 Active substance concentration: Fenoxaprop-P-ethyl: 110.1 g/L Cloquintocet mexyl: 54.8 g/L
Test Species:	*Daphnia magna* was used in the study. The original source of the test system: Toxkit ephippia, Microbiotest, Kleimoer 15, 9030 Gent, Begium.
Test Design:	Semi-static test Exposure duration: 48 hours
Endpoints:	LC_{10}/48h; LC_{20}/48h; LC_{50}/48h; LOEC/48h; NOEC/48h
Test Concentrations:	9 test item concentrations: 0.48, 0.86, 1.55, 2.80, 5.04, 9.07, 16.33, 29.40, 52.92 mg/L
Test Conditions:	Temperature: measured temperature between 20.4 – 20.9°C Light condition: 16-hour light and 8-hour dark cycle; the measured average light intensity: 1481.37 lux

The impact of CHR/H/FETEC-PARTB 110 EC on *Daphnia magna* was investigated during a 48-hour toxicity study. Five daphnids in four replicates were exposed to the test item solutions.
Preliminary experiment (non-GLP) were performed in order to determine test item concentrations for the main experiment. In the preliminary experiment, 5 concentrations were used: 0.86, 2.8, 9.07, 29.40 and 95.26 mg/L. Concentrations were chosen based upon known toxicity data of the fenoxaprop-P-ethyl. Based on the results of the preliminary experiment, 9 concentrations for the main experiment plus control were selected. Chosen concentrations were: 0.48, 0.86, 1.55, 2.80, 5.04, 9.07, 16.33, 29.40, 52.92 mg/L (separation factor 1.8).
In relation to chemical determinations, samples of all test item concentrations and control were collected at

the beginning of the experiment, after 24 hours of exposure in spent and fresh concentrations and at the end of the treatment. Active substance – fenoxaprop-P-ethyl and the safener – cloquintocet mexyl concentrations were determined using a validated liquid chromatography method with mass spectroscopy. Number of immobilized daphnids at 24 and 48 hours after the beginning of the test and any abnormal behavior or appearance were reported.

Results

Immobilisation of *Daphnia magna* exposed to the test item, CHR/H/FETEC-PART B 110 EC, was investigated during a 48-hour static test. After 24 hours of exposure, in the test item concentrations R1 (0.48 mg/L), R2 (0.86 mg/L), R3 (1.55 mg/L), R4 (2.80 mg/L) and R5 (5.04 mg/L) daphnids had normal behavior and appearance similar to control group. In the test item concentration R6 (9.07 mg/L), daphnids were swimming slower and had normal appearance. In the test item concentrations R7 (16.33 mg/L), R8 (29.40 mg/L) and R9 (52.92 mg/L), daphnids were lying at the bottom, additionally in the test item concentrations R8 (29.40 mg/L) and R9 (52.92 mg/L), daphnids were white.
After 48 hours of exposure, in the test item concentrations R1 (0.48 mg/L), R2 (0.86 mg/L), R3 (1.55 mg/L) and R4 (2.80 mg/L) daphnids had normal behavior and appearance similar to control group. In the test item concentration R5 (5.04 mg/L) immobilized daphnids were trapped at the surface. In the test item concentrations R6 (9.07 mg/L) and R7 (16.33 mg/L), daphnids were lying at the bottom and were white.

Table 1. Observations and number of immobilized daphnids after 24 and 48 hours

Test item concentrations		After 24 h		After 48 h	
Nominal test item concentration [mg/L]	Test vessel	Number of immobilized organisms (x/5)	Behaviour and appearance	Number of immobilized organisms (x/5)	Behaviour and appearance
Control	K/A	0/5	Normal behaviour and appearance	0/5	Normal behaviour and appearance
	K/B	0/5		0/5	
	K/C	0/5		0/5	
	K/D	0/5		0/5	
R1 [0.48]	R1/A	0/5	Normal behaviour and appearance	0/5	Normal behaviour and appearance
	R1/B	0/5		0/5	
	R1/C	0/5		0/5	
	R1/D	0/5		0/5	
R2 [0.86]	R2/A	0/5	Normal behaviour and appearance	0/5	Normal behaviour and appearance
	R2/B	0/5		0/5	
	R2/C	0/5		0/5	
	R2/D	0/5		0/5	
R3 [1.55]	R3/A	0/5	Normal behaviour and appearance	0/5	Normal behaviour and appearance
	R3/B	0/5		0/5	
	R3/C	0/5		0/5	
	R3/D	0/5		0/5	
R4 [2.80]	R4/A	0/5	Normal behaviour and appearance	1/5	Normal behaviour and appearance
	R4/B	0/5		1/5	
	R4/C	0/5		0/5	
	R4/D	0/5		0/5	
R5 [5.04]	R5/A	0/5	Normal behaviour and appearance	1/5	Immobilised ones trapped at the surface
	R5/B	0/5		2/5	
	R5/C	0/5		0/5	
	R5/D	0/5		0/5	
R6 [9.07]	R6/A	2/5	Slower swimming, normal appearance	5/5	Lying at the bottom, white colour
	R6/B	1/5		5/5	
	R6/C	1/5		4/5	
	R6/D	2/5		5/5	
R7 [16.33]	R7/A	4/5	Lying at the bottom	5/5	Lying at the bottom, white colour
	R7/B	3/5		5/5	
	R7/C	5/5		5/5	
	R7/D	5/5		5/5	

Test item concentrations		After 24 h		After 48 h	
Nominal test item concentration [mg/L]	Test vessel	Number of immobilized organisms (x/5)	Behaviour and appearance	Number of immobilized organisms (x/5)	Behaviour and appearance
R8 [29.40]	R8/A	5/5	Lying at the bottom, white colour	5/5	Lying at the bottom, white colour
	R8/B	5/5		5/5	
	R8/C	5/5		5/5	
	R8/D	5/5		5/5	
R9 [52.92]	R9/A	5/5	Lying at the bottom, white colour	5/5	Lying at the bottom, white colour
	R9/B	5/5		5/5	
	R9/C	5/5		5/5	
	R9/D	5/5		5/5	

Table 2. Endpoint values based on the nominal test item concentrations [mg/L]

Endpoint value [mg/L]		After 48 h
EC_{10}	Test item	3.815 (2.547 – 4.677)
	Fenoxaprop-P-ethyl	0.406 (0.271 – 0.497)
	Cloquintocet mexyl	0.202 (0.135 – 0.247)
EC_{20}	Test item	4.667 (3.463 – 5.490)
	Fenoxaprop-P-ethyl	0.496 (0.368 – 0.584)
	Cloquintocet mexyl	0.247 (0.183 – 0.290)
EC_{50}	Test item	6.328 (5.346 – 7.203)
	Fenoxaprop-P-ethyl	0.673 (0.568 – 0.766)
	Cloquintocet mexyl	0.335 (0.283 – 0.381)
LOEC	Test item	2.800
	Fenoxaprop-P-ethyl	0.298
	Cloquintocet mexyl	0.148
NOEC	Test item	1.550
	Fenoxaprop-P-ethyl	0.165
	Cloquintocet mexyl	0.082

Table 8. The effects on immobility in *Daphnia magna*

Concentration [mg/L]	Total number of daphnids	After 24 h		After 48 h	
		Immobile	% immobility	Immobile	% immobility
Control	20	0	0	0	0
R1 [0.48]	20	0	0	0	0
R2 [0.86]	20	0	0	0	0
R3 [1.55]	20	0	0	0	0
R4 [2.80]	20	0	0	2	10
R5 [5.04]	20	0	0	3	15
R6 [9.07]	20	6	30	19	95
R7 [16.33]	20	17	85	20	100
R8 [29.40]	20	20	100	20	100
R9 [52.92]	20	20	100	20	100

VALIDITY CRITERIA

For the test to be valid, the following performance criteria specified in OECD Guideline No. 202 (2004) were met for both experimental parts:

• In the control 0% of daphnids were immobilized (criterium: not more than 10%);

• The concentration of dissolved oxygen in the test and control vessels was ≥ 3 mg/L at the end of the test.

Table 9. Calculations made on the basis of the nominal test item concentrations [mg/L] at the end of the experiment, with 95% confidence limit.

Endpoint value [mg/L]		After 48 h
EC_{10}	Test item	3.815 (2.547 – 4.677)
	Fenoxaprop-P-ethyl	0.406 (0.271 – 0.497)
	Cloquintocet mexyl	0.202 (0.135 – 0.247)
EC_{20}	Test item	4.667 (3.463 – 5.490)
	Fenoxaprop-P-ethyl	0.496 (0.368 – 0.584)
	Cloquintocet mexyl	0.247 (0.183 – 0.290)
EC_{50}	Test item	6.328 (5.346 – 7.203)
	Fenoxaprop-P-ethyl	0.673 (0.568 – 0.766)
	Cloquintocet mexyl	0.335 (0.283 – 0.381)
LOEC	Test item	2.800
	Fenoxaprop-P-ethyl	0.298
	Cloquintocet mexyl	0.148
NOEC	Test item	1.550
	Fenoxaprop-P-ethyl	0.165
	Cloquintocet mexyl	0.082

A 2.2.1.2 Study 2

Comments of zRMS:	The study is acceptable for risk assessment. The study was conducted according to OECD guideline 201. The formulation CHR/H/FETEC-PART B 110 EC was the test item. The validity criteria were met: • yield in control during 72 hours of test increased exponentially 184.1 times (requirements according to OECD 201: ≥16); • the coefficient of variance for the average specific growth rate for all repetitions of the control culture over the entire time of the test was 0.3% (requirements according to OECD 201: <7%) • the average coefficient of variance for a specific growth rate day after day (0-24 h, 24-48 h, 48-72 h) for the control culture was 29.1% (requirements according to OECD 201: <35%). and no deviation was reported. The following endpoints were derived:

	72 h	
	Growth rate	Yield
	nominal concentration mg formulation/L	
EC_{10}	0.392	0.262
EC_{50}	0.826	0.445
NOEC	< 0.520	< 0.520
LOEC	≤ 0.520	≤ 0.520

Reference:	KCP 10.2/02
Report	Freshwater algae (*Raphidocelis subcapitata*) growth inhibition test of the test item CHR/H/FETEC-PART B 110 EC; Domagała, J.; SORBOLAB Research Laboratory LLC, Zaniemyska Street 11, 61-029 Poznań, Poland Study Code: 0038/0111/E
Guideline(s):	according to OECD 201 guideline
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test Item: CHR/H/FETEC-PART B 110 EC
Fenoxaprop-P-ethyl : 109.01 g/L; Cloquintocet-mexyl: 53.52 g/L,

batch no.: 2020012
production date: 01.04.2020
expiry date: 01.04.2022

Test Species:	*Raphidocelis subcapitata,* obtained from culture from Laboratory of Ecotoxicology in SORBOLAB Research Laboratory. The organisms originally came from the Academy of Sciences of the Czech Republic, v.v.i. Institute of Botany, Třeboň, Czech Republic, collection CCAP 278/4.
Test Design:	**Stabillity test:** tested concentration and control in 2 replicates (test item solutions and test item solutions inocululated with algae) **Range-finding:** tested concentrations in 2 replicates and control in 4 replicates **Definitive test**: tested concentration in 3 replicates and control in 6 replicates
Test Concentration:	**Stability test:** control (0 mg/L); 1.0 mg/L; 100 mg/L **Range finding test:** control (0 mg/L); 1 mg/L; 10 mg/L; 100 mg/L **Definitive test:** control (0 mg/L) nominal concentration 0.666 mg/L (corresponds to determined 0.52 mg/L) nominal concentration 1.332 mg/L (corresponds to determined 0.92 mg/L) nominal concentration 2.664 mg/L (corresponds to determined 1.64 mg/L) nominal concentration 5.328 mg/L (corresponds to determined 3.95 mg/L) nominal concentration 10.656 mg/L (corresponds to determined 7.91 mg/L)
Test Conditions:	**Stability test:** average temperature 22.875°C (min 22.0°C, max 23.7°C) continuous fluorescent lightening: 6450-6850 lux **Range-finding** test: average temperature 22.883°C (min 22.0°C, max 23.7°C) continuous fluorescent lightening: 6450-6850 lux **Definitive test:** average temperature 22.933°C (min 22.1°C, max 23.9°C) continuous fluorescent lightening: 6490-6870 lux

The stability test was performed for the concentrations of 1 mg of test item/L of medium, 100 mg of test item/L of medium and controI (0 mg of test item/L of medium). All test item concentrations and control group was prepared in two replicates. An algae inoculum was introduced into one replicate of each concentration.
The range-finding test was performed to determine the number and range of doses of the test item to be used in the definitive test. The following concentrations of the test item was used in the range-finding test:

1 mg of test item/L of medium, 10 mg of test item/L of medium, 100 mg of test item/L of medium and control (0 mg of test item/L of medium). All concentrations of the test item was prepared in two replicates and the control in four. In addition, one replicate was prepared for each concentration without the addition of algae to measure background absorbance.

The definitive test was carried out with the use of the following doses of the test item: control (0 mL of test item/L of medium), 0.666 mg of test item/L of medium, 1.332 mg of test item/L of medium, 2.664 mg of test item/L of medium, 5.328 mg of test item/L of medium and 10.656 mg of test item/L of medium. All concentrations of the test item was prepared in three replicates. The control, which was the medium without the addition of the test item was consist of 6 replicates. Additionally, one replicate of each concentration was prepared without the addition of algae to measure the background absorbance. Separate replicates was also be prepared and treated identically to the test (including the presence of algae) for chemical analysis. The flasks were arranged randomly in accordance with SPT-E/55 procedure. The inoculum volume was 10000 cells/mL, and the preculture was established 4 days before the study. The experiment was carried out using the static method.

Results
In course of the experiment, the test item CHR/H/FETEC-PART B 110 EC shown effect on the freshwater algae *Raphidocelis subcapitata* in yield and average specific growth rate in the concentrations range from 0.52 mg/L to 7.91 mg/L (nominal concentrations 0.666 mg/L-10.656 mg/L) and sectional specific growth rate in the concentration range from 0.92 mg/L to 7.91 mg/L (nominal concentrations 1.332 mg/L – 10.656 mg/L).

A 2.2.1.3 Study 3

Comments of zRMS:	The study is acceptable for risk assessment. The study was conducted according to OECD guideline 201. The formulation CHR/H/FETEC-PART B 110 EC was the test item. The validity criteria were met: • yield in control during 72 hours of test increased exponentially 97.1 times (requirements according to OECD 201: ≥16); • the coefficient of variance for the average specific growth rate for all repetitions of the control culture over the entire time of the test was 1.8% (requirements according to OECD 201: <7%) • the average coefficient of variance for a specific growth rate day after day (0-24 h, 24-48 h, 48-72 h) for the control culture was 6.5% (requirements according to OECD 201: <35%). The deviation in test temperature was reported. The temperature value was slightly lower and short-lived- after 30 min. temperature returned to the required range, and was in the required range to the end of the test. The above deviations did not affect the test result. The following endpoints were derived:

			72 h		
			Growth rate	Yield	
			nominal concentration mg formulation/L		
		EC_{10}	1.245	< 0.324	
		EC_{50}	1.646	1.040	
		NOEC	0.634	< 0.324	
		LOEC	1.294	≤ 0.324	

Reference:	KCP 10.2/03
Report	Freshwater alga (*Navicula pelliculosa*) growth inhibition test of the test item CHR/H/FETEC-PART B 110 EC; Woźniak, A., SORBOLAB Research Laboratory LLC; Zaniemyska Street 11 61-029 Poznań, Poland; Study code: 0038/0110/E
Guideline(s):	according to OECD 201 guideline
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test Item:	CHR/H/FETEC-PART B 110 EC Fenoxaprop-P-ethyl : 109.01 g/L; Cloquintocet-mexyl: 53.52 g/L, batch no.: 2020012 production date: 01.04.2020 expiry date: 01.04.2023
Test Species:	The study was conducted on diatoms from the family of Naviculaceae - *Navicula pelliculosa* (strain CCAP 1050/9) originating from the culture conducted by the Department of Ecotoxicology IOS-PIB in Warsaw.
Test Design:	**Stability test:** tested concentrations and control in one repetition **Range finding test**: tested concentrations in two repetitions and control in four repetitions **Definitive test:** tested concentrations in three repetitions and control in six repetitions
Test Concentration:	**Stability test:** control (0 mg/L); 1 mg/L; 100 mg/L

Range finding test:
control (0 mg/L); 1 mg/L; 10 mg/L; 100 mg/L**
Range finding test:
control (0 mg/L); 1 mg/L; 5 mg/L; 10 mg/L
Definitive test:
nominal concentrations:
control (0 mg/L); 0.625 mg/L; 1.25 mg/L; 2.5 mg/L; 5.0 mg/L, 10 mg/L
geometric mean of the measured concentration
control (0 mg/L); 0.324 mg/L; 0.634 mg/L; 1.294 mg/L; 2.551 mg/L, 5.440 mg/L

** The range- finding test was repeated due to failure of the test validation criteria - the mean coefficient of variation of replicate over time was 128.3 %. Maximum value of this validation criterion is <35.0%.

Test Conditions:

Stability test – test conditions:
average temperature 22.719°C (min 22.5°C, max 22.80°C)
continuous fluorescent lighting: 3350-4300 lux
Stability test – storage and transport conditions:
average temperature for storage and transport conditions -19.247°C (min -18.1.°C, max -20.3°C)*
darkness during the stability test under storage and transport conditions
Range finding test:
average temperature 21.925°C (min 21.6°C, max 22.4°C)
continuous fluorescent lighting 3750-4250 lux
Definitive test:
average temperature 21.200°C (min 20.8°C, max 21.7°C)***
continuous fluorescent lighting 3760-4200 lux

*** Deviations from the Study plan was found, concerning change in temperature.

In order to determine the stability of the test item solution under the experimental and storage and transport conditions, the test vessels containing the test item solution in the appropriate concentration and without addition of the test item (control) were stored under the above-mentioned conditions. Then, analytical determinations were performed.
The stability test was performed at the Test Facility. The f/2+Si medium was transported for the test in temperature 2-15°C and next stored until test in temperature 6±2°C. The following concentrations of the test item were used in the stability test: 1 mg/L, 100 mg/L, and control (0 mg/L). All concentrations of the test item and control were prepared in one replicate for the experimental and storage and transport conditions.

In order to determine the dose range of the test item in the definitive test, a range-finding test was performed.* The following concentrations of the test item were used in the range-finding test: 1 mg/L, 5 mg/L, 10 mg/L and control. All concentrations of the test item were prepared in two replicates and the control in four. In addition, one replicate was prepared for each concentration without the addition of algae

to measure background absorbance. During the range-finding test the chemical analysis was not performed.

* The range- finding test, was repeated due to failure of the test validation criteria - the mean coefficient of variation of replicate over time was 128.3 %. Maximum value of this validation criterion is <35.0%.

All concentrations of the test item were prepared in three replicates. The control, which was the f/2+Si medium without the addition of the test item consisted of 6 replicates.
The following nominal concentrations of the test item were used in the definitive test: 0.625 mg/L, 1.25 mg/L, 2.5 mg/L, 5 mg/L, 10 mg/L and control. All concentrations of the test item were prepared in three replicates. The control, which was the f/2+Si medium without the addition of the test item consisted of 6 replicates.

Results
The test item in the course of the present test show a statistically significant effect on the yield of *Navicula pelliculosa* in the nominal concentrations 0.625 mg/L to 10.0 mg/L (corresponding to 0.324 mg/L to 5.44 mg/L of geometric mean of determined concentrations), the average specific growth rate of *Navicula pelliculosa* in the nominal concentrations 2.5 mg/L to 10 mg/L (corresponding to 1.294 mg/L to 5.44 mg/L of geometric mean of determined concentrations), and the sectional growth rate of *Navicula pelliculosa* algae in the nominal concentrations 5 mg/L and 10 mg/L (corresponding to 2.551 mg/L to 5.44 mg/L of geometric mean of determined concentrations).

Table 1. Final results

Results calculated by ToxRat Professional using geometric mean of the measured concentration			
Parameter	**Yield**	**Average specific growth rate**	**Sectional average specific growth rate**
EC_{10} - 72 h [mg/L]	<0.324*	1.245	0.654
EC_{20} - 72 h [mg/L]	0.428	1.370	1.248
EC_{50} - 72 h [mg/L]	1.040	1.646	4.300
LOEC - 72 h [mg/L]	≤0.324	1.294	2.551
NOEC - 72 h [mg/L]	<0.324	0.634	1.294

EC_{10} effective concentration of test item for 10% reduction
EC_{20} effective concentration of test item for 20% reduction
EC_{50} effective concentration of test item for 50% reduction
LOEC lowest observe effective concentration cause statistically significant differences in comparison to the control
NOEC highest non observe effective concentration cause no statistically significant differences in comparison to the control
* based on the interpretation of the results

A 2.2.1.4 Study 4

Comments of zRMS:	The study is acceptable for risk assessment. The study was conducted according to OECD guideline 221. The formulation CHR/H/FETEC-PART B 110 EC was the test item. The validity criteria were met: • duckweed frond number doubling time in control: 1.6 day (required according to OECD 221: <2.5 days) • average growth rate was 0.435/day (required according to OECD 221: >0.275/day). The deviation in test temperature was reported. from the Study plan was found concerning change of day of observations and reading in definitive test and change of Study Code of reference test. This deviation had no effect on the course of the study and obtained results. The following endpoints were derived:

	72 h	
	Growth rate	Yield
	mg formulation/L	
EC_{10}	6.496	2.153
EC_{50}	22.892	11.480
NOEC	0.700	0.700
LOEC	2.150	2.150

Reference:	KCP 10.2/04
Report	*Lemna gibba* growth inhibition test of the test item CHR/H/FETEC-PART B 110 EC; Kubisiak, K.; SORBOLAB Research Laboratory LLC, Zaniemyska Street 11, 61-029 Poznań, Poland Study Code: 0038/0112/E
Guideline(s):	according to OECD guideline 221
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test Item:	CHR/H/FETEC-PART B 110 EC Fenoxaprop-P-ethyl : 109.01 g/L; Cloquintocet-mexyl: 53.52 g/L, batch no.: 2020012 production date: 01.04.2020 expiry date: 01.04.2023

Test Species:	The test was conducted on gibbous duckweed (*Lemna gibba*) acquired primary from the University of Waterloo in Canada the Canadian Phycological Culture Center (CPCC).
Test Design:	**Stability test:** - test item concentrations and control in one replicate. **Range-finding test:** - test item concentrations and control in two replicates. **Definitive test:** - test item concentrations in three replicates and control in six replicates.
Test Concentration:	**Stability test:** - control (20xAAP medium) - 1 mg of test item/L of 20xAAP medium - 81 mg of test item/L of 20xAAP medium **Range-finding test:** - control (20xAAP medium) - 0.1 mg of test item/L of 20xAAP medium - 1 mg of test item/L of 20xAAP medium - 10 mg of test item/L of 20xAAP medium - 100 mg of test item/L of 20xAAP medium **Definitive test:** - control (20xAAP medium) - 1 mg of test item/L of 20xAAP medium (determined geometric mean: 0.70 mg of test item/L of 20xAAP medium) - 3 mg of test item/L of 20xAAP medium (determined geometric mean: 2.15 mg of test item/L of 20xAAP medium) - 9 mg of test item/L of 20xAAP medium (determined geometric mean: 6.77 mg of test item/L of 20xAAP medium) - 27 mg of test item/L of 20xAAP medium (determined geometric mean: 20.24 mg of test item/L of 20xAAP medium) - 81 mg of test item/L of 20xAAP medium (determined geometric mean: 67.13 mg of test item/L of 20xAAP medium)
Test Conditions:	**Stability test**: - average medium temperature 24.200°C (min 22.0°C; max 24.4°C) - continuous fluorescent lighting: 112.18-118.04 µE·m-2·s-1 **Range-finding test:** - average medium temperature 23.864°C (min 23.8°C; max 24.5°C) - continuous fluorescent lighting: 112.97-117.74 µE·m-2·s-1 **Definitive test:** - average medium temperature 23.904°C (min 23.7°C; max 24.4°C) - continuous fluorescent lighting: 114.25-123.11 µE·m-2·s-1

In order to determine the stability of the test item in test conditions, a stability test was performed. The stability test was carried out for the lowest and highest concentrations of the test item that were used in the definitive test: 1 mg of the test item/L of 20xAAP medium and 81 mg of the test item/L of 20xAAP medium and control (20xAAP medium).
In order to determine the number and range of concentrations of the test item for stability test and for definitive test the range-finding test was performed. During the range-finding test, chemical analytics of solutions was not performed. Due to the stability test not being performed, range-finding test was performed as a semi-static test with test item solutions renewal every 24 h since start of the test.

