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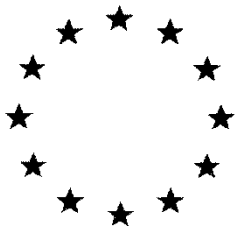

Draft Renewal Assessment Report prepared according to the Commission Regulation (EU) N° 1107/2009

Fenoxaprop-P-ethyl

Volume 3 – B.9 (PPP) – Fenoxaprop-P-ethyl + Mefenpyr-diethyl EW 144 (69+75 g/L)

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

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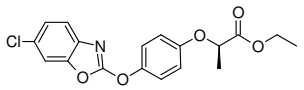
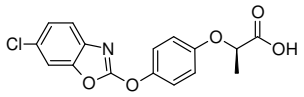
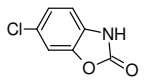
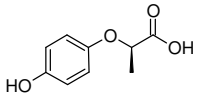
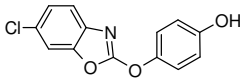
B.9. ECOTOXICOLOGY DATA AND ASSESSMENT OF RISKS FOR NON-TARGET SPECIES

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 from Bayer CropScience (FPP+MPR EW 144 (69+75 g/L)).

Ecotoxicological data of Fenoxaprop-P-ethyl and its major metabolites as well as for the formulated product FPP+MPR EW 144 (69+75 g/L) had been submitted within the EU Dossier (Baseline Dossier), which resulted in the Annex I inclusion under Directive 91/414/EEC.

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] Fenoxaprop-P-ethyl Mefenpyr-diethyl

Cereals (Spring and winter wheat, durum wheat, rye, winter rye, triticale, spring and winter barley)	BBCH 11-39	1	-	0.4 - 1.2	0.028 – 0.083 0.030 – 0.090

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 and bobwhite quail. Studies were already submitted for the first EU peer-review of the active substance Fenoxaprop-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 Puma S69 EW 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 relevant for risk assessment 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 M-118214-01-1
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

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

An acute toxicity study with the formulation Fenxoaprop-P-ethyl 500 SC ([redacted] 1991) has been submitted. The formulation Fenxoaprop-P-ethyl 500 SC is not considered comparable to the EU representative formulation Fenoxaprop-P-ethyl + Mefenpyr-diethyl EW 144 (69+75 g/L) because the formulation does not contain a safener and is a different formulation type. However the intended lead formulation Fenoxaprop-P-ethyl + Mefenpyr-diethyl EW 144 (69+75 g/L) is not assumed to be more toxic than the active substance.

Reference: **Fenoxaprop-P-ethyl; oil in water emulsion; 69 G/L – Testing for acute oral**

	toxicity in the male and female Japnese quail (*Coturnix coturnix japonica*)
Author(s), year:	[redacted]., 1991
Report/Doc. number:	91.0200 / Reference no. M-130636-01-1
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 500 SC, oil in water emulsion 69 g/L, Identification code: Hoe 046360 24 EW14 A203
Test species:	Japanese quail (*Coturnix coturnix japonica*)
Number of organisms:	10 animals per group (5 males and 5 females)
Age:	approx. 6 months (at start of the test)
Weight:	191 – 221 g (males) /222 – 291 g (females)
Acclimatisation period:	14 days under laboratory conditions
Type of test:	Acute oral toxicity
Applied concentrations:	1000 and 2000 mg a.s./kg bw, dosage volume: 5 mL/kg bw
Type of application:	The test substance was emulsified in the stated concentrations in deionised water, distributed homogeneously by means of a magnetic stirrer and administered into the stomach or preventriculus by silicon tube. The controls were treated analogously with the vehicle.
Time of exposure:	One single application, monitoring during 15 days
Test conditions:	Test temperature: 19 – 21 °C, relative humidity: 45 – 75 %, lighting: 8 h light and 16 h darkness. Feed (quail grower ration prepared by the Baierseich Experimental Farm, HOECHST AG) was provided ad libitum.
Observations:	After treatment, signs of intoxication, mortality rate and times of death were recorded. The birds were weighed on days 4, 8 and 15 of the 15-day observation period. The total food consumption per group was also recorded for days 1-4, 4-8 and 8-15 after treatment (day 1 = day of treatment). Lethally intoxicated birds dissected and examined macroscopically. At the end of the observation period, the surviving birds (excl. controls) were killed by carbon dioxide asphyxiation, dissected and also examined for macroscopically visible changes.
Statistics:	The LD_{50}, the 95 % confidence range and the mathematical equation of the probit curves could not be calculated by probit analysis on the basis of the mortality rate.

Findings:

Mortalities: No mortality occurred in the groups treated with 1000 or 2000 mg/kg body weight. One male of the vehicle control group died spontaneously on study day 3. Based on this result, the median lethal dose (LD_{50}) is with certainty greater than 2000 mg/kg body weight.

Body weight and food consumption: The food consumption and the body weights were slightly reduced between days 1 and 4 of the study in the group treated with 2000 mg/kg body weight. No significant changes were observed in the group treated with 1000 mg/kg body weight as compared with the control group.

Clinical signs: All animals treated with the test substance showed gular flutter and ruffled feathers on the day of application only. The animals of the vehicle control showed no clinical signs of intoxication. The death of one control cock was preceded by decreased respiration rate, prone position and cold on touch on study day 3.

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]		
			1	4	8	15	1-4	4-8	8-15
Control	1	♂	182	187	190	187	21.1	47.6	17.3
	0	♀	213	236	239	222	32.1	44.3	28.7
1000	0	♂	192	200	204	205	13.0	22.6	16.4
	0	♀	236	248	252	243	22.7	33.2	24.9
2000	0	♂	198	197	208	200	8.1	23.3	14.0
	0	♀	217	210	230	223	15.8	33.5	27.9

Conclusion: LD_{50} > 2000 mg a.s./kg bw

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 10 %
- 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 10 %

	Acceptability of the analytical methods used in the test: The available information is not sufficient to evaluate the acceptability of the analytical methods according to the guidance documents SANCO/3029/99 rev. 4. **Endpoints:** LD_{50} >2000 mg/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.

Reference:	**Fenoxaprop-P-ethyl; oil in water emulsion; 69 G/L – Testing for acute oral toxicity in the male and female Japanese quail (*Coturnix coturnix japonica*)**
Author(s), year:	[redacted] 1992
Report/Doc. number:	91.0007 / Reference no. M-135735-01-1
Guideline(s):	US EPA Subdivision E, Section 71-1 (Avian single-dose oral LD_{50}), October 1982
GLP:	Yes
Deviations:	Testing of female animals was omitted due to prominent emesis even at low concentrations shortly after dosing.
Acceptability:	Not conclusive. Not essential.

Material and methods:

Test substance:	Fenxoaprop-P-ethyl 500 SC, oil in water emulsion 69 g/L, Identification code: Hoe 046360 24 EW14 A203
Test species:	Mallard duck (*Anas platyrhynchos*)
Number of organisms:	5 animals per group (5 males). No female birds were dosed
Age:	approx. 12 months (at start of the test)
Weight:	1073 g (mean)
Acclimatisation period:	15 days under laboratory conditions
Type of test:	Acute oral toxicity
Applied concentrations:	0, 50 and 2000 mg a.s./kg bw, dosage volume: 5 mL/kg bw
Type of application:	The substance was weighed out in the stated quantities into a volumetric flask and filled up to the mark with deionised water and distributed homogeneously by means of a magnetic stirrer. The emulsion was administered into the stomach or preventriculus by means of silicon catheter and with a constant application volume of 5 ml/kg body weight. The controls were treated analogously with the vehicle.
Time of exposure:	One single application, monitoring during 15 days

Test conditions: Test temperature: 18 - 22°C, relative humidity: 40 – 80%, lighting: 8h light and 16h darkness.
During the study the birds were given a special diet (duck grower ration prepared by the Baierseich Experimental Farm of HOECHST AG. Food and water were available *ad libitum*.

Observations: After treatment, signs of intoxication, mortality rate and times of death were recorded. The birds were weighed on days 1, 4, 8 and 15 of the 15-day observation period. The total food consumption per group was also recorded for days 1-4, 4-8 and 8-15 after treatment (day 1 = day of treatment). Lethally intoxicated birds dissected and examined macroscopically. At the end of the observation period, the surviving birds (excl. controls) were killed by intravenous application of T61^{R}, dissected and also examined for macroscopically visible changes.

Statistics: The LD_{50}, the 95 % confidence range and the mathematical equation of the probit curves could not be calculated by probit analysis on the basis of the mortality rate.

Findings:

Mortalities: No mortality occurred in the treated groups at dose levels of 50 and 2000 mg/kg body weight. However, no statement can be made on the toxicological effective dose and thus on the oral LD_{50} value due to emesis in all dose level groups.

Body weight and food consumption: Food consumption and body weight gains were unaffected by the test substance.

Clinical signs: After dosing of 50 and 2000 mg/kg body weight all birds showed emesis between 10 minutes and two hours after treatment. No additional clinical signs of intoxication could be observed.

Table B. 9.1.1-3: Mortality and growth (bodyweights and food consumption) of mallard duck following acute oral exposure (gavage)

Test substance [mg a.s./kg]	Cumulative mortality	Mean bodyweight [g]				Food consumption [g/bird/d]		
		1	4	8	15	1-4	4-8	8-15
Control	0	1135	1194	1168	1141	109.4	80.4	77.6
50	0	1091	1149	1126	1101	90.5	79.9	67.1
2000	0	995	1034	1031	1008	99.5	73.6	77.8

Conclusion: The acute oral toxicity (LD_{50} value) could not be determined. After dosing of 50 and 2000 mg/kg body weight all ducks exhibited emesis within 10 minutes and 2 hours after application. No mortality or any other clinical sign were observed. Body weight and food intake were unaffected and no macroscopic changes were seen at necropsy. Because the acute oral toxicity could not be determined due to emesis in all treated animals shortly after dosing it was not possible to administer systematically toxic doses, testing of female animals was omitted.

Comment RMS:	**Validity:** The study was conducted according to the OECD test guideline 401 (1987). The study is demonstrated to be acceptable, even under consideration of the current test guidelines, e.g. US EPA guideline (OPPTS 850.2100, April 1996) and OECD guideline (OECD 223, July 2010). No effects on mortality and body weight were observed. However, some animals showed toxic effects (diarrhoea) after the application of the test substance. The limit test was conducted without a negative control group. Hence, no information on the health and husbandry of the test birds are available and no assessment of the reliability of the results can be done. In addition, no information on the statistical analysis of the results was provided. **Endpoints:** The study is not considered valid; hence no endpoint was determined by the RMS. **Conclusion of the RMS:** The study is not considered valid.

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 (Baeder et al 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

Test species	Test design	Ecotoxicological endpoint	Reference
Rat	Long-term	NOAEL = 10 mg/kg bw	[redacted], 2016

Bold values were used for the risk assessment

Toxicity of the formulated product:

The acute oral toxicity of PUMA S 69 EW was determined in a study on rats (refer to section Volume 3 CP B.6). Based on the results of the study, the formulation toxicity is considered to be covered by the risk assessment with the active substance.

Table B. 9.1.2-2: Toxicity of the formulated product to mammals

Test species	Test design	Ecotoxicological endpoint	Reference
Rat	Acute, oral	LD_{50} > 4000 mg prod./kg bw	[redacted], 1993b

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.

Further data on the degradation of Fenoxapop-P-ethyl on cereal shoots were submitted for the first EU peer-review of the active substance Fenoxaprop-P-ethyl. The results of the study summarised in the DAR (2005) is given below.

Reference: Kley, C. (2002): Residues of Fenoxaprop-P-ethyl in cereal shoots: Initial residue levels and their dissipation. Report No. C024368

Test guideline: not applicable

GLP: not applicable

Material and methods:

Based on 32 residue trials conducted throughout Europe a realistic (mean) initial residue of total Fenoxaprop-P (-ethyl, -acid and chlorbenzoxazolone) in cereal shoots and the dissipation behaviour were determined.

The standard residue trials are primarily not designed to determine kinetics of residue decline in shoots and the second sampling was typically done 14 d or later after application. In all trials only two or three data points were available. The lack of initial data may lead to an overestimation of half-lives, if the dissipation does not follow a mono-exponential first-order decay. Accordingly, a rapid dissipation of Fenoxaprop-P could not be described scientifically and the assumption of a mono-exponential first-order decay therefore represents the worst case.

Residue levels of total Fenoxaprop-P over time (PEC) were calculated with first-order dissipation equation.

Time-weighted average residues were determined by integrating and averaging the PEC values over the respective period of time (21 d after application).

Initial residue levels of Fenoxaprop-P-ethyl and the dissipation behaviour of these residues were determined on the basis of data from 32 field trials (12 studies) in common or durum wheat, barley or rye. An EW or SE formulation of Fenoxaprop-P-ethyl had been applied at rates between 40.1 and 92.4 g ai/ha, and a safener, either

Mefenpyr-diethyl or diclofop-methyl was applied in all cases. The residues reported in the field trials were expressed as equivalents of Fenoxaprop-P-ethyl and only analyses of cereal shoots were used for the evaluation. In all studies residue data were available for the day of application (d 0) and for one or two later sampling dates, typically starting 2 or 3 weeks after application.

Findings:

Initial residues: The scaled initial residues of total Fenoxaprop-P ranged from 0.73 to 8.1 mg/kg (referring to an application rate of 100 g ai/ha). The mean initial residue was 3.85 mg/kg with a standard deviation of 2. This figure was considered as representative value for a long-term ecotoxicological risk assessment by the study authors. The 90th percentile concentration was found at 6.5 mg/kg. The experimental initial residues are scattered very wide. This may result from drift or wind effects during the application or from different overlapping of the leaves in different studies. No significant dependence on the cereal type was determined.

Dissipation kinetics:

All experimental residue data sets are summarised in the figure below, scaled to an application rate of 100 g ai/ha. As from each trial only 2 or three data points are available, an ideal fit for each trial can be reached. A lack of initial data may lead to an overestimation of half-lives, if the dissipation does not follow a monoexponential first-order decay. This represents a worst-case assumption with regard to risk assessment purpose. Based on these considerations, an evaluation, with fitting the initial residue c_0 and the dissipation rate k in parallel, lead to values of c_0 of 3.842 mg/kg and of DT_{50} of 5.6 d. These values were further used for PEC and TWAC calculations of total Fenoxaprop-P in cereals.

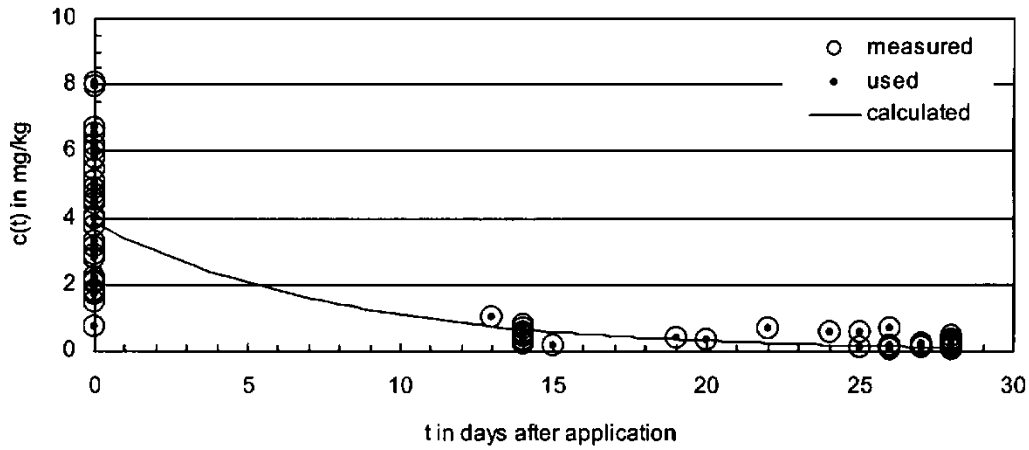


Figure 9.3.2-1: all experimental and simulated plant residues of total Fenoxaprop-P, normalised to a rate of 100 g ai/ha.

PEC and TWA residues: With the DT_{50} of 5.6 d (k = 0.1248 d^{-1}), the residues of total Fenoxaprop-P and the corresponding TWA values over 1 to 21 d were estimated using the mean initial residue of 3.84 mg/kg for an application rate of 100 g ai/ha. The resulting PECi and TWAC 21 d after application are 0.28 mg/kg and 1.36 mg/kg.

Comment (RMS): Study considered acceptable except the estimation of the DT_{50}. The modelling of pooled initial residue levels is considered not acceptable. Instead, the RMS performed individual modelling of residue trials and estimated the mean of the resulting individual DT_{50}`s, which is 7 days. This DT_{50} is used in the refined

risk assessment.

Comment RMS:	The study is not considered necessary for the risk assessment of birds and terrestrial vertebrates and was not re-evaluated by the RMS.

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).

FPP+MPR EW 144 (69+75 g/L) is intended to be applied as an herbicide in cereals (BBCH 11-39) at a maximum single application rate of 0.083 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.

Screening Step:

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 11-39	Small omnivorous bird	158.8	64.8

Acute risk assessment for birds:

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	0.083	1	13.2	2000	151

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	0.083	1.0	0.53	2.85	30.8	10

The TER_{LT} value is above the trigger of 5 for long-term exposure, indicating 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 11 – 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	83	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 POW value above 3. Log POW values of almost all Fenoxaprop-P-ethyl metabolites are below 3 at ecologically relevant pH values.

