European Commission

Draft Renewal Assessment Report prepared according to the Commission Regulation (EU) N° 1107/2009

Fenoxaprop-P-ethyl

Volume 3 – B.9 (PPP) – Fenoxaprop-P-ethyl 69 g/L EW (CHA 4960)

Rapporteur Member State: Austria
Co-Rapporteur Member State: Finland

Version History

When	What
2005/April	Initial DAR CHA 4960 was not the representative formulation
2018/March	DRAR

Table of contents

B.9. ECOTOXICOLOGY DATA AND ASSESSMENT OF RISKS FOR NON-TARGET SPECIES 4

B.9.1. EFFECTS ON BIRDS AND OTHER TERRESTRIAL VERTEBRATES 6

B.9.1.1. Effects on birds 6
B.9.1.2. Effects on terrestrial vertebrates other than birds 11

B.9.2. RISK ASSESSMENT FOR BIRDS AND OTHER TERRESTRIAL VERTEBRATES 12

B.9.2.1. Risk assessment for birds 12
B.9.2.2. Risk assessment for mammals 16

B.9.3. EFFECTS ON AQUATIC ORGANISMS 21

B.9.3.1. Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes 21
B.9.3.2. Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms 34
B.9.3.3. Further testing on aquatic organisms 38

B.9.4. RISK ASSESSMENT FOR AQUATIC ORGANISMS 39

B.9.4.1. Acute risk 44
B.9.4.2. Chronic risk 45
B.9.4.3. Bioaccumulation 50

B.9.5. EFFECTS ON ARTHROPODS 51

B.9.5.1. Effects on bees 51
B.9.5.2. Effects on non-target arthropods other than bees 77

B.9.6. RISK ASSESSMENT FOR ARTHROPODS 94

B.9.6.1. Risk assessment for honeybees 94
B.9.6.2. Risk assessment for non-target arthropods 103

B.9.7. EFFECTS ON NON-TARGET SOIL MESO- AND MACROFAUNA 105

B.9.7.1. Earthworms 105
B.9.7.2. Effects on non-target soil meso- and macrofauna (other than earthworms) 109

B.9.8. RISK ASSESSMENT FOR NON-TARGET SOIL MESO- AND MACROFAUNA 115

B.9.9. EFFECTS ON SOIL NITROGEN TRANSFORMATION 118

B.9.10. RISK ASSESSMENT FOR SOIL NITROGEN TRANSFORMATION 121

B.9.11. EFFECTS ON TERRESTRIAL NON-TARGET HIGHER PLANTS 122

B.9.11.1. Summary of screening data 122
B.9.11.2. Testing on non-target plants 122
B.9.11.3. Extended laboratory studies on non-target plants 132
B.9.11.4. Semi-field and field tests on non-target plants 132

B.9.12. RISK ASSESSMENT FOR TERRESTRIAL NON-TARGET HIGHER PLANTS 133

B.9.12.1. Deterministic risk assessment 133

B.9.13. EFFECTS ON OTHER TERRESTRIAL ORGANISMS (FLORA AND FAUNA) 134

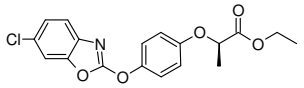
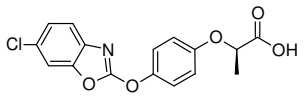
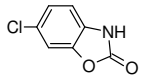
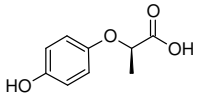
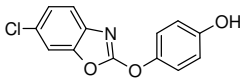
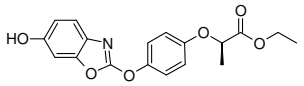
B.9.14. RISK ASSESSMENT FOR OTHER TERRESTRIAL ORGANISMS (FLORA AND FAUNA) 134

B.9.15. REFERENCES RELIED ON 135

B.9. ECOTOXICOLOGY DATA AND ASSESSMENT OF RISKS FOR NON-TARGET SPECIES

This summary on "Ecotoxicological Studies on the Plant Protection Product" has been prepared to support the AIR submission of Fenoxaprop-P-ethyl which is prepared on behalf of the Regulatory Task Force Fenoxaprop-P-ethyl, existing since 2013 and represented by Cheminova A/S and Bayer CropScience. This summary was especially prepared to support the representative formulation fromCheminova A/S (CHA 4960).

Table B.9-1: Substances and metabolites (structure, synonyms and codes)

Code number (Synonyms)	Chemical name and molecular formula	Mol weight (g/mol)	Occurrence (% AR)	Structure
Fenoxaprop-P-ethyl[(a)] (AE F046360)	ethyl (2R)-2-{4-[(6-chloro-1,3-benzoxazol-2-yl)oxy] phenoxy}propanoate $C_{18}H_{16}ClNO_5$	361.8	Not applicable	
Fenoxaprop-P-acid[(b)] (AE F088406)	(2R)-2-{4-[(6-chloro-1,3-benzoxazol-2-yl)oxy] phenoxy}propanoic acid $C_{16}H_{12}ClNO_5$	333.7	**Aerobic soil: 87.2 %** **Anaerobic soil: 94.3 %** Soil photolysis: - Aquatic hydrolysis: 95.6 % (*p*H 9, 25 °C) Aerobic surface water: 101.4 % **Water/sediment: 97.2 %**	
Chlorobenz-oxazolone (AE F054014)	6-chloro-1,3-benzoxazol-2(3H)-one $C_7H_4ClNO_2$	169.6	**Aerobic soil: 19.1 %** **Anaerobic soil: 7.5 %** **Soil photolysis: 6.8 %** Aquatic hydrolysis: 102.4 % (*p*H 4, 25 °C) Aquatic photolysis: 7.1 % Aerobic surface water: 36.8 % **Water/sediment: 8.5 %**	
HOPP-acid[(c)] (AE F096918)	(2R)-2-(4-hydroxyphenoxy) propanoic acid $C_9H_{10}O_4$	182.2	Aerobic soil: - **Anaerobic soil: 74.1 %** Soil photolysis: - Aquatic hydrolysis: 14.2 % (*p*H 9, 25 °C) Aquatic photolysis: 2.1 % Aerobic surface water: 21.0 % **Water/sediment: 26.3 %**	
Phenol metabolite (AE F040356)	4-[(6-chloro-1,3-benzoxazol-2-yl) oxy]phenol $C_{13}H_8ClNO_3$	261.7	Aerobic soil: 1.2 % Anaerobic soil: 2.2 % Soil photolysis: - Aquatic hydrolysis: - Aquatic photolysis: 5.9 % Aerobic surface water: - **Water/sediment: 13.1 %**	
Fenoxaprop-P-ethyl-dechloro-hydroxy (EHBPP, BCS-CY11272)	ethyl (2R)-2-{4-[(6-hydroxy-1,3-benzoxazol-2-yl)oxy] phenoxy}propanoate $C_{18}H_{17}NO_6$	343.3	Aerobic soil: - Anaerobic soil: - Soil photolysis: - Aquatic hydrolysis: - **Aquatic photolysis: 17.7 %** Aerobic surface water: - Water/sediment: -	

AE F029062	ethyl (2R)-2-(4-hydroxyphenoxy) propanoate $C_{11}H_{14}O_4$	210.2	Aerobic soil: - Anaerobic soil: - Soil photolysis: - Aquatic hydrolysis: 101.2 % (*p*H 4, 25 °C) Aquatic photolysis: 3.3 % Aerobic surface water: - Water/sediment: -	
Hydroxybenz-oxazolone (AE 0316854)	6-hydroxy-1,3-benzoxazol-2(3H)-one $C_7H_5NO_3$	151.1	Aerobic soil: - Anaerobic soil: - Soil photolysis: - Aquatic hydrolysis: - Aquatic photolysis: 5.5 % Aerobic surface water: - Water/sediment: -	
AE F031886	ethyl (2R)-2-[4-(1,3-benzoxazol-2-yloxy) phenoxy]propanoate $C_{18}H_{17}NO_5$	327.3	Aerobic soil: - Anaerobic soil: - Soil photolysis: - Aquatic hydrolysis: - Aquatic photolysis: 1.4 % Aerobic surface water: - Water/sediment: -	
AE F064124	6-chloro-5-hydroxy-1,3-benzoxazol-2(3H)-one $C_7H_4ClNO_3$	185.6	Aerobic soil: - Anaerobic soil: - Soil photolysis: - Aquatic hydrolysis: 1.0 % (*p*H 4, 40 °C) Aquatic photolysis: - Aerobic surface water: - Water/sediment: -	
HOPP-acid dimer (AE F096918 dimer)	$C_{18}H_{17}O_8$	361.1	Aerobic soil: - Anaerobic soil: - Soil photolysis: - Aquatic hydrolysis: - Aquatic hydrolysis: 10.6 % (*p*H 9, 40 °C) Aerobic surface water: - Water/sediment: -	

(a) Racemic mixture of R/S (approx. 1/1) is called AE F033171
(b) Racemic mixture of R/S (approx. 1/1) is called AE F053022
(c) Arithmetic mean of ClPh and Ph label applied to the same soil
(d) Racemic mixture of R/S (approx. 1/1) is called AF F020686
(e) Racemic mixture (AE F020686) of HOPP-acid (AE F096918) observed after application of racemic fenoxaprop-ethyl (AE F033171); HOPP acid (AE F096918) max. 49.2 % of AR in study with non-racemic Fenoxaprop-P-ethyl (AE F046360) applied

The critical use pattern for this formulation is summarised in Table B.9-2.

Table B.9-2: Intended application pattern

Crop	Timing of application (range)	Number of applications	Application interval [days]	Maximum label rate (range) [L prod./ha]	Maximum application rate, individual treatment (ranges) [kg a.s./ha]
Cereals (Spring and winter wheat, durum wheat, rye, winter rye, triticale, spring and winter barley)	BBCH 12-39	1	-	0.4 - 1.2	0.069 – 0.0828

B.9.1. EFFECTS ON BIRDS AND OTHER TERRESTRIAL VERTEBRATES

B.9.1.1. Effects on birds

Several acute, dietary and reproductive toxicity studies with Fenxoaprop-P-ethyl have been performed with mallard duck, patridge and bobwhite quail. Studies were already submitted for the first EU peer-review of the active substance Fenxoaprop-P-ethyl. No new studies with the active substance were submitted for the re-newal of the EU peer-review.

The study summaries are provided under point B.9.1.1 of Volume 3 – B.9 (AS).

In addition, an acute toxicity study with the EU representative formulation CHA 4960 was conducted addressing the risk to birds from exposure to the formulated product. A summary is provided under Point B 9.1.1.

A summary of the toxicity of Fenxoaprop-P-ethyl to birds is given in table B.9.1.1-1.

Table B. 9.1.1-1: Toxicity of Fenxoaprop-P-ethyl to birds

Test species	Test design	Ecotoxicological endpoint	Reference
Japanese quail	Acute, oral	LD_{50} > 2000 mg a.s./kg bw	[redacted] 1987
Bobwhite quail		LD_{50} > 2000 mg a.s./kg bw	[redacted] 1986
Mallard duck		LD_{50} > 2000 mg a.s./kg bw	[redacted] 1986
Patridge		**LD_{50} = 2000 mg a.s./kg bw**	[redacted] 1986
Japanese quail	*Short-term, dietary*	*LC_{50} > 5000 ppm* *LDD_{50} > 401 mg a.s./kg bw/d*	[redacted] *1986d*
Bobwhite quail		*LC_{50} > 500 ppm* *LDD_{50} > 1301 mg a.s./kg bw/d*	[redacted] *1986*
Mallard duck		*LC_{50} > 500 ppm* *LDD_{50} > 841 mg a.s./kg bw/d*	[redacted] *1986e*
Bobwhite quail	21 weeks feeding chronic, reproduction	NOEC = 400 ppm **NOEL = 30.8 mg a.s./kg bw**	[redacted] 2002

Bold values were used for the risk assessment

Toxicity of the formulated product

An acute toxicity study with the formulation Fenxoaprop-P-69 g/L EW ([redacted] 2005) has been submitted.

Reference:	**Fenoxaprop-P-ethyl 69 g/L EW: An acute oral toxicity study with the northern bobwhite**
Author(s), year:	[redacted] 2005
Report/Doc. number:	232-125 / Reference no. 139 FPE
Guideline(s):	US EPA Subdivision E, Section 71-1 (Avian single-dose oral LD_{50}), October 1982
GLP:	Yes
Deviations:	During the study days 6 – 8 the temperature was about 26°C, of cause a malfunction of the air condition
Acceptability:	Acceptable

Material and methods:

Test substance:	Fenxoaprop-P-ethyl 69 g/L EW, Batch No.: 660-PSH-49, Code: CHA 4960, content of active substance: 7.11 % (w/w), Safener: Cloquintocet-mexyl 3.41 % w/w
Test species:	Northern bobwhite (*Colinus virginianus*)
Number of organisms:	10 animals per group (5 males and 5 females)
Age:	approx. 22 weeks (at start of the test)
Weight:	172 – 228 g
Acclimatisation period:	14 days under laboratory conditions
Type of test:	Acute oral toxicity
Applied concentrations:	292, 486, 810, 1350 and 2250 mg a.s./kg bw
Type of application:	The test substance was dispersed in deinonized water. The concentration of the test substance in the diluent was adjusted to provide a constant volume to body weight dosage for all treatment birds. At experimental start, a single dose of the test substance in diluent was orally intubated directly into the crop or preventriculus of each bird using a syringe and stainless steel cannula. Each bird was individually weighed and dosed on the basis of milligrams of test substance per kilogram of body weight. The control birds received a corresponding volume of diluent only. All treatment and control birds received a constant dosage volume of four millilitres per kilogram of body weight.
Time of exposure:	One single application, monitoring during 14 days

Test conditions:	Test temperature: 23.4°C ± 0.2 (SD), relative humidity: 60% ± 12 (SD), The photoperiod (maintained by a time clock) was approximately seven hours of light per day/17 hours dark during acclimation and throughout the test. The light source was fluorescent lights that closely approximate noon-day sunlight. The birds were exposed to an average of approximately 287 lux of illumination. Throughout acclimation and testing all test birds were fed a game bird ration formulated to Wildlife International, Ltd´s specification by Cargill Animal Nutrition. Water, from the town of Easton public water supply, and feed were provided ad libitum during acclimation and during the test, except during period of fasting prior to testing. Beginning two days following arrival in the test facility, test birds were give water soluble antibiotics in their drinking water for seven consecutive days. The birds received no form of antibiotic medication during the test.
Observations:	During acclimation, all birds were observed at least daily. Birds exhibiting abnormal behaviour or physical injury were not used. Following dosing, multiple observations were performed on Day 0 of the test, with particular attention being paid for signs of regurgitation. All birds were observed at least twice daily during the test. A record was maintained of all mortality, signs of toxicity, and abnormal behaviour.
Statistics:	There were no mortalities observed in this study. Therefore, it was not possible to perform the calculation of a LD_{50} value using the computer program of C.E. Stephan. The LD_{50} value was determined to be greater than the highest dosage tested. No statistical analyses were applied to separate mean responses among treatment groups for the endpoints of food consumption and body weight. The no-observed-effect level was determined by detailed observations of the birds during testing and inspection of the data.

<u>Findings:</u>

Biological results: There were no mortalities in the control group, and all control birds were normal in appearance and behaviour throughout the test. Additionally, there were no mortalities in the 292, 486, 810, 1350 and 2250 mg/kg treatment groups.

There were no overt signs of toxicity in the 292 and 486 mg/kg treatment groups.
At the 810 mg/kg dosage level, signs of toxicity were first observed approximately two hours and 15 minutes after dosing when one male was noted with a slight ruffled appearance which recovered by the morning of Day 1. While the observation of ruffled appearance was transient in nature and isolated to one bird, a treatment-related effect could not be precluded.
At the 1350 mg/kg dosage level slight ruffled appearance and/or ruffled appearance were noted in 4/10 birds from approximately one and a half hours after dosing. All birds had recovered by the morning of Day 1 and were normal in appearance and behaviour for the remainder of the test.
At the 2250 mg/kg dosage level slight ruffled appearance and/or ruffled appearance were noted in 6/10 birds from approximately one hour after dosing. All birds were normal in behavior and appearance on the morning of Day 8 and throughout the remainder of the test.
When compared to the control group, there were no treatment-related effects on body weight among males or females at the 292, 486, 810 or 1350 mg/kg dosage levels or among females in the 2250 mg/kg dosage level. There was a loss of mean body weight among males at the 2250 mg/kg dosage level from Day 0 to Day 3. While this loss was primarily due to a single male who lost 18 g from Day 0 to Day 3, the weight loss and corresponding signs of toxicity for this individual suggest the loss was related to treatment.

When compared to the control group, there were no apparent treatment-related effects upon feed consumption at any of the dosage levels tested.

Table B. 9.1.1-2: Mortality and growth (bodyweights and food consumption) of Bobwhite quail following acute oral exposure (gavage)

Test substance [mg a.s./kg]	Cumulative mortality	Sex	Mean bodyweight [g]				Food consumption [g/bird/d]		
			0	3	7	14	0-3	4-7	8-14
Control	0	♂	197	200	206	207	19	21	17
	0	♀	197	199	203	204	16	17	15
292	0	♂	199	203	206	207	14	16	14
	0	♀	192	197	204	205	18	23	18
486	0	♂	191	195	201	200	28	26	20
	0	♀	201	205	211	211	25	26	22
810	0	♂	190	195	197	196	19	23	18
	0	♀	200	207	213	216	24	25	21
1350	0	♂	192	196	200	203	12	17	15

Test substance [mg a.s./kg]	Cumulative mortality	Sex	Mean bodyweight [g]				Food consumption [g/bird/d]		
			0	3	7	14	0-3	4-7	8-14
	0	♀	191	193	199	203	17	21	16
2250	0	♂	198	196	202	206	32	31	27
	0	♀	194	197	201	206	13	22	20

Conclusion: The acute oral LD_{50} value for northern bobwhite exposed to Fenoxaprop-P-ethyl 69 g/LEW as a single oral dose was determined to be greater than 2250 mg/kg, the highest dose tested. The no-mortality level was 2250 mg/kg. Based on transient signs of toxicity noted in one bird at the 810 mg/kg dosage level, the no-observed-effect level was 486 mg/kg.

Comment RMS:

Validity: The study was evaluated following the recommendations of the currently valid test guidelines OCSPP 850.2100 (January, 2012) and OECD 223 (July, 2010)

Check of validity criteria of OCSPP 850.2100:

- Birds were not randomly assigned to treatment and control pens: fulfilled
- More than 10% of the control birds died during the test: fulfilled, actual 0 %
- A minimum of ten birds were not used for each dose level of the test substance and control: fulfilled
- The test substance was not orally administered, via either capsule or gavage: fulfilled
- In the definitive test a minimum of five dose levels of the test substance, plus an appropriate control, were tested.

Check of validity criteria of OECD 223:

- 10 % mortality in the control: fulfilled, actual 0 %

Acceptability of the analytical methods used in the test:

Not necessary as no analytics have been performed.

Endpoints: No LD_{10} or LD_{20} values have been calculated by the applicant. As required by regulation (EU) 283/2013.

LD_{50} > 2250 mg a.s./kg

Conclusion of the RMS:

In conclusion, the discussed deviations add uncertainty as no specific information about the analytic is given. However considering the administration route the RMS is of the opinion that the study is still valid and should be used for the risk assessment.

Relevance and toxicity of the metabolites:

The two major metabolites fenoxaprop-P-acid (AE F088406) and chlorobenzoxazolone (AE F054014) which

were found in concentrations >10% TRR in cereals, were also identified in poultry and rat metabolism studies. Therefore the toxicity is considered to be covered by the studies with the parent Fenoxaprop-P-ethyl.

B.9.1.2. Effects on terrestrial vertebrates other than birds

A summary of the toxicity of Fenxoaprop-P-ethyl to mammals is given in the table B.9.1.2-1.
No additional studies were submitted for the re-newal of the active substance Fenxoaprop-P-ethyl. Hence, the risk assessment is based on the EU peer review acute and long-term endpoints identified for the first EU approval of the active substance.

For the re-newal of the active substance Fenxoaprop-P-ethyl an ecotoxicological relevant endpoint based on the fetal skeletal ossification findings in the rat developmental study toxicity study ([redacted] 1986) has been determined. The NOAEL of 10 mg a.s./kg bw/d should be used for risk assessment (for further information refer to Volume 3 CA B.9.).

Table B. 9.1.2-1: Toxicity of Fenxoaprop-P-ethyl to mammals

Test species	Test design	Ecotoxicological endpoint	Reference
Rat	Acute, oral	4000 > LD_{50} > 3150 mg/kg bw	[redacted] 1992
		2000 > LD_{50} > 300 mg/kg bw	[redacted] 2008
		LD_{50} =1098 mg/kg bw	[redacted] 2005
Mouse		LD_{50} > 5000 mg/kg bw	[redacted] 1985a
Rat	Long-term	NOAEL = 10 mg/kg bw/d	Bomann, W.; Diesing, L.; 2016

Bold values were used for the risk assessment

<u>Toxicity of the formulated product:</u>

Table B. 9.1.2-2: Toxicity of the formulated product to mammals (CHA 4960)

Test species	Test design	Ecotoxicological endpoint	Reference
Rat	Acute, oral	LD_{50} > 2000 mg prod./kg bw	[redacted] 2005a (Volume 3CP section B.6)

<u>Relevance and toxicity of the metabolites:</u>

The two major metabolites fenoxaprop-P-acid (AE F088406) and chlorobenzoxazolone (AE F054014) which were found in concentrations >10% TRR in cereals, were also identified in poultry and rat metabolism studies. Therefore the toxicity is considered to be covered by the studies with the parent Fenoxaprop-P-ethyl.

B.9.2. RISK ASSESSMENT FOR BIRDS AND OTHER TERRESTRIAL VERTEBRATES

The risk assessment for birds and mammals was conducted according to the EFSA Guidance Document on Risk Assessment for Birds and Mammals (EFSA Journal 2009;7(12):1438).

Fenoxaprop-P-ethyl 69 g/L EW (CHA 4960), is intended to be applied as an herbicide in cereals (BBCH 12-39) at a maximum single application rate of 0.0828 kg a.s./ha.

B.9.2.1. Risk assessment for birds

Birds and other terrestrial vertebrates may be exposed to Fenxoaprop-P-ethyl by eating contaminated vegetation, seeds and fruits, invertebrate prey like arthropods (i.e. insects) or earthworms or vertebrate prey. Another possible route is via drinking water.

In the screening step it is assumed that animals satisfy all their dietary needs in the treated area feeding on only one food type and do not avoid contaminated food. Therefore, avoidance, fraction of diet obtained in the treated area and fraction of food type in the diet are all set to 1.

Table B. 9.2.1-1: Relevant generic avian focal species for the screening step

Crop	Scenario	Indicator species	SV_{90}	SV_m
Cereals	BBCH 12-39	Small omnivorous bird	158.8	64.8

<u>Acute risk assessment for birds:</u>

Table B. 9.2.1-2: Screening step - acute risk assessment for birds

Crop	Indicator species	SV_{90}	Application rate [kg a.s./ha]	MAF_{90}	DDD_A	LD_{50} [mg a.s./kg bw]	TER_A
Cereals	Small omnivorous bird	158.8	0.0828	1	13.2	2000	152

The TER_A value is above the trigger of 10 for acute exposure, indicating an acceptable risk to birds for the use in cereals.

Long-term risk assessment for birds:

Table B. 9.2.1-3: Long-term risk assessment for birds – screening step

Crop	Generic focal species	SV_m	Application rate [kg a.s./ha]	MAF_m	f_{twa}	DDD_{LT}	NOEL [mg a.s./kg bw/d]	TER_{LT}
Cereals	Small omnivorous bird	64.8	0.0828	1.0	0.53	2.85	30.8	10.8

The TER_{LT} value is above the trigger of 5 for long-term exposure, indication an acceptable risk to birds for the use in cereals.

Drinking water risk assessment:

The risk to birds from exposure via drinking water was conducted according to the EFSA Guidance Document on Birds and Mammals (2009). The risk assessment for birds is limited to the scenario of puddles formed on the ground after application. The leaf scenario is not relevant considering the intended crops and the time of application (BBCH 12 – 39).

According to the EFSA guidance document for risk assessment for bird and mammals (2009) "*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 3000 in the case of more sorptive substances (Koc > 500 L/kg).*" This is the case for Fenoxaprop-P-ethyl and therefore, the long-term risk for birds from drinking water that may contain residues from Fenoxaprop-P-ethyl is acceptable.

Table B. 9.2.1-4: Drinking water risk assessment

K_{OC} [L/kg]	Application rate [g a.s./ha]	MAF	Endpoint [mg a.s./kg bw/d]		Ratio effective application rate/endpoint		Conclusion
			Acute	Long-term	Acute	Long-term	
9445.1	82.8	1.0	LD_{50} = 2000	NOAEL = 30.8	0.04	2.7	No concerns (Ratio ≤ 3000)

This evaluation confirms that the risk for birds from drinking water that may contain residues from the use of the product is acceptable. Hence, no specific calculation of exposure and TER is deemed necessary.

Secondary poisoning:

Substances with a high potential to bioaccumulate in the food chain could theoretically bear a risk of secondary poisoning for birds and mammals if feeding on contaminated prey like fish or earthworms. For organic chemicals, a log P_{OW} > 3 is used to trigger an in-depth evaluation of the potential for bioaccumulation.

Effects on secondary poisoning have been assessed for Fenoxaprop-P-ethyl, due to a log P_{OW} value above 3. Log P_{OW} values of almost all Fenoxaprop-P-ethyl metabolites are below 3 at ecologically relevant pH values. Only the Log P_{OW} value of the Fenoxaprop-P-ethyl metabolite phenol (AE F040356) is slightly above the trigger of 3. As the risk assessment with the parent indicates no unacceptable risk with a high margin of safety and the log P_{OW} value of phenol (AE F040356) is significantly lower than the log P_{OW} of the parent the risk of secondary poisoning is covered by the assessment with the parent Fenoxaprop-P-ethyl. Therefore, there is no risk to birds through secondary poisoning.

Table B. 9.2.1-5: Log P_{OW} of Fenxoaprop-P-ethyl and its metabolites

Substance	Log P_{OW}	Reference
Fenxoaprop-P-ethyl	4.58*	KCA 2.7/01 Schollmeier, M.; Eyrich, U.; Uhl, A.; 1992
Fenoxaprop-P-acid (AE F088406)	pH 5: 1.9 pH 7: 0.3 pH 9: 0.0	KCA 2.7/10 Fischer, A.; 2016
Chlorobenzoxazolone (AE F054014)	pH 5: 1.7 pH 7:1.5 pH 9: 1.4	KCA 2.7/08 Fischer, A.; 2015
HOPP-P-acid (AE F096918)	pH 5: - 1.6 pH 7: -2.6 pH 9: -3.1	KCA 2.7/09 Fischer, A.; 2016
6-hydroxybenzoazolone (AE 0316854)	pH 5: 1.0 pH 7: 1.0 pH 9: 0.8	KCA 2.7/11 Fischer, A.; 2016
Phenol (AE F040356)	pH 5: 3.1 pH 7: 3.1 pH 9: 2.4	KCA 2.7/07 Sonnenschein, L.; 2015;
Fenoxaprop-dechloro-hydroxy (BCS-CY11271)	pH 5: 2.6 pH 7: 2.6 pH 9: 2.0	KCA 2.7/13 Sonnenschein, L.; 2015
HOPP-ethyl-ester (AE F087795)	pH 5: 1.7 pH 7: 1.7 pH 9: 1.6	KCA 2.7/12 Sonnenschein, L.; 2015

* The active substance does not dissociate at environmentally relevant pH and thus the effects of pH on the P_{OW} is not considered

<u>Food chain from earthworm to earthworm-eating birds</u>

The risk to earthworm-eating birds from bioaccumulation of Fenxoaprop-P-ethyl is calculated with the following equations in accordance with the EFSA Guidance (2009).

Calculation of the PEC_{worm} for earthworm-eating birds:

$BCF = (0.84 + 0.012 * K_{OW}) / (f_{OC} * K_{OC})$

$PEC_{worm} = PEC_{soil} * BCF$

Where:

PEC_{worm}	Predicted concentration in earthworms [mg/kg]
PEC_{soil}	Initial PEC_{soil} in soil [mg/kg soil dw]
BCF	Bioconcentration factor in earthworms

K_{OW}	Octanol/water partition coefficient
F_{OC}	Organic carbon content of soil, default = 0.02
K_{OC}	Organic carbon adsorption coefficient

The factor of 1.05 is used to convert the residues in worms to a daily dose based on a bird of 100 g eating 104.6 g worms per day, according to EFSA.
The risk assessment was performed for the single application of 0.0828 kg a.s./ha.

Table B. 9.2.1-6: Parameters and calculations for the assessment of the long-term risk to earthworm-eating birds

Parameter	Cereals
$NOEL_{long\text{-}term}$ [mg a.s./kg bw/d]	30.8
K_{oc} (Organic carbon adsorption coefficient)	9445.1
K_{ow} (Octanol water partition coefficient)	38019
f_{oc} (Organic carbon content of soil)	default value: 0.02
PEC_{soil} (initial) [mg a.s./kg]	0.111
BCF_{worm}	2.42
PEC_{worm} [mg a.s./kg]	0.27
Daily dose [mg a.s./kg bw/d]	0.28
TER	110
Trigger	5

The TER-value following use according to the GAP are above the trigger of 5 for long-term risk, indicating that the use of Fenxoaprop-P-ethyl poses an acceptable risk to earthworm-eating birds.

<u>Food chain from fish to fish-eating birds</u>

The risk to fish-eating birds from bioaccumulation of Fenxoaprop-P-ethyl is calculated with the following equations in accordance with EFSA Guidance (2009):

Calculation of the Daily Dietary Dose (DDD) for fish-eating birds:
$PEC_{fish} = PEC_{sw} * BCF$

Where:

PEC_{fish}	Predicted concentration in fish [mg/kg]
PEC_{sw}	PEC in surface water [mg/L]
BCF	Bioconcentration factor in fish

The factor of 0.159 is used to convert the residues in fish to a daily dose based on a bird of 1000 g eating 159 g per day, according to EFSA.
The risk assessment is based on the use according to GAP for which the highest initial PEC_{sw} at FOCUS Step 1 was calculated as 2.48 µg a.s./L (based on 1 x 83 g a.s./ha). The initial PEC was used instead of the 21 days twa as it represents a worst-case.

Table B. 9.2.1-7: Parameters and calculations for the assessment of the long-term risk to fish-eating birds

Parameter	Cereals
$NOEL_{long-term}$ [mg a.s./kg bw/d]	30.8
PEC_{water} (initial, FOCUS step 1) [mg a.s./L]	0.00248
BCF_{fish}	343
PEC_{fish} [mg a.s./kg]	0.85
Daily dose [mg a.s./kg bw/d]	0.13
TER	228
Trigger	5

The TER-value following use according to the GAP is above the long-term trigger of 5, indicating that the use of Fenxoaprop-P-ethyl poses an acceptable risk to fish-eating birds.

Biomagnification in terrestrial food chains

The potential for accumulation is stated as low in the human toxicology section.

B.9.2.2. Risk assessment for mammals

With regard to the relevant scenarios small insectivorous, small omnivorous and large herbivorous mammals are considered as the relevant generic focal species for risk assessment in the category cereals.

In the Tier 1 assessment it is assumed that animals satisfy all their dietary needs in the treated area feeding on only one food type and do not avoid contaminated food. Therefore, avoidance, fraction of diet obtained in the treated area and fraction of food type in the diet are all set to 1.

Table B. 9.2.2-1: Relevant indicator species for the screening step

Crop	Scenario	Indicator species	SV_{90}	SV_m
Cereals	BBCH 12-39	Small herbivorous mammal	118.4	48.3

Acute risk assessment for mammals:

The acute risk assessment is based on the lowest acute toxicity endpoint (LD_{50} = 1098 mg a.s./kg be) derived from standard acute oral laboratory study with rats (Sanders, A. 2005a).

Table B. 9.2.2-2: Acute risk assessment for mammals – Screening step

Crop	Indicator species	SV_{90}	Application rate [kg a.s./ha]	MAF_{90}	DDD_A	LD_{50} [mg a.s./kg bw]	TER_A
Cereals	Small herbivorous mammal	118.4	0.0828	1.0	9.8	1098	112

The TER_A value is above the trigger of 10 for acute exposure, indicating an acceptable risk to mammals for the use in cereals.

The long-term risk assessment is based on the reproductive endpoint of NOAEL = 10 mg a.s./kg bw/d derived from a 2-generation study in rats (Baeder et al., 1985).

Table B. 9.2.2-3: Long-term risk assessment for mammals – Screening step

Crop	Generic focal species	SV_m	Application rate [kg a.s./ha]	MAF_m	f_{twa}	DDD_{LT}	NOAEL [mg a.s./kg bw/d]	TER_{LT}
Cereals	Small herbivorous mammal	48.3	0.0828	1.0	0.53	2.12	10	**4.7**

The TER_{LT} value for small herbivorous mammals was identified to be below the trigger of 5. Hence, a Tier 1 risk assessment according to the EFSA Guidance Document (2009) has to be conducted.

Table B. 9.2.2-4: Relevant generic mammalian focal species for the Tier 1 risk assessment

Crop	Growth stage (BBCH)	Generic focal species	Representative species	SV_m
Cereals	BBCH 10-19	Small insectivorous mammal “shrew”	Common shrew	4.2
	BBCH ≥ 20	Small insectivorous mammal “shrew”	Common shrew	1.9
	Early (shoots)	Large herbivorous mammal “lagomorph”	Rabbit	22.3
	BBCH 10-29	Small omnivorous mammal “mouse”	Wood mouse	7.8
	BBCH 30-39	Small omnivorous mammal “mouse”	Wood mouse	3.9

Table B. 9.2.2-5: Tier 1 long-term risk assessment for mammals

Crop	Generic focal species	SV_m	Application rate [kg a.s./ha]	MAF_m	f_{twa}	DDD_{LT}	NOAEL [mg a.s./kg bw/d]	TER_{LT}
Cereals	Small insectivorous mammal “shrew”	4.2	0.0828	1	0.53	0.18	10	55
	Small insectivorous mammal “shrew”	1.9				0.08		125
	Large herbivorous mammal “lagomorph”	22.3				0.98		10.2

Crop	Generic focal species	SV_m	Application rate [kg a.s./ha]	MAF_m	f_{twa}	DDD_{LT}	NOAEL [mg a.s./kg bw/d]	TER_{LT}
	Small omnivorous mammal "mouse"	7.8				0.34		29
	Small omnivorous mammal "mouse"	3.9				0.17		59

Based on the Tier 1 risk assessment an acceptable risk to feeding mammals in cereals was identified. All TER_{LT} are above the trigger of 5, indicating an acceptable risk.

Drinking water risk assessment:

The risk to mammals from exposure via drinking water was conducted according to the EFSA Guidance Document on Birds and Mammals (2009). The risk assessment for mammals is limited to the scenario of puddles formed on the ground after application.

According to the EFSA guidance document for risk assessment for bird and mammals (2009) "*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 3000 in the case of more sorptive substances (Koc > 500 L/kg).*" This is the case for Fenoxaprop-P-ethyl and therefore, the long-term risk for birds from drinking water that may contain residues from Fenoxaprop-P-ethyl is acceptable.

Table B. 9.2.2-6: Drinking water risk assessment

K_{OC} [L/kg]	Application rate [g a.s./ha]	MAF	Endpoint [mg a.s./kg bw/d]		Ratio effective application rate/endpoint		Conclusion
			Acute	Long-term	Acute	Long-term	
9445.1	82.8	1.0	LD_{50} = 1098	NOAEL = 10	0.07	8.3	No concerns (Ratio ≤ 3000)

This evaluation confirms that the risk for mammals from drinking water that may contain residues from the use of the product is acceptable. Hence, no specific calculation of exposure and TER is deemed necessary.

Secondary poisoning:

Substances with a high potential to bioaccumulate in the food chain could theoretically bear a risk of secondary poisoning for birds and mammals if feeding on contaminated prey like fish or earthworms. For organic chemicals, a log P_{OW} > 3 is used to trigger an in-depth evaluation of the potential for bioaccumulation.

Effects on secondary poisoning have been assessed for Fenoxaprop-P-ethyl, due to a log P_{OW} value above 3. Log P_{OW} values of almost all Fenoxaprop-P-ethyl metabolites are below 3 at ecologically relevant pH values. Only the Log P_{OW} value of the Fenoxaprop-P-ethyl metabolite phenol (AE F040356) is slightly above the trigger of 3.

As the risk assessment with the parent indicates no risk and the log P_{OW} value of phenol (AE F040356) is significantly lower than the log P_{OW} of the parent the risk of secondary poisoning is covered by the assessment with the parent Fenoxaprop-P-ethyl. Therefore, there is no unaccepatble risk to mammals through secondary poisoning.

Food chain from earthworm to earthworm-eating mammals

The risk to earthworm-eating mammals from bioaccumulation of Fenxoaprop-P-ethyl is calculated with the following equations in accordance with the EFSA Guidance (2009).

Calculation of the PEC_{worm} for earthworm-eating mammals:

$BCF = (0.84 + 0.012 * K_{OW}) / (f_{OC} * K_{OC})$

$PEC_{worm} = PEC_{soil} * BCF$

Where:

PEC_{worm}	Predicted concentration in earthworms [mg/kg]
PEC_{soil}	Initial PEC_{soil} in soil [mg/kg soil dw]
BCF	Bioconcentration factor in earthworms
K_{OW}	Octanol/water partition coefficient
F_{OC}	Organic carbon content of soil, default = 0.02
K_{OC}	Organic carbon adsorption coefficient

The factor of 1.28 is used to convert the residues in worms to a daily dose based on a mammal of 10 g eating 12.8 g worms per day, according to EFSA.

Table B. 9.2.2-7: Parameters and calculations for the assessment of the long-term risk to earthworm-eating mammals

Parameter	Cereals
$NOEL_{long-term}$ [mg a.s./kg bw/d]	10
K_{oc} (Organic carbon adsorption coefficient)	9445.1
K_{ow} (Octanol water partition coefficient)	38019
f_{oc} (Organic carbon content of soil)	default value: 0.02
PEC_{soil} (initial) [mg a.s./kg]	0.111
BCF_{worm}	2.42
PEC_{worm} [mg a.s./kg]	0.27
Daily dose [mg a.s./kg bw/d]	0.35
TER	29
Trigger	5

The TER-value following use according to the GAP are above the trigger of 5 for long-term risk, indicating that the use of Fenxoaprop-P-ethyl poses a low risk to earthworm-eating mammals.