Results
The test item in the course of the test showed a toxic effect on frond number yield, frond number growth rate, dry weight yield, dry weight growth yield and dry weight sectional growth rate of gibbous duckweed *Lemna gibba* in the nominal concentration range from 3 mg/L to 81 mg/L (corresponds to geometric mean of determined concentrations range from 2.150 mg/L to 67.130 mg/L) as well as on frond number sectional growth rate in the nominal concentration range from 9 mg/L to 81 mg/L (corresponds to geometric mean of determined concentration range from 6.770 mg/L to 67.130 mg/L). LOEC and NOEC values have been determined for all rated values.

Table 1. Final results

Final results of definitive test calculated by ToxRat Professional using geometric mean of the measured concentrations*					
Rated value	EC_{10} [mg/L]	EC_{20} [mg/L]	EC_{50} [mg/L]	LOEC [mg/L]	NOEC [mg/L]
Frond number yield	2.153	3.825	11.480	2.150**	0.700**
Frond number growth rate	6.496	10.010	22.892	2.150**	0.700**
Frond number sectional	5.900	8.644	17.950	6.770**	2.150**
Dry weight yield	2.443	3.921	9.692	2.150**	0.700**
Dry weight growth rate	6.528	9.930	22.149	2.150**	0.700**
Dry weight sectional	6.528	9.930	22.149	2.150**	0.700**

EC_{10} effective test item concentration causing reduction by 10%
EC_{20} effective test item concentration causing reduction by 20%
EC_{50} effective test item concentration causing reduction by 50%
NOEC the highest no observed effect concentration that cause no statistically significant differences in comparison to the control
LOEC the lowest observed effect concentration that cause statistically significant differences in comparison to the control
* statistical data analysis in the definitive test was carried out using the geometric mean of determined concentrations of the test item at the beginning and the end of each renewal period
** geometric mean of 0.700 mg/L corresponds to 1 mg/L of nominal concentration, geometric mean of 2.150 mg/L corresponds to 3 mg/L of nominal concentration, geometric mean of 6.770 mg/L corresponds to 9 mg/L of nominal concentration

A 2.2.2 KCP 10.2.2 Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms

No additional studies were performed.

A 2.2.3 KCP 10.2.3 Further testing on aquatic organisms

No additional studies were performed.

A 2.3 KCP 10.3 Effects on arthropods

A 2.3.1 KCP 10.3.1 Effects on bees

A 2.3.1.1 KCP 10.3.1.1 Acute toxicity to bees

A 2.3.1.1.1 KCP 10.3.1.1.1 Acute oral toxicity to bees

Comments of zRMS:	The study was accepted. The study was conducted in accordance with OECD guidance 213 (acute oral). The validity criteria were met: • the average mortality for the total number of controls was 6.7% at the end of the experiment (criterion: it must not exceed 10%). • the 24 h LD_{50} of the reference item (dimethoate technical) was 0.226 µg a.i./bee (criterion: 0.10 - 0.35 µg a.i./bee).; The following endpoint was derived: LD_{50} 48 h >200 µg formulation/bee

Reference:	KCP 10.3.1.1/01
Report	Honeybees (*Apis mellifera* L.), Acute Oral Toxicity Test; Grzesica, M.; Ecomelius Institute Sp. z o. o. Kalinowa 2, Zaborze 43-520 Chybie, Poland; Study code: EMI/4/538/2020; 2020
Guideline(s):	according to the OECD Guideline for the Testing of Chemicals No. 213 (1998)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test Item:	CHR/H/FETEC-PARTB 110 EC Fenoxaprop-P-ethyl : 110.1 g/L; Cloquintocet-mexyl: 54.8 g/L, batch no.: 2020012 production date: 01.04.2020 expiry date: 01.04.2022

Test Species: the honeybee, *Apis mellifera* L., strain: carnica
– age: approximately 3 weeks

Test Design: **-the test item:**
- exposure duration: 48 hours
- number of doses: 5 doses and a control
- number of replicates: 3 replicates
- number of bees: 10 bees/replicate

-the reference item:
- exposure duration: 24 hours
- number of doses: 3 doses
- number of replicates: 3 replicates
- number of bees: 10 bees/replicate

Endpoints: – honeybee mortality after 24 and 48 hours of the exposure,
– the oral LD_{50}/24 h of the reference item (dimethoate).

Test Concentration: 12.5, 25.0, 50.0, 100.0 and 200.0 µg test item/bee and a control (0.0 µg/bee)

Test Conditions:

Conditions	Temperature (required: 25 ± 2°C)	Relative air humidity (required: 50 - 70%)
Preliminary experiment (Figure 3)	24.5 – 26.0°C	55.8 – 59.4%
Main experiment (Figure 4)	23.9 – 29.4°C	59.9 – 79.0%

Preliminary non-GLP test

In the preliminary and in the main experiment, the test item was mixed with the 50% saccharose solution. In the preliminary experiment the highest dose of the test item of 200.0 µg/bee was prepared. For this purpose 200 mg of the test item was weighed into a volumetric flask with a capacity of 10 mL. Then, the flask was filled up to the total volume of 10 mL with the saccharose solution. In the preliminary experiment the remaining liquids of the test item at the doses of 40.0 and 8.0 µg/bee were prepared by making sequential 1:4 dilutions with the 50% saccharose solution (volume per volume).

Definitive test

In the main experiment the highest dose of the test item of 200.0 µg/bee was prepared. For this purpose 200 mg of the test item were weighed into a glass flask with a capacity of 10 mL. Then, the flask was filled up to the total volume of 10 mL with the saccharose solution. The remaining liquids of the test item at the doses of 100.0, 50.0, 25.0, and 12.5 µg/bee were prepared by making sequential 1:1 dilutions with the 50% saccharose solution (v/v).
In the main experiment dimethoate technical was used in the study in order to verify the sensitivity of the test system and the susceptibility of the bees. Dimethoate technical at three different doses was administered orally. They included the one expected to be the LD_{50} value mentioned in the OECD Guideline for the Testing of Chemicals No. 213 and the EU Method C.16. A separation factor was 2. On

average, each insect received 0.1, 0.2, or 0.4 µg of the active ingredient in 10 µL of the 50% saccharose solution. The route of administration was the same as in case of the test item.
A stock solution, i.e. R0 (4 µg of dimethoate in a 10 µL of ultra-pure water) was prepared. For this purpose 40 mg of the reference item was weighed into a glass flask with a capacity of 100 mL, and filled up to 100 mL with ultra-pure water. A solution R1 at the dose of 0.4 µg/10 µL was prepared by measuring 1.0 mL of the liquid R0 and filling up to 10 mL with the 50% saccharose solution. The doses of 0.2 and 0.1 µg/10 µL were obtained by making sequential 1:1 dilutions with the 50% saccharose solution (volume per volume). The results refer to all doses, time points and replicates, and they are presented in the form of raw data collected during the observations.

Result and discussion

Mortality of the control group after 48 hours of exposure was 0.0%. The percentages of mortality of the bees treated with the test item at the doses of 8.0, 40.0, and 200.0 µg/honeybee were 0.0, 0.0 and 30.0%, respectively. No abnormal behavioural effects were observed during the experiment.

Mortality of the bees in the control group after 48 hours of exposure was 6.7%. The corrected mortality percentages (mortality corrected using the formula of Abbott), of the bees treated groups 12.5 25.0, 50.0, 100 and 200.0 µg/honeybee after 48 hours of exposure were 0.0, 0.0, 0.0, 0.0 and 28.6% respectively. Sublethal toxicity effects (behavioural abnormalities) such as affected bees were observed after 4 h in the doses 100.0 and 200.0 µg/honeybee.
The median lethal doses (LD_{50}/48 h oral) are higher than the highest dose used in the test, i.e. 200.0 µg/honeybee.
The reduction after 24 and 48 h ranged from 9.0 to 72.7% as compared to the control. The median lethal dose of dimethoate (LD_{50} oral) after 24 hours determined with the log-probit method, with 95% confidence limits is 0.226 µg a.i./bee (confidence limits: 0.182 - 0.289 µg a.i./bee). In the group treated with the test item no abnormal behavioural effects were observed.

Table 1. Honeybee mortality after 24 hours of exposure – preliminary experiment

Dose	Initial number of tested bees [no.]	Mortality	
		Number of dead bees [no.]	Total
[µg/bee]		Replicate	
		I	[%]
0.0 (Control)	10	0/10	**0.0**
8.0	10	0/10	**0.0**
40.0	10	0/10	**0.0**
200.0	10	3/10	**30.0**

The preliminary experiment lasted from 05 to 07 May 2021.

Table 2. Honeybee mortality after 48 hours of exposure – preliminary experiment

Dose [µg/bee]	Initial number of tested bees [no.]	Mortality	
		Number of dead bees [no.] Replicate I	Total [%]
0.0 (Control)	10	0/10	**0.0**
8.0	10	0/10	**0.0**
40.0	10	0/10	**0.0**
200.0	10	3/10	**30.0**

Table 3. Honeybee mortality after 4 hours of exposure – main experiment

Dose [µg/bee]	Number of tested bees [no.]	Mortality				
		Number of dead bees [no.] Replicates			Total	
		I	II	III	[no.]	[%]
0.0 (Control)	**30**	0	0	0	0	**0.0**
12.5	**30**	0	0	0	0	**0.0**
25.0	**30**	0	0	0	0	**0.0**
50.0	**30**	0	0	0	0	**0.0**
100.0	**30**	0	0	0	0	**0.0**
200.0	**30**	0	0	0	0	**0.0**

The main experiment lasted from 05 to 07 May 2021.

Table 4. Honeybee mortality and the LD_{50} after 24 hours of exposure – main experiment

Dose [µg/bee]	Number of tested bees [no.]	Mortality						LD_{50}
		Number of dead bees [no.] Replicates			Total			
		I	II	III	[no.]	[%]	[%][e]	[µg/bee]
0.0 (Control)	**30**	0	1	0	1	**3.3**	**-**	>200.0
12.5	**30**	0	0	0	0	**0.0**	**0.0**	
25.0	**30**	0	0	0	0	**0.0**	**0.0**	
50.0	**30**	0	0	0	0	**0.0**	**0.0**	
100.0	**30**	1	0	0	1	**3.3**	**0.0**	
200.0	**30**	3	3	2	8	**26.7**	**24.1**	

[e]: the control response of 3.3% was compensated using Abbott's formula [5].

Table 5. Honeybee mortality and the LD_{50} after 48 hours of exposure – main experiment

Dose [µg/bee]	Number of tested bees [no.]	Mortality						LD_{50}
		Number of dead bees [no.] Replicates			Total			
		I	II	III	[no.]	[%]	[%][e]	[µg/bee]
0.0 (Control)	30	0	1	1	2	6.7	-	>200.0
12.5	30	0	0	1	1	3.3	0.0	
25.0	30	0	1	0	1	3.3	0.0	
50.0	30	1	0	0	1	3.3	0.0	
100.0	30	1	0	1	2	6.7	0.0	
200.0	30	3	3	4	10	33.3	28.6	

[e]: the control response of 6.7% was compensated using Abbott's formula [5].
The main experiment lasted from 15 to 17 June 2021.

Table 6. Behavioural effects on honeybees – main experiment.

Dose [µg/bee]	Time of exposure / replicates	4 h	24 h	48 h
		Number of bees showing signs of toxicity* / number of living bees		
0.0 (control)	I	0/10	0/10	0/10
	II	0/10	0/9	0/9
	III	0/10	0/10	0/9
12.2	I	0/10	0/10	0/10
	II	0/10	0/10	0/10
	III	0/10	0/10	0/9
25.0	I	0/10	0/10	0/10
	II	0/10	0/10	0/9
	III	0/10	0/10	0/10
50.0	I	0/10	0/10	0/9
	II	0/10	0/10	0/10
	III	0/10	0/10	0/10
100.0	I	1a/10	0/9	0/9
	II	0/10	0/10	0/10
	III	1a/10	0/10	0/9
200.0	I	2a/10	0/7	0/7
	II	3a/10	0/7	0/7
	III	3a/10	0/8	0/6

Signs of toxicity:
m - moribund c - cramps v - vomiting
a - affected ap - apathy

Table 7. Saccharose solution consumption after 24 and 48 hours [mg] – main experiment

Dose [µg/bee]	Time of exposure							
	24 h				48 h			
	Replicates							
	I	II	III	Σ	I	II	III	Σ
0.0 (Control)	1775	1497	1669	**4941**	1011	676	1105	**2792**
12.5	917	1498	1429	**3844**	932	835	792	**2559**
25.0	1275	1404	1441	**4120**	836	853	939	**2628**
50.0	328	499	521	**1348**	269	270	512	**1051**
100.0	355	796	699	**1850**	302	289	339	**930**
200.0	348	619	709	**1676**	571	417	286	**1274**

Table 8. Average food consumption per bee [mg] and difference in food consumption between the treated and the control groups [%] – main experiment

Dose [µg/bee]	Food consumption per bee [mg]		Difference in food consumption compared to the control [%]	
	Time of exposure			
	24 h	48 h	24 h	48 h
0.0 (Control)	54.90	32.90	-	
12.5	42.71	28.43	22.2	11.4
25.0	45.78	29.20	16.6	9.0
50.0	14.98	11.68	72.7	63.6
100.0	20.56	10.69	62.6	66.7
200.0	18.62	19.30	66.1	39.9

Table 9. Honeybee mortality after 4 hours of exposure on the reference item (dimethoate technical) – main experiment

Dose [µg a.i./bee]	Number of tested bees [no.]	Mortality				
		Number of dead bees [no.] Replicates			Total	
		I	II	III	[no.]	[%]
0.0 (control)	30	0	0	0	0	0.0
0.10	30	0	0	0	0	0.0
0.20	30	0	0	1	1	3.3
0.40	30	2	2	2	6	20.0

Table 10. Honeybee mortality after 24 hours of exposure on the reference item (dimethoate technical) – main experiment

Dose [µg a.i./bee]	Number of tested bees [no.]	Mortality						LD_{50} [µg a.i./bee]
		Number of dead bees [no.] Replicates			Total			
		I	II	III	[no.]	[%]	[%]*	
0.0 (control)	30	0	1	0	1	3.3	-	0.226 (0.182 - 0.289)*
0.10	30	2	1	2	5	16.7	13.8	
0.20	30	4	5	4	13	43.3	41.4	
0.40	30	7	8	9	24	80.0	79.3	

*: the control response of 3.3% was compensated using Abbott's formula [5].
*: the LD_{50} (with 95% confidence limits) was calculated with the log-probit method (ToxRat Proffesional 3.3.0 computer) [SOP/P/28]

The validity criteria

The following validity criteria were met during the test:
- the average mortality for the total number of controls was 6.7% at the end of the experiment (criterion: it must not exceed 10%).
- the 24 h LD_{50} of the reference item (dimethoate technical) was 0.226 µg a.i./bee (criterion: 0.10 - 0.35 µg a.i./bee).

A 2.3.1.1.2 KCP 10.3.1.1.2 Acute contact toxicity to bees

Comments of zRMS:	The study was accepted. The study was conducted in accordance with OECD guidance 214 (acute contact). The validity criteria were met: • the average mortality for the total number of controls was 3.3% at the end of the experiment (criterion: it must not exceed 10%); • the 24 h LD_{50} of the reference item (dimethoate) was 0.122 µg a.i./bee (criterion: 0.10 - 0.30 µg a.i./bee).

	The following endpoint was derived: LD_{50} 48 h > 200 µg formulation/bee
Reference:	KCP 10.3.1.1/02
Report	Honeybees (*Apis mellifera* L.), Acute Contact Toxicity Test; Grzesica, M.; Ecomelius Institute Sp. z o. o. Kalinowa 2, Zaborze 43-520 Chybie, Poland; Study code: EMI/4/539/2020; 2020
Guideline(s):	according to the OECD Guideline for the Testing of Chemicals No. 214 (1998)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test Item: CHR/H/FETEC-PARTB 110 EC
Fenoxaprop-P-ethyl : 110.1 g/L; Cloquintocet-mexyl: 54.8 g/L,
batch no.: 2020012
production date: 01.04.2020
expiry date: 01.04.2022

Test Species: the honeybee, *Apis mellifera* L., strain: carnica
– age: approximately 3 weeks

Test Design: **-the test item:**
- exposure duration: 48 hours
- number of doses: 5 doses and a control
- number of replicates: 3 replicates
- number of bees: 10 bees/replicate

-the reference item:
- exposure duration: 24 hours
- number of doses: 3 doses
- number of replicates: 3 replicates
- number of bees: 10 bees/replicate

Endpoints: – honeybee mortality after 24 and 48 hours of the exposure,
– the oral LD_{50}/24 h of the reference item (dimethoate).

Test Concentration: 12.5, 25.0, 50.0, 100.0 and 200.0 µg test item/bee and a control (0.0 µg/bee)

Test Conditions:

Conditions	Temperature (required: 25 ± 2°C)	Relative air humidity (required: 50 - 70%)
Preliminary experiment	24.5 – 26.1°C	55.5 – 59.7%
Main experiment	23.3 – 25.6°C	69.3 – 74.8%

Preliminary non-GLP test

In the preliminary and in the main experiment, the test item was diluted in ultra pure water. In the preliminary experiment the highest dose of the test item of 200.0 µg/bee was prepared. For this purpose 2000 mg of the test item was weighed into a volumetric flask with a capacity of 10 mL. Then, the flask was filled up to the total volume of 10 mL with the ultra-pure water. In the preliminary experiment the remaining liquids of the test item at the doses of 40.0 and 8.0 µg/bee were prepared by making sequential 1:4 dilutions with the ultra-pure water (volume per volume).

Definitive test

In the main experiment the highest dose of the test item of 200.0 µg/bee was prepared. For this purpose 2000 mg of the test item were weighed into a glass flask with a capacity of 10 mL. Then, the flask was filled up to the total volume of 10 mL with the ultra-pure water. The remaining liquids of the test item at the doses of 100.0, 50.0, 25.0, and 12.5 µg/bee were prepared by making sequential 1:1 dilutions with ultra-pure water (v/v).

In the main experiment dimethoate technical was used in the study in order to verify the sensitivity of the test system and the susceptibility of the bees. Dimethoate technical at three different doses was applied to the dorsal part of the honeybee thorax. They included the one expected to be the LD_{50} value mentioned in the OECD Guideline for the Testing of Chemicals No. 214and the EU Method C.17. A separation factor was 2. On average, each insect received 0.1, 0.2 or 0.4 µg of the active ingredient in 1 µL of the ultra-pure water. The route of administration was the same as in case of the test item.

A stock solution, i.e. R1 (0.4 µg of dimethoate in a 1 µL of ultra-pure water) was prepared by weighing 20 mg of the reference item and filling up to 50 mL with ultra-pure water. The doses of 0.2 and 0.1 µg/1 µL were obtained by making sequential 1:1 dilutions with the ultra-pure water (volume per volume). The emulsions of the test item were applied using the hand microapplicator produced by

Burkard Manufacturing Co Ltd.The bees in the preliminary and main experiment were placed in groups of 10 in cages before the initiation of the treatment. Then the bees from one cage were anaesthetized for 15 seconds with carbon di oxide. Next they were placed on a plastic tray in order to apply the test item. 1 µL of the liquid was applied to the dorsal part of the thorax of each bee. After the application, the bees were allocated to cages. There were 10 bees in each cag e. This procedure was repeated for all the replicates and treatments. Three control series, each with ten bees, were conducted simultaneously. They were treated with 1 µL of ultra pure water. The experiment was terminated by anaesthesia and next freezing the test cages including the bees.

Result and discussion

Mortality of the control group after 48 hours of exposure was 0.0%. The percentages of mortality of the bees treated with the test item at the doses of 8.0, 40.0, and 200.0 µg/honeybee were 0.0, 10.0, and 10.0%, respectively. No abnormal behavioural effects were observed during the test. They contain raw data which were then converted to percentages in order to calculate the LD_{50}.

The percentages of corrected mortality of the honeybees treated with the test item at the doses of 12.5, 25.0,

50.0, 100.0, and 200.0 µg/honeybee were 0.0, 0.0, 0.0, 0.0 and 0.0%, respectively.
The median lethal doses (LD_{50}/24 h and LD_{50}/48 h) are higher than the maximum dose used in the test, i.e. 200.0 µg test item/bee.
No signs of toxicity (behavioural abnormalities) such as excitement (uncoordinated movement. increased activity or intensive cleaning) or paralysis were observed during the 48-hour exposure. The median lethal dose of dimethoate (LD_{50}/24 h) determined with the log-probit method is 0.122 µg a.i./bee (95% confidence limits: 0.083 – 0.155 µg a.i./bee).

Table 1. Honeybee mortality after 24 hours of exposure – preliminary experiment.

Dose [µg/bee]	Number of tested bees [no.]	Mortality	
		Number of dead bees [no.]	Total
		Replicate	
		I	[%]
0.0 (Control)	10	0	0.0
8.0	10	0	0.0
40.0	10	1	10.0
200.0	10	1	10.0

Table 2. Honeybee mortality after 48 hours of exposure – preliminary experiment.

Dose [µg/bee]	Number of tested bees [no.]	Mortality	
		Number of dead bees [no.]	Total
		Replicate	
		I	[%]
0.0 (Control)	10	0	0.0
8.0	10	0	0.0
40.0	10	1	10.0
200.0	10	1	10.0

The preliminary experiment lasted from 05 to 07 May 2021.

Table 3. Honeybee mortality after 4 hours of exposure – main experiment.

Dose [µg/bee]	Number of tested bees [no.]	Mortality				
		Number of dead bees [no.] Replicates			Total	
		I	II	III	[no.]	[%]
0.0 (Control)	30	0	0	0	0	**0.0**
12.5	30	0	0	0	0	**0.0**
25.0	30	0	0	0	0	**0.0**
50.0	30	0	0	0	0	**0.0**
100.0	30	0	0	0	0	**0.0**
200.0	30	0	0	0	0	**0.0**

The main experiment lasted from 27 to 29 May 2021.

Table 4. Honeybee mortality and the LD_{50} after 24 hours of exposure – main experiment.

Dose [µg/bee]	Number of tested bees [no.]	Mortality					LD_{50}
		Number of dead bees [no.] Replicates			Total		
		I	II	III	[no.]	[%]	[µg/bee]
0.0 (Control)	30	0	0	0	0	**0.0**	above 200.0
12.5	30	0	0	0	0	**0.0**	
25.0	30	0	0	0	0	**0.0**	
50.0	30	0	0	0	0	**0.0**	
100.0	30	0	0	0	0	**0.0**	
200.0	30	0	0	0	0	**0.0**	

Table 5. Honeybee mortality and the LD_{50} after 48 hours of exposure – main experiment

Dose [µg/bee]	Number of tested bees [no.]	Mortality						LD_{50}
		Number of dead bees [no.] Replicates			Total			
		I	II	III	[no.]	[%]	[%][c]	[µg/bee]
0.0 (Control)	30	0	1	0	1	**3.3**	-	above 200.0
12.5	30	1	0	0	1	**3.3**	**0.0**	
25.0	30	0	0	0	0	**0.0**	**0.0**	
50.0	30	0	0	1	1	**3.3**	**0.0**	
100.0	30	0	0	0	0	**0.0**	**0.0**	
200.0	30	0	0	0	0	**0.0**	**0.0**	

[c]: the control response of 3.3% was compensated using Abbott's formula [5].