Only the Log POW 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 saftey and the log POW value of phenol (AE F040356) is significantly lower than the log POW 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; M-138162-01-1
Fenoxaprop-P-acid (AE F088406)	pH 5: 1.9 pH 7: 0.3 pH 9: 0.0	KCA 2.7/10 Fischer, A.; 2016; M-547422-01-1
Chlorobenzoxazolone (AE F054014)	pH 5: 1.7 pH 7:1.5 pH 9: 1.4	KCA 2.7/08 Fischer, A.; 2015; M-538121-01-1
HOPP-P-acid (AE F096918)	pH 5: - 1.6 pH 7: -2.6 pH 9: -3.1	KCA 2.7/09 Fischer, A.; 2016; M-547403-01-1
6-hydroxybenzoazolone (AE 0316854)	pH 5: 1.0 pH 7: 1.0 pH 9: 0.8	KCA 2.7/11 Fischer, A.; 2016; M-547427-01-1
Phenol (AE F040356)	pH 5: 3.1 pH 7: 3.1 pH 9: 2.4	KCA 2.7/07 Sonnenschein, L.; 2015; M-526725-01-1
Fenoxaprop-dechloro-hydroxy (BCS-CY11271)	pH 5: 2.6 pH 7: 2.6 pH 9: 2.0	KCA 2.7/13 Sonnenschein, L.; 2015; M-526729-01-1
HOPP-ethyl-ester (AE F087795)	pH 5: 1.7 pH 7: 1.7 pH 9: 1.6	KCA 2.7/12 Sonnenschein, L.; 2015; M-526723-01-1

* 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 0.083 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
$NOEL_{long-term}$ [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. 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
$NOEL_{long\text{-}term}$ [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]	0.133
TER	231
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

Supplementary information on tissue concentrations in quail after administration of Fenoxaprop-P-ethyl indicates that the potential for accumulation is low. Furthermore the potential for accumulation is stated as low in the human toxicology section, therefore no risk assessment is conducted.

B.9.2.2. Risk assessment for mammals

Screening Step:

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.

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

Crop	Scenario	Indicator species	SV_{90}	SV_m
Cereals	BBCH 11-39	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 studies with rats ([redacted] 2005).

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	0.083	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.

Long-term risk assessment for mammals:

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 ([redacted] 1986).

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	0.083	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.

Tier1 Riskassement:

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. 9.2.2-4: 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	0.083	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
	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.

<u>Drinking water risk assessment:</u>

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 mammals 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	83	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 POW value above 3. Log POW values of almost all Fenoxaprop-P-ethyl metabolites are below 3 at ecologically relevant pH values. Only the Log POW 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 POW value of phenol (AE F040356) is significantly lower than the log POW of the parent the risk of secondary poisoning is covered by the assessment with the parent Fenoxaprop-P-ethyl (see table B.9.2.1-5). Therefore there is no 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.

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

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 bird of 3000 g eating 425 g per day, according to EFSA.

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

Parameter	Cereals
$NOEL_{long\text{-}term}$ [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 PUMA S 69 EW were conducted with fish, aquatic invertebrates and algae.

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

Reference:	**Fenoxaprop-P-ethyl – oil in water emulsion 69 g/L (Hoe 046360 24 EW14 A203) Effect to *Oncorhynchus mykiss* (Rainbow trout) in a Static-Acute Toxicity Test (method OECD)**
Author(s), year:	[redacted], 1992a
Report/Doc. number:	CE91/045 / M-137461-01-1
Guideline(s):	OECD 203 (1984)
GLP:	Yes
Deviations:	None
Validity:	Acceptable

Material and methods:	
Test substance:	Fenoxaprop-P-ethyl – oil in water emulsion (Hoe 046360 24 EW14 A203), content a.s..: 7.1 %,
Test species:	Rainbow trout (*Oncorhynchus mykiss*)
Number of organisms:	10 fish per control and test concentrations, 1 replicate per treatment
Age, length, weight:	Age: 6 months old Length: mean: 593 mm Weight: mean: 3.37 g
Loading	0.17 g/L fish loading per test vessel
Type of test:	Static, 96 hours
Applied concentrations:	
Nominal:	0 (control), 0.32, 0.56, 1.0, 1.8, 3.2, 5.6 and 10 mg test item/L
Solvent:	None
Test conditions:	
Water quality:	60 % filtered tap water and 40 % deionized water, total hardness: 205 – 212 mg/L as $CaCO_3$, alkalinity: 160 – 162 mg/L as $CaCO_3$
Conductivity:	463 – 471 µS/cm
Temperature:	14.1 – 16.0 °C
pH:	7.7 – 8.2
O_2 content:	6.8 – 10.5 mg/L
Light regime:	Light/dark cycle of 16/8
Feeding	The fish were not fed during the 96 hours study period.

Methods: Test chambers were 300 L stainless steel tanks containing 200 L test medium, with internal dimensions of 810 mm x 600 mm x 680 mm (length x width x height). At the initiation of the study ten fish were allocated at random to each test vessel.

Test parameters: All test vessels were monitored for mortality and sub-lethal effects in 24 hour intervals.

Measurements of temperature, pH and dissolved oxygen were made daily in all treatment solutions. In addition, temperature was continuously measured in the control vessel.

Analytical measurements: Samples of the test substance were measured at the start and the end of the test from the high, middle and lowest concentrations by high performance liquid chromatography.

Statistics: The LC_{50} values and the 95 % confidence intervals were calculated using one of three statistical techniques: binominal probability, moving average or probit analysis.

Findings:

Analytical data: The chemical analysis showed that the actual concentration of Fenoxaprop-P-ethyl was in the range from 82% to 106% of the nominal concentrations. Hence, the endpoints are based on 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/L]			% of nominal concentrations
		0 hours	96 hours	Mean	
Control	Control	0.00	0.00	-	-
0.32	0.0227	0.0208	0.0165	0.01865	82
1.8	0.1278	0.1115	0.1233	0.1174	92
10.0	0.710	0.7559	-	-	106

Biological results: The lowest concentration that resulted in 100% mortality within the period of the test was 5.6 mg test item/L.

The highest concentration with no mortality was 3.2 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 [%]			
	24 h	48 h	72 h	96 h
Control	0	0	0	0
0.32	0	0	0	0
0.56	0	0	0	0

Test concentration [mg test item/L]	Mortality [%]			
	24 h	48 h	72 h	96 h
1.0	0	0	0	0
1.8	0[b]	0[a,b]	0[a,b,d]	0
3.2	0[b,c,e]	0[a,b,c]	0[a]	0[a,b]
5.6	50[c]	100	100	100
10.0	100	100	100	100

[a] Slow reaction, [b] Surfacing, [c] Lethargic, [d] Head up swimming, [e] Gulping air

Conclusion: Based on these results a LC_{50} of 4.2 mg test item/L (95%, CL = 3.2 to 5.6 mg test item/L) based on nominal 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. It is noted that only three concentrations out of 7 were analytically verified.

In addition, the following points deviated from the test guideline or were not reported in detail:

- The conductivity was 463 – 471 µS/cm which is higher than the recommended 10 µS/cm.

The deviation to the test guideline is 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.

Method: HPLC/UV

No information on the linearity, accuracy, precision and the limit of quantification and detection is given in the study report. The information is not sufficient to evaluate the acceptability of the analytical methods according to the guidance documents SANCO/3029/99 rev. 4.

Endpoints:

	The RMS agrees on the endpoints given in the study report. LC_{50} = 4.2 mg test item/L (95% C.I. = 3.2 – 5.6 mg test item/L) corresponding to 0.3 mg a.s./L (95% C.I. = 0.23 – 0.40 mg a.s./L) NOEC = 1.0 mg test item/L corresponding to 0.071 mg a.s./L The endpoints are based on nominal concentrations. **Conclusion of the RMS:** Based on the evaluation of the study the acute fish toxicity test is considered valid.

Reference:	**Fenoxaprop-P-ethyl – oil in water emulsion 69 g/L (Hoe 046360 24 EW14 A203) Effect to *Cyprinus carpio* (Mirror carp) in a Static-Acute Toxicity Test (method OECD)**
Author(s), year:	[redacted], 1992b
Report/Doc. number:	CE91/044 / M-137208-01-1
Guideline(s):	OECD 203 (1984)
GLP:	Yes
Deviations:	None
Validity:	Acceptable

Material and methods:

Test substance:	Fenoxaprop-P-ethyl – oil in water emulsion (Hoe 046360 24 EW14 A203), content a.s..: 7.1 %,
Test species:	Mirror carp (*Cyprinus carpio*)
Number of organisms:	10 fish per control and test concentrations, 1 replicate per treatment
Age, length, weight:	Age: 7 months old Length: mean: 331 mm Weight: mean: 1.05 g
Loading	0.05 g/L fish loading per test vessel
Type of test:	Static, 96 hours
Applied concentrations:	
Nominal:	0 (control), 1.0, 1.8, 3.2, 5.6 and 10 mg test item/L
Solvent:	None
Test conditions:	
Water quality:	60 % filtered tap water and 40 % deionized water, total hardness: 197 – 198 mg/L as $CaCO_3$, alkalinity: 165 – 169 mg/L as $CaCO_3$
Conductivity:	410 – 419 µS/cm
Temperature:	21.4 – 22.6 °C
pH:	8.3 – 8.5
O_2 content:	7.4 – 9.3 mg/L

Light regime: Light/dark cycle of 16/8

Feeding The fish were not fed during the 96 hours study period.

Methods: Test chambers were 300 L stainless steel tanks containing 200 L test medium, with internal dimensions of 810 mm x 600 mm x 680 mm (length x width x height). At the initiation of the study ten fish were allocated at random to each test vessel.

Test parameters: All test vessels were monitored for mortality and sub-lethal effects in 24 hour intervals.

Measurements of temperature, pH and dissolved oxygen were made daily in all treatment solutions. In addition, temperature was continuously measured in the control vessel.

Analytical measurements: Samples of the test substance were measured at the start and the end of the test by high performance liquid chromatography.

Statistics: The LC_{50} values and the 95 % confidence intervals were calculated using one of three statistical techniques: binominal probability, moving average or probit analysis.

Findings:

Analytical data: The chemical analysis showed that the actual concentration of Fenoxaprop-P-ethyl was in the range from 90% to 98 % of the nominal concentrations. 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/L]			% of nominal concentrations
		0 hours	96 hours	Mean	
Control	Control	0.00	0.00	-	-
1.0	0.071	0.06704	0.06113	0.0641	90
3.2	0.2272	0.241	0.2037	0.222	98
10.0	0.710	0.6415	-	-	90

Biological results: The lowest concentration that resulted in 100% mortality within the period of the test was 5.6 mg test item/L.

The highest concentration with no mortality was 1.8 mg test item/L. In the control 0 % mortality occurred.

Table B. 9.3.1-4: Mortality and sub-lethal effects

Test concentration [mg test item/L]	Mortality [%]			
	24 h	48 h	72 h	96 h
Control	0	0	0	0
1.0	0	0	0	0

Test concentration [mg test item/L]	Mortality [%]			
	24 h	48 h	72 h	96 h
1.8	0[a,b,f]	0[a,c]	0[a]	0[a,c]
3.2	0[c,d,e,g]	0[c,d,g,h]	20[a,i]	20[a,c]
5.6	20[b,c]	100	100	100
10.0	100	100	100	100

[a] Slow reaction, [b] Lethargic, [c] Surfacing, [d] Loss of equilibrium, [e] Gulping air, [f] Floating, [g] Horizontal turns, [h] Lateral swimming, [i] Head down swimming

Conclusion: Based on these results a LC_{50} of 3.8 mg test item/L (95%, CL = 1.8 to 5.6 mg test item/L) based on nominal 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. It is noted that only three concentrations out of 5 were analytically verified.

In addition, the following points deviated from the test guideline or were not reported in detail:

- The conductivity was 410 – 419 µS/cm which is higher than the recommended 10 µS/cm.

The deviation to the test guideline is 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.

Method: HPLC/UV

No information on the linearity, accuracy, precision and the limit of quantification and detection is given in the study report. The information is not sufficient to evaluate the acceptability of the analytical methods according to the guidance documents SANCO/3029/99 rev. 4.

Endpoints:

	The RMS agrees on the endpoints given in the study report. LC_{50} = 3.8 mg test item/L (95% C.I. = 1.8 – 5.6 mg test item/L) corresponding to 0.27 mg a.s./L (95% C.I. = 0.13 – 0.40 mg a.s./L) NOEC = 1.0 mg test item/L corresponding to 0.071 mg a.s./L The endpoints are based on nominal concentrations. **Conclusion of the RMS:** Based on the evaluation of the study the acute fish toxicity test is considered valid.

Reference:	***Daphnia magna*, acute Toxicity Test Fenocxaprop-P-ethyl + mefenopyr-diethyl; oil in water emulsion, 69 + 75 g/L**
Author(s), year:	Schäfers, C., 2002a
Report/Doc. number:	C027502 / M-213453-01-1
Guideline(s):	OECD 202 (1984)
GLP:	Yes
Deviations:	None
Validity:	Acceptable

Material and methods:	
Test substance:	Fenoxaprop-P-ethyl + mefenyr-diethyl; oil in water emulsion, 69 + 75 g/L (AE F046360 24 EW14 A716), batch no.: AAH00610, content a.s..: 6.81 % 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:	Static, 48 hours
Applied concentrations:	
Nominal:	0 (control), 1.0, 2.0, 4.0, 8.0 and 16 mg test item/L
Solvent:	None
Test conditions:	
Water quality:	Purified drinking water, total hardness: 0.40 – 0.50 mmol/L, alkalinity: 1.0 – 1.2 mmol/L, Conductivity: 172 – 183 µS/cm, pH: 7.3 – 7.5
Temperature:	20.0 – 20.1 °C
pH:	7.8 – 8.4
O_2 content:	7.9 – 8.6 mg/L 93 – 99 % of air saturation
Light regime:	Light/dark cycle of 16/8
Feeding:	Daphnids were not fed during the study.
Methods:	The test was conducted in 60 mL glass jars with a working volume of 50 mL.
Test parameters:	Immobility and sub-lethal effects were assessed daily.

Measurements of pH, temperature and dissolved oxygen concentrations were made at the start of the test and after 48 hours.

Analytical measurements: Samples of the test solutions were measured at the start of the test and after 48 hours by high performance liquid chromatography.

Statistics: The EC_{50} value and the 95 % confidence intervals were calculated using probit analysis. NOEC and LOEC were determined by using ANOVA followed by William`s test.

Findings:

Analytical measurements: The mean measured concentration of the test medium was between 54.4 and 88.3% of nominal values. Hence, the endpoints are based on nominal concentrations.

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

Nominal concentrations [mg test item/L]	Nominal concentrations [µg a.s./L]	Measured concentrations [µg/L]			% of nominal concentrations
		0 hours	48 hours	Mean	
Control	Control			-	-
1.0	70	51.2	31.4	41.3	59
2.0	140	112.6	65.8	89.2	63.7
4.0	280	221.6	118.1	169.9	60.7
8.0	560	427.8	181.5	304.7	54.4
16.0	1120	1108.9	868.5	988.7	88.3

Biological Effects: The lowest concentration that resulted in 100% mortality within the period of the test was 16 mg test item/L.

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

Table B. 9.3.1-6: Effects on daphnids (*D. magna*)

Nominal concentrations [mg/L]	Mean cumulative immobilized organisms [%]	
	24 hours	48 hours
Control	0	0
1.0	0	0
2.0	0	5
4.0	5	15
8.0	15	45
16.0	100	100

Conclusion: Based on these results an EC_{50} of 7.0 mg/L (95% C.I. 5.7 – 8.9 mg/L) based on nominal concentrations was determined.

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:** Method: HPLC/UV Linearity: Calibration is based on single determination at 14 concentrations. The calibration function was linear within the range from 2.5 – 100 µg/L and 75 – 600 µg/L. Accuracy: 3 fortifications levels (each 2 measurements, 4 measurements at the 100 µg/L concentration): 10, 100 and 500 µg/L. Mean recoveries for each level: 103.5, 100.75 and 99 % Precision: The relative standard deviation per fortification level is not reported. LOQ: The limit of quantification is 1.58 µg/L. LOD: The limit of detection is 0.79 µg/L. No information on the r^2 is given in the study report. **Endpoints:** The study author determined the endpoint based on nominal concentrations. The RMS does not agree on this approach as no stable exposure could be shown. The endpoint should have been based on mean measured concentrations. The RMS conducted a re-evaluation based on mean measured concentrations of Fenoxaprop-P-ethyl, which are 40.1, 86.1, 161.8, 278.6 and 981.4 µg a.s./L. The following endpoint (based on mean measured concentrations) was calculated. 48 h EC_{50} = 281.7 µg a.s./L (95% C.I. 225.3 – 380.3 µg a.s./L) NOEC = 40.1 µg a.s./L **Conclusion of the RMS:** Based on the evaluation of the study the acute Daphnia test is considered valid.

Reference: Heusel, R. (1991b): Effect to *Scenedesmus subspicatus* (green alga) in a growth inhibition test (method OECD) Fenoxaprop-P-ethyl oil in water emulsion 69 g/L Code: Hoe 046360 24 EW14 A203. Report No. CE91/041

Test guideline: OECD 201

GLP: yes

Test item: Hoe 046360 24 EW14 A203: 7.1 % Fenoxaprop-P-ethyl, 7.4 % AE F107892 (Mefenpyr-diethyl, safener)

Material and methods:

The growth inhibition effects of the formulation to the unicelluar green alga Scenedesmus subspicatus were studied under static conditions. The algal cultures (initial cell density: 10^4 cells/ml) were exposed to nominal concentrations of 1.0, 1.8, 3.2, 5.6 and 10 mg/L.