Food chain from fish to fish-eating mammals

The risk to fish-eating mammals from bioaccumulation of Fenxoaprop-P-ethyl is calculated with the following equations in accordance with EFSA Guidance (2009):

Calculation of the Daily Dietary Dose (DDD) for fish-eating mammals:

$PEC_{fish} = PEC_{sw} * BCF$

Where:

PEC_{fish}	Predicted concentration in fish [mg/kg]
PEC_{sw}	PEC in surface water [mg/L]
BCF	Bioconcentration factor in fish

The factor of 0.142 is used to convert the residues in fish to a daily dose based on a mammal of 3000 g eating 425 g per day, according to EFSA.

The risk assessment is based on the use according to GAP for which the highest initial PEC_{sw} at FOCUS Step 1 was calculated as 2.48 µg a.s./L (based on 1 x 83 g a.s./ha). The initial PEC was used instead of the 21 days twa as it represents a worst-case.

Table B. 9.2.2-8: Parameters and calculations for the assessment of the long-term risk to fish-eating mammals

Parameter	
$NOEL_{long-term}$ [mg a.s./kg bw/d]	10
PEC_{water} (initial, FOCUS step 1) [mg a.s./L]	0.00248
BCF_{fish}	343
PEC_{fish} [mg a.s./kg]	0.85
Daily dose [mg a.s./kg bw/d]	0.12
TER	83
Trigger	5

The TER-value following use according to the GAP is above the long-term trigger of 5, indicating that the use of Fenxoaprop-P-ethyl poses acceptable risk to fish-eating mammals.

Biomagnification in terrestrial food chains

The potential for accumulation is stated as low in the human toxicology section.

B.9.3. EFFECTS ON AQUATIC ORGANISMS

In addition to the (acute and chronic) toxicity studies with the active substance and its metabolites (see RAR, Volume 3, B.9. (AS)), studies with the EU representative formulation CHA 4960 were conducted with fish, aquatic invertebrates, algae and aquatic plants.

B.9.3.1. Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes

Reference:	**Acute Toxicity of Fenoxaprop-P-ethyl 69 g/L EW to Rainbow Trout (*Oncorhynchus mykiss*) in a 96-hour Semi Static Test**
Author(s), year:	[redacted] 2005a
Report/Doc. number:	24783230 / 98 FPE
Guideline(s):	OECD test guideline 203 (1992), EU Commission Directive 92/69/EEC, C.1 (1992)
GLP:	Yes
Deviations:	None
Validity:	Acceptable

Material and methods:	
Test substance:	Fenoxaprop-P-ethyl 69 g/L EW, batch no.: 660-PSH-49, content a.s..: 7.11 %, content safener: 3.41 % (Cloquintocet-mexyl), purity: 95.6 % (w/w)
Test species:	Rainbow trout (*Oncorhynchus mykiss*)
Number of organisms:	7 fish per control and test concentrations, 1 replicate per treatment
Age, length, weight:	Age: Juveniles Length: mean: 513 mm Weight: mean: 0.95g
Loading	0.06 g/L fish loading per test vessel
Type of test:	Semi-static, 96 hours
Applied concentrations:	
Nominal:	0 (control), 0.46, 1.0, 2.1, 4.6 and 10 mg test item/L
Solvent:	None
Test conditions:	
Water quality:	Deionized water, total hardness: 250 mg/L as $CaCO_3$, alkalinity: 0.8 mmol/L
Temperature:	14.0 – 15.0 °C
pH:	7.8 – 7.9
O_2 content:	9.0 – 10.2 mg/L
Light regime:	Light/dark cycle of 16/8
Aeration:	Supplement aeration
Methods:	Test chambers were 18 L glass aquaria containing 15 L test medium. At the initiation of the study seven fish were allocated at random to each test vessel.

Test parameters: All test vessels were monitored for mortality and sub-lethal effects after 2, 24, 48, 72 and 96 hours.

Measurements of temperature, pH and dissolved oxygen were made daily in the freshly prepared and old test media of all test concentrations and the control.

Analytical measurements: Samples of the test substance were measured daily in the freshly prepared and old test media by high performance liquid chromatography.

Statistics: The LC_{50} values and the 95 % confidence intervals were calculated by Probit analysis interpolation.

Findings:

Analytical data: The chemical analysis showed that the actual concentration of Fenoxaprop-P-ethyl was in the range from 66 % to 78 % of the nominal concentrations.

Table B. 9.3.1-1: Analytical measurements of Fenoxaprop-P-ethyl

Nominal concentrations [mg test item/L]	Nominal concentrations [mg a.s./L]	Measured concentrations [mg a.s./L]					% of nominal concentrations
		0 h (new)	24 h (old)	72 h (new)	96 h (old)	Mean	
Control	Control	< 0.028	< 0.028	< 0.028	< 0.028	-	-
0.46	0.033	0.03	0.0145	0.0375	0.0155	0.024	74
1.0	0.071	0.0685	0.033	0.072	0.031	0.051	72
2.1	0.149	0.1335	0.066	0.1215	0.0745	0.098	66
4.6	0.327	0.2975	0.1635	0.2495	0.203	0.228	70
10.0	0.711	0.6425	0.461	-	-	0.552	78

Limit of Quantification = 0.028 mg a.s./L

Biological results: The lowest concentration that resulted in 100% mortality within the period of the test was 10 mg test item/L.

The highest concentration with no mortality was 2.1 mg test item/L. In the control 0 % mortality occurred.

Table B. 9.3.1-2: Mortality and sub-lethal effects

Test concentration [mg test item/L]	Mortality [%]				
	2 h	24 h	48 h	72 h	96 h
Control	0	0	0	0	0
0.46	0	0	0	0	0
1.0	0	0	0	0	0
2.1	0	0	0	0	0
4.6	0	0[a,c]	29[a,b,c]	43[c]	71[c]
10.0	0[a,b,c,d]	100	100	100	100

[a] Tumbling, [b] Apathy, [c] Strong ventilation, [d] Convulsions

Conclusion: Based on these results a LC_{50} of 3.83 mg test item/L (95% CL = 2.939 to 4.990 mg

test item/L) based on nominal concentrations and 0.19 mg a.s./L based on mean measured concentrations was determined.

Comment RMS:	**Validity:** The study was evaluated following the recommendations of the currently valid test guideline OECD 203 (1992, updated 2009). - The mortality in the controls should not exceed 10% (or 1 fish if less than 10 fish are used) at the end of the test. - Constant conditions should be maintained throughout the test. - The dissolved oxygen concentration must have been at least 60% of the air saturation value throughout the test. - There must be evidence that the concentration of the test substance has been satisfactorily maintained, and preferably, it should be at least 80% of the nominal concertation throughout the test. If the deviation from the nominal concentration is greater than 20%, results should be based on the measured concentrations. All validity criteria are met. **Acceptability of the analytical methods used in the test:** Evaluation of the analytical methods (water/sediment/soil) according to the Guidance Document SANCO/3029/99 rev. 4. Based in the evaluation (see B.5 (CP), B.5.1.2.5) the analytical method is considered acceptable covering the LOQ (= 0.028 mg a.s./L) mentioned. **Endpoints:** The RMS agrees on the endpoints given in the study report. However, the arithmetic mean was used instead of the geometric mean for the calculation of the mean measured concentration. The RMS conducted a re-calculation of the measured concentration, which are 0.022, 0.047, 0.095, 0.223, 0.544 mg a.s./L. The following endpoint (based on mean measured concentrations) was calculated. LC_{50} = 0.17 mg a.s./L (95% C.I. = 0.095 – 0.544 mg a.s./L) NOEC = 0.095 mg a.s./L **Conclusion of the RMS:** Based on the evaluation of the study the acute fish toxicity test is considered valid.

Reference:	**Acute Toxicity of Fenoxaprop-P-ethyl 69 g/L EW to *Daphnia magna* in a Semi-Static 48-hour Immobilization Test**
Author(s), year:	Grade, R., Wydra, V., 2005
Report/Doc. number:	24782220 / 97 FPE
Guideline(s):	OECD 202 (2004), Directive 92/69/EEC, C.2 (1992),
GLP:	Yes

Deviations:	None
Validity:	Acceptable

Material and methods:

Test substance:	Fenoxaprop-P-ethyl g/L EW, batch no.: 660-PSH-49, content a.s..: 7.11 % w/w
Test species:	Water flea (*Daphnia magna*)
Number of organisms:	20 daphnids per controls and test concentrations, 4 replicates per treatment
Age:	First instar, < 24 hours old
Type of test, duration:	Semi-Static, 48 hours

Applied concentrations:

Nominal:	0 (control), 0.46, 1.0, 2.1, 4.6 and 10 mg test item/L
Solvent:	None

Test conditions:

Water quality:	Deionised water, total hardness: 250 mg/L as $CaCO_3$, alkalinity: 0.8 mmol/L
Temperature:	20.0 – 21.0 °C
pH:	7.7 – 7.9
O_2 content:	8.3 – 8.9 mg/L
Light regime:	Light/dark cycle of 16/8
Methods:	The test was conducted in 100 mL glass jars with a working volume of 80 mL.
Test parameters:	Immobility and sub-lethal effects were assessed after 24 and 48 hours. Measurements of pH, temperature and dissolved oxygen concentrations were made at the start of the test and after 24 and 48 hours.
Analytical measurements:	The test medium was renewed every 24 hours. Samples of the test solutions were measured at the start of the test and after 24 and 48 hours by high performance liquid chromatography.
Statistics:	The EC_{50} value and the 95 % confidence intervals were calculated using probit analysis.

Findings:

Analytical measurements:	The mean measured concentration of the test medium was between 80 and 99% of nominal values. Hence, the endpoints are based on nominal concentrations.

Table B. 9.3.1-3: Analytical measurements of Fenoxaprop-P-ethyl

Nominal concentrations [mg test item/L]	Nominal concentrations [mg a.s./L]	Measured concentrations [mg a.s./L]					% of nominal concentrations
		0 h (new)	24 h (old)	24 h (new)	48 h (old)	Mean	
Control	Control	< 0.028	< 0.028	< 0.028	< 0.028	-	-
0.46	0.033	0.029 0.028	0.038 0.033	0.033 0.036	0.031 0.031	0.033	99
1.0	0.071	0.071	0.066	0.070	0.064	0.068	96

Nominal concentrations [mg test item/L]	Nominal concentrations [mg a.s./L]	Measured concentrations [mg a.s./L]					% of nominal concentrations
		0 h (new)	24 h (old)	24 h (new)	48 h (old)	Mean	
		0.069	0.070	0.069	0.065		
2.1	0.149	0.132 0.120	0.134 0.124	0.146 0.131	0.111 0.105	0.125	84
4.6	0.327	0.278	0.255	0.294	0.230	0.262	80
		0.259	0.266	0.284	0.235		
10.0	0.711	0.627 0.647	0.542 0.575	- -	- -	0.597	84

Limit of Qantification = 0.028 mg a.s./L

Biological Effects: The lowest concentration that resulted in 100% mortality within the period of the test was 10.0 mg/L.

The highest concentration with no mortality was 1.0 mg a.s./L. In the control 0 % mortality occurred.

Table B. 9.3.1-4: Effects on daphnids (*D. magna*)

Nominal concentrations [mg test item/L]	Mean cumulative immobilized organisms [%]	
	24 hours	48 hours
Control	0	0
0.46	0	0
1.0	0	0
2.1	0	20
4.6	60	80
10.0	100	100

[a] Surfacing

Conclusion: Based on these results an EC_{50} of 3.1 mg test item/L (95% C.I. 2.6 – 83.8 mg/L) based on nominal concentrations was determined corresponding to 0.22 mg a.s./L.

Comment RMS: **Validity:** The study was evaluated following the recommendations of the currently valid test guideline, the OECD test guideline 202 (2004).

- In the control, including the control containing the solubilising agent, not more than 10 per cent of the daphnids should have been immobilised;
- The dissolved oxygen concentration at the end of the test should be ≥ 3 mg/l in control and test vessels.

All validity criteria are met; hence, the acute daphnia toxicity test is considered valid.

Acceptability of the analytical methods used in the test: Evaluation of the analytical methods (water/sediment/soil) according to the Guidance Document SANCO/3029/99 rev. 4. Based in the evaluation (see B.5 (CP), B.5.1.2.5) the

	analytical method is considered acceptable covering the LOQ (= 0.028 mg a.s./L) mentioned. **Endpoints:** The RMS agrees on the endpoint given in the study report. 48 h EC_{50} = 3.1 mg test item/L corresponding to 0.22 mg a.s./L based on nominal concentrations **Conclusion of the RMS:** Based on the evaluation of the study the acute Daphnia test is considered valid.

Reference:	**Toxicity of Fenoxaprop-P-ethyl 69 g/L EW to *Desmodesmus subspicatus* in an Algal Growth Inhibition Test**
Author(s), year:	Pawlowski, S., Wydra, V., 2005b
Report/Doc. number:	24781210 / 96FPE
Guideline(s):	OECD 201 (1984), OECD 201 (2004), Commission Directive 92/69/EEC C.3 (1992)
GLP:	Yes
Deviations:	None
Validity:	Acceptable

Material and methods:

Test substance:	Fenoxaprop-P-ethyl 69 g/L EW, batch no.: 660-PSH-49, content a.s..: 7.11 %, content safener: 3.41 % (Cloquintocet-mexyl),
Test species:	Green alga (*Desmodesmus subspicatus*, strain 86.81 SAG)
Number of organisms:	5000 cells/mL; 6 replicates per control and 3 replicates per treatment
Type of test, duration:	Static, 72 hours
Applied concentrations:	
Nominal:	0 (control), 0.10, 0.31, 0.98, 3.13 and 10.0 mg/L
Solvent:	None
Test conditions:	
Water quality:	Algal nutrient medium (OECD medium)
Temperature:	23.0 – 24.0 °C
pH:	7.8 – 9.9
Incubation:	Continuous illumination 6040 – 7500 lux
Methods:	The test was conducted in 50 mL Erlenmeyer flasks, which were filled with 50 mL medium.
Test parameters:	Samples were taken daily to determine the cell densities by spectrophotometrical measurement. The shape of the treated algal cells compared to the control was microscopically examined.

Measurement of pH was made at test initiation and test termination. Furthermore, water temperature was monitored daily in a surrogate water filled vessel.

Analytical measurements: The concentration of the test substance was determined at test initiation and test termination using high performance liquid chromatography.

Statistics: The $E_{b/r}C_x$ value with confidence intervals was calculated by probit analysis.

Findings:

Analytical data: The mean measured concentration was between 39.9 and 63.6 % of nominal concentrations.

All reported results are expressed in terms of the nominal test item concentrations, nominal concentrations of the active substance and on mean measured concentrations of the active substance.

Table B. 9.3.1-5: Analytical measurements of Fenoxaprop-P-ethyl

Nominal concentrations [mg test item/L]	Nominal concentrations [mg a.s./L]	Measured concentrations [mg/L]			% of nominal concentrations
		0 h	48 h (old)	Mean	
Control	Control	< 0.003	< 0.003	-	-
0.1	0.007	0.007 0.007	n.d n.d	0.007	-
0.31	0.022	0.021 0.018	0.008 0.008	0.014	63.6
0.98	0.070	0.062 0.067	*0.026* 0.010	0.037	52.9
3.13	0.223	0.177 0.135	0.024 0.020	0.089	39.9
10.0	0.711	0.558 0.456	0.094 0.103	0.303	42.6

Limit of Quantification (LOQ) = 0.003 mg/L

Italic value is strongly influenced by interfering signal

Biological effects: The microscopic examination of the shape of the algal cells after 72 hours showed no difference between the algae at a nominal test concentration of 10 mg/L and the cells in the control.

Biomass and growth rates are given in the Table B. 9.3.1-6.

Table B. 9.3.1-7: Effects of Fenoxaprop-P-ethyl 69 g/L EW on the green algae *Desmodesmus subspicatus*

Nominal concentrations [mg test item/L]	Biomass		Growth rate	
	Area under the curves	% inhibition relative to the control	Mean growth rate [d^{-1}]	% inhibition relative to the control
Control	60.761	0.0	1.642	0.0
0.1	65.824	-8.3	1.687	-2.7
0.31	60.704	0.1	1.650	-0.5

Nominal concentrations [mg test item/L]	Biomass		Growth rate	
	Area under the curves	% inhibition relative to the control	Mean growth rate [d^{-1}]	% inhibition relative to the control
0.98	51.824	14.7*	1.605	2.3
3.13	11.684	80.8*	1.028	37.4*
10.0	1.193	98.0*	0.538	67.2*

* Statistical significant different compared to the control

Validity criteria: The cell number in the control cultures increased by a factor of 139 within the test period of 72 h.

The coefficient of variation of the section by section specific growth rates in the control was 33.5 %.

The coefficient of variation of average specific growth rates during the whole test period in the control was 2.0 %.

Conclusion: 72 h E_bC_{50} = 1.85 mg/L (95% C.I.: 1.75 – 1.95 mg/L) corresponding to 0.13 mg a.s./L (95% C.I.: 0.12– 0.14 mg a.s./L)

72 h E_bC_{10} = 0.85 mg/L (95% C.I.: 0.77 – 0.93 mg/L) corresponding to 0.06 mg a.s./L (95% C.I.: 0.05– 0.07 mg a.s./L)

72 h E_rC_{50} = 5.37 mg/L (95% C.I.: n.d. – n.d.) corresponding to 0.38 mg a.s./L (95% C.I.: n.d. – n.d.)

72 h E_rC_{10} = 1.15 mg/L (95% C.I.: n.d. – n.d.) corresponding to 0.08 mg a.s./L (95% C.I.: n.d. – n.d.)

72 h NOEC = 0.31 mg/L corresponding to 0.02 mg a.s./L (biomass)

72 h NOEC = 0.98 mg/L corresponding to 0.07 mg a.s./L (growth rate)

The toxicity endpoints are based on nominal concentrations.

72 h E_bC_{50} = 0.06 mg a.s./L

72 h E_bC_{10} = 0.04 mg a.s./L

72 h E_rC_{50} = 0.16 mg a.s./L

72 h E_rC_{10} = 0.04 mg a.s./L

The toxicity endpoints are based on mean measured concentrations.

Comment RMS: **Validity:** The study was evaluated following the recommendations of the currently valid test guidelines, the OECD test guideline 201 (2011).

- The biomass in the control cultures should have increased exponentially by a

	factor of at least 16 within the 72-hour test period. This corresponds to a specific growth rate of 0.92/day. - The mean coefficient of variation for section-by-section specific growth rates (days 0-1, 1-2 and 2-3, for 72-hour tests) in the control cultures must not exceed 35%. - The coefficient of variation of average specific growth rates during the whole test period in replicate control cultures must not exceed 7% in tests with *Pseudokirchneriella subcapitata* and *Desmodesmus subspicatus*. All validity criteria were met; hence, the study is considered valid according to the OECD test guideline 201 (2011). **Acceptability of the analytical methods used in the test:** Evaluation of the analytical methods (water/sediment/soil) according to the Guidance Document SANCO/3029/99 rev. 4. Based in the evaluation (see B.5 (CP), B.5.1.2.5) the analytical method is considered acceptable covering the LOQ (= 0.007 mg a.s./L) mentioned. **Endpoints:** The analytically verification of the test concentration was between 39.9 and 63.6 % of nominal concentrations. The endpoints should be expressed on mean measured concentrations. For the calculation of the mean measured concentration the arithmetic mean was used instead of the geometric mean. The RMS conducted a re-calculation of the measured concentrations which are 0.007, 0.012, 0.025, 0.059, 0.223 mg a.s./L. The following endpoints (based on geometric mean measured concentrations) were calculated. 72 h E_bC_{50} = 0.04 mg a.s./L 72 h E_bC_{10} = 0.02 mg a.s./L 72 h E_rC_{50} = 0.12 mg a.s./L 72 h E_rC_{10} = 0.02 mg a.s./L 72 h NOEC = 0.012 mg a.s./L (biomass) 72 h NOEC = 0.025 mg a.s./L (growth rate) **Conclusion of the RMS:** Based on the evaluation the algae test is considered valid.

Reference:	**Toxicity of Fenoxaprop-P-ethyl 69 g/L EW to the Aquatic Plant *Lemna gibba* in a Semi Static Growth Inhibition Test**
Author(s), year:	Pawlowski, S., Wydra, V., 2006
Report/Doc. number:	24780240 / 154 FPE

Guideline(s):	OECD 221 (2004), EPA OPPTS 850.4400 (1996)
GLP:	Yes
Deviations:	None
Validity:	Acceptable

Material and methods:

Test substance:	Fenoxaprop-P-ethyl 69 g/L EW, batch no.: 660-PSH-49, content a.s..: 7.11 %, content safener: 3.41 % (Cloquintocet-mexyl),
Test species:	Duckweed *(Lemna gibba* G3)
Number of organisms:	12 fronds per test vessel, 36 fronds per controls and test concentrations, 3 replicates per treatment
Type of test, duration:	Semi-static, 7 days
Applied concentrations:	
Nominal:	0 (control), 0.03, 0.1, 0.31, 0.98, 3.13 and 10 mg test item/L
Solvent:	None
Test conditions:	
Water quality:	20X-AAP medium, pH 7.5
Temperature:	23 – 24 °C
pH:	7.5 – 9.0
Light regime:	Continuous light, 7140 – 7990 lux
Methods:	The test was conducted in 250 mL glass flasks, which were filled with 150 mL medium. The test medium was renewed at day 3, 4 and 5.
Test parameters:	Frond counts and abnormal appearance were visual evaluated on Days 3, 5 and 7. At test start the dry weight of a sample of fronds identical to that used to inoculate the test vessels was determined. At test end the dry weight of all plants from each vessel was determined. Measurements of pH were taken at test start and in all freshly prepared and aged test concentrations. Furthermore, water temperature was monitored daily in a reference vessel.
Analytical measurements:	Sampling and analysis of test concentration were carried out on day 3, 4 and 5 of the freshly prepared test media and at day 4, 5 and 6 for the aged test media using gas chromatography.
Statistics:	EC_{50} values and confidence limits were calculated by probit analysis. NOEC-values were determined by using multiple Dunnett-test for frond number, Bonferroni U-test for growth rate, Williams test for biomass gain and and Bonferroni t- test for area under the growth curve.

Findings:

Analytical measurements:	Mean measured concentrations of test solutions were in the range of 51 to 66 % of nominal concentrations. The results are based on nominal concentrations and mean

measured concentrations.

Table B. 9.3.1-8: Analytical measurements of Fenoxaprop-P-ethyl

Nominal concentrations [mg test item/L]	Nominal concentrations [mg a.s./L]	Measured concentrations [mg/L]							% of nominal concentrations
		Day 3	Day 4 (old)	Day4 (new)	Day 5 (old)	Day 5 (new)	Day6 (old)	Mean	
Control	Control	< 0.0007	< 0.0007	< 0.0007	< 0.0007	< 0.0007	< 0.0007	-	-
0.03	0.00213	0.00166 0.00159	0.00088 0.00074	0.00188 0.00187	0.00043 0.00032	0.00193 0.00196	0.00024 0.00021	0.0012	54
0.10	0.00711	*0.01483* 0.00809	0.00257 0.00225	0.00648 0.00695	0.00186 0.00135	0.00632 0.00598	0.0063 0.00034	0.004	55
0.31	0.02204	0.02246 0.02047	0.00461 0.00501	0.02107 0.02065	0.00277 0.00289	0.01904 0.02026	0.00057 0.00086	0.012	53
0.98	0.06968	0.06322 0.06103	0.02144 0.02114	0.05206 0.05286	0.01601 0.01460	0.05510 0.05798	0.00471 0.00542	0.036	51
3.13	0.22254	0.19253 0.19974	0.11341 0.11842	0.19492 0.21636	0.07516 0.14220	0.21459 0.20150	0.03127 0.04885	0.147	66
10.0	0.71100	0.65574 0.61309	0.56507 0.58434	0.57123 0.58165	0.59108 0.47627	0.71803 0.62164	0.43063 0.44158	0.569	80

Limit of Quantification (LOQ) = 0.0007 mg/L

Italic value was considered to be an outlier

Biological effects: The shape of fronds and colonies after the test period of 7 days was not different to those in the control at the nominal test concentrations up to nominal 0.98 mg/L. At 3.12 and 10 mg/L, chlorosis of the fronds could be observed. In addition to this observation, at 10 mg/L several fronds were dead.

Table B. 9.3.1-9: Effects of Fenoxaprop-P-ethyl 69 g/L EW on the duckweed *Lemna gibba* for 7days

Nominal concentrations [mg test item/L]	Frond number		Growth rate		Biomass		Dry weight	
	No. [d^{-1}]	% inhibition	Mean[d^{-1}]	% inhibition	Area under the curve [d^{-1}]	% inhibition	Biomass gain	% inhibition
Control	183.667	0.0	0.389	0.0	373.667	0.0	22.300	0.0
0.03	154.000	16.2#	0.363	6.7#*	305.167	18.3#*	20.867	6.4
0.10	169.000	8.0#	0.378	2.9#*	334.000	10.6#	21.000	5.8
0.31	195.333	-6.4	0.398	-2.3#*	395.667	-5.9	25.267	-13.3
0.98	180.667	1.6	0.387	0.5#*	364.000	2.6	23.667	-6.1
3.13	116.000	36.8*	0.324	16.7*	242.167	35.2*	16.700	25.1*
10.0	30.000	83.7*	0.131	66.4*	60.667	83.8*	3.800	83.0*

* Statistically significant difference from control

observed inhibition was not treatment related and therefore not considered for NOEC and LOEC evaluations.

Validity: The doubling time of fronds was 1.8 and thus less than 2.5 d (60 h), corresponding to an approximately 15.3-fold increase in 7 days.

Conclusion: Growth rate:

EC_{50} = 7.021 mg /L (95% C.I.: 5.304 – 9.413 mg/L) corresponding to 0.499 mg a.s./L (95% C.I.: 0.377– 0.669 mg a.s./L)

EC_{10} = 2.410 mg /L (95% C.I.: 0.925 – 3.573 mg/L) corresponding to 0.171 mg a.s./L (95% C.I.: 0.066 – 0.254 mg a.s./L)

NOEC = 0.980 mg/L corresponding to 0.070 mg a.s./L

Area under the growth curve:

EC_{50} = 4.345 mg /L (95% C.I.: 1.162 – 23.241 mg/L) corresponding to 0.309 mg a.s./L (95% C.I.: 0.083 – 1.652 mg a.s./L)

EC_{10} = 1.494 mg /L (95% C.I.: 0.000 – 2.874 mg/L) corresponding to 0.106 mg a.s./L (95% C.I.: 0.000 – 0.204 mg a.s./L)

NOEC = 0.980 mg/L corresponding to 0.070 mg a.s./L

Frond number:

EC_{50} = 4.256 mg /L (95% C.I.: n.d. – n.d.) corresponding to 0.303 mg a.s./L (95% C.I.: n.d. – n.d.)

EC_{10} = 1.451 mg /L (95% C.I.: n.d. – n.d.) corresponding to 0.103 mg a.s./L (95% C.I.: n.d. – n.d.)

NOEC = 0.980 mg/L corresponding to 0.070 mg a.s./L

Biomass gain:

EC_{50} = 5.063 mg /L (95% C.I.: 4.053 – 6.404 mg/L) corresponding to 0.360 mg a.s./L (95% C.I.: 0.288 – 0.455 mg a.s./L)

EC_{10} = 2.037 mg /L (95% C.I.: 1.147 – 2.748 mg/L) corresponding to 0.145 mg a.s./L (95% C.I.: 0.082 – 0.195 mg a.s./L)

NOEC = 0.980 mg/L corresponding to 0.070 mg a.s./L

The toxicity endpoints are based on nominal concentrations.

Growth rate:

EC_{50} = 0.376 mg a.s./L (95% C.I.: 0.297 – 0.479 mg a.s./L)

EC_{10} = 0.108 mg a.s./L (95% C.I.: 0.053 – 0.157 mg a.s./L)

NOEC = 0.036 mg a.s./L

Area under the growth curve:

EC_{50} = 0.215 mg a.s./L (95% C.I.: 0.037 – 1.707 mg a.s./L)

EC_{10} = 0.061 mg a.s./L (95% C.I.: 0.000 – 0.133 mg a.s./L)
NOEC = 0.036 mg a.s./L

Frond number:
EC_{50} = 0.209 mg a.s./L (95% C.I.: n.d. – n.d.)
EC_{10} = 0.059 mg a.s./L (95% C.I.: n.d. – n.d.)
NOEC = 0.036 mg a.s./L

Biomass gain:
EC_{50} = 0.215 mg a.s./L (95% C.I.: 0.037 – 1.707 mg a.s./L)
EC_{10} = 0.061 mg a.s./L (95% C.I.: 0.000 – 0.133 mg a.s./L)
NOEC = 0.036 mg a.s./L

The toxicity endpoints are based on mean measured concentrations.

Comment RMS:	The study was evaluated following the recommendations of the currently valid test guideline, the OECD test guideline 221 (2006). - The doubling time of frond number in the control must be less than 2.5 days (60h), corresponding to approximately a seven-fold increase in seven days and an average specific growth rate of 0.275 d^{-1}. All validity criteria were met. In addition, the following points deviated from the test guideline or were not reported in detail: -According to OECD 221 a reference substance should be tested at least twice a year. No information about reference testing is provided in the current study report. -The test concentration was not analytically dertermined at the beginning of the test. The first sampling was conducted on day 3. The deviations to the test guideline are not considered to have an impact on the validity of the test. **Acceptability of the analytical methods used in the test:** Evaluation of the analytical methods (water/sediment/soil) according to the Guidance Document SANCO/3029/99 rev. 4. Based in the evaluation (see B.5 (CP), B.5.1.2.5) the analytical method is considered acceptable covering the LOQ (= 0.0007 mg a.s./L) mentioned. **Endpoints:** According to the current valid OECD test guideline 221 (2006) the primary measurement variable is frond number and at least one additional measurement variable should be measured. The calculation of ECx values should be based on

	the growth rate and yield of the measured variables. No growth rate for dry weight and yield for frond number and dry weight are presented in the study report. Furtheremore, the test concentrations were between 51 to 66 % of nominal concentrations. The endpoints should be expressed as mean measured concentrations. Therefore, the RMS conducted a statistical re-evaluation of the results of the study using the software Tox Rat®. The geometric mean measured concentrations are 0.0009, 0.0029, 0.007, 0.026, 0.1272, 0.5657 mg a.s./L. The following endpoints (based on geometric mean measured) were calculated. $E_rC_{50\ (frond\ number)}$ = 0.359 mg a.s./L (95% C.I.: 0.277 – 469 mg a.s./L) $E_rC_{50\ (dry\ weight)}$ 0.336 mg a.s./L (95% C.I.: 0.300 – 0.374 mg a.s./L) $E_rC_{20\ (frond\ number)}$ = 0.145 mg a.s./L (95% C.I.: 0.083 – 0.199 mg a.s./L) $E_rC_{20\ (dry\ weight)}$ = 0.168 mg a.s./L (95% C.I.: 0.138 – 0.195 mg a.s./L) $E_rC_{10\ (frond\ number)}$ = 0.091 mg a.s./L (95% C.I.: 0.041 – 0.137 mg a.s./L) $E_rC_{10\ (dry\ weight)}$ = 0.117 mg a.s./L (95% C.I.: 0.091 – 0.142 mg a.s./L) $E_yC_{50\ (frond\ number)}$ = 0.166 mg a.s./L (95% C.I.: 0.025 – 4.397 mg a.s./L) $E_yC_{50\ (dry\ weight)}$ = 0.201 mg a.s./L (95% C.I.: 0.152 – 0.293 mg a.s./L) $E_yC_{20\ (frond\ number)}$ = 0.074 mg a.s./L (95% C.I.: n.d. – 0.137 mg a.s./L) $E_yC_{20\ (dry\ weight)}$ = 0.105 mg a.s./L (95% C.I.: 0.061 – 0.140 mg a.s./L) $E_yC_{10\ (frond\ number)}$ = 0.048 mg a.s./L (95% C.I.: n.d. – 0.102 mg a.s./L) $E_yC_{10\ (dry\ weight)}$ = 0.075 mg a.s./L (95% C.I.: 0.034 – 0.106 mg a.s./L) The 50% effect concentrations were calculated by probit analysis using linear max. likelihood regression. $NOE_rC_{(frond\ number)}$ = 0.026 mg a.s./L $NOE_rC_{(dry\ weight)}$ = 0.026 mg a.s./L $NOE_yC_{(frond\ number)}$ = 0.026 mg a.s./L $NOE_yC_{(dry\ weight)}$ = 0.026 mg a.s./L The NOEC were determined by calculation of the statistical significance of growth rate and yield using the Williams Multiple Sequential t-Test Procedure. **Conclusion of the RMS:** Based on the evaluation of the study the macrophyte toxicity test is considered valid.

B.9.3.2. Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms

Reference:	**Influence of Fenoxaprop-P-ethyl 69 g/L EW to *Daphnia magna* in a Reproduction Test**

Author(s), year:	Kley, A., Wydra, V., 2010
Report/Doc. number:	37571221 / 314 FPE
Guideline(s):	OECD 211 (1998)
GLP:	Yes
Deviations:	None
Validity:	Acceptable

Material and methods:

Test substance:	Fenoxaprop-P-ethyl EW, CHA 4960 containing 7.11 % Fenoxaprop-P-ethyl and 3.41 % Cloquintocet-mexyl (Safener), Batch no: 660–PSH- 49, density: 1.03 g/mL
Test species:	Water flea (*Daphnia magna*)
Number of organisms:	10 daphnids per control and test concentrations, 10 replicates per treatment
Age:	First instar, < 24 hours old
Type of test, duration:	Semi-static, 21 days
Applied concentrations:	
Nominal:	0 (control), 0.031, 0.1, 0.31, 1.0 and 3.2 mg test item/L
Solvent:	None
Test conditions:	
Water quality:	M4 medium (Elendt medium), Hardness: 250 mg/L as $CaCO_3$, Alkalinity: 0.9 mmol/L,
Temperature:	20 – 21°C
pH:	7.6 – 9.1
O_2 content:	8.2 – 10.7 mg/L
Light regime:	Light/dark cycle of 16/8
Feeding:	Daphnids were fed during the test with suspensions of the unicellular alga *Desmodesmus subspicatus.*
Methods:	The test was conducted in glass beakers of 100 mL capacity, containing 80 mL test medium. The test solutions were renewed on Days 3, 5, 7, 10, 12, 14, 17 and 19 of the exposure period.
Test parameters:	Immobilisation of adults and number of offspring were assessed daily. Dissolved oxygen, pH and water temperature were measured in all test concentrations and in the control at the start and the end of each exposure period.
Analytical measurements:	The actual concentrations of Fenoxaprop-P-ethyl, cloquintocet-mexyl and fop-acid were determined at each test medium renewal period in the freshly prepared and old test media by liquid chromatography. The test media of nominal 0.1 and 0.031 mg test item/L were not analysed, since they were below the NOEC determined in this test.
Statistics:	The NOEC was determined using Williams` test. Concentration-response relationship was analysed by Probit-analysis.

Findings:

Analytical measurements: The concentration of Fenoxaprop-P-ethyl was 90 – 98 % of nominal concentrations in all measured freshly prepared test media and was close to zero in the respective aged test media. No FOP-acid was found in the freshly prepared test media and 63 - 101 % of nominal in the aged test media. The recovery values of cloquintocet-mexyl for the fortification levels of 0.3 and 0.03 mg test item/L resulted in very high standard deviations. However, for the concentration of 3.2 mg test item/L the results are reproducible. Therefore, at least for the highest concentration the correct dosing could be confirmed which was already demonstrated by measurement of Fenoxaprop-P-ethyl. Thus, it can be concluded that cloquintocet-mexyl was present in the correct concentration also in the test media, which were below the Limit of Quanitification.

The results are based on nominal concentrations.

Table B. 9.3.2-1: Analytical measurements of Fenoxaprop-P-ethyl

Nominal concentrations [mg test item/L]	Nominal concentrations [µg a.s./L]	Measured concentrations [µg a.s./L]								% of nominal concentrations
		Day 5 (new)	Day 5 (old)	Day 7 (old)	Day 10 (new)	Day 12 (old)	Day 14 (new)	Day 17 (old)	Mean	
Control	Control	< LOQ	-	n.a.	n.a.	n.a.	< LOQ	n.a.	-	-
0.31	22.041	20.049 19.667	- -	*107.651* *96.959*	16.765 15.467	n.a. n.a.	17.987 16.536	n.a. n.a.	21.600	98
1.0	71.100	57.167 52.890	- -	9.891 11.113	50.599 49.072	< LOQ < LOQ	55.564 50.905	< LOQ < LOQ	63.990	90
3.2	227.520	128.272 145.075	46.628 62.972	- -	- -	- -	- -	- -	222.97	98

Limit of Quantification (LOQ) = 0.08 mg/L

n.a. – not applicable

Italic value was considered not reliable (perhaps result of a preparation error); respective fop-acid concentration is close to 100%

Table B. 9.3.2-2: Analytical measurements of Fenoxaprop-p-acid

Nominal concentrations [mg test item/L]	Nominal concentrations [µg FOP/L]	Measured concentrations [µg FOP/L]								% of nominal concentrations
		Day 5 (new)	Day 5 (old)	Day 7 (old)	Day 10 (new)	Day 12 (old)	Day 14 (new)	Day 17 (old)	Mean	
Control	Control	n.a.	-	n.a.	n.a.	n.a.	n.a.	n.a.	-	-
0.31	20.329	< LOQ < LOQ	- -	19.502 19.144	< LOQ < LOQ	20.884 19.835	< LOQ < LOQ	21.702 22.240	20.532	101

Nominal concentrations [mg test item/L]	Nominal concentrations [µg FOP/L]	Measured concentrations [µg FOP/L]								% of nominal concentrations
		Day 5 (new)	Day 5 (old)	Day 7 (old)	Day 10 (new)	Day 12 (old)	Day 14 (new)	Day 17 (old)	Mean	
1.0	65.578	< LOQ < LOQ		50.078 49.822	< LOQ < LOQ	65.686 64.407	< LOQ < LOQ	69.268 69.012	61.643	94
3.2	209.849	< LOQ < LOQ	125.303 136.306	- -	- -	- -	- -	- -	132.21	63

Limit of Quantification (LOQ) = 0.0015 mg/L

Biological effects: In the control and in the concentrations of 0.1 and 1.0 mg/L the survival rate of adult *Daphnia* was 100 %. 100% mortality was observed in the highest test concentration of 3.2 mg/L.