Table 6. Behavioural effects on honeybees – main experiment

Dose [µg/bee]	Time of exposure / replicates	4 h	24 h	48 h
		Number of bees showing signs of toxicity* / number of living bees		
0.0 (control)	I	0/10	0/10	0/10
	II	0/10	0/10	0/9
	III	0/10	0/10	0/10
12.5	I	0/10	0/10	0/9
	II	0/10	0/10	0/10
	III	0/10	0/10	0/10
25.0	I	0/10	0/10	0/10
	II	0/10	0/10	0/10
	III	0/10	0/10	0/10
50.0	I	0/10	0/10	0/10
	II	0/10	0/10	0/10
	III	0/10	0/10	0/9
100.0	I	0/10	0/10	0/10
	II	0/10	0/10	0/10
	III	0/10	0/10	0/10
200.0	I	0/10	0/10	0/10
	II	0/10	0/10	0/10
	III	0/10	0/10	0/10

Table 7. Honeybee mortality after 4 hours of exposure on the reference item (dimethoate technical) – main experiment

Dose [µg a.i./bee]	Number of tested bees [no.]	Mortality				
		Number of dead bees [no.] Replicates			Total	
		I	II	III	[no.]	[%]
0.0 (control)	30	0	0	0	0	0.0
0.10	30	0	0	0	0	0.0
0.20	30	0	1	1	2	6.6
0.40	30	9	8	6	23	76.7

Table 8. Honeybee mortality after 24 hours of exposure on the reference item (dimethoate technical) – main experiment

Dose [µg a.i./bee]	Number of tested bees [no.]	Mortality					LD_{50} [µg a.i./bee]
		Number of dead bees [no.] Replicates			Total		
		I	II	III	[no.]	[%]	
0.0 (control)	30	0	0	0	0	0.0	0.122* (0.083 – 0.155)
0.10	30	4	5	4	13	43.3	
0.20	30	7	6	7	20	66.7	
0.40	30	9	10	10	29	96.7	

*: the LD_{50} (with 95% confidence limits) was calculated with the log-probit method (ToxRat Proffesional 3.3.0 computer) [SOP/P/28].

The validity criteria

The following validity criteria were met during the test: - the average mortality for the total number of controls was 3.3% at the end of the experiment (criterion: it must not exceed 10%). - the 24 h LD_{50} of the reference item (dimethoate) was 0.122 µg a.i./bee (criterion: 0.10 - 0.30 µg a.i./bee).

A 2.3.1.2 KCP 10.3.1.2. Chronic toxicity to bees

Comments of zRMS:	The study was accepted. The validity criteria were met: • at the end of the experiment average mortality of the control groups was 0.0% (criterion: it must not exceed 15%), • after 10 days of exposure corrected mortality of the honeybees exposed to the reference item at the concentration of 0.024 µg/30 mg/day (0.012 µg/bee/day) was 90.0%. The deviations in air humidity ranges from the recommended test conditions did not affect final study results. The following endpoints were calculated: LC_{50} > 1200 mg formulation/kg food LDD_{50} > 39.39 µg formulation/bee/d NOEC ≥ 1200 mg formulation/kg food

	NOEDD ≥ 39.39 µg formulation/bee/day

Reference:	KCP 10.3.1.1/02
Report	Honeybees (*Apis mellifera* L.), Chronic Oral Toxicity Test; Grzesica, M.; Ecomelius Institute Sp. z o. o. Kalinowa 2, Zaborze 43-520 Chybie, Poland; Study code: EMI/4/551/2020; 2020
Guideline(s):	according to the OECD Guideline for the Testing of Chemicals No. 245 (2017)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test Item: CHR/H/FETEC-PARTB 110 EC
Fenoxaprop-P-ethyl : 110.1 g/L; Cloquintocet-mexyl: 54.8 g/L,
batch no.: 2020012
production date: 01.04.2020
expiry date: 01.04.2022

Test Species: the honeybee, *Apis mellifera* L., strain: carnica
– age: approximately 3 weeks

Test Design: **-the test item:**
- exposure duration: 48 hours
- number of doses: 5 doses and a control
- number of replicates: 3 replicates
- number of bees: 10 bees/replicate

-the reference item:
- exposure duration: 24 hours
- number of doses: 3 doses
- number of replicates: 3 replicates
- number of bees: 10 bees/replicate

Endpoints: – Lethal Concentrations (LC_{50} , LC_{20} and LC_{10}), Lethal Dietary Doses (LDD_{50} , LDD_{20} and LDD_{10}), the No Observed Effect Concentration (NOEC), and the No Observed Effect Dietary Dose (NOEDD).

Test Concentration: 30.72, 76.8, 192, 480, and 1200 mg/kg

Test Conditions:

Conditions:	Temperature (required: 33 ± 2°C)	Relative air humidity (required: 50 - 70%)
Preliminary experiment (Figure 2)	33.5 – 34.0°C	52 – 69%
Main experiment (Figure 3)	34.5 – 35.0°C	69 – 74%

Preliminary non-GLP test

In the preliminary experiment, the concentrations of the test item were prepared in conversion to amount of a treated diet per one bee, i.e. 30 mg. A stock suspension, i.e. R1 at the concentration of 1200 mg/kg of diet was prepared. For this purpose, 30 mg of the test item was weighed and filled with 50% saccharose solution up to total weight of 25 g. The remaining suspensions of the test item at the concentrations of 480, 192, 76.8 and 30.72 mg/kg of diet (i.e. 14.4, 5.76, 2.30 and 0.92 µg/30 mg of diet) were prepared by making sequential 1:1.5 dilutions with a 50% saccharose solution (weight per volume).

Definitive test

In the main experiment, the concentrations of the test item were prepared in conversion to amount of a treated diet per one bee, i.e. 30 mg.
A solution, i.e. R1 at the concentration of 1200 mg/kg was prepared. For this purpose, 30 mg of the test item was weighed and mixed with 25 g of 50% saccharose solution (weight per weight). The remaining suspensions of the test item at the concentrations of 480 ,
1 92 , 76.8 and 3 0.72 m g/kg were prepared by making sequential 1:1.5 dilutions with a 50% saccharose solution (weight per weight). A stock solution of the reference item, i.e. R01 at the concentration of 800 mg dimethoate/kg was prepared by weighing 80 mg of the reference item and filling up to a total weight of 100 g with ultra-pure water. Solution R02 at the concentration of 8.0 mg dimethoate/kg was prepared by weighing 1 g of stock solution R01 and filling up to a total weight of 100 g with ultra-pure water.
Solution R1 at the concentration of 0.8 mg dimethoate/1 kg (0.024 µg/30 mg/day) of food was prepared by mixing 1 g of solution R02 with 9 g of a 50% saccharose solution.

Result and discussion
In the preliminary experiment after 10 days, no dead bees in the control group were observed. Mortality of the bees exposed to the test item at the concentrations of 30.72, 76.8, 192, 480, and 1200 mg/kg of diet (i.e. 0.92, 2.30, 5.76, 14.4, and 36.0 µg/30 mg of diet, respectively) was 0.0, 0.0, 0.0, and 0.0%, respectively.
Average consumption of a 50% saccharose solution in the control group was 33.64 mg/bee/day.
No symptoms of behavioural abnormality were observed.
The experiment was terminated by anaesthesia and next freezing the test cages including the bees at ≤ -10°C.

Mortality in the control group was 0.0% after 10 days of exposure. The percentages of mortality of the honeybees exposed to the CHR/H/FETEC-PARTB 110 EC at the concentrations of 30.72, 76.8, 192, 480, and 1200 mmg/kg (0.92, 2.30, 5.76, 14.4, and 36 µg/bee/day) were 0.0, 0.0, 3.3, 6.7, and 3.3% respectively.
There was no statistically significantly differences in mortality of the all group treated with the test item and the control group.
On the basis of the obtained mortality results, the LC_{10}, LC_{20} and LC_{50} value s are above 1200 mg t.i./kg (132.12 mg Fenoxaprop P ethyl/kg + 65.76 mg Cloquintocet mexyl/kg). The NOEC value is higher than or

equal to 1200 mg t.i./kg. The LDD $_{10}$, LDD $_{20}$, and LDD $_{50}$ value s are above 39.39 µg t.i./bee/day (4.34 µg Fenoxaprop P ethyl/bee/day + 2.16 µg Cloquintocet mexyl/bee/day). The NOEDD value is higher than or equal to 39.39 µg t.i./bee/day. Average consumption of a 50% saccharose solution in the control group was 29.09 mg/bee/day. Average consumption in the groups treated with the test item at the concentrations of 3 0.72 , 76.8 , 1 92 , 480 , and 1200 mg/kg (i.e. 0.92, 2.30, 5.76, 14.4, and 36 µg/bee/day) were 34.82, 30.66, 32.55, 35.85 and 32.83 mg/bee/day, respectively. All doses consumed by the bees were calculated taking into account the mean evaporation value. In all study groups average consumption of a 50% saccharose solution was 30.51 mg/bee/day. On the basis of average consumption of a 50% saccharose solution in the study groups, it may be concluded that each bee treated with the test item at the doses of 0.92, 2.30, 5.76, 14.4, and 36 µg/bee/day of CHR/H/FETEC-PARTB 110 EC ingested 1.07, 2.35, 6.25, 17.21, and 39.39 µg/bee/day.

Each insect from the group fed with a 50% saccharose solution containing the reference item at the concentration of 0.024 µg/30 mg of emulsion ingested 0.012 µg of dimethoate/day (0.8 mg/kg).

The following behavioral abnormalities were noted.

The validity criterion concerning mortality of the honeybees exposed to the reference item, dimethoate was met, because mortality was 90.0% after 10 days of exposure. The results obtained in the reference item group showed that the insects were sensitive to dimethoate. The experiment was terminated by anaesthesia and next freezing the test cages including the bees at ≤ -10°C.

Table 5. Honeybee mortality at each observation time – preliminary experiment

Consumed:		Mortality after:	1st day	2nd day	3rd day	4th day	5th day	6th day	7th day	8th day	9th day	10th day
Dose [µg/bee/day]	Concentration [mg/kg]	Replicate	Number of dead bees									
0.0 (Control)		I	0	0	0	0	0	0	0	0	0	0
0.92	30.72	I	0	0	0	0	0	0	0	0	0	0
2.30	76.8	I	0	0	0	0	0	0	0	0	0	0
5.76	192	I	0	0	0	0	0	0	0	0	0	0
14.4	480	I	0	0	0	0	0	0	0	0	0	0
36	1200	I	0	0	0	0	0	0	0	0	0	0

Table 8. Honeybee mortality at each observation time – main experiment

Consumed		Mortality after:	1st day	2nd day	3rd day	4th day	5th day	6th day	7th day	8th day	9th day	10th day
Dose [µg/bee/day]	Concentration [mg/kg]	Replicate	Number of dead bees									
0.0 (Control)		I	0	0	0	0	0	0	0	0	0	0
		II	0	0	0	0	0	0	0	0	0	0
		III	0	0	0	0	0	0	0	0	0	0
CHR/H/FETEC-PARTB 110 EC												
0.92	30.72	I	0	0	0	0	0	0	0	0	0	0
		II	0	0	0	0	0	0	0	0	0	0
		III	0	0	0	0	0	0	0	0	0	0
2.30	76.8	I	0	0	0	0	0	0	0	0	0	0
		II	0	0	0	0	0	0	0	0	0	0
		III	0	0	0	0	0	0	0	0	0	0
5.76	192	I	0	0	0	0	0	0	0	0	0	0
		II	1	1	1	1	1	1	1	1	1	1
		III	0	0	0	0	0	0	0	0	0	0
14.4	480	I	0	0	0	0	0	0	0	0	0	1
		II	0	0	0	0	0	0	0	0	0	0
		III	0	0	0	0	0	0	0	1	1	1
36	1200	I	0	0	0	0	0	0	0	0	0	1
		II	0	0	0	0	0	0	0	0	0	0
		III	0	0	0	0	0	0	0	0	0	0
Dimethoate												
0.024	0.0008	I	0	2	5	5	5	5	5	8	8	10
		II	0	1	1	4	5	8	8	8	8	9
		III	0	1	1	1	7	7	8	8	8	8

Table 9. Honeybee mortality and the LDD_X and LC_X/10 d – main experiment

Initial		Consumed*	Number of tested bees [no]	Mortality		LC_{XX}		LDD_{XX}	
Dose	Concentration	Dose		Total		[mg t.i./kg]	[mg a.i./kg]	[µg t.i./bee /day]	[µg a.i./bee /day]
[µg/bee/day]	[mg/kg]	[µg/bee/day]		No.	[%]				
CHR/H/FETEC-PARTB 110 EC									
0.0 (Control)			30	0	0.0	LC_{10}		LDD_{10}	
0.92	30.72	**1.07**	30	0	0.0	**>1200** (n.d.)	**132.12[a] + 65.76[b]**	**>39.39** (n.d.)	**4.34[a] + 2.16[b]**
2.30	76.8	**2.35**	30	0	0.0	LC_{20}		LDD_{20}	
5.76	192	**6.25**	30	1	3.3	**>1200** (n.d.)	**132.12[a] + 65.76[b]**	**>39.39** (n.d.)	**4.34[a] + 2.16[b]**
14.4	480	**17.21**	30	2	6.7	LC_{50}		LDD_{50}	
36	1200	**39.39**	30	1	3.3	**>1200** (n.d.)	**132.12[a] + 65.76[b]**	**>39.39** (n.d.)	**4.34[a] + 2.16[b]**
NOEC				**≥1200 [mg t.i./kg]**		**132.12[a] + 65.76[b] [mg a.i./kg]**			
NOEDD				**≥39.39 [µg t.i./bee/day]**		**4.34[a] + 2.16[b] [µg a.i./bee/day]**			
Initial		Consumed*	Dimethoate						
Dose	Concentration	Dose							
[µg/bee/day]	[mg/kg]	[µg/bee/day]							
0.024	0.8	**0.012**	30	27	**90.0**	not determined			

*: consumed doses were calculated on the basis of the initial doses of the test item and average saccharose solution consumption
+: statistically significant difference
n.d.: 95% confidence limits not determined due to mathematical reasons
[a]: Fenoxaprop-P-ethyl
[b]: Cloquintocet-mexyl
t.i.: test item
a.i.: active ingredient
The main experiment was performed between 26.08 - 05.09.2021.

Table 12. Behavioural effects on honeybees – preliminary experiment

Consumed:		Effects after:	1st day	2nd day	3rd day	4th day	5th day	6th day	7th day	8th day	9th day	10th day
Dose [µg/bee/day]	Concentration [mg/kg]	Replicate	Number of bees with toxic symptoms* / number of living bees									
0.0 (Control)		I	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10
0.92	30.72	I	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10
2.30	76.8	I	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10
5.76	192	I	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10
14.4	480	I	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10
36	1200	I	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10

* The bees with sublethal toxicity effects were classified according to the following criteria:
m- moribund, a- affected,
c- cramps, ap- apathy,
v- vomiting.

Table 13. Behavioural effects on honeybees – main experiment

Consumed		Effects after:	1st day	2nd day	3rd day	4th day	5th day	6th day	7th day	8th day	9th day	10th day
Dose [µg/bee/day]	Concentration [g/kg]	Replicate	Number of bees with toxic symptoms* / number of living bees									
0.0 (Control)		I	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10
		II	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10
		III	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10
CHR/H/FETEC-PARTB 110 EC												
0.92	30.72	I	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10
		II	0 /10	0 /10	0 /10	1a /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10
		III	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10
2.30	76.8	I	0 /10	1a /10	0 /10	1a /10	0 /10	0 /10	0 /9	0 /9	0 /8	0 /8
		II	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10
		III	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10
5.76	192	I	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10
		II	0 /9	0 /9	0 /9	0 /9	0 /9	0 /9	0 /9	0 /9	0 /9	0 /9
		III	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10
14.4	480	I	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /9
		II	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10
		III	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /9	0 /9
36	1200	I	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /9
		II	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10
		III	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10	0 /10
Dimethoate												
0.024	0.0008	I	0 /10	2a /8	4a /5	4a /5	3a /5	2a /5	2a /5	2a /2	2a /2	-
		II	0 /10	1a /9	4a /9	4a /6	2a /5	2a, /2	1a /2	2a /2	2a /2	1a /1
		III	0, /10	1a /9	4a /9	4a /9	2a /3	1a /3	2a /2	2a /2	2a /2	1a /2

* The bees with sublethal toxicity effects were classified according to the following criteria:
m- moribund, a- affected,
c- cramps, ap- apathy,
v- vomiting.

The validity criteria

The following validity criteria were met during the experiment:
- at the end of the experiment average mortality of the control groups was 0.0% (criterion: it must not exceed 15%),
- after 10 days of exposure corrected mortality of the honeybees exposed to the reference item at the concentration of 0.024 µg/30 mg/day (0.012 µg/bee/day) was 90.0%.

A 2.3.1.3 KCP 10.3.1.3 Effects on honey bee development and other honey bee life stages

Comments of zRMS:	The study was accepted. The validity criteria were met: • larvae mortality in the control was below 15%; observed 11.1%; • in control the adults emergence rate on day 22 was 77.778% (required: ≥70%), • larvae mortality in the reference item mortality was ≥ 50 %; observed 100%. The negligible deviations in study plan were noted. The deviations did not affect the course of the study and the reliability of the results. The following endpoints were calculated: LD_{10} = 23.897 µg formulation/larva LD_{50} = 82.134 µg formulation/larva NOED = 25.00 µg formulation/larva LC_{10} = 182.92 mg formulation/kg diet LC_{50} = 552.1 mg formulation/kg diet NOEC = 162.50 mg formulation/kg diet

Reference:	KCP 10.3.1.1/04
Report	Honey bee larval toxicity test following repeated exposure of the test item CHR/H/FETEC-PART B 110 EC; Woźniak, A.; Study code: 0038/0114/E; 2022
Guideline(s):	according to OECD GD 239 ENV/JM/MONO(2016)34
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test Item:	CHR/H/FETEC-PARTB 110 EC Fenoxaprop-P-ethyl : 109.01 g/L; Cloquintocet-mexyl: 53.52 g/L, batch no.: 2020012 production date: 01.04.2020 expiry date: 01.04.2023
Test Species:	the honeybee, *Apis mellifera* L., strain: carnica – age: approximately 3 weeks
Test Design:	-**the stability test:** - exposure duration: 72 hours - number of doses: 2 dose and a control - number of replicates: 1 replicate - number of bees: one replicate -**range-finding, definitive, reference test** - exposure duration: 22 days - number of doses: -range-finding: 4 doses and a control -definitive test: 5 doses and a control -reference test: 1 dose (dimethoate) - number of replicates: 1 replicate - number of bees: 36 larvae per replicate, 12 larvae from 3 different breeding
Endpoints:	– LC_{10}, LC_{20}, LC_{50} and LD_{10}, LD_{20}, LD_{50} values were determined, as well as NOEC and NOED
Test Concentration:	30.72, 76.8, 192, 480, and 1200 mg/kg
Test Conditions:	**Stability test:** average temperature 5.418°C (min 3.9°C; max 9.2°C); darkness **Range-finding test:** - for larval stage (day 1-8): average temperature 34.428°C (min 33.0°C, max 4.7°C); average relative humidity 95.646% (min 80%, max 97.9%), darkness - for pre-pupal stage (day 8-15): average temperature 34.439°C (min 33.0°C; max 35.6°C); average relative humidity 80.814% (min 74.0%; max 88.3%), darkness - for pupal/imago stage (day 15-22): average temperature 34.395°C (mini 34.0°C, max 34.4°C); average relative humidity 74.858% (min 72.8%, max 76.0%), darkness **Definitive test and reference test:** - for larval stage (day 1-8): average temperature 34.354°C (min 32.9°C, max 36.0°C); average relative humidity 95.248% (min 64.2%, max 99.9%), darkness

- for pre-pupal stage (day 8-15): average temperature 34.331°C (min 33.9°C, max 34.9°C); average relative humidity 77.679% (min 74.4%, max 85.9%), darkness
- for pupal/imago stage (day 15-22): average temperature 34.373°C (min 34.3°C, max 34.4°C); average relative humidity 76.799% (min 76.6%, max 77.3%), darkness

The test was carried out based on the OECD GD 239 ENV/JM/MONO(2016)34 Guideline and in accordance with the SPB-E/53 procedure.
On day 1, the frames with freshly brooded larvae were transferred from the hive to laboratory in the temperature optimal for larvae (range-finding test 26.6°C, definitive test 27.0°C). Frames were placed under the inactive laminar-flow hood heated to 30°C (not above 35°C). For the study, larvae, which has not yet formed C-shape or the ones laying on the top of royal jelly were chosen. The larvae were carefully placed in the same position at the bottom of queen-cell cup filled with diet A (composition of food described in point 5.2) placed in breeding plate's well. Plates were placed in desiccators, in which, during 1-8 days, humidity was maintained on level of 95±5% using saturated solution of K_2SO_4 placed in the dish at the bottom of desiccator.
On day 8, larvae were transferred to the fresh plates with pieces of absorption paper placed at the bottom of each well. Plates with larvae were placed in the desiccator, in which humidity was maintained at the level of 80±5% with saturated solution of NaCl placed ate the bottom of desiccator. Desiccators were placed in test room.
On day 15, plated were transferred to plastic cages with ad libitum access to 50% (w/v) sucrose solution and pine pollen. Cages were placed in test room of humidity 50-80% maintained with humidifier.

Stability test
The stability of the test item in an aqueous solution under storage conditions was determined (temperature 6±2°C, darkness). Due to the highly complex composition of the food for the larvae (royal jelly), the stability of the test item in the food was not tested under the experimental conditions.

Test item stability in storage conditions was confirmed based on results solutions chemical analysis at the test beginning and after 24, 48 and 72 hours for all tested concentrations and control.
Test item concentrations differed by no more than ±20% from initial concentrations for 72 hours. Based on the results, test item was found to be stable for 72 h in storage conditions.

Range-finding test
The range-finding test was performed to determine the number and range of doses of the test item to be used in the definitive test.
In range-finding test, test item was administrated in larvae diet in aqueous solution in proper concentration during 4-days exposition. During the test, mortality observations and behavioral changes were performed.

Table 13. Final results – range-finding test

Final results calculated using ToxRat Professional software		
Stadium	**Parameter**	**Value**
Larval mortality (day 8)	LOEC	650 mg of test item/kg of food*
	NOEC	65 mg of test item/kg of food
Pupal mortality (day 22)	LOEC	>650 mg of test item/kg of food*
	NOEC	≥650 mg of test item/kg of food
Emerged adults (day 22)	NOEC	650 mg of test item/kg of food
	NOED	100 µg of test item/larva

NOEC the highest test item concentration not causing statistically significant differences in relations to the control
LOEC the lowest test item concentration causing statistically significant differences in relations to the control
NOED the highest test item dose not causing statistically significant differences in relations to the control
* **values determined based on the analysis of the results**

Definitive test

In definitive test, test item was administrated in aqueous solution in proper concentration during 4-days exposition. During the test, mortality observations and behavioral changes were performed.

In the definitive test, were used following concentration of test item:
-control (0 mg of test item/kg of food)), corresponding to 0 µg of test item/larva (0 g of test item/L of solution)
-40.63 mg of test item/kg of food, corresponding to 6.25 µg of test item/larva (3.13 g of test item/L of solution)
-81.25 mg of test item/kg of food, corresponding to 12.5 µg of test item/larva (6.25 g of test item/L of solution)
-162.5 mg of test item/kg of food, corresponding to 25.0 µg of test item/larva (12.5 g of test item/L of solution)
-325 mg of test item/kg of food, corresponding to 50.0 µg of test item/larva (25.0 g of test item/L of solution)
-650.00 mg of test item/kg of food, corresponding to 100.00 µg of test item/larva (50.0 g of test item/L of solution).
Each concentration and control were prepared in one replicate, 36 larvae (12 larvae from 3 different breedings) on single breeding plate.
Parallel to the definitive test, reference test was performed using dimethoate (48 mg of test item/kg of food) as reference item.