The test samples were incubated for up to 72 hours under static conditions, at temperature ranging from 25.1 – 25.6°C, pH 7.7 – 8.9, and continuous illumination. Cell densities were determined by cell counts (5 x 1 mm^2 x 0.1mm in a counting chamber) under a microscope. The evaluation of growth inhibition was based on AUC comparison as given by OECD 201 (1984). Chemical analysis for the active substance was not performed.

Findings:

All endpoints are based on nominal concentrations. No significant growth inhibition was found in treatments up to 1.8 mg/L, thus the NOEC was estimated be 1.8 mg/L, expressed as Fenoxaprop-P-ethyl 0.13 mg a.s./L. The 72 h E_bC_{50} was calculated to be 4.9 mg/L (95% CL 3.2 – 5.6 mg/L) and 0.35 mg a.s./L (95% CL 0.23 – 0.4 mg/L) expressed as Fenoxaprop-P-ethyl.

Conclusion: 72 h E_bC_{50}: 0.35 mg a.s./L, NOEC: 0.13 mg a.s./L, based on nominal concentrations.

Comment (RMS): The concentration of test substance in test media was not measured, therefore study considered not acceptable.

Comment RMS:	This study was considered not acceptable at the first approval of the active substance. The study summary from the DAR is included in the RAR as additional information.

Reference:	**Alga, (*Pseudokirchneriella subcapitata*), Growth Inhibition Test (OECD 201), static exposure**
Author(s), year:	Wenzel, A., 2005
Report/Doc. number:	C046105 / M-242775-01-1
Guideline(s):	OECD 201 (2004)
GLP:	Yes
Deviations:	None
Validity:	Acceptable

Material and methods:

Test substance:	AE F046360 24 EW14 A717, batch no.: AAKH02042, content: AE F046360 7.14 %, AE F107892 7.83 %
Test species:	Green alga (*Raphidocelis subcapitata*, strain 61.81 SAG, formerly known as *Selenastrum capricornutum* and *Pseudokirchneriella subcapitata)*
Number of organisms:	10000 cells/mL; 6 replicates per control and 3replicates per treatment
Type of test, duration:	Static, 72 hours
Applied concentrations:	
Nominal:	0 (control), 1.0, 2.0, 4.0, 8.0 and 16.0 mg/L

Solvent: None

Toxic reference: Zinc sulphate

Test conditions:

Water quality: Algal nutrient medium (OECD-medium)

Temperature: 21.9 – 22 °C

pH: 7.69 – 8.51

Incubation: Continuous illumination 7927 to 8187 lux

Methods: The test was conducted in 250 mL Erlenmeyer flasks, which were filled with 100 mL medium.

Test parameters: Samples were taken daily to determine the cell densities using a electronic particle counter.

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 concentrations of the active substance, the additive and the metabolites were determined at test initiation after 48 hours and at test termination using high performance liquid chromatography.

Statistics: The $E_{b/y/r}C_x$ values with confidence intervals were calculated using probit analysis.

Findings:

Analytical data: At the start of the test 99 - 121 % of the nominal concentrations of AE F046360 were found. At the end of the test after 72 hours 0 – 68.2 % of nominal concentrations of AE F046360 were found. The concentration of AE F088406 was below the limit of detection at the start of the test. At the end of the test 19 – 52 % of nominal concentrations of AE F088406 were found. The concentration of the additive AE F017892 was between 80 – 102 % of nominal concentrations at the start of the test and between 36 – 61 % at the end of the test. All reported results are expressed in terms of the nominal concentrations of the test item.

Biological effects: Yield, biomass and growth rates are given in the Table B. 9.3.1-7..

Table B. 9.3.1-8: Effects of AE F046360 24 EW14 A717 on the green algae *Pseudokirchneriella subcapitata*

Nominal concentrations [mg/L]	Yield		Growth rate		Biomass	
	Yield [10 000 cells/mL]	% inhibition relative to the control	Mean growth rate [d^{-1}]	% inhibition relative to the control	Area under the curve	% inhibition relative to the control
Control	108.7		1.563		76.6	
1.0	99.0	9.0	1.531	2.0	69.2	9.6
2.0	88.4	18.7*	1.492	4.5	62.6	18.2*
4.0	74.5	31.5*	1.436	8.1*	52.5	31.4*
8.0	21.1	80.6*	0.998	36.2*	14.7	80.8*
16.0	2.4	97.8*	0.290	81.4*	1.6	98.0*

* Statistical significant different compared to the control

Toxic reference:	The results are in agreement with published EC_{50}-values regarding biomass increase related to the Zn^{2+}-ion ranging between 45.0 and 65.4 µg/L for biomass. E_rC_{50} = 34.7 – 68.3 µg/L E_bC_{50} = 13.5 – 46.9 µg/L
Validity criteria:	The cell number in the control cultures increased by a factor of 109 within the test period of 72 h. The pH of the control cultures did not deviate by more than 0.31 units during the test. The coefficient of variation of the section by section specific growth rates in the control was 10.4 %. The coefficient of variation of average specific growth rates during the whole test period in the control was 5.7 %.
Conclusion:	72 h E_yC_{50} = 4.72 mg/L (95% C.I.: 3.03 – 7.33 mg/L) 72 h E_yC_{20} = 2.50 mg/L (95% C.I.: 0.81 – 3.67 mg/L) 72 h E_yC_{10} = 1.79 mg/L (95% C.I.: 0.36 – 2.86 mg/L) 72 h E_bC_{50} = 4.70 mg/L (95% C.I.: 3.01 – 7.36 mg/L) 72 h E_bC_{20} = 2.51 mg/L (95% C.I.: 0.80 – 3.70 mg/L) 72 h E_bC_{10} = 1.81 mg/L (95% C.I.: 0.36 – 2.88 mg/L) 72 h E_rC_{50} = 9.66 mg/L (95% C.I.: 8.60 – 10.9 mg/L) 72 h E_rC_{20} = 5.89 mg/L (95% C.I.: 4.69 – 6.82 mg/L) 72 h E_rC_{10} = 4.54 mg/L (95% C.I.: 3.31 – 5.50 mg/L) 72 h NOEC = 1.0 mg/L (biomass and yield) 72 h NOEC = 2.0 mg/L (growth rate) The toxicity endpoints are based on nominal 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).

In addition, the following points deviated from the test guideline or were not reported in detail:

- No information on morphological changes of the algae is given in the study report.

The deviation to the test guideline is 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.

Method: HPLC/UV

Linearity: Calibration is based on single determination at 11 concentrations.

The calibration function was linear within the range from 0.0025 – 0.1 mg/L and 0.075 – 0.75 mg/L.

Accuracy: not reported.

Precision: The relative standard deviation: ± 1.8 % AE F046362
± 1.7 % AE F088406
± 1.3 % AE F107892

AE F046362:

LOQ: The limit of quantification (LOQ) = 5.36 µg/L.

LOD: The limit of detection (LOD) = 1.44 µg/L

AE F088406:

LOQ: The limit of quantification (LOQ) = 4.98 µg/L.

LOD: The limit of detection (LOD) = 1.34 µg/L

AE F107892:

LOQ: The limit of quantification (LOQ) = 4.50 µg/L.

LOD: The limit of detection (LOD) = 1.21 µg/L

No information on r^2 is given in the study report.

Endpoints:

The study author determined the endpoint based on nominal concentrations. The RMS does not agree on this approach as no stable exposure could be shown. The endpoint should have been based on mean measured concentrations. The RMS conducted a re-evaluation based on mean measured concentrations of Fenoxaprop-P-ethyl and Fenoxaprop-P-acid, which are 41.4, 87.1, 187.5, 374.8 and 561.8 µg a.s./L. The following endpoints (based on mean measured concentrations) were calculated.

72 h E_yC_{50} = 243.5 µg a.s./L (95% C.I.: 180.5 – 328.2 µg a.s./L)

	72 h E_yC_{20} = 159.9 µg a.s./L (95% C.I.: 124.6 – 205.1 µg a.s./L) 72 h E_yC_{10} = 128.3 µg a.s./L (95% C.I.: 100.1 – 165.4 µg a.s./L) 72 h E_bC_{50} = 230.9 µg a.s./L (95% C.I.: 216.4 – 245.7 µg a.s./L) 72 h E_bC_{20} = 142.1 µg a.s./L (95% C.I.: 126.3 – 155.9 µg a.s./L) 72 h E_bC_{10} = 110.2 µg a.s./L (95% C.I.: 94.2 – 124.3 µg a.s./L) 72 h E_rC_{50} = 418.5 µg a.s./L (95% C.I.: 393.5 – 442.9 µg a.s./L) 72 h E_rC_{20} = 312.3 µg a.s./L (95% C.I.: 270.7 – 340.6 µg a.s./L) 72 h E_rC_{10} = 267.9 µg a.s./L (95% C.I.: 219.8 – 300.9 µg a.s./L) 72 h NOEC = 41.4 µg a.s./L (biomass and yield) 72 h NOEC = 87.1 µg a.s./L (growth rate) **Conclusion of the RMS:** Based on the evaluation the algae test is considered valid.

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

Reference:	**Fenoxaprop-P-ethyl – oil in water emulsion 69 g/L Code: Hoe 046360 24 EW14 A703 Effect to *Daphnia magna* (Waterflea) in a 21-day Reproduction Test (method OECD)**
Author(s), year:	Heusel, R., 1994
Report/Doc. number:	CE94/006 / M-133804-01-1
Guideline(s):	OECD 202 (1984)
GLP:	Yes
Deviations:	None
Validity:	Not acceptable

Material and methods:

Test substance:	Fenoxaprop-P-ethyl – oil in water emulsion 69 g/L Code: Hoe 046360 24 EW14 A703 containing 7.4 % Fenoxaprop-P-ethyl (Hoe 046360) and 7.2 % Hoe 107892
Test species:	Water flea (*Daphnia magna*)
Number of organisms:	40 daphnids per controls and test concentrations, 4 replicate per treatment
Age:	First instar, < 24 hours old
Type of test, duration:	Semi-static, 21 days
Applied concentrations:	
Nominal:	0 (control), 0.1, 0.18, 0.32, 0.56 and 1.0 mg/L
Solvent:	None

Test conditions:

Water quality:	Artificial medium (M4, Elendt, 1990), total hardness: 239.2 – 248.7 mg/L as $CaCO_3$, alkalinity: 42.0 – 45.0 mg/L as $CaCO_3$
Conductivity:	565 – 673 µS/cm
Temperature:	19.5 – 20.0 °C
pH:	7.8 – 8.0
O_2 content:	7.1 – 9.0 mg/L
Light regime:	Light/dark cycle of 16/8
Feeding:	Daphnids were fed three times a week with a mixture of algae.
Aeration:	No supplement aeration.
Methods:	The test was conducted in glass beakers of 600 mL capacity, containing 400 mL test water. The test solutions were renewed three times a week.
Test parameters:	Immobilisation, number of immobile and alive offspring and development of embryos were assessed three times a week. Dissolved oxygen, pH, water temperature and depth of water were measured before and after- each test media renewal. Additionally, water temperature was recorded in a separate vessel continuously during the whole test period.
Analytical measurements:	Chemical analyses of test substance concentrations were conducted from the nominal concentrations of 0.1, 0.32 and 1.0 mg/L from freshly prepared test solutions on test day 0, 2, 5, 7, 9, 12, 14, 16 and 19 and from the aged test solutions on test day 2, 5, 7, 9, 12, 14, 16, 19 and 21 by high performance liquid chromatography.
Statistics:	The NOEC was determined by General Linear Models using Duncan`s Multiple t-Test.

Findings:

Analytical measurements:	Analyses of fresh prepared water for Hoe 046360 and its free acid resulted in test substance concentrations ranging from 83.0% to 124.4% of nominal values with mean values per concentration between 100.8% and 110.4% of nominal. Analyses of fresh prepared water for Hoe 107892 and its mono and di free acids resulted in test substance concentrations ranging from 85.0% to 123.5% of nominal values with mean values per concentration between 103.5% and 112.1 % of nominal. Analyses of aged water for Hoe 046360 and its free acid resulted in test substance concentrations ranging from 84.9% to 108.8% of nominal values with mean values per concentration between 93.6 and 99.5% of nominal. Analyses of aged water for Hoe 107892 and its mono and di free acids resulted in test substance concentrations ranging from 79.3% to 117.9% of nominal values with mean values per concentration between 97.0% and 104.3% of nominal. Hence, the results are based on nominal concentrations.

Reproduction: The immobilization of adults was statistically different from the control in the highest tested concentration. Significant differences in reproduction in comparison with the control group were observed in concentrations of and higher than 0.18 mg/L.

Table B. 9.3.2-1: Effects on parental survival and reproduction

Nominal concentrations [mg/L]	Parental survival [%]	No. of dead larvae	No. of alive larvae at Day 21	Mean offspring/female at Day 21
Control	100	0	148.5	14.9
0.1	100	0	192.75	19.3
0.18	100	0	122.75*	12.3*
0.32	100	0	119.00*	11.9*
0.56	95	0	96.25*	10.1*
1.0	80*	0	13.75*	1.7*

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

Conclusion: The NOEC for reproduction was determined to be the tested concentration, 0.1 µg/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 (2009):

- 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.

Not all validity criteria could be verified, as 10 parent animals per replicate were maintained together in one test vessel, it is not possible to calculate a mean number of living offspring produced per parent animal. Therefore the study is not 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.

Method: HPLC/UV

Linearity: The calibration range was within 0.25 – 1.25 mg/L.

Accuracy: 3 fortifications levels (each 2 measurements): 7.4, 23.68 and 74 µg/L. Mean recoveries: 93.7 % (fresh water) and 89.9 % (aged water)

Precision: The relative standard deviation per fortification level: 4.8, 4.3 and 1.5 % (fresh water) and 4.0, 16.4 and 9.5 % (aged water)

LOQ: The limit of quantification (LOQ) = 0.461 µg/L.

LOD: The limit of detection (LOD) = 0.309 µg/L

	No information on the number of concentrations used for the calibration range and on r^2 is given in the study report. **Endpoints:** The study is not considered valid; hence no endpoint was determined by the RMS. **Conclusion of the RMS:** Based on the evaluation of the study the chronic reproduction test is not considered valid.

Reference:	***Daphnia magna*, Reproduction test, dosed at two life stages Part B: reproduction test Fenoxaprop-P-ethyl + mefenpyr-diethyl; oil in water emulsion, 69 + 75 g/L**
Author(s), year:	Schäfers, C., 2002b
Report/Doc. number:	ACS-044/4-21B / M-213455-01-1
Guideline(s):	OECD 211 (1998), US EPA § 72-4
GLP:	Yes
Deviations:	None
Validity:	Acceptable

Material and methods:	
Test substance:	Fenoxaprop-P-ethyl + mefenpyr-diethyl; oil in water emulsion, 69 + 75 g/L , Code: AE F046360 24 EW14 A716 containing 7.0 % Fenoxaprop-P-ethyl (Hoe 046360) and 7.18 % mefenpyr-diethyl, Batch no: AAKH00610
Test species:	Water flea (*Daphnia magna*)
Number of organisms:	Individual exposure: 10 daphnids per control and test concentrations, 10 replicate per treatment Group exposure: 15 daphnids per control and test concentrations, 3 replicate per treatment
Age:	First instar, < 24 hours old
Type of test, duration:	Semi-static, 21 days
Applied concentrations:	
Nominal:	0 (control), 0.125, 0.250, 0.500, 1.00 and 2.00 mg/L
Solvent:	None
Test conditions:	
Water quality:	Purified drinking water, total hardness: 0.40 – 0.50 mmol/L, alkalinity: 1.0 – 1.2 mmol/L, pH: 7.3 – 7.5, conductivity: 172 – 183 µS/cm
Temperature:	19.9 – 20.1 °C
pH:	7.7 – 8.8
O_2 content:	5.0 – 8.5 mg/L 60 – 102 % air saturation

Light regime:	Light/dark cycle of 16/8
Feeding:	Daphnids were fed during the test with suspensions of the unicellular alga *Scenedesmus subspicatus*.
Aeration:	No supplement aeration.
Methods:	Individual exposure: The test was conducted in glass beakers of 250 mL capacity, containing 200 mL test water. The test solutions were renewed once after 10 days. Group exposure: The test was conducted in glass beakers of 500mL capacity, containing 400 mL test water.
Test parameters:	Immobilisation of adults, number of immobile and alive offspring and development of embryos were assessed daily. The lengths of the individually exposed adults were measured at the end of the test. Dissolved oxygen, pH and water temperature were measured at the start of the test and two times week during the study.
Analytical measurements:	Chemical analyses of test substance concentrations were conducted from freshly prepared test solutions on test day 0 and 10 and from the aged test solutions on test day 5, 10, 15 and 21 by high performance liquid chromatography.
Statistics:	The NOEC was determined by means of ANOVA using Williams` test. Concentration-response relationship was analysed by Probit-analysis.