The effects on the mean reproduction rate were significantly reduced in the 1.0 and 3.2 mg/L test concentration.

Beside the reported mortality and the reduced reproduction rates, the adult animals in the 1.0 mg/L test concentration were smaller and paler than the animals in the control.

Table B. 9.3.2-3: Effects on parental survival and reproduction, Individual exposure

Nominal concentrations [mg/L]	Parental survival [%]	Mean number of offspring/survivor at Day 21 ± SD	Date of First Brood [Day]
Control	100	132.5 ± 21.7	10
0.031	90	139 ± 32.9	10
0.1	100	140.3 ± 14.9	10
0.31	90	127.4 ± 27.9	10
1.0	100	36.1 ± 36.1*	11
3.2	0*	-*	-

* Statistically significant compared to the control ($p < 0.05$)

Conclusion: The NOEC for reproduction was determined to be the tested concentration 0.31 mg test item/L corresponding to 0.021 mg a.s./L. The EC_{50} for the reproduction was 0.742 mg test item/L corresponding to 0.051 mg a.s./L The toxicity endpoint is based on nominal concentrations.

Comment RMS:	**Validity:** The study was evaluated following the recommendations of the currently valid test guidelines, the OECD test guideline 211 (2012): - the mortality of the parent animals (female Daphnia) does not exceed 20% at the end of the test;

	- the mean number of living offspring produced per parent animal surviving at the end of the test is > 60. All validity criteria were met; hence, the study is considered valid. **Acceptability of the analytical methods used in the test:** Evaluation of the analytical methods (water/sediment/soil) according to the Guidance Document SANCO/3029/99 rev. 4. Based in the evaluation (see B.5 (CP), B.5.1.2.5) the analytical method is considered acceptable covering the LOQ (= 0.0021 mg a.s./L and 0.0014 mg FOP/L) mentioned. **Endpoints:** The study author determined the endpoints based on nominal concentrations. The RMS does not agree on this approach as no stable exposure could be shown. In general, the endpoint should have been expressed on mean measured concentrations. The RMS conducted a re-evaluation based on mean measured concentrations of Fenoxaprop-P-ethyl and the metabolite Fenoxaprop-P-acid. The mean measured concentrations were 0.019 mg a.s./L, 0.052 mg a.s./L and 0.113 mg a.s./L. The following endpoints (based on mean measured concentrations) were calculated. NOEC = 0.019 mg a.s./L The NOEC were determined by calculation of the statistical significance of reproduction using the Williams Multiple Sequential t-Test Procedure. The calculation of an EC_{10} was not possible because only three test concentrations were analytically verified. **Conclusion of the RMS:** Based on the evaluation of the study the chronic reproduction test is considered valid.

B.9.3.3. Further testing on aquatic organisms

No further studies were submitted with the EU representative formulation CHA 4960.

B.9.4. RISK ASSESSMENT FOR AQUATIC ORGANISMS

The aquatic risk assessment was conducted according to the EFSA Guidance Document (EFSA, 2013)[1].
Toxicity data are available for the active substance Fenoxaprop-P-ethyl and the EU representative formulation CHA 4960 and the environmentally relevant metabolites Fenoxaprop-P-acid, Chlorobenzoxazolone, HOPP-acid, Phenol and Fenoxaprop-dechloro. Furthermore, the notifiers submitted studies with the metabolite 6-hydroxy-benzoxazolone, which were evaluated by the RMS (see RAR, Volume 3, B.9. (AS)). However, this metabolite is not an environmentally relevant metabolite and will not be considered in the risk assessment for aquatic organisms.

In aquatic systems the active substance Fenoxaprop-P-ethyl hydrolises to the metabolite Fenoxaprop-P-acid which depends on the pH of the system. The hydrolysis (DT_{50}) of Fenoxaprop-P-ethyl is between 0.6 and 0.9 days at pH 9 and between 2.1 and 4.3 days at pH 4. At a neutral pH value, the DT_{50} is between 8.6 and 111 days.
The applicant submitted several studies under static and semi-static conditions. However, due to the rapid hydrolyses no reliable endpoints could be derived as no appropriate exposure to the test organisms could be shown. The measured concentrations were below the LOQ or LOD at the first sampling point or at the end of the study. Furthermore, the main metabolite Fenoxaprop-P-acid was not analytically verified in all studies.

The applicant proposed the use of nominal or mean measured endpoints for the tier 1 risk assessment. The RMS does not agree on this approach based on the recommendations given in the EFSA GD (2013) and the EFSA Technical Report (2015)[2].
According to the EFSA Technical Report (2015) "*the validity of a study is questionable when the test concentrations were not maintained and significant residues were not present at the end of the exposure period (or at the end of the renewal period for semi-static design)*".

A summary of toxicity endpoints for the active substance and the representative formulation are given in the tables below. For the sake of completeness, all endpoints are included in the table, irrespective if a reliable endpoint could be determined or not. Endpoints derived from studies for which no appropriate exposure could be shown are expressed in terms of nominal concentrations.

[1] EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2013. Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters. EFSA Journal 2013;11(7):3290, 186 pp. doi:10.2903/j.efsa.2013.3290.

[2] EFSA, 2015. Outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology. EFSA Supporting publication 2015:EN-924

Table B. 9.4-1: Endpoints: Toxicity of Fenoxaprop-P-ethyl to aquatic organisms

Test organism	Test condition	Time	Endpoint	Test conc.	NOEC [mg/L]	EC_{50}/LC_{50} [mg/L]	Reference
Fish							
Oncorhynchus mykiss Rainbow trout	Flow-through	96 h	Mortality	mm	0.16	0.39	[redacted] 1999a
Oncorhynchus mykiss Rainbow trout	Static	96 h	Mortality	n	0.24	0.46	[redacted] 1986a
Lepomis macrochirus Bluegill sunfish	Flow-through	96 h	Mortality	mm	0.088	0.19	[redacted] 1999b
Pimephales promelas Fathead minnow	Flow-through	96 h	Mortality	n	0.215	0.466	[redacted] 2011a
Oncorhynchus mykiss Rainbow trout	Flow-through	ELS (91 d)	Reproduction Growth	mm	**0.02832**	-	[redacted] 1999d
Pimephales promelas Fathead minnow	Flow-through	ELS (33 d)	Mortality Growth	n	0.043 0.0719	-	[redacted] 2011b
Aquatic invertebrates							
Daphnia magna Waterflea	Semi-static	48 h	Immobility	mm	0.8411	> 0.8411	Stachura, J.B. & Ruff, D.F., 1998
Mysidopsis bahia Mysid shrimp	Flow-through	96 h	Immobility	mm	n.d.	**0.109**	Murphy, D. & Peters, G. T., 1991
Mysidopsis bahia Mysid shrimp	Flow-through	28 d	Reproduction	mm	**0.011**	-	Boeri, R. L., Magazu, J. P., & Ward, T. J., 1999
Sediment dwelling organisms							
Chironomus riparius Midge	Static	26 d	Emergence Development	n	0.2	-	Memmert, U., 2000
Algae							
Raphidocelis subcapitata Green algae	Static	72 h	Growth rate Yield	n	0.33	> 0.71	Meister-Werner, A. & Wydra, V., 2009*
Skeletonema costatum Saltwater diatom	Static	72 h	Growth rate Biomass Yield	n	0.19	12 1.6 1.5	Seyfried, B., 2008*
		96 h	Growth rate Biomass Yield	n	0.19	41 2.2 3.3	
Navicula pelliculosa Diatom	Static	72 h	Growth rate Yield	mm	0.049	> 0.811 > 0.811	Meister-Werner, A. & Wydra, V., 2008
Anabaena flos-aquae Blue-green algae	Static Limit Test	72 h	Growth rate Biomass	mm	0.94	> 0.94	Pawlowski, S. & Wydra, V., 2005
Anabaena flos-aquae Blue-green algae	Static	72 h	Growth rate	mm	0.518	> 0.518	Banman, C.S., Howerton, J.H. & Lam, C.V., 2011a
		96 h	Growth rate	mm	0.518	> 0.518	
Aquatic macrophytes							
Lemna gibba	Semi-static	14 d	Growth rate	n	3.0	> 3.0	Christ, M.T. &

Test organism	Test condition	Time	Endpoint	Test conc.	NOEC [mg/L]	EC_{50}/LC_{50} [mg/L]	Reference
Duckweed			(frond number)				Ruff, D.F., 1997*
Lemna gibba Duckweed	Semi-static Limit test	7 d	Growth rate (frond number) Biomass (dry weight)	mm	0.80	>0.80	Pawlowski, S., 2005*
Myriophyllum spicatum Water milfoil	Semi-static Limit test	14 d	Growth rate Yield	mm	0.0336	> 0.0336	Banman, C.S., Alexander, T.M. & Moore, S., 2013

n…nominal, mm…mean measured, im…initially measured
n.d…. not determined
* Studies are considered valid; however, no reliable endpoint could be determined taken into account the results of the analytical measurements

Table B. 9.4-2: Endpoints: Toxicity of metabolites to aquatic organisms

Test substance	Test organism	Test condition	Time	Endpoint	Test conc.	NOEC [mg/L]	EC_{50}/LC_{50} [mg/L]	Reference
Fish								
Fenoxaprop-P acid AE F088406	*Oncorhynchus mykiss* Rainbow trout	Static	96 h	Mortality	mm	68.82	**> 68.82**	[redacted] 1996
Chlorobenzoxazolone AE F054014	*Oncorhynchus mykiss* Rainbow trout	Semi-static	96 h	Mortality	n	10	**> 10**	[redacted] 1999c
HOPP-acid AE F0962918	*Oncorhynchus mykiss* Rainbow trout	Semi-static	96 h	Mortality	n	250	**353**	[redacted] 2004b
Phenol AE F040356	*Oncorhynchus mykiss* Rainbow trout	Semi-static	96 h	Mortality	mm	0.248	**0.590**	[redacted] 2015
Fenoxaprop-P-ethyl-dechloro-hydroxy BCS-CY11271	*Oncorhynchus mykiss* Rainbow trout	Semi-static	96 h	Mortality	mm	0.307	**0.734**	[redacted] 2015a
Chlorobenzoxazolone AE F054014	QSAR	-	-	Reproduction	-	**0.02832**[a]		Vrbka, S., & Christl, H., 2016
Phenol AE F040356	QSAR	-	-	Reproduction	-	**0.02832**[a]		Vrbka, S., & Christl, H., 2016
Aquatic invertebrates								
Fenoxaprop-P acid AE F088406	*Daphnia magna* Waterflea	Static	48 h	Immobility	n	56	**126**	Heusel, R., 1993a
Chlorobenzoxazolone AE F054014	*Daphnia magna* Waterflea	Semi-static	48 h	Immobility	n	1.3	**6.6**	Young, B.M. & Ruff, D.F., 1999a

Test substance	Test organism	Test condition	Time	Endpoint	Test conc.	NOEC [mg/L]	EC_{50}/LC_{50} [mg/L]	Reference
HOPP-acid AE F0962918	*Daphnia magna* Waterflea	Static	48 h	Immobility	n	n.d.	> 200	Schäfers, C., 2004c
HOPP-acid AE F0962918	*Daphnia magna* Waterflea	Static	48 h	Immobility	n	25	**86.8**	Pupp, A. & Wydra, V., 2008
Phenol AE F040356	*Daphnia magna* Waterflea	Static	48 h	Immobility	mm	0.848	**1.75**	Börschig, C. & Emnet, P., 2015b
Fenoxaprop-P-ethyl-dechloro-hydroxy BCS-CY11271	*Daphnia magna* Waterflea	Static	48 h	Immobility	mm	9.98	**> 9.98**	Kuhl, R. & Emnet, P., 2016
Fenoxaprop-P acid AE F088406	*Daphnia magna* Waterflea	Semi-static	21 d	Reproduction Growth	n	1.0	**0.49** (EC_{10})	Ebeling, M., Nguyen, D. & Gosch, H., 2002
Chlorobenzoxazolone AE F054014	QSAR	-	-	Reproduction	-	**0.011**[a]	**-**	Vrbka, S., & Christl, H., 2016
HOPP-acid AE F0962918	*Daphnia magna* Waterflea	Semi-static	21 d	Reproduction Growth	n	3.2	**3.0** (EC_{10})	Schäfers, C., 2004d
Phenol AE F040356	QSAR	-	-	Reproduction	-	**0.011**[a]	**-**	Vrbka, S., & Christl, H., 2016
Algae								
Fenoxaprop-P acid AE F088406	*R. subcapitata* Green algae	Static	72 h	Growth rate Biomass Yield	mm	13.72	**69.9** 35.8 33.9	Heusel, R., 1993b
Chlorobenzoxazolone AE F054014	*R. subcapitata* Green algae	Static	72 h	Growth rate Yield	n	5.1	**8.78** 8.12	Börschig, C. & Emnet, P., 2016
HOPP-acid AE F0962918	*R. subcapitata* Green algae	Static [a]	72 h	Growth rate Biomass Yield	n	10.0 1.0 3.2	**53.4** 9.56 14.3	Wenzel, A., 2004
Phenol AE F040356	*R. subcapitata* Green algae	Static	72 h	Growth rate Yield	mm	0.828	**> 3.33** 3.04	Börschig, C., Emnet, P., 2015c
Fenoxaprop-P-ethyl-dechloro-hydroxy BCS-CY11271	*R. subcapitata* Green algae	Static	72 h	Growth rate Yield	mm	2.74	**> 8.73**	Kuhl, R., Emnet, P., 2015b
Aquatic macrophytes								
Fenoxaprop-P acid AE F088406	*Lemna gibba* Duckweed	Static	7 d	Growth rate Yield (frond number)	n	10 3.2	**> 100** 64.1	Hengsberger, A. & Emnet, P., 2015

Test substance	Test organism	Test condition	Time	Endpoint	Test conc.	NOEC [mg/L]	EC_{50}/LC_{50} [mg/L]	Reference
				Growth rate Yield (dry weight)		32 32	**> 100** > 100	
Phenol AE F040356	*Lemna gibba* Duckweed	Semi-static	7 d	Growth rate Yield (frond number)	mm	0.137 0.137	**> 2.70** > 2.70	Börschig, C. & Emnet, P., 2015d
				Growth rate Yield (dry weight)		1.21 1.21	**> 2.70** > 2.70	
Fenoxaprop-P-ethyl-dechloro-hydroxy BCS-CY11271	*Lemna gibba* Duckweed	Semi-static	7 d	Growth rate Yield (frond number)	mm	2.09 2.09	**> 29.4** 12.9	Kuhl, R., Emnet, P., 2015c
				Growth rate Yield (dry weight)		2.09 2.09	**> 29.4** 16.0	

n…nominal, mm…mean measured
n.d…. not determined
[a] Endpoint of the active substance supported by QSAR is used for the risk assessment

Table B. 9.4-3: Endpoints: Toxicity of CHA 4960 to aquatic organisms

Test organism	Test condition	Time	Endpoint	Test conc.	NOEC [mg a.s./L]	EC_{50}/LC_{50} [mg a.s./L]	Reference
Fish							
Oncorhynchus mykiss Rainbow trout	Semi-static	96 h	Mortality	mm	0.095	**0.17**	[redacted] 2005a
Aquatic invertebrates							
Daphnia magna Waterflea	Semi-static	48 h	Immobility	n	0.071	0.22	Grade, R. & Wydra, V., 2005
Daphnia magna Waterflea	Semi-static	21 d	Reproduction	mm	0.019	n.d.	Kley, A. & Wydra, V., 2010
Algae							
D. subspicatus Green algae	Static	72 h	Growth rate Biomass	mm	0.025 0.012	**0.12** 0.04	Pawlowski, S., Wydra, V., 2005b
Aquatic macrophytes							
Lemna gibba Duckweed	Semi-static	7 d	Growth rate Yield (frond number)	mm	0.026 0.026	0.359 0.166	Pawlowski, S. & Wydra, V., 2006
			Growth rate Yield (dry weight)		0.026 0.026	0.366 0.201	

n…nominal, mm…mean measured
n.d…. not determined

B.9.4.1. Acute risk

Acute risk to fish

Acute toxicity tests were submitted by the notifiers with the active substance Fenoxaprop-P-ethyl and its relevant metabolites Fenoxaprop-P-acid, Chlorobenzoxazolone, HOPP-acid, Phenol and Fenoxaprop-dechloro.

For Fenoxaprop-P-ethyl the most sensitive species was observed to be the bluegill sunfish with a 96 h LC_{50} of 0.19 mg a.s./L [redacted] 1999b). In addition a study with the rainbow trout exposed to the formulation CHA 4960 was submitted ([redacted] 2005a) resulting in a 96 h LC_{50} of 0.17 mg a.s./L resulting in a $RAC_{fish\ acute}$ of 1.7 µg a.s./L.

The risk assessment for fish was conducted based on the endpoint derived from the formulation with rainbow trout.

Table B. 9.4.1-1: Tier 1 risk assessment – PEC/RAC ratios, FOCUS PECsw Step 1 and Step 2 – winter cereals, 1 x 83 g a.s./ha

FOCUS		Fish, acute					
		Fenoxaprop-P-ethyl RAC = 1.7 µg a.s./L	Fenoxaprop-P-acid RAC = 688.2 µg/L	Chlorobenzoxazolone RAC = 100 µg/L	HOPP-acid RAC = 3530 µg/L	Phenol RAC = 5.9 µg/L	Fenoxaprop-P-ethyl-dechloro-hydroxy RAC = 7.34 µg/L
Step 1		**1.46**	0.06	0.025	0.004	0.53	0.65
Step 2	N-EU	0.45	0.012	0.071	0.000028	0.049	0.018
	S-EU	0.45	0.010	0.0057	0.000028	0.042	0.018

Bold: PEC_{SW}/RAC ratios > 1

Table B. 9.4.1-2: Tier 1 risk assessment – PEC/RAC ratios, Step 1 and Step 2 – spring cereals, 1 x 83 g a.s./ha

FOCUS		Fish, acute					
		Fenoxaprop-P-ethyl RAC = 1.7 µg a.s./L	Fenoxaprop-P-acid RAC = 688.2 µg/L	Chlorobenzoxazolone RAC = 100 µg/L	HOPP-acid RAC = 3530 µg/L	Phenol RAC = 5.9 µg/L	Fenoxaprop-P-ethyl-dechloro-hydroxy RAC = 7.34 µg/L
Step 1		**1.46**	0.06	0.025	0.004	0.53	0.65
Step 2	N-EU	0.45	0.0054	0.003	0.000028	0.027	0.018
	S-EU	0.45	0.010	0.0057	0.000028	0.042	0.018

Bold: PEC_{SW}/RAC ratios > 1

Under consideration of FOCUS Step 2 PECsw values an acceptable acute risk to fish was identified for Fenoxaprop-P-ethyl and the respective metabolites.

Acute risk to aquatic invertebrates

Acute toxicity tests were submitted by the notifiers with the active substance Fenoxaprop-P-ethyl and its relevant metabolites Fenoxaprop-P-acid, Chlorobenzoxazolone, HOPP-acid, Phenol and Fenoxaprop-dechloro.

The Tier 1 LC_{50} for aquatic invertebrates (*Mysidopsis bahia*) was determined to be 107.8 µg a.s./L, resulting in a $RAC_{invertebrate\ acute}$ of 1.078 µg a.s./L. In addition, the acute toxicity test with *Daphnia magna* resulted in 48 h EC_{50} of > 841.1 µg a.s./L.

Furthermore, a study with the representative formulation was submitted. The endpoint derived from the study with the water flea *Daphnia magna* was 220 µg a.s./L.

Table B. 9.4.1-3: Tier 1 risk assessment – PEC/RAC ratios, FOCUS PECsw Step 1 and Step 2 – winter cereals, 1 x 83 g a.s./ha

FOCUS		Aquatic invertebrates, acute					
		Fenoxaprop-P-ethyl RAC = 1.09 µg a.s./L	Fenoxaprop-P-acid RAC = 1260 µg/L	Chlorobenzoxazolone RAC = 66 µg/L	HOPP-acid RAC = 868 µg/L	Phenol RAC = 17.5 µg/L	Fenoxaprop-P-ethyl-dechloro-hydroxy RAC = 99.8 µg/L
Step 1		**2.27**	0.03	0.037	0.016	0.18	0.048
Step 2	N-EU	0.69	0.0068	0.011	0.00012	0.017	0.0013
	S-EU	0.69	0.006	0.0086	0.00012	0.014	0.0013

Bold: PEC_{SW}/RAC ratios > 1

Table B. 9.4.1-4: Tier 1 risk assessment – PEC/RAC ratios, FOCUS PECsw Step 1 and Step 2 – spring cereals, 1 x 83 g a.s./ha

FOCUS		Aquatic invertebrates, acute					
		Fenoxaprop-P-ethyl RAC = 1.09 µg a.s./L	Fenoxaprop-P-acid RAC = 1260 µg/L	Chlorobenzoxazolone RAC = 66 µg/L	HOPP-acid RAC = 868 µg/L	Phenol RAC = 17.5 µg/L	Fenoxaprop-P-ethyl-dechloro-hydroxy RAC = 99.8 µg/L
Step 1		**2.27**	0.03	0.037	0.016	0.18	0.048
Step 2	N-EU	0.69	0.0030	0.0045	0.00012	0.0091	0.0013
	S-EU	0.69	0.006	0.0086	0.00012	0.014	0.0013

Bold: PEC_{SW}/RAC ratios > 1

Based on a Tier 1 risk assessment considering FOCUS Step 1 and 2 PEC_{sw} values a low acute risk to aquatic invertebrates from exposure to the active substance Fenoxaprop-P-ethyl and the metabolites Fenoxaprop-P-acid, Chlorobenzoxazolone, HOPP-acid, Phenol and Fenoxaprop-dechloro was identified

B.9.4.2. Chronic risk

Chronic risk to fish

Two fish early life stage (ELS) studies conducted with the active substance were submitted, one for the first EU peer review and the second for the renewal of the active. The studies were conducted with the species *Oncorhynchus mykiss* and *Pimephales promelas* under flow-through conditions. The lowest endpoint derived from these studies was a 91 d NOEC of 0.02832 mg a.s./L based on mean measured concentrations resulting in a $RAC_{fish\ chronic}$ of 2.832 µg a.s./L.

QSAR predictions for the metabolite Phenol and Chlorobenzoxazolone are available for chronic effects on fish. In the risk assessment the same RAC value is used as for the parent considering that the experimentally derived endpoint is lower than the predicted QSAR values.

Table B. 9.4.2-1:Tier 1 risk assessment – PEC/RAC ratios, FOCUS PECsw Step 1 and Step 2 – winter cereals, 1 x 83 g a.s./ha

FOCUS		Fish, chronic		
		Fenoxaprop-P-ethyl RAC = 2.832 µg a.s./L	Chlorobenzoxazolone RAC = 2.832 µg/L	Phenol RAC = 2.832 µg/L
Step 1		0.88	0.87	**1.11**
Step 2	N-EU	0.27	0.25	0.10
	S-EU	0.27	0.20	0.088

Bold: PEC_{SW}/RAC ratios > 1

Table B. 9.4.2-2: Tier 1 risk assessment – PEC/RAC ratios, FOCUS PECsw Step 1 and Step 2 – spring cereals, 1 x 83 g a.s./ha

FOCUS		Fish, chronic		
		Fenoxaprop-P-ethyl RAC = 2.832µg a.s./L	Chlorobenzoxazolone RAC = 2.832 µg/L	Phenol RAC = 2.832 µg/L
Step 1		0.88	0.87	**1.11**
Step 2	N-EU	0.27	0.11	0.056
	S-EU	0.27	0.20	0.088

Bold: PEC_{SW}/RAC ratios > 1

Based on a Tier 1 risk assessment considering FOCUS Step 1 and 2 PEC_{sw} values a low chronic risk to fish from exposure to the active substance Fenoxaprop-P-ethyl and respective metabolites was identified.

Chronic risk to invertebrates

Two chronic studies conducted with the active substance were submitted for the first EU peer review. The studies were conducted with the species *Daphnia manga* and *Mysidopsis bahia* under semi-static and flow-through conditions. The study with *Daphnia magna* was not considered valid according to the recommendations of the currently valid test guideline. The lowest endpoint derived from the study with *Mysidopsis bahia* was a 28 d NOEC of 11 µg a.s./L based on mean measured concentrations resulting in a $RAC_{invertebrate\ chronic}$ of 1.1 µg a.s./L.

In addition studies with the metabolites Fenoxaprop-P-acid, and HOPP-acid were conducted addressing the risk to aquatic invertebrates. QSAR predictions for the metabolite Phenol and Chlorobenzoxazolone are available for chronic effects on daphnids. In the risk assessment the same RAC value is used as for the parent considering that the experimentally derived endpoint is lower than the predicted QSAR values.

Furthermore, a reproduction study with the representative formulation was submitted. The NOEC derived from the study with the water flea *Daphnia magna* was 19 µg a.s./L.

Table B. 9.4.2-3: Tier 1 risk assessment – PEC/RAC ratios, FOCUS PECsw Step 1 and Step 2 – winter cereals, 1 x 83 g a.s./ha

FOCUS		Aquatic invertebrates, chronic				
		Fenoxaprop-P-ethyl RAC = 1.1 µg a.s./L	Fenoxaprop-P-acid RAC = 49 µg/L	Chlorobenzoxazolone RAC = 1.1 µg/L	HOPP-acid RAC = 300 µg/L	Phenol RAC = 1.1 µg/L
Step 1		**2.25**	0.81	**2.23**	0.047	**2.85**
Step 2	N-EU	0.69	0.017	0.65	0.00033	0.26
	S-EU	0.69	0.014	0.52	0.00033	0.23

Bold: PEC_{SW}/RAC ratios > 1

Table B. 9.4.2-4: Tier 1 risk assessment – PEC/RAC ratios, FOCUS PECsw Step 1 and Step 2 – spring cereals, 1 x 83 g a.s./ha

FOCUS			Aquatic invertebrates, chronic			
		Fenoxaprop-P-ethyl RAC = 1.1 µg a.s./L	Fenoxaprop-P-acid RAC = 49 µg/L	Chlorobenzoxazolone RAC = 1.1 µg/L	HOPP-acid RAC = 300 µg/L	Phenol RAC = 1.1 µg/L
Step 1		**2.25**	0.81	**2.23**	0.047	**2.85**
Step 2	N-EU	0.69	0.076	0.27	0.00033	0.15
	S-EU	0.69	0.14	0.52	0.00033	0.23

Bold: PEC_{SW}/RAC ratios > 1

Based on a Tier 1 risk assessment considering FOCUS Step 1 and 2 PEC_{sw} values a low chronic risk to aquatic invertebrates from exposure to the active substance Fenoxaprop-P-ethyl and respective metabolites was identified.

Chronic risk to sediment dwelling organisms

One study on effects on chironomids (*Chironomus riparius*) was submitted by the notifiers addressing the risk to sediment dwelling organisms. A NOEC of 0.2 mg a.s./L based on nominal concentrations in the overlaying water was determined resulting in a RAC of 20 µg a.s./L.

Table B. 9.4.2-5: Tier 1 risk assessment – PEC/RAC ratios, FOCUS PEC_{SW} Step 1 and Step 2

FOCUS		Sediment dwelling organisms, chronic, RAC = 20 µg a.s./L (Tier 1)	
		Winter cereals, 1 x 83 g a.s./ha	Spring cereals, 1 x 83 g a.s./ha
Step 1		0.124	0.124
Step 2	N-EU	0.038	0.038
	S-EU	0.038	0.038

Bold: PEC_{SW}/RAC ratios > 1

The risk to sediment dwelling organisms is considered acceptable based on FOCUS Step 1 PECsw values.

Risk to algae

Several studies with algae were submitted for the risk assessment. Most of the studies submitted for the first EU approval of Fenxoaprop-P-ethyl were identified to be not valid considering deficiencies observed in the studies.

Toxicity tests were submitted by the notifiers with the active substance Fenoxaprop-P-ethyl and its relevant metabolites Fenoxaprop-P-acid, Chlorobenzoxazolone, HOPP-acid, Phenol and Fenoxaprop-dechloro.
The lowest endpoint for the active substance was determined for the species *Anabaena-flos-aquae* with an E_rC_{50} of > 518 µg a.s./L.

In addition, a study with the representative formulation was submitted. The endpoints derived from the study with the green algae *Desmodesmus subspicatus* indicate a higher toxicity than observed in the studies with the active substance. The E_rR_{50} for algae was 120 µg a.s./L, resulting in a RAC_{algae} of 12 µg a.s./L.
It is noted that *D. subspicatus* was tested with the product whereas the lowest endpoint for the active stubance was derived with *Anabaena-flos-aquae*. However, no algae study with *D. subspicatus* was provided for the active substance. The risk assessment is based on the lowest endpoint derived from the study with the representative formulation.

Table B. 9.4.2-6: Tier 1 risk assessment – PEC/RAC ratios, FOCUS PECsw Step 1 and Step 2 – winter cereals, 1 x 83 g a.s./ha

FOCUS		Algae					
		Fenoxaprop-P-ethyl RAC = 12 µg a.s./L	Fenoxaprop-P-acid RAC = 6990 µg/L	Chlorobenzoxazolone RAC = 878 µg/L	HOPP-acid RAC = 5340 µg/L	Phenol RAC = 333 µg/L	Fenoxaprop-P-ethyl-dechloro-hydroxy RAC = 873 µg/L
Step 1		0.21	0.0057	0.0028	0.0026	0.0094	0.0055
Step 2	N-EU	0.063	0.0012	0.00081	0.000019	0.00087	0.00015
	S-EU	0.063	0.001	0.00065	0.000019	0.00075	0.00015

Bold: PEC_{SW}/RAC ratios > 1

Table B. 9.4.2-7: Tier 1 risk assessment – PEC/RAC ratios, FOCUS PECsw Step 1 and Step 2 – spring cereals, 1 x 83 g a.s./ha

FOCUS	Algae

		Fenoxaprop-P-ethyl RAC = 12 µg a.s./L	Fenoxaprop-P-acid RAC = 6990 µg/L	Chlorobenzoxazolone RAC = 878 µg/L	HOPP-acid RAC = 5340 µg/L	Phenol RAC = 333 µg/L	Fenoxaprop-P-ethyl-dechloro-hydroxy RAC = 873 µg/L
Step 1		0.21	0.0057	0.0028	0.0026	0.0094	0.0055
Step 2	N-EU	0.063	0.00053	0.00034	0.000019	0.00048	0.00015
	S-EU	0.063	0.00099	0.00065	0.000019	0.00075	0.00015

Bold: PEC_{SW}/RAC ratios > 1

Based on a Tier 1 risk assessment considering FOCUS Step 1 and 2 PEC_{sw} values a low risk to algae from exposure to the active substance Fenoxaprop-P-ethyl and respective metabolites was identified.

Risk aquatic macrophytes

Studies with the aquatic macrophytes *Lemna gibba* and *Myriophyllum spicatum* were submitted to address the risk to aquatic macrophytes. Based on the results of the studies with the technical active substance the water milfoil *Myriophyllum spicatum* was observed to be the most sensitive species with an E_rC_{50} of 33.6 µg a.s./L resulting in a $RAC_{macrophyte}$ of 3.36 µg a.s./L.

In addition a study with the representative formulation was submitted. The E_rC_{50} derived from the study with the aquatic macrophyte *Lemna gibba* was 359 µg a.s./L.

No studies with the metabolites Chlorobezoxazolone and HOPP-acid was submitted by the notifiers. Hence, the risk assessment for the metabolites is based on a ten times higher toxicity of the metabolites compared to the parent compound.

Table B. 9.4.2-8: Tier 1 risk assessment – PEC/RAC ratios, FOCUS PECsw Step 1 and Step 2 – winter cereals, 1 x 83 g a.s./ha

FOCUS		Aquatic macrophytes					
		Fenoxaprop-P-ethyl RAC = 3.36 µg a.s./L	Fenoxaprop-P-acid RAC = 10000 µg/L	Chlorobenzoxazolone RAC = 0.336 µg/L	HOPP-acid RAC = 0.336 µg/L	Phenol RAC = 270 µg/L	Fenoxaprop-P-ethyl-dechloro-hydroxy RAC = 2940 µg/L
Step 1		0.74	0.0040	**7.29**	**41.96**	0.012	0.0016
Step 2	N-EU	0.23	0.00085	**2.11**	0.30	0.0011	0.000044
	S-EU	0.23	0.00069	**1.70**	0.30	0.0009	0.000044

Bold: PEC_{SW}/RAC ratios > 1

Table B. 9.4.2-9: Tier 1 risk assessment – PEC/RAC ratios, FOCUS PECsw Step 1 and Step 2 – spring cereals, 1 x 83 g a.s./ha

FOCUS		Aquatic macrophytes					
		Fenoxaprop-P-ethyl RAC = 3.36 µg a.s./L	Fenoxaprop-P-acid RAC = 10000 µg/L	Chlorobenzoxazolone RAC = 0.336 µg/L	HOPP-acid RAC = 0.336 µg/L	Phenol RAC = 270 µg/L	Fenoxaprop-P-ethyl-dechloro-hydroxy RAC = 2940 µg/L
Step 1		0.74	0.0040	**7.29**	**41.96**	0.012	0.0016
Step 2	N-EU	0.23	0.00037	0.89	0.30	0.00059	0.000044
	S-EU	0.23	0.00069	**1.70**	0.30	0.00093	0.000044

Bold: PEC_{SW}/RAC ratios > 1

Based on the risk assessment a low risk to aquatic plants was identified for Fenoxaprop-P-ethyl and respective metabolites except for Chlorobenzoxazolone and HOPP-acid. However, the risk is considered acceptable as a 10 times higher toxicity was assumed for the metabolites.

B.9.4.3. Bioaccumulation

As the log P_{OW} of the active substance Fenoxaprop-P-ethyl is 4.58, the accumulation and elimination of Fenoxaprop-P-ethyl has been determined in a fish bioaccumulation study ([redacted] 1999).

The kinetic bioconcentration factor (BCF_K) of Fenoxaprop-P-ethyl was determined to be 343 in whole fish. The steady state bioconcentration factor for edible, non-edible tissues and whole fish was 36, 619 and 338, respectively. Depuration was very rapid with a calculated elimination half-life of < 1 day.

According to the EFSA Aquatic Guidance Document (EFSA, 2013) a risk assessment addressing biomagnification is not considered necessary as the BCF is below the trigger of 1000 and the elimination of during the 14-day depuration phase is > 95%.

B.9.5. EFFECTS ON ARTHROPODS

B.9.5.1. Effects on bees

Regarding the toxicity data on the technical Fenxoaprop-P-ethyl please refer to Volume 3, B.9. (AS).
In addition studies with the representative formulation Fenoxaprop-P-ethyl 69 g/L EW (CHA 4960) were submitted by the notifier Cheminova.

B.9.5.1.1. Acute toxicity to bees

Reference:	**Acute contact and oral toxicity of Fenoxaprop-P-ethyl 69 g/L EW to honey bees (*Apis mellifera* L.)**
Author(s), year:	Schmidt T., 2005
Report/Doc. number:	Report No. A22948, Reference No. 120 FPE
Guideline(s):	EPPO Guideline 170 (1992), OECD 213 & 214 (1998)
GLP:	Yes
Deviations:	None relevant
Validity:	Acceptable

Material and Methods:	
Test substance:	CHA 4960, Fenoxaprop-P-ethyl 69 g/L EW (Fenoxaprop-P-ethyl 7.11 % w/w, Cloquintocet mexyl 3.41 % w/w), Batch no. 660-PSH-49, Density: 1.03 g/mL
Reference:	Roxion EC (Dimethoate 400 g/L), Batch no. D 077 A Density: 1.09 g/mL
Solvent:	None (oral test), 1 % Etalfix (contact test)
Test species:	*Apis mellifera* L., adult worker honeybees
Type of test:	Acute oral and contact test
Number of organisms:	Each treatment consisted of 3 replicates with 10 bees per replicate. Therefore, a total of 30 bees per test item treatment, reference item treatment and control were set up.
Food:	50% sucrose solution
Oral toxicity test:	
Applied concentrations:	Control: 50% (w/w) aqueous sucrose solution Test item: 91, 181, 363, 725 and 1450 µg a.s./bee Reference item: 0.09.273 and 0.954 µg a.s./bee
Exposure route:	The test item was dissolved in sucrose solution was added and offered to the bees. The test bees were starved for 1 hour before they were fed with the solutions. 0.2 mL of the test solution was fed to groups of 10 bees via a small vial.
Contact toxicity test:	
Applied concentrations:	Control: emulsified in deinised water with 1 % wetting agent Test item: 64.4, 128.8, 257.5, 746.2 and 1030 µg a.s./bee

Reference item: 0.09.273 and 0.818 µg a.s./bee

Exposure route: The undiluted formulation Fenoxaprop-P-ethyl 69 g/L EW was used as highest test dose. Prior to the initiation of the contact test, 2 mL of the formulation was intensively stirred for one minute. One µL of the undiluted formulation corresponds to 1.030 µg Fenxoaprop-P-ethyl 69 g/L EW (regarding a density of 1.03 g/mL). This highest test dose was diluted further with deinoised water to obtain the application solutions for the lower doses.

A droplet with the volume of 1 µL of the application solution was placed on the dorsal side of the bee thorax using a calibrated micro-pipette. Bees were anaesthetised with carbon dioxide before treatment.

Test conditions: Oral: Temperature 24.5 – 24.9°C, Humidity 52-67%

Contact: Temperature 24.4 – 25.1°C, Humidity 57-69%

Test parameter: The mortality of honey-bees was recorded at 4, 24 and 48 h in the oral test and at 4, 24, 48 and 72 h in the contact test.

Analytical measurements: None

Findings:

Biological results: In the oral test, at the 48 hour assessment, the mortality in the test material treatments showed a dose-response relationship, increasing from 0% at the lowest dose of 91 µg/bee to 97% at the ingested dose of 575 µg/bee. At the highest ingested dose (866 µg/bee) mortality decreased to 53%. This highest ingested dose was excluded from the statistical analysis due to the low homogeneity of variance. In the oral test, validity criteria were met as mortality in the control did not exceed 10% at the 48 hour timepoint and, for the reference material, the oral LD_{50} at the 24-hour timepoint was 0.104 µg dimethoate/bee, within the required range of 0.10 – 0.35 µg a.s./bee.