During the test, the following data and activities are recorded:
-Larval mortality from day 4 to day 8, observations were made during feeding; immobile or an unresponsive larva was noted as dead; dead individuals were removed during feedings for sanitary reasons.
-Pre-pupal mortality on day 15; individuals that do not pupate were noted as dead.
-On day 22 the number of emerged or non-emerged pupae.
-On day 22 adult insects - alive or dead.
-At the end of the test, the emergence rate was calculated (by comparing the number of emerged individuals on day 22 with the number of larvae on day 3), pupal mortality (percentage calculated by comparing the number of non-emerged pupae and dead pre-pupa from day 8 to day 22 with the number of larvae on day

8) and larval mortality (percentage calculated by comparing the number of dead larvae from day 4 to day 8 with the number of larvae on day 3).
-On day 8 the presence of food that has not been consumed.
-Temperature and humidity during the definitive test was recorded continuously by a temperature and humidity recorder.
-All other observations (for larvae, pre-pupae, pupae and imago: appearance, size, behavior, morphological differences).

During definitive test, statistically significant effect on larval mortality was observed on day 8 at a concentration of 325 mg of the test item/kg of food and 650 mg of the test item/kg of food.
The test item showed no statistically significant apitoxic effect on the mortality of pupae on day 22 at concentration 40.63 mg test item/kg of food to 650 mg test item/kg of food.
For emerged adults, a statistically significant effect was observed at the concentration of 325 mg of the test item/kg of food and 650 mg of the test item/kg of food.

Table 14. Larval mortality – definitive test

Concentration [mg of test item/kg of food]	Time [day]										
	3	4		5		6		7		8	
	Introduced larvae [pcs.]	Dead larvae*) [pcs.]	Intoxication signs	Dead larvae*) [pcs.]	Intoxication signs	Dead larvae*) [pcs.]	Intoxication signs	Dead larvae*) [pcs.]	Intoxication signs	Dead larvae*) [pcs.]	Intoxication signs
Control	36	0	none	1	none	2	none	3	none	4	none
40.63	36	0	none	0	none	0	none	1	none	3	none
81.25	36	0	none	0	none	1	none	3	none	3	none
162.50	36	0	none	0	none	3	stun. dev. – 2	4	none	8	none
325.00	36	0	none	0	none	8	stun. dev. – 6	10	stun. dev. – 5	15	stun. dev. – 10
650.00	36	0	none	0	none	12	stun. dev. – 10	20	stun. dev. – 3	23	stun. dev. – 10

*) cumulative amount
stun. dev. stunted development

Table 15. Final larval mortality results – definitive test

Concentration [mg of test item/kg of food]	Time [day]											
	4		5		6		7		8			
	Mortality [%]	Statistical significance*)	Mortality [%]	Statistical significance*)	Mortality [%]	Statistical significance*)	Mortality [%]	Statistical significance*)	Mortality [%]	Statistical significance*)	LOEC [mg of test item/kg of food]	NOEC [mg of test item/kg of food]
Control	0.000	not applicable	2.778	not applicable	5.556	not applicable	8.333	not applicable	11.110	not applicable		
40.63	0.000	-	0.000	-	0.000	-	2.778	-	8.333	-		
81.25	0.000	-	0.000	-	2.778	-	8.333	-	8.333	-		
162.50	0.000	-	0.000	-	8.333	-	11.110	-	22.220	-	325.00**	162.500
325.00	0.000	-	0.000	-	22.220	-	27.780	-	41.670	+		
650.00	0.000	-	0.000	-	33.330	+	55.560	+	63.890	+		

- statistically insignificant
+ statistically significant
*) values calculated using ToxRat Professional using Fisher's Test after Bonferroni-Holm correction with significance level p>0.05
**) values determined based on the analysis of the results

Table 16. Pupal mortality – definitive test

Concentration [mg of test item/kg of food]	Time [day]			
	8	15		22
	Alive larvae [pcs.]	Dead pupae [pcs.]	Intoxication signs	Dead pupae* [pcs.]
Control	32	3	none	5
40.63	33	3	none	6
81.25	33	4	none	7
162.50	28	2	none	3
325.00	21	1	none	1
650.00	13	1	stunted development – 6	2

*) cumulative amount from day 15 to day 22

Table 17. Final pupal mortality results – definitive test

Concentration [mg of test item/kg of food]	Time [day]					
	15		22			
	Mortality [%]	Statistical significance*)	Mortality [%]	Statistical significance*)	LOEC [mg of test item/kg of food]	NOEC [mg of test item/kg of food]
Control	9.375	not applicable	15.630	not applicable	>650.00**	≥650.00
40.63	9.091	-	18.180	-		
81.25	12.120	-	21.210	-		
162.50	7.143	-	10.710	-		
325.00	4.762	-	4.762	-		
650.00	7.692	-	15.380	-		

- statistically insignificant
*) values calculated using ToxRat Professional using Chi2 2x2 table test after Bonferroni correction with significance level p>0.05
** **values determined based on the analysis of the results**

Table 18. Number of emerged adults – definitive test

Concentration [mg of test item/kg of food]	Time [day]					
	3	22				
	Introduced larvae [pcs.]	Emerged adults [pcs.]	Number of emerged adults [%]	Unemerged adults [pcs.]	Number of unemerged adults [%]	Statistical significance*)
Control	36	27	75.000	9	25.000	not applicable
40.63	36	27	75.000	9	25.000	-
81.25	36	26	72.222	10	27.778	-
162.50	36	25	69.444	11	30.556	-
325.00	36	20	55.556	16	44.444	+
650.00	36	11	30.556	25	69.444	+

- statistically insignificant
+ statistically significant
*) values calculated using ToxRat Professional using Cochran-Armitrage test with significance level p>0.05

Result and discussion

In course of the experiment, the test item has shown apitoxic effect in mortality of following developmental stages of bees after 22 days of the test.

At the end of the study, the concentration and the dose causing 10%, 20% and 50% mortality of the population in the test (LC_{10}, LC_{20}, LC_{50} and LD_{10}, LD_{20}, LD_{50} values) were determined, as well as NOEC and NOED values were determined at 22nd day.

Table 1. Final results of the study

Parameter	Concentration [mg of test item/kg of food]	Parameter	Dose [µg of test item/larva]
LC_{10}	182.924	**LD_{10}**	23.897
LC_{20}	284.046	**LD_{20}**	39.087
LC_{50}	552.142	**LD_{50}**	82.134
NOEC	162.500	**NOED**	25.000
LOEC	325.000*	**LOED**	50.000*

LC_{10} test item concentration causing mortality of 10% population
LC_{20} test item concentration causing mortality of 20% population
LC_{50} test item concentration causing mortality of 50% population
NOEC the highest test item concentration not causing statistically significant differences in relations to the control
LOEC the lowest test item concentration causing statistically significant differences in relations to the control
LD_{10} test item dose causing mortality of 10% population
LD_{20} test item dose causing mortality of 20% population
LD_{50} test item dose causing mortality of 50% population
NOED the highest test item dose not causing statistically significant differences in relations to the control
LOED the lowest test item dose causing statistically significant differences in relations to the control
* **values determined based on the analysis of the results**

Validity criteria

The test met the validity criteria (acc. to OECD GD 239 ENV/JM/MONO(2016)34):
- in control cumulative larval mortality from day 3 to day 8 was 11.11% (required: ≤15%)
- in control the adults emergence rate on day 22 was 77.778% (required: ≥70%)

A 2.3.1.4 KCP 10.3.1.4 Sub-lethal effects

No additional studies were performed.

A 2.3.1.5 KCP 10.3.1.5 Cage and tunnel tests

No additional studies were performed.

A 2.3.1.6 KCP 10.3.1.6 Field tests with honeybees

No additional studies were performed.

A 2.3.1.7 KCP 10.3.1.3 Effects on non-target arthropods (other than bees)

A 2.3.1.7.1 Study 1

Comments of zRMS:	The study was accepted. The validity criteria were met. The following endpoints for *Typhlodromus pyri* were derived: 7-day LR_{50} > 706.4 mL formulation/ha; ER_{50} > 706.4 mL formulation/ha NOERmort ≥ 706.4 mL mL formulation/L NOERrepr < 176.6 mL mL formulation/L The endpoints were used for risk assessment.

Reference:	KCP 10.3.2/01
Report	An extended laboratory test for evaluating the effects of CHR/H/FETEC – PART B 110 EC on the predatory mite, *Typhlodromus pyri* (Sch.) Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna Ecotoxicology Research Group Doświadczalna 27, 43 – 200 Pszczyna, Poland Study Code: B-111-22
Guideline(s):	according to the ESCORT 1 (Barrett K.L. et al., 1994) and the ESCORT 2 (Candolfi M. P. et al., 2001) guidance documents and the guidelines developed by the IOBC, BART, and EPPO Joint Initiative (Blümel S. et al., 2000))
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test Item:	CHR/H/FETEC-PART B 110 EC Fenoxaprop-P-ethyl : 109.01 g/L; Cloquintocet-mexyl: 53.52 g/L, batch no.: 2020012 production date: 01.04.2020 expiry date: 01.04.2023

Test Species:	the predatory mite, *Typhlodromus pyri* (Sch.) (Acari: Phytoseiidae) – age: 24-hour-old protonymphs – source: a laboratory culture at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna; the culture was augmented from a commercial breeder
Test Design:	number of replicates: 3/group number of mites in each replicate: 20
Endpoints:	– mite mortality after 7 days of the treatment – LR_{50} and $NOER_{mortality}$ – reproduction reduction (Pr) after 14 days of the treatment – ER_{50} and $NOER_{reproduction}$
Test Concentration:	5 study groups: − a control group (0.0 mL/ha) − CHR/H/FETEC – PART B 110 EC at the rate of 176.6 mL/ha − CHR/H/FETEC – PART B 110 EC at the rate of 353.2 m/ha − CHR/H/FETEC – PART B 110 EC at the rate of 706.4 mL/ha − reference item: dimethoate at the rate of 4.0 g/ha
Test Conditions:	– temperature: 24 – 26 °C – relative air humidity: 62 – 98 % – photoperiod: 16 h light : 8 h dark – light intensity: 535 lx

The study was performed according to the 'island method' described by Joisten M. Each test set consisted of a glass tray filled with water and a glass bench containing 5 test units. Leaf discs (ø 45 mm) were floating on the water surface in glass Petri dishes ('island dishes', ø 54 mm) with central holes at the bottom (ø 6 mm). Water in the test units prevented the mites from escaping. Leaf discs were prepared, placed on wet tissue paper, and sprayed using the Potter laboratory spray tower (standard model; manual load version; producer: Burkard Scientific, England).
The application rate of 200 ± 20 L spray fluid/ha was used to calibrate the spray tower. The aim was to provide 2 ± 0.2 mg spray fluid/cm2. The applied amount of water on the calibration discs (Ø 4.5 cm, 16 cm2) was determined by weighing the discs before and immediately after the treatment.
As the results show, the mean rates of the spray fluid were 2.0 mg/cm2 in the preliminary test (1.81 – 2.19 mg/cm2) and in the definitive test 1.94 mg/cm2 (1.75 – 2.13 mg/cm2).
After calibration, the leaf discs were sprayed with distilled water (the control group), emulsions of test item (the treated groups) mentioned in section 4.2 and a water solution of dimethoate at the rate of 4.0 g/ha (the reference item group). Before spraying the leaf discs with the reference item, the Potter spray tower had been cleaned and flushed several times with distilled water and acetone.
When the spray residues dried, the leaf discs were transferred from tissue paper to the test units. Then, 20 mite protonymphs were transferred onto each leaf disc using a fine brush and a stereomicroscope. Pine pollen (*Pinus* sp.) and *T. urticae* eggs were served as food. During the whole experiment, the mites had

continuous access to water, and food deficits were supplemented when the need arose. The mites were observed for mortality (dead and escaped individuals) after 7 days of the treatment. Mites were considered dead if they were shrivelled or remained motionless after being touched with a fine brush. Escapees were those mites which were lost or drowned.

Reproduction of the surviving mites from the control group and the groups treated with test item at the rates of 176.6, 353.2 and 706.4 mL/ha was assessed since mortality of these groups was < 50.0%. After 7 days of exposure, the surviving mites were sexed, and the sex ratio was determined. The numbers of males, females, eggs, and larvae hatched from eggs were recorded on days 10, 12 and 14 of exposure. On each occasion, dead mites, eggs, and larvae were removed, and food was supplemented, if necessary. Eggs that were laid until the 7th day were removed from the test units and not counted.

Results

In the definitive test, mortality of the control group after 7 days of exposure was 0.0%. After 7 days of exposure to CHR/H/FETEC – PART B 110 EC at rates of 176.6, 353.2 and 706.4 mL/ha, the percentages of mortality, were 0.0, 3.3, 5.0%, respectively.

There were no statistically significant difference in mortality the group treated with the test item at all rates in comparison to the control group (Chi2 2x2 Table Test with Bonferroni Correction).

The LR_{50} value is higher than 706.4 mL/ha (> 77.0 g of fenoxaprop-P-ethyl/ha + 37.8 g of cloquintocet-mexyl/ha). $NOER_{mortality}$ is higher than or equal to 706.4 mL/ha (≥ 77.0 g of fenoxaprop-P-ethyl/ha + 37.8 g of cloquintocet-mexyl/ha).

After 7 days of exposure to dimethoate at the rate of 4.0 g/ha, mortality was 88.3%. Therefore, the validity criterion specified in the method description was met. The results obtained in the reference item group showed that the test organisms were sensitive to dimethoate.

Reproduction of the surviving mites from the control group and all groups treated with test item was assessed since mortality of these groups was < 50.0%.

The mean reproduction rate (Rr) in the control group was 10.3 eggs/female. The mean Rr after 14 days of exposure to test item at the rates of 176.6, 353.2 and 706.4 mL/ha were 8.3, 8.0 and 7.3 eggs/female, respectively. The percentages of reproduction reduction (Pr) caused by test item at the rates of 176.6, 353.2 and 706.4 mL/ha were 19.9, 22.4 and 29.1%, respectively.

There were statistically significant difference in reproduction between all group treated with the test item, i.e. 176.6, 353.2 and 706.4 mL/ha and the control group (Williams Multiple Sequential t-test Procedure,|t|>|t*|).

The calculated ER_{50} value is higher than 706.4 mL/ha (> 77.0 g of fenoxaprop-P-ethyl /ha + 37.8 g of cloquintocet-mexyl/ha). $NOER_{reproduction}$ is lower than 176.6 mL/ha (< 19.3 g of fenoxaprop-P-ethyl/ha + 9.5 g of cloquintocet-mexyl/ha).

Conclusions:

Based on the results it can be stated that CHR/H/FETEC – PART B 110 EC at all rates has no adverse effect on mortality of the mites. The test item at all rates has an adverse effect on reproduction of the mites.

Parameter (endpoint)				
Mortality		Reproduction		
Test item rate [mL/ha]	Total [%]	Test item rate [mL/ha]	Mean number of eggs/ female (Rr) [no.]	Repro-duction reduction Pr [%]
control	0.0	control	10.3	–
176.6	0.0	176.6+	8.3	19.9
353.2	3.3	353.2+	8.0	22.4
706.4	5.0	706.4+	7.3	29.1
LR_{50}	> 706.4 mL/ha > 77.0 g of fenoxaprop-P-ethyl/ha + 37.8 g of cloquintocet-mexyl/ha	ER_{50}	> 706.4 mL/ha > 77.0 g of fenoxaprop-P-ethyl/ha + 37.8 g of cloquintocet-mexyl/ha	
$NOER_{mortality}$	≥706.4 mL/ha ≥ 77.0 g of fenoxaprop-P-ethyl/ha + 37.8 g of cloquintocet-mexyl/ha	$NOER_{reproduction}$	< 176.6 mL/ha < 19.3 g of fenoxaprop-P-ethyl /ha + 9.5 g of cloquintocet-mexyl /ha	
Reference item: dimethoate				
Rate [g/ha]	Total [%]	Reproduction		
4.0	88.3	not assessed		

+: statistically significant differences between control and groups exposed to test item; ToxRat Professional 3.3.0. software [12], [SOP/B/67]

A 2.3.1.7.2 Study 2

Comments of zRMS:	The study was accepted. The validity criteria were met. The following endpoints for *Aphidius rhopalosiphi* were derived: LR_{50}≥ 700 mL formulation/ha; ER_{50} ≥ 700 mL formulation/ha NOERrepr = 350 mL formulation/L. The endpoints were used for risk assessment.

Reference:	KCP 10.3.2/02
Report	Extended laboratory test to evaluate effects on *Aphidius rhophalosiphi* (DeStephani-Perez) of the test item CHR/H/FETEC-PART B 110 EC; SORBOLAB Research Laboratory LLC; Zaniemyska Street 11; 61-029

	Poznań, Poland Study Code: 0038/0113/E
Guideline(s):	according to IOBC, BART and EPPO Joint Initiative. M.P. Candolfi, et al. (2000) and Mead-Briggs M.A. et al. (2010)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test Item:	CHR/H/FETEC-PART B 110 EC Fenoxaprop-P-ethyl : 109.01 g/L; Cloquintocet-mexyl: 53.52 g/L, batch no.: 2020012 production date: 01.04.2020 expiry date: 01.04.2023
Test Species:	The study was conducted on the parasitic wasp *Aphidius rhopalosiphi* (Hymenoptera: Braconidae), which is one of the most sensitive standard indicator species for non-target arthropod regulatory testing for plant protection products. *Aphidius rhopalosiphi* were purchased as synchronized aphid mummies *Rhopalosiphum* padi from breeder which has a certificate confirming their species, ie. Katz Biotech AG, An der Birkenpfuhlheide 10, D-15837 Baruth, Germany. In the study were used adults, 1-2 days old *Aphidius rhopalosiphi* individuals.
Test Design:	**Range-finding test:** tested doses and control in 3 replicates, 5 females per replicate **Definitive test:** tested doses and control in 6 replicates, 5 females per replicate **Reference test:** tested dose and control in 6 replicates, 5 females per replicate
Test Concentration:	**Range-finding test:** control: 0 mL the test item/400 L water/ha 112 mL of the test item/400 L water/ha 280 mL of the test item/400 L water/ha 700 mL of the test item/400 L water/ha **Definitive test:** control: 0 mL the test item /400 L water/ha

43.75 mL of the test item/400 L water/ha
87.50 mL of the test item/400 L water/ha
175.00 mL of the test item/400 L water/ha
350.00 mL of the test item/400 L water/ha
700.00 mL of the test item/400 L water/ha
Reference test:
4 g dimethoate/400 L water/ha

Test Conditions:

Range-finding:
48 hours (mortality phase)
temperature: average 20.640°C (min. 20.0°C, max. 22.0°C)
relative humidity: average 57.637% (min. 47.4%, max. 61.6%)*
lighting: daily cycle, 16 h light/8 h darkness
light intensity: 830-850 lux
Definitive test:
14 days (48 hours of mortality phase, 24 hours parasitation phase and 10 days of fecundity phase)
Definitive test and reference test– mortality phase:
temperature: average 20.541°C (min. 20.3°C, max. 20.9°C)
relative humidity: average 58% (min. 52%, max. 69%)*
lighting: daily cycle, 16 h light/8 h darkness
light intensity: 420-450 lux
Definitive test – parasitation period:
temperature: average 20.683°C (min.20.4°C, max. 21.5°C)
relative humidity: average 59% (min. 53%, max. 63%)*
lighting: daily cycle, 16 h light/8 h darkness
light intensity: 423-450 lux
Definitive test – reproduction phase (after parasitation):
temperature: average 18.333°C (min. 17.0°C, max. 22.5°C)*
lighting: daily cycle, 16 h light/8 h darkness
light intensity: 5840-6310 lux

* Deviations from the Study plan were found concerning changes in temperature and humidity during the range-finding test and definitive test. The way of humidity measurements during definitive test was changed The above deviations did not affect the test result.

reference test (conducted in parallel with the definitive test):
48 hours days (mortality phase)

The test item was applied on the barley seedlings in five doses by using a spray chamber T&B Masters s.c. in amount corresponding to application volume 400 L of water/ha. The on the barley seedlings with the applied test item were left to dry and then used in the test.
The reference item was applied on the barley seedlings in one dose by using a spray chamber in amount

corresponding to application volume 400 L of water/ha. The barley seedlings with the applied reference item were left to dry and then used in the test.
Parameter of spraying:
- work pressure: 2.0 bar
- flat fan nozzles: Lechler, type 652.307.

Those parameter ensured a target volume of the applied solutions that correspond to the dose of test item/reference item/400L of water/ha (with an accuracy of ±10%).
The range-finding test was performed in two replicate for control and tested doses. The 3 doses of the test item were used.
In the test, no older than 48 hours old females of *Aphidius rhopalosiphi* (5 females per replicate were used). Based on the results from the range-finding test, in the definitive test were used 5 doses of the test item and control in six replicates were used and control.

Results
The test item in extended laboratory test did not show the statistically significant impact on survival of wasps *Aphidius rhophalosiphi* from dose 43.75 mL of the test item/400L water/ha to dose 700 mL of the test item/400L water/ha. The test item shows significant effect on the reproduction of wasps *Aphidius rhophalosiphi* at tested dose 700 mL of the test item/400L water/ha No repellency effect after 3 h after introducing of insects to test units was observed in the range of doses 43.75 mL of the test item/400L water/ha to dose 700 mL of the test item/400L water/ha.
The endpoints of the test causing 50% mortality of the population in the test (LR_{50}) and 50% decrease in the reproduction of the test organisms (ER_{50}) were determined. The NOER and LOER values were also determined.

Table 1. Final results

Impact of test item on survival					
Dose [mL test item/400 L water/ha]	Mortality [%]	Abbott corrected mortality [%]	LR_{50}	NOER	LOER
			[mL of the test item/400 L water/ha]		
Control	0.000	not applicable	≥700*	≥700*	≥700*
43.75	0.000	0.00			
87.50	0.000	0.00			
175.00	0.000	0.00			
350.00	0.000	0.00			
700.00	0.000	0.00			
Reference item 4 g dimethoate/ 400 L water/ha	96.67	96.67			
Impact of test item on reproduction					
Dose [mL test item/400 L water/ha]	Average number of offspring per female [psc.]	Reduction of offspring [%]	ER_{50}	NOER	LOER
			[mL of the test item/400 L water/ha]		
Control	8.80	not applicable	≥700*	350	700
43.75	9.3	5.303			
87.50	7.7	12.879			
175.00	7.7	12.879			
350.00	7.0	20.455			
700.00	6.4	27.273			
Repellency assessment					
Dose [mL test item/400 L water/ha]	% average wasps settled outside the treated plates				
	30 min	1 h	1.5 h	2 h	3 h
control	36.67	33.33	43.33	36.67	50.00
43.75	46.67	43.33	36.67	30.00	53.33
87.50	50.00	46.67	40.00	43.33	56.67
175.00	53.33	56.67	36.67	46.67	50.00
350.00	70.83	73.33	63.33	53.33	50.00
700.00	83.33	80.00	74.17	53.33	56.67

LR_{50} lethal rate of the test item causing mortality in 50% of individuals
ER_{50} effective rate of the test item causing effect of 50%
LOER the lowest rate of the test item causing statistically significant differences in comparison to the control
NOER the highest rate of the test item causing no statistically significant differences in comparison to the control
* based on the analysis of the results, these values were determined as >700 L/ha

A 2.3.1.7.3 Study 3

Comments of zRMS:	The study was accepted. The validity criteria were met. The following endpoints for *Chrysoperla carnea* were derived: LR_{50} > 706.4 mL formulation/ha NOERmort ≥ 706.4 mL formulation/L. The endpoints were used for risk assessment.