Findings:

Analytical measurements:	The analytical data of the fresh solutions indicated that the mean measured Fenoxaprop-P-ethyl concentrations were between 79.5 and 83.5 % of the nominal test concentrations. The concentrations of the aged solutions were below the limit of quantification. The concentrations of the main metabolites AE F053022 and AE F113225 ranged in the fresh solutions between 6.1 and 7.0 % and 8.0 and 11.7 % and in the old solutions between 82 and 116.4 % and 81.4 and 94.7 %. The concentration of the additive (AE F107892) was between 86 and 110.5 % in the fresh solutions and 16.7 and 21.5 % in the aged solutions. The results are based on nominal concentrations.
Biological effects:	Individual exposure: The immobilization of adults was not statistically different from the control in the tested concentration. Adult body weight and length remained unaffected in all groups. Significant differences in reproduction in comparison with the control group were observed in concentrations of and higher than 0.250 mg/L. Group exposure: The immobilization of adults was not statistically different from the control in the tested concentration. The body length was significantly lower at 2.0 mg/L. At the highest concentration of 2.0 mg/L the number of live offspring was decreased by 20 %. Although not statistically significant, this effect was considered to be treatment-related.

Table B. 9.3.2-2: Effects on parental survival and reproduction, Individual exposure

Nominal concentrations [mg/L]	Parental survival [%]	Weight [mg]	Length [mm]	Mean number of offspring/survivor at Day 21	Intrinsic rate [/d]
Control	100	0.73	4.28	137.8	0.400
0.125	100	0.65	4.15	119.4	0.386
0.250	100	0.64	4.21	108.6*	0.374*
0.500	100	0.57	4.26	108.1*	0.378*
1.00	100	0.45	4.05	98.3*	0.369*
2.00	90	0.61	4.05	87.8*	0.337*

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

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

Nominal concentrations [mg/L]	Parental survival [%]	Length [mm]	Mean number of survivor at Day 21	Intrinsic rate [/d]
Control	100	3.92	89.9	0.386
0.125	100	3.98	80.0	0.352
0.250	100	4.09	90.3	0.360
0.500	100	3.92	87.5	0.358
1.00	87	3.92	79.1	0.366
2.00	100	3.52*	72.4	0.342

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

Conclusion: The NOEC for reproduction was determined to be the tested concentration, 0.125 mg/L and 2.0 mg/L after individual and group exposure. The NOEAEC is 1.0 mg/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.

In the study a mortality of the parent animals of 0 % was observed. The mean number of living offspring was 137.8.

All validity criteria were met; hence, the study is considered valid.

In addition, the following points deviated from the test guideline or were not reported in detail:

- The renewal of the active substance was conducted once at day 10. The guideline recommends a medium renewal at least three times per week.

The deviation to the test guideline is 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. Method: HPLC/UV Linearity: Calibration is based on duplicate determination at sixteen concentrations. The calibration function was linear within the range from 2.5 – 100 µg/L (low concentrations) and 75 – 600 µg/L (high concentrations). Accuracy: 4 fortifications levels (each 5 measurement): 10, 100, 100 and 500 µg/L. Mean recoveries for each level: 98.6, 100.4, 102.4, 99 % LOQ: The limit of quantification (LOQ) = 1.58 µg/L. LOD: The limit of detection (LOD) = 0.79 µg/L No information on r^2 and the precision is given in the study report. **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. It is assumed that the active substance is converted to the metabolite Fenoxaprop-P-acid. No analytical verification of the metabolite was conducted on day 15 and 21 due to analytical problems. Taking into account the available information on analytical measurements, no reliable endpoint based on mean measured concentrations could be calucalted by the RMS. **Conclusion of the RMS:** Based on the evaluation of the study the chronic reproduction test is considered valid. However, no reliable endpoint could be determined.

Reference:	**Fenoxaprop-P-ethyl & Mefenpyr-Diethyl; Oil in Water Emulsion; 69 + 75 g/l *Daphnia magna* Chronic Toxicity Test, Dosed at Two Life Stages in an uncovered Static Laboratory Test System.**
Author(s), year:	Bruns, E., 2006
Report/Doc. number:	EBFPX008 / M-270407-01-2
Guideline(s):	OECD 211 (1998)
GLP:	Yes
Deviations:	None
Validity:	Acceptable

Material and methods:

Test substance:	Fenoxaprop-P-ethyl + mefenpyr-diethyl; oil in water emulsion, 69 + 75 g/L ,

	Code: AE F046360 24 EW14 A717 containing 7.06 % Fenoxaprop-P-ethyl (AE F046360) and 7.60 % mefenpyr-diethyl (AE F107892), Batch no: AAKH02042
Test species:	Water flea (*Daphnia magna*)
Number of organisms:	10 daphnids per control and test concentrations, 10 replicate per treatment
Age:	First instar, < 24 hours old
Type of test, duration:	Semi-static, 21 days
Applied concentrations:	
Nominal:	0 (control and blank control), 0.125, 0.250, 0.500, 1.00 and 2.00 mg/L
Solvent:	None
Blank formulation control:	1.7 mg/L
Test conditions:	
Water quality:	M4 medium (Elendt medium)
Temperature:	20.2 – 20.8°C
Conductivity:	581 – 688 µS/cm
Total hardness:	249.2 – 284.8 mg/L as $CaCO_3$
Alkalinity:	53.4 – 71.2 mg/L as $CaCO_3$
pH:	7.8 – 8.4
O_2 content:	8.7 – 9.7 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.*
Aeration:	No supplement aeration.
Methods:	The test was conducted in glass beakers of 250 mL capacity, containing 200 mL test water. The test solutions were renewed once after 10 days.
Test parameters:	Immobilisation of adults, number of immobile and alive offspring and development of embryos were assessed daily with exception of day 3 and 4. The lengths of the surviving adults were measured at the end of the test. Dissolved oxygen, pH and water temperature were measured at day 0 and 10 for the freshly prepared test solutions and at day 10 and 21 for the aged test solutions. Additionally, environmental temperature was recorded continuously during the test.
Analytical measurements:	Chemical analyses of the actual concentrations of the parent substances Fenoxaprop-P-ethyl and mefenpyr-diethyl and their main metabolites AE F053022 and AE F113225 were conducted from freshly prepared test solutions on test day 0 and 10 and from the aged test solutions on test day 5, 10, 15 and 21 by high performance liquid chromatography.
Statistics:	Parametric procedures involved subjecting reproduction data to a standard one way analysis of variance (ANOVA). If significant differences among the means

were indicated, multiple comparison procedures (e.g. Dunnett's multiple t-test procedure or ,in case of monotonous decrease of responses, adequate step down trend tests (e.g. Williams multiple sequential t-test procedure) were performed on a 5% level of significance to indicate which treatment groups differed significantly from the control. For non-parametric procedures, the Mann-Whitney-Wilcoxon U-test for independent samples was applicable, which allows a pairwise comparison of the medians from unpaired datasets of different sizes. Alternatively corresponding multiple comparison procedure with Bonferroni-Correction were applicable.

Findings:

Analytical measurements: The corresponding summarised recovery rates ranged between 98 % and 130 % for Fenoxaprop-P-ethyl and between 100 % and 113 % for Mefenpyr-diethyl. None of these substances were found in samples from untreated water control and blank formulation group. The results are based on nominal concentrations.

Biological effects: Survival Rate and sub-lethal Effects: Two cases of premature death were recorded during the course of exposure. One parental daphnid exposed to 1700 µg/L of the blank formulation and one daphnid exposed to 200 µg/L of the formulation were found dead one day before study termination. A further parental female from 1700 µg/L blank formulation had to be excluded from reproduction statistics, since this animal was not able to produce offspring during the whole course of the study.

Table B. 9.3.2-4: Effects on parental survival and reproduction, Individual exposure

Nominal concentrations [mg/L]	Parental survival [%]	Length [mm]	Mean offspring/survivor at Day 21
Control	100	4.9	204.4
0.125	100	4.8	206.9
0.250	100	4.9	202.9
0.500	100	4.8	202.7
1.00	100	4.9	210.5
2.00	90	4.4*	139.6*
1.7 (blank formulation)	90	4.6	189.1

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

Conclusion: The NOEC was determined to be the tested concentration 1000 µg/L, based on parental immobilisation and a reduced number of living offspring per surviving parent animal at 2000 µg/L. The toxicity endpoint is based on nominal concentrations.

Reference: **Statement – EC_{10}/EC_{20} calculation for chronic Daphnia toxicity test with Fenoxaprop-P-ethyl & Mefenpyr-Diethyl; Oil in Water Emulsion; 69 + 75 g/L (M-270407-01-1, E. Bruns, 2006)**

Author(s), year:	Hager, J., 2016i
Report/Doc. number:	M-553439-01-1

Conclusion:	EC_{10} = 1324.7 mg/L (95% C.I.: 8633.7 – 1530.5 mg/L) EC_{20} = 1659 mg/L (95% C.I.: 1358.3 – 1802.3 mg/L)

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 (AS), B.5.1.2.2) the analytical method is considered acceptable covering the LOQ (= 0.05 µg/L) **Endpoints:** The RMS agrees on the endpoint given in the study report. NOEC = 1.0 mg/L corresponding to 0.0706 mg a.s./L EC_{10} = 1.3247 mg/L (95% C.I.: 0.8637 – 1.5305 mg/L) The endpoints are based on nominal concentrations. **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 PUMA S 69 EW.

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 Puma S 69 EW and the environmentally relevant metabolites Fenoxaprop-P-acid, Chlorobenzoxazolone, HOPP-acid, Phenol and Fenoxaprop-deschloro. 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-ehtyl 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 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
Salmo gairdneri Rainbow trout	Static	96 h	Mortality	n	0.24	0.46	[redacted] 1986b
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	mm	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	in	**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							

Test organism	Test condition	Time	Endpoint	Test conc.	NOEC [mg/L]	EC_{50}/LC_{50} [mg/L]	Reference
Lemna gibba Duckweed	Semi-static	14 d	Growth rate (frond number)	n	3.0	>3.0	Christ, M.T. & 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 [a]	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 F096918	*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] 2015a
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

Test substance	Test organism	Test condition	Time	Endpoint	Test conc.	NOEC [mg/L]	EC_{50}/LC_{50} [mg/L]	Reference
Chlorobenzoxazolone AE F054014	*Daphnia magna* Waterflea	Semi-static	48 h	Immobility	n	1.3	**6.6**	Young, B.M. & Ruff, D.F., 1999a
HOPP-acid AE F096918	*Daphnia magna* Waterflea	Static	48 h	Immobility	n	n.d.	> 200	Schäfers, C., 2004c
HOPP-acid AE F096918	*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 F096918	*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 F096918	*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								

Test substance	Test organism	Test condition	Time	Endpoint	Test conc.	NOEC [mg/L]	EC_{50}/LC_{50} [mg/L]	Reference
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
				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 Puma S 69 EW 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	Static	96 h	Mortality	n	0.071	0.3	[redacted] 1992a
Cyprinus carpio Mirror carp	Static	96 h	Mortality	n	0.071	0.27	[redacted] 1992b
Aquatic invertebrates							
Daphnia magna Waterflea	Static	48 h	Immobility	mm	0.0401	0.282	Schäfers, C., 2002a
Daphnia magna Waterflea	Semi-static	21 d	Reproduction	n	0.0875	n.d.	Schäfers, C., 2002b*
Daphnia magna Waterflea	Semi-static	21 d	Reproduction	n	0.0706	n.d.	Bruns, E., 2006
Algae							
R. subcapitata Green algae	Static	72 h	Growth rate Biomass Yield	mm	0.087 0.041 0.041	**0.418** 0.231 0.243	Wenzel, A., 2005

n…nominal, mm…mean 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.

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-deschloro.

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) resulting in a $RAC_{fish\ acute}$ of 1.9 µg a.s./L. In addition a study with the mirror carp exposed to the formulation PUMA S 69 EW was submitted ([redacted] 1992b) resulting in a 96 h LC_{50} of 0.27 mg a.s./L.
The risk assessment for fish was conducted based on the endpoint derived from the active substance with bluegill sunfish.

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 = 1.9 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		**1.31**	0.06	0.025	0.004	0.53	0.65
Step 2	N-EU	0.40	0.012	0.0071	0.000028	0.049	0.018
	S-EU	0.40	0.01	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, FOCUS PECsw Step 1 and Step 2 – spring cereals, 1 x 83 g a.s./ha

FOCUS		Fish, acute					
		Fenoxaprop-P-ethyl RAC = 1.9 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		**1.31**	0.06	0.025	0.004	0.53	0.65
Step 2	N-EU	0.40	0.0054	0.003	0.000028	0.027	0.018
	S-EU	0.40	0.010	0.0057	0.000028	0.042	0.018

Bold: PEC_{SW}/RAC ratios > 1

Under consideration of FOCUS Step 2 PEC_{sw} 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-deschloro.

The Tier 1 EC_{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 respresentative formulation was submitted. The EC_{50} derived from the study with the water flea *Daphnia magna* was 282 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	0.0068	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-deschloro 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 substance. 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 70.6 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-deschloro.
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 *Raphidocelis subcapitata* indicate a similar toxicity than observed in the studies with the active substance with the blue-green species *Anabaena-flos-aquae*. The E_rR_{50} for algae was 418 µg a.s./L, resulting in a RAC_{algae} of 41.8 µg a.s./L.
It is noted that *R. subcapitata* was tested with the product whereas the lowest endpoint for the active stubance was derived with *Anabaena-flos-aquae*. One algae study with *R. subcapitata* is available; however no reliable endpoint could be determined due to the results of the analytical measurements. 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 = 41.8 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		0.059	0.0057	0.0028	0.0026	0.0094	0.0055
Step 2	N-EU	0.018	0.0012	0.00081	0.000019	0.00087	0.00015
	S-EU	0.018	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 = 41.8 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		0.059	0.0057	0.0028	0.0026	0.0094	0.0055
Step 2	N-EU	0.018	0.00053	0.00034	0.000019	0.00048	0.00015
	S-EU	0.018	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.

No study with the representative formulation was submitted by the notifier.
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-	Fenoxaprop-	Chlorobenzoxazolone	HOPP-acid	Phenol	Fenoxaprop-

		P-ethyl RAC = 3.36 µg a.s./L	P-acid RAC = 10000 µg/L	RAC = 0.336 µg/L	RAC = 0.336 µg/L	RAC = 270 µg/L	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 + Mefenpyr-diethyl EW 144 (69+75 g/L)** were submitted by the notifier Bayer CropScience.

B.9.5.1.1. Acute toxicity to bees

Reference:	**Oral toxicity (LD_{50}) to honey bees (*Apis mellifera* L.) Fenoxaprop-P-ethyl + AE F107892 Oil in water emulsion 69 + 75 g/L**
Author(s), year:	Waltersdorfer A., 2000a
Report/Doc. number:	Report No. CW00/029, Reference No. C010124
Guideline(s):	EPPO Guideline 170 (1992)
GLP:	Yes
Deviations:	None
Validity:	Additional information

Material and Methods:

Test substance:	AE F046360 24 EW14 A715 (Fenoxaprop-P-ethyl 6.51 % w/w, mefenpyr-diethyl 6.92 % w/w), Batch no. AAKH00773, Density: 1.052 g/mL
Reference:	AE F0029600 00 EC40 C667 Triazophos technical 41.1 % w/w, Density: 1.036 g/mL
Solvent:	None
Test species:	*Apis mellifera* L., adult worker honeybees
Type of test:	Acute oral test
Number of organisms:	Five replicates with 10 bees for control, the reference item treatments and the test item treatment groups
Food:	50% sucrose solution

Oral toxicity test:

Applied concentrations:	Control: 50% (w/w) aqueous sucrose solution Test item: 32.9, 225.7 and 1406.4 µg a.s./bee Reference item: 0.21.032 and 0.91 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 2 hours before they were fed with the solutions. 0.2 mL of the test solution was fed to groups of 10 bees via feeding tubes
Test conditions:	Temperature: 24 – 26.5 °C, Humidity: 55-65 %
Test parameter:	The mortality of honey-bees was recorded at 24, 48 and 72 h.
Analytical measurements:	None

Findings:

Biological results: Food consumption showed a dose-related decrease in the two highest dosing groups as compared with the control. No significant mortality occurred in the control and lowest dosing group. The positive reference group treated with triazophos EC_{40} yielded a 72h LC_{50} of 0.227 µg/bee. Mortality data are shown in the following table:

Table B. 9.5.1.1-1: Mortality in honeybees after oral exposure to Puma S 69EW

diet concentration	food consumption	dose per bee	total number of dead bees after		
% product in diet	per bee (g)	(µg test item)	24 h	48 h	72 h
control	0.042	---	0	0	2
0.075	0.044	32.9	0	0	0
0.745	0.030	225.7	10	10	12
7.446	0.019	1406.4	46	47	47
		LD_{50} (µg/bee)	449	430	**356**
		CF 95%	346 - 584	334 - 556	281 - 464

Conclusion: Puma S 69 EW was shown to have an oral LD_{50} (72 h) of 355.9 µg product / bee to *Apis mellifera*, corresponding to 23.2 µg a.s./bee.