The contact test assessment period was extended to 72-hours as mortality values increased by more than 10% between the 24 and 48-hour timepoints in four out of five treatments. At the 72- hour assessment the mortality in the test treatments ranged between 22-30% at the three lower doses and increased to 52% and 67% at the highest two doses, 746 µg/bee and 1030 µg/bee, respectively. Performance criteria were met as mortality in the control did not exceed 10% at the 48 hour timepoint and, for the reference material, the contact LD_{50} at the 24-hour timepoint was 0.182 µg dimethoate/bee, within the required range of 0.10 – 0.35 µg a.s./bee.

Lethal and sublethal effects for oraland contact toxicity are shown in the following tables:

Table B. 9.5.1.1-1: Healthy, affected, moribund and dead bees in oral toxicity test

Treatment	Repl.	Number of bees	Corrected*

(ingested µg CHA 4960/bee)		healthy	affected	moribund	dead	mortality
4 hours after application						
	1	10	0	0	0	
control	2	10	0	0	0	
	3	10	0	0	0	0.0
91	1	10	0	0	0	
	2	10	0	0	0	
	3	10	0	0	0	0.0
181	1	8	0	0	2	
	2	6	3	0	1	
	3	9	0	0	1	13.3
330	1	8	0	0	2	
	2	4	3	0	3	
	3	7	3	0	0	16.7
575	1	2	3	0	5	
	2	1	8	0	1	
	3	4	4	0	2	26.7
866	1	9	1	0	0	
	2	1	6	0	3	
	3	3	4	0	3	20.0
	1	10	0	0	0	
0.081	2	10	0	0	0	
	3	10	0	0	0	0.0
	1	10	0	0	0	
0.273	2	10	0	0	0	
	3	10	0	0	0	0.0
	1	8	0	0	2	
0.848	2	7	0	0	3	
	3	0	0	0	10	50.0
24 hours after application						
	1	9	0	0	1	
control	2	10	0	0	0	
	3	10	0	0	0	0.0
91	1	10	0	0	0	
	2	10	0	0	0	
	3	10	0	0	0	-3.4
181	1	5	0	0	5	
	2	6	0	0	4	
	3	8	0	0	2	34.5
330	1	6	0	0	4	
	2	4	0	0	6	
	3	6	0	0	4	44.8
575	1	0	0	0	10	
	2	0	1	0	9	
	3	0	0	0	10	96.6
866	1	9	1	0	0	
	2	0	2	0	8	
	3	5	0	0	5	41.4
	1	10	0	0	0	
0.081	2	10	0	0	0	
	3	10	0	0	0	-3.4
	1	4	0	0	6	
0.273	2	7	0	0	3	
	3	5	0	0	5	44.8
	1	0	0	0	10	
0.848	2	0	0	0	10	
	3	0	0	0	10	100.0

48 hours after application						
control	1	9	0	0	1	
	2	9	0	0	1	
	3	9	0	0	1	0.0
91	1	10	0	0	0	
	2	10	0	0	0	
	3	10	0	0	0	-11.1
181	1	5	0	0	5	
	2	6	0	0	4	
	3	8	0	0	2	29.6
330	1	6	0	0	4	
	2	4	0	0	6	
	3	6	0	0	4	40.7
575	1	0	0	0	10	
	2	1	0	0	9	
	3	0	0	0	10	96.3
866	1	9	0	0	1	
	2	0	0	0	10	
	3	4	1	0	5	48.1

* Mortality corrected after ABBOTT

Table B. 9.5.1.1-2: Healthy, affected, moribund and dead bees in contact toxicity test

Treatment (ingested µg CHA 4960/bee)	Repl.	Number of bees				Corrected* mortality
		healthy	affected	moribund	dead	
4 hours after application						
Control	1	10	0	0	0	
	2	10	0	0	0	
	3	10	0	0	0	0.0
64.4	1	10	0	0	0	
	2	10	0	0	0	
	3	10	0	0	0	0.0
128.8	1	10	0	0	0	
	2	10	0	0	0	
	3	10	0	0	0	0.0
257.5	1	10	0	0	0	
	2	10	0	0	0	
	3	10	0	0	0	0.0
746.2	1	1	9	0	0	
	2	5	5	0	0	
	3	9	6	0	0	0.0
1030	1	3	7	0	0	
	2	5	3	0	2	
	3	1	9	0	0	6.7
0.090	1	10	0	0	0	
	2	10	0	0	0	
	3	10	0	0	0	0.0
0.273	1	10	0	0	0	
	2	10	0	0	0	
	3	10	0	0	0	0.0
0.818	1	5	3	0	2	
	2	8	0	0	2	
	3	5	5	0	0	13.3
24 hours after application						
Control	1	10	0	0	0	
	2	10	0	0	0	
	3	10	0	0	0	0.0
64.4	1	9	1	0	0	

Treatment (ingested µg CHA 4960/bee)	Repl.	Number of bees				Corrected* mortality
		healthy	affected	moribund	dead	
	2	9	1	0	0	
	3	9	1	0	0	0.0
128.8	1	9	1	0	0	
	2	9	1	0	0	
	3	9	0	0	1	3.3
257.5	1	9	1	0	0	
	2	10	0	0	0	
	3	9	0	0	1	3.3
746.2	1	9	0	0	1	
	2	0	0	0	10	
	3	9	0	0	2	43.3
1030	1	7	1	0	2	
	2	4	1	0	5	
	3	5	3	0	2	30.0
	1	10	0	0	0	
0.090	2	9	0	0	1	
	3	9	0	0	1	6.7
	1	10	0	0	0	
0.273	2	10	0	0	0	
	3	10	0	0	0	0.0
	1	1	0	0	9	
0.818	2	2	0	0	8	
	3	1	0	0	9	86.7
48 hours after application						
	1	9	0	0	1	
Control	2	9	0	0	1	
	3	9	0	0	1	0.0
64.4	1	8	0	0	2	
	2	7	0	0	3	
	3	7	0	0	3	18.5
128.8	1	5	0	0	5	
	2	8	0	0	2	
	3	9	0	0	1	18.5
257.5	1	8	0	0	1	
	2	8	0	0	2	
	3	6	0	0	4	14.8
746.2	1	7	0	0	3	
	2	0	0	0	10	
	3	9	0	0	4	51.9
1030	1	5	0	0	5	
	2	2	0	0	8	
	3	2	0	0	8	66.7
72 hours after application						
	1	9	0	0	1	
Control	2	9	0	0	1	
	3	9	0	0	1	0.0
64.4	1	7	0	0	3	
	2	6	0	0	4	
	3	6	0	0	4	29.6
128.8	1	4	0	0	6	
	2	7	0	0	3	
	3	8	0	0	2	29.6
257.5	1	8	0	0	2	
	2	8	0	0	2	
	3	5	0	0	5	22.2

Treatment (ingested µg CHA 4960/bee)	Repl.	Number of bees				Corrected* mortality
		healthy	affected	moribund	dead	
746.2	1	7	0	0	3	
	2	0	0	0	10	
	3	9	0	0	4	51.9
1030	1	5	0	0	5	
	2	2	0	0	8	
	3	2	0	0	8	66.7

* Mortality corrected after ABBOTT

Conclusion: The oral median lethal dose (48-hour LD_{50}) in the honeybee, *Apis mellifera* is 356.1 µg/bee, equivalent to 23.9 µg a.s./bee. The contact median lethal dose (72-hour LD_{50}) in the honeybee is 598.6 µg/bee, equivalent to 40.1 µg a.s./bee.

Comment RMS:

Validity: The study was evaluated following the recommendations of the currently valid test guideline OECD 213 (acute oral) and OECD 214 (acute contact).

The validity criteria according to the OECD test guideline are the following:

- The average mortality for the total number of controls must not exceed 10% at the end of the test. The control mortality was between 0% and 10% for the acute and the oral test.
- The LD_{50} of the toxic standard (dimethoate) must be in the range between 0.1 and 0.3 µg a.s./bee. The LD50 of dimethoate was 0.280 (oral test) and 0.182 (contact test).

All validity criteria according to the OECD test guideline are met taking into account the contact and oral toxicity tests.

Acceptability of the analytical methods used in the test: Not necessary.

Endpoints: The RMS agrees on the endpoints given in the study report.

48 h LD_{50} (oral) = 356.1 µg prod./bee, equivalent to 23.9 µg a.s./bee

72 h LD_{50} (contact) = 598.6 µg prod./bee, equivalent to 40.1 µg a.s./bee

Conclusion of the RMS: Based on the evaluation of the study, the acute oral and contact toxicity test is considered valid.

B.9.5.1.2. Chronic toxicity to bees

According to the data requirements for active substances (Commission Regulation (EU) 283/2013) and/or plant protection products (Commission Regulation (EU) 284/2013) the chronic risk to adult honeybees has to be evaluated.

Reference:	**Fenoxaprop-P-ethyl EW 69: Chronic oral toxicity test on the honey bee (*Apis mellifera* L.) in the laboratory**
Author(s), year:	Theis, M., 2017
Report/Doc. number:	E31804950-0 / M-577004-01-1
Guideline(s):	No agreed ring-tested guideline available - Proposal for a New Guideline for the Testing of Chemicals. Honey Bee (*Apis mellifera* L.), Chronic Oral Toxicity Test. 10 Day Feeding Test in the Laboratory, OECD Publishing, Paris, February 2016.
GLP:	Yes
Deviations:	None
Validity:	Acceptable

Material and Methods:

Test substance:	Test Item: Fenoxaprop-P-ethyl EW 69 (69 g/L): Fenoxaprop-P-ethyl (AE F046360): 6.78 % w/w, 69.97 g/L, Batch ID: 2015-000235, density: 1.032 g/mL
Reference:	Dimethoate 400 EC, 37.9% w/w, 407.8 g/L (analytical), density: 1.032 g/cm^3
Solvent:	none
Test species:	Honey bees (*Apis mellifera* L.); young adult female worker bees (at test start 2 days old)
Type of test:	Chronic 10 days continuous feeding test
Number of organisms:	Three replicates with 10 bees for control, reference item and the test item treatment groups
Applied concentrations:	Control: 50% (w/v) aqueous sucrose solution Test item: 60, 30, 15, 7.5 and 3.75 µg a.s./bee/day (nominal) 27.45, 18.77, 11.22, 7.15 and 3.95 µg a.s./bee/day (actual) Toxic reference: One concentration with 0.85 mg a.s. dimethoate/kg feeding solution was used
Exposure route:	Over a period of 10 days, honeybees were exposed to 50 % (w/v) aqueous sucrose application (feeding) solution, containing concentrations of the test item by continuous and ad libitum feeding. The syringes were weighed daily before introduction into the cages and after the feeding interval (before replacement with fresh food).
Test conditions:	Temperature: 31.6 – 33.1 °C, mean: 33.0 °C; relative humidity: 30.2 – 63.3 %, mean relative humidity: 61.2 %; photoperiod: 24 h darkness.
Test parameter:	Mortality: Number of dead bees was assessed daily (at the same time of the day)

until test end, ten days following start of exposure.

Behavioural Abnormalities: Behavioural abnormalities were assessed daily until test end (day 1 to day 10). Sub-lethal effects such as symptoms of poisoning or any abnormal behaviour in comparison to the control were recorded according to the following categories:

m = moribund (bees cannot walk and show only very feeble movements of legs and antennae, only weak response to stimulation, *e.g.* light or blowing; bees may recover but usually die), **a** = affected (bees still upright and attempting to walk but showing signs of reduced coordination),

c = cramps (bees contracting abdomen or entire body),

ap = apathy (bees show only low or delayed reactions to stimulation e.g. light or puff of air; bees are sitting motionless in the unit).

v = vomiting

Food consumption: The food consumption per bee was calculated by dividing the amount of food consumed by the number of bees at the start of the respective feeding interval.

Evaporation: In order to adjust for possible evaporation of test solutions from the feeders, 3 similar replicate cages were set up. These cages contained no bees, only pre-weighed feeders containing diet of untreated control. These were placed in the test environment alongside the test units. At the daily feeder exchange the feeders were re-weighed and replaced with new feeders. The mean evaporation figure was then being subtracted from the calculated uptake to give the real uptake accounting the loss by evaporation.

Statistics: The $LC_{10, 20, 50}$, $LDD_{10, 20, 50}$ values of the test item were estimated with Probit Analysis (according to Finney 1971).

The NOEC/NOEDD of the test item was estimated using Step-down Cochran-Armitage Test Procedure was evaluated based on α=0.05 one-sided greater, which is a distribution-free test and does not require testing for normality or homogeneity prior to analysis.

The software used to perform the statistical analysis was ToxRat Pro, Version 3.2.1, ® ToxRat Solutions GmbH.

Findings:

Analytical results: The actual concentrations of Fenoxaprop-P-ethyl EW 69 (69g/L) in the feeding solutions were analysed in the analytical phase (31804950-0-P1), which is attached to the final report. The actual concentrations of the feeding solutions were in a range of 99 % - 113 %.

Biological results: The test item was daily administered to the bees in a sugar solution at the following concentrations: 2000, 1000, 500, 250 and 125 mg a.s./kg sugar solution. These concentrations led to an actual consumed daily mean dose of 27.45, 18.77,

11.22, 7.15 and 3.95 µg a.s./bee/day after 10 days.

At test end, 10 days following start of exposure, 0 % mortality occurred in the untreated water control (50 % w/v sucrose solution). At 2000, 1000, 500 and 250 mg a.s./kg (corresponding to 27.45, 18.77, 11.22 and 7.15 µg a.s./bee/day) statistically significant effects on mortality occurred (Step-down Cochran-Armitage Test Procedure, α = 0.05, one sided greater).

At 125 mg a.s./kg sugar solution (corresponding to 3.95 µg a.s./bee/day) the mortality was 0% and was not statistically significantly different compared to the control (Step-down Cochran-Armitage Test Procedure, α = 0.05, one sided greater).

Table B. 9.5.1.2-1: 10-Day Chronic Feeding of Fenoxaprop-P-ethyl EW 69 (69g/L) to young honey bees; laboratory test

Test item		*Apis mellifera carnica*	
Treatment Group	Concentration [mg a.s. /kg]	Dose Level [1] [µg a.s./bee/day]	Mortality at day 10 [2,] [% Mean]
Fenoxaprop-P-ethyl EW 69 (69g/L)	2000	27.45	100 (*)
Fenoxaprop-P-ethyl EW 69 (69g/L)	1000	18.77	100 (*)
Fenoxaprop-P-ethyl EW 69 (69g/L)	500	11.22	53.3 (*)
Fenoxaprop-P-ethyl EW 69 (69g/L)	250	7.15	20 (*)
Fenoxaprop-P-ethyl EW 69 (69g/L)	125	3.95	0
Water control	0.00	0.00	0
Reference Item	0.85	0.01	100 (*)
Endpoint at test termination (day 10)			
LC_{10}	**227.91 mg a.s./kg**		
LC_{20}	**281.07 mg a.s./kg**		
LC_{50}	**419.74 mg a.s./kg**		
LDD_{10}	**6.63 µg a.s./bee/day**		
LDD_{20}	**7.65 µg a.s./bee/day**		
LDD_{50}	**10.06 µg a.s./bee/day**		
NOEC	**125.00 mg a.s./kg**		
NOEDD	**3.95 µg a.s./bee/day**		

[1]mean dose per bee per day; dose measured based on consumed feeding solution
[2]Mortality at study termination 10 days after start of first feeding
Statistics: LC_x/LDD_x: Probit analysis using maximum linear likelihood
NOEC/NOEDD: was estimated using Step-down Cochran-Armitage Test Procedure,
* = statistically significant difference compared to the control

Validity criteria: All validity criteria for the study were met.

Validity	**Recommended**	**Obtained**
Control	≤ 15%	0%

LD_{50} of	≥ 50%	100%

Reference item: The reference item (dimethoate) at a concentration of 0.85 mg a.s. dimethoate/kg sugar solution corresponding to actual 0.01 µg a.s./bee/day caused 100 % mortality at day 10.

Conclusion: The chronic oral toxicity of Fenoxaprop-P-ethyl EW 69 (69g/L) was tested over 10 days in an ad libitum feeding scenario. The LC_{50} value (10 days) was 419.74 mg a.s./kg feeding solution. The LDD_{50} value (10 days) was 10.06 µg a.s./bee/day. The NOEC was 125.00 mg a.s./kg feeding solution. The NOEDD value (10 days) was 3.95 µg a.s./bee/day.

Comment RMS:

Validity: No test guideline has been available to address the chronic risk to adult honeybees during the submission of the renewal for Fenoxaprop-P-ethyl.

Recently the OECD Guideline 245: Honey Bee (*Apis mellifera* L.), Chronic Oral Toxicity Test (10-Day feeding) has been published.

The following validity criteria are mentioned:

- The average mortality across replicates for the untreated control and solvent control group is ≤ 15 % at the end of the test (10 days following start of exposure); when a solvent control is included, the average mortality across replicates for the solvent control should also be ≤ 15%.
- The average mortality in the reference substance treated group is ≥ 50% at the end of the test (10 days following start of exposure).

In the actual test the control mortality was 0% and 100% in the reference substance group at day 10. The test is considered valid all validity have been met.

Acceptability of the analytical methods used in the test: Evaluation of the analytical methods (water/sediment/soil) according to the Guidance Document SANCO/3029/99 rev. 4. Based on the evaluation (see B.5 (AS), B.5.1.2.2) the analytical method is considered acceptable covering the LOQ (= 0.01 mg/kg) mentioned.

Endpoints:

The RMS agrees on the endpoints given in the study report.

LC_{50} = 419.74 mg a.s./kg

LDD_{50} = 10.06 µg a.s./bee/day

NOEC = 125.00 mg a.s./kg feeding solution

NOEDD = 3.95 µg a.s./bee/day

Conclusion of the RMS: The study is well in line with OECD Guideline 245 therefore considered as valid and appropriate for risk assessment purposes.

B.9.5.1.3. Effects on honeybee development and other honeybee life stages

A honeybee brood study with the solo formulation Fenoxaprop 69 g/L EW (CHA 4960) according to the test guideline by Oomen *et al*. was conducted to address the risk on the honeybee brood.

Reference:	**Fenoxaprop 69 g/L EW: Effects on Honey Bee Brood (*Apis mellifera* L.) – Brood Feeding Test -**
Author(s), year:	Schmitzer, S., 2015
Report/Doc. number:	Study No.: 521 FPE, Reference No. 94671031
Guideline(s):	Oomen P.A., de Ruijter, A. & van der Steen, J., 1992: Method for honey bee brood feeding tests with insect growth-regulating insecticides, OEPP/EPPO Bulletin 22:613-616 (1992)
GLP:	Yes
Deviations:	Test concentration of reference item: 3.0 g reference item (Insegar) in 1 L sugar solution, equivalent to an nominal active substance concentration of 0.75 g fenoxycarb/L deviation: Deviation due to human error: 3.2 g reference item (Insegar) was weighed in to 1 L sugar solution, which resulted to an nominal active substance concentration of 0.8 g fenoxycarb/L No adverse effect on the study. This is a slight (6.7 %) deviation of the targeted concentration. No excessive Brood Termination Rates were observed. All BTR`s were < 100 %.
Validity:	Acceptable

Material and Methods:

Test substance:	Fenoxaprop 69 g/L EW (CHA 4960); Fenoxaprop-P-ethyl: 6.8 % w/w (70 g/L analytical), safener: Cloquintocet-mexyl 3.32% w/w (34.2 g/L analytical), batch no.: 0001002083, density: 1.03 g/mL
Reference:	Insegar (insect growth regulator), a.s.: fenoxycarb, Batch no.: L166662, Content 25% (nominal)
Test species:	Honey bees (*Apis mellifera* L.), all ages and all stages Honey bees (*Apis mellifera* L.); honey bee colonies were maintained according to normal beekeeping practice, containing two magazines with 11 combs, each. The preliminary brood check indicated healthy colonies with all brood stages present and a sufficient supply of nectar and pollen. The mean strength of the colonies per treatment group, one day before application, ranged between 15060 and 16200

	adult bees. Colonies were free flying, with access to natural food sources, but due to the season, there were no main flowering, bee attractive crops or flowering weeds in the surrounding area.
Location:	Darmstadt-Dieburg, Germany Test site: Uncultivated fields, surrounding area underlies agricultural use mainly with arable crops and meadow.
Test conditions:	Natural field conditions. Temperature, relative humidity and rain were recorded during the experimental time. Temperature (daily mean values): 12.7 – 24.7 °C Rain: 0.0 – 21.2 mm (total precipitation per day) Rel. humidity (daily mean values): 55.3 – 96.2%
Feeding:	Natural food and water sources. No additional food was provided during the course of the study.
Test design:	One single application per colony during the afternoon in order to prevent robbery. Three bee colonies were used per treatment group. 1 L contaminated (test item and reference item) or untreated commercial ready-to-use sugar syrup (Apiinvert, 30 % sucrose, 31 % glucose and 39 % fructose) per colony was provided. Concentrations were 3.09 g Fenoxaprop-P-ethyl 69 g/l EW/L for the test item and 3.2 g Insegar/L for the reference item. The ready prepared sugar solutions were offered per colony in a feeding trough (for feeding bees according to routine bee keeping practice). The feeding troughs and empty magazines were removed after complete uptake of the feeding solutions. Thereafter, the exact uptake of food was determined by reweighing the feeder. Ontogenesis of a defined number of honey bee eggs, young- and old larvae was observed for a period of 21 days following the application for each treatment group and colony. This was assessed one day before the application, by selecting one (or several) brood comb(s) from of each colony and by taking a digital photo of this (these) brood comb(s). After saving the photo-file on a computer, eggs, young- and old larvae were marked at this first Brood area Fixing Day (BFD0). For each subsequent brood assessment (BFDn), again, the same comb(s) was (were) selected from the respective colony and another digital photo was taken, in order to investigate the progress of brood development. Ontogenesis of the bee brood was observed for a period of 21 days after application (i.e. 22 days following BFD0). Mortality of adult bees and pupae was also assessed.
Test concentrations:	Control: 1 L untreated ready-to-use syrup (Apiinvert) per hive. Test item: 3.09 g test item (Fenoxaprop 69 g/L EW) in 1 L sugar solution (ready-to-use syrup, Apiinvert), equivalent to a concentration of 0.21 g Fenoxaprop-P-ethyl (a.s.)/L + 0.103 g Cloquintocet-mexyl/L. Reference item: 3.2 g reference item (Insegar; 25 % fenoxycarb) in 1 L

commercial ready-to-use sugar syrup per hive, corresponding to a nominal active substance concentration of 0.8 g a.s./L.

Test parameter: Mortality of adult bees as well as pupae or larvae: between 3 days before to 21 days after application (= end of the trial);

Bee brood development (eggs, young- and old larvae): one day before (= BFD0) and 6, 10 , 16, 22 days after the application.

Behavioural abnormalities (e.g. moribund, affected, cramps, apathy, intensive cleaning, agressiveness) were observed during the assessment of mortality.

Statistics: Statistical evaluation was done for mortality and the brood termination rates using Shapiro-Wilk´s test (check for normal distribution), Levene´s test (check for homogeneity of variance), Student´s or Welch t-test (pairwise). Software: ToxRat Professional, Version 2.10.05, ToxRat Solutions GmbH.

Findings:

Biological results: No effect on the development of eggs was observed after consumption of the test item treated sugar solution. The mean termination rate of eggs in the test item treatment group was slightly higher with a mean of 16.0 % compared to 13.8 % in the control group. This difference was not statistically significant compared to the control group.

There was also no effect on the development of young larvae after consumption of the test item via treated sugar solution. The development success of the young larvae in the test item treatment group resulted in a mean termination rate of 12.2 % compared to 8.0 % in the control group. This difference was not statistically significant compared to the control group.

The mean termination rate of old larvae was lower in the test item treatment group (5.6 %) compared to the values obtained in the control group (12.9 %). There was no statistically significant difference.

Adult bee mortality in the test item treatment group was lower (mean of 8.8 dead bees per day) when compared to the control group (10.2 dead bees per day) and not statistically significantly different.

No direct acute effects of the test item on honey bee pupae and larvae were observed, when assessing the mortality observed in the dead bee traps.

Table B. 9.5.1.3-1: Effects of Fenoxaprop 69 g/L EW on honey bee brood

Test item	**Fenoxaprop 69 g/L EW**
Test object	**Honeybee *Apis mellifera* L. (complete colonies)**
Exposure	**Via treated sugar solution**

Treatment	**Untreated control**	**Fenoxaprop 69 g/L EW**	**Reference Item (Insegar, a.s. = fenoxycarb)**
Rate per L sugar solution [product][1)]	-	3.09 g test item/L	3.2 g/L
Rate per L sugar solution [a.s.][1)]	-	0.21g Fenoxaprop-P-ethyl (a.s./L)+ 0.103 g Cloquintocet-mexyl (a.s./L)	0.8 g a.s./L
Termination rate of the eggs [%] [2)]	13.8%	16.0% (n.s.)	97.3% (*)
Termination rate of the young larvae [%] [2)]	8.0%	12.2% (n.s.)	94.7% (*)
Termination rate of the old larvae [%] [2)]	12.9%	5.6% (n.s.)	81.1% (*)
Mean brood termination rate over all stages	11.6%	11.3% (n.s.)	91.0% (*)
Mean mortality of worker bees/colony/day during pre-application phase [3)] during the entire post-application phase [3)]	 7.1 10.2	 6.8 (n.s.) 8.8 (n.s.)	 6.6 (n.s.) 38.5 (*)
Mean mortality of pupae/colony/day during pre-application phase [4)] during the entire post-application phase [4)]	 0.1 1.2	 0.2 (n.s.) 0.5 (n.s.)	 0.0 (n.d.) 6.5 (*)
Mean number of bees before application[5)]	16200	15060	16200

1) test and reference item was mixed in sugar solution
2) mean termination rate of 3 colonies per treatment group
3) mean number of dead honeybees per day and colony found in dead bee traps
4) mean number of dead pupae/larvae per day and colony found in dead bee traps
5) mean number of bees per colony
Statistics: n.s. = not statistically significant compared to the control;* = statistically significant compared to the control; Student-t-test, α = 0.05, pairwise comparison, two-sided (before application), one-sided greater (after application). n.d. not determined

Reference item: The reference item treatment (Insegar, a.s. = fenoxycarb) resulted in a statistically significantly increase of unsuccessful eggs, young- and old larvae development and thus confirmed the sensitivity of the test system and the validity of the test conditions.

Conclusion: Overall, it can be concluded according to the results of this study that the administration of Fenoxaprop 69 g/L EW fortified sugar syrup (210 mg Fenoxaprop-P-ethyl/L) to honey bee colonies did not adversely affect honey bee colonies or bee brood development.

Comment RMS:	The study was conducted according to the test guideline by Oomen *et al*. (1992). No validity criteria are given in the test guideline. The study was well conducted

	and is therefore considered valid and acceptable for use in the risk assessment.

B.9.5.1.4. Cage and tunnel tests

Honey bee semi-field studies with additional focus on brood development (OECD GD 75) have been conducted with and Fenoxaprop-P-ethyl EW 69 "CHA 4960".

A semi-field brood study according to the OECD guideline 75 was submitted by the applicant to address the risk to all stages of honey bees and the colony health.

Reference:	**CHA 4960 (Fenoxaprop P-ethyl g/L EW): Assessment of Side Effects on Honeybees (*Apis mellifera* L.) and Determination of Residues in a Semi-Field Study in *Phacelia tanacetifolia* in Germany**
Author(s), year:	Rexer, H.U., 2016
Report/Doc. number:	S15-00053 / M-556072-01-1
Guideline(s):	OECD Guidance Document No. 75 (2007) and current recommendations of the AG Bienenschutz (PISTORIUS et al., 2012), OEPP/EPPO Guideline No. 170(4) (2010), Guideline 1607/VI/97 (rev. 2) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009
GLP:	Yes
Deviations:	None
Validity:	Acceptable

Material and Methods:

Test substance:	CHA 4960 (Fenoxaprop-P-ethyl 69 g/L EW), alternate name: Fenoxaprop 69 g/L EW; Formulation code: CHA 4960; Batch-ID: 0001002083; analyzed content of a.s. Fenoxaprop-P-ethyl: 70.0 g/L and analyzed content of safener cloquintocet-mexyl: 34.2 g/L
Reference:	Insegar (fenoxycarb), batch no.: SMO1A411, content a.s.: 25 % w/w (nominal)
Test concentrations:	Control: Tap water (300 L/ha) Test item: The target application rate of the test item CHA 4960 (Fenoxaprop-P-ethyl 69 g/L EW) was 83.0 g a.s./ha (actual mean rate applied 84.5 g a.s./ha). Toxic reference: Insegar was applied at a target rate of 1200 g product/ha in the reference item group (corresponding to 300 g fenoxycarb/ha). Applications were made at full-flowering (BBCH 65) with honeybees actively foraging on the crop.
Test organism:	Honey bees (*Apis mellifera carnica* L.) Life stage: adult honeybes and honeybee brood of all stages Healthy and queen-right bee colonies were used.

Test location/ plots design:	The semi-field test was located in Bodelshausen, region Tübingen, Germany and was conducted on a field of *Phacelia tanacetifolia*, a surrogate crop specifically recommended in the OECD guidance document No. 75 (2007) for this kind of study. The experimental design of this study comprised three experimental groups with five replicates in the control group C and the test item treatment group T (four for biological assessments, one for residue sampling) and with four replicates in the reference item group R (for biological samplings). Fourteen tunnels were set-up before moving the colonies to the experimental field. One bee colony was used per tunnel. A container filled with a sufficient amount of water was placed in each tunnel as a water supply for the bees. The surface of the water was covered with floatable material to prevent the bees from drowning. To facilitate and standardise the mortality assessment in the crop, *Phacelia tanacetifolia* plants were removed prior to the set-up of the colonies from the areas as shown in Figure 3 and water-permeable linen sheets were spread out on the ground.
Application:	The test item solution was prepared shortly before the application. The application was carried out with portable boom sprayers simulating a commercial application. For each treatment group, a separate boom sprayer was used. The following conditions during the applications were met: – Crop at full flowering during application (BBCH 65) – Bees were actively foraging during the applications in C, T and R (≥ 10 bees/m² per treatment group shortly before application) – Wind speed did not exceed 2.0 m/s during all applications – Air temperature did not exceed 30.0 °C except for application in the test item treatment group T with a maximum of 30.9 °C (but average temperature in T was 28.1 °C) – The accepted spray tolerance of ±10 % per treatment group was met in all treatment groups – There was no rainfall within at least two hours after the applications The amount of test item, control or reference item solution actually applied was determined by measuring the prepared and the remaining spray solution. During the application the bee colonies inside the tunnels were covered with plastic sheets and the water supply was moved out of the tunnels until the end of application to avoid direct contamination.
Weather conditions:	Natural field conditions. The data include the weather conditions at the field site and at the monitoring site after confinement of the colonies in the tunnels. During confinement of the colonies in the tunnels from 4DBA to 7DAA, good foraging conditions and hardly any rain prevailed during the majority of the days of the confined period, except for 5DAA when flight intensity was lower due to poor

weather conditions. The temperature was between 5.7 °C (overall minimum during confinement) and 34.0 °C (overall maximum during confinement). During the period of confinement, the daily precipitation was between 0.0 mm and 1.0 mm. Slight rainfall occurred on 1DBA, 4DAA and 5DAA.

During the monitoring period outside the tunnels (8DAA to 27DAA), good foraging conditions with high temperatures prevailed on the majority of days. The temperature was between 4.8 °C (overall minimum during monitoring period) and 35.9 °C (overall maximum during monitoring period). Slight rainfall was recorded from 8DAA to 10DAA, 12DAA to 15DAA, on 18DAA, 22DAA and from 25DAA to 27DAA during the monitoring period. On 26DAA, a high precipitation value of 33.2 mm was documented.

Feeding: Natural food sources. A container was placed into each tunnel as water supply for the bees.

Test parameter: The following parameters were assessed during the study period:

Mortality: Mortality of the honeybees was recorded by counting the number of dead honeybees in the dead bee traps in front of the hives, on the bottom drawer inside the hives and on the linen sheets which were spread out in the tunnels. For calculation of the mean values per treatment and day, the number of dead bees on the linen sheets, inside the hives (bottom drawer) and in front of the hives (dead bee trap) were summarized per replicate and counted as one value. Dead bees were differentiated into worker bees, pupae and larvae. Dead male bees and male brood stages werehm

also recorded but were not evaluated.

Flight Intensity: During the presence of the colonies in the tunnels, the flight intensity of honeybees was assessed in three randomly chosen flight observation areas per tunnel (1 m^2 per observation area). At each assessment, the number of bees that were both foraging on flowers in the observation areas and flying over the crop was counted for 10-15 seconds in each observation area.

Behaviour of the Honeybees: The assessments of behavior were performed according to the time schedule of the flight intensity assessments in the tunnels and at the monitoring site according to the mortality assessments until 27DAA, with respect to the following criteria:

- filtering at the hive entrance (aggressiveness towards other bees),
- intensive cleaning,
- flying without landing on the crop (i.e. *Phacelia* blossoms),
- clustering of large numbers of bees at the hive entrance,
- cramping,
- locomotion problems,
- trembling,

- inactive (i.e. alive but motionless during duration of assessment, in the crop area and/or at the hive),
- hanging bees (holding on to plants with one or two legs)

Any other observation regarding unusual behavior of the honeybees was recorded in the raw data.

Conditions of the Colonies:

The following parameters were assessed during the colony assessments:

- Colony strength (number of bees, estimation adapted to IMDORF & GERIG, 1999, and IMDORF *et al*., 1987)
- Presence of a healthy queen (e.g. presence of eggs)
- Pollen storage area and area with nectar or honey (estimation adapted to IMDORF & GERIG, 1999, and IMDORF *et al*., 1987)
- Area containing cells with eggs, larvae and capped cells (estimation adapted to IMDORF & GERIG, 1999, and IMDORF *et al*., 1987)

At each colony assessment, the comb area covered with bees or containing cells with nectar, pollen, eggs, larvae, and capped cells was estimated per comb side. The coverage was recorded in area units per comb side with increments of 0.5. One unit corresponded to an area of 100 cm^2 and one comb side contained a total of eight units.

The total number of bees and the total area (number of cells) containing the single brood stages, pollen and nectar was calculated for each colony. Afterwards the mean values were calculated for each treatment and assessment date. The calculation of the area containing brood and food stages was based on a comb area of 800 cm^2 per comb side and assuming 400 cells per 100 cm2 (800 cm^2 = 3200 cells per comb side). For the calculation of colony strength, 130 honeybees per 100 cm^2 were assumed as full coverage (800 cm^2 = 1040 honeybees per comb side).

At each colony assessment, each comb of the colonies was assessed visually for symptoms of bee diseases by a beekeeper according to standard beekeeping practice, in particular with respect to unusual observations and clear symptoms of disease (e.g. chalk brood, sacbrood, *Nosema*, American or European foulbrood) or pests (e.g. *Varroa* sp., *Aethina tumida*, *Tropilaelaps* spp.).

Development of the Bee Brood: The development of the bee brood was assessed in individually marked brood cells. At the assessment before the application in the treatment groups C, T and R (Brood Area Fixing Day = BFD), one or several brood combs were taken out of each colony to mark areas containing eggs on the comb(s). A minimum of 214 cells per colony containing eggs were marked. The

selected combs were uniquely identified. The fixed brood areas were photographed during each brood stage assessment (BFD assessments) and the digital photos were transferred to a computer for analysis. The exact positions of the markers on the wooden frames and of each cell were marked on the digital image. By this means, each selected cell could be identified and the content of the cell was evaluated on the digital images. Thereby, the development of the selected cells was determined throughout the duration of the study.

The time schedule of the bee brood development assessments was chosen in order to observe the brood at different stages during the development . The pre-imaginal development period of worker honeybees from egg to hatched bee typically averages 21 days. In case of normal development, the cells were expected to be empty after hatch of an adult bee or again filled with eggs, young larvae, pollen or nectar at the last assessment date.

For evaluation of the data, the different brood stages were first determined automatically by the software "Hive Analyzer®". These results were checked and, if necessary, corrected manually with "Hive Analyzer®" software (HÖFERLIN & HÖFERLIN 2015).

Residue analyses: Samples of flowers, old honeybee larvae collected from combs, nectar and pollen prepared from forager bees, as well as nectar and pollen collected from combs were analyzed for residues of Fenoxaprop-P-ethyl. The samples were analysed within 7 months from sampling to analysis.

<u>Nectar residue results:</u>

No residues of Fenoxaprop-P-ethyl were detected at or above the limit of quantification (0.01 mg/kg) in any of the treated and untreated nectar sampled from combs or prepared from forager bees.

<u>Pollen residue results:</u>

Residues of Fenoxaprop-P-ethyl in the pollen sampled from combs taken at 2DAA were at 0.02 mg/kg and at 6DAA were at the limit of quantification (0.01 mg/kg).

Residues of Fenoxaprop-P-ethyl in the pollen prepared from forager bees taken at 2DAA were at 0.05 mg/kg and at 6DAA were at 0.04 mg/kg.

No residues of Fenoxaprop-P-ethyl were detected at or above the limit of quantification (0.01 mg/kg) in any of the untreated pollen sampled from combs or prepared from forager bees specimens.

<u>Flower residue results:</u>

Residues of Fenoxaprop-P-ethyl in the *Phacelia tanacetifolia* flowers samples taken at 2DAA were at 0.48 mg/kg and at 6DAA were at 0.15 mg/kg.

No residues of Fenoxaprop-P-ethyl were detected at or above the limit of quantification (0.01 mg/kg) in any of the untreated *Phacelia tanacetifolia* flower specimens.

Old honeybee larvae residue results:

No residues of Fenoxaprop-P-ethyl were detected at or above the limit of quantification (0.01 mg/kg) in any of the treated and untreated old honeybee larvae specimens.

Statistics: For the pre-application period, the means of mortality and flight intensity of every treatment group were compared through comparisons with the Tukey's test. The data of mortality and flight intensity in the post-application period of the test item treatment group and the reference item group were compared to the control in a separate approach but in the same way. The data were tested for normality and homoscedasticity using the Shapiro-Wilk Test ($p > 0.05$) and folded F-Test ($p > 0.05$), respectively. Data were statistically compared using Student's t-Test (method pooled, one-sided, $p \leq 0.05$) in case of normality and homoscedasticity. In case of non-homoscedasticity but proven normality, t-Test was conducted with method Satterthwaite (one-sided, $p \leq 0.5$). In case of non-normality and non-homoscedasticity, Mann-Whitney exact test (one-sided, $p \leq 0.5$) was used. Log-transformations were conducted if necessary to achieve better fit to normality and homoscedasticity of data.