Reference:	KCP 10.3.2/03
Report	An extended laboratory test for evaluating effects of CHR/H/FETEC - PART B 110 EC on the green lacewing, *Chrysoperla carnea* (Sch.) Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna Ecotoxicology Research Group Doświadczalna 27, 43 – 200 Pszczyna, Poland Study Code: B-113-22
Guideline(s):	according to the ESCORT 1 (Barrett K.L. et al., 1994) and the ESCORT 2 (Candolfi M.P. et al., 2001) guidance documents and the guidelines developed by the IOBC, BART, and EPPO Joint Initiative (Vogt H. et al., 2000)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test Item:	CHR/H/FETEC-PART B 110 EC Fenoxaprop-P-ethyl : 109.01 g/L; Cloquintocet-mexyl: 53.52 g/L, batch no.: 2020012 production date: 01.04.2020 expiry date: 01.04.2023
Test Species:	the green lacewing, *Chrysoperla carnea* (Steph.), Neuroptera: *Chrysopidae* – age: first instars' larvae (3 days old) – source: a laboratory culture at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna; the culture was augmented by commercial breeder
Test Design:	number of replicates: 30 replicates/group number of larvae: 1 larva of *Chrysoperla carnea* /replicate
Test Concentration:	− a control group (0.0 mL/ha) − CHR/H/FETEC - PART B 110 EC at the rates of: − 176.6 mL/ha (19.3 g fenoxaprop-P-ethyl + 9.5 g cloquintocet-mexyl/ ha) − 353.2 mL/ha (38.5 g fenoxaprop-P-ethyl + 18.9 g cloquintocet-mexyl/ ha) − 706.4 mL/ha (77.0 g fenoxaprop-P-ethyl + 37.8 g cloquintocet-mexyl/ ha)

− dimethoate at the rate of 15.0 g/ha

Test Conditions:
– temperature: 23.4 − 27.0°C
– relative air humidity: 60.4 − 83.6%
– photoperiod: 16 hours light : 8 hours dark
– light intensity 2034 lux

The study was divided into a preliminary non-GLP range-finding test and a definitive test. The preliminary non-GLP test was conducted to determine the range of rates to be used in the definitive test. The preliminary test involved only the mortality assessment of green lacewings exposed to test item. It was performed on one control group and three test item groups. There were ten replicates of each group (1 larva/replicate).
The definitive test (mortality stage) was performed on one control group, three groups treated with the test item, and one group treated with the reference item. Each group was divided into 30 replicates. There was 1 larva in each replicate.
The reproduction assessment was conducted on three groups treated with the test item and an untreated control group. Reproductive performance of the reference item group was not assessed.

When the spray fluids dried (after 1 hour after the treatment), the insects were introduced into the test units. Survival of larvae, development of pupae, and hatching of adults were observed during the mortality assessment. All pupae were removed from the exposure units (at least 5 days after pupation), carefully cleaned from mill moth *E. kuehniella*, and transferred to the glass containers covered with cotton gauze. Then, the process of emergence of adults from these pupae was observed. To determine mortality of the lacewings in each test group, general condition of the insects was observed regularly at intervals of 1 – 3 days.

Reproduction of the lacewings from the control group and the groups treated with the test item at the rates of 176.6, 353.2 and 706.4 mL/ha was assessed, since the mortality were < 50%.
All adults from the same treatment, hatched within a period of up to 7 days were placed together in the glass oviposition containers covered with cotton gauze. Gauze was used for egg laying and to avoid escaping the insects. Adults with deformities were not included in the reproduction assessment.
Before the reproduction assessment started, sex of the lacewings had been determined on the basis of the shape of the abdomen. The numbers of males and females had been recorded. A week after first batch of eggs was observed, the reproductive performance started.
Two egg samples were taken during approximately a one-week period. Each sample covered an egg-laying period of 24 hours. The first egg sample was taken on 35th day after the treatment; the second sample was taken on 37th day after the treatment.
Carbon dioxide (CO_2) was used to anaesthetize the adults for replacing the gauze. The number of eggs from each sample was counted (eggs laid on the walls of the container were counted as well; however, they were not taken into account in the hatching assessment).
To assess egg viability, each egg sample was incubated. Incubation lasted 5 – 6 days. Food in the form of mill moth E. kuehniella eggs was added before hatching to avoid cannibalism. The numbers of live larvae was determined.

Results
The validity criterion concerning mortality was met, because mortality of the green lacewings, *Chrysoperla carnea* (Steph.) in the control group was 10.0%. The percentages of mortality, corrected according to the

formula od Abbott, of the green lacewings exposed to the test item at the rates of 176.6, 353.2 and 706.4 mL test item/ha of the test item were 3.7, 7.4 and 25.9%, respectively.
There were no statistically significant differences in mortality of the green lacewings in the groups treated with the test item at the rates of 176.6, 353.2 and 706.4 mL/ha in comparison to the control group (Chi2 2x2 Table Test with Bonferroni Correction, p(z) > Alpha, (Alpha=0.05)).
On the basis of the obtained results it can be concluded that the LR50 value is higher than 706.4 L test item/ha (i.e. > 77.0 g of fenoxaprop-P-ethyl/ha + 37.8 g of cloquintocet-mexyl/ha). The $NOER_{mortality}$ value is higher than or equal to 706.4 mL/ha (≥ 77.0 g of fenoxaprop-P-ethyl/ha + 37.8 g of cloquintocet-mexyl/ha).
The percentage of corrected mortality of *Ch. carnea* (Steph.) exposed to dimethoate at rate of 15.0 g/ha was 88.9%. The results obtained in the reference item group indicated that the biological test system was sensitive to dimethoate.
The mean number of eggs/female/day in the control group was equal to 16.6 (criterion: ≥ 15.0). The mean numbers of eggs/female/day in the groups treated with the test item at the rates of 176.6, 353.2 and 706.4 mL/ha were equal to 15.2, 12.9 and 10.5, respectively. The mean hatching rate in the control group was 97.1% (criterion: ≥ 70%). The mean hatching rate in the groups treated with the test item at the rates of 176.6, 353.2 and 706.4 mL/ha were 94.7, 94.2 and 94.6%, respectively. Fecundity reduction (Pr) in the group treated with the test item at the rates 176.6, 353.2 and 706.4 mL/ha were 2.4, 3.0 and 2.5%, respectively.
Based on the results it can be stated that CHR/H/FETEC - PART B 110 EC at the rates of 176.6, 353.2 and 706.4 mL/ha has no an adverse effect on mortality of the tested organisms. The test item at the rates of 353.2 and 706.4 mL/ha has an adverse effect on the mean number of layed eggs by green lacewings, however it has no adverse effect on mean hatching rate at all tested rates, i.e. 176.6, 353.2 and 706.4 mL/ha.

Study group [application rate]	Parameter (endpoints)						
	Mortality				Reproduction		
Test item: CHR/H/FETEC - PART B 110 EC							
[mL test item/ha]	[%]	Corr. [%][a]	LR_{50} [mL test item/ha]	LR_{50} [g a.s./ha]	Mean number of eggs/ female/ day [no.]	Mean hatching rate [%]	Reduction [%]
Control (0.0)	10.0	–	**> 706.4**	> 77.0 g of fenoxaprop -P-ethyl + 37.8 g of cloquintocet -mexyl	16.6	97.1	–
176.6	13.3	3.7			15.2	94.7	2.4
353.2	16.7	7.4			12.9	94.2	3.0
706.4	33.3	25.9			10.5	94.6	2.5
$NOER_{mortality}$	**≥ 706.4 [mL/ha]**						
	≥ 77.0 g of fenoxaprop-P-ethyl/ha + 37.8 g of cloquintocet-mexyl/ha						
Reference item: Dimethoate							
[g/ha]	**[%]**	**Corr. [%][a]**	**Reproduction**				
15.0	90.0	88.9	not assessed				

[a]: mortality corrected according to the formula of Abbott [10]

A 2.3.1.7.4 Study 4

Comments of zRMS:	The study was accepted. The validity criteria were met. The following endpoints for *Coccinella septempunctata* were derived: LR_{50} = 442.4 mL formulation/ha NOERmort = 113.0 mL formulation/L. The endpoints were used for risk assessment.

Reference:	KCP 10.3.2/04
Report	An extended laboratory test for evaluating effects of CHR/H/FETEC - PART B 110 EC on the ladybird beetle, *Coccinella septempunctata* (L.)

	Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna Ecotoxicology Research Group Doświadczalna 27, 43 – 200 Pszczyna, Poland Study Code: B-112-22
Guideline(s):	according to the ESCORT 1 (Barrett K.L. et al., 1994) and the ESCORT 2 (Candolfi M.P. et al., 2001) guidance documents and the guidelines developed by the IOBC, BART, and EPPO Joint Initiative (Schmuck et al., 2000)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test Item:	CHR/H/FETEC-PART B 110 EC Fenoxaprop-P-ethyl : 109.01 g/L; Cloquintocet-mexyl: 53.52 g/L, batch no.: 2020012 production date: 01.04.2020 expiry date: 01.04.2023
Test Species:	the ladybird beetle, *C. septempunctata* L. (Arthropoda: *Coccinellidae*) – age: 4-day-old larvae – source: Commercial supplier (Katz Biotech AG, Germany)
Test Design:	number of replicates: 40 replicates/group number of larvae: 1 larva of *Coccinella septempunctata* /replicate
Test Concentration:	− a control group (0.0 mL/ha) − CHR/H/FETEC - PART B 110 EC at the rates of: - 18.1 mL/ha (1.97 g fenoxaprop-P-ethyl + 0.97 g cloquintocet-mexyl/ ha) - 45.2 mL/ha (4.93 g fenoxaprop-P-ethyl + 2.42 g cloquintocet-mexyl/ ha) - 113.0 mL/ha (12.3 g fenoxaprop-P-ethyl + 6.05 g cloquintocet-mexyl/ ha) - 282.6 mL/ha (30.8 g fenoxaprop-P-ethyl + 15.1 g cloquintocet-mexyl/ ha) − 706.4 mL/ha (77.0 g fenoxaprop-P-ethyl + 37.8 g cloquintocet-mexyl/ ha) − dimethoate at the rate of 3.2 g/ha
Test Conditions:	– temperature: 23.4 – 27.0°C – relative air humidity: 60.4 − 83.6%

– photoperiod: 16 hours light : 8 hours dark
– light intensity 1878 lx

The study was divided into a preliminary non-GLP range-finding test and a definitive test. The preliminary non-GLP range-finding test was conducted to determine the range of rates to be used in the definitive test. The preliminary non-GLP range-finding test involved only the mortality assessment of ladybirds exposed to the test item. It was performed on one control group and three test item groups. There were ten replicates of each group (1 larva/replicate).
The definitive test were performed on one control group, five groups treated with the test item, and one group treated with the reference item. Each group was divided into 40 replicates. There was 1 larva in each replicate.
The reproduction assessment were conducted on four groups treated with the test item, and the control group. Reproductive performance of the reference item group was not assessed.

When the spray residues on the leaves discs dried, the exposure units were assembled. Then, a single larva of *Coccinella septempunctata* L. was placed on the leaf disc surface using a fine brush. The larvae were fed with the fresh aphids, *Acyrthosiphon pisum ad libitum* every day except for the weekends. Dead aphids from the previous feeding session were removed (using a fine brush) in order to maintain constant contact of the larvae with the treated surface. Survival, condition and development of the larvae were observed at intervals of 1 to 3 days until the end of their metamorphosis. During the exposure, observations were made for 21 days in the definitive test and 20 days in the preliminary non-GLP range-finding test.
As soon as the adult beetles appeared in the definitive test, they were transferred to untreated glass terrariums, separately for the control group and for the four groups treated with the test item. On 21 day (definitive test) after the exposure, the number and sex of the beetles were determined, since the beetles reached adulthood in the control group and the groups treated with the test item at rates of 18.1, 45.2, 113.0 and 282.6 mL/ha. Beetles' sex was determined on the basis of the beetle's size and shape of the abdomen. Adult beetles with deformities were excluded from reproduction performance.

In the definitive test reproduction of the ladybird beetles from the control group and the groups treated with the test item at the rates of 18.1, 45.2, 113.0 and 282.6 mL/ha was assessed, since the mortality were < 50%.
The adults, grouped in the terrariums, were observed until the moment of first egg batch laying in the control group. After the first egg batch had been observed in the control group, sex of adult beetles was determined again and reproductive performance observations were made for the next days.
The beetles were provided with one Petri dish with pine pollen (*Pinus sp.*), one Petri dish with a honey-water solution (2:1), and broad bean stems infested with the aphids, *A. pisum*. Fresh aphids on broad bean stems were introduced to the reproduction units every day except the weekends. Every week, the beetles were transferred to clean reproduction units containing fresh bean stems infested with the aphids, a fresh source of pollen, and a fresh cotton pad with a honey-water solution.
Folded sheets of paper towel were offered to the beetles for egg laying. They were checked twice a day to reduce possible cannibalism of eggs by the adults. Freshly laid eggs were cut out of the paper sheets and stored in Petri dishes.
Mortality of the beetles during the egg laying period was recorded daily, and sex of all dead insects was determined. The laid eggs were counted daily (except weekends) over a period of a reproductive performance. Egg batches were stored under laboratory conditions until the larval hatch. To assess the larval hatch, live larvae were counted over the hatching period (up to 5 days after the first larvae occurred). If the

mean number of fertile eggs per viable female per day was below 2 only in treated group, the effect on the reproductive performance was considered as treatment related.

Results

The validity criterion concerning mortality was met, because mortality of the ladybird beetle, *Coccinella septempunctata* L. in the control group was equal to 2.5% (≤ 30.0%). The corrected mortality according to the Abbott's formula of the ladybird beetles exposed to the test item at the rates of 18.1, 45.2, 113.0, 282.6 and 706.4 mL/ha, were 2.6, 0.0, 2.6, 25.6 and 76.9%, respectively.
At the significance level of 0.05, there were no statistically significant differences in mortality between the ladybirds exposed to the test item at the rates of 18.1, 45.2 and 113.0 mL/ha of CHR/H/FETEC - PART B 110 EC and the control group (Step-down Cochran-Armitage Test Procedure p(trend) > Alpha). There were statistically significant differences in mortality between the ladybirds exposed to the test item at the rates of 282.6 and 706.4 mL/ha of CHR/H/FETEC - PART B 110 EC and the control group (Step-down Cochran-Armitage Test Procedure p(trend) < Alpha).
The LR50 value is equal to 442.4 mL/ha of CHR/H/FETEC - PART B 110 EC (48.2 g fenoxaprop-P-ethyl + 23.7 g of cloquintocet-mexyl/ ha). The $NOER_{mortality}$ is equal to 113.0 mL/ha of CHR/H/FETEC - PART B 110 EC (12.3 g of fenoxaprop-P-ethyl + 6.1 g of cloquintocet-mexyl /ha).
The mortality corrected according to the Abbott's formula, of the ladybird beetles exposed to the reference item at the rate of 3.2 g of dimethoate/ha, was equal to 94.9%. Therefore, the validity criterion was met. The results showed that the insects were sensitive to dimethoate.
The mean number of fertile eggs/female/day in the control group was 6.5 (criterion: ≥ 2 eggs/female/day). The mean numbers of fertile eggs/female/day in the group treated with the of CHR/H/FETEC - PART B 110 EC at the rates of 18.1, 45.2, 113.0 and 282.6 mL/ha were equal to 5.0, 3.5, 3.6 and 3.8, it refers to 23.3, 46.1, 45.3 and 41.2% of reproduction reduction.
It can be concluded that CHR/H/FETEC - PART B 110 EC at the rates of 18.1, 45.2 and 113.0 mL/ha had no adverse effect on mortality of the ladybird beetle. However, at the rates of 282.6 and 706.4 mL/ha the test item has an adverse effect on mortality of the ladybird beetle.
Based on the results, it can be stated that CHR/H/FETEC - PART B 110 EC at the rates of 18.1, 45.2, 113.0 and 282.6 mL/ha has no adverse effect on the reproduction capacity of the ladybird beetle.

Study group	Parameters (endpoints)						
	Mortality				Reproduction		
Test item [mL/ha]	[%]	Corr.[a] [%]	LR_{50} [mL test item/ha]	LR_{50} [g a.s./ha]	Mean no. of eggs/female/day	Mean no. of fertile eggs/female/day	Reproduction reduction Pr [%]
Test item: CHR/H/FETEC - PART B 110 EC							
Control (0.0)	2.5	-	**442.4** *(n.d.)**	48.2 g of fenoxaprop-P-ethyl + 23.7 g of cloquintocet-mexyl	6.8	6.5	-
18.1	5.0	2.6			5.2	5.0	23.3
45.2	2.5	0.0			3.7	3.5	46.1
113.0	5.0	2.6			3.9	3.6	45.3
282.6+	27.5	25.6			4.1	3.8	41.2
706.4+	77.5	76.9			Not assessed		
$NOER_{mortality}$	**113.0 [mL test item/ha]**						
	[12.3 g of fenoxaprop-P-ethyl + 6.1 g of cloquintocet-mexyl /ha]						
Reference item: dimethoate							
[g/ha]	**[%]**	**Corr. [%][a]**	**Reproduction**				
3.2	95.0	94.9	not assessed				

[a]: Mortality corrected according to the formula of Abbott [1]
+: stastistically significant difference
*: the LD_{50} value (with 95%- confidence limits) calculated using ToxRat Professional 3.3.0. software [10], [SOP/B/67]

A 2.3.1.7.4 Study 5

Comments of zRMS:	The extended laboratory study was accepted. The validity criteria were met. According to the guideline of Schmuck *et al.* (2000), the reproductive performance of these beetles can only be evaluated qualitatively and a minimum value of 2.0 viable eggs/female/day is to be taken as being indicative of no harmful effect. The test item treatment did achieve > 2 viable eggs/female/day in the bioassays initiated at 0 and 14 DAT, therefore indicating no harmful effects were observed in these two consecutive bioassays. The study results were used for risk assessment.

Reference:	KCP 10.3.2/05
Report	CHR/H/FETEC-Part B 110 EC – A Series of Aged-Residue Extended Laboratory Tests to Determine Effects on the Ladybird Beetle, Coccinella septempunctata (Coleoptera: Coccinellidae); Mambo-Tox A Division of Cawood Scientific Ltd., 2 Venture Road, University Science Park Southampton SO16 7NP, UK; Ch. Van Staden Study Code: CHR-23-01
Guideline(s):	Blümel et al. (2000). Laboratory residual contact test with the predatory mite Typhlodromus pyri Scheuten (Acari: Phytoseiidae) for regulatory testing of plant protection products.)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Product code = CHR/H/FETEC-Part B 110 EC
Formulation type = emulsifiable concentrate (EC)
Batch number = 2020012
Active substance = a) cloquintocet-mexyl b) fenoxaprop-P-ethyl
Nominal content of a.s. = a) 50 g/L b) 110 g/L
Analysed content of a.s. = a) 54.47 g/L b) 108.05 g/L
Appearance = amber liquid
Analysed density = 1.04 g/cm3
Date of expiry = 28 April 2024
Storage at Test Facility = ambient laboratory conditions
Spray volume rate in test = 300 L/ha

CHR/H/FETEC-Part B 110 EC was evaluated at a single application rate, equivalent to 0.7 L test item/ha. The bioassay programme commenced on the day of treatment application, with the test item being compared to a water-treated control. A toxic reference treatment of dimethoate (an EC formulation nominally 400 g a.s./L, applied at a rate of 75 mL in 300 L water/ha) was also included in the initial bioassay only.
Treatments were applied to plants of the dwarf French bean, Phaseolus vulgaris L., var. The Prince). Applications were made using a hand-held small-plot sprayer fitted with a 2-m-wide spray boom. This was calibrated so that when the boom was moved over the tops of the plants it delivered a volume rate equivalent to 300 L spray solution/ha. Following treatment applications, the plants were maintained outdoors, but their foliage was protected from rainfall by suspending a sheet of polythene permeable to UV light above them.
Extended laboratory bioassays were carried out using leaves collected from the treated plants. The first bioassay commenced shortly after residues had dried following the treatment applications, hereafter referred to as 0 days after treatment (0 DAT), and a subsequent bioassay commenced at 14 DAT.

Excised leaves were used to line the floor of the test arenas (n = 40 per treatment) into which individual larvae of C. septempunctata (3-5 days old) were introduced. The larvae were fed with pea aphids (Acyrthosiphon pisum (Harris)) and any pre imaginal mortality of the ladybirds was recorded. A check was then made for sub-lethal effects on the reproductive performance of the adults surviving in the control and the test-item treatment rate in the 0 and 14 DAT bioassays, since the test item resulted in ≤ 50% corrected pre-imaginal mortality in each bioassay. For this assessment, the number of eggs produced by the beetles (i.e., a measure of fecundity) was recorded for a 14-day period and the number that hatched (i.e., a measure of fertility) was also assessed.
The intention of the bioassay programme was to demonstrate that residues of the test item did not result in unacceptable effects in two consecutive bioassays (i.e., demonstrating that corrected pre-imaginal mortality was ≤ 50% and that certain fecundity and fertility criteria were met).

Results and discussion

The test item in this study was CHR/H/FETEC-Part B 110 EC, an emulsifiable concentrate formulation containing cloquintocet-mexyl (nominally 50 g/L) and fenoxaprop-P-ethyl (nominally 110 g/L). The aim of this study was to evaluate the effects of both freshly-dried and field-aged foliar residues of the test item on the ladybird beetle, Coccinella septempunctata L. (Coleoptera: Coccinellidae), under extended laboratory test conditions.

The results of the mortality assessments are summarised below.

Bioassay initiated	Treatment	Test-item rate (L/ha)	% pre-imaginal mortality [a)]	Corrected % pre-imaginal mortality [b)]
0 DAT	Control	-	2.5	-
	CHR/H/FETEC-Part B 110 EC	0.7	7.5	5.1
	Toxic reference	-	97.5*	97.4
14 DAT	Control	-	7.5	-
	CHR/H/FETEC-Part B 110 EC	0.7	5.0	-2.7

a) For each bioassay, pre-imaginal mortality in the test item treatment, and the toxic reference in the 0 DAT bioassay, was compared to the control using Fisher's exact binomial test (one sided, > control, $\alpha = 0.05$). An asterisk (*) indicates where differences were significant.

b) Corrected mortalities were calculated using Abbott's formula. A positive value indicates an increase in mortality, a negative value indicates a decrease, relative to the control.

The results of the reproduction assessments are summarised below.

Bioassay initiated	Treatment	Test-item rate (L/ha)	Mean no. eggs/♀/ day	Mean % egg viability	Mean no. viable eggs/♀/ day
0 DAT	Control	-	26.2	56.7	14.9
	CHR/H/FETEC-Part B 110 EC	0.7	18.7	46.4	8.7
14 DAT	Control	-	11.9	53.1	6.3
	CHR/H/FETEC-Part B 110 EC	0.7	10.2	39.3	4.0

In the 0 and 14 DAT bioassays, the mean numbers of viable eggs produced in the test item treatment rate was > 2.0 eggs/female/day. This threshold is currently viewed as being indicative of no harmful treatment effect.

Conclusions

The effects of both fresh and aged foliar residues of CHR/H/FETEC-Part B 110 EC on the ladybird beetle, Coccinella septempunctata, were evaluated under extended laboratory conditions. When applied at a rate equivalent to 0.7 L test item/ha, freshly dried residues (0-day-old) of CHR/H/FETEC-Part B 110 EC and the subsequent bioassay evaluating 14-day-old field-aged foliar residues of CHR/H/FETEC-Part B 110 EC, showed no unacceptable effects on either the survival or the subsequent reproductive capacity of the ladybirds.