Comment RMS: **Validity:** The study was conducted according to the EPPO Guideline 170 (1992) and is in general agreement with the current valid test guideline according to OECD 213 (1998). No specific validity criteria are given in the EPPO guideline. However, taking into account the validity criteria stated in the OECD guideline 2013 (1998) the study is considered valid.
The study has already been evaluated according to the current valid guideline in the DAR of Fenoxaprop-P-ethyl, therefore no re-evaluation is considered necessary.
Conclusion of the RMS: The study has been conducted with Puma S 69 EW, a study with the intended lead formulation is also available therefore the study is considered as additional information

Reference:	**Contact toxicity (LD_{50}) to honey bees (*Apis mellifera* L.) Fenoxaprop - P - ethyl + AE F107892 Oil in water emulsion 69 + 75 g/l**
Author(s), year:	Waltersdorfer, A., 2000b
Report/Doc. number:	C010015 / M-108222-01-1
Guideline(s):	EPPO Guideline 170 (1992)
GLP:	Yes
Deviations:	None
Validity:	Additional information

Material and Methods:

Test substance:	AE F046360 24 EW14 A715 (Fenoxaprop-P-ethyl 6.51 % w/w, mefenpyr-diethyl 6.92 % w/w), Batch no. AAKH00773, Density: 1.052 g/mL
Reference:	AE F0029600 00 EC40 C667 Triazophos technical 41.1 % w/w, Density: 1.036 g/mL
Wetting agent	None
Test species:	*Apis mellifera* L., adult worker honeybees
Type of test:	Acute contact limit test
Number of organisms:	Five replicates with 10 bees for controls, the reference item treatments and the test item treatment groups
Food:	50% sucrose solution
Applied concentrations:	Control: 50% (w/w) aqueous sucrose solution Test item: 372.3 and 558.5 µg a.s./bee Reference item: 0.2, 0.3 and 0.4 µg a.s./bee
Test parameter:	After being anaesthetized the bees were placed in groups of 10 into petri-dishes lined with filter paper, after which each was treated with a single dose of 1.0 µl test or reference substance on the ventral thorax with the aid of a microapplicator. Controls were treated with 1.0 µl drinking water.
Test conditions:	Temperature: 27 - 28 °C, Relative humidity: 55 - 75 %, Darkness (except during observation)
Test parameter:	Mortality counts were made after exposure for 24, 48 and 72 h.

Findings:

Biological results: No significant mortality occurred in the control and both groups treated with the test item. The positive reference group treated with triazophos EC_{40} yielded a 72h LD_{50} of 0.259 µg/bee. Mortality data are shown in the following table:

Table B. 9.5.1.1-2: Mortality in honeybees after topical exposure to Puma S 69EW

Dosage µg product/ bee	Total number of dead/ damaged bees after :		
	24 h	48 h	72 h
control	0 / 0	1	1
372.3	3 / 0	3 / 1	5
558.5	3 / 0	3	3
LD_{50}	> 558.5	> 558.5	> 558.5

Conclusion: The test item was of low toxicity to the worker honey bee *Apis mellifera* after topical contact as evidenced by a LD_{50} (72 h) > 558.9 µg Puma S 69EW/bee, corresponding to > 36.4 µg a.s./bee.

Comment RMS:	**Validity:** The study is considered acceptable. All validity criteria according to the OECD

	guidelines 214 are met. The study has already been evaluated according to the current valid guideline in the DAR of Fenoxaprop-P-ethyl, therefore no re-evaluation is considered necessary. **Conclusion of the RMS:** The study has been conducted with Puma S 69 EW, a study with the intended lead formulation is also available therefore the study is considered as additional information

Reference:	**Effects of Fenoxaprop-P-ethyl + mefenpyr-diethyl EW 144 (69+75) G (Acute Contact and Oral) on Honey Bees (*Apis mellifera* L.) in the Laboratory**
Author(s), year:	Schmitzer, S. & Ehmke, A., 2013
Report/Doc. number:	81321035 / M-472286-01-1
Guideline(s):	OECD 213 & 214 (1998)
GLP:	Yes
Deviations:	None
Validity:	Acceptable

Material and Methods:

Test substance:	Fenoxaprop-P-ethyl + Mefenpyr-diethyl EW 144 (69+75) G: Fenoxaprop-P-ethyl (AE F046360): 6.89 % w/w, 72.60 g/L; mefenpyr-diethyl (AE F107892): 7.24 % w/w, 76.22 g/L (all values analytical); Batch ID: EFKH003297, density: 1.053 g/mL (20 °C)
Reference:	Perfekthion (Dimethoate 400 g/L), Batch no 0001017331, Density: 1.072 g/mL
Solvent:	None (oral test), 0.5 % Adhäsit (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 5 replicates with 10 bees per replicate. Therefore, a total of 50 bees per test item treatment, reference item treatment and control were set up.
Food:	Commercial ready-to-use sugar syrup (Apiinvert; 30 % sucrose, 31 % glucose, 39 % fructose) *ad libitum*.

Oral toxicity test:

Applied concentrations:	Control: 50% (w/w) aqueous sucrose solution Test item: 200 µg product/bee (nominal), 211.8 µg product/bee (measured) Reference item: 0.30, 0.15, 0.08 and 0.05 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 20 minutes before they were fed with the solutions. The treated food was offered in syringes, which were weighed before and after

introduction into the cages (duration of uptake was 50 minutes for the test item treatments).

Contact toxicity test:

Applied concentrations: Control: emulsified in tap water with 0.5 % wetting agent
Test item: 200 µg product/bee
Reference item: 0.30, 0.20, 0.15 and 0.10 µg a.s./bee

Exposure route: The test item was applied as one 5 µL droplet of Fenoxaprop-P-ethyl + mefenpyr-diethyl EW 144 (69+75) G, dissolved in tap water with 0.5 % Adhäsit, placed on the dorsal bee thorax using a Burkard – Applicator. The reference was applied as one 5 µL droplet of dimethoate, dissolved in tap water with 0.5% Adhäsit. For the control, one 5 µL droplet of tap water containing 0.5 % Adhäsit was used. A 5 µL droplet was chosen in deviation to the guideline recommendation of a 1 µL droplet, since a higher volume ensured a more reliable dispersion of the test item..

Test conditions: Temperature 24 – 25°C, Humidity 51-77%

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

Findings:

Biological results:

Contact Test:

At the end of the contact toxicity test (48 hours after application), there was 4.0 % mortality at 200.0 µg product/bee. No mortality occurred in the control group (water + 0.5 % Adhäsit). After the first 4 hours two bees at the 200.0 µg/bee dose level showed apathy. During the 24 hours assessment after application one single bee in the test item treated group was apathetic. These bees died after 24 and 48 hours, respectively. This was the only occurrence of test item induced behavioural abnormalities.

Oral Test:

In the oral toxicity test, the maximum nominal test level of Fenoxaprop-P-ethyl + Mefenpyr-diethyl EW 144 (69+75) G (*i.e.* 200 µg product/bee) corresponded to an actual intake of 211.8 µg product/bee. This dose level led to 2.0 % mortality after 48 hours. No mortality occurred in the control group (50 % aqueous sugar syrup solution). Two bees were found apathetic during the 48 hours assessment in the oral toxicity test.

Table B. 9.5.1.1-3: Toxicity to Honey Bees; laboratory tests

Test Item	Fenoxaprop-P-ethyl + Mefenpyr-diethyl EW 144 (69+75) G	
Test Object	*Apis mellifera*	
Exposure	contact (solution in Adhäsit (0.5 %)/water)	oral (sugar syrup solution)
Application rate µg product/bee	200.0	211.8

LD_{50} µg product/bee	> 200.0	> 211.8
LD_{20} µg product/bee	> 200.0	> 211.8
LD_{10} µg product/bee	> 200.0	> 211.8
NOED µg product/bee*	≥ 200.0	≥ 211.8

* The NOED was estimated using Fisher's Exact Test (pairwise comparison, one-sided greater, α = 0.05).

Reference item: The contact and oral LD_{50} (24 h) values of the reference item (dimethoate) were calculated to be 0.19 and 0.13 µg a.s./bee, respectively.

Conclusion: The toxicity of Fenoxaprop-P-ethyl + Mefenpyr-diethyl EW 144 (69+75) G was tested in both, an acute contact and an acute oral toxicity test on honey bees.
The contact LD_{50} (48 h) was > 200.0 µg product/bee. The oral LD_{50} (48 h) was > 211.8 µg product/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 4% and 2% 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 0.13 (oral test) and 0.18 (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 required according to the OECD test guideline.
Endpoints: The RMS agrees on the endpoints given in the study report.
48 h LD_{50} (oral) > 211.8 µg prod./bee (>14.59 µg a.s./bee)
48 h LD_{50} (contact) > 200 µg prod./bee (>13.78 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: 1.076 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 dimethoate/kg sugar solution corresponding to actual 0.01 µg dimethoate/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 formulation Fenoxaprop-P-ethyl + mefenpyr-diethyl EW 144 (69+75 g/L) according to the test guideline by Oomen et al. was conducted to address the risk on the honeybee brood.

Reference:	**Fenoxaprop-P-ethyl + mefenpyr-diethyl EW 144 (69+75 g/L): Effects on Honey Bee Brood (*Apis mellifera* L.) – Brood Feeding Test**
Author(s), year:	Schmitzer, S., 2014
Report/Doc. number:	IBACON project no.: 79061031 / M-486086-01-1
Guideline(s):	Oomen *et al*. (1992)
GLP:	Yes
Deviations:	None
Validity:	Acceptable

Material and Methods:

Test substance:	Fenoxaprop-P-ethyl + Mefenpyr-diethyl EW 144 (69 + 75 g/L), Sample description: FAR01685-00, content: Fenoxaprop-P-ethyl (AE F046360): 6.89% w/w, 72.60 g/L (analytical), Mefenpyr-diethyl (AE F107892): 7.24%, 76.22 g/L (analytical).
Reference:	Insegar (insect growth regulator), a.s.: fenoxycarb, Batch no.: L160112, Content 25% (nominal)
Test species:	Honey bees (*Apis mellifera* L.), all ages and all stages Honey bee colonies were maintained according to normal beekeeping practice, containing two magazines with 11 frames, each. Colonies were well fed and queen-right, each colony occupied two magazines ("Deutsch Normalmaß, DN") with 11 frames each. At the start of the experiment, each colony had 7-18 brood combs containing eggs, larvae and capped cells and a sufficient amount of honey and pollen. The colonies were assembled at the same time with healthy queens in order to guarantee uniform bee material in all treatments. 1 year old sister queens were used. The colonies contained about 13860 - 22395 adult honey bees. All colonies were equipped with a dead bee trap at the entrance. 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:	Rossdorf, 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): 8.6 – 31.6 °C (mean: 12.9 – 24.6 °C) Rain: 0.0 – 7.4 mm (total precipitation per day) Rel. humidity (daily mean values): 57.1 – 90.4%

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. 1 L contaminated (test item and reference item) or untreated (control) commercial ready-to-use sugar syrup per colony was used. Three bee colonies were used per treatment group. The test item and reference item solutions were mixed with ready-to-use sugar syrup (Apiinvert) and applied to the bee colonies via a feeding trough, which was put directly into the colony on top of the second magazine. Pure sugar syrup (Apiinvert) was used for the control group. Each feeding trough was weighed before introduction to the bee colonies and after uptake of the contaminated food. 24 hours after application, the bees did not ingest the offered food completely in most of the colonies, therefore the feeding troughs remained in the hives until food uptake was complete. 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 containing 30% sucrose, 31% glucose and 39% fructose) per hive. Test item: 3.11 g test item (Fenoxaprop-P-ethyl + mefenpyr-diethyl EW 144 (69+75 g/L)) in 1 L commercial ready-to-use sugar syrup (Apiinvert), equivalent to a concentration of 0.21 g Fenoxaprop-P-ethyl (a.s.)/L + 0.23 g mefenpyr-diethyl (a.s.)/L. Reference item: 3.0 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 0.75 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 5, 9, 16 and 22 days after the application.

Behavioural abnormalities (e.g. intensive cleaning, restlessness or moving coordination problems) were observed during the assessment of mortality.

Statistics: The data were tested for normal distribution using Shapiro-Wilk`s test and homogeneity of variance using Levene`s test.

Mortality:

A pairwise comparison (α = 0.05) was conducted for the mortality data (two-sided before application and one-sided greater, after application) using Student t-test for homogeneous variances.

Brood Development:

A pairwise comparison (one-sided greater, α = 0.05) was conducted for the comparison of the brood data (egg and larvae termination rates), using Student t-test for homogenous variances.

The software used to perform the statistical analysis was 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 18.4 % compared to 9.6 % 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 was slightly better and resulted in a mean termination rate of 11.8 % compared to 24.4 % in the control group. This difference was not statistically significant compared to the control group.

The mean termination rate of old larvae was slightly higher in the test item treatment group (7.3 %) compared to the values obtained in the control group (3.3 %). There was no statistically significant difference.

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 10.2 dead bees per day) and thus not statistically significantly different when compared to the control group (8.5 dead bees per day).

No effects of the test item on honey bee pupae and larvae were observed.

Table B. 9.5.1.3-1: Effects of Fenoxaprop-P-ethyl + Mefenpyr-diethyl EW 144 (69 +75 g/L) on honey bee brood

Test item	Fenoxaprop-P-ethyl + mefenpyr-diethyl EW 144 (69 + 75 g/L)

Test object	Honeybee *Apis mellifera* L. (complete colonies)		
Exposure	Via treated sugar sugar solution		
Treatment	Untreated control	Fenoxaprop-P-ethyl + mefenpyr-diethyl EW 144 (69 + 75 g/L)	Reference Item (Insegar, a.s. = fenoxycarb)
Rate per L sugar solution [product][1)]	-	3.11 g/L	3.0 g/L
Rate per L sugar solution [a.s.][1)]	-	0.21 g Fenoxaprop-P-ethyl/L + mefenpyr-diethyl/L	0.75 g a.s./L
Termination rate of the eggs [%] [2)]	9.6 %	18.4 % (n.s.)	99.8 % (*)
Termination rate of the young larvae [%] [2)]	24.4 %	11.8 % (n.s.)	99.8 % (*)
Termination rate of the old larvae [%] [2)]	3.3 %	7.3 % (n.s.)	26.9 % (*)
Mean brood termination rate over all stages	12.4 %	12.5 % (n.s.)	75.5 % (*)
Mean mortality of worker bees/colony/day during pre-application phase [3)] during the entire post-application phase [3)]	8.9 8.5	10.8 (n.s.) 10.2 (n.s.)	14.2 (n.s.) 18.7 (*)
Mean mortality of pupae/colony/day during pre-application phase [4)] during the entire post-application phase [4)]	0.1 1.7	0.7 (n.s.) 1.0 (n.s.)	2.9 (n.s.) 0.8 (n.s.)
Mean number of bees before application[5)]	16770	22395	13860

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 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)

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-P-ethyl + Mefenpyr-diethyl EW 144 (69+75 g/L) fortified sugar syrup (210 ppm Fenoxaprop-P-ethyl) to honey bee colonies does neither adversely affect honey bee colonies nor bee brood development.

Comment RMS: **Validity:**

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.

There was a high number of impacted bee brood, which resulted in 75.5 % mean loss of the initial observed cells in the reference item group (99.8 % eggs, 99.8 % young larvae and 26.9 % old larvae stages, respectively). The termination rate of

	the eggs, young and old larvae termination rates were statistically significantly higher compared to the control. Thus, the reference item values were on an absolute scale sufficiently high to demonstrate the sensitivity of the test system.