During the post-application phase (0DAA to 27DAA), right-sided tests were used for mortality of T and R compared to C and left-sided tests were used for flight intensity of T and R compared to C. The data for brood indices, compensation indices and termination rates were compared to the control using the same tests as the data of mortality and flight intensity, with left-sided tests for brood and compensation indices and right sided tests for the termination rates after the application.

All statistical analysis was conducted using SAS release Version 9.3.

Findings:

Mortality: Throughout the study (before and following exposure) worker bee mortality was similar across all treatments, indicating no effect of the test item. Statistically significantly higher values (Student's t-test, method pooled, one-sided, $\alpha = 0.05$) in T compared to C were found on 19DAA (3.8 vs. 1.3 dead worker bees/colony/day) and 20DAA (5.5 vs. 2.3 dead worker bees/colony/day), but these were only of minor nature and not considered to be relevant with respect to a potential test item treatment effect.

The pupal mortality in T and C was on a very low level throughout the study. No statistically significantly higher mean daily mortality values were observed on any individual day of the pre- or post-application period in T compared to C.

The mean pupal mortality value for the entire confinement period (0DAA to 7DAA) was on a very low level in T (0.1 dead pupae/colony/day) and statistically

not significantly higher compared to C (0.3 dead pupae/colony/day).

For the whole post-application period (0DAA to 27DAA), the mean daily pupal mortality in T (0.0 dead pupae/colony/day) was very low and statistically not significantly higher compared to C (0.1 dead pupae/colony/day).

In the reference item group, the overall mean daily pupal mortality for the whole post-application period (0DAA to 27DAA) was significantly higher in the reference item treatment group compared to the control group (Mann-Whitney-Exact Test, two-tailed, α = 0.05). Furthermore, a statistically significantly higher mean mortality value in the reference item treatment group compared to the control group was observed on 15DAA (Mann-Whitney-Exact Test, one-sided, α = 0.05). Elevated, but not statistically significantly higher values were observed on several days (e.g. 12DAA to 13DAA). Moreover, few dead malformed pupae with white eyes or sickle shaped (rimmed) eyes were observed in R during the post-application period. Effects on pupae of the reference substance are a well-known effect.

No dead larvae were found in any of the colonies throughout the whole assessment period.

Table B. 9.5.1.4-1: Mortality

Treatment group		Control (C)	Test item (T)	Reference Item (R)
Daily mean mortality (dead worker bees/colony) ± STD	4DBA to 0DBA	23.0 ± 6.9	23.9 ± 8.2	39.5 ± 14.5
	0DAA	17.0 ± 7.0	22.8 ± 7.8	44.8 ± 38.7
	0DAA to 7DAA	37.2 ± 14.2	39.5 ± 10.5	61.5 ± 29.5
	0DAA to 27DAA	13.0 ± 4.9	13.9 ± 3.3	19.5 ± 8.7
Daily mean mortality (dead pupae/ colony) ± STD	4DBA to 0DBA	0.2 ± 0.1	0.0 ± 0.0	0.2 ± 0.2
	0DAA	0.0 ± 0.0	0.3 ± 0.5	0.3 ± 0.5
	0DAA to 7DAA	0.3 ± 0.2	0.1 ± 0.2	0.2 ± 0.2
	0DAA to 27DAA	0.1 ± 0.1	0.0 ± 0.1	1.1 ± 1.3*

DAA: days after application; DBA: days before application; STD: standard deviation
* statistically significantly higher than the control

Flight intensity: During the pre-application period (4DBA to 0DBA), flight intensity in T was not statistically significantly lower compared to the control (Tukey's test, two-sided, α = 0.05). Pre-application flight intensity in R was on the same level as the control (not significantly different; Tukey's test, two-sided, α = 0.05). Therefore, pre-application flight intensity in T was on a normal level for this kind of crop and within the natural range of variability.

After the application until the end of the confinement period (0DAA to 7DAA),

flight intensity in the test item treatment was not statistically significantly lower compared to the control. Since the mean flight intensity in T during the post-application period was slightly higher compared to the pre-application period, no repellence effect was detected.

On the day of the application (0DAA), the mean daily flight intensity, assessed over a period of 6 hours, accounted to 19.4, 24.5 and 23.3 forager bees/m², for C, T, and R, respectively (no statistically significant differences; Student's t-test, method pooled, one-sided, α = 0.05). Flight intensity in T was on a normal level (higher than before the application at 0DBA) throughout this day.

Overall, no test-item related effect was detected.

Table B. 9.5.1.4-2: Flight intensity

Treatment group		Control (C)	Test item (T)	Reference Item (R)
Daily mean flight intensity (bees/m²) ± STD	4DBA to 0DBA	13.3 ± 2.1	14.5 ± 2.8	16.2 ± 0.7
	0DAA	19.4 ± 0.8	24.5 ± 1.1	23.3 ± 3.7
	1DAA	23.0 ± 2.0	29.8 ± 1.7	24.9 ± 3.5
	0DAA to 7DAA	17.2 ± 1.4	20.5 ± 2.1	20.1 ± 3.0

DAA: days after application; DBA: days before application; STD: standard deviation

Behaviour of the bees

In all four replicates under observation, only single honeybees (a total of 12 honeybees from four colonies) displaying unusual behaviour (locomotion problems, inactivity, intensive cleaning) were detected in the test item treatment group on a few occasions after the application (0DAA, 2DAA and 3DAA). However, similar observations were also made in T during the pre-application period (on 4DBA and 0DBA). On 0DAA, honeybees clustering at the hive entrance in one replicate (Tc) were observed within a very short period of time, but this was not considered as related to the test item treatment. After 3DAA, only normal behaviour was observed in all replicates of the test item treatment group.

Therefore, no test item related adverse effect on honeybee behaviour was detected.

Development of Honeybee Brood in Individual Cells

In the control group C, successful development was observed in the majority of the marked brood cells, indicating a healthy development of brood. The mean termination rate at the end of the observation period (BFD+22) was very low at 8.10 %.

In the test item treatment group T the brood and compensation indices were slightly reduced, and the brood termination rate was slightly increased compared with the control, on all assessment dates after BFD+5. Although these differences were statistically significant, they were not considered to be treatment related. The mean brood termination rate in T at the end of the observation period (BFD+22) was 17.66 %, at less than 20 % this was considered as still very low.

For numerous published studies conducted under the same test guideline, the mean brood termination rates for control replicates were reported to be well above 20 % (values between 21.7 % and 34.7 % have been reported). The observed mean brood termination rate of 17.66 % in the test item treatment group of the present study was well below the range average brood termination rates for control replicates and was therefore not considered to reflect any adverse effect of the test item on honeybee brood development.

The mean brood and compensation indices as well as the mean termination rates in R were statistically significantly different from the respective values in the control for all post treatment assessments from 4DAA (BFD+5) to 15DAA (BFD+16) (Student's t-Test, method pooled, one-sided, α = 0.05). The mean brood index and the mean termination rates in R were also statistically significantly different from the respective values in the control on 21DAA (BFD+22). The mean termination rate at the end of the observation period (BFD+22) was 71.38%, indicating that the majority of the initially marked eggs had not completed development.

In replicate Ra, no distinct differences from the control group in terms of brood termination rate as well as brood and compensation indices were detected during the photographic assessments of marked brood cells. However, Ra displayed a notably decreased overall number of brood cells during the colony assessments after application of the reference item, indicating the sensitivity of the test system to detect potential brood effects.

Table B. 9.5.1.4-3: Summary of the brood and compensation indices and termination rates

Replicate	Brood index / Compensation index at x days after brood area fixing day (BFD)					Termination rate (BFD +22)
	0	+5	+10	+16	+22	
Control	**1.00/1.00**	**2.86/2.88**	**3.75/3.76**	**3.71/3.77**	**4.60/4.81**	**8.10**
STD	0.00/0.00	0.13/0.11	0.14/0.12	0.16/0.13	0.17/0.10	3.33
Test item T	**1.00/1.00**	**2.62/2.64**	**3.36*/3.38***	**3.31*/3.41***	**4.12*/4.51***	**17.66***
STD	0.00/0.00	0.28/0.28	0.31/0.31	0.32/0.25	0.42/0.18	8.45
Reference item R	**1.00/1.00**	**1.07*/1.09***	**1.37*/1.39***	**1.21*/1.58***	**1.43*/2.77**	**71.38***
STD	0.00/0.00	1.28/1.29	1.69/1.70	1.64/1.50	2.01/1.99	40.18

BFD: Brood area fixing day; STD: Standard deviation
*: Statistically significantly lower (brood and compensation indices) or higher (termination rate) compared to the control

Strength of the Colonies: The mean colony strength values of the test item treatment group followed a pattern of development similar to the control group during the entire study, with both groups showing a comparable increasing tendency during the course of the trial. Therefore, no test-item related adverse effects on colony strength were observed.

In the reference item treatment group R, the mean colony size remained relatively

static during the assessment period. This observation was in accordance with the expected and typical effect of the reference item on the honeybee brood and with the observed high brood termination rate as a result of the application of the reference item.

Development of the Brood Area: The mean amount of brood in the colonies (sum of cells containing eggs, larvae, and pupae) was assessed. Overall, on the level of whole colonies, honeybee brood development in the test item treatment group T was not affected by the test item treatment and followed a similar pattern when compared to the control.

In the reference item treatment group R, a strong decrease of the abundance of brood was observed after application of the reference item. This was mainly due to a reduction in the abundance of larvae and pupae and was in accordance with the expected and typical effect of the reference item on the honeybee brood development.

Development of the Food Storage Area: The mean amount of food stores in the colonies (sum of cells containing nectar and pollen) was assessed. Overall, the colonies were well provided during the course of the study and there was no lack of pollen or nectar in any colony at any assessment date. No test-item related adverse effects on the development of the food storage area were observed.

Residues: Residues of Fenoxaprop-P-ethyl at or above the limit of quantification (0.01 mg/kg) were not detected in untreated samples (i.e. control samples). Residues of Fenoxaprop-P-ethyl at or above the limit of quantification were found in pollen collected from combs (up to 0.02 mg/kg), pollen prepared from forager bees (up to 0.05 mg/kg), and in Phacelia tanacetifolia flowers (up to 0.48 mg/kg). No residues at or above the limit of quantification were detectable in nectar collected from combs, nectar prepared from forager bees and in old honeybee larvae.

Table B. 9.5.1.4-4: Summary of the results of the residue analysis in treated samples

Replicate/ Treatment	Timing	Nectar from combs	Nectar from forager bees	Pollen from combs	Pollen from forager bees	Phacelia flowers	Old honey-bee larvae
		Fenoxaprop-P-ethyl [mg/kg]					
T	2DAA	n. d.	n. d.	0.02	0.05	0.48	-
	5DAA	-	-	-	-	-	n. d.
	6DAA	n. d.	n. d.	0.01	0.04	0.15	-
	7DAA	-	-	-	-	-	n. d.
C	2DAA	n. d.	n. d.	n. d.	n. d.	n. d.	-
	5DAA	-	-	-	-	-	n. d.
	6DAA	n. d.	n. d.	n. d.	n. d.	n. d.	-

	7DAA	-	-	-	-	-	n. d.

LOQ = 0.01 mg/kg; LOD = at least 30 % of LOQ; n. d. = not detected (< LOQ)
DAA = days after application; - = not applicable

Conclusion: CHA 4960 (Fenoxaprop-P-ethyl 69 g/L EW) was applied at a rate of 84.5 g a.s./ha (corresponding to 1207.7 g product/ha) with a spray volume of 300 L/ha during full flowering of Phacelia tanacetifolia (BBCH 65) and during daily honeybee flight. The effects on honeybee colonies under confined conditions considering mortality, flight intensity, behaviour, colony strength and brood development were evaluated.

The quantitative assessments of brood development in individually marked cells performed in this study, brood index, compensation rate and brood termination rate were slightly increased in the CHA 4960 (Fenoxaprop-P-ethyl 69 g/L EW) treatment compared to the control group. Although these small increases were statistically significant overall they were considered as minor in view of the comparably low brood termination rate in the test item treatment group (< 20 %). The observed mean brood termination rate of 17.66 % in the test item treatment group of the present study was well below the reported average brood termination rates for control replicates of 21.7 % to 34.7 % and was therefore not considered to reflect any adverse effect of the test item on honeybee brood development.

This conclusion is in line with other brood-related parameters that were assessed in the course of the study. The overall honeybee brood development in the test item treatment group T, evaluated by the number of cells per colony containing the different types of brood cells, was not affected when compared to the control. In addition, no test-item related adverse effects on colony strength or on the development of the food storage area were observed.

The mean mortality values for worker bees and pupae in the test item treatment group T during the entire confined period inside the tunnels after application (0DAA to 7DAA) as well as during the entire observation period after application (0DAA to 27DAA) were both statistically not significantly higher than the mortality in the control group. Therefore, no evidence for a noticeable effect of the test item on adult and pupal honeybee mortality was found.

Furthermore, no test-item related adverse effects on flight intensity and behaviour were observed.

Residues of Fenoxaprop-P-ethyl at or above the limit of quantification (0.01 mg/kg) were found in pollen collected from combs (up to 0.02 mg/kg), pollen prepared from forager bees (up to 0.05 mg/kg), and in *Phacelia tanacetifolia* flowers (up to 0.48 mg/kg). No residues at or above the limit of quantification

were detectable in nectar collected from combs, nectar prepared from forager bees and in old honeybee larvae.

Comment RMS:	**Validity:** The study was evaluated following the recommendations of the OECD test guideline No. 75. The study was well conducted according to the recommendations given in the OECD test guideline. However, the following points deviated from the guidelines or were not reported in detail: **Acceptability of the analytical methods used in the test:** See section on physical-chemical properties. **Endpoints:** The RMS agrees on the conclusion given in the study report. A single application of 1185.71mL/formulation/ha during bee flight did not adversely affect the survival and fitness of honey bee colonies. **Conclusion of the RMS:** Based on the evaluation, the semi-field bee brood study is considered valid.

B.9.5.1.5. Field tests

Based on the results reported in the available laboratory studies (acute oral and contact toxicity to honey-bees, chronic toxicity to adult honey-bees and effects on larvae of honey-bees), no further studies are required addressing the risk to honey-bees.

B.9.5.2. Effects on non-target arthropods other than bees

The notifiers submitted Standard laboratory studies using artificial substrate were performed with the formulation CHA 4960 (Fenoxaprop-P-ethyl 69 g/L EW).

Reference:	**Dose-Response Toxicity of Fenoxaprop-P-ethyl 69 g/L EW to Adults of the Parasitoid Wasp *Aphidius rhopalosiphi* (Hymenoptera: Aphidiidae) in the Laboratory**
Author(s), year:	Schmidt T., 2006a
Report/Doc. number:	A22937 / 156 FPE
Guideline(s):	MEAD-BRIGGS, M. A. et al. (2000): A laboratory test for evaluating the effects of plant protection products on the parasitic wasp, *Aphidius rhopalosiphi* (De Stephani-Perez) (Hymenoptera: Braconidae). In: Guidelines to evaluate side-effects of plant protection products to non-target arthropods (eds. Candolfi et al., 2000), IOBC/WPRS, Gent, p. 13-25
GLP:	Yes
Deviations:	None relevant
Validity:	Acceptable

Material and Methods:

Test substance:	Fenoxaprop-P-ethyl 69 g/L EW (CHA 4960), Content: Fenoxaprop-P-ethyl: 7.11 w/w, Content: Cloquintocet-mexyl: 3.41 % w/w, Batch no. 660-PSH-49
Toxic reference:	Roxion EC, Batch no. D 077 A, Content of dimethoate: 400 g/L
Test species:	*Aphidius rhopalosiphi* (Hymenoptera: Braconidae), adults, < 48 h old
Type of test:	Acute contact laboratory test
Number of organisms:	Exposure period: 4 replicates per control, reference item treatment and per test item rate with 10 adult wasps per replicate Post-exposure period: 15 replicates/treatment group; 1 female per unit
Treatments:	Control: 200 L deionised water/ha Toxic reference: 1 mL Roxion/ha in 200 L/ha Test item: 63, 125, 250, 500 and 1000 mL prod./ha; deionised water as diluent;
Exposure route:	Two glass plates (approx.. 9.9 cm in square length) held apart by a shallow untreated squared frame made of stainless steel. The glass plates were sprayed with the reference item, with deionised water (control) and with the test item, respectively, and left to dry for approximately one hour. Afterwards, the parts of test unit were joined together and ten adult wasps per replicate were transferred into each test unit. After 48 hours of exposure surviving female wasps were removed from the test units and transferred individually into the reproduction test units for assessment of fecundity. Following exposure to dried test item residues, female wasps were individually

assessed for fecundity.

Feeding: Small moist paper towel for water supply. A drop of honey was placed on the gaze as food for the emerged wasps. During the mortality test the wasps were provided with a honey-water solution (e.g. 1:3 v/v) by inserting a piece of cotton wool soaked with the honey-water solution.

Test conditions: The test period was 13 days (i.e. 48 hours for the mortality assessment, 24 hours for the parasitisation phase of individual wasps and 10 days for the reproduction assessment). The study was performed in a temperature-and-humidity-controlled climatic chamber during the mortality assessment and the parasitisation phase and in a temperature-controlled climatic room during the reproduction assessment.

During the mortality assessment and the parasitisation phase, the temperature ranged from 18.9 – 22.4 °C and the relative humidity from 46.1 to 76.7%.

During the reproduction assessment, the temperature ranged from 17.3 to 26.8 °C. Due to the annual calibration procedure of the data logger, the temperature of approx.. 5 hours during Day 3 of the reproduction phase was not measured.

Light intensity during the light period was within the range of 500-1700 Lux (measured at mortality test unit level) for both the mortality assessment and the parasitisation phase and 4520-7000 Lux (measured at reproduction test unit level) for the reproduction phase.

Test parameters: Mortality and behavioural abnormalities were assessed 2, 24 and 48 h after introduction of the wasps to the test units.

The mean number of parasitized aphids (i.e. mummies) per female wasp after a parasitisation phase of 24 hours has been assessed.

Reproduction phase was performed where the corrected mortality was ≤ 50%.

No reproduction testing was performed with the reference item group.

Statistics: The LR50 and its 95% confidence limits were calculated by Probit Analysis (FINNEY, 1971; DAVIES, 1971).

The NOER and LOER for mortality were determined according to the results of the DUNNETT-test (DUNNETT, 1955 & 1964).

Findings:

Biological results: Mean mortality in the treatments increased with a rate-response relationship from 0% at 64.4 g Fenoxaprop-P-ethyl 69 g/L EW /ha to 92.5% at 1030 g Fenoxaprop-P-ethyl 69 g/L EW /ha. In the treatments with the two highest test item rates of 515 and 1030 g Fenoxaprop-P-ethyl 69 g/L EW /ha, the mean mortality was statistically significantly higher than in the control (results of a Dunnett-test, α = 0.05, one-sided larger).

The LR_{50} was calculated to be 578 g Fenoxaprop-P-ethyl 69 g/L EW /ha (95% confidence limits: 365-959 g Fenoxaprop-P-ethyl 69 g/L EW /ha).

The mean parasitisation success of the wasps was 15.1 parasitised aphids per

female in the control and thus fulfilled the validity criterion for reproduction.

The values of mean parasitisation success of the wasps varied between 10.3 and 20.6 mummies per wasp in the treatments from 64.4 to 515 g Fenoxaprop-P-ethyl 69 g/L EW /ha. No parasitisation success was recorded at 1030 g Fenoxaprop-P-ethyl 69 g/L EW /ha since mortality was >50% in this treatment. The mean number of mummies produced per wasp in all test item treatments up to and including 515 g Fenoxaprop-P-ethyl 69 g/L EW /ha were not statistically significantly lower than in the control (results of a Dunnett-test, α = 0.05, one-sided smaller).

Table B. 9.5.2-1: Effects of Fenoxaprop-P-ethyl 69 g/L EW on *Aphidius rhopalosiphi* in the laboratory

Treatment group [g product/ha]		Mortality after 48 hours of exposure [%][1]		Fecundity (number of parasitised aphids per female)[2]		
		mean	s.d.	mean	s.d.	% of control
Control		0.0	0.0	15.1	11.2	---
64.4	(4.6 g a.s./ha)	0.0	0.0	20.6	13.2	137
128.8	(9.2 g a.s./ha)	7.5	5.0	16.3	9.6	108
257.5	(18.8 g a.s./ha)	15.0	12.9	16.5	8.6	110
515	(36.6 g a.s./ha)	32.5[1]	23.3	10.3	8.4	64
1030	(73.2 g a.s./ha)	92.5[1]	5.0	--- [3]	--- [3]	--- [3]
Toxic standard		100.0	0.0	---	---	---

[1]Mortality mean values of the 515 and 1030 g Fenoxaprop-P-ethyl 69 g/L EW /ha treatment were statistically significantly higher than in the control.
[2]Reproduction mean values did not differ statistically significantly from the control.
[3]Reproduction mean values of the 1030 g Fenoxaprop-P-ethyl 69 g/L EW /ha treatment was not determined since mortality was > 50% in this treatment.

Validity criteria: After 48 days of exposure the mean mortality was 0.0% in the control and 100% in the reference item treatment which were within the set validity limits.

Conclusion: The 48-hour LR_{50} value for *Aphidius rhopalosiphi* exposed to fresh dried residues of Fenoxaprop-P-ethyl 69 g/L EW applied to an inert substrate (glass plate) was calculated to be 578 g product/ha (95% confidence limits: 365-959 g Fenoxaprop-P-ethyl 69 g/L EW /ha) and 41.1 g a.s./ha (95% confidence limits: 26.0-68.2 g active ingredient /ha).

The NOER was 257.5 g Fenoxaprop-P-ethyl 69 g/L EW /ha (18.3 g active ingredient /ha), and the corresponding LOER was 515 g Fenoxaprop-P-ethyl 69 g/L EW /ha (36.6 g active ingredient /ha).

Comment RMS: **Validity:** The study was conducted and evaluated according to the currently valid test guideline by Mead-Briggs (2000). The study is considered valid if

	- the mortality in the control treatment is below 13%; - the level of mortality expected in the toxic reference is in line with the mortality specified in the study protocol; - the wasps in the control produce a minimum of 5 mummies per female. Lower fecundity levels would not allow a meaningful comparison of treatment. In the control, there should be no more than two wasps producing zero values. Taking into account the current test guideline (Mead-Briggs, 2000) the study is considered valid. The validity criteria considering mortality (0% mortality after 48 hours) and reproduction assessment (15.1 mummies/female) as well as the toxic reference (100% mortality after 24 hours) are met. In addition, the following points deviated from the test guideline or were not reported in detail: - During the mortality assessment phase, the temperature was once for a short period above the required limit of 22°C and the relative humidity at the same short period below the required minimum limit of 60% due to handling of the wasps. This short-term deviation was not considered to have an impact on the biological results, since mortality values in the control and in the treatment with the reference item were within the limits of the study validity criteria. - During the 10 days of the reproduction phase, the temperature of the second half of Day 3 and the first half of Day 4 of the reproduction phase were not measured since the data logger was not available due to the obligate annual calibration procedure. From Day 0 to the first half of Day 4 of the reproduction phase the temperature ranged from 19.5 to 24.7°C with a mean of 22.5°C. From the second half of Day 5 to Day 10 of the reproduction phase, the temperature ranged from 17.3 to 26.8°C with a mean of 23.0°C. The high mean temperature was caused by the high light intensity of the light source during the light period and not be regulated to lower levels during the study period. However, these deviations were not considered to have an impact on the biological results, since the reproduction values in the control were within the limits of the study validity criteria. **Acceptability of the analytical methods used in the test:** Not necessary as no analytics have been performed. **Endpoints:** The RMS agrees on the endpoints given in the study report. 48 h LR_{50} = 578 g test item/ha corresponding to 41.1 g a.s./ha **Conclusion of the RMS:** Based on the evaluation of the study, the standard glass plate toxicity test is considered valid.

Reference:	**Dose-Response Toxicity of Fenoxaprop-P-ethyl 69 G/L EW to the predatory mite *Typhlodromus pyri* (Acari, Phytoseiidae) in the Laboratory**

Author(s), year:	Schmidt, T., 2006b
Report/Doc. number:	Report no. A22926, Reference no. 155 FPE
Guideline(s):	BLÜMEL, S. et al. (2000): Laboratory residual contact test with the predatory mite *Typhlodromus pyri* Scheuten (Acari: Phytoseiidae) for regulatory testing of plant protection products. In: Guidelines to evaluate side-effects of plant protection products to non-target arthropods (eds.: Candolfi et al., 2000), IOBC/WPRS, Gent, p. 121-143
GLP:	Yes
Deviations:	None
Validity:	Acceptable

Material and Methods:

Test substance:	Fenoxaprop-P-ethyl 69 g/L EW (CHA 4960), Content: Fenoxaprop-P-ethyl: 7.11 w/w, Content: Cloquintocet-mexyl: 3.41 % w/w, Batch no. 660-PSH-49
Toxic reference:	Roxion EC, Content of dimethoate: 400 g/L, Batch no. D 077 A
Test species:	*Typhlodromus pyri* protonymphs, < 24 h old
Type of test:	Acute contact laboratory test, 14 days
Number of organisms:	4 replicates with 20 individuals per replicate
Treatments:	Control: 200 L/ha deionised water Toxic standard: 5 mL Roxion/ha Test item: 62.5, 125, 250, 500 and 1000 mL prod./ha The test items were sprayed in 200 L/ha on the glasses.
Application:	After the glass plates had been sprayed with the test item and after the spray deposits had dried, 20 protonymphs per replicate were placed onto the surface of the treated glass plates.
Feeding:	The mites were fed with a mixture of walnut and apple pollen at day 0 (after application) and at Day 3, 6, 9 and 12
Test conditions:	Temperature: 18.8 – 25.7°C; relative humidity: 56.6 – 82.3%, light intensity: 1890 – 2740 Lux
Test parameter:	Mortality was recorded on day 3 and 7 after test initiation. If necessary, the sex-ratio was adjusted to at least 1 male : 5 females on day 7. The number of eggs per female was determined by counting the number of females and eggs at the assessment days from day 7 to day 14. No reproduction testing was performed with the reference item group.
Statistics:	The LR_{50} and its 95% confidence limits were calculated by Probit Analysis (FINNEY; 1971 DAVIES, 1971). The mean mortality values were corrected according to the formula of Abbott (ABBOTT, 1925) with improvements by SCHNEIDER-ORELLI (1947). For a better fit of the data (i.e. calculation of the 95% confidence limits of LR50), the mean mortality value of the lowest test rate

was not included into the Probit Analysis.

The NOER and LOER for mortality were determined according to the results of the DUNNETT-test (DUNNETT, 1955 & 1964).

Findings:

Biological results: In the treatments with 64.4, 128.8, 257.5, 515 and 1030 g Fenoxaprop-P-ethyl 69 g/L EW /ha, the mean overall mortality was 17.5%, 12.5%, 18.8%, 57.5%, and 95.0%.

The mean mortality on Day 7 was statistically significantly higher in the treatments with 515 and 1030 g Fenoxaprop-P-ethyl 69 g/L EW /ha when compared with the control (results of a Dunnett-test with arcsin-transformed values for mortality, $\alpha = 0.05$, one-sided larger).

The corrected overall mortality on Day 7 was 8.3%, 2.8%, 9.7%, 52.8% and 94.4% in the treatments with 64.4, 128.8, 257.5, 515 and 1030 g Fenoxaprop-P-ethyl 69 g/L EW /ha.

It was noted that there the percentage of escaped mites in treated units compared with the control indicates a repellent effect of the test item on the mites.

The 7-day LR_{50} was calculated with corrected mortality values and was 478 g Fenoxaprop-P-ethyl 69 g/L EW /ha (95% confidence limits: 301-798 g Fenoxaprop-P-ethyl 69 g/L EW /ha).

Mean egg production from day 7 to day 14 was 4.36 eggs per female in the control and thus fulfilled the validity criterion for reproduction.

The average egg production of the females in the test item treatments was 3.51, 4.41 and 2.84 eggs per female in the treatments with 64.4, 128.8 and 257.5 g Fenoxaprop-P-ethyl 69 g/L EW /ha. The number of eggs laid per female did not differ statistically significantly from the control up to and including the test rate of 257.5 g Fenoxaprop-P-ethyl 69 g/L EW /ha (results of a Dunnett-test, $\alpha = 0.05$, one-sided smaller).

The reproduction in the treatments with 515 and 1030 g Fenoxaprop-P-ethyl 69 g/L EW /ha was not measured since mortality after 7 days of exposure was larger than 50% in these treatments.

Table B. 9.5.2-2: Effects of Fenoxaprop-P-ethyl 69 g/L EW on *T. pyri* in the laboratory

Treatment group [g product/ha]		Mortality after 7 days of exposure [%][1]			Reproduction from Day 7 to Day 14 (number of eggs per female)[2]		
		mean	s.d.	Corrected mean	mean	s.d.	% of control
Control		10.0	4.1	---	4.36	1.03	---
64.4	(4.6 g a.s./ha)	17.5	10.4	8.3	3.51	0.46	81
128.8	(9.2 g a.s./ha)	12.5	6.5	2.8	4.14	0.69	95
257.5	(18.8 g a.s./ha)	18.8	7.5	9.7	2.84	2.18	65

515	(36.6 g a.s./ha)	57.5[1]	17.1	52.8	-	-	-
1030	(73.2 g a.s./ha)	95.0[1]	10.0	94.4	-	-	-
Toxic standard		56.3	11.1	51.4	---	---	---

[1]Mortality means in the treatments with 515 and 1030 g Fenoxaprop-P-ethyl 69 g/L EW /ha did differ statistically significantly from the control.

[2]Reproduction means did not differ statistically significantly from the control.

[a:]Mortality was corrected by means of the formula of Abbott (ABBOTT, 1925) with improvements by SCHNEIDER-ORELLI (1947).

Validity criteria: After 7 days of exposure the mean overall mortality in the control and in the reference treatment was 10.0% and 56.3%, respectively, and were thus within the set validity limits.

Conclusion: Under worst- case laboratory conditions, the 7-day LR_{50} for *Typhlodromus pyri* exposed to Fenoxaprop-P-ethyl 69 g/L EW applied onto an inert substrate (glass plates) was calculated to be 478 g product/ha (95% confidence limits: 301-798 g Fenoxaprop-P-ethyl 69 g/L EW /ha) and 34.0 g a.s./ha (95% confidence limits: 21.4-56.7 g active ingredient /ha). The NOER was 257.5 g Fenoxaprop-P-ethyl 69 g/L EW /ha (18.3 g active ingredient /ha), and the corresponding LOER was 515 g Fenoxaprop-P-ethyl 69 g/L EW /ha (36.6 g active ingredient /ha).

Comment RMS: **Validity:** The study was conducted according to the IOBC test guidelines (Blümel et al., 2000). The study is considered acceptable taking into account the validity criteria stated in the IOBC test guideline.

The arithmetic mean mortality (dead and escaped) in the control treatment was below 20% on day 7 after treatment application (being: 10%). The cumulative mean number of eggs per female in the control (from day 7 to day 14) was ≥ 4 eggs/female (being: 4.36 eggs/ female).

The cumulative mean mortality (control corrected) of protonymphs on day 7 exposed to the reference item was 94.4% and therefore in the recommended range between 50% and 100%.

Acceptability of the analytical methods used in the test: Not necessary as no analytics have been performed.

Endpoints:

The RMS agrees on the LR_{50} given in the study report.

48 h LR_{50} = 478 g product/ha

Conclusion of the RMS: Hence, the RMS is of the opinion that the study is considered valid and acceptable for the use in the risk assessment.

In addition, extended laboratory studies using the artificial substrate were performed with the formulation Fenoxaprop-P-ethyl 69 g/L EW.

Reference:	**Effects of Fenoxaprop-P-ethyl 69 g/l EW on the Parasitoid *Aphidius rhopalosiphi* Extended Laboratory Study – Dose Response Test -**
Author(s), year:	Moll, M., 2007
Report/Doc. number:	37572002 / 229 FPE
Guideline(s):	Meadbriggs et al. 2000: A laboratory test for evaluating the effects of plant protection products on the parasitic wasp, *Aphidius rhopalosiphi* (De Stephani-Perez) (Hymenoptera: Braconidae). Mead-Briggs et al. 2006: Current improvements by the ring-test group.
GLP:	Yes
Deviations:	None
Validity:	Acceptable

Material and Methods:

Test substance:	Fenoxaprop-P-ethyl 69 g/L EW (CHA 4960), batch no.: 660-PSH-49, content of a.s.: 7.11 % w/w Fenoxaprop-P-ethyl, content of safener: 3.41 % w/w Cloquintocet-mexyl.
Toxic reference:	BAS 152 11 I, EC formulation, batch no.: 1812, content a.s.: 414.4 g dimethoate/L
Test species:	Adult female wasps *Aphidius rhopalosiphi* (Hymenoptera: Braconidae), < 49 h old
Type of test:	Extended laboratory test
Number of organisms:	Mortality assessment: 7 treatment groups, 6 replicates per treatment with 5 female wasps Reproduction assessment: 1 female per replicate
Test substrate:	Treated pots (13 cm in diameter) with 8-10 barley seedlings (*Hordeum vulgare* "Xanadu") per pot, BBCH 12
Treatments:	Control: deionised water Toxic reference: 10 mL Perfekthion/ha Test item: 14.8, 44.4, 133, 400 and 1200 mL product/ha Treatments applied with a calibrated sprayer in 400 L water/ha
Mortality assessment:	Observations of mortality were recorded approximately 2, 24 and 48 hours after test initiation. The number of parasitoids alive, affected, moribund and dead were recorded. Moribund parasitoids were counted as dead. To determine whether residues of the test item were repellent to the wasps, observations on the position of the individual insects were made during the initial 3h after their release. Five separate observations were made at 30-minute intervals starting approximately 30 minutes after the introduction of all wasps.
Reproduction assessment:	Number of aphid mummies was counted 11-12 days after the 24 hours parasitisation period in all replicates where the females were alive after the 24 hour parasitisation period (n = 19-20). The number of live, dead or not found females after the 24 hours parasitisation period was documented. The fecundity

assessment was performed where the corrected mortality (M_{corr}) was ≥ 50 %. No fecundity assessment was performed for the reference item.

Test conditions: Temperature: 18-21°C; relative humidity: 68-89% (acclimatisation, exposure) and 70-75% (post-exposure period, within the test units), 16 h light, 800-1100 lux (acclimatisation, exposure), 460-1900 lux (parasitisation period) and 9900-15000 lux (post-parasitisation period)

Test parameters: Mortality and behavioural abnormalities were assessed 2, 24 and 48 h after introduction of the wasps to the test units.

The parasitation rate was determined at the end of the parasitation phase by counting the number of mummies for each individual wasp.

Findings:

Biological results: No statistically significant mortality was recorded in any of the treatment groups 48 hours after application. Additionally, no behavioural abnormalities were observed in any of the treatment groups. No repellent effect was observed in the test item treatment groups and in the reference item group compared to the control. Under extended laboratory conditions the LR50 of Fenoxaprop-P-ethyl 69 g/L EW is estimated to be greater than 1200 mL product/ha.

At the lowest dose rate of 14.8 mL product/ha reproduction was statistically lower compared to the control, with an effect slightly above the trigger value of 50 % (51.5 %). However as the reproductive capacity at doses 44.4, 133 and 400 mL product/ha was not affected statistically significantly it can be assumed that the effect on reproduction at 14.8 mL product/ha is not test item related. At 1200 mL product/ha reproduction was statistically significantly affected compared to the control, but the effect on reproduction was below the trigger value of 50 %.

Table B. 9.5.2-3: Mortality and parasitisation efficiency of the parasitoids

Treatment group [mL/ha]	Mortality [%]	Corrected Mortality [%]	Parasitisation Rate [mummies per female]		Reduction of Parasitisation Efficiency [%]
			mean	s.d.	
Control	3.3 ± 8.2	0.0	45.82	24.8	-
14.8	0.0 ± 0.0 n.s.[1]	-3.4	22.2*[2]	13.8	51.5
44.4	0.0 ± 0.0 n.s.[1]	-3.4	36.72 n.s	19.5	19.8
133	0.0 ± 0.0 n.s.[1]	-3.4	34.62 n.s	18.1	24.4
400	3.3 ± 8.2 n.s.[1]	0.0	31.92 n.s	16.9	30.4
1200	3.3 ± 8.2 n.s.[1]	0.0	26.0*[2]	19.9	43.2
Toxic standard	96.7 ± 8.2 *[1]	96.6	-	-	-

[1] Fisher Exact test, α = 0.05; n.s. = not significant, * = significant.
[2] Dunnett-T-Test, α = 0.05; n.s. = not significant.

Validity criteria:	The reference item mortality was 96.6 % at the single application rate of 0.3 mL Perfekthion/ha. This value corresponds with the validity criterion specified by Mead-Briggs et. al. (2000) and, together with a control mortality of 3.3 % and with a mean control reproduction rate of 45.8 mummies per female (no control parasitoids produced a zero-value), demonstrates the validity of the test.
Conclusion:	The 48-hour LR_{50} value for *Aphidius rhopalosiphi* exposed to Fenoxaprop-P-ethyl 69 g/L EW under extended laboratory conditions was determined to be > 1200 mL product/ha (corresponding to 85.3 g a.s./ha). Reproduction was not affected up to and including 1200 mL product/ha compared to the control.

Comment RMS:	**Validity:** The study was evaluated following the recommendations of the currently valid test guidelines, the IOBC guideline by Mead-Briggs et al. (2000). - Mortality in the control treatment should not exceed 5 out of 40 wasps (13%). The level of mortality expected in the toxic reference treatment should be specified in the study protocol and should be based on the previous experience of the test laboratory. - Wasps in the control treatment should produce a minimum of 5 mummies per female, as it is considered that lower fecundity levels would not allow a meaningful comparison of treatments. More typically, the production of greater than 10 mummies per female would be expected over a 24 h period. In the control treatment, there should be no more than two wasps producing zero values, since this will markedly reduce the ability of the test to determine true treatment effects. The validity criteria given in the IOBC guideline are met, hence the study is considered valid. **Acceptability of the analytical methods used in the test:** Not necessary as no analytics have been performed. **Endpoints:** The RMS agrees on the LR_{50} given in the study report. 48 h LR_{50} > 1200 g test item/ha **Conclusion of the RMS:** Based on the evaluation, the extended laboratory toxicity test conducted with the parasitoid *A. rhopalosiphi* is considered valid.