TEST VALIDITY CRITERIA

According to the guideline of Schmuck et al. (2000), for the test to be considered valid:

a) Pre-imaginal mortality (this includes dead larvae, pupae and adults dying during emergence from their pupae) in the control treatment should not exceed 30%.
b) The level of mortality in the toxic reference treatment should be ≥ 50%.
c) Mean egg production should be > 2 viable eggs/female/day in the control treatment.
All of these criteria were met throughout the study, where applicable.

A 2.4 KCP 10.4 Effects on non-target soil meso- and macrofauna

A 2.4.1 KCP 10.4.1 Earthworms

A 2.4.1.1 KCP 10.4.1.1 Earthworms - sub-lethal effects

Comments of zRMS:	The study was accepted. The validity criteria were met. No deviation was noted. The following endpoints for mortality were derived: NOEC = 320 mg formulation/kg d.w.; LC_{50} = 473.7 mg formulation/kg d.w. and for reproduction the following endpoints were derived: NOEC = 100 mg formulation/kg d.w.; EC_{50} = 383.56 mg formulation/kg d.w.

Reference:	KCP 10.4.1/01
Report	CHR/H/FETEC-PART B 110 EC Earthworm reproduction test (*Eisenia andrei*) Pieczka, P.; Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna, Department of Ecotoxicological Studies, Doświ-adczalna 27, 43-200 Pszczyna, Poland; STUDY CODE: G-01-22, 2022
Guideline(s):	According to the OECD Guideline No. 222 (2016)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test Item:	CHR/H/FETEC-PART B 110 EC batch no.: 2020012
Test Species:	the earthworm, *Eisenia andrei* obtained from a standard laboratory culture cultivated at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna, Department of Ecotoxicological Studies, Laboratory of Soil Organisms Toxicology
Test Design:	test duration: 8 weeks; number of replicates: 4 replicates/concentration + 8 replicates/control; number of earthworms: 10 earthworms/replicate
Endpoints:	EC_{10}, EC_{20}, EC_{50}, NOEC, LOEC (reproduction) LC_{50}, NOEC, LOEC (survival)
Test Concentration:	control, 5.6, 10.0, 18.0, 32.0, 56.0, 100.0, 180.0, 320.0, 560.0 and 1000.0 mg/kg dry weight of the artificial soil
Test Conditions:	temperature: 20.0 – 22.0°C; pH at the beginning of the experiment: 5.79 – 5.87; pH at the end of the experiment: 5.75 – 5.83; soil moisture content at the beginning of the experiment: 21.6 – 24.3% (50.0 – 56.2% of the maximum water holding capacity); soil moisture content at the end of the experiment: 22.2 – 25.1% (51.4 – 58.1% of the maximum water holding capacity); light-dark cycle: 16h : 8h; light intensity at the beginning of the experiment: 620.7 – 649.8 lux light intensity at the end of the experiment: 587.2 to 677.1 lux

Results and discussion:

Parameter	Value [mg test item/kg dry weight of artificial soil]	Value [mg of fenoxaprop – p – ethyl /kg dry weight of artificial soil]	Value [mg of cloquintocet – mexyl/kg dry weight of artificial soil]
EC_{10}	260.6 (177.0 – 303.4)	27.58 (18.73 – 32.11)	13.79 (9.37 –16.06)
EC_{20}	297.6 (227.7 – 337.8)	31.50 (24.10 – 35.75)	15.75 (12.05 – 17.88)
EC_{50}	383.5 (337.9 – 452.4)	40.59 (35.76 – 47.88)	20.29 (17.88 – 23.94)
NOEC (reproduction)	100.0	10.58	5.29
LOEC (reproduction)	180.0	19.05	9.53
LC_{50}	473.7 (150.9 – 969.8)	50.14 (16.0 – 102.6)	25.07 (7.99 – 51.32)
NOEC (survival)	320.0	33.87	16.93
LOEC (survival)	560.0	59.27	29.64

Mortality of the adult earthworms

After 4 weeks of the experiment, at the control group mortality of adult earthworms was equal to 7.5%. At concentrations ranging from 5.6 to 560.0 mg of the test item/kg dry weight of artificial soil, after 4 weeks of exposure to the test item, mortality of the adult earthworms was between 2.5% and 80.0%. At the concentration equal to 1000.0 mg of the test item/kg dry weight of artificial soil, 100% mortality of adult earthworms was observed. The concentration of the test item causing 50% mortality of the adult earthworms (LC_{50}) **is equal to 473.7 mg/kg dry weight of the artificial soil** (equal to 50.14 mg of fenoxaprop – p – ethyl and 25.07 mg of cloquintocet – mexyl/kg dry weight of the artificial soil).

Table 5. Mortality of the adult earthworms (*Eisenia andrei*) after 4 weeks of the exposure period.

Concentration of the test item [mg/kg dry weight of the artificial soil]	Replicate	Number of tested earthworms [no.]	Number of alive earthworms [no.]	Total mortality	
				[no.]	[%]
0.0 (control)	1 2 3 4 5 6 7 8	10 10 10 10 10 10 10 10	10 9 9 9 8 9 10 10	6	7.5
5.6	1 2 3 4	10 10 10 10	10 10 9 10	1	2.5
10.0	1 2 3 4	10 10 10 10	10 8 8 10	4	10.0
18.0	1 2 3 4	10 10 10 10	9 10 9 10	2	5.0
32.0	1 2 3 4	10 10 10 10	9 9 8 10	4	10.0
56.0	1 2 3 4	10 10 10 10	10 10 10 8	2	5.0
100.0	1 2 3 4	10 10 10 10	8 10 10 9	3	7.5
180.0	1 2 3 4	10 10 10 10	9 8 9 10	4	10.0
320.0	1 2 3 4	10 10 10 10	8 10 8 10	4	10.0
560.0	1 2 3 4	10 10 10 10	3 1 2 2	32*	80.0
1000.0	1 2 3 4	10 10 10 10	0 0 0 0	40*	100.0

* - statistically significant difference (Fisher's Exact Binomial Test with Bonferroni Correction, alpha = 0.05, one-sided greater)

Observations of the earthworms

After 4 weeks of the experiment, at the concentrations between 5.6 and 1000.0 mg of the test item/kg dry weight of the artificial soil, the changes in appearance and behaviour of the adult earthworms were not observed.

Body weights of the living adult earthworms

After 4 weeks of the exposure period of the test item at the concentrations ranging from 5.6 to 560.0 mg/kg dry weight of artificial soil, the body weight change was between -15.9 and 5.6%. As for the co trol group, the body weight increase was equal to 3.4%.

Impact of the test item on reproduction of the earthworms

After the application of the test item at the concentrations ranging from 5.6 to 1000.0 mg/kg dry weight of the artificial soil, the mean number of juveniles was between 0.0 and 71.0 per replicate. The mean number of juveniles in the control group was equal to 68.3 per replicate. After 8 weeks of the experiment, it was concluded that CHR/H/FETEC-PART B 110 EC had a statistically significant impact on reproduction of

the earthworms at the concentrations ranging from 180.0 to 1000.0 mg/kg dry weight of artificial soil. The concentration of the test item causing a 10% reduction in the number of juveniles produced within the exposure period **(EC_{10}) is equal to 260.6 mg/kg dry weight of the artificial soil** (equal to 27.58 mg of fenoxaprop – p – ethyl and 13.79 mg of cloquintocet – mexyl/kg dry weight of the artificial soil) The concentration of the test item causing a 20% reduction in the number of juveniles produced within the exposure period **(EC_{20}) is equal to 297.6 mg/kg dry weight of the artificial soil** (equal to 31.5 mg of fenoxaprop – p – ethyl and 15.75 mg of cloquintocet – mexyl/kg dry weight of the artificial soil). The concentration of the test item causing a 50% reduction in the number of juveniles produced within the exposure period **(EC_{50}) is equal to 383.5 mg/kg dry weight of the artificial soil** (equal to 40.59 mg of fenoxaprop – p – ethyl and 20.29 mg of cloquintocet – mexyl/kg dry weight of the artificial soil). The highest concentration at which the test item is observed to have no statistically significant effects on r production **(NOEC) is equal to 100.0 mg/kg dry weight of the artificial soil** (equal to 10.58 mg of f noxaprop – p – ethyl and 5.29 mg of cloquintocet – mexyl/kg dry weight of the artificial soil). The lowest concentration at which the test item is observed to have a statistically significant effect on reproduction **(LOEC) is equal to 180.0 mg/kg dry weight of the artificial soil** (equal to 19.05 mg of fenoxaprop – p – ethyl and 9.53 mg of cloquintocet – mexyl/kg dry weight of the artificial soil).

Observations of the juveniles of earthworms

After 8 weeks of the experiment, the juveniles of earthworms did not exhibit any changes in appearance and behaviour.

Table 10. Results of the observations for changes in behaviour and in morphology of the juveniles earthworms.

Concentration of the test item [mg/kg dry weight of the artificial soil]	Replicate	Number of juveniles after 8 weeks of the exposure [no.]	Changes in behaviour and in morphology
0.0 (control)	1	82	nc
	2	83	nc
	3	77	nc
	4	59	nc
	5	42	nc
	6	70	nc
	7	71	nc
	8	62	nc
5.6	1	71	nc
	2	68	nc
	3	57	nc
	4	61	nc
10.0	1	67	nc
	2	63	nc
	3	58	nc
	4	70	nc
18.0	1	56	nc
	2	67	nc
	3	67	nc
	4	94	nc
32.0	1	62	nc
	2	58	nc
	3	75	nc
	4	59	nc
56.0	1	71	nc
	2	69	nc
	3	74	nc
	4	56	nc
100.0	1	72	nc
	2	67	nc
	3	73	nc
	4	54	nc
180.0	1	59	nc
	2	34	nc
	3	64	nc
	4	68	nc
320.0	1	65	nc
	2	55	nc
	3	43	nc
	4	40	nc
560.0	1	0	-
	2	0	-
	3	18	nc
	4	6	nc
1000.0	1	0	-
	2	0	-
	3	0	-
	4	0	-

nc – no changes

Results of the reference test

The lowest concentration at which the test item is observed to have a statistically significant effect on reproduction (LOEC) is equal to 2.25 mg/kg dry weight of the artificial soil.
According to the OECD Guideline No. 222, the LOEC should be between 1 – 5 mg/kg dry weight of the artificial soil; hence, it may be concluded that the sensitivity of the test organisms was proper.

VALIDITY CRITERIA

The results are considered valid because the following criteria were satisfied in the controls:

- • each replicate produced from 42 to 83 juveniles (68.3 mean) at the end of the exposure period (criterion: ≥ 30 juveniles by the end of the experiment),
- • the coefficient of variation of reproduction was 20.0% (criterion: ≤ 30%),
- • adult mortality over the initial 4 weeks of the experiment was 7.5% (criterion: ≤ 10%).

DEVIATIONS IN THE STUDY

No deviations from OECD Guideline No. 222 (2016), SOP/G/36 and the Study Plan were noticed.

A 2.4.1.2 KCP 10.4.1.2 Earthworms - field studies

No additional studies were performed.

A 2.4.2 KCP 10.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms)

Comments of zRMS:	The submitted study was accepted. The validity criteria were met: • mean adult mortality: ≤ 20 %; observed 5.0 %; • mean number of juveniles per test vessel: ≥ 100; observed: average 875 per vessel; • coefficient of variation for the mean number of juveniles: < 30 %; observed 23.6%. The following endpoints were derived: **mortality**: NOEC = 56.0 mg test item/kg soil d.w. LC_{50} = 101.85 mg test item/kg soil d.w. **reproduction**: NOEC = 56.0 mg test item/kg soil d.w. EC_{50} = 96.98 mg test item/kg soil d.w. The study results can be used in risk assessment.

A 2.4.2.1.1 Study 1

Reference:	KCP 10.4.2/01
Report	CHR/H/FETEC-PART B 110 EC Collembolan (*Folsomia candida*) Reproduction Test, A. Wróbel; Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna, Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland; STUDY CODE: G-02-22; 2022
Guideline(s):	according to the OECD Guideline No. 232 (2016)
Deviations:	Yes
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test Item:	CHR/H/FETEC-PART B 110 EC batch no.: 2020012
Test Species:	the collembolan, *Folsomia candida* obtained from a standard laboratory culture at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna, Laboratory of Soil Toxicology. The collembolans used in the study were 9 – 12 days old.
Test Design:	Exposure time: 28 days number of replicates: 4 replicates / concentration + 8 replicates / control; number of collembolans: 10 / replicate
Endpoints:	EC_{10}, EC_{20}, EC_{50}, NOEC LC_{10}, LC_{20}, LC_{50}, NOEC
Test Concentration:	a control, 5.6, 10, 18, 32; 56; 100; 180; 320; 560; 1000 mg of the test item/kg of dry weight of the artificial soil
Test Conditions:	temperature: 20.0 – 22.0°C; pH at the beginning of the test: 5.55 – 5.61; pH at the end of the test: 5.44 – 5.56; soil moisture content at the beginning of the test: 16.7 – 17.2% (49.3 – 50.8% of the maximum water holding capacity); soil moisture content at the end of the test: 15.1 – 15.9% (44.6 – 47.0% of the maximum water holding capacity); lighting: 16 h light and 8h dark; light intensity at the beginning of the experiment: 427.2 – 474.3 lux; light intensity at the end of the experiment: 448.1 – 500.8 lux;

Results and discussion:

Mortality

After the application of the test item at the concentrations ranging from 5.6 to 180.0 mg/kg dry weight of the artificial soil, the mortality of adults was between 2.5 and 80.0%. No survival collembolans after application of the test item at the concentrations: 320.0, 560.0 and 1000.0 mg/kg dry weight of the artificial soil were observed. As for the control group, mortality of collembolans was equal to 5.0%. The concentration of the test item causing a 50% mortality of adults within the exposure period (LC_{50}) is equal to 101.85 mg/kg dry weight of the artificial soil (i.e. 10.68 mg of fenoxaprop-P-ethyl + 5.25 mg of cloquintocet mexyl/kg dry weight of the artificial soil).

Table 6. Endpoint values – the impact of the test item on the mortality of adult collembolans (*Folsomia candida*).

Endpoint	Value [mg test item/kg dry weight of the artificial soil]	Value [mg of fenoxaprop-p-ethyl/kg dry weight of the artificial soil]	Value [mg of cloquintocet-mexyl/kg dry weight of the artificial soil]
LC_{10}	49.40 (18.09 – 72.15)	5.18 (1.90 – 7.57)	2.54 (0.93 – 3.72)
LC_{20}	64.52 (31.13 – 90.23)	6.77 (3.27 – 9.46)	3.32 (1.60 – 4.65)
LC_{50}	101.85 (68.79 – 151.36)	10.68 (7.22 – 15.88)	5.25 (3.54 – 7.79)
NOEC	56.0	5.87	2.88

Impact on reproduction

After the exposure of collembolans to the test item at the concentrations ranging from 5.6 to 180.0 mg/kg dry weight of the artificial soil, the mean number of juveniles was between 66.3 and 1150.3 per replicate. No juvenile collembolans after application of the test item at the concentrations 320.0, 560.0 and 1000.0 mg/kg dry weight of artificial soil were observed. As for the control group, the number of juveniles was equal to 875.8 per replicate.

The obtained results led to the following conclusions:
-The concentration of the test item causing a 10% reduction in the number of juveniles produced within the exposure period (EC_{10}) is equal to 64.28 mg/kg dry weight of the artificial soil (i.e. 6.74 mg of fenoxaprop-P-ethyl + 3.31 mg of cloquintocet mexyl/kg dry weight of the artificial soil);

The concentration of the test item causing a 20% reduction in the number of juveniles produced within the exposure period (EC_{20}) is equal to 74.03 mg/kg dry weight of the artificial soil (i.e. 7.76 mg of fenoxaprop-P-ethyl + 3.81 mg of cloquintocet mexyl/kg dry weight of the artificial soil);

The concentration of the test item causing a 50% reduction in the number of juveniles produced within the exposure period (EC_{50}) is equal to 96.98 mg/kg dry weight of the artificial soil (i.e. 10.17 mg of fenoxaprop-p-ethyl + 4.99 mg of cloquintocet mexyl/kg dry weight of the artificial soil).

The highest concentration at which the test item is observed to have no statistically significant effects on collembolan reproduction (NOEC) is equal to 56.0 mg/kg dry weight of the artificial soil (i.e. 5.87 mg of fenoxaprop-P-ethyl + 2.88 mg of cloquintocet mexyl/kg dry weight of the artificial soil).

Table 8. Endpoint values – the impact of the test item on reproduction of collembolans (*Folsomia candida*).

Endpoint	Value [mg test item/kg dry weight of the artificial soil]	Value [mg of fenoxaprop-p-ethyl/kg dry weight of the artificial soil]	Value [mg of cloquintocet-mexyl/kg dry weight of the artificial soil]
EC_{10}	64.28 (53.82 – 71.21)	6.74 (5.64 – 7.47)	3.31 (2.77 – 3.67)
EC_{20}	74.03 (65.33 – 79.77)	7.76 (6.85 – 8.37)	3.81 (3.36 – 4.11)
EC_{50}	96.98 (92.43 – 101.48)	10.17 (9.69 – 10.64)	4.99 (4.76 – 5.23)
NOEC	56.0	5.87	2.88

Observations of the collembolans

After 4 weeks of the experiment, at the concentrations between 5.6 and 180.0 mg of the test item/kg dry weight of the artificial soil, the changes in appearance and behaviour of the collembolans were not observed. No juvenile collembolans after application of the test item at the concentrations 320.0, 560.0 and 1000.0 mg/kg dry weight of artificial soil were observed.

Results of the reference test

The concentration of boric acid causing a 50% reduction in the number of juveniles produced within the exposure period (EC_{50}) is 93.2 mg/kg dry weight of the artificial soil.
According to the OECD Guideline No. 232, the EC_{50} should be about 100 mg/kg dry weight of the artificial soil; hence, it may be concluded that the sensitivity of the test organisms was proper. The test was conducted 25.01.2022 – 22.02.2022.

VALIDITY CRITERIA

The results are considered valid because the following criteria were satisfied in the controls:
-mean adult mortality: 5.0% (criterion: ≤ 20%),

-the mean number of juveniles per vessel at the end of the test: 875.8 (criterion: ≥100 juveniles at the end of the test),

-the coefficient of variation calculated for the number of juveniles: 23.6% (criterion: ≤ 30%).

DEVIATIONS IN THE STUDY

Deviations from the OECD Guideline No. 232 (2016):
- culturing of collembolans takes place in plastic containers containing an artificial substrate consisting of plaster and charcoal in ratio 9:1 and not 10:1 or 8:1 as is mentioned in OECD Guideline No. 232 (2016),

- at the end of the test the soil moisture content was determined by drying small sample of the artificial soil in 105°C instead of weighing the test vessels as it is mentioned in OECD Guideline No. 232 (2016). The deviations did not affect the results of the study.

A 2.4.2.1.1 Study 2

Comments of zRMS:	The submitted study was accepted. The validity criteria were met: • mean mortality of adult females: ≤ 20 %; observed 0 %; • mean number of juveniles per replicate: ≥ 50; observed 134.3; • coefficient of variation (mean number of juveniles per replicate): ≤ 30 %; observed 15.5 %. The following endpoints were derived: • mortality: NOEC = 100 mg test item/kg soil d.w. LC_{50} = 508.87 mg test item/kg soil d.w. • reproduction: NOEC = 180 mg test item/kg soil d.w. EC_{50} = 310.06 mg test item/kg soil d.w. The study results can be used in risk assessment.

Reference:	KCP 10.4.2/02
Report	CHR/H/FETEC-PART B 110 EC Predatory mite (*Hypoaspis (Geolaelaps) aculeifer*) reproduction test in soil; Wróbel, A.; Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna, Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland; STUDY CODE: G-03-22; 2022
Guideline(s):	according to the OECD Guideline No. 226 (2016)
Deviations:	Yes
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test Item:	CHR/H/FETEC-PART B 110 EC batch number: 2020012

Test Species:	the predatory mites, *Hypoaspis (Geolaelaps) aculeifer* (adult female mites from a synchronized culture) obtained from a standard laboratory culture at the Łukasiewicz Research Network - Institute of Industrial Organic Chemistry Branch Pszczyna, Department of Ecotoxicological Studies, Laboratory of Soil Organisms Toxicology. The mites were introduced 7 – 14 days after becoming adult.
Test Design:	exposure period: 14 days number of replicates: 4 replicates / concentration + 8 replicates / control; number of mites: 10 mites / replicate
Endpoints:	EC_{10}, EC_{20}, EC_{50}, NOEC LC_{10}, LC_{20}, LC_{50}, NOEC
Test Concentration:	a control, 5.6, 10, 18, 32, 56, 100, 180, 320, 560 and 1000 mg test item/kg dry weight of the artificial soil.
Test Conditions:	temperature: 21.2 – 22.0°C pH at the beginning of the test: 5.56 – 5.63 pH at the end of the test: 5.48 – 5.66 soil moisture content at the beginning of the test: 15.3 – 16.1% (45.2 – 47.6% of the maximum water holding capacity) soil moisture content in the middle of the test: 14.0 – 16.4% (41.4 – 48.4% of the maximum water holding capacity) soil moisture content at the end of the test: 14.0 – 15.6% (41.4 – 46.1% of the maximum water holding capacity) light-dark cycle: 16 h light and 8 h dark light intensity at the beginning of the test: 631.7 – 662.8 lux light intensity at end of the test: 639.3 – 659.1 lux

Results and discussions

Mortality of adult females

Mortality of the predatory mites exposed to the test item at the concentrations ranging from 5.6 to 560.0 mg/kg dry weight of the artificial soil was between 0.0% and 42.5%. Mortality of the predatory mites exposed to the test item at the concentration of 1000.0 mg/kg dry weight was equal to 100.0%.
Mortality of the control group was equal to 0.0%.
The concentration of the test item causing a 50% mortality of adults within the exposure period (LC_{50}) is equal to 508.87 mg/kg dry weight of the artificial soil (i.e. 53.37 mg of fenoxaprop-P-ethyl + 26.20 mg og cloquintocet mexyl/kg dry weight of artificial soil).

Table 6. Mortality of adult mites (*Hypoaspis aculeifer*) after 14 days of the experiment.

Concentration [mg/kg dry weight of the artificial soil]	Replicate	Number of tested mites	Number of alive mites after 14 days [no.]	Mortality	
				no.	%
0.0 (control)	1 2 3 4 5 6 7 8	10 10 10 10 10 10 10 10	10 10 10 10 10 10 10 10	0	0.0
5.6	1 2 3 4	10 10 10 10	10 10 10 10	0	0.0
10.0	1 2 3 4	10 10 10 10	10 10 10 8	2	5.0
18.0	1 2 3 4	10 10 10 10	10 10 10 10	0	0.0
32.0	1 2 3 4	10 10 10 10	10 10 10 10	0	0.0
56.0	1 2 3 4	10 10 10 10	10 10 10 10	0	0.0
100.0	1 2 3 4	10 10 10 10	10 10 10 10	0	0.0
180.0	1 2 3 4	10 10 10 10	8 6 10 10	6*	15.0
320.0	1 2 3 4	10 10 10 10	8 8 8 9	7*	17.5
560.0	1 2 3 4	10 10 10 10	5 6 3 9	17*	42.5
1000.0	1 2 3 4	10 10 10 10	0 0 0 0	40*	100.0

* statistically significant difference between the control and the treatment group (Fisher's Exact Binomial Test with Bonferroni Correction, significance level = 0.05, one-sided greater)

Table 7. Endpoint values – the impact of the test item on survival of adult females.