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 FPP + MPR EW 144 "Ralon Super" 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:	**Fenoxaprop-P-ethyl + mefenpyr-diethyl EW 144 (69+75 g/L): Effects on Honey Bee Brood (*Apis mellifera* L.) under Semi-Field Conditions – Tunnel Test**
Author(s), year:	Tänzler, V., 2016
Report/Doc. number:	98861033 / M-553368-01-1
Guideline(s):	- OEPP/EPPO (2010): Guideline for the efficacy evaluation of plant protection products – Side effects on honeybees. OEPP/EPPO, PP 1/170(4) update 2010, 313 - 319. - OECD No. 75, "Guidance Document on the Honey Bee (*Apis mellifera* L.) Brood Test under Semi-Field Conditions", No. 75, ENV/JM/MONO(2007)22 - Current recommendations of the AG Bienenschutz (2011), "Effectiveness of method improvements to reduce variability of brood termination rate in honeybee brood studies under semi-field conditions", 11th International Symposium of ICPBR, 2 - 4.11.2011, Wageningen, The Netherlands
GLP:	Yes
Deviations:	None
Validity:	Acceptable

Material and Methods:

Test substance:	Fenoxaprop-P-ethyl + mefenpyr-diethyl EW 144 (69+75 g/L): fenoxaprop- P-ethyl (AE F046360): 6.67 % w/w (analytical), Fenoxaprop-P-ethyl D+L (AE F046360 D+L): 6.88 % w/w (analytical), mefenpyr-diethyl (AE F107892): 7.02 % w/w (analytical); Batch ID: EFKH003528; Sample Description: TOX10564-00; Specification No.: 102000011507.
Reference:	Insegar (fenoxycarb), batch no.: L160112, content a.s.: 255 g/kg (analysed)

Test concentrations:	Control: Tap water (400 L/ha) Test item: 83 g a.s./ha via 400 L spray solution/ha; according to Certificate of Analysis: 1.179 L (1.244 kg) product in 400 L tap water/ha (corresponding to 3.11 g product/L tap water) Toxic reference: 300 g fenoxycarb (1200 g product)/ha in 400 L spray solution/ha (corresponding to nominally 3.00 g product/L), All applied during full flowering of the crop when honey bees were actively foraging on the *Phacelia*-crop
Test species:	Honey bees (*Apis mellifera carnica* L.); small bee colonies, maintained according to normal beekeeping practice, containing 11 combs with honey, pollen and brood. The preliminary brood check indicated healthy colonies with all brood stages present and a minimum reserve of food (uncontaminated nectar and pollen) to guarantee colony viability and brood status but also to ensure that enough space is available for exposure of the brood to new food sources. The mean strength of the colonies per treatment group, one day before the application, was similar and ranged between 6593 and 7133 adult bees per colony.
Test design:	The test was conducted under forced/confined exposure conditions (tunnel), in order to assess potential effects of Fenoxaprop-P-ethyl + Mefenpyr-diethyl EW 144 (69+75 g/L) to honey bee colonies including brood development under semi-field conditions. Tunnels (20 m length × 5 m width × 2.5 m height) were set up on a ca. 75 m² plot of *Phacelia tanacetifolia* (2 × 20 m²). Small bee colonies were introduced to the tunnels 3 days before the application. One honey bee colony was used per tunnel. The test item, water and a reference item were applied on the whole plot of plants in two operations, with foraging bees present. The trial was carried out using four tunnels (i.e. replicates) for the test item treatment, the control and the reference item treatment (Insegar, 300 g/kg fenoxycarb), respectively. The confined exposure phase of the honey bees inside the treated crop was 7 days following the test item application. In the evening of day 7 (7 days of confined exposure), all bee colonies (i.e. the colonies from the test item, the control and the reference item group, respectively) were relocated from their respective tunnels and placed in an area with no main flowering, bee attractive crops. After foliar (spray) application of the water (control), test item and the reference item, ontogenesis of a defined number of honey bee eggs was observed for each group and colony. Mortality of adult bees and pupae/larvae as well as foraging activity of the adult bees was also assessed. The condition of the colonies was assessed in regular intervals until the end of the trial. Ontogenesis of the bees from egg to adult workers was observed for a period of 22 days (i.e. one complete honey bee brood cycle). This was done one day before the

application by taking out one or more brood combs and taking a digital picture of the brood comb(s). After saving the file on a computer, 200 eggs per colony were marked at this first brood area fixing day BFD0 (BFD = Brood Area Fixing Day). For each subsequent brood assessment (BFDn), again, the respective comb(s) was taken out of the hive and another digital photo was taken in order to investigate the progress of the brood development until day 21 following the application (BFD22 following BFD0).

Application: Applications were conducted during daytime and during full flowering of the Phacelia-crop (BBCH 65), with confined honey bees actively foraging on the crop during application. The whole plot of plants was sprayed evenly and in two subsequent operations with a hand-held portable boom sprayer equipped with an extension tube including 4 spraying nozzles by compressed air; distance between nozzles: 50 cm. All applications were carried out only, if wind velocity was < 2 m/s (in practice, the applications were conducted at < 1.0 m/s). The bees were very actively foraging at the time of the spraying during the application (13.4 to 17.4 mean bees/m2).

Test conditions: Natural field conditions. On the application day, it was warm and sunny and accordingly there was a good honeybee foraging activity on the crop within the tunnels. The mean temperature on the day of application was 15.9°C.

Mean temperature during the whole experiment (until day 27 following application) was between 12.0 and 30.0°C.

First precipitation (5 mm) occurred on day 1 (ca. 25 hours following the application of control tunnels, ca. 24 hours following the application of the test item tunnels and ca. 23 hours following the last application of the reference item tunnels). Thereafter, rain occurred on days 3 (3.0 mm), 4 (0.5 mm), 5 (24.0 mm), 6 (12.0 mm), 7 (3.0 mm), 10 (4.0 mm), 18 (3.0 mm), 19 (4.0 mm), 21 (3.0 mm), 22 (7.0 mm), 23 (0.5 mm), 26 (4.0 mm), and 27 (11.0 mm).

Feeding: Natural food sources. Water was offered in each tunnel in a drinking trough (the trough was removed during application)

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

Mortality: Bee mortality was assessed by collecting dead bees from the gauze strips in the tunnels (placed on the bare ground at both ends of the tunnels and in the middle of the tunnels) and from dead-bee traps placed in front of each hive. The number of dead bees was assessed as adult worker bees, larvae, pupae and males (drones). Larvae and pupae were summed up together in the following evaluation. Drones were counted and documented in the raw data, but were not considered for the final evaluation. Dead bees were collected on gauze strips. To facilitate collecting of the bees, in the middle of the tunnel, the plants were removed in order to prepare a plane path at ground level and covered by 0.5 m

wide gauze. Additionally, at the front and back end of each tunnel, gauze was laid on the ground in order to collect the dead bees To assess mortality in the colonies, dead-bee traps (wooden boxes, approximately 50 cm x 50 cm x 15 cm, upper side covered by wire mesh with a mesh size of ca. 1 cm; according to an ibacon design) were placed in front of each bee hive. Dead bees removed from the hives by workers were dropped in the trap as they tried to fly through the mesh cover.

Foraging activity: Foraging activity on the plants was recorded within each tunnel at three different plots on an area of 1 m2, respectively. Foraging honey bees were counted on these 1 m2 plots in order to assess the number of bees foraging on flowering plants per unit area. The honey bees were counted on the marked areas during a short time period (e.g. 10-15 seconds).

Behavioural Abnormalities: Sub-lethal effects such as symptoms of poisoning or any abnormal behaviour at the hive entrance or on the plants 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 blowing; bees are sitting motionless in the unit or are able to walk but not correctly)

ic = intensive cleaning

ag = aggressiveness

Brood development: The bee brood was assessed at different expected stages during the development covering one complete development period of the honey bee. The development of the bee brood in individual marked cells was observed by photographing the combs. At the assessment one day before the application (=BFD0; Brood Area Fixing Day), one or more brood comb(s) with an appropriate amount of eggs (200) was taken out of each colony and a digital picture of the comb(s) was taken. The edges of the comb served as hallmark for orientation and retrieval of the marked positions on the comb(s). After saving the file on a computer 200 cells containing eggs were selected, automatically numbered and marked using an image analysis program (Honeybee Brood Logger; Supplier: WSC Scientific GmbH). For each subsequent brood assessment (BFDn), again the respective comb(s) was taken out of the hive and another digital photo was taken and the file was saved. For each photo, the orientation points were marked again in order to allow an automated allocation of the previous marked cells. After retrieval

of the cells on each assessment date, the cell content was assigned. This allowed a continuous photo-documentation following the first brood fixing date (BFD0) until the end of the assessment period. After completion of the cell assessments, a gallery of the cells was automatically generated. Based on this the development of each individually marked cell throughout the duration of the test could be determined.

The different brood stages on the assessment dates were transcribed into indices (0=empty; 1=egg; 2=young larvae, 3=old larvae; 4=pupa; N=nectar; P=pollen) to calculate the termination rate.

If not enough eggs were found on one side of the comb, the brood on the second side (or an additional comb) was photographed and inspected accordingly. 200 cells were marked. Assessment of the development took place according to the following scheme:

Assessment Date	Expected Brood Stage
1 day before application (=BFD0)	eggs (1)
5 days after BFD0 (= BFD +5)	young (2) to old larvae (3) or capped cells (4)
9 days after BFD0 (= BFD +9)	capped cells (4)
16 days after BFD0 (= BFD +16)	closed brood (4) shortly before hatch
22 days after BFD0 (= BFD+22)	empty cells or cells with eggs or young larvae or food

Because of biological variances (e.g. an accelerated or delayed development) the definite development pattern was adapted.

Statistics: Statistical evaluation was done for mortality, foraging activity, colony strength, brood termination rate and brood indices using Shapiro-Wilk`s test (check for normal distribution), Levene`s test (check for homogeneity of variance), Student or Welch t-test (pairwise comparison); (software: TOX Rat Professional, Version 2.10.05, ® ToxRat Solutions GmbH).

Findings:

Biological results: **Mortality of the adult bees (worker bees)**

Pre-application phase (day- 3 to day 0 before application)

Mortality of the pre-application phase in the control, test item and reference item group was 59.4, 17.3 and 59.9 dead bees/colony/day, respectively. The comparison of the mean mortality values of the pre-application phase between the test item treatment and the control group showed a statistical significant difference to the control (Student t-test, pairwise comparison, two-sided, $\alpha = 0.05$). However, this can be seen as disregarded since the mortality values in the test item were lower

(17.3 dead bees/colony/day) in comparison to the control (59.4 dead bees/colony/day).

Exposure phase in the tunnels (day 0 after application to day 7)
There was no sign of an acute effect on the mortality of the bees following the test item treatment. The average control, test item and reference item group mortality of adult bees during the exposition phase (day 0 to day 7 following the application) was 53.5, 32.9 and 57.8 dead bees/colony/day, respectively. This was not statistically significantly different compared to the water control (Student t-test, pairwise comparison, one-sided greater, α = 0.05).

Phase outside the tunnels (day 8 after application to day 27):
An overall comparison of the mean number of dead bees found in the traps after the application from day 8 to day 27 did also not show a statistical significant difference between the control and the test item treatment group (Student t-test, pairwise comparison, one-sided greater, α = 0.05). A mean of 8.2 and 9.7 dead bees per day was found for the period from day 8 to day 27 after treatment in the control and test item group, respectively. Neither did the overall evaluation of the post-application period from day 0 to day 27 show a statistical significant difference between the control and the test item treatment (Student t-test, pairwise comparison, α = 0.05, one-sided greater). From day 0 to day 27 that the number of dead bees found in the test item treatment was 16.3 dead bees /day/tunnel and the number of dead bees found in the control group was 21.1 dead bees/day/colony. There was no impact of the reference item to the adult bee mortality.

Mortality of pupae

Pre-application phase (day -3 to day 0 before application):
Mortality of the pupae in the control, test item and reference item groups was 0.1, 0.3 and 0.4 dead pupae/colony/day, respectively. There was no statistical significant difference between the treatment groups (Welch t-test, pairwise comparison to the control, two-sided, α = 0.05).

Exposure phase in the tunnels (day 0 after application to day 7):
Mean pupae mortality during exposure phase in the control and test item group was also very low (0.1 and 0.4 dead pupae/day/colony, respectively). Accordingly, this was not statistically significantly different to the control group (Welch t-test, pairwise comparison one-sided greater, α = 0.05). Mean pupae mortality in the reference item group was 0.7 dead pupae/day/colony. This was statistically significantly different when compared to the control group (Welch t-test, pairwise

comparison one-sided greater, α = 0.05).

Phase outside the tunnels (day 8 after application to day 27):
Mean pupae mortality from day 8 to day 27 was 0.1 dead pupae/colony/day in the test item group and 0.1 dead pupae/colony/day in the control group. This was not statistically significant when compared to the control group (Welch t-test, pairwise comparison to the control, one-sided greater, α = 0.05). Pupae mortality in the reference item group was distinctly increased and thus, statistically significantly different to the control group. The reference item induced pupae mortality was 36.8 dead pupae/colony/day from day 8 to day 27 and 26.5 dead pupae/colony/day from day 0 to day 27 after the day of application. In both cases, this was statistically significantly different to the control group (Welch t-test, pairwise comparison one-sided greater, α = 0.05).

Foraging activity

Pre-application phase (day -3 to day 0 before application):
The mean foraging activities in the intended test item and reference item groups were comparable to the control group, resulting in overall daily mean values of 10.1, 11.0 and 10.8 bees/m²/day in the control, test item and reference item groups, respectively. No statistical significant differences were found between the control, the test and reference item treatment groups at the overall daily mean comparison of this period (Student t-test, pairwise comparison two-sided, α = 0.05).

Exposure phase in the tunnels (day 0 after application to day 7):
Overall, mean foraging activities from day 1 to day 7 in the test item and reference item group were comparable to the control values on these days. The overall daily mean foraging activity from day 0 to day 7 in the test item and reference item group was 8.4 and 7.2 bees/m²/day, respectively compared to 7.8 bees/m²/day the control group. This was not statistically significantly different (Student t-test, pairwise comparison one-sided smaller, α = 0.05).

Behavioural abnormalities

No test item related behavioural abnormalities occurred at any time during the whole assessment period (up to day 27). No behavioural abnormalities were observed in the control group.

Condition of the Colonies

At the beginning of the trial, all queens and all brood stages (eggs, larvae and closed brood), as well as a sufficient amount of nectar and pollen storage was found in all colonies as an indication of healthy colonies.

All queens and/or a sufficient presence of eggs were found in the test item treated colonies during all brood checks indicating that the queens were alive and healthy. After application, no indication of a test item related effect on the condition of the colonies was observed. All test item treated colonies remained vital with increasing bee numbers and healthy brood. There was no indication of any hazard of the test item on the condition of the bee colonies.

Colony Strength

The mean number of honey bees per colony in all treatment groups was very similar one day before application and did not differ statistically (mean of 6593 to 7133 per colony). There was a strong increase of colony strength in the control and test item group over the course of the study with a maximum of 143% in the control group on day +21 and 176% in the test item group on day +27. At the end of the trial on day +27 following the application, the increase in the test item group was higher (176%) compared to the data of the control group (131%). The mean number of honey bees per colony in the reference item group increased also over the course of the study and resulted in final mean colony strength of 122% on day +27 compared to the beginning of the observation.

No statistically significant difference in the colony strength between the test item treated colonies and the control colonies occurred at any assessment date. The subsequent development of the colony strength among the colonies in the control and test item treatment groups followed more or less the same pattern. Overall, no adverse effects of the test item on colony strength and population development were observed throughout the study.

Considering the initial mean number of bees per treatment group before the application as 100 %, the following relative mean numbers of bees were determined:

Table B. 9.5.1.4-1: Colony development

Treatment Group	Day1 -1	Day +5	Day +9	Day +16	Day +21	Day 27
Control	100%	127%	119%	135%	143%	131%
Test Item	100%	138% (n.s.)	136% (n.s.)	165% (n.s.)	170% (n.s.)	176% (n.s.)
Reference Item	100%	114% (n.s.)	124% (n.s.)	128% (n.s.)	131% (n.s.)	122% (n.s.)

[1] in relation to the application
n.s. = not statistically significant to the control; Student t-test, α=0.05, pairwise; one-sided smaller.

Development of Bee Brood:

Brood Termination Rate

Following the assessment of single cells from the egg stage to the successfully hatched worker bee, the mean termination rate at BFD (Brood Fixing Day) 22 in the test item group was with a mean of 21.3 % negligible higher compared to the

control group (18.6 %). This Brood Termination Rate in the test item group was not statistically significantly different compared to the control group (Student t-test, pair-wise comparison to the control, one-sided greater, α = 0.05).

Treatment with the reference item Insegar (a.s.: fenoxycarb) caused a decrease of brood development of the marked eggs, resulting in a termination rate of 55.0 %. This decrease was statistically significantly different compared to the control group (Student t-test, pair-wise comparison to the control, one-sided greater, α = 0.05).

Brood Compensation Index

The Brood Compensation Index is an indication for recovery and shows the development of the brood at each assessment. A continuous brood development was observed in the test item group as well as in the control group. The Brood Compensation Indices following the labelling of the egg stage up to day 21 after application (BFD+22) were either identical or slightly lower in the test item group compared to the control. There was no statistically significantly difference of the test item group compared to the control group (Student t-test, pair-wise comparison, one-sided smaller, α = 0.05). At the end of the assessment period the Brood Compensation Index of the test item group was comparable to the control group (4.5 vs 4.3) and no statistical difference was detected. The higher termination rate of the marked cells after treatment with the reference item Insegar (a.s.: fenoxycarb) is also reflected by the statistically significantly lower Brood Compensation Indices in the reference item group when compared to the control (Student t-test, pair-wise comparison, one-sided smaller, α = 0.05).

Table B. 9.5.1.4-2: Brood Compensation Index

Treatment Group	BFD +6	BFD +10	BFD +17	BFD +22
Control	2.9	3.4	3.4	4.5
Test Item	2.8 (n.s.)	3.2 (n.s.)	3.4 (n.s.)	4.3 (n.s.)
Reference Item	1.9 (*)	2.4 (n.s.)	2.5 (*)	3.3 (*)

n.s. = not statistically significant to the control, * = statistically significant to the control, Student t-test, α=0.05, pairwise; one-sided smaller

Brood Index: The Brood Index as an additional indicator for the bee brood development facilitates a comparison between the different treatments. Following the labelling of the egg stage, the Brood Indices of the test item group were either identical or slightly lower in the test item group compared to the control. Therefore no statistically significantly difference compared to the control group was detected (Student t-test, pair-wise comparison, one-sided smaller, α = 0.05). The higher termination rate of the marked cells after treatment with the reference item Insegar (a.s.: fenoxycarb) is also reflected by the statistically significantly lower Brood Indices in the reference item group when compared to the control (Student t-test,

pair-wise comparison, one-sided smaller, α = 0.05). Accordingly, no adverse effects of the test item on brood development have been observed throughout the study, following the labelling of the egg stage up to day 21 after application (BFD+22).

Table B. 9.5.1.4-3: Brood Index

Treatment Group	BFD +6	BFD +10	BFD +17	BFD +22
Control	2.9	3.3	3.3	4.1
Test Item	2.8 (n.s.)	3.2 (n.s.)	3.2 (n.s.)	3.9 (n.s.)
Reference Item	1.9 (*)	2.2 (n.s.)	1.8 (*)	2.3 (*)

n.s. = not statistically significant to the control, * = statistically significant to the control, Student t-test, α=0.05, pairwise; one-sided smaller.