Reference:	**Effects of Fenoxaprop-P-ethyl 69 g/l EW on the Predatory Mite *Typhlodromus pyri* Extended Laboratory Study – Dose Response Test -**
Author(s), year:	Moll, M., 2008a
Report/Doc. number:	37573062 / 230 FPE
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. In: Guidelines to evaluate side-effects of plant protection

	products to non-target arthropods (eds.: Candolfi et al., 2000), IOBC/WPRS, Gent, p. 121-143.
	Oomen (1988): Guideline for the evaluation of side-effects of pesticides on *Phytoseiulus persimilis* A.-H.
GLP:	Yes
Deviations:	None relevant
Validity:	Additional information

Material and Methods:

Test substance:	Fenoxaprop-P-ethyl 69 g/L EW (CHA 4960), batch no.: 660-PSH-49, content of a.s.: 7.11 % w/w Fenoxaprop-P-ethyl, content of safener: 3.41 % w/w Cloquintocet-mexyl.
Toxic reference:	Perfekthion (BAS 152 11 I), batch no.: 1812, content a.s.: 414.4 g dimethoate/L
Test species:	*Typhlodromus pyri* protonymphs, < 24 h old
Type of test:	Extended laboratory test
Number of organisms:	6 replicates per treatment, with 10 individuals per replicate
Test substrate:	Detached primary leaves of bean plants (*Phaseolus vulgaris* L. "St. Andreas", 19 days old) were cut to discs of about 45 mm. These leaf cuts were treated on their upper surface
Treatments:	Control: deionised water Toxic standard: 40 mL test Perfekthion/ha Test item: 14.8, 44.4, 133, 400 and 1200 mL test item/ha The test item was sprayed in 200 L/ha on the glasses.
Course of test:	The mites were exposed to dried residues on treated leaf surfaces (bean leaves). Survival of the mites was assessed after 3 and 7 days. For the reproduction assessment surviving mites from the control and from all test item groups were the corrected mortality was < 50% were sexed and the number of eggs per females was recorded on 3 assessment days within one week.
Feeding:	A mixture of pine (*Pinus nigra*) and birch (*Betula sp.*) pollen (3:1) ad libitum on the day of the test start and on each assessment day except for the last one resp. at least every four days.
Test conditions:	Temperature: 25-26°C; relative humidity: 60-78%, 16 h photoperiod (560-1530 lux)
Test parameter:	Mortality: The number of living, dead and escaped mites was counted twice in the first week (on day 3 and at day 7) after test ignition. Dead mites were removed, escaped mites were considered as dead. Reproduction: Number of eggs laid and number of live and dead juvenile stages per female were counted and removed afterwards on 3 assessment days from day 7 on with a maximum interval of 3 days up to day 14 (inclusive). Eggs laid until day

7 inclusive were removed from the test arena and were not counted.

The reproduction assessment was performed where the corrected mortality (M_{corr}) was ≥ 50 %.

Statistics: Mortality data were analysed for significance using the Fisher Exact Test, which is a distribution-free test and does not require testing for normality or homogeneity prior analysis.

Reproduction data were tested for normal distribution using the Kolmogoroff-Smirnov-Test (α = 0.05) and the Cochran-Test (α = 0.05). Because reproduction data were normally distributed and homogenous the Dunnett-Test (multiple comparison, one-sided, α = 0.05) was used.

The software used to perform the statistical analysis was ToxRat Professional, Version 2.09, ToxRat Solutions GmbH 2001-2005.

Findings:

Table B. 9.5.2-4: Effects of Fenoxaprop-P-ethyl 69 g/L EW on T. pyri

Treatment group [mL product/ha]	Mortality [%]	Corrected Mortality [%]	Reproduction [eggs per female]	Effect on Reproduction [%]
Control	0.0 ± 0.0	-	7.6 ± 2.2	-
14.8	20.0 ± 17.9 *[1]	20.0	6.5 ± 4.4 n.s.[2]	13.9
44.4	25.0 ± 21.7 *[1]	25.0	4.4 ± 2.9 n.s.[2]	42.1
133	16.7 ± 16.3 *[1]	16.7	3.2 ± 2.1 *[2]	58.1
400	25.0 ± 12.2 *[1]	25.0	1.8 ± 1.7 *[2]	76.1
1200	41.7 ± 19.4 *[1]	41.7	2.0 ± 3.7 *[2]	73.7
Reference item	100.0 ± 0.0 *[1]	100.0	-	-

[1] Fisher Exact test, α = 0.05; n.s. = not significant, * = significant.
[2] Dunnett Test, α = 0.05; n.s. = not significant.

Validity criteria: In the reference item treatment there was 100.0% mortality. This value corresponds with the validity criterion specified by Blümel et al. (2000) and, together with a control mortality of 0.0% and a reproduction rate in the control of 7.6 eggs/female (i.e. >4 eggs/female), demonstrates the validity of the test.

Conclusion: Under extended laboratory conditions the LR_{50} of Fenoxaprop-P-ethyl 69 g/L EW is estimated to be greater than 1200 mL product/ha (85.3 g a.s./ha). At 133, 400 and 1200 mL product/ha there was a statistical significant reduced reproduction compared to the control.

Comment RMS: **Validity:** The study was evaluated following the recommendations of the currently valid test guidelines, the IOBC guideline by Blümel et al. (2000).

- The arithmetic mean mortality (dead and escaped individuals) in the control should not exceed 20% on day 7 after treatment application. 0 %
- The cumulative mean number of eggs per female in the control (from day 7 to day 14) should be ≥ 4 eggs/female. 7.6 eggs/female
- The cumulative mean mortality (control corrected) of protonymphs on day 7

	exposed to the toxic reference item, at a rate between 9 and 10 mL product/ha, should range between 50% and 100%. The validity criteria given in the IOBC guideline are met, hence the study is considered valid. In addition, the following points deviated from the recommendations given in the IOBC test guideline: - According to the IOBC test guideline each treatment should be replicated five times, with each replicate containing 20 protonymphs. However, in the study 6 replicates per treatment, with each replicate containing 10 protonymphs was used. **Acceptability of the analytical methods used in the test:** Not necessary as no analytics have been performed. **Endpoints:** The endpoints have been recalculated with TOXRAT: 7 d LR_{50} > 1200 mL/ha (85.3 g a.s./ha) 7d ER50 = 78.3 ml/ha (5.6 g a.s./ha) **Conclusion of the RMS:** Based on the evaluation, the laboratory toxicity test conducted with the predatory mite *T. pyri* is considered valid according to the validity criteria. However due to the deviations mentioned above the study is considered solely as additional information.

Reference:	**Effects of Fenoxaprop-P-ethyl 69 g/l EW on the Lacewing, *Chrysoperla carnea* Extended Laboratory Study – Dose Response Test -**
Author(s), year:	Moll, M., 2008b
Report/Doc. number:	37574047 / 231 FPE
Guideline(s):	Vogt et al. (2000). Laboratory method to test effects of plant protection products on larvae of *Chrysoperla carnea* (Neuroptera: Chrysopidae).
GLP:	Yes
Deviations:	None
Validity:	Acceptable

Material and Methods:

Test substance:	Fenoxaprop-P-ethyl 69 g/L EW (CHA 4960), batch no.: 660-PSH-49, content of a.s.: 7.11 % w/w Fenoxaprop-P-ethyl, content of safener: 3.41 % w/w Cloquintocet-mexyl.
Toxic reference:	Perfekthion (Dimethoate, 414.4 g/L (nominal: 400 g/L)).
Test species:	*Chrysoperla carnea* (Neuroptera, Chrysopidae), 2 d old larvae
Type of test:	Extended laboratory test
Number of organisms:	40 individuals. 7 treatment groups with 40 replicates each containing 1 larvae.

Treatments: Control: deionised water
Toxic reference: 100 mL Perfekthion/ha
Test item: 14.8 mL product/ha, 44.4 mL product/ha, 133 mL product/ha, 400 mL product/ha and 1200 mL product/ha
in 200 L water/ha

Exposure route, duration: This study encompassed 7 treatment groups (5 dose rates of the test item, control, reference item) with 40 replicates each containing 1 larva. The larvae were exposed to dried residues on treated leaf surfaces (bean leaves). Exposure time lasted as long as pupae were transferred to the reproduction units for development of adults. Mortality checks were carried out regularly until hatching of adult lacewings. In addition, for the control and the test item treatment groups where the corrected mortality was < 50% the reproduction performance, i.e. egg deposition and larval hatching rate, was determined (2 checks/week, 24 hours period each assessment).

Test conditions: Temperature: 23-27°C; relative humidity: 60-87%, 16 h light/8 h darkness

Test parameters: Mortality: The number of living and dead larvae and number of pupae developed was determined at least 3 times a week after test start and number of adults hatched was checked regularly.
Reproduction: The number of eggs were counted after 24 hours egg-laying periods (checks) and 2 checks were done within one week. The number of larvae was determined after hatching of all larvae and the hatching rate was calculated. Reproduction was performed where the corrected mortality (M_{corr}) was ≤ 50%. No reproduction testing was performed with the reference item.

Statistics: Mortality data were analysed for significance using the Fisher Exact Test, which is a distribution-free test and does not require testing for normality or homogeneity prior analysis. The software used to perform the statistical analysis was ToxRat Professional, Version 2.09, ToxRat Solutions GmbH 2001-2005.

Findings:

Table B. 9.5.2-5: Effects of Fenoxaprop-P-ethyl 69 g/L EW on *C. carnea*

Treatment group [mL product/ha]	Mortality [%]	Corrected Mortality [%]	Eggs per female [per day]	Larval hatching rate [%]
Control	15	-	20.9 ± 0.5	88.9 ± 1.8
14.8	27.5 n.s	14.7	25.3 ± 1.1	93.5 ± 0.0
44.4	30.0 n.s	17.6	20.5 ± 3.4	88.8 ± 1.2
133	10.0 n.s	-5.9	14.7 ± 0.8	87.5 ± 2.4
400	12.5 n.s	-2.9	15.5 ± 2.8	91.0 ± 4.3
1200	17.5 n.s	2.9	18.3 ± 2.6	87.6 ± 0.5
Reference item	92.5 *	91.2	-	-

Fisher Exact test, α = 0.05; n.s. = not significant, * = significant.

Validity criteria:	In the reference item treatment there was 91.2 % corrected mortality. This value corresponds with the validity criterion and, together with a control mortality of 15.0% and a fecundity and fertility in the control group of 20.9 eggs per female/day and 88.9 % larval hatching rate, demonstrates the validity of the test.
Conclusion:	Under extended laboratory conditions the LR_{50} of Fenoxaprop-P-ethyl 69 g/L EW is estimated to be greater than 1200 mL product/ha (85.3 g a.s./ha). Additionally, the results indicate that there are no negative effects of the test item on reproductive performance of *Chrysoperla carnea* up to and including 1200 mL product/ha (85.3 g a.s./ha).

Comment RMS:	**Validity:** The study was conducted according to the IOBC test guidelines, using the methodology described by Vogt et al. (2000) According to the currently valid test guideline by Vogt et al. (2000) the study is considered valid if - the maximum acceptable cumulative morality (dead larvae and pupae and adults dying during emergence or not successfully moulted) is below 20%; (15%) - the fecundity (mean number of eggs per female per day) is greater than 15; (20.9) - the fertility (mean hatching rate) is greater than 70%; (88.9 %) - the level of mortality in the reference item treatment is greater than 50%. (91.2%) According to the validity criteria, the study is considered acceptable. The validity criteria considering mortality (15% control mortality) and reproduction assessment (> 15 eggs/female, hatching rate 88.9%) as well as the toxic reference (91.2% reference mortality) are met. **Acceptability of the analytical methods used in the test:** Not necessary as no analytics have been performed. **Endpoints:** The RMS agrees on the endpoints given in the study report. 48 h LR_{50} > 1200 mL prod./ha corresponding to > 85.3 kg a.s./ha 48 h ER_{50} > 1200 mL prod./ha corresponding to > 85.3 kg a.s./ha **Conclusion of the RMS:** Based on the evaluation of the study, the extended laboratory toxicity test is considered valid.

Reference:	**Aged-residue extended laboratory tests to determine the effects of Fenoxaprop 69 g/L EW on the predatory mite, *Typhlodromus pyri* (Acari: Phytoseiidae)**
Author(s), year:	Fallowfield, L., 2010
Report/Doc. number:	CVA-10-1 / 353 FPE
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.
GLP:	Yes
Deviations:	None
Validity:	Acceptable

Material and Methods:

Test substance:	Fenoxaprop-P-ethyl 69 g/L EW (CHA 4960), batch no.: 660-PSH-76, content of a.s.: 6.97 % w/w Fenoxaprop-P-ethyl
Toxic reference:	Perfekthion (BAS 152 11 I), batch no.: 90924, content a.s.: 414.8 g dimethoate/L (analysed)
Test species:	*Typhlodromus pyri* protonymphs, < 24 h old
Type of test:	Extended laboratory test
Number of organisms:	5 replicates per treatment, with 20 individuals per replicate
Test substrate:	Leaves of bean plants (*Phaseolus vulgaris* L.), BBCH 14. Discs were cute from flattened sections of the excised first true leaves using a 5-cm-diameter Petri dish as a template.
Treatments:	Control: deionised water Toxic standard: 60 mL test Perfekthion/ha Test item: 1200 mL test item/ha The test item was sprayed in 400 L/ha on the glasses.
Course of test:	Sufficient number of dwarf French bean plants were treated to provide foliage for a series of bioassays to determine the effects of both fresh and field-aged foliar residues. The treatment variants evaluated were one rate of the test item, a water-treated control and a toxic reference item. It was planned that extended laboratory bioassays would dommence on the day of treatment application, i.e. 0 days after treatment (DAT), and then at weekly intervals thereafter. The endpoints in each completed bioassay were an assessment of mite mortality 7 days after their introduction (DAI) and an assessment of the reproductive capacity of the mites (as mean number of eggs per female) over the subsequent 7 days (i.e. 7-14 DAI). Since the individual bioassays lasted 14 days, there were inevitably periods of overlap between bioassays commencing at 7-day intervals. It was intended that once the test-item treatment resulted in < 30& corrected mortality and <30% reduction in reproduction, relative to the control, in a specific bioassay, no further assessments were to be carried out for the subsequent bioassays.
Feeding:	Pollen was provided as food for the mites. This was a 1:1 v/v mixture of almond (*Prunus* sp. Var. Butte) and apple (*Malus* sp. Var. Red Delicious)
Test conditions:	Temperature: 23-27°C; relative humidity: 60-90%, 16 h photoperiod (600-970 lux)
Test parameter:	Mortality: The conditions of the mites was assessed with the a.s.d of a binocular

microscope at 1 and 7 days after introduction (DAI).

Reproduction: The numbers of male and female mites in each replicate were recorded at 7 DAI (females are identifiable as being significantly larger and more rounded than males), this was to ensure a male to female ratio of at least one male per five females. Any eggs that were produced prior to 7 DAI were discarded. Untreated pollen was provided as food and this was replenished daily over the following week.

For 7 days, the total egg production (number of eggs plus live and dead juvenile stages) was recorded for each unit. Three assessments of oviposition activities were carried out between 7 and 14 DAI. Any eggs and nymphs present were recorded and then removed. In addition, the condition of the adult female and male mites in each arena was recorded on each date.

Statistics: The mean percentage mortality after 7 days was calculated for the individual treatments in the definitive test and then corrected for any losses in the control treatment using Abbott´s formula (Abbott, 1925). The percentage mortality of the treatment was compared to the control using Fisher´s Exact Test (Sokal & Rohlf, 1981; SPSS, 2009). Treatments were not considered to differ significantly at the experimental error rate of $\alpha = 0.05$.

For the reproduction data, the mean cumulative number of eggs per female was determined for the period 7-14 DAI. The individual values were totalled for each replicate and the average for the five replicates was calculated. The results were compared by t-test for independent samples (SPSS; Fowler & Cohen, 1990).

Findings:

Biological results: After 7 days, the mortality in the control group was 4%, which compared with 10% mortality in the 1200 ml/ha treatment rate of Fenoxaprop 69 g/L EW (equivalent to 6% after correction). Mortality in the reference toxicant group was 100%.

Table B. 9.5.2-6: Mite mortality observed in the initial leaf exposure bioassay performed on freshly dried foliar residues applied to dwarf French bean plants

Treatment	Rate ml product/ha (g a.s./ha)	Mortality (%)	Corrected mortality (%)
Control	-	4	-
Fenoxaprop 69 g/l EW	1200 (86.16)	10	6
Toxic reference	24.88	100***	100

(*** P < 0.001).

In the 7 day reproduction assessment, the mean number of eggs produced per female was 7.7 for the control treatment, and 7.6 for the 1200 ml/ha treatment rate of Fenoxaprop 69 g/L EW.

Table B. 9.5.2-7: Mite reproductive capacity following exposure to freshly dried foliar residues on dwarf French bean plants

Treatment	Rate ml product/ha	Mean number of eggs per	Effects on

	(g a.s./ha)	female	reproduction (%)
Control	-	7.7	-
Fenoxaprop 69 g/L EW	1200 (86.16)	7.6	1.6

Conclusion: The effects of freshly dried foliar residues of Fenoxaprop 69 g/L EW on the predatory mite (*Typhlodromus pyri*) were evaluated under aged residue test conditions. Dried residues of Fenoxaprop 69 g/L EW when applied to French bean plants, had no significant effect on survival or reproduction of the predatory mite (*Typhlodromus pyri*). Therefore, as the LR_{50} (mortality) and NOER (reproduction) for dried residues on French bean plant are both considered to be > 1200 mL product/ha, further aged residues testing is not considered necessary.

Comment RMS:

Validity: The study was evaluated following the recommendations of the currently valid test guidelines, the IOBC guideline by Blümel et al. (2000).

- The arithmetic mean mortality (dead and escaped individuals) in the control should not exceed 20% on day 7 after treatment application.
- The cumulative mean number of eggs per female in the control (from day 7 to day 14) should be ≥ 4 eggs/female.
- The cumulative mean mortality (control corrected) of protonymphs on day 7 exposed to the toxic reference item, at a rate between 9 and 10 mL product/ha, should range between 50% and 100%.

The validity criteria given in the IOBC guideline are met, hence the study is considered valid.

In addition, the following points deviated from the recommendations given in the IOBC test guideline:

- According to the IOBC test guideline each treatment should be replicated five times, with each replicate containing 20 protonymphs. However, in the study one replicate in the treatment group was excluded because all mites escaped at 7 DAI.

Acceptability of the analytical methods used in the test: Not relevant as no analytics were performed.

Endpoints: The RMS agrees on the endpoints given in the study report.

7 d LR_{50} > 1200 mL product/ha

Conclusion of the RMS: Based on the evaluation, the aged residue laboratory toxicity test conducted with the predatory mite *T. pyri* is considered valid.

B.9.6. RISK ASSESSMENT FOR ARTHROPODS

B.9.6.1. Risk assessment for honeybees

Honeybees may be exposed to formulated Fenxoaprop-P-ethyl by direct spraying of the plant protection product

while bees are foraging on flowers and weeds present in or adjacent to the crop treated. They may also be exposed through contact with fresh or dry residues or by oral uptake of contaminated pollen, nectar and honey dew.

The EU representative use is in cereals (spring and winter wheat, durum wheat, rye, winter rye, triticale, spring and winter barley) at a BBCH of 11-39. The maximum total rate of the active substance must not exceed 0.083 kg a.s./ha/year. The risk assessment for honeybees is based on the maximum single application rate of 0.083 kg a.s./ha.

Acute risk assessment:

Table B. 9.6.1-1: Summary of effects of Fenxoaprop-P-ethyl on honeybees (acute exposure)

Test substance	Exposure route	Endpoint	Toxicity	Reference
Fenxoaprop-P-ethyl tech.	Acute oral Acute contact	48 h LD_{50}	> 200 µg a.s./bee > 200 µg a.s./bee	KIeiner, R., 2000
	Acute oral Acute contact	48 h LD_{50}	> 109.5 µg a.s./bee > 100 µg a.s./bee	Sekine, T., 2013
	Acute oral Acute contact	48 h LD_{50}	> 108.9 µg a.s./bee > 100 µg a.s./bee	Schmitzer, S., 2007
CHA 4960	Acute oral Acute contact	48 h LD_{50} 72h LD_{50}	356.1 µg prod./bee 23.9 µg a.s./bee 598.6 µg prod./bee 40.1 µg a.s./bee	Schmidt, T., 2005

The acute risk from oral and contact exposure was conducted in accordance with the Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002). The acute risk for bees was expressed as a Hazard Quotient (Q_H) calculated by the following formula (single application rate in g/ha, LD_{50} in µg/bee):

Hazard quotient (Q_H) = application rate [g a.s./ha] / LD_{50} [µg a.s./bee]

Table B. 9.6.1-2: Risk to honeybees from oral and contact exposure to Fenxoaprop-P-ethyl

Test substance	Exposure route	Application rate [g a.s./ha]	Endpoint [µg a.s./bee]	Q_H
Fenxoaprop-P-ethyl tech.	Oral	1 x 83	> 108.9	< 0.76
	Contact		> 100	< 0.83
CHA 4960	Oral	1 x 83	48 h LD_{50} = 23.9	3.5
	Contact		48 h LD_{50} = 40.1	2.1

The resulting Hazard Quotients are clearly below the trigger of 50 indicating an acceptable risk to honeybees after the use of Fenxoaprop-P-ethyl according to representative uses.

Risk assessment according to EFSA guidance document on bees (EFSA Journal 2013;11(7):3295):

Acute risk assessment

Acute oral toxicity - Screening Step

The acute exposure-toxicity (ETR) ratio for adult honey-bees was calculated using the following formula:

$ETR_{acute\ adult\ oral} = AR \times SV / LD_{50\ oral}$

With:

AR…Application rate [kg a.s./ha]

SV…Shortcut value (for an application made via sideward spraying)

LD_{50}…Lethal dietary dose [µg a.s./bee/day]

Table B. 9.6.1-3: Screening risk assessment for honeybees and other pollinators from oral exposure to Fenoxaprop-P-ethyl

Crop	Test species	Test substance	Endpoint	Ef x SV	ETRacute oral	Trigger
Cereals (Spring and winter wheat, durum wheat, rye, winter rye, triticale, spring and winter barley) 1 x 1.264 kg form./ha* (1 x 0.0828 kg a.s./ha)	*Apis mellifera*	CHA 4960	LD_{50} > 356.1 µg from./bee	7.6	< 0.03	0.2
	Apis mellifera	Fenoxaprop-P Ethyl	LD_{50} > 108.9 µg a.s./bee	7.6	< 0.06	0.2
	Bombus terrestris	Fenoxaprop-P Ethyl	LD_{50} > 124.7 µg a.s./bumble bee	11.2	< 0.01	0.03

* based on formulation density: 1.03 g/mL

Based on the screening risk assessment an acceptable risk to honey bees and bumble bees from oral exposure was identified. No first tier risk assessment is required.

Acute contact toxicity – Screening Step:

The contact Hazard Quotient was calculated using the following formula:

$HQ_{contact} = AR / LD_{50\ contact}$

With:

AR…Application rate [g a.s./ha]

LD_{50}…Lethal contact dose [µg a.s./bee/day]

Table B. 9.6.1-4: Screening risk assessment for honeybees and other pollinators from contact exposure to

Fenoxaprop-P-ethyl

Crop	Test species	Test substance	Endpoint	$HQ_{contact}$	Trigger
Cereals 1 x 0.0828 kg a.s./ha BBCH 11-39	*Apis mellifera*	CHA 4960	LD_{50} > 589.6 µg form./bee	< 2.1	42
	Apis mellifera	Fenoxaprop-P Ethyl	LD_{50} > 100 µg a.s./bee	< 0.8	42
	Bombus terrestris	Fenoxaprop-P Ethyl	LD_{50} > 100 µg a.s./bumble bee	< 0.8	7

Based on the screening risk assessment an acceptable risk to honey bees and bumble bees from contact exposure was identified. No first tier risk assessment is required.

In conclusion, the risk to honey bees and bumble bees from acute contact exposure to the active substance and the EU representative formulation is considered acceptable for the intended uses.

Chronic risk assessment:

Table B. 9.6.1-5: Summary of effects of Fenxoaprop-P-ethyl on honeybees (chronic exposure)

Test substance	Exposure route	Endpoint	Toxicity	Reference
CHA 4960	Chronic oral	10 d LDD_{50} 10 d NOEDD	10.06 µg a.s./bee/d 3.95 µg a.s./bee/d	Theis, M., 2017

Based on the available chronic toxicity study with the representative formulation CHA 4960 a chronic risk assessment considering chronic oral toxicity was conducted. No information regarding the effects on the hypopharyngeal glands (HPGs) has been made available.

The chronic study with the representative formulation was designed as dose-response test by exposing adult honey-bees for 10 consecutive days to a maximum concentration of nominally 125 mg a.s./kg in aqueous sugar solution.

No adverse lethal-, sub-lethal, behavioural or delayed effects were observed by exposing adult honeybees for ten consecutive days exclusively to sugar solution, containing 125 mg Fenxoaprop-P-ethyl/kg, corresponding to 3.95 µg a.s./bee/day.

No guidance is available how to assess the risk to adult honey-bees from chronic exposure to the active substance. Hence, the chronic risk assessment was conducted based on the draft EFSA guidance document on bees (EFSA Journal 2013;11(7):3295).

Chronic oral toxicity - screening step:

The chronic exposure-toxicity ratio ($ETR_{chronic\ adult\ oral}$) is calculated using the following formula:

$ETR_{chronic\ adult\ oral}$ = AR * SV / 10 d LDD_{50}

With
AR…Application rate [kg a.s./ha]
SV…Short-cut value for the respective kind of application
LDD_{50}…Lethal dietary dose [µg a.s./bee/day]

Table B. 9.6.1-6: Chronic oral toxicity to bees

Crop	Endpoint	SV	ETR	Trigger
Cereals 1 x 0.083 kg a.s./ha	10d LDD_{50} = 10.06 µg a.s./bee/d	7.6 (down-ward application)	**0.062**	ETR > 0.03

The $ETR_{chronic\ adult\ oral}$ for the active substance is above the trigger value of 0.03 indicating a potential chronic risk to adult honey-bees. Hence, a Tier 1 chronic risk assessment taking into account various exposure routes has to be conducted.

Chronic oral toxicity - Tier 1:

The following exposure routes have to be considered in the tier 1 risk assessment according to the draft EFSA guidance document on bees.

- Risk from foraging on the treated crop
- Risk from foraging on an adjacent crop
- Risk from foraging on weeds on the treated field
- Risk from foraging in the field margin
- Risk form foraging the following year on a permanent crop or on a succeeding crop for annual crops

Therefore the ETR is recalculated using the following formula:

$ETR_{chronic\ adult\ oral}$ = AR * Ef * SV * twa / 10 d LDD_{50}

With
AR…Application rate [kg a.s./ha]
Ef…Exposure factor
twa…Time weighted average
SV…Short-cut value for the respective kind of application
LDD_{50}…Lethal dietary dose [µg a.s./bee/day]

Table B. 9.6.1-7: Risk from foraging in the field margin and adjacent crops

Exposure	Crop	Endpoint	SV	Ef	twa	ETR	Trigger
Treated crop BBCH 10-29	Cereals 1 x 0.083 kg a.s./ha BBCH 11-39	10d LDD_{50} = 10.06 µg a.s./bee/d	0.92	1	0.72	0.005	ETR > 0.03
Treated crop BBCH 30-39			0.92	1	0.72	0.005	
Weeds BBCH 10-29			2.9	1	0.72	0.017	
Weeds BBCH 30-39			2.9	0.5	0.72	0.009	
Field margin BBCH 10-29			2.9	0.0092	0.72	0	
Field margin BBCH 30-39			2.9	0.0092	0.72	0	
Adjacent crop BBCH 10-29			5.8	0.0033	0.72	0	
Adjacent crop BBCH 30-39			5.8	0.0033	0.72	0	
Adjacent crop BBCH 40-69			5.8	0.0033	0.72	0	
next crop BBCH 10-29			0.54	1	0.72	0.003	
next crop BBCH 30-39			0.54	1	0.72	0.003	

Based on the Tier 1 risk assessment an acceptable chronic risk to adult honey-bees was identified.

Risk assessment for honeybee brood:

Table B. 9.6.1-8: Summary of effects of formulated Fenxoaprop-P-ethyl (CHA 4960) on honeybees and honeybee brood

Test substance	Exposure route	Results	Reference
CHA 4960	Honeybee brood feeding	No adverse effects on mortality, bee brood development (eggs, young larvae, old larvae, pupae) and colony development by feeding honey bee colonies sugar syrup at a concentration of 3.09 g test item/L.	Schmitzer, S., 2015
CHA 4960 (Fenoxaprop-P-ethyl 69 g/L EW)	Effect on Honey Bee Brood under Semi-Field Conditions – Tunnel Test (OECD Guidance document 75)	Overall, Fenoxaprop-P-ethyl 69 g/L EW was applied at a rate of 84.5 g a.s./ha to a flowering crop under semi-field (tunnel) conditions during bee flight. No biologically relevant adverse effects on mortality of worker bees or pupae were observed. Foraging activity, behavior as well as queen survival was not affected. No effects on colony development or colony strength. Although the brood termination rate (BTR) at day BFD 22 (Brood Fixation Day) was significantly different from control group, both control and treatment BTR were <20% and effects are not considered to reflect any adverse effects of the test item on honeybee brood development. Historical and published data indicate that natural range of BTR is often in excess of 20% under these confined test conditions. A lack of adverse impact on brood is also supported by the high BTR of the reference item. BTR at BFD22: Control: 8.1% Test item 17.66% Reference: 71.38 %	Rexer, H. U.; 2016;

A bee brood feeding study has been conducted by following the provisions/method of Oomen P.A., de Ruijter, A. & van der Steen, J. (OEPP/EPPO Bulletin 22:613-616 (1992), which require, amongst other parameters to "…use formulated products only… products are fed at a concentration recommended for high-volume use…". The honey bee brood feeding test is a worst-case screening test, by feeding the honey bees directly in the hive with a treated sugar solution which contains the test substance at a concentration typically present in the spray tank (and as such at a very high concentration) and by investigating the development of eggs, young and old larvae by employing digital photo imaging technology. In this study with formulated CHA 4960 at a concentration of 0.21 g a.s./L, the mean termination rate of eggs in the treatment group was 16.0% and 13.8% in the control. The development success of young larvae in the test item treatment group was higher and resulted in a mean termination rate of 12.2% compared to 8.0% in the control. The termination rate for old larvae in the test

item treatment group was 5.6% compared to 12.9% obtained in the control. These measured differences for eggs, young and old larvae were not statistically significant compared to the control group. In both, in the test item treatment group and in the control group, post-application adult mortality was on the same level as the corresponding pre-application adult mortality, with the post-application adult mortality in the test item treatment group being only slightly higher (mean of 8.8 dead bees per day) and thus not statistically significantly different when compared to the control group (10.2 dead bees per day). No effects of the test item on honey bee pupae and larvae were observed. Overall, it can be concluded according to the results of this study that the administration of CHA 4960 fortified sugar syrup (210 ppm Fenoxaprop-P-ethyl) to honey bee colonies does neither adversely affect honey bee colonies nor bee brood development.

In two separate semi-field (tunnel) tests conducted according to OECD guidance document 75 colonies were exposed to FPP + MPR EW 144 or to CHA 4960 (Fenoxaprop-P-ethyl 69 EW) applied directly as a spray and as residues on flowers (nectar and pollen) to the foraging area. No biologically relevant adverse effects on mortality of worker bees or pupae were observed. Foraging activity, behavior, nectar-and pollen storage as well as queen survival was not affected. No adverse effects on colony development, colony strength or bee brood were observed. Based on the results of these studies, it can be concluded that FPP + MPR EW 144 and CHA 4960 (Fenoxaprop-P-ethyl 69 EW) do not adversely effect honey bees and honey bee brood when applied at rates up to 83 g a.s./ha, when honey bees are actively foraging on a bee-attractive, flowering crop.

Conclusion

Overall, it can be concluded that CHA 4960, when applied at the maximum application rate of 1.2 L product/ha (83 g a.s./ha), does not pose an unacceptable risk to honey bees and honey bee colonies.

Risk assessment from exposure to contaminated water

An assessment of the risk from exposure to contaminated drinking water (guttation water, surface water and water in puddles) was conducted for honey bees considering acute and chronic exposure.

The calucation of the ETR_{acute} for adult and larvae consuming contaminated water based on the following formula:

$ETR_{acute} = W * PEC/LD_{50}$

and

$ETR_{chronic} = W * PEC/LC_{50}$

and

$ETR_{chronic\ larvae} = W * PEC/NOEC$

Where:

W…water uptake of adult bees (= 11.4 µL/bee/d and 111 µL/larva/d)

PEC…predicted environmental concentration in water

PEC (guttation water) = water solubility (0.7 mg/L)

PEC (surface water) = FOCUS Step 1 ($PEC_{sw, vine}$ = 2.48 µg a.s./L)

PEC (water in puddles) = FOCUS Step 1 ($PEC_{sw, vine}$ = 2.48 µg a.s./L) (worst case assumption)

Table B. 9.6.1-9: Risk to honey bees (*Apis mellifera*) from exposure to contaminated water

Crop	Test substance	Exposure route	Endpoint	W	ETR	Trigger
Guttation water						
Cereals 1 x 0.083 kg a.s./ha BBCH 11-39	CHA 4960	Acute oral (adult honey bees)	LD_{50} > 23.9 µg a.s./bee	11.4	< 0.001	0.2
	Fenoxaprop-P-ethyl	Chronic oral (adult honey bees)	LDD_{50} > 10.06 µg a.s./bee/day	11.4	< 0.001	0.03
Surface water						
Cereals 1 x 0.083 kg a.s./ha BBCH 11-39	CHA 4960	Acute oral (adult honey bees)	LD_{50} > 23.9 µg a.s./bee	11.4	< 0.001	0.2
	Fenoxaprop-P-ethyl	Chronic oral (adult honey bees)	LDD_{50} > 10.06 µg a.s./bee/day	11.4	< 0.001	0.03
Water in puddles						
Cereals 1 x 0.083 kg a.s./ha BBCH 11-39	CHA 4960	Acute oral (adult honey bees)	LD_{50} > 23.9 µg a.s./bee	11.4	< 0.001	0.2
	Fenoxaprop-P-ethyl	Chronic oral (adult honey bees)	LDD_{50} > 10.06 µg a.s./bee/day	11.4	< 0.0001	0.03

In conclusion, the risk to honey bees (adults) considering acute and chronic exposure to contaminated drinking water is considered acceptable for the intended use in cereals.

Risk assessment for metabolites

No information has been made available by the applicant.

B.9.6.2. Risk assessment for non-target arthropods

Standard laboratory studies with the two standard arthropod species *Aphidius rhopalosiphi* and *Typhlodromus pyri* have been submitted. In addition, an extended laboratory study with an additional arthropod species *Chrysoperla carnea* was conducted.

Table B. 9.6.2-1: Summary of effects of Fenxoaprop-P-ethyl on non-target-arthropods (laboratory studies)

Test species	Exposure	Test item	Rate [g/ha]	Type of effect	Effect [%]	Reference
Aphidius rhopalosiphi (adults)	contact with dried residues on glass plates	CHA 4960	64.4 128.8 257.5 515 1030	Mortality / Reproduction	0.0 / 137 7.5 /108 15.0 / 110 32.5* / 64 92.5* / not assessed	Schmidt T., 2006a
				48 h LR_{50} = 578 g/ha		
Typhlodromus pyri (protonymphs)	contact with dried residues on glass plates	CHA 4960	64.4 128.8 257.5 515 1030	Corrected mortality / Reproduction	8.3 / 81 2.8 / 95 9.7 / 65 52.8* / not assessed 94.4* / not assessed	Schmidt T., 2006b
				7 d LR_{50} = 478 g/ha		

Non-target arthropods may be exposed to formulated Fenoxaprop-P-ethyl by direct spraying, contact with fresh or dry residues or by oral uptake of contaminated food.

A risk assessment for non-target arthropods was performed according to the recommendations of ESCORT II. In the first tier hazard quotients were calculated for exposure in in-field and off-field areas according to the following formulas:

$$HQ_{in-field} = \frac{\text{application rate} \times \text{MAF}}{LR_{50}}$$

$$HQ_{off\text{-}field} = \text{correction factor} \times \frac{\text{application rate} \times \text{MAF} \times \left(\frac{\text{drift factor}}{\text{vegetation distribution factor}} \right)}{LR_{50}}$$

drift factor = % drift/100 (90 %ile drift according to Ganzelmeier et al. 1995)

The correction factor and the vegetation distribution factor were set to 10. Drift figures were chosen according to crop type in 1 m distance.

The intended use cereals is a single rate of 1.2 L prod./ha, hence no MAF is applied.

Table B. 9.6.2-2: HQ calculations for *Aphidius rhopalosiphi* and *Typhlodromus pyri* in cereals

Species	Application rate [g prod./ha]	MAF	Drift [%]	LR_{50} [g prod./ha]	$HQ_{in\text{-}field}$	$HQ_{off\text{-}field}$
Aphidius rhopalosiphi	1236*	1	2.77	578	**2.1**	0.06
Typhlodromus pyri				478	**2.6**	0.07

*based on a product density of 1.03 g/mL

All HQ-values for both indicator species in-field are above the trigger value of 2 indicating a risk to non-target arthropods. Further refinement is considered necessary. The HQ values regarding the off-field area are below the trigger of 2 and indicate an acceptable risk.

In addition to the two standard laboratory studies, studies with one additional arthropod species was conducted.