Endpoint	Value [mg of the test item/kg dry weight of the artificial soil]	Value [mg of fenoxaprop-P-ethyl/kg dry weight of the artificial soil]	Value [mg of cloquintocet-mexyl/kg dry weight of the artificial soil]
LC_{10}	128.66 (<5.6 – 342.36)	13.49 (<0.59 – 35.91)	6.63 (<0.29 – 17.63)
LC_{20}	206.27 (<5.6 – 856.40)	21.64 (<0.59 – 89.83)	10.62 (<0.29 – 44.10)
LC_{50}	508.87 (173.06 – >1000.0)	53.37 (18.15 – >104.89)	26.20 (8.91 – >51.50)
NOEC (survival)	100.0	10.49	5.15

Impact on reproduction

After the application of the test item at the concentrations ranging from 5.6 to 320.0 mg/kg dry weight of the artificial soil the mean number of juveniles was between 56.8 and 161.0 per replicate. No juveniles mites after application of the test item at the concentrations of 560.0 and 1000.0 mg/kg dry weight of artificial soil were observed. The mean number of juveniles in the control group was equal to 134.3 per replicate.

The obtained results led to the following conclusions:

-The concentration of the test item causing a 10% reduction in the number of mites produced within the exposure period (EC_{10}) is equal to 248.22 mg/kg dry weight of the artificial soil (i.e. 26.03 mg of fenoxaprop-P-ethyl + 12.78 mg of cloquintocet mexyl/kg dry weight of the artificial soil).

-The concentration of the test item causing a 20% reduction in the number of mites produced within the exposure period (EC_{20}) is equal to 269.46 mg/kg dry weight of the artificial soil (i.e. 28.26 mg of fenoxaprop-P-ethyl + 13.88 mg of cloquintocet mexyl/kg dry weight of the artificial soil).

-The concentration of the test item causing a 50% reduction in the number of mites produced within the exposure period (EC_{50}) is equal to 310.06 mg/kg dry weight of the artificial soil. (i.e. 32.52 mg of fenoxaprop-P-ethyl + 15.97 mg of cloquintocet mexyl/kg dry weight of the artificial soil).

-The highest concentration at which the test item is observed to have no statistically significant effects on mite reproduction (NOEC) is equal to 180.0 mg/kg dry weight of the artificial soil (i.e. 18.88 mg of fenoxaprop-P-ethyl + 9.27 mg of cloquintocet mexyl/kg dry weight of the artificial soil).

Table 8. Number of juvenile mites (*Hypoasis aculeifer*) after 14 days of the exposure.

Concentration [mg/kg dry weight of soil]	Replicate	Number of juvenile mites	Mean ±SD	Comparison to the control [%]	CV* [%]
0.0 (control)	1 2 3 4 5 6 7 8	140 106 138 127 105 164 142 152	134.3 ± 20.7	-	15.5
5.6	1 2 3 4	180 147 146 171	161.0 ± 17.1	119.9	10.6
10.0	1 2 3 4	149 191 152 140	158.0 ± 22.6	117.7	14.3
18.0	1 2 3 4	140 109 151 167	141.8 ± 24.5	105.6	17.3
32.0	1 2 3 4	159 179 139 133	152.5 ± 20.9	113.6	13.7
56.0	1 2 3 4	126 152 163 113	138.5 ± 23.0	103.2	16.6
100.0	1 2 3 4	148 140 116 166	142.5 ± 20.7	106.1	14.6
180.0	1 2 3 4	140 105 166 151	140.5 ± 26.0	104.7	18.5
320.0	1 2 3 4	55 65 46 61	56.8⁺ ± 8.3	42.3	14.6
560.0	1 2 3 4	0 0 0 0	0.0⁺	0.0	-
1000.0	1 2 3 4	0 0 0 0	0.0⁺	0.0	-

* - coefficient of variation

⁺ statistically significant difference between the control and the treatment group (Williams Multiple Sequential t-test Procedure, significance level = 0.05, one-sided smaller)

Table 9. Endpoint values - the impact of the test item on reproduction of the predatory mites (*Hypoaspis aculeifer*).

Endpoint	Value [mg of the test item/kg dry weight of the artificial soil]	Value [mg of fenoxaprop-P-ethyl/kg dry weight of the artificial soil]	Value [mg of cloqiontocet-mexyl/kg dry weight of the artificial soil]
EC_{10}	248.22 (185.24 – 271.21)	26.03 (19.43 – 28.45)	12.78 (9.54 – 13.97)
EC_{20}	269.46 (221.04 – 286.11)	28.26 (23.18 – 30.01)	13.88 (11.38 – 14.73)
EC_{50}	310.06 (298.96 – 313.53)	32.52 (31.36 – 32.89)	15.97 (15.40 – 16.15)
NOEC (reproduction)	180.0	18.88	9.27

Results of the reference test

The concentration of boric acid causing a 50% reduction in the number of juveniles produced within the exposure period (EC_{50}) is 293.9 mg/kg dry weight of the artificial soil. According to the OECD Guideline No. 226, the EC_{50} should be between 100 and 500 mg/kg dry weight of the artificial soil; hence, it may be concluded that the sensitivity of the test organisms was proper.

VALIDITY CRITERIA

The results are considered valid because the following criteria were satisfied in the control:
-mean adult mortality: 0.0% (criterion: ≤ 20%),

-the mean number of juveniles per vessel at the end of the test: 134.3 (criterion: ≥ 50 juveniles at the end of the test),

-the coefficient of variation for the number of juveniles: 15.5% (criterion: ≤ 30%).

DEVIATIONS IN THE STUDY

There are three deviations from the OECD Guideline No. 226 (2016), however they did not affect the results:
1. According to the OECD Guideline No. 226 (2016) the water content of the artificial soil should be maintained throughout the test by weighing and if needed re-watering the vessels periodically. In the study to maintain proper moisture content, a small sample of soil was drying at 105°C and re-weighing at the beginning, after 7 days of the test and at the end of the test.

2. Due to the use of the temperature extraction method, there was no need for euthanasia of the extracted organisms since the mites are fixed in a 70% ethanol solution.

3. Due to the use of the temperature extraction method, it was not possible to record the symptoms with behavioral and morphology changes of the extracted predatory mites.

All above mentioned deviations did not influence the study course and results.

A 2.4.2.2 KCP 10.4.2.1 Species level testing

No additional studies were performed.

A 2.4.2.3 KCP 10.4.2.2 Higher tier testing

No additional studies were performed.

A 2.5 KCP 10.5 Effects on soil nitrogen transformation

Comments of zRMS:	The submitted study was accepted. The validity criteria were met. No adverse effects on soil nitrogen transformation (measured as NO_3-N-production) at the end of the 28-day incubation period were observed. The effect less than 25% was observed at application rate of 4.83 and 24.15 mg formulation/kg dw soil.

Report	CHR/H/FETEC- PARTB 110 EC Soil Microorganisms: Nitrogen Transformation Test, Dec, W.; Ecomelius Institute Sp. z o. o. Kalinowa 2, Zaborze 43-520 Chybie, Poland; study code: EMI/4/547/2020; 2020
Guideline(s):	according to OECD Guideline No. 216 (2000)
Deviations:	Yes
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test Item:	CHR/H/FETEC-PARTB 110 EC batch no.: 2020012
Test Species:	Agricultural soil (Type 5M) purchased from LUFA Speyer Obere Langgasse 40, 67346 Speyer. Storage conditions (before the experiment): temperature: 4.3 – 4.6°C in darkness for one day. Soil was preincubated under test conditions (temperature: 19.4 - 20.4°C, soil moisture: 45.09% of the maximum water holding capacity) for a period of 6 days before the start of the experiment in darkness.
Test Design:	Three portions of soil weighing 1800 g each: one control group and two groups containing the test item. Every portion was divided into three replicates weighing about 600 g each. Test duration: 28 days.
Endpoints:	The concentration of nitrate [mg/kg dry weight soil] after 0, 7, 14, and 28 days of incubation The nitrate formation rate [mg/kg dry weight of soil/day] for selected time intervals of soil incubation, i.e. 0 - 7, 0 – 14, 0 – 28 days. Percent deviation from the control in nitrate formation rate calculated for selected time intervals i.e. 0 - 7, 0 – 14, 0 – 28 days.
Test Concentration:	control, PEC: 4.83 mg of the test item/kg dry weight of soil (0.51 mg of fenoxaprop-P-ethyl and 0.36 mg of cloquintocet mexyl /kg dry weight of soil), upper PEC: 24.15 mg of the test item/kg of soil (2.55 mg of fenoxaprop-P-ethyl and 1.83 mg of cloquintocet mexyl /kg dry weight of soil).
Test Conditions:	temperature: 19.3 – 20.4°C, soil moisture: 47.17% – 53.80% of the maximum water holding capacity, incubation in darkness.

Results and discussion:

On day 0 and after 7 and 28 days of incubation, no statistically significant differences in the nitrate concentration between the control soil and the soil treated with the test item at the concentration of 4.83 mg of the test item/kg dry weight of soil (0.51 mg of fenoxaprop-P-ethyl and 0.36 mg of cloquintocet mexyl /kg dry weight of soil) (PEC) were noticed. After 14 days of incubation statistically significant differences in the nitrate concentration between the control soil and the soil treated with the test item at the concentration corresponded to the PEC was observed.

Table 5 Concentration of the nitrate ions in soil on day 0 of incubation

Concentration	Replicate	Nitrate ion concentration [mg/kg dry weight of soil]	Mean nitrate ion concentration ± SD [mg/kg dry weight of soil]	Coefficient of variation [%]
Control	1	42.067	39.515 ± 4.391	11.1
	2	42.034		
	3	34.445		
PEC 4.83 mg of the test item/kg dry weight of soil (0.51 mg of fenoxaprop-P-ethyl and 0.36 mg of cloquintocet mexyl /kg dry weight of soil)	1	32.448	35.962 ± 4.101	11.4
	2	34.972		
	3	40.467		
Upper PEC 24.15 mg of the test item/kg of soil (2.55 mg of fenoxaprop-P-ethyl and 1.83 mg of cloquintocet mexyl /kg dry weight of soil)	1	40.467	36.805 ± 4.055	11.0
	2	32.448		
	3	37.500		

Mean, SD and Coefficient of variation based on the data obtained from ToxRat statistical analysis (Appendix No. 5).

After 7 and 14 days of incubation, statistically significant differences in the nitrate concentration between the control soil and the soil treated with the test item at the concentration of 24.15 mg of the test item/kg of soil (2.55 mg of fenoxaprop-P-ethyl and 1.83 mg of cloquintocet mexyl /kg dry weight of soil) (upper PEC) were noticed. Apart from that, there were no statistically significant differences in the nitrate concentrations at any day of incubation between control soil and the upper PEC.

Table 6 Concentration of the nitrate ions in soil on day 7 of incubation

Concentration	Replicate	Nitrate ion concentration [mg/kg dry weight of soil]	Mean nitrate ion concentration ± SD [mg/kg dry weight of soil]	Coefficient of variation [%]
Control	1	104.500	108.000 ± 8.789	8.1
	2	101.500		
	3	118.000		
PEC 4.83 mg of the test item/kg dry weight of soil (0.51 mg of fenoxaprop-P-ethyl and 0.36 mg of cloquintocet mexyl /kg dry weight of soil)	1	114.000	117.000 ± 3.606	3.1
	2	116.000		
	3	121.000		
Upper PEC 24.15 mg of the test item/kg of soil (2.55 mg of fenoxaprop-P-ethyl and 1.83 mg of cloquintocet mexyl /kg dry weight of soil)	1	129.000	130.500* ± 9.836	7.5
	2	121.500		
	3	141.000		

* statistically significant differences in nitrate concentrations between the control soil and the soil treated with the test item (STUDENT-t test for homogeneous variances, two-sided)

Mean, SD and Coefficient of variation based on the data obtained from ToxRat statistical analysis (Appendix No. 5)

At the time interval 0 - 14 days, statistically significant differences in the nitrate formation rate between the control soil and the soil treated with the test item at the concentration of 4.83 mg of the test item/kg dry weight of soil (0.51 mg of fenoxaprop-P-ethyl and 0.36 mg of cloquintocet mexyl /kg dry weight of soil) (PEC) were noticed.

Table 7 Concentration of the nitrate ions in soil on day 14 of incubation

Concentration	Replicate	Nitrate ion concentration [mg/kg dry weight of soil]	Mean nitrate ion concentration ± SD [mg/kg dry weight of soil]	Coefficient of variation [%]
Control	1	153.500	153.333 ± 6.252	4.1
	2	147.000		
	3	159.500		
PEC 4.83 mg of the test item/kg dry weight of soil (0.51 mg of fenoxaprop-P-ethyl and 0.36 mg of cloquintocet mexyl /kg dry weight of soil)	1	193.500	188.333* ± 8.949	4.8
	2	193.500		
	3	178.000		
Upper PEC 24.15 mg of the test item/kg of soil (2.55 mg of fenoxaprop-P-ethyl and 1.83 mg of cloquintocet mexyl /kg dry weight of soil)	1	183.000	180.667* ± 18.113	10.0
	2	197.500		
	3	161.500		

* statistically significant differences in nitrate concentrations between the control soil and the soil treated with the test item (STUDENT-t test for homogeneous variances, two-sided)

Mean, SD and Coefficient of variation based on the data obtained from ToxRat statistical analysis (Appendix No. 5).

At the time intervals: 0 – 7, 0 - 14 days, statistically significant differences in the nitrate formation rate between the control soil and the soil treated with the test item at the concentration of 24.15 mg of the test item/kg of soil (2.55 mg of fenoxaprop-P-ethyl and 1.83 mg of cloquintocet mexyl /kg dry weight of soil) (upper PEC) were noticed. Apart from that, there were no statistically significant differences in the nitrate formation rates at any time interval between control soil and both soil treated with the test item at the concentration of of 4.83 mg of the test item/kg dry weight of soil (0.51 mg of fenoxaprop-P-ethyl and 0.36 mg of cloquintocet mexyl /kg dry weight of soil) (PEC) and soil treated with the test item at the concentration of 24.15 mg of the test item/kg of soil (2.55 mg of fenoxaprop-P-ethyl and 1.83 mg of cloquintocet mexyl /kg dry weight of soil) (upper PEC). When results from tests with agrochemicals are evaluated, and the difference in the rates of nitrate formation between the lower treatment (i.e. the maximum predicted concentration) and control is equal to or less than 25% at any sampling time after day 28, the product can be evaluated as having no long-term influence on nitrogen transformation in soils.

Table 8 Concentration of the nitrate ions in soil on day 28 of incubation

Concentration	Replicate	Nitrate ion concentration [mg/kg dry weight of soil]	Mean nitrate ion concentration ± SD [mg/kg dry weight of soil]	Coefficient of variation [%]
Control	1	233.500	232.333 ± 25.770	11.1
	2	206.000		
	3	257.500		
PEC 4.83 mg of the test item/kg dry weight of soil (0.51 mg of fenoxaprop-P-ethyl and 0.36 mg of cloquintocet mexyl /kg dry weight of soil)	1	239.500	222.833 ± 29.738	13.3
	2	240.500		
	3	188.500		
Upper PEC 24.15 mg of the test item/kg of soil (2.55 mg of fenoxaprop-P-ethyl and 1.83 mg of cloquintocet mexyl /kg dry weight of soil)	1	262.500	261.167 ± 2.754	1.1
	2	258.000		
	3	263.000		

Mean, SD and Coefficient of variation based on the data obtained from ToxRat statistical analysis (Appendix No. 5)

As regards to the obtained results, it was concluded that CHR/H/FETEC-PARTB 110 EC at the concentrations corresponding to the PEC – 4.83 mg of the test item/kg dry weight of soil (0.51 mg of fenoxaprop-P-ethyl and 0.36 mg of cloquintocet mexyl /kg dry weight of soil) and upper PEC (5xPEC) – 24.15 mg of the test item/kg of soil (2.55 mg of fenoxaprop-P-ethyl and 1.83 mg of cloquintocet mexyl /kg dry weight of soil) can be perceived as having no long-term influence on nitrogen transformations in soil.

A deviation from the study plan occurred:
1. Contrary to what had been planned, the study was finalized in April 2021, not in February 2021.

Described deviation did not affect the study results.
No others deviations from OECD Guideline No. 216 (2000), the Study Plan, and the SOPs mentioned in chapter 8 occurred in the study.

A 2.6 KCP 10.6 Effects on terrestrial non-target higher plants

A 2.6.1 KCP 10.6.1 Summary of screening data

No additional studies were performed.

A 2.6.2 KCP 10.6.2 Testing on non-target plants

A 2.6.2.1.1 Study 1

Comments of zRMS:	The submitted study was accepted. The validity criteria were met: The following endpoints were derived: • ER_{50} > 706 mL test item/ha, equivalent to > 76.96 g a.s./ha; • NOER ≥ 706 mL test item/ha, equivalent to > 76.96 g a.s./ha. The endpoint ER_{50} will be used in risk assessment.

Reference:	KCP 10.6/01
Report	CHR/H/FETEC-PART B 110 EC Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test; Wróbel, A. Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna, Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland; STUDY CODE: G-05-22
Guideline(s):	according to the OECD Guideline No. 208 (2006)
Deviations:	Yes
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test Item:	CHR/H/FETEC-PART B 110 EC batch number: 2020012 active substance: fenoxaprop-P-ethyl – 109.01 g/L safener: cloquintocet-mexyl – 53.52 g/L
Test Design:	number of rates: 8 + control; number of replicates/rate: 7 (sunflower, pea, cabbage), 4 (onion, perennial ryegrass and oats). The total number of seeds per application rate: 21 (sunflower, pea, cabbage) and 20 (onion, perennial ryegrass and oats)
Endpoints:	ER_{10}, ER_{25}, ER_{50}, NOER

Test Concentration:

Test item (mL/ha)	Content of fenoxaprop-P-ethyl (g/ha)	Content of cloquintocet-mexyl (g/ha)
1.2	0.13	0.06
2.9	0.32	0.16
7.2	0.78	0.39
18.1	1.97	0.97
45.2	4.93	2.42
113.0	12.32	6.05
282.4	30.78	15.11
706.0	76.96	37.79

In case of each species, there was one untreated control group. A separation factor was 2.5. The volume of deionised water used to prepare the test item at the highest rate corresponded to 300 L of spraying liquid/ha.

Test Conditions:

temperature: 18.3 – 26.3°C, humidity: 56.2 – 87.3%,
lighting: 16 h light : 8 h dark; light intensity: 92.4 – 232.3 µE/m2/s; carbon dioxide concentration: 333 – 357 ppm

Results and discussion:

Table 36. ER_{10}, ER_{25}, ER_{50} and NOER values (mL of test item/ha) – sunflower, pea, cabbage

	Sunflower *Helianthus annuus*	**Pea** *Pisum sativum*	**Cabbage** *Brassica oleracea var. capitata*
Plant number at the end of the experiment			
ER_{10}	> 706.0	> 706.0	> 706.0
ER_{25}	> 706.0	> 706.0	> 706.0
ER_{50}	> 706.0	> 706.0	> 706.0
NOER	≥ 706.0	≥ 706.0	≥ 706.0
Shoot length			
ER_{10}	> 706.0	> 706.0	> 706.0
ER_{25}	> 706.0	> 706.0	> 706.0
ER_{50}	> 706.0	> 706.0	> 706.0
NOER	≥ 706.0	≥ 706.0	≥ 706.0
Shoot dry weight			
ER_{10}	> 706.0	> 706.0	495.76 (n.d.)
ER_{25}	> 706.0	> 706.0	> 706.0
ER_{50}	> 706.0	> 706.0	> 706.0
NOER	≥ 706.0	≥ 706.0	≥ 706.0
Plant damages			
ER_{50}	> 706.0	≥ 706.0	> 706.0

The ER_{10}, ER_{25}, ER_{50} and NOER values were calculated using the ToxRatPro Version 3.3.0 computer software.

n.d. – not determined

Table 37. ER_{10}, ER_{25}, ER_{50} and NOER values (mL of test item/ha) – onion, perennial ryegrass, oats

	Onion *Allium cepa*	Perennial ryegrass *Lolium perenne*	Oats *Avena sativa*
Plant number at the end of the experiment			
ER_{10}	> 706.0	> 706.0	> 706.0
ER_{25}	> 706.0	> 706.0	> 706.0
ER_{50}	> 706.0	> 706.0	> 706.0
NOER	≥ 706.0	≥ 706.0	> 706.0
Shoot length			
ER_{10}	> 706.0	> 706.0	> 706.0
ER_{25}	> 706.0	> 706.0	> 706.0
ER_{50}	> 706.0	> 706.0	> 706.0
NOER	≥ 706.0	≥ 706.0	> 706.0
Shoot dry weight			
ER_{10}	> 706.0	> 706.0	680.68 (n.d.)
ER_{25}	> 706.0	> 706.0	> 706.0
ER_{50}	> 706.0	> 706.0	> 706.0
NOER	≥ 706.0	≥ 706.0	≥ 706.0
Plant damages			
ER_{50}	> 706.0	> 706.0	> 706.0

The ER_{10}, ER_{25}, ER_{50} and NOER values were calculated using the ToxRatPro Version 3.3.0 computer software.

n.d. – not determined

Table 38. ER_{10}, ER_{25}, ER_{50} and NOER values (g of fenoxaprop-P-ethyl/ha) – sunflower, pea, cabbage

	Sunflower *Helianthus annuus*	**Pea** *Pisum sativum*	**Cabbage** *Brassica oleracea var. capitata*
Plant number at the end of the experiment			
ER_{10}	> 76.96	> 76.96	> 76.96
ER_{25}	> 76.96	> 76.96	> 76.96
ER_{50}	> 76.96	> 76.96	> 76.96
NOER	≥ 76.96	≥ 76.96	≥ 76.96
Shoot length			
ER_{10}	> 76.96	> 76.96	> 76.96
ER_{25}	> 76.96	> 76.96	> 76.96
ER_{50}	> 76.96	> 76.96	> 76.96
NOER	≥ 76.96	≥ 76.96	≥ 76.96
Shoot dry weight			
ER_{10}	> 76.96	> 76.96	54.04 (n.d.)
ER_{25}	> 76.96	> 76.96	> 76.96
ER_{50}	> 76.96	> 76.96	> 76.96
NOER	≥ 76.96	≥ 76.96	≥ 76.96
Plant damages			
ER_{50}	> 76.96	≥ 76.96	> 76.96

n.d. – not determined

Table 39. ER_{10}, ER_{25}, ER_{50} and NOER values (g of fenoxaprop-P-ethyl/ha) – onion, perennial ryegrass, oats

	Onion *Allium cepa*	Perennial ryegrass *Lolium perenne*	Oats *Avena sativa*
Plant number at the end of the experiment			
ER_{10}	> 76.96	> 76.96	> 76.96
ER_{25}	> 76.96	> 76.96	> 76.96
ER_{50}	> 76.96	> 76.96	> 76.96
NOER	≥ 76.96	≥ 76.96	> 76.96
Shoot length			
ER_{10}	> 76.96	> 76.96	> 76.96
ER_{25}	> 76.96	> 76.96	> 76.96
ER_{50}	> 76.96	> 76.96	> 76.96
NOER	≥ 76.96	≥ 76.96	> 76.96
Shoot dry weight			
ER_{10}	> 76.96	> 76.96	74.20 (n.d.)
ER_{25}	> 76.96	> 76.96	> 76.96
ER_{50}	> 76.96	> 76.96	> 76.96
NOER	≥ 76.96	≥ 76.96	≥ 76.96
Plant damages			
ER_{50}	> 76.96	> 76.96	> 76.96

n.d. – not determined

Table 40. ER10, ER25, ER50 and NOER values (g of cloquintocet-mexyl/ha) – sunflower, pea, cabbage

	Sunflower *Helianthus annuus*	**Pea** *Pisum sativum*	**Cabbage** *Brassica oleracea var. capitata*
Plant number at the end of the experiment			
ER_{10}	> 37.79	> 37.79	> 37.79
ER_{25}	> 37.79	> 37.79	> 37.79
ER_{50}	> 37.79	> 37.79	> 37.79
NOER	≥ 37.79	≥ 37.79	≥ 37.79
Shoot length			
ER_{10}	> 37.79	> 37.79	> 37.79
ER_{25}	> 37.79	> 37.79	> 37.79
ER_{50}	> 37.79	> 37.79	> 37.79
NOER	≥ 37.79	≥ 37.79	≥ 37.79
Shoot dry weight			
ER_{10}	> 37.79	> 37.79	26.53 (n.d.)
ER_{25}	> 37.79	> 37.79	> 37.79
ER_{50}	> 37.79	> 37.79	> 37.79
NOER	≥ 37.79	≥ 37.79	≥ 37.79
Plant damages			
ER_{50}	> 37.79	≥ 37.79	> 37.79

n.d. – not determined

Table 41. ER_{10}, ER_{25}, ER_{50} and NOER values (g of cloquintocet-mexyl/ha) – onion, perennial ryegrass, oats

	Onion *Allium cepa*	Perennial ryegrass *Lolium perenne*	Oats *Avena sativa*
Plant number at the end of the experiment			
ER_{10}	> 37.79	> 37.79	> 37.79
ER_{25}	> 37.79	> 37.79	> 37.79
ER_{50}	> 37.79	> 37.79	> 37.79
NOER	≥ 37.79	≥ 37.79	> 37.79
Shoot length			
ER_{10}	> 37.79	> 37.79	> 37.79
ER_{25}	> 37.79	> 37.79	> 37.79
ER_{50}	> 37.79	> 37.79	> 37.79
NOER	≥ 37.79	≥ 37.79	> 37.79
Shoot dry weight			
ER_{10}	> 37.79	> 37.79	36.43 (n.d.)
ER_{25}	> 37.79	> 37.79	> 37.79
ER_{50}	> 37.79	> 37.79	> 37.79
NOER	≥ 37.79	≥ 37.79	≥ 37.79
Plant damages			
ER_{50}	> 37.79	> 37.79	> 37.79

n.d. – not determined

Sunflower (*Helianthus annuus*)

After the application of the test item at the rates between 1.2 and 706.0 mL/ha, seedling emergence of sunflower was not delayed compared with the control. At the control group, 100.0% of plants emerged. At the rates ranging from 1.2 to 706.0 mL/ha, total number of plants at the end of the experiment was between 85.7 and 100.0% in comparison to the control group.