Table B. 9.5.1.4-4: Effects of Fenoxaprop-P-ethyl + Mefenpyr-diethyl EW 144 (69+75 g/L) on honey bee brood under semi-field conditions (Tunnel Test)

Parameter	Treatment group1)		
	Control	Fenoxaprop-P-ethyl + Mefenpyr-diethyl EW 144 (69+75 g/L)	Reference Item Insegar [0.3 kg a.s./ha]
Mean mortality of worker bees / colony / day [n] during			
pre-application phase 2)	59.4 ± 32.6	17.3 ± 6.0 (*)	59.9 ± 22.6 (n.s.)
exposure phase in the tunnels 2)	53.5 ± 28.0	32.9 ± 19.4 (n.s.)	57.8 ± 30.2 (n.s.)
phase outside the tunnels 3)	8.2 ± 6.3	9.7 ± 9.4 (n.s.)	8.3 ± 7.1 (n.s.)
overall after application	21.1 ± 25.8	16.3 ± 16.5 (n.s.)	22.4 ± 28.1 (n.s.)
Mean mortality of larvae and pupae [n] during			
pre-application phase 4)	0.1 ± 0.1	0.3 ± 0.2 (n.s.)	0.4 ± 0.3 (n.s.)
exposure phase in the tunnels 4)	0.1 ± 0.1	0.4 ± 0.7 (n.s.)	0.7 ± 0.5 (*)
phase outside the tunnels 5)	0.1 ± 0.2	0.1 ± 0.2 (n.s.)	36.8 ± 59.9 (*)
overall after application	0.1 ± 0.2	0.2 ± 0.4 (n.s.)	26.5 ± 52.9 (*)
Mean foraging activity / m² / colony / day [n] during			
pre-application phase	10.1 ± 2.6	11.0 ± 4.7 (n.s.)	10.8 ± 2.6 (n.s.)
exposure phase in the tunnels	7.8 ± 5.2	8.4 ± 5.0 (n.s.)	7.2 ± 4.3 (n.s.)
Mean brood termination rate [%] 6)	18.6	21.3 (n.s.)	55.0 (*)

1) each with four tunnels (replicate)
2) mean number of dead honey bees per day and colony found in dead bee traps and on gauze strips in the tunnels
3) mean number of dead honey bees per day and colony found in dead bee traps, only
4) mean number of dead pupae/larvae per day and colony found in dead bee traps and on gauze strips in the tunnels
5) mean number of dead pupae/larvae per day and colony found in dead bee traps, only
6) at BFD 22
Statistic: Student or Welch t-test, α=0.05, pairwise; before application: two-sided; after application one-sided greater (mortality and termination rate), one-sided smaller (foraging activity, colony strength).
n.s. = not statistically significant compared to the control; * = statistically significant compared to the control

Conclusion: To assess the potential effects of Fenoxaprop-P-ethyl + Mefenpyr-diethyl EW 144 (69+75 g/L) on honey bee colonies including brood development, 1.244 kg product in 400 L tap water/ha (corresponding to 83 g a.s./ha), tap water for the control and a reference item were applied to a full-flowering and highly bee-attractive crop (i.e. *Phacelia tanacetifolia*) under semi-field (tunnel) conditions

	during bee-flight. No biologically relevant adverse effects on mortality of worker bees or pupae were observed. Foraging activity, behaviour, nectar- and pollen storage as well as queen survival was not affected. No effects on colony development, colony strength or bee brood were observed. Based on the results of this study, it can be concluded that Fenoxaprop-P-ethyl + Mefenpyr-diethyl EW 144 (69+75 g/L) does not adversely affect honey bees and honey bee brood when applied at a rate of 1.244 kg product in 400 L tap water/ha (corresponding to 83 g a.s./ha), during honey bees actively foraging on a bee-attractive, flowering crop. The observed, characteristic brood effects of the reference item Insegar (a.s.: fenoxycarb) in terms of typicality, time of occurrence and extent, showed that the prevailing test conditions allowed for a profound detection of effects on immature honey bee life stages.
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: - The ratio of brood to food (nectar and pollen) should not exceed 4:1 in order to ensure exposure of the brood and to prevent that larvae feed on uncontaminated food. The ratio was quite variable within the honeycombs, however overall a sufficient number had achieved the ratio to assume that the exposure was sufficient. **Acceptability of the analytical methods used in the test:** See section physchem properties. **Endpoints:** The RMS agrees on the conclusion given in the study report. A single application of 1.244 kg product in 400 L tap water/ha (corresponding to 83 g a.s./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

Not necessary when considering the outcome of the risk assessment and the results of the lower-tiered studies.

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

The notifier Bayer CropScience submitted standard laboratory studies with the two standard arthropod species *Aphidius rhopalosiphi* and *Typhlodromus pyri* and an extended laboratory study with *Typhlodromus pyri* upon request. In addition, laboratory studies with additional arthropod species, *Aleochara bilineata*, *Pardosa amentata, Chrysoperla carnea* and *Poecilus cupreus* which were submitted for the first EU approval are available. Studies on non-target arthropods have been performed with the formulations "Puma S 69 EW" and the very similar formulation "HOE 04630 24 EW 14 A 203", both containing 69 g/L Fenoxaprop-P-ethyl and 75 g mefenpyr-diethyl as safener, the formulations are considered compareable (refer to Volume 4 for detailed compositions).

Reference:	**Effects of AE F046360 24 EW14 A715 on the parasitoid *Aphidius rhopalosiphi* in the laboratory – dose response test**
Author(s), year:	Moll, M. & Groer M., 2001
Report/Doc. number:	8081001 / C011097
Guideline(s):	Polgar (1988)
GLP:	Yes
Deviations:	The relative humidity according to the study plan was set to 50 - 90 %. During acclimatisation period on 2 days for approximately 30 minutes the humidity was above 90 % (max. 95%). This deviation is considered to have no impact on the study results.
Validity:	Acceptable

Material and Methods:

Test substance:	AE F046360 24 EW14 A715, Content Fenoxaprop-P-ethyl: 6.51 & w/w, Content mefenpyr-diethyl: 6.92 % w/w, Batch no. AAKH00773
Toxic reference:	Perfekthion (BAS 152 11 I), Content of dimethoate: 395.7 g/L (analysed)
Test species:	*Aphidius rhopalosiphi* (Hymenoptera: Braconidae), adults, < 48 h old
Type of test:	Acute contact laboratory test
Number of organisms:	Exposure period: 4 replicates with 10 adult wasps (7 females, 3 males) per replicate Post-exposure period: 15 replicates/treatment group; 1 female per unit
Treatments:	Control: 200 L deionised water/ha Toxic reference: 0.3 mL Perfekthion/ha in 200 L/ha (corresponding to 1.5 µL Perfekthion EC/L) Test item: 75, 150, 300, 600 and 1200 mL prod./ha; deionised water as diluent;
Exposure route, duration:	Exposure units: 2 treated glass plates, held apart by an untreated aluminium frame and held together with at least 2 clamps. Post-exposure units: Untreated pots with barley seedlings infested with host aphids (*Rhopalosiphum*

padi) of all developmental stages enclosed within a clear polyacrylic cylinder. Exposure time: 48 h, parasitation period: 24 h, post-parasitation period: 12 days.

Feeding: A 1:3 solution of honey in water and a solution of fructose (25 %) on a cotton wool pad

Test conditions: Temperature: acclimatisation period 17 - 19 °C, exposure period 17 – 20 °C, post-exposure period 17-22°C; relative humidity: acclimatisation period 80 – 95%, exposure period 80-90%, post-exposure period: 78-90%; 16 h light : 8 h dark, light intensity: acclimatisation period 1690 lux, exposure period 2120-2320 lux, post-exposure period 2600-5430 lux

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

Number of aphid mummies were counted 12 days after the 24 hours parasitation period.

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

No reproduction testing was performed with the reference item group.

Statistics: Mortality data were analysed for significance using Fisher Exact Test, which is a distribution-free test and does not require testing for normality or homogeneity prior analysis. Reproduction was tested for normal distribution using Kolmogoroff-Smirnov-Test (p = 0.05); because reproduction data were not normally distributed Bonferroni-U-Test (multiple comparison, two-sided, p = 0.05) was used. The software used to perform the statistical analysis was EASY ASSAY, Multiple Testing, © SPiRiT, Version 4.0 and SYSTAT Version 9, © SPSS Inc., 1998.

Findings: After 48 hours of exposure, a statistically significant increase in mortality was observed in the groups treated with 600 and 1200 mL test item/ha. The LR50 was calculated to be 678.2 (563-816) mL/ha. The positive reference substance dimethoate EC 400 caused 100 % mortality.

No statistically significant differences in the parasitation efficiency were observed in all test substance groups compared to the control.

Table B. 9.5.2-1: Summary of the effects AE F046360 24 EW14 A715 on *A. rhopalosiphi* following exposure on glass plates for 48 h under laboratory conditions

Nominal application rate (mL prod./ha)	Mortality		Parasitation efficiency	
	Cumulative [%]	Control corrected [%] [a]	Parasitation rate [mummies/female]	% Reduction relative to control
Control	12.5 ± 9.6	-	12.7 ± 9.3	-
75	5.0 ± 5.8	-8.6	18.0 ± 12.3	-41.7
150	10.0 ± 8.2	-2.9	13.7 ± 9.3	-7.9
300	22.5 ± 5.0	11.4	7.5 ± 8.8	40.9
600	45.0 ± 17.3	37.1 *	7.3 ± 8.8	42.5
1200	87.5 ± 12.6	85.7 *	-	-

Reference item	100 ± 0.0	100 *	-	-

* Statistically significant compared to the control, according to Fisher's Exact Test, α = 0.05

Conclusion: 48 h LR_{50} = 678.2 mL prod./ha

48 h ER_{50} > 600 mL prod./ha

Comment RMS: **Validity:** The study was conducted according to the test guideline by Polgár (1988). 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% (< 5 out of 40 wasp).
- 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.

All validity criteria have been met.

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

Endpoints: The proposed endpoints from the study reported are considered acceptable

48 h LR_{50} = 678.2 mL prod./ha

48 h ER_{50} > 600 mL prod./ha

Conclusion of the RMS: Based on the evaluation of the study, the standard glass plate toxicity test is considered valid and appropriate for risk assessment purposes.

Reference:	**Toxicity to the predatory mite *Typhlodromus pyri* SCHEUTEN (Acari, Phytoseiidae) in the laboratory Fenoxaprop-P-ethyl + AE F107892 Oil in water emulsion 69 + 75 g/L**
Author(s), year:	Waltersdorfer, A., 2000c
Report/Doc. number:	Report no. CW00/025, Reference no. C010041
Guideline(s):	-
GLP:	Yes
Deviations:	None
Validity:	Acceptable

Material and Methods:

Test substance: AE F046360 24 EW14 A715 (oil in water emulsion 69 + 75 g/L), Content of a.s.: Fenoxaprop-P-ethyl (AE F046360) 6.51 % w/w, mefenpyr-diethyl (AE F107892) 6.92 % w/w, Batch no. AAKH00773, Density: 1.052 g/ml

Toxic reference: AE F020846 00 EC37 A202 (BAS 152 11 I), Content of dimethoate: 395.7 g/L,

	Batch no.: 98-1, Density: 1.076 g/ccm
Test species:	*Typhlodromus pyri* protonymphs, < 24 h old
Type of test:	Acute contact laboratory test, 14 days
Number of organisms:	5 replicates with 20 individuals per replicate
Treatments:	Control: 200 L/ha deionised water Toxic standard: 2.5 g/ha Test item: 1.2, 0.048 and 0.012 L prod./ha The test items were sprayed in 200 L/ha on the glasses.
Application:	The suspensions for the test and reference substances were prepared on the day of application. The concentrations were applied to the test cover glasses using a sprayer. Prior to application, each glass was placed on a 60 mm plastic Petri dish lid and bottom with a small edge on the flat outside, labelled with a waterproof crayon and laid with the flat side upwards. After the spray coating had dried, the cover glasses were moved from the treatment dishes into the corresponding petri dishes with the aid of a microscope needle. A small volume of deionized water was then poured slowly into the surrounding plastic vessel so that the glass arenas were lifted from the bottom and floated at approximately half the height of the dish edges.
Feeding:	Pollen (mixture or pine and birch)
Test conditions:	Temperature: 24 - 26°C; relative humidity: 52 – 72%, 16 h photo period, light intensity: not stated
Test parameter:	Mortality was recorded on day 1, 3, 7, 10, 12 and 14 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:	Reproduction of the treated and untreated series was compared with Duncan´s multiple range test, α= 0.05; the computer program used to perform the statistical analyses was the SAS System for Windows (1989-1996).

Findings:

Biological results:	The mean corrected mortality of the nymphs, and the mean reproduction rate of the surviving females exposed to the test material and the toxic reference are shown in the following table.

Table B. 9.5.2-2: Summary of the effects of Puma S 69EW on *Typhlodromus pyri*

test item (mL/ha)	corrected mortality (%) after						reproduction (eggs/fem./7d)	% reduction of reproduction
	1 d	3 d	7 d	10 d	12 d	14 d		
control	-	-	-	-	-	-	12.17	-
12	-1.1	-3.4	4.1	-0.5	15.7	17.0	11.37	6.6
48	0.9	-1.4	2.0	2.6	8.5	3.3	11.16	8.3
1200	22.3	28.0	36.9	42.4	45.4	47.5	1.64 *	87

toxic standard	27.3	58.7	62.7	64.8	66.3	64.3	6.93 *	43.1

* statistically different from the control (p<0.05, one-way analysis of variance)

Conclusion: Based on the results of this study it can be concluded that residues of Puma S 69EW at 1.2 L/ha caused increased mortality and reduced reproduction (R = 87 %) in *T. pyri*. The toxic standard caused significant mortality (64.8 %) and reduced reproduction (43 %). The mortality rates indicated a LR_{50} of > 1200 mL/ha test item equivalent to 82.2 g a.s./ha.

Comment RMS:

Validity:

The study is considered acceptable taking into account the validity criteria stated in the current valid IOBC test guideline (Blümel et al., 2000).

The arithmetic mean mortality (dead and escaped) in the control treatment was below 20% on day 7 after treatment application (being: 11%). The cumulative mean number of eggs per female in the control (from day 7 to day 14) was ≥ 4 eggs/female (being: 10.3 eggs/ female).

The cumulative mean mortality (control corrected) of protonymphs on day 7 exposed to the reference item was 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 endpoints given in the study report.

LR_{50} > 1200 mL prod./ha corresponding to > 82.2 g a.s./ha

ER_{50} > 48 mL prod./ha corresponding to > 3.3 g a.s./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.

Extended laboratory:

Reference:	**Dose-response toxicity (LR50) of AE F046360 24 EW14 A717 to the predatory mite *Typhlodromus pyri* (Scheuten) under extended laboratory conditions**
Author(s), year:	Röhling U., 2005
Report/Doc. number:	05 10 48 051 / M-252427-01-1
Guideline(s):	IOBC (BLÜMEL et al. 2000), modified
GLP:	Yes
Deviations:	None
Validity:	Additional information

Material and Methods:

Test substance: AE F046360 24 EW14 A717 (69 + 75 g/L), Content of a.s.: Fenoxaprop-P-ethyl

	(AE F046360) 7.3 % w/w, mefenpyr-diethyl (AE F107892) 7.83 % w/w, Batch no. AAKH02042, Density: not available
Toxic reference:	Dimethoate EC 400, Content of dimethoate: 408.7 g/L (analysed), Batch no.: 37M 01030 06/1000, Density: 1.0747 g/ccm
Test species:	*Typhlodromus pyri* protonymphs, < 24 h old
Type of test:	Acute contact extended laboratory test, 14 days
Number of organisms:	5 replicates with 20 individuals per replicate
Treatments:	Control: 200 L/ha deionised water Toxic standard: 15 mL prod./ha Test item: 1200, 600, 300, 150, 75 and 15 mL prod./ha The test items were sprayed to 2-D bean leaf discs.
Application:	The application cabin (track-sprayer) was calibrated three times with deionised water immediately before application and once with the spray solution after adjusting the application speed or spray pressure. According to the order the spray fluids were applied in a 2-D system, once on the surface of the bean leaf discs in an automatic application cabin, to ensure an uniform deposit (200 L/ha = 2 mg/cm2, ±10%). The quantity of the test solution per area was checked by weighing four glass plates (4.9 cm x 4.9 cm) placed at representative spots of the application cabin (levelled with the test leaves) before and immediately after application.
Feeding:	Pollen (*Pinus nigra* and *Betula pendula*)
Test conditions:	Temperature: 24 – 27 °C; relative humidity: 75 – 82 %, 16 h photo period, light intensity: 2200 lx
Test parameter:	Mortality: number of surviving, dead and escaped predatory mites Reproduction: number of eggs laid per evaluation period
Statistics:	The software ToxRat Professional 2.09 (RATTE, 2004) was used to perform the statistical analyses. For statistical calculation of mortality the FISHER´s Exact Binomial-test and of fecundity the WELCH-t-test for inhomogeneous variances with BONFERRONI adjustment were used. The accepted significance level was $p \leq 0.05$.). A calculation of the LR_{50} (median lethal rate) was not possible, because of low or no mortality.
<u>Findings:</u>	
Biological results:	The mean corrected mortality of the nymphs, and the mean effect on reproduction rate of the surviving females exposed to dried spray deposits on bean leaf discs the three dose rates of the test material and the toxic reference are shown in the following table

Table B. 9.5.2-3: Summary of mortality and reproduction findings

Test item [mL/ha]	Corrected Mortality after 7 days (%)	Effect on Reproduction (%)

75	1	14.6
150	1	4.0
300	0	5.6
600	0	-2.0
1200	2	27.3
Toxic Standard	96	-
LR_{50} / ER_{50}	> 1200 mL/ha	> 1200 mL/ha
NOEC	1200 mL/ha	1200 mL/ha

Validity criteria: The validity criteria, i.e. control mortality of < 20% for negative control and >50 - 100 % for toxic standard at day 7 and of > 4 eggs per control female, were fulfilled in this study demonstrating the validity and sensitivity of the test system.