Table B. 9.6.2-3: Summary of effects of Fenxoaprop-P-ethyl on non-target-arthropods (extended laboratory studies)

Test species	Exposure	Test item	Rate [ml/ha]	Type of effect	Effect	Reference
Aphidius rhopalosiphi	Dried residues on treated plant surfaces (barley plants)	CHA 4960	14.8 44.4 133 400 1200	Corrected mortality / reduction in parasitisation	[%] -3.4 /51.5 -3.4 / 19.8 -3.4 / 24.4 0.0 / 30.4 0.0 / 43.2	Moll M.,2007
				ER_{50} > 1200 ml/ha		
Typhlodromus pyri	Fresh and aged residues on treated plant surfaces (French bean plants)	CHA 4960	1200	Corrected mortality / Effects on reproduction 0 DAT	[%] 6 / 1.6	Fallowfield, L., 2010
				48 h ER_{50} > 1200 ml/ha		
Chrysoperla carnea (larvae)	dried residues on treated leaf surfaces (bean leaves)	CHA 4960	14.8 44.4 133 400 1200	Corrected mortality / larval hatching rate / eggs per femal	Corr. Mortality [%] 14.7 17.6 -5.9 -2.9 2.9 Larval hatching rate [%] 93.5 88.8 87.5 91.0 87.6 Eggs per female [per day] 25.3 20.5 15.5 18.3	Moll M., 2008b
				48 h ER_{50} > 1200 ml/ha		

Under consideration of a field rate of 1200 ml/ha the risk to non-target arthropods is considered acceptable. No statistically significant adverse effects were observed at the field rate or at the drift rate.

B.9.7. EFFECTS ON NON-TARGET SOIL MESO- AND MACROFAUNA

Additional studies on the reproductive toxicity of the representative formulation Fenoxaprop-P-ethyl 69 g/L EW (CHA 4960) were submitted by the notifier for the re-newal of the EU approval of Fenxoaprop-P-ethyl.

New studies on other soil macro-organisms (*Hypoaspis aculeifer*, *Folsomia candida*) were submitted with the formulation Fenoxaprop-P-ethyl 69 g/L EW (CHA 4960).

The study summaries for studies with the active substance Fenoxaprop-P-ethyl and the soil metabolites are provided in the RAR, Volume 3, B.9 (A.S.). The study summaries for the studies with the formulation CHA 5960 are given below.

B.9.7.1. Earthworms

According to the data requirements for active substances (Commission Regulation (EU) 283/2013) and/or plant protection products (Commission Regulation (EU) 284/2013) no acute toxicity tests with earthworms are required. A new acute toxicity study was submitted for the renewal of the active substance Fenoxaprop-P-ethyl. The study has not been evaluated by the RMS.

Reference: Lürs, U. (2005): Acute Toxicity (14 Days) of Fenoxaprop-P-ethyl 69 g/L EW to the Earthworm Eisenia fetida in Artificial Soil
Guideline: OECD Guideline 207 (1984) and ISO 11268, part 1 (1993)
GLP: Yes
Proposed endpoint by author: 14 days LC_{50}= 356.6 mg test item/kg dry weight soil (25.4 mg a.s./kg soil)

In order to address new data requirements according to Regulation (EC) No. 1107/2009, a study on chronic exposure to earthworms has been performed with Fenoxaprop 69 g/L EW.

Reference:	**Fenoxaprop-P-ethyl 69 g/L EW Earthworm (*Eisenia fetida*), Effects on Reproduction**
Author(s), year:	Krome, K., 2010
Report/Doc. number:	100528CM / 373 FPE
Guideline(s):	OECD 222 (2004), ISO 11268-2 (1998)
GLP:	Yes
Deviations:	Deviations: deviation in soil moisture as it exceeded 10% of the initial soil moisture at the end of the test. This was considered to be a minor deviation

	(+23%) of no biological significance and no impact on study integrity as the control group validity criteria were satisfied
Validity:	Acceptable

Material and methods:

Test substance:	Fenoxaprop 69 g/L EW, Batch no.: 660-PSH-76, 71.8 g/L Fenxoaprop-P-ethyl (analysed), density: 1.03 g/ml
Test species:	Earthworm *Eisenia fetida* (Savigny, 1826)
Number of organisms:	8 replicates per control and 4 replicates per treatment group, each with 10 individuals.
Weight, age:	Mean: 0.3 – 06 g/worm, adults with clitellum, approximately 2-12 months
Type of test, duration:	Laboratory sub-lethal test, 8 weeks (4 weeks adult mortality, 4 weeks juvenile development)
Applied concentrations:	Nominal: 0 (artificial soil moistened with demineralised water), 13.5, 27, 53.8, 107.6 and 215.2 mg test item/kg soil dw
Solvent:	None
Toxic standard:	Carbendazim, tested at concentrations of 1, 2.5, and 5 mg a.s.kg soil dw
Test substrate:	Artificial soil, 10 % peat air dried and finely ground, 20 % kaolin clay, 69 % air dried quartz sand, 0.35% calcium carbonate
Substrate/test vessel:	600 g dry weight/test container
Temperature:	17.5 – 22.5 °C
Light regime:	16 hours light (400-800 lx) / 8 hours dark
Water content:	Test start: 26.7-28.5% Test end: 32.5-38.2%
pH:	Test start: 6.06 – 6.22 Test end: 6.70 – 6.97
Feeding:	The earthworms were fed with cattle manure weekly. At test start and at day 28 the food was mixed into the soil, on the other days food was placed on the soil surface.
Test parameters:	At start and end of the test, pH-value and moisture content of the test medium were determined in every treatment and control from pooled samples of replicates. Water content of the test container was checked weekly by weighing. If necessary, the weight loss was replenished with the appropriate amount of demineralised water. The body weight of the adult earthworms was individually determined at day 0 and day 28 for each test container. After the first four weeks the adult earthworms were removed. Mortality and morphological changes were recorded for each test container. After the first four weeks the adult earthworms were removed. Mortality and morphological changes were recorded for each test container. After further four weeks, the number of offspring hatched from the cocoons was counted for each test container.

Statistics: One Way Analysis of Variance (ANOVA) was carried out for the determination of statistically significant differences compared to the control. A Normality Test and an Equal Variance Test were conducted prior to running the ANOVA. P-values for both Normality and Equal Variance test are 0.05. The α-value for ANOVA test (acceptable probability of incorrectly concluding that there is a difference) is α = 0.05.

Findings:

Analytical results: The recovery of the active ingredient; Fenoxaprop-P-ethyl, in the application solutions ranged between 95 – 109 % of the nominal concentrations.

Table B. 9.7.1-1: Reproductive toxicity of Fenoxaprop-P-ethyl 69 g/L EW to the earthworm *Eisenia fetida*

Fenoxaprop-P-ethyl 69 g/L EW [mg product/kg]	**Control**	**13.5**	**27.0**	**53.8**	**107.6**	**215.2**
[mg Fenoxaprop-P-ethyl kg dry soil]	-	0.94	1.88	3.75	7.50	15.0
Adult mortality (day 28) [%]	0	0	0	0	0	10
Weight change (day 28) [%]	39.1 ± 6.28	37.3 ± 7.60	31.2 ± 4.97	34.5 ± 4.74	34.9 ± 5.26	35.6 ± 5.65
No. of juveniles (day 56)	263 ± 45.4	257 ± 37.6	258 ± 20.5	251 ± 35.2	235 ± 24.9	229 ± 26.3
Reproduction in [%] of control (day 56)	-	97.6	97.9	95.4	89.0	87.0
Endpoints [mg product/kg dry soil]						
NOEC (reproduction, mortality and weight)	> 215.2					
LOEC (reproduction, mortality and weight)	215.2					

Validity criteria Mortality and weight loss in the control group were within the limits set by the validity criteria of the study.

Conclusion: In the earthworm reproduction and growth study with Fenoxaprop-P-ethyl 69 g/L EW, the NOEC (reproduction, mortality and growth) and was determined to be >215.2 mg/kg soil dry weight. Corrected by a factor of 2 due to the high log Pow of 4.58 of Fenoxaprop-P-ethyl this results in an endpoint of 107.6 mg product/kg soil dry weight or 7.72 mg active substance/kg soil dry weight.

Comment RMS: **Validity:** The study was evaluated following the recommendations of the test guideline OECD 222 (July, 2016)

Check of validity criteria:

- each replicate (containing 10 adults) to have produced ≥ 30 juveniles by the end of the test: fulfilled, mean offspring number was 263.4.
- the coefficient of variation of reproduction to be ≤ 30 %: fulfilled, the coefficient of variation was 17.2 %.

- adult mortality over the initial 4 weeks of the test to be ≤ 10 %: fulfilled: adult mortality was 0.0 %

Acceptability of the analytical methods used in the test: Not relevant as no analytics were performed

Endpoints:

NOEC values body weight change and reproduction were determined. An analysis of the statistical power of the test was not performed, but the study design is in line with the recommendations of the currently valid guideline. An EC_X was not calculated, but the study was also not designed to generate EC_X values, though respective recommendations for test-design are included in the cited guideline. However, the statistics were re-calculated with the software tool Toxrat pro 3.1.0:

LC_{10} = not determined

LC_{20}= not determined

LC_{50} = not determined

NOEC $_{mortality}$ = not determined

$EC_{10\ reproduction}$ = 8.825 mg/kg sdw (95% C.L. = 1.464; 53.206), Normalised width = 5.863, EC_{10} considered not reliable

$EC_{50\ reproduction}$ = not determined

NOEC $_{reproduction}$ = > 215.2 mg/kg sdw (Williams Multiple Sequential t-test)

$EC_{10\ weight\ change}$ = 0.023 mg/kg sdw (95% C.L. = not determined; 13.214), Normalised width = 574 (0 is used for lower C.L.), EC_{10} considered not reliable

$EC_{20\ weight\ change}$ = not determined

$EC_{50\ weight\ change}$ = not determined

NOEC $_{weight\ change}$ = not determined

EC_x concentrations were calculated by 3-parametric normal cumulative distribution function.

The RMS proposes as conservative approach a lower endpoints as given in the study report due to effects on reproduction which could be deemed as biologically relevant.

NOEC = 53.8 mg/kg sdw (uncorrected)

Conclusion of the RMS:

The study is considered to be valid.

B.9.7.2. Effects on non-target soil meso- and macrofauna (other than earthworms)

Reference:	**Effects of Fenoxaprop-P-ethyl 69 g/L EW on the reproduction of the Collembola *Folsomia candida***
Author(s), year:	Friedrich, F., 2016g
Report/Doc. number:	Study no. 16 10 48 146 S, 581 FPE
Guideline(s):	OECD 232 (2009)
GLP:	Yes
Deviations:	None
Validity:	Acceptable

Material and methods:

Test substance:	Fenoxaprop-P-ethyl 69 g/L EW (CHA 4960), Batch no.: 0001002083, 70.0 g/L Fenxoaprop-P-ethyl (analysed), safener: 34.2 g/L cloquintocet-mexyl (analysed), density: 1.03 g/mL
Test species:	Collembola *Folsomia candida* (Willem, 1902)
Number of organisms:	8 replicates per control and 4 replicates per treatment group, 2 additional replicate per treatment and control to check the pH and water content of the test substrate after 28 days, each replicate with 10 individuals.
Life stage, age:	Juveniles / adults, 9-12 days old
Type of test, duration:	Laboratory sub-lethal test, 28 days
Applied concentrations:	Nominal: 0 (control), 32.7, 58.8, 106, 191, 343, 617, 1111 and 2000 mg prod./kg soil dw
Solvent:	None
Toxic standard:	Boric acid, Purity: 100.0% (analysed), concentrations: 44, 67, 100, 150 and 225 mg/kg soil dw
Test substrate:	Artificial soil, 5 % sphagnum peat, 20 % kaolin clay, 74.7 % industrial quartz sand, 0.3% calcium carbonate, deionised water
Substrate/test vessel:	30 g wet weight, crumbly structured
Temperature:	19.2 – 21.9 °C
Light regime:	16 hours light (540 lx) / 8 hours dark
Water content:	Test start: 24.9 – 25.0% (equivalent to 58.3 – 58.5% of WHC) Test end: 24.4 – 24.9% (equivalent of 57.1 – 58.3% of WHC)
pH:	Test start: 6.04 – 6.22 Test end: 5.85 - 5.91
Feeding:	Granulated dry yeast
Test parameters:	pH and water content were determined at test start and test end. Water content maintenance was checked on day 14 after application.

Mortality of adults, behavioural effects and number of juvenile Collembola were assessed after 28 days

Statistics: The statistical analysis was performed with the software ToxRat Professional 3.2.1 (Ratte 2015). Multiple Sequentially-rejective Fisher Test After Bonferroni-Holm and the Williams-t-test were used to compare the control with the independent test item groups. Mortality of adult collembolans was corrected using the formula by Abbott (1925). The LCx and ECx values were calculated using the Trimmed Spearman-Karber procedure and by Probit analysis using the maximum likelihood regression, respectively. Confidence limits (95%) of the ECx values were computed by normal approximation.

Findings:

Table B. 9.7.2-1: Effects of Fenoxaprop-P-ethyl 69 g/L EW on mortality of parental collembolans

Treatment group	mg test item/kg soil d.w.								
	Control	**32.7**	**58.8**	**106**	**191**	**343**	**617**	**1111**	**2000**
Replicate	**Number of surviving parental collembolans per replicate (4 weeks after test initiation)**								
1	10	10	10	10	9	3	0	0	0
2	10	9	10	10	10	3	0	0	0
3	9	10	9	9	10	3	0	0	0
4	10	10	10	10	10	4	0	0	0
5	9								
6	10								
7	9								
8	10								
Mean	**9.6**	**9.8**	**9.8**	**9.8**	**9.8**	**3.3**	**0.0**	**0.0**	**0.0**
SD	0.5	0.5	0.5	0.5	0.5	0.5	0.0	0.0	0.0
cv (%)	5.4	5.1	5.1	5.1	5.1	15.4	-	-	-
Mortality (%)	**3.8**	**2.5**	**2.5**	**2.5**	**2.5**	**67.5***	**100.0***	**100.0***	**100.0***

* statistically significantly different compared to control (Multiple Sequentially-rejective Fisher Test After Bonferroni-Holm for mortality, $\alpha = 0.05$, one-sided greater)
SD: standard deviation, cv %: coefficient of variation, d.w.: dry weight (of artificial soil)

Table B. 9.7.2-2: Effects of Fenoxaprop-P-ethyl 69 g/L EW on number of juvenile collembolans

Treatment group	mg test item/kg soil d.w.								
	Control	**32.7**	**58.8**	**106**	**191**	**343**	**617**	**1111**	**2000**
Replicate	**Number of juveniles per replicate (4 weeks after test initiation)**								
1	897	1125	1144	1216	1117	52	22	5	0
2	1262	853	1023	1365	1396	101	42	22	0
3	1224	1191	997	782	868	165	19	19	0
4	893	1189	981	873	756	113	26	24	0
5	986								
6	952								
7	1153								
8	1097								
Mean	**1058**	**1090**	**1036**	**1059**	**1034**	**108***	**27***	**18***	**0***
SD	146.0	160.6	73.9	276.7	284.5	46.4	10.2	8.6	0.0
cv (%)	13.8	14.7	7.1	26.1	27.5	43.1	37.6	49.0	-
Reduction of reproduction	**-**	**-3**	**2**	**0**	**2**	**90**	**97**	**98**	**100**

(% compared to control)									

* statistically significantly different compared to control (Williams-t-test for reproduction, $\alpha = 0.05$, one-sided smaller)
calculations were done using unrounded values
Percent reduction: $(1-R_t/R_c) * 100$ %
R_t = mean number of juveniles observed in the treated groups
R_c = mean number of juveniles observed in the control group
Negative values = increase, relative to control

Table B. 9.7.2-3: Effects of Fenoxaprop-P-ethyl 69 g/L EW on collembolans: summary of statistical analysis

Endpoints	mg test item/kg soil dry weight
NOEC (mortality)	**191**
NOEC (reproduction)	**191**
LC_{50} (mortality) [1]	**312** (95 % confidence limits 286 to 341)
EC_{10} (reproduction) [2]	**217** (95 % confidence limits 197 to 239)
EC_{20} (reproduction) [2]	**235** (95 % confidence limits 217 to 255)
EC_{50} (reproduction) [2]	**273** (95 % confidence limits 259 to 288)

[1] Trimmed Spearman-Karber procedure; [2] Probit analysis

Conclusion: In a 28-day Collembola reproduction study with Fenoxaprop-P-ethyl 69 g/L EW, the LC_{50} value for mortality was calculated to be 312 mg test item/kg soil dry weight. The NOEC for mortality of the parental collembolans and for reproduction was determined to be 191 mg test item/kg soil dry weight. The EC_{10}, EC_{20} and EC_{50} values (based on reproduction) were calculated to be 217, 235 and 273 mg test item/kg soil dry weight, respectively.

Comment RMS: **Validity:** The study was evaluated following the recommendations of the test guideline OECD 232 (July, 2016)
Check of validity criteria:
- Mean adult mortality should not exceed 20% at the end of the test: fulfilled, actual value in test was 3.8%
- The mean number of juveniles per vessel should be at least 100 at the end of the test: fulfilled, actual value in test was 1058
- The coefficient of variation calculated for the number of juveniles should be less than 30% at the end of the definitive test: fulfilled actual value in test = 13.8%

Acceptability of the analytical methods used in the test: Not relevant as no analytics were performed

Endpoints:

	A NOEC, EC_{10}, EC_{20} and an EC_{50} values were determined. An analysis of the statistical power of the test is not considered necessary as the test followed the recommendations of the cited guideline for deriving a NOEC. The statistics were re-calculated with the software tool Toxrat pro 3.1.0: LC_{10} = 138.59 mg/kg sdw (95% C.L. = n.d.; n.d.) LC_{20} = 176.912 mg/kg sdw (95% C.L. = = n.d.; n.d.) LC_{50} = 282.222 mg/kg sdw (95% C.L. = = n.d.; n.d.) $NOEC_{mortality}$ = 191 mg/kg sdw $EC_{10\ reproduction}$ = 216.273 mg/kg sdw (95% C.L. = 149.904; 312.04), Normalised width = 0.75, EC_{10} considered reliable $EC_{20\ reproduction}$ = 234.156 mg/kg sdw (95% C.L. = 166.627; 334.017) $EC_{50\ reproduction}$ = 272.591 mg/kg sdw (95% C.L. = 183.867; 409.305) $NOEC_{reproduction}$ = 191 mg/kg sdw (Bonferroni Welch-test) EC_x concentrations were calculated by 3-parametric normal cumulative distribution function. The RMS agrees on the endpoints given in the study report. A reliable EC_{10} could be identified in addition. **Conclusion of the RMS:** The study is considered to be valid.

Reference:	**Effects of Fenxoaprop-P-ethyl 69 g/L EW on reproduction of the predatory mite *Hypoaspis aculeifer***
Author(s), year:	Schulz, L., 2016g
Report/Doc. number:	Report no. 16 10 48 147 S, 580 FPE
Guideline(s):	OECD 226 (2008)
GLP:	Yes
Deviations:	None
Validity:	Acceptable

Material and methods:

Test substance:	Fenoxaprop-P-ethyl 69 g/L EW (CHA 4960), Batch no.: 0001002083, 70.0 g/L Fenxoaprop-P-ethyl (analysed), safener: 34.2 g/L cloquintocet-mexyl (analysed), density: 1.03 g/mL
Test species:	Predatory mites, *Hypoaspis aculeifer* (Canestrini, 1883)
Number of organisms:	8 replicates per control and 4 replicates per treatment group, 2 additional replicate per treatment and control to check the pH and water content of the test substrate

	after 14 days, each replicate with 10 female adults.
Life stage, age:	Adults from a synchronised culture with an age difference of 2 days
Type of test, duration:	Laboratory sub-lethal test, 14 days
Applied concentrations:	Nominal: 0 (control), 32.7, 58.8, 106, 191, 343, 617, 1111 and 2000 mg prod./kg soil dw
Solvent:	None
Toxic standard:	Dimethoate, purity: 99.8 % (analysed)
Test substrate:	Artificial soil, 5 % sphagnum peat, 20 % kaolin clay, 74.8 % industrial quartz sand, 0.2% calcium carbonate
Substrate/test vessel:	20 g dry weight/test container
Temperature:	19.8 – 20.7 °C
Light regime:	16 hours light (421 lx) / 8 hours dark
Water content:	Test start: 17.31 – 18.83% (equivalent to 45.71 – 49.74% of WHC) Test end: 17.07 – 18.23% (equivalent of 45.09 – 48.14% of WHC)
pH:	Test start: 5.9 – 6.0 Test end: 5.5 – 5.7
Feeding:	*Tyrophagus putrescentiae* (SCHRANK), supplied twice to three times a week
Test parameters:	pH and water content were determined at test start and test end. Water content maintenance was checked on day 7 after application. Mortality of adults and number of juveniles were assessed after 14 days
Statistics:	Mortality: Fisher´s Exact Binomial Test with Bonferroni Correction (α = 0.05, one-sided greater), Trimmed Speraman-Karber procedure for LCx estimation. Reproduction: Williams-t-test (α = 0.05, one-sided smaller), Probit analysis using linear max. likelihood regression for ECx estimation

Findings:

Table B. 9.7.2-4: Effects of the test item on mortality of adult mites

Treatment group (mg test item / kg soil d.w.)	Number of surviving adult mites per replicate (14 days after test start)								Mean	Standard deviation	Mortality [%]
	1	2	3	4	5	6	7	8			
Control	8	10	10	9	10	10	10	10	9.6	0.7	3.8
32.7	10	10	10	10	-	-	-	-	10.0	0.0	0.0
58.8	10	10	10	9	-	-	-	-	9.8	0.5	2.5
106	10	10	10	8	-	-	-	-	9.5	1.0	5.0
191	10	10	10	10	-	-	-	-	10.0	0.0	0.0
343	9	10	10	10	-	-	-	-	9.8	0.5	2.5
617	10	10	8	9	-	-	-	-	9.3	1.0	7.5
1111	2	1	0	3	-	-	-	-	1.5 *	1.3	85.0
2000	2	1	0	0	-	-	-	-	0.8 *	1.0	92.5

* statistically significantly different compared to the control (Fisher's Exact Binomial Test with Bonferroni Correction for mortality,α = 0.05, one-sided greater)

Table B. 9.7.2-5: Effects of the test item on number of juvenile mites

Treatment group (mg test item / kg soil d.w.)	Number of juvenile mites per replicate (14 days after test start)								Mean	Standard deviation	Coefficient of variation [%]	Reproduction [% to control]
	1	2	3	4	5	6	7	8				
Control	295	279	276	161	291	258	258	307	265.6	45.6	17.2	100
32.7	353	278	232	322	-	-	-	-	296.3	52.7	17.8	112
58.8	285	310	339	317	-	-	-	-	312.8	22.2	7.1	118
106	277	265	306	346	-	-	-	-	298.5	36.0	12.1	112
191	248	250	315	260	-	-	-	-	268.3	31.6	11.8	101
343	219	263	202	196	-	-	-	-	220.0 *	30.3	13.8	83
617	13	39	46	44	-	-	-	-	35.5 *	15.3	43.1	13
1111	0	0	1	1	-	-	-	-	0.5 *	0.6	115.5	0
2000	0	0	0	0	-	-	-	-	0.0 *	0.0	-	0

* statistically significantly different compared to the control (Williams-t-test for reproduction, α = 0.05, one-sided smaller)

Table B. 9.7.2-6: Effects of the test item on *Hypoaspis aculeifer*: 14-d endpoints

Endpoint	mg test item/kg soil d.w.
NOEC (mortality)	617
NOEC (reproduction)	191
LC_{50} (mortality)	448.9 (95 % confidence limits 297.0 - 678.4)
EC_{10} (reproduction)	311.8 (95 % confidence limits 310.5 - 313.1)
EC_{20} (reproduction)	353.5 (95 % confidence limits 352.3 - 354.7)
EC_{50} (reproduction)	449.5 (95 % confidence limits 448.3 - 450.8)

Conclusion: In a 14-day *Hypoapsis aculeifer* reproduction study with Fenoxaprop-P-ethyl 69 g/L EW, the LC_{50} value for mortality was calculated to be 921.4 mg test item/kg soil dry weight. The NOEC values for mortality and for reproduction were determined to be 617 and 191 mg test item/kg soil dry weight, respectively. The EC_{10}, EC_{20} and EC_{50} values (based on reproduction) were calculated to be 311.8, 353.5 and 449.5 mg test item/kg soil dry weight.

Comment RMS: **Validity:** The study was evaluated following the recommendations of the test guideline OECD 226 (July, 2016)

Check of validity criteria:

- control treatment mortality should not exceed 20% at the end of the test: fulfilled,

actual value in definitive test = 3.8%).
- the mean number of juvenile recorded in the control treatment should be at least 50 per replicate at the end of the test: fulfilled, actual value in definitive test = 265.6.
- the coefficient of variation of reproduction in the control should not exceed 30%: fulfilled, actual value in definitive test = 3.8.

Acceptability of the analytical methods used in the test: Not relevant as no analytics were performed

Endpoints:
A NOEC, EC10, EC20 and an EC_{50} values were determined. An analysis of the statistical power of the test is not considered necessary as the test followed the recommendation of the cited guideline.
The statistics were re-calculated with the software tool Toxrat pro 3.1.0.

LC_{10} = 321.201 mg/kg sdw (95% C.L. = n.d.; n.d.)
LC_{20} = 446.916 mg/kg sdw (95% C.L. = n.d.; n.d.)
LC_{50} = 840.73 mg/kg sdw (95% C.L. = n.d.; n.d.)
$NOEC_{mortality}$ = 617 mg/kg sdw
$EC_{10\ reproduction}$ = 289.687 mg/kg sdw (95% C.L. = 240.534; 348.884), Normalised width = 0.4, EC_{10} considered reliable
$EC_{20\ reproduction}$ = 332.439 mg/kg sdw (95% C.L. = 277.13; 399.532)
$EC_{50\ reproduction}$ = 432.597 mg/kg sdw (95% C.L. = 344.543; 539.8)
$NOEC_{reproduction}$ = 191 mg/kg sdw (Williams t-test)
EC_x concentrations were calculated by 3-parametric normal cumulative distribution function.

The RMS agrees on the endpoints given in the study report:
$NOEC_{mortality}$ = 617 mg a.s./kg soil
$NOEC_{reproduction}$ = 191 mg a.s./kg soil

Conclusion of the RMS:
The study is considered to be valid.

B.9.8. RISK ASSESSMENT FOR NON-TARGET SOIL MESO- AND MACROFAUNA

Table B. 9.8-1: Summary of effects on soil meso- and macrofauna

Species	Substance	Endpoint	Reference
Eisenia fetida	CHA 4960	NOEC = 53.8 mg a.s./kg soil dw	Krome, K., 2010
	Fenxoaprop-P-ethyl	NOEC ≥ 56 mg/kg soil dry weight	Friedrich, S., 2014
	Fenxoaprop-P-acid	NOEC = 100 mg/kg soil dw	Friedrich, S., 2006
	Chlorobenzoxazolone	NOEC = 89 mg/kg soil dw	Friedrich, S., 2016
	HOPP acid	NOEC = 158 mg/kg soil dw	Friedrich, S., 2016
Folsomia candida	CHA 4960	NOEC = 191 mg/kg soil dw	Friedrich, F., 2016
	Fenxoaprop-P-ethyl	NOEC ≥ 1000 mg/kg soil dw	Friedrich, S., 2015
	Fenoxaprop-P-acid	NOEC ≥ 111.6 mg/kg soil dw	Friedrich, S., 2015
	Chlorobenzoxazolone	NOEC ≥ 100 mg/kg soil dw	Friedrich, S., 2016
	HOPP acid	NOEC ≥ 100 mg/kg sdw	Friedrich, S., 2016
Hypoaspis aculeifer	CHA 4960	NOEC = 191 mg /kg soil dw	Schulz, L., 2016
	Fenxoaprop-P-ethyl	NOEC ≥ 1000 mg/kg soil dw	Lopez, M. I. L., 2015
	Chlorobenzoxazolone	NOEC ≥ 100 mg/kg sdw	Schulz, L., 2016
	Fenoxaprop-P-acid	NOEC ≥ 111.6 mg/kg soil dw	Schulz, L., 2015

The risk assessment for soil organisms was conducted according to the Terrestrial Guidance Document (SANCO/10329/2002).

The endpoints for the active substance / the representative formulation were corrected by a factor of 2 irrespective of the peat content in the study. During an EFSA expert meeting (PRAS 91, April 2012) the use of a correction factor for substances with a log P_{OW} > 2 was discussed and it was agreed that the correction factor should always be used for those substances, unless it can be demonstrated that toxicity to earthworms is independent of f_{oc}.

Table B. 9.8-2: TER long-term for earthworms and other soil macro-organisms

GAP use	Test substance	NOEC [mg/kg soil dw]	max PEC_{soil} [mg/kg soil dw]	TER_{LT}	Trigger
Earthworms					
Cereals 1 x 1.2 L form./ha	CHA 4960	NOEC = 26.9 *	1.648	> 16	5
	Fenxoaprop-P-ethyl	NOEC ≥ 28 *	0.111	≥ 252	5
	Fenxoaprop-P-acid	NOEC = 100	0.097	1030	5
	Chlorobenzoxazolone	NOEC = 89	0.01	8900	5
	HOPP acid	NOEC = 158	0.041	3853	5
Folsomia candida					
Cereals 1 x 1.2 L form./ha	CHA 4960	NOEC = 95.5 mg *	1.648	58	5
	Fenxoaprop-P-ethyl	NOEC ≥ 500 *	0.111	≥ 4504	5
	Fenoxaprop-P-acid	NOEC ≥ 111.6	0.097	≥ 1150	5
	HOPP acid	NOEC ≥ 50 *	0.041	≥ 1219	5

GAP use	Test substance	NOEC [mg/kg soil dw]	max PEC_{soil} [mg/kg soil dw]	TER_{LT}	Trigger
	Chlorobenzoxazolone	NOEC ≥ 100	0.01	≥ 5000	5
Hypoaspis aculeifer					
Cereals 1 x 1.2 L form./ha	CHA 4960	NOEC = 95.5 *	1.648	58	5
	Fenxoaprop-P-ethyl	NOEC ≥ 500 *	0.111	≥ 4504	5
	HOPP acid	NOEC ≥ 50 *[1]	0.041	≥ 1219	5
	Chlorobenzoxazolone	NOEC ≥ 100	0.01	≥ 5000	5
	Fenoxaprop-P-acid	NOEC ≥ 111.6	0.097	≥ 1150	5

* corrected by a factor of 2 due to the log P_{OW} of Fenxoaprop-P-ethyl > 2
[1] parent/10

The long-term risk to earthworms was identified to be acceptable. The TER_{LT} values are above the relevant trigger indicating an acceptable risk.

The risk to the other soil macro-organisms, *Folsomia candida* and *Hypoaspis aculeifer* was identified to be acceptable. The TER_{LT} values are above the relevant trigger indicating an acceptable risk.

B.9.9. EFFECTS ON SOIL NITROGEN TRANSFORMATION

According to the EU data requirements for active substances (Regulation 283/2013) and plant protection products (Regulation 284/2013) the impact on soil microbial activity should be evaluated, in terms of nitrogen transformation.

In addition to the studies with the active substance a new nitrogen and carbon mineralisation study with the representative formulation Fenoxaprop-P-ethyl 69 g/L EW (CHA 4960) was submitted. A summary of the study is provided below.

Reference:	**Effects of Fenoxaprop-P-ethyl 69 g/L EW on the Activity of the Soil Microflora in the Laboratory**
Author(s), year:	Reis, K.-H, 2005
Report/Doc. number:	Report no.: 24787080, 112 FPE
Guideline(s):	OECD 216/217 (2000)
GLP:	Yes
Deviations:	None
Validity:	Acceptable

Material and methods:

Test substance:	Fenoxaprop-P-ethyl 69 g/L EW (CHA 4960), Batch no.: 660-PSH-49, 7.11 % w/w Fenxoaprop-P-ethyl (analysed), safener: 3.41 % w/w cloquintocet-mexyl (analysed), density: 1.03 g/mL
Test species:	Soil microorganisms
Type of test, duration:	Nitrogen transformation test, 28 days,
Applied concentrations:	Control, 2.75 mg test item/kg soil dry weight and 13.73 mg test item/kg soil dry weight
Toxic standard:	Dinoterb Acetate was applied at a rate of 16 mg/kg dry soil
Test substrate:	The soil used in this study was according to the Guidelines and was taken from a fallow grass land near Rossdorf. For at least two years prior to test initiation, no pesticides had been used on the soil. No organic or mineral fertilizer had been applied to the soils for two years prior to study initiation, respectively. The field was let test since 2000.

Soil origin	**pH**	**OC (%)**	**Clay (%)**	**Silt (%)**	**Sand (%)**	**CEC (mmol Ba/kg dry wt)**	**NO_3-N (mg/kg dry wt)**	**Microbial biomass (mg C/kg dry soil)**
Germany	6.9	1.06	10.4	30.9	58.7	66.5	20.47	727

Substrate/test vessel:	Disposable plastic boxes, 250 g to 500 g (dry weight), box size approx. 0.5 L. The soil was loosely filled into the boxes and they were covered by perforated lids to enable a slight, but sufficient air exchange (to ensure aerobic incubation

conditions).

Incubation: 20 ±2 °C

Water content: Soil moisture: 49 to 52 % of its maximum water holding capacity. The water content was controlled at day 0 and afterwards once a week until experimental end by re-weighing the test containers and adding evaporated water.

pH: pH was determined at test start and at each sampling date. pH 7.1 – 7.3

Test parameters: For the determination of nitrogen content, soil samples were taken within 6 hours after application and afterwards on each sampling date (7, 14 and 28 days). The nitrogen content was determined in each sample of treated and control soils. Extraction was done using 0.1 M KCL-solution. For the extraction, approximately 25 g soil were suspended in 100 mL KCL-solution and agitated one hour. The suspension was centrifuged and the extracts were filtrated using nitrogen-free membrane filters. The amounts of NH_4^+, NO_2^- and NO_3—N/kg soil dry weight. The Nmin-content is calculated from the three nitrogen species (sum of nitrite-N, nitrate-N and ammonium-N).

Statistics: Data were tested for normality and homogeneity of variance using R/S Test (α = 0.05) and Bartlett´s-Test (α = 0.05). Student-t-test (pair wise comparison, two sided, α = 0.05) was used for analysis.

Findings:

Biological results: The soil nitrate formation rate deviated by less that ±25% from the control at the test concentration 2.75 mg/kg dry soil, throughout the test. At day 28 the difference from control was 5.6%. At the higher test concentration the soil nitrate formation rate value deviated by more than ±25% from the control between days 7 and 14, however between days 14 and 28 the rate fell below the trigger value of 25%. Thus CHA 4960 has no long-term influence on nitrogen transformation in soils.

Table B. 9.9-1: Effects of CHA 4960 on soil nitrogen transformation in a loamy sand soil

	Mean NO3 – Nitrogen Formation rate (mg / kg soil dry weight/day)				
	Control	**2.75 mg CHA 4960/kg dry soil**		**13.73 mg CHA 4960/kg dry soil**	
	Nitrate–N Formation	**Nitrate-N-Formation**	**Deviation[1]**	**Nitrate-N-Formation**	**Deviation[1]**
Day 0-7	-2.35	-2.33	-0.8	-2.51	6.8
Day 7-14	0.76	0.63	-17.1	0.50	-34.2
Day 14-28	1.07	1.13	5.6	1.16	8.4

1 = % deviation to control

Conclusion: Fenoxaprop-P-ethyl 69 g/L EW (CHA 4960) will not have a long term influence on soil microflora, even when applied at 5 × the recommended application rate (13.73 mg CHA 4960/kg dry soil).

Comment RMS:	**Validity:** The study was evaluated following the recommendations of the test guideline OECD 216 (2000) Check of validity criteria: - The variation between replicate control samples should be less than ± 15%. **Acceptability of the analytical methods used in the test:** Not relevant as no analytics were performed. **Endpoints:** The RMS agrees on the endpoints given in the study report: No long-term adverse effect on nitrogen turnover up to 13.73 mg test item/kg soil dry weight. **Conclusion of the RMS:** The study is considered to be valid**.**

B.9.10. RISK ASSESSMENT FOR SOIL NITROGEN TRANSFORMATION

Table B. 9.10-1: Summary of effects on non-target micro-organisms

Test substance	Test parameter	Test concentration	Time	Effects (deviation from control)	Reference
CHA 4960	Nitrogen mineralisation	2.75 mg from./kg dry soil	28 days	+1.13	Reis, K.-H, 2005
		13.73 mg/kg soil dw		+1.16	
Fenoxaprop-P-ethyl		0.133 mg /kg dry soil	56 days	+ 0.3	McMurray A., 2002
		0.67 mg /kg dry soil		+ 5.4	
Fenoxaprop-P-ethyl		0.11 mg/kg soil dw	42 days	1.6%	Reis, K.-H.., 2008
		0.55 mg/kg soil dw		-19%	
Fenoxaprop-P-acid		0.1049 mg/kg soil dw	28 days	-3.7	Schulz, L., 2016b
		0.5244 mg/kg soil dw		+24.8	
Chlorobenzoxazolone		0.053 mg/kg soil dw	28 days	+2.1	Schulz, L., 2016c
		0.263 mg/kg soil dw		-12	
HOPP acid		0.060 mg/kg soil dw	28 days	-6.5	Schulz, L., 2016d
		0.3 mg/kg soil dw		-5.3	

According to the Terrestrial Guidance Document (SANCO/10329/2002) the risk is considered acceptable if the effect on nitrogen mineralisation at a recommended application rate is below 25% after 100 days.

Table B. 9.10-2: Risk assessment

Test substance	Effects < 25% at test concentration	$PEC_{soil, max}$	Risk acceptable?
CHA 4960	13.73 mg from./kg dry soil	1.648 mg form./kg soil dw	Yes
Fenoxaprop-P-ethyl	0.67 mg/kg soil dw	0.111 mg a.s./kg soil dw	Yes
Fenoxaprop-P-acid	0.5244 mg/kg soil dw	0.097 mg a.s./kg soil dw	Yes
Chlorobenzoxazolone	0.263 mg/kg soil dw	0.01 mg a.s./kg soil dw	Yes
HOPP acid	0.3 mg/kg soil dw	0.041 mg a.s./kg soil dw	Yes

The formulated active substance Fenxoaprop-P-ethyl did not significantly affect the activity of the soil nitrogen transformation under test conditions at application rates up to 13.73 mg from./kg dry soil. Furthermore the exposure concentrations in the tests with the active substance and the soil metabolites Fenoxaprop-P-acid, Chlorobenzoxazolone and HOPP acid -propionic acid were significantly higher than the maximal expected PEC_{soil} of the relevant substance when applied according to the GAP. In the study with the metabolite Fenoxaprop-P-acid 24.8 % effect has been seen after 28 days, and an extension of study duration would have been indicated. However as the active substance Fenoxaprop-P-ethyl is rapidly degradated to the metabolite Fenoxaprop-P-acid the risk is considered to be covered by the active substance data.