After the application of the test item at the ranging from 1.2 to 706.0 mL/ha, the sunflower shoot length was between 109.6 and 134.4% of the control shoot length.

After the application of the test item at the rates ranging from 1.2 to 706.0 mL/ha, the sunflower shoot weight was between 95.4 and 121.0% of the control shoot weight. At the end of the exposure period the plant damages were not observed.

Pea (*Pisum sativum*)
After the application of the test item at the rates between 1.2 and 706.0 mL/ha, seedling emergence of plants was not delayed when compared with the control. The death of plants was not observed. At the control group 100.0% of plants emerged. At the rates ranging from 1.2 to 706.0 mL/ha, total number of plants at the end of the experiment was between 90.5 and 100.0% in comparison to the control group.
After the application of the test item at the rates ranging from 1.2 to 706.0 mL/ha, the pea shoot length was between 105.3 and 129.7% of the control shoot length.
After the application of the test item at the rates ranging from 1.2 to 706.0 mL/ha, the pea shoot weight was between 82.8 and 120.3% of the control shoot weight. At the end of the exposure period the plant damages were not observed.

Cabbage (*Brassica oleracea var. capitata*)
After the application of the test item at the rates between 1.2 and 706.0 mL/ha, seedling emergence of cabbage was not delayed when compared with the control. The death of plants was not observed. At the control group 100.0% of plants emerged. At the rates ranging from 1.2 to 706.0 mL/ha, total number of plants at the end of the experiment was between 95.2 and 100.0% in comparison to the control group.
After the application of the test item at the rates ranging from 1.2 to 706.0 mL/ha, the cabbage shoot length was between 89.4 and 116.1% of the control shoot length.
After the application of the test item at the rates ranging from 1.2 to 706.0 mL/ha, the cabbage shoot weight was between 87.2 and 113.2% of the control shoot weight.
At the end of the exposure period the plant damages were not.

Onion (*Allium cepa*)
After the application of the test item at the rates between 1.2 and 1500.0 mL/ha seedling emergence of onion was not delayed when compared with the control. At the control group 90.0% of plants emerged. At the rates ranging from 1.2 to 706.0 mL/ha, total number of plants at the end of the experiment was between 88.9 and 105.6% in comparison to the control group.
After the application of the test item at the rates ranging from 1.2 to 706.0 mL/ha, the onion shoot length was between 91.9 and 126.6% of the control shoot length.
After the application of the test item at the rates ranging from 1.2 to 706.0 mL/ha, the onion shoot weight was between 100.0 and 126.9% of the control shoot weight.
At the end of the exposure period the plant damages were not observed.

Perennial ryegrass (*Lolium perenne*)
After the application of the test item at the rates between 1.2 and 706.0 mL/ha seedling emergence of plants was not delayed when compared with the control group. The death of plants was not observed. At the control group 95.0% of plants emerged. At the rates ranging from 1.2 to 706.0 mL/ha, total number of plants at the end of the experiment was between 89.5 and 105.3% in comparison to the control group.
After the application of the test item at the rates ranging from 1.2 to 706.0 mL/ha, the perennial ryegrass shoot length was between 89.5 and 101.9% of the control shoot length.
After the application of the test item at the rates ranging from 1.2 to 706.0 mL/ha, the perennial ryegrass shoot weight was between 89.3 and 110.1% of the control shoot weight.
At the end of the exposure period the plant damages were not observed.

Oats (*Avena sativa*)

After the application of the test item at the rates between 1.2 and 706.0 mL/ha, seedling emergence of oats was not delayed when compared with the control. The death of plants was not observed. At the control group 80.0% of plants emerged. At the rates ranging from 1.2 to 706.0 mL/ha, total number of plants at the end of the experiment was between 100.0 and 118.8% in comparison to the control group.
After the application of the test item at the rates ranging from 1.2 to 706.0 mL/ha, the oats shoot length was between 98.5 and 110.9% of the control shoot length.
After the application of the test item at the rates ranging from 1.2 to 706.0 mL/ha, the oats shoot weight was between 87.7 and 105.2% of the control shoot weight.
At the end of the exposure period the plant damages were not observed.

CONCLUSIONS
On the basis of the obtained results it was proved that the test item i.e. CHR/H/FETEC-PART B 110 EC had no impact on seedling emergence and seedling growth of the tested plant species.
Mortality of plants was not observed.
On the basis of NOER, ER_{10}, ER_{25} and ER_{50} values determined from the plant number it was proved that the test item dot not inhibite seedling emergence of all test species.
On the basis of NOER, ER_{10}, ER_{25} and ER_{50} values determined from the shoot length it was proved that the test item did not inhibite process of the growth of all tested species.
On the basis of NOER, ER_{10}, ER_{25} and ER_{50} values determined from the dry shoot weight it was proved that the test item slightly inhibited process of growth of cabbage and oats. Process of growth of sunflower, pea, onion and perennial ryegrass was not inhibited.
During the experiment no phytotoxic symptoms in cultivation of sunflower, pea, cabbage, onion and oats were observed. Stunted growth (10 %) of perennial ryegrass was observed on day 7. However, this symptom disappeared at the end of exposure period.

VALIDITY CRITERIA
On the basis of the obtained results, it was stated that the following validity criteria of the study aimed at evaluating the impact of CHR/H/FETEC-PART B 110 EC on seedling emergence and seedling growth of terrestrial plants were met:
- the seedling emergence in the control (validity criterion: at least 70%) was as follows:
100% – sunflower,
100% – pea,
100.0% – cabbage,
90.0% – onion,
95.0% – perennial ryegrass,
80.0% – oats,
- the mean survival of the emerged control seedlings was 100% for each tested plant species (validity criterion: 90%);
- the control seedlings did not exhibit any visible phytotoxic effects;
- environmental conditions for all plants of the same species were identical.

DEVIATIONS IN THE STUDY
Deviation from OECD Guideline No. 208:
According to OECD Guideline No. 208 (2006), the light intensity should be 350 ± 50μE/m2/s. However, these values are recommended for tests conducted in greenhouses. The experiment was conducted in a test room, where only artificial lighting was used. The light intensity was between 92.4 and 232.3 μE/m2/s. Good control plant vigour was observed. Therefore, it was concluded that the light intensity was suitable

for plant growing.

A 2.6.2.1.2 Study 2

Comments of zRMS:	The submitted study was accepted. The validity criteria were met: An oats *Avena sativa* was the most sensitive plant. The following endpoints were derived: • ER_{50} = 177.4 mL test item/ha, equivalent to 19.34 g a.s./ha; • NOER = 45.2 mL test item/ha, equivalent to 4.93 g a.s./ha; The endpoint ER_{50} will be used in risk assessment.

Reference:	KCP 10.6/01
Report	CHR/H/FETEC-PART B 110 EC Terrestial Plant Test: Vegetative Vigour Test, P. Pieczka; Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna, Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland; STUDY CODE: G-04-22; 2022
Guideline(s):	according to the OECD Guideline No. 227 (2006)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test Item:	CHR/H/FETEC-PART B 110 EC batch number: 2020012 active substance: fenoxaprop-P-ethyl – 109.01 g/L safener: cloquintocet-mexyl – 53.52 g/L
Test Design:	number of rates: 8 + control; number of replicates/rate: 7 (sunflower, pea, cabbage), 4 (onion, perennial ryegrass, oats). The total number of plants per application rate: 21 (sunflower, pea, cabbage) or 20 (onion, perennial ryegrass, oats)

Endpoints: ER_{10}, ER_{25}, ER_{50}, NOER

Test Concentration:

Test item (mL/ha)	Content of fenoxaprop-P-ethyl (g/ha)	Content of cloquintocet-mexyl (g/ha)
1.2	0.13	0.06
2.9	0.32	0.16
7.2	0.78	0.39
18.1	1.97	0.97
45.2	4.93	2.42
113.0	12.32	6.05
282.4	30.78	15.11
706.0	76.96	37.79

In case of each species, there was one untreated control group.
volume of deionized water used to prepare the highest rate corresponded to 300 L spraying liquid/ha.

Test Conditions: temperature: 18.3 – 26.3°C, humidity: 56.2 – 87.3%, lighting: 16 h light : 8 h dark; light intensity: 101.7 – 236.1 µE/m2/s; carbon dioxide concentration: 338 – 358 ppm

Results and discussion:

Table 30. ER_{10}, ER_{25}, ER_{50} and NOER values (mL test item/ha) – sunflower, pea, cabbage.

	Sunflower *Helianthus annuus*	**Pea** *Pisum sativum*	**Cabbage** *Brassica oleracea var. capitata*
Plant number at the end of the experiment			
ER_{10}	>706.0	>706.0	>706.0
ER_{25}	>706.0	>706.0	>706.0
ER_{50}	>706.0	>706.0	>706.0
NOER	>706.0	>706.0	>706.0
Shoot length			
ER_{10}	>706.0	>706.0	162.06 (21.0 - >706.0*)
ER_{25}	>706.0	>706.0	>706.0
ER_{50}	>706.0	>706.0	>706.0
NOER	≥706.0	≥706.0	45.20
Shoot dry weight			
ER_{10}	>706.0	631.1	>706.0
ER_{25}	>706.0	>706.0*	>706.0
ER_{50}	>706.0	>706.0	>706.0
NOER	≥706.0	≥706.0	≥706.0
Plant damages			
ER_{50}	>706.0	>706.0	>706.0

* - determined value is higher than the highest tested application rate

The ER_{10}, ER_{25}, ER_{50} and NOER values were calculated using the ToxRat Professional 3.3.0 computer software.

Table 31. ER_{10}, ER_{25}, ER_{50} and NOER values (mL test item/ha) –onion, perennial ryegrass, oats.

	Onion *Allium cepa*	Perennial ryegrass *Lolium perenne*	Oats *Allium cepa*
Plant number at the end of the experiment			
ER_{10}	>706.0	>706.0	263.5 (49.5 - >706.0)
ER_{25}	>706.0	>706.0	>706.0
ER_{50}	>706.0	>706.0	>706.0
NOER	>706.0	>706.0	282.4
Shoot length			
ER_{10}	436.3 (181.0 - >706.0*)	>706.0	104.9 (88.6 – 124.3)
ER_{25}	>706.0* (227.9 - >706.0*)	>706.0	134.6 (113.5 – 159.8)
ER_{50}	>706.0	>706.0	177.4 (146.4 – 215.9)
NOER	282.4	≥706.0	45.2
Shoot dry weight			
ER_{10}	678.4 (0.0 - >706.0)	>706.0	141.7 (32.0 - >706.0*)
ER_{25}	>706.0*	>706.0	165.0 (66.4 – 332.6)
ER_{50}	>706.0*	>706.0	192.2 (102.6 – 283.8)
NOER	282.4	≥706.0	113.0
Plant damages			
ER_{50}	>706.0	>706.0	178.7 (153.6 – 207.8)

* - determined value is higher than the highest tested application rate
The ER_{10}, ER_{25}, ER_{50} and NOER values were calculated using the ToxRat Professional 3.3.0 computer software.

Table 32. ER_{10}, ER_{25}, ER_{50} and NOER values (g of fenoxaprop-P-ethyl/ha) – sunflower, pea, cabbage.

	Sunflower *Helianthus annuus*	Pea *Pisum sativum*	Cabbage *Brassica oleracea var. capitata*
Plant number at the end of the experiment			
ER_{10}	>76.96	>76.96	>76.96
ER_{25}	>76.96	>76.96	>76.96
ER_{50}	>76.96	>76.96	>76.96
NOER	>76.96	>76.96	>76.96
Shoot length			
ER_{10}	>76.96	>76.96	17.73 (2.29 - >76.96*)
ER_{25}	>76.96	>76.96	>76.96
ER_{50}	>76.96	>76.96	>76.96
NOER	≥76.96	≥76.96	4.93
Shoot dry weight			
ER_{10}	>76.96	68.80	>76.96
ER_{25}	>76.96	>76.96*	>76.96
ER_{50}	>76.96	>76.96	>76.96
NOER	≥76.96	≥76.96	≥76.96
Plant damages			
ER_{50}	>76.96	>76.96	>76.96

* - determined value is higher than the highest tested application rate

Table 33. ER_{10}, ER_{25}, ER_{50} and NOER values (g of fenoxaprop-P-ethyl/ha) – onion, perennial ryegrass, oats.

	Onion *Allium cepa*	Perennial ryegrass *Lolium perenne*	Oats *Allium cepa*
Plant number at the end of the experiment			
ER_{10}	>76.96	>76.96	28.72 (5.40 - >76.96)
ER_{25}	>76.96	>76.96	>76.96
ER_{50}	>76.96	>76.96	>76.96
NOER	>76.96	>76.96	30.78
Shoot length			
ER_{10}	47.56 (19.73 - >76.96*)	>76.96	11.44 (9.66 – 13.55)
ER_{25}	>76.96* (24.84 - >76.96*)	>76.96	14.67 (12.37 – 17.42)
ER_{50}	>76.96	>76.96	19.34 (15.96 – 23.54)
NOER	30.78	≥76.96	4.93
Shoot dry weight			
ER_{10}	73.95 (0.0 - >76.96)	>76.96	15.45 (3.49 - >76.96*)
ER_{25}	>76.96*	>76.96	17.99 (7.24 – 36.26)
ER_{50}	>76.96*	>76.96	20.95 (11.18 – 30.94)
NOER	30.78	≥76.96	12.32
Plant damages			
ER_{50}	>76.96	>76.96	19.48 (16.74 – 22.65)

* - determined value is higher than the highest tested application rate

Table 34. ER_{10}, ER_{25}, ER_{50} and NOER values (g of cloquintocet-mexyl/ha) – sunflower, pea, cabbage.

	Sunflower *Helianthus annuus*	**Pea** *Pisum sativum*	**Cabbage** *Brassica oleracea var. capitata*
Plant number at the end of the experiment			
ER_{10}	>37.79	>37.79	>37.79
ER_{25}	>37.79	>37.79	>37.79
ER_{50}	>37.79	>37.79	>37.79
NOER	>37.79	>37.79	>37.79
Shoot length			
ER_{10}	>37.79	>37.79	8.70 (1.12 - >37.79*)
ER_{25}	>37.79	>37.79	>37.79
ER_{50}	>37.79	>37.79	>37.79
NOER	≥37.79	≥37.79	2.42
Shoot dry weight			
ER_{10}	>37.79	33.78	>37.79
ER_{25}	>37.79	>37.79*	>37.79
ER_{50}	>37.79	>37.79	>37.79
NOER	≥37.79	≥37.79	≥37.79
Plant damages			
ER_{50}	>37.79	>37.79	>37.79

* - determined value is higher than the highest tested application rate

Table 35. ER_{10}, ER_{25}, ER_{50} and NOER values (g of cloquintocet-mexyl/ha) – onion, perennial ryegrass, oats.

	Onion *Allium cepa*	Perennial ryegrass *Lolium perenne*	Oats *Allium cepa*
Plant number at the end of the experiment			
ER_{10}	>37.79	>37.79	14.10 (2.65 - >37.79)
ER_{25}	>37.79	>37.79	>37.79
ER_{50}	>37.79	>37.79	>37.79
NOER	>37.79	>37.79	15.11
Shoot length			
ER_{10}	23.35 (9.69 - >37.79*)	>37.79	5.61 (4.74 – 6.65)
ER_{25}	>37.79* (12.20 - >37.79*)	>37.79	7.20 (6.08 – 8.55)
ER_{50}	>37.79	>37.79	9.49 (7.84 – 11.56)
NOER	15.11	≥37.79	2.42
Shoot dry weight			
ER_{10}	36.31 (0.0 - >37.79)	>37.79	7.58 (1.71 - >37.79*)
ER_{25}	>37.79*	>37.79	8.83 (3.55 – 17.80)
ER_{50}	>37.79*	>37.79	10.29 (5.49 – 15.19)
NOER	15.11	≥37.79	6.05
Plant damages			
ER_{50}	>37.79	>37.79	9.56 (8.22 – 11.12)

* - determined value is higher than the highest tested application rate

Sunflower (*Helianthus annuus*)

After the application of the test item at the rates ranging from 1.2 to 706.0 mL/ha the mortality of plants was not observed.

After the application of the test item at the rates ranging from 1.2 to 706.0 mL/ha, the Sunflower shoot length was between 91.8 and 111.7% of the control shoot length.

After the application of the test item at the rates ranging from 1.2 to 706.0 mL/ha, the sunflower shoot dry weight was between 97.5 and 131.8% of the control shoot dry weight.

After 21 days of exposure period the plant damages were not observed at the rates between 1.2 and 706.0 mL/ha.

Pea (*Pisum sativum*)
After the application of the test item at the rates ranging from 1.2 to 706.0 mL/ha the mortality of plants was not observed. After the application of the test item at the rates ranging from 1.2 to 706.0 mL/ha, the pea shoot length was between 85.6 and 99.3% of the control shoot length.
After the application of the test item at the rates ranging from 1.2 to 706.0 mL/ha, the pea shoot dry weight was between 85.5 and 104.1% of the control shoot dry weight.
After 21 days of exposure period the plant damages were not observed at the rates between 1.2 and 706.0 mL/ha.

Cabbage *(Brassica oleracea var. capitata)*
After the application of the test item at the rates between 1.2 and 706.0 mL/ha the mortality of plants was not observed.
After the application of the test item at the rates ranging from 1.2 to 706.0 mL/ha, the cabbage shoot length was between 86.0 and 100.5% of the control shoot length.
After the application of the test item at the rates ranging from 1.2 to 706.0 mL/ha, the cabbage shoot dry weight was between 91.1 and 110.0% of the control shoot dry weight.
After 21 days of exposure period the plant damages were observed at the rates between 113.0 and 706.0 mL/ha and they were ranging from 10.0 to 30.0%.

Onion (*Allium cepa)*
After the application of the test item at the rates between 1.2 and 706.0 mL/ha, the mortality of plants was not observed.
After the application of the test item at the rates ranging from 1.2 to 706.0 mL/ha, the onion shoot length was between 87.0 and 118.6% of the control shoot length.
After the application of the test item at the rates ranging from 1.2 to 706.0 mL/ha, the onion shoot dry weight was between 81.4 and 107.8% of the control shoot dry weight.
After 21 days of exposure period the plant damages were not observed at the rates between 1.2 and 706.0 mL/ha.

Perennial ryegrass (*Lolium perenne)*
After the application of the test item the mortality of plants was not observed at the rates between 1.2 and 706.0 mL/ha.
After the application of the test item at the rates ranging from 1.2 to 706.0 mL/ha, the perennial ryegrass shoot length was between 96.4 and 113.1% of the control shoot length.
After the application of the test item at the rates ranging from 1.2 to 706.0 mL/ha, the perennial ryegrass shoot dry weight was between 93.6 and 117.1% of the control shoot dry weight.
After 21 days of exposure period the plant damages were not observed at the rates between 1.2 and 706.0 mL/ha.

Oats (*Avena sativa)*
After the application of the test item at the rates equal to 282.4 and 706.0 mL/ha the mortality of plants was observed. The total number of plants at the end of the exposure was ranging from 80.0 to 100.0% in comparison to the control group.
After the application of the test item at the rates ranging from 1.2 to 706 mL/ha, the oats shoot length was between 9.5 and 107.1% of the control shoot length.

After the application of the test item at the rates ranging from 1.2 to 706.0 mL/ha, the oats shoot dry weight was between 3.2 and 119.2% of the control shoot dry weight.
After 21 days of exposure period the plant damages were observed at the rates ranging from 113.0 to 706.0 mL/ha and they were between 10.0 and 90.0%.

CONCLUSIONS
The test item, i.e. CHR/H/FETEC-PART B 110 EC, applied at rates ranging from 1.2 to 706.0 mL/ha, had a varied impact on vegetative vigour of oats, onion, cabbage and pea.
On the basis of NOER, ER_{10}, ER_{25} and ER_{50} values determined from the plant numer at the end of the experiment it was proved that the test item inhibited the process of growth of oats.
On the basis of NOER, ER_{10}, ER_{25} and ER_{50} values determined from the shoot length it was proved that the test item inhibited the process of growth of oats. Slight effect was observed in cultivation of cabbage and onion.
On the basis of NOER, ER_{10}, ER_{25} and ER_{50} values determined from the dry shoot weight it was proved that the test item inhibited the process of growth of oats. Slight effect was observed in cultivation of pea and onion.
During the experiment the phytotoxic symptoms of the test item were noticed in cultivation of cabbage and oats.
In the study, the lowest endpoints were observed for oats.
The most resistant species for influence of the test item was sunflower and perennial ryegrass.

VALIDITY CRITERIA
On the basis of the obtained results, it was stated that the following validity criteria of the study aimed at evaluating the impact of CHR/H/FETEC-PART B 110 EC on vegetative vigour of terrestrial plants were met:
- the seedling emergence of plants (validity criterion: at least 70%) was as follows:
85.7 – 95.2 – sunflower,
85.7 – 92.9 – pea,
83.3 – 95.2 – cabbage,
92.5 – 100.0 – onion,
92.5 – 100.0 – perennial ryegrass,
92.5 – 100.0 – oats,
- the mean plant survival of the control was 100% for all tested species (validity criterion: at least 90%),
- the control plants did not exhibit any visible phytotoxic symptoms,
- environmental conditions for all plants belonging to the same species were identical.

DEVIATIONS IN THE STUDY
Deviation from OECD Guideline No. 227:
According to OECD Guideline No. 227 (2006), the light intensity should be 350 ± 50µE/m2/s. However, these values are recommended for tests conducted in greenhouses. The experiment was conducted in a test room, where only artificial lighting was used. The light intensity was between 101.7 – 236.1 µE/m2/s. Good control plant vigour was observed. Therefore, it was concluded that the light intensity was suitable for plant growing. The deviation did not affect the results of the experiment.

A 2.6.3 KCP 10.6.3 Extended laboratory studies on non-target plants

A 2.7 KCP 10.7 Effects on other terrestrial organisms (flora and fauna)

No additional studies were performed.

A 2.8 KCP 10.8 Monitoring data

No additional studies were performed.