According to the results of the data provided for the active substance Fenxoaprop-P-ethyl it can be assumed that the risk for soil micro-organisms is low when applied according to the GAP.

B.9.11. EFFECTS ON TERRESTRIAL NON-TARGET HIGHER PLANTS

B.9.11.1. Summary of screening data

Not necessary as guideline GLP studies for terrestrial plants are available (see Section B.9.11.2).

B.9.11.2. Testing on non-target plants

Seedling emergence and vegetative vigour studies have been conducted with the representative formulation Fenoxaprop-P-ethyl 69 g/L EW (CHA 4960) following the OECD test guidelines (OECD 227 and OECD 208). These studies were not evaluated during the first EU peer-review of the active substance.

Reference:	**Effects of Fenoxaprop-P-ethyl 69 g/L EW on seedling emergence of terrestrial plants**
Author(s), year:	Siemoneit, R., 2005a
Report/Doc. number:	Study no. AS11, 114 FPE
Guideline(s):	OECD Guideline 208
GLP:	Yes
Deviations:	None relevant
Validity:	Acceptable

Material and Methods:

Test substance:	Fenoxaprop-P-ethyl 69 g/L EW (CHA 4960), batch no.: 660-PSH-49, Fenoxaprop-P-ethyl 7.11% w/w (analysed)
Type of test:	Seedling emergence test
Test duration:	21 days
Test species:	The non-target plants comprised four dicotyledonous species (Oilseed rape, *Brassica napus*; Pea, *Pisum sativum*; Sugar beet, *Beta vulgaris* var. *altissima*; Carrot, *Daucus carota*) and two monocotyledonous species (Onion, *Allium cepa*; Corn, *Zea mays*).
Test soil:	The soil medium used for the test was classified as a silty sand with a particle size

distribution of 6.6% clay (< 2µm), 29.1% silt (2-63 µm) and 64.3% sand (> 63 µm). The pH was 7.6 and organic carbon content 1.4%.

Applied concentrations: Control: Deionized water

Test item: 40.39, 76.73, 145.79, 277.01, 526.32 and 1000 mL prod./ha

Exposure route: The seeds were sown one day before the application at different densities (5-10 seeds per plot) and depths (0.5-1.5 cm) in the pots according to the requirements of the respective species. There were five replicates per treatment and the pots were completely randomised within each species. The pots were watered one day before application and water was available from bottom watering according to consumption after the application.

Test conditions: Photoperiod: 16 h light, 8 h dark; additional light when outdoor illumination was less than 5 klx

Temperature: 23-28 °C

Relative humidity: 46 – 75 %

Test parameter: Assessments for seedling emergence and phytotoxicity were conducted 7, 14, and 21 DAA (± 1) for all plants. Phytotoxicity was rated as % affected plant per volume of the replicate compared to the control. Ratings were based on the following scale: 0% (= no damage on the plants in the pot) to 100% (= all plants in the pots died off).

Statistics : Calculation of mean values, standard deviations, Analysis of variance (ANOVA) followed by Dunnett´s t-test (α = 5%), two parametric Logit-Model for ER_{25} and ER_{50} calculation.

Findings:

Analytical results: Recovery of active ingredient from the duplicate samples analysed by HPLC at the highest application rate were 95% and 98%.

Biological results: The test was performed under worst case conditions within a greenhouse with good a permanent wetting of the soil in combination with a low clay and organic carbon content of the soil medium which ensured a high availability of Fenoxaprop-P-ethyl 69 g/L EW for the plants. Additionally, the soil was completely uncovered by vegetation at the time of application and the pots were irrigated from the bottom, i.e. the test item could not be removed by dissipation.

Table B. 9.11.2-1: Effects of Fenoxaprop-P-ethyl 69 g/L EW on seedling emergence, phytotoxicity, and plant fresh weight of Oilseed rape 21 DAA (± 1 day)

Test rate		Oilseed rape (*Brassica napus*) mean values per test rate		
[mL test item/ha]	[g a.s./ha]	Seedling emergence [number seedlings/replicate]	Phytotoxicity [% visual damage]	Plant fresh weight [g/replicate]
0	0	5.8 of 6	0	10.71

40.39	2.96	5.6 of 6	0	9.59
76.73	5.62	5.8 of 6	0	9.77
145.79	10.7	5.8 of 6	0	10.14
277.01	20.3	6 of 6	0	7.32*
526.32	38.5	5.6 of 6	0	8.54
1000	73.2	6 of 6	0	7.07*

*mean of replicates is statistically significantly different from the mean of the control replicates, Dunnett's test, $p \leq 0.05$

Table B. 9.11.2-2: Effects of Fenoxaprop-P-ethyl 69 g/L EW on seedling emergence, phytotoxicity, and plant fresh weight of Pea 21 DAA (± 1 day)

Test rate		Pea (*Pisum sativum*) mean values per test rate		
[mL test item/ha]	[g a.s./ha]	Seedling emergence [number seedlings/replicate]	Phytotoxicity [% visual damage]	Plant fresh weight [g/replicate]
0	0	4.8 of 5	0	15.96
40.39	2.96	5 of 5	0	14.97
76.73	5.62	4.6 of 5	0	13.80
145.79	10.7	4.8 of 5	0	13.61
277.01	20.3	4.6 of 5	0	13.81
526.32	38.5	4.4 of 5	0	14.01
1000	73.2	4.6 of 5	0	14.82

Table B. 9.11.2-3: Effects of Fenoxaprop-P-ethyl 69 g/L EW on seedling emergence, phytotoxicity, and plant fresh weight of Sugar beet 21 DAA (± 1 day)

Test rate		Sugar beet (*Beta vulgaris* var. *altissima*) mean values per test rate		
[mL test item/ha]	[g a.s./ha]	Seedling emergence [number seedlings/replicate]	Phytotoxicity [% visual damage]	Plant fresh weight [g/replicate]
0	0	7.8 of 8	0	10.45
40.39	2.96	8 of 8	0	10.24
76.73	5.62	7.6 of 8	0	11.50
145.79	10.7	7.6 of 8	0	11.35
277.01	20.3	7.6 of 8	0	11.45
526.32	38.5	6.6 of 8	0	9.30
1000	73.2	7.8 of 8	0	12.27

Table B. 9.11.2-4: Effects of Fenoxaprop-P-ethyl 69 g/L EW on seedling emergence, phytotoxicity, and plant fresh weight of Carrot 21 DAA (± 1 day)

Test rate		Carrot (*Daucus carota*) mean values per test rate		
[mL test item/ha]	[g a.s./ha]	Seedling emergence [number seedlings/replicate]	Phytotoxicity [% visual damage]	Plant fresh weight [g/replicate]
0	0	8.4 of 10	0	0.62
40.39	2.96	8 of 10	0	0.72

76.73	5.62	8.6 of 10	0	0.66
145.79	10.7	9.8 of 10	0	0.85*
277.01	20.3	7.6 of 10	0	0.59
526.32	38.5	8.6 of 10	0	0.64
1000	73.2	9 of 10	0	0.64

*mean of replicates is statistically significantly different from the mean of the control replicates, Dunnett's test, $p \leq 0.05$

Table B. 9.11.2-5: Effects of Fenoxaprop-P-ethyl 69 g/L EW on seedling emergence, phytotoxicity, and plant fresh weight of Onion 21 DAA (± 1 day)

Test rate		Onion (*Allium cepa*) mean values per test rate		
[mL test item/ha]	[g a.s./ha]	Seedling emergence [number seedlings/replicate]	Phytotoxicity [% visual damage]	Plant fresh weight [g/replicate]
0	0	7.4 of 9	0	0.18
40.39	2.96	7.2 of 9	0	0.19
76.73	5.62	6.2 of 9	0	0.19
145.79	10.7	7.2 of 9	0	0.17
277.01	20.3	7.4 of 9	0	0.22
526.32	38.5	5.8 of 9	0	0.17
1000	73.2	6 of 9	0	0.16

Table B. 9.11.2-6: Effects of Fenoxaprop-P-ethyl 69 g/L EW on seedling emergence, phytotoxicity, and plant fresh weight of Corn 21 DAA (± 1 day)

Test rate		Corn (*Zea mays*) mean values per test rate		
[mL test item/ha]	[g a.s./ha]	Seedling emergence [number seedlings/replicate]	Phytotoxicity [% visual damage]	Plant fresh weight [g/replicate]
0	0	5 of 5	0	30.04
40.39	2.96	5 of 5	0	29.82
76.73	5.62	5 of 5	0	29.39
145.79	10.7	5 of 5	0	29.74
277.01	20.3	5 of 5	0	29.71
526.32	38.5	5 of 5	0	27.81
1000	73.2	5 of 5	0	30.62

Table B. 9.11.2-7: Effects of Fenoxaprop-P-ethyl 69 g/L EW applied pre-emergence on the seedling growth of Oilseed rape, Pea, Sugar beet, Carrot, Onion and Corn

No Observed Effect Rates (NOER), ER_{25} and ER_{50} for non-target plants at test termination							
Plant species		Oilseed rape	Pea	Sugar beet	Carrot	Onion	Corn
Seedling emergence							
NOER	[mL TI/ha]	1000	1000	1000	1000	1000	1000
	[g a.s./ha]	73.2	73.2	73.2	73.2	73.2	73.2
ER_{25}	[mL TI/ha]	>1000	>1000	>1000	>1000	>1000	>1000
	[g a.s./ha]	>73.2	>73.2	>73.2	>73.2	>73.2	>73.2

ER_{50}	[mL TI/ha]	>1000	>1000	>1000	>1000	>1000	>1000
	[g a.s./ha]	>73.2	>73.2	>73.2	>73.2	>73.2	>73.2
Phytotoxicity							
NOER	[mL TI/ha]	1000	1000	1000	1000	1000	1000
	[g a.s./ha]	73.2	73.2	73.2	73.2	73.2	73.2
Plant fresh weight (shoots above ground)							
NOER	[mL TI/ha]	145.79	1000	1000	1000	1000	1000
	[g a.s./ha]	10.7	73.2	73.2	73.2	73.2	73.2
ER_{25}	[mL TI/ha]	503.55	>1000	>1000	>1000	>1000	>1000
	[g a.s./ha]	36.9	>73.2	>73.2	>73.2	>73.2	>73.2
ER_{50}	[mL TI/ha]	>1000	>1000	>1000	>1000	>1000	>1000
	[g a.s./ha]	>73.2	>73.2	>73.2	>73.2	>73.2	>73.2

TI: Test item a.s.: active substance

Validity criteria: The validity criteria of the test were met as all emerged control plants remained healthy throughout the test period and the rate of seedling emergence in the control was >70% for all tested plant species.

Conclusions: The test item did not affect the seedling emergence of any of the non-target plant species tested and there were no phytotoxic symptoms observed on any species throughout the experimental period. With the exception of oilseed rape, the fresh weight of all other species was not significantly influenced by the pre-emergence application of the test item. Based on a significant reduction in the plant fresh weight at 277.01 mL test item/ha, the NOER for oilseed rape was calculated to be 145.79 mL test item/ha (10.7g a.s./ha) with an ER_{25} of 503.55 mL test item/ha (36.9 g a.s./ha). The ER_{50} for oilseed rape (like all other species tested) was >1000 ml test item/ha (> 73.2 g a.s./ha).

Comment RMS: **Validity:** The seedling emergence test was conducted according to the current OECD test guideline 208 (July 2006) the following validity criteria are given:

- The seedling emergence in the controls is at least 70%
- In the controls the plants do not exhibit visible phytotoxic effects (e.g. chlorosis, necrosis, and wilting, leaf and stem deformations). Plants exhibit only normal variation in growth and morphology for that particular species.
- In the controls the mean plant survival is at least 90% for the duration of the study.
- In the controls environmental conditions for a particular species are identical and growing media contain the same amount of soil matrix, support media, or substrate from the same source.

The seedling emergence in the control groups is at least 70% at test termination (82-100 %).

For the duration of the test no visible phytotoxic effects were observed in the controls.

	The plant survival of all tested plant species was at least 90% for the duration of the test (100%). The environmental conditions and the used test substrate are identical for a particular species. **Acceptability of the analytical methods used in the test:** The available information is not sufficient to evaluate the requirements of guideline SANCO/3029/99 rev. 4. **Endpoints:** The RMS agrees on the endpoints given in the study report. ER50 >1000 ml test item/ha (> 73.2 g a.s./ha) **Conclusion of the RMS:** The study is considered to be valid and can be used for the risk assessment.

Reference:	**Effects of Fenoxaprop-P-ethyl 69 g/L EW on vegetative vigour of terrestrial plants**
Author(s), year:	Siemoneit, R., 2005b
Report/Doc. number:	Study no. AS12 / 116 FPE
Guideline(s):	OECD Guideline 227 (Draft Document March 2005)
GLP:	Yes
Deviations:	None relevant
Validity:	Acceptable

Material and Methods:

Test substance:	Fenoxaprop-P-ethyl 69 g/L EW (CHA 4960), batch no.: 660-PSH-49, Fenoxaprop-P-ethyl 7.11% w/w (analysed)
Type of test:	Vegetative vigour test
Test duration:	21 days
Test species:	The non-target plants comprised four dicotyledonous species (Oilseed rape, *Brassica napus*; Pea, *Pisum sativum*; Sugar beet, *Beta vulgaris* var. *altissima*; Carrot, *Daucus carota*) and two monocotyledonous species (Onion, *Allium cepa*; Corn, *Zea mays*).
Test soil:	Soil medium: The soil medium used for the plant species Oilseed rape, Pea and Corn was classified as a silty sand with a particle size distribution of 6.6% clay (< 2 µm), 29.1% silt (2-63 µm) and 64.3% sand (> 63 µm). The pH was 7.6 and organic carbon content 1.4%.

The soil medium used for the plant species Sugar beet, Carrot and Onion was classified as a loamy sand with a particle size distribution of 11.2% clay (< 2 µm), 29.4% silt (2-63 µm) and 59.4% sand (> 63 µm). The pH was 7.8 and organic carbon content 1.3%.

Applied concentrations: Control: Deionized water

Test item: 40.39, 76.73, 145.79, 277.01, 526.32 and 1000 mL prod./ha

Replicates: There were 5 replicates per treatment, 1 plant pot per replicate and 5-10 plants per pot (species dependent).

Exposure route: The test item was applied post-emergence when the target species had reached BBCH 12-14 (2-4 true leaf stage). Spray solutions were mixed just before application by firstly preparing a solution at the highest application rate then using aliquots of this solution to obtain the desired concentration range. Samples of the control and highest application solutions were analysed by HPLC. Applications were made at 200 L/ha using a single pass from calibrated laboratory spray cabin. The application was made to the plants using Teejet 8001E nozzles with a driving speed of approximately 1.44 km/h at 1.5 bar positioned approximately 35 cm above the plant stand.

Test conditions: Photoperiod: 16 h light 8 h dark with additional light when outdoor illumination was less than 5 lux.

Temperature: 25 – 28.0 °C

Relative humidity: 45 – 64 %

Test parameter: Assessments for phytotoxicity were conducted 7, 14, and 21 DAA (± 1) for all plants. Phytotoxicity was rated as % affected plant per volume of the replicate compared to the control. Ratings were based on the following scale: 0% (= no damage on the plants in the pot) to 100% (= all plants in the pots died off).

Statistics : Calculation of mean values, standard deviations, Analysis of Variance (ANOVA) followed by Dunnett's t-test (α = 5%), two parametric Logit-Model for ER_{25} and ER_{50} calculation.

Findings:

Analytical results: Recovery of active ingredient from the sample analysed by HPLC at the highest application rate was 97%.

Biological results: The test was performed under worst case conditions within a greenhouse environment that ensured an optimal distribution of test item on the plants during application and reduced the possibility that the test item could be washed off the leaves.

Table B. 9.11.2-8: Effects of Fenoxaprop-P-ethyl 69 g/L EW on phytotoxicity, and plant fresh weight of Oilseed rape 21 DAA (± 1 day)

Test rate	Oilseed rape (*Brassica napus*) mean values per test rate

[mL test item/ha]	[g a.s./ha]	Phytotoxicity [% visual damage]	Plant fresh weight [g/replicate]
0	0	0	29.57
40.39	2.96	0	30.04
76.73	5.62	0	29.34
145.79	10.7	0	29.00
277.01	20.3	0	32.65
526.32	38.5	0	28.92
1000	73.2	0	30.90

Table B. 9.11.2-9: Effects of Fenoxaprop-P-ethyl 69 g/L EW on phytotoxicity, and plant fresh weight of Pea 21 DAA (± 1 day)

Test rate		Pea (*Pisum sativum*) mean values per test rate	
[mL test item/ha]	[g a.s./ha]	Phytotoxicity [% visual damage]	Plant fresh weight [g/replicate]
0	0	0	31.88
40.39	2.96	0	32.20
76.73	5.62	0	31.12
145.79	10.7	0	31.39
277.01	20.3	0	32.41
526.32	38.5	0	32.10
1000	73.2	0	31.54

Table B. 9.11.2-10: Effects of Fenoxaprop-P-ethyl 69 g/L EW on phytotoxicity, and plant fresh weight of Sugar beet 21 DAA (± 1 day)

Test rate		Sugar beet (*Beta vulgaris* var. *altissima*) mean values per test rate	
[mL test item/ha]	[g a.s./ha]	Phytotoxicity [% visual damage]	Plant fresh weight [g/replicate]
0	0	0	30.64
40.39	2.96	0	32.32
76.73	5.62	0	31.51
145.79	10.7	0	33.48
277.01	20.3	0	32.45
526.32	38.5	0	32.87
1000	73.2	0	32.74

Table B. 9.11.2-11: Effects of Fenoxaprop-P-ethyl 69 g/L EW on phytotoxicity, and plant fresh weight of Carrot 21 DAA (± 1 day)

Test rate		Carrot (*Daucus carota*) mean values per test rate	
[mL test item/ha]	[g a.s./ha]	Phytotoxicity [% visual damage]	Plant fresh weight [g/replicate]
0	0	0	15.87
40.39	2.96	0	15.17
76.73	5.62	0	16.54

145.79	10.7	0	17.94
277.01	20.3	0	17.20
526.32	38.5	0	17.23
1000	73.2	0	16.55

Table B. 9.11.2-12: Effects of Fenoxaprop-P-ethyl 69 g/L EW on phytotoxicity, and plant fresh weight of Onion 21 DAA (± 1 day)

Test rate		Onion (*Allium cepa*) mean values per test rate	
[mL test item/ha]	[g a.s./ha]	Phytotoxicity [% visual damage]	Plant fresh weight [g/replicate]
0	0	0	10.34
40.39	2.96	0	8.23
76.73	5.62	0	9.32
145.79	10.7	0	9.25
277.01	20.3	0	8.77
526.32	38.5	0	9.62
1000	73.2	0	7.86*

*mean of replicates is statistically significantly different from the mean of the control replicates, Dunnett's test, $p \leq 0.05$

Table B. 9.11.2-13: Effects of Fenoxaprop-P-ethyl 69 g/L EW on phytotoxicity, and plant fresh weight of Corn 21 DAA (± 1 day)

Test rate		Corn (*Zea mays*) mean values per test rate	
[mL test item/ha]	[g a.s./ha]	Phytotoxicity [% visual damage]	Plant fresh weight [g/replicate]
0	0	0	65.08
40.39	2.96	0	66.84
76.73	5.62	0	40.95*
145.79	10.7	0	2.58*
277.01	20.3	0	1.76*
526.32	38.5	0	1.72*
1000	73.2	0	1.71*

*mean of replicates is statistically significantly different from the mean of the control replicates, Dunnett's test, $p \leq 0.05$

Table B. 9.11.2-14: Effects of Fenoxaprop-P-ethyl 69 g/L EW applied post-emergence on the appearance (phytotoxicity) and plant growth of Oilseed rape, Pea, Sugar beet, Carrot, Onion and Corn

No Observed Effect Rates (NOER), ER_{25} and ER_{50} for non-target plants at test termination							
Plant species		Oilseed rape	Pea	Sugar beet	Carrot	Onion	Corn
Phytotoxicity							
NOER	[mL TI/ha]	1000	1000	1000	1000	1000	40.39
	[g a.s./ha]	73.2	73.2	73.2	73.2	73.2	2.96
Plant fresh weight (shoots above ground)							
NOER	[mL TI/ha]	1000	1000	1000	1000	526.32	40.39
	[g a.s./ha]	73.2	73.2	73.2	73.2	38.5	2.96
ER_{25}	[mL TI/ha]	>1000	>1000	>1000	>1000	>1000	63.81

	[g a.s./ha]	>73.2	>73.2	>73.2	>73.2	>73.2	4.68
ER_{50}	[mL TI/ha]	>1000	>1000	>1000	>1000	>1000	84.85
	[g a.s./ha]	>73.2	>73.2	>73.2	>73.2	>73.2	6.22

TI: Test item a.s.: active substance

Validity criteria: The validity criteria of the test were met as the control plants did not exhibit visible phytotoxic effects and the survival of the control plants at termination was 100%.

Conclsuion: There were no symptoms of phytotoxicity for any of the treated plant species with the exception of Corn. In addition, the fresh weight of the plant species Corn and Onion were significantly affected when assessed at study termination. The most sensitive plant species was Corn with a NOER calculated to be 40.39 mL test item/ha (2.96 g a.s./ha) with an ER_{25} of 63.81 mL test item/ha (4.68 g a.s./ha) and an ER_{50} of 84.85 mL test item/ha (6.22 g a.s./ha). The NOER for Onion was calculated to be 526.32 mL test item/ha (38.5 g a.s./ha), however, the EC_{25} and the EC_{50} were both >1000 mL test item/ha (>73.2 g a.s./ha). The ER_{50} for all other species tested were >1000 ml test item/ha (> 73.2 g a.s./ha).

Comment RMS:

Validity:

The vegetative vigour test was conducted according to the OECD test guideline 227.

Taking into account the current valid OECD test guideline 227 (July 2006) the following validity criteria are given:

- The seedling emergence is at least 70% (control and treatment groups)
- In the control groups the plants do not exhibit visible phytotoxic effects (e.g. chlorosis, necrosis, and wilting, leaf and stem deformations). Plants exhibit only normal variation in growth and morphology for that particular species.
- In the control groups the mean plant survival is at least 90% for the duration of the study.
- In the control groups environmental conditions for a particular species are identical and growing media contain the same amount of soil matrix, support media, or substrate from the same source.

The vegetative vigour test does meet the given validity criteria according to the OECD test guideline 227 (2006).

The seedling emergence in the control and treatment groups has been sufficient (> 70%).

In the control groups no phytotoxic effects were observed and the mean plant survival was 100% for all tested terrestrial plants.

According to the OECD test guideline the temperature and the humidity has to be

	in a range of 20 °C ± 10 °C and 70 % ± 25% (OECD 227), respectively. There were slight and temporal deviations in the current test. However, under consideration of the observed effects on plant survival and plant phytotoxicity the influence of the deviations on the test plants is considered to be low. **Acceptability of the analytical methods used in the test:** The available information is not sufficient to evaluate the requirements of guideline SANCO/3029/99 rev. 4. **Endpoints:** The RMS agrees on the endpoints given in the study report. ER_{50} = 84.85 mL test item/ha (6.22 g a.s./ha) **Conclusion of the RMS:** The study is considered to be valid and can be used for the risk assessment.

B.9.11.3. Extended laboratory studies on non-target plants

Based on the risk assessment on non-target terrestrial plants indicating an acceptable risk, further testing on non-target plants is not required.

B.9.11.4. Semi-field and field tests on non-target plants

Based on the risk assessment on non-target terrestrial plants indicating an acceptable risk, further testing on non-target plants is not required.

B.9.12. RISK ASSESSMENT FOR TERRESTRIAL NON-TARGET HIGHER PLANTS

Seedling emergence and vegetative vigour studies have been conducted with Fenoxaprop-P-ethyl 69 g/L EW (CHA 4960) following the current OECD guidelines OECD 227 and OECD 208.

Table B. 9.12-1: Summary of non-target plant tests performed with the formulation Fenoxaprop-P-ethyl 69 g/L EW (CHA 4960)

Test organisms	Study type	Test duration	Lowest ER_{50} [mL prod./ha]	Most sensitive species	Reference
Terrestrial non-target plants (6 species)	Seedling emergence (Tier 2)	21 days	ER_{50} > 1000	-	Siemoneit, R., 2005a
Terrestrial non-target plants (6 species)	Vegetative vigour (Tier 2)	21 days	ER_{50} = 84.85	Corn (*Zea mays*)	Siemoneit, R., 2005b

The risk assessment is based on the Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 rev 2 final, 2002).

The representative formulation is applied on cereals at a rate of 1.2 L prod./a (corresponding to 0.082 kg a.s./ha). The number of applications per season is 1. The corresponding off-field predicted environmental rates (PER) for three different use patterns are presented in the table below.

Table B. 9.12-2: Predicted environmental rates (PER) at 1 m distance from the edge of field

Crop	Timing of application	No. of applications	Single application rate	Drift	MAF	$PER_{off\text{-}field}$ (at 1 m distance)
Cereals	BBCH 11-39	1	1200 mL prod./ha	2.77%	1.0	33.24 mL prod./ha

Effects on non-target plants are of concern in the off-field environment, where they may be exposed to spray drift. For a single application to cereals, 2.77% of the full application rate of 1200 m L prod./ are assumed to reach areas at 1 m from the edge of the crop, respectively. The amount of spray drift from one application reaching off-crop habitats is calculated using the 90th percentile estimates derived by the BBA (2000) from spray-drift predictions of Ganzelmeier & Rautmann (2000).

B.9.12.1. Deterministic risk assessment

According to the Terrestrial Guidance Document, the risk to non-target terrestrial plants is assessed by comparing the exposure in field margins caused by drift with the lowest ER_{50} obtained from the non-target plant studies. An assessment factor of 5 is required in order to prove safe use.

Table B. 9.12.1-1: Deterministic risk assessment based on the lowest ER_{50}

Distance	Drift rate	Drift reducing nozzles	$PER_{off\text{-}field}$ [mL prod./ha]	Toxicity [mL prod./ha]	TER
1 m	2.77%	-	33.24	ER_{50} = 84.85	**2.6**

		50%	16.62		5.1
		75%	8.31		10
		90%	3.3		26
5 m	0.57%	-	6.84		12

According to the results of the deterministic approach involving the most sensitive endpoint in the vegetative vigour study the risk to non-target plants is considered acceptable if risk mitigation measures such as 50 % nozzle reduction or a 5 meter buffer zone is applied.

B.9.13. EFFECTS ON OTHER TERRESTRIAL ORGANISMS (FLORA AND FAUNA)

No other studies on other non-target species are required.

B.9.14. RISK ASSESSMENT FOR OTHER TERRESTRIAL ORGANISMS (FLORA AND FAUNA)

Not required, as no additional studies were submitted addressing the risk to other terrestrial organisms.

B.9.15. REFERENCES RELIED ON

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KCP 10.1.1.1	[redacted]	2005	Fenoxaprop-P-ethyl 69 g/L EW: An Acute Oral Toxicity Study with the Northern Bobwhite [redacted] Study No 232-125 Cheminova A/S Report No.: 139 FPE Date: 2005-12-13 GLP/GEP: yes, unpublished	Y	Y	Study not reviewed on EU level; new additional representative formulation	CHA	Submitted for the purpose of renewal
KCP 10.2.1	[redacted]	2005a	Acute Toxicity of Fenoxaprop-P-ethyl 69 g/l EW to Rainbow Trout (*Oncorhynchus mykiss*) in a 96-hour Semi Static Test. [redacted] Study No.: 24783230 Cheminova A/S Report No.: 98 FPE Date: 2005-09-29 GLP/GEP: yes, unpublished	Y	Y	Study not reviewed on EU level; new additional representative formulation	CHA	Submitted for the purpose of renewal
KCP 10.2.1	Grade R., Wydra V.	2005	Revised Final Report No.1 Acute Toxicity of Fenoxaprop-P-ethyl 69 g/l EW to *Daphnia magna* in a Semi Static 48-hour Immobilization Test IBACON - Institut für Biologische Analytik und Consulting IBACON GmbH, Study No.: 24782220 Cheminova A/S Report No.: 97 FPE Date: 2016-06-15 GLP/GEP: yes, unpublished	N	Y	Study not reviewed on EU level; new additional representative formulation	CHA	Submitted for the purpose of renewal
KCP 10.2.1	Powlowski S., Wydra V.	2005b	Toxicity of Fenoxaprop-P-ethyl 69 g/l EW to *Desmodesmus subspicatus* in an Algal Growth Inhibition Test IBACON - Institut für Biologische Analytik und Consulting IBACON GmbH, Study No.: 24781210 Cheminova A/S Report No.: 96 FPE Date: 2005-11-14 GLP/GEP: yes, unpublished	N	Y	Study not reviewed on EU level; new additional representative formulation	CHA	Submitted for the purpose of renewal
KCP 10.2.1	Powlowski S., Wydra V.	2006	Toxicity of Fenoxaprop-P-ethyl 69 g/L EW to the Aquatic Plant *Lemna gibba* in a Semi Static Growth Inhibition Test IBACON - Institut für Biologische Analytik und Consulting IBACON GmbH, Study No.: 24780240	N	Y	Study not reviewed on EU level; new additional representative	CHA	Submitted for the purpose of renewal

			Cheminova A/S Report No.: 154 FPE Date: 2006-02-03 GLP/GEP: yes, unpublished			formulation		
KCP 10.2.2	Kley A., Wydra V	2010	Influence of Fenoxaprop-P-ethyl 69 g/l EW to *Daphnia magna* in a Reproduction Test IBACON - Institut für Biologische Analytik und Consulting IBACON GmbH, Study No.: 37571221 Cheminova A/S Report No.: 314 FPE Date: 2010-02-12 GLP/GEP: yes, unpublished	N	Y	Study not reviewed on EU level; new additional representative formulation	CHA	Submitted for the purpose of renewal
KCP 10.3.1.1.1; KCP 10.3.1.1.2	Schmidt. T.	2005	Acute Contact and Oral Toxicity of Fenoxaprop-P-ethyl 69 g/l EW to Honey Bees (*Apis Mellifera* L). RCC Ltd., Study No A22948 Cheminova A/S Report No.:120 FPE Date: 2005-10-31 GLP/GEP: yes, unpublished	N	Y	Study not reviewed on EU level; new additional representative formulation	CHA	Submitted for the purpose of renewal
KCP 8.3.1.2	Theis, M.	2017	Fenoxaprop-P-ethyl EW 69: Chronic oral toxicity test on the honey bee (*Apis mellifera* L.) in the laboratory Bayer AG – Crop Science Division, Study No E31804950-0 M-577004-01-1 Date: 2017-01-12	N	Y	Study not reviewed on EU level; new additional representative formulation	CHA	Submitted for the purpose of renewal
KCP 10.3.1.3	Schmitzer, S.	2015	Fenoxaprop 69 g/L EW: Effects on Honey Bee Brood (*Apis mellifera* L.) - Brood Feeding Test Ibacon GmbH, Study No.: 94671031 Cheminova A/S Report No.: 521 FPE Date: 2015-11-19 GLP/GEP: yes, unpublished	N	Y	Study not reviewed on EU level; new additional representative formulation	CHA	Submitted for the purpose of renewal
KCP 10.3.1.5	Rexer, H. U.	2016	CHA 4960 (fenoxaprop P-ethyl 69 g/L EW): Assessment of side-effects on honeybees (Apis mellifera L.) and determination of residues in a semi-field study in Phacelia tanacetifolia in Germany Eurofins Agroscience Services EcoChem GmbH, Niefern- Oeschelbronn, Germany TF- BCS-CHA, Report No.: S15-00053, Report includes Trial Nos.: S15-00053-01 S15-00053-L1 S15-00053-L2 Edition Number: M-556072-01-1	N	Y	Data requirement according to Regulation (EC) No 1107/2009 or 283/2013	TF- BCS-CHA	Submitted for the purpose of renewal

			Date: 2016-06-07 GLP/GEP: yes, unpublished					
KCP 10.3.2.1	Schmidt. T.	2006a	Dose-Response Toxicity of Fenoxaprop-P-ethyl 69 g/l EW to Adults of the Parasitoid Wasp *Aphidius rhopalosiphi* (Hymenoptera: Aphidiidae) in the Laboratory. RCC Ltd., Study No A22937 Cheminova A/S Report No.: 156 FPE Date: 2006-02-23 GLP/GEP: yes, unpublished	N	Y	Study not reviewed on EU level; new additional representative formulation	CHA	Submitted for the purpose of renewal
KCP 10.3.2.1	Schmidt. T.	2006b	Dose-Response Toxicity of Fenoxaprop-P-ethyl 69 g/l EW to the Predatory Mite *Typhlodromus pyri* (Acari: Phytoseiidae) in the Laboratory RCC Ltd., Study No.: A22926 Cheminova A/S Report No.: 155 FPE Date: 2006-02-23 GLP/GEP: yes, unpublished	N	Y	Study not reviewed on EU level; new additional representative formulation	CHA	Submitted for the purpose of renewal
KCP 10.3.2.2	Moll, M.	2007	Effects of Fenoxaprop-P-ethyl 69 g/L EW on the Parasitoid *Aphidius rhopalosiphi* Extended Laboratory Study: Dose Response Test IBACON - Institut für Biologische Analytik und Consulting IBACON GmbH, Study No.: 37572002 Cheminova A/S Report No.: 229 FPE Date: 2007-12-20 GLP/GEP: yes, unpublished	N	Y	Study not reviewed on EU level; new additional representative formulation	CHA	Submitted for the purpose of renewal
KCP 10.3.2.2	Moll, M.	2008a	Effects of Fenoxaprop-P-ethyl 69 g/L EW on the Predatory Mite *Typhlodromus pyri*, Extended Laboratory Study - Dose Response Test IBACON - Institut für Biologische Analytik und Consulting IBACON GmbH, Study No.: 37573062 Cheminova A/S Report No.: 230 FPE and 1st Amendment Date: 2008-01-29 GLP/GEP: yes, unpublished	N	Y	Study not reviewed on EU level; new additional representative formulation	CHA	Submitted for the purpose of renewal
KCP 10.3.2.2	Moll, M.	2008b	Effects of Fenoxaprop-P-ethyl 69 g/L EW on the Lacewing *Chrysoperla carnea*, Extended Laboratory Study - Dose Response Test IBACON - Institut für Biologische Analytik und Consulting IBACON GmbH, Study No.: 37574047 Cheminova A/S Report No.: 231 FPE and 1st Amendment Date: 2008-02-04	N	Y	Study not reviewed on EU level; new additional representative formulation	CHA	Submitted for the purpose of renewal

			GLP/GEP: yes, unpublished					
KCP 10.3.2.2	Fallowfield, L.	2010	Aged-Residue extended Laboratory Tests to determine the Effects of Fenoxaprop 69 g/l EW on the predatory Mite, *Typhlodromus pyri* (Acari: Phytoseiidae) Mambo-Tox, Study No.: CVA-10-1 Cheminova A/S Report No.: 353 FPE Date: 2010-05-26 GLP/GEP: yes, unpublished	N	Y	Study not reviewed on EU level; new additional representative formulation	CHA	Submitted for the purpose of renewal
KCP 10.4.1	Lührs U.	2005	Acute Toxicity (14 Days) of Fenoxaprop-P-ethyl 69 g/l EW to the Earthworm *Eisenia fetida* in Artificial Soil. IBACON - Institut für Biologische Analytik und Consulting IBACON GmbH, Study No.: 24785021 Cheminova A/S Report No.: 109 FPE Date: 2005-09-26 GLP/GEP: yes, unpublished	N	Y	Study not reviewed on EU level; new additional representative formulation	CHA	Submitted for the purpose of renewal
KCP 10.4.1.1	Krome, K.	2010	Fenoxaprop-P-ethyl 69 g/L EW Earthworm (*Eisenia fetida*), Effects on Reproduction Dr. Noack, Study No.: RBN 13762 Cheminova A/S Report No.: 373 FPE Date: 2010-12-23 GLP/GEP: yes, unpublished	N	Y	Study not reviewed on EU level; new additional representative formulation	CHA	Submitted for the purpose of renewal
KCP 10.4.2.1	Friedrich, S.	2016g	Effects of Fenoxaprop-P-ethyl 69 g/L EW on the reproduction of the collembolan *Folsomia candida* BioChem agrar - Labor für biologische und chemische Analytik GmbH, BioChem project No.: 161048146S Cheminova A/S Report No.: 581 FPE Date: 2016-05-31 GLP/GEP: yes, unpublished	N	Y	Study not reviewed on EU level; new additional representative formulation	CHA	Submitted for the purpose of renewal
KCP 10.4.2.1	Schulz, L.	2016g	Effects of Fenoxaprop-P-ethyl 69 g/L EW on the reproduction of the predatory mite *Hypoaspis aculeifer* BioChem agrar - Labor für biologische und chemische Analytik GmbH, BioChem project No.: 161048147S Cheminova A/S Report No.: 580 FPE Date: 2016-05-30 GLP/GEP: yes, unpublished	N	Y	Study not reviewed on EU level; new additional representative formulation	CHA	Submitted for the purpose of renewal
KCP 10.5	Reis. K-H	2005	Effects of Fenoxaprop-P-ethyl 69 g/l EW on the Activity of the Soil Microflora in the Laboratory IBACON - Institut für Biologische Analytik und Consulting IBACON GmbH, Study No.: 24787080 Cheminova A/S Report No.: 112 FPE Date: 2005-10-17 GLP/GEP: yes, unpublished	N	Y	Study not reviewed on EU level; new additional representative formulation	CHA	Submitted for the purpose of renewal

KCP 10.6.2	Siemoneit S.	2005a	Effects of Fenoxaprop-P-ethyl 69 g/L EW on seedling emergence of terrestrial plants Rheinland-Pfalz AgroScience GmbH, Study No.: AS11 Cheminova A/S Report No.: 114 FPE Date: 2005-10-11 GLP/GEP: yes, unpublished	N	Y	Study not reviewed on EU level; new additional representative formulation	CHA	Submitted for the purpose of renewal
KCP 10.6.2	Siemoneit, S.	2005b	Effect of Fenoxaprop-P-ethyl 69 g/L EW on vegetative vigour of terrestrial plants Rheinland-Pfalz AgroScience GmbH, Study No.: AS12 Cheminova A/S Report No.: 116 FPE and 1st Amendment Date: 2005-10-11 GLP/GEP: yes	N	Y	Study not reviewed on EU level; new additional representative formulation	CHA	Submitted for the purpose of renewal