Conclusion: In a dose - response toxicity study on Typhlodromus pyri exposed to dried residues of the test item on bean leaves the NOEC for survival and reproduction was determined to be 1200 mL/ha test item. The LR_{50} and ER_{50} was therefore > 1200 mL/ha test item.

Comment RMS:

Validity: The study is considered acceptable taking into account the validity criteria stated in the current valid IOBC test guideline (Blümel et al., 2000).

The arithmetic mean mortality (dead and escaped) in the control treatment was below 20% on day 7 after treatment application (being: 2%). The cumulative mean number of eggs per female in the control (from day 7 to day 14) was ≥ 4 eggs/female.

The cumulative mean mortality (control corrected) of protonymphs on day 7 exposed to the reference item was 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 mortality endpoints given in the study report. LR_{50} > 1200 mL prod./ha

However no information on larvae is given in the report therefore it was not possible to recalculate the cumulative mean number of eggs per female.

Conclusion of the RMS:

Hence, the RMS is of the opinion that the study is considered as not reliable with regard to the effects on reproduction and could only used as additional information.

Reference: **Toxicity to the foliage dwelling predator *Chrysoperla carnea* Steph. (Neuroptera, Chrysopidae) in the laboratory Fenoxaprop-P-ethyl + AE F107892 Oil in water emulsion 69 + 75 g/L**

Author(s), year: Waltersdorfer, A., 2000d

Report/Doc. number:	C010123 / M-198462-01-1
Guideline(s):	Suter & Bigler (2000)
GLP:	Yes
Deviations:	None
Validity:	Acceptable

Material and Methods:

Test substance:	AE F046360 24 EW14 A715, batch no.: AAKH00773, content of a.s.: 6.51 % w/w Fenoxaprop-P-ethyl, content of safener: 6.92 % w/w Mefenpyr - diethyl., Density: 1.052 g/ml
Toxic reference:	AE F020846 00 EC37 A202 (Dimethoate, 395.7 g/L), batch no.: 98-1, Density: 1.076 g/ml
Test species:	*Chrysoperla carnea* (Neuroptera, Chrysopidae), 3 d old larvae
Type of test:	Glass petridishes
Number of organisms:	3 treatment groups with 50 replicates each containing 1 larvae.
Treatments:	Control: 200 l water/ha Toxic reference: 55 ml/ha Dimethoate 40EC applied in 200 L water Test item: 1.2 L /ha applied in 200 L water
Exposure route, duration:	This study encompassed 3 treatment groups (1 dose rates of the test item, control, reference item) with 50 replicates each containing 1 larva. The larvae were exposed to dried residues on glass petridishes.
Test conditions:	The experiment was performed in a controlled environment room at a temperature of 22 – 25 °C and a relative humidity of 47 – 58 % (with a short term deviation to 25 %). The light/ dark cycle was 16:8 hours.
Test parameters:	Mortality: The number of dead larvae was recorded workdaily. Reproduction: The reproduction phase of the study started 8 days after emergence of the adults. The eggs were removed twice weekly over a period of 2 weeks, in each case over complete 24-hour laying intervals (e.g. from Monday to Tuesday and Thursday to Friday). Only eggs laid on the gauze lid were used for the fertility and fecundity counts. All eggs on each gauze were counted. A record was kept of any animals dying during the 24-hour laying interval, and for calculating total fecundity, the total number of females was reduced by 0.5 for each dead female found.

Findings:

Biological results:	The corrected pre-imaginal mortality was 9.5 % in the treatment group and 88.1 % in the toxic standard group.

Table B. 9.5.2-4: Summary of effects of Puma S 69EW on *C. carnea*

Treatment	% larvae surviving		egg production (fertile eggs/fem./d)	egg viability (% hatch)
	to pupation	to emergence		

control	94	84	21.5 ± 3.2	84.9
test item 1200 mL/ha	96	74	21.8 ± 2.4	85.6
toxic standard	14	8	31.7 ± 9.3	89.6

Conclusion: As shown in the table, no significant effects on survival and reproduction of *Chrysoperla carnea* could be observed after treatment equivalent to 1200 mL/ha Puma S 69EW.

Comment RMS:	**Validity:** The study was conducted according to the test guidelines methodology described by Suter & Bigler (1984) and 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%; (12%) - the fecundity (mean number of eggs per female per day) is greater than 15; (21.8) - the fertility (mean hatching rate) is greater than 70%; 85.6 % - the level of mortality in the reference item treatment is greater than 50%. According to the validity criteria, the study is considered acceptable. **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 > 82 kg a.s./ha 48 h ER_{50} > 1200 mL prod./ha corresponding to > 82 kg a.s./ha **Conclusion of the RMS:** Based on the evaluation of the study, the extended laboratory toxicity test is considered valid.

Additionally studies with the similiar product HOE 046360 24 EW14 A203 are available, the studies have been considered as not essential and were not re-evaluated (the studies are copied from the original DAR and are marked in italic):

Reference: Petto R. & Klepka S. (1995): Effects of HOE 046360 24 EW14 A203 on Pardosa amenata (Clerck) (Araneae, Lycosidae) in Laboratory. Document No. A54209

Test guideline: BBA Draft Guideline (1992)

GLP: Yes

Material and methods:

The effect of the product AE F046360 24 EW14 A203 (batch no. 415/91) on adult Pardosa amentata was tested. The test item was sprayed at an application rate equivalent to 85 g a.s./ha onto moistened sand with the spiders. Endosulfan (Thiodan 35) served as toxic standard; three trays with 4 males and three trays with 4 females were used per group. Spiders were regularly fed with Drosophila sp.. Test endpoints were mortality and feeding activity in comparison with the control group. The results were statistically evaluated.

Findings:

After 14 d of exposure, the total mortality without cannibalism was 8.3 % in the test item treated group and 4.2 % in the water control group. Consequently mortality results did not show any indications of toxic effects of the test item on P. amentata. The toxic standard caused 96 % mortality within 24 h of exposure and complete mortality after 8 d of exposure. Food consumption of the spiders exposed to the test substance over two weeks was 34.2 flies per spider as compared to 36.5 flies in the negative control. Therefore, the test item did not cause any significant impact to P. amenata at the tested rate.
Comment (RMS): Study considered acceptable. Study not essential.

Reference: Pietrzik J. (1992): Determination of the side-effects of Hoe 046360 24 EW14 A203 on the ground beetle Poecilus cupreus L. in the laboratory. Document No. A48217
Test guideline: BBA-Guideline VI, 23 – 2.1.8 (1991)
GLP: Yes
Material and methods:
The test item AE F046360 24 EW14 A203 (batch no. 415/91) was sprayed at an application rate equivalent to 85 g a.s./ha onto moistened sand with Poecilus cupreus. Each test series consisted of 5 replicates with 3 pairs of beetles per replicate. Pyrazophos served as toxic reference. Beetles were fed Musca pupae. Test endpoints were mortality and feeding activity between days 8 and 15 in comparison with the control group.
Findings:
No mortality occurred in the untreated control and the test item treated group. The average feeding activity of the control and test item group was 3.8 and 4.4 pupae/beetle, respectively, and thus not indicative of any adverse substance-related effect. After treatment with the toxic standard 90 % of the beetles were found dead. In summary, survival and feeding activity of P. cupreus were not affected at a rate equivalent to 85 g a.s./ha.
Comment (RMS): Study considered acceptable. Study not essential.

Reference: Kühner Ch. (1993): Testing for side-effects of Hoe 046360 24 EW14 A203 on the staphylinid Aleochara bilineata Gyll. (Coleoptera, Staphylinidae) in the laboratory. Document No. A51546
Test guideline: Naton (1988) - modified semi-field test
GLP: Yes
Material and methods:
The test item AE F046360 24 EW14 A203 (batch no. 415/91) was sprayed at an application rate equivalent to 85 g a.s./ha onto moistened sand with 2-5 day old pairs of the rove beetle Aleochara bilineata. To evaluate the hatching rate, pupae of Delia antiqua were buried in the sand as hosts. Three replicates with 10 beetle pairs (60 individuals) were used for each variant. Test endpoints were mortality and hatching rate in comparison with the control group.
Findings:
No behavioural changes or increased mortality were observed in the beetles. The average hatching rate in the test item treated variant was 20.79 % as compared with 17.82 % in the control. In summary, survival and hatching rate of Aleochara bilineata were not affected at a dose rate equivalent to 85 g a.s./ha.
Comment (RMS): Study considered acceptable. Study not essential.

Reference: Petto R. (1992): Effects of Hoe 046360 24 EW14 A203 on the reproduction of Aleochara bilineata Gyll. (Coleoptera, Staphylinidae) in laboratory. Document No. A47601

Test guideline: Naton (1988)

GLP: Yes

Material and methods:

The test item AE F046360 24 EW14 A203 (batch no. 415/91) was sprayed at an application rate equivalent to 85 g a.s./ha onto moistened sand with 2-5 day old pairs of the rove beetle Aleochara bilineata. The beetles were fed with fly larvae. All tests were performed in 3 replicates with 10 pairs of beetles each. On days 8, 15 and 22 after application 190 onion fly pupae were worked into the sand as hosts for Aleochara larvae. On day 36 of the test, the pupae were sieved out and transferred to petri dishes. After eight weeks (day 57) the pupae were examined for parasitation. The parasitation efficiency was calculated for each replicate and statistically compared with the control group.

Findings:

No behavioural changes or increased mortality were observed in the beetles. The average parasitation of the fly pupae was 66 % in the vials treated with the test item and 78 % in the control group; there was no statistically significant difference. As compared with control group, the average parasitation rate in the test item group was 89 %. In summary, survival and reproduction of A. bilineata were not significantly affected at a dose rate equivalent to 85 g a.s./ha.

Comment (RMS): Study considered acceptable. Study not essential.

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

Test substance	Exposure route	Endpoint	Toxicity	Reference
	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
FPP+MPR EW 144 (69+75 g/L)	Acute oral Acute contact	48 h LD_{50} 72h LD_{50}	> 211.8 µg prod./bee (>14.61 µg a.s./bee) > 200 µg prod./bee (>13.8 µg a.s./bee)	Schmitzer, S., 2013

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/ha]	Endpoint [µg /bee]	Q_H
Fenxoaprop-P-ethyl tech.	Oral	1 x 83	> 108.9 µg a.s./bee	< 0.75
	Contact		> 100 µg a.s./bee	< 0.83
FPP+MPR EW 144 (69+75 g/L)	Oral	1 x 1264*	LD_{50} > 211.8 µg prod./bee	< 5.97
	Contact		LD_{50} > 200 µg prod./bee	< 6.32

*Intended product application rate multiplied with a density of 1.053 g/mL

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 use.

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 x 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 0.083 kg a.s./ha)	*Apis mellifera*	FPP+MPR EW 144 (69+75 g/L)	LD_{50} > 211.8 µg from./bee	7.6	< 0.05	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 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 1.264 kg form./ha (1 x 0.083 kg a.s./ha) BBCH 11-39	*Apis mellifera*	FPP+MPR EW 144 (69+75 g/L)	LD_{50} > 200 µg form./bee	< 6.3	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: Effects of FPP+MPR EW 144 (69+75 g/L) on honeybees (chronic exposure)

Test substance	Exposure route	Endpoint	Toxicity	Reference
FPP+MPR EW 144 (69+75 g/L)	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

The chronic study with FPP+MPR EW 144 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 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 refined 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

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 LDD50 = 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	
next crop BBCH 10-29			0.54	1	0.72	0.003	

Exposure	Crop	Endpoint	SV	Ef	twa	ETR	Trigger
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 on honeybees and honeybee brood

Test substance	Exposure route	Results	Reference
FPP + MPR EW 144 (69+75) "Ralon Super"	Honey bee brood feeding (Oomen *et al.*, 1992)	Slightly increased termination rate of eggs and old larvae and decreased termination rate of young larvae. No effects on honey bee pupae and larvae were observed. 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.	Schmitzer, S., 2014
FPP + MPR EW 144 "Ralon Super"	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 %	Taenzler, V. 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 FPP + MPP EW 144 at a concentration of 0.21 g a.s./L, the mean termination rate of eggs in the treatment group was 18.4% and 9.6% in the control. The development success of young larvae in the test item treatment group was lower and resulted in a mean termination rate of 11.8% compared to 24.4% in the control. The termination rate for old larve in the test

item treatment group was 7.3% compared to 3.3% 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 10.2 dead bees per day) and thus not statistically significantly different when compared to the control group (8.5 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 FPP + MPP EW 144 fortified sugar syrup (210 ppm fenopxaprop-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 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 Fenoxaprop-P-ethyl 69 EW do not adversely affect 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 FPP + MPR EW 144, 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	FPP+MPR EW 144 (69+75 g/L)	Acute oral (adult honey bees)	LD_{50} > 14.61 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	FPP+MPR EW 144 (69+75 g/L)	Acute oral (adult honey bees)	LD_{50} > 14.61 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	FPP+MPR EW 144 (69+75 g/L)	Acute oral (adult honey bees)	LD_{50} > 14.61 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

The notifier Bayer CropScience submitted standard laboratory studies with the two standard arthropod species *Aphidius rhopalosiphi* and *Typhlodromus pyri*. In addition, laboratory studies with additional arthropod species, *Aleochara bilineata*, *Pardosa amentata, Chrysoperla carnea* and *Poecilus cupreus* which were submitted for the first EU approval are available.

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 [mL/ha]	Type of effect	Effect [%]	Reference
Aphidius rhopalosiphi (adults)	contact with dried residues on treated glass plates	Puma S 69 EW	75 150 300 600 1200	Corrected mortality / Reproduction	-8.6 / -41.7 -2.9 / -7.9 11.4 / 41.0 37.1* /42.5 85.7* / not assessed	Moll, M. & Groer, 2001
				48 h LR_{50} = 678 mL prod./ha 48 h ER_{50} > 600 mL prod./ha		
Typhlodromus pyri (protonymphs)	contact with dried residues on treated glass plates	Puma S 69 EW	12 48 1200	Corrected mortality / Reproduction	4.1 / 6.6 2.0 / 8.3 36.9 / 87*	Waltersdorfer 2011
				7 days LR_{50} > 1200 mL prod./ha 14 d ER_{50} > 48 mL prod./ha		

Non-target arthropods may be exposed to formulated Fenxoaprop-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 [mL prod./ha]	MAF	Drift [%]	LR_{50} [mL prod./ha]	$HQ_{in\text{-}field}$	$HQ_{off\text{-}field}$
Aphidius rhopalosiphi	1200	1	2.77	678	1.8	0.05
Typhlodromus pyri		1		> 1200	< 1	< 0.03

All HQ-values for both indicator species and the in-field and off-field area are below the trigger of 2 and indicate a low and acceptable risk. It has to be noted that effects on reproduction occurred in the glas plate test with *Typhlodromus pyri* (ER_{50} > 48 mL) which would have resulted in a potential in-field risk. However the first tier glas plate tests and the HQ approach have not been validated for reproductive effects. The applicant submitted a laboratory study with *Typhlodromus pyri* upon request but this study was no considered reliable because no information on the larvae was given in the report. The number of eggs per female seemed to be within the validity criterium but this could not be confirmed with the formula given in Blümel et. al 2000 without information on larvae.

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

A study on the reproductive toxicity of the representative formulation FPP+MPR EW 144 (69+75 g/L) was submitted by the notifier for the re-newal of the EU approval of Fenxoaprop-P-ethyl.

Further new studies on other soil macro-organisms (*Hypoaspis aculeifer*, *Folsomia candida*) were submitted with the formulation FPP+MPR EW 144 (69+75 g/L).

The study summaries for studies with the active substance Fenxoaprop-P-ethyl and the relevant soil metaoblies are provided in the RAR, Volume 3, B.9 (A.S.). The study summaries for the studies with the representative formulation 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. No new acute toxicity studies were submitted for the renewal of the active substance Fenoxaprop-P-ethyl. The results of the acute studies summarised in the DAR (2005) are given below.

Reference: Heusel, R. (1991c): Fenoxaprop-P-ethyl; oil in water emulsion; 69 g/L (Hoe 046360 24 EW14 A203): Effect to Eisenia fetida (earthworm) in a 14 day artificial soil test (method OECD). (Report CE91/042; Document A46759)

Guideline: OECD Guideline 207

GLP: Yes

Material and methods: A 14-days acute toxicity study with Fenoxaprop-P-ethyl, oil in water emulsion, 69 g/l (identification code: Hoe 046360 24 EW14 A203) was conducted on artificial soil. The test substance contained 7.1% Fenoxaprop-P-ethyl (Hoe 046360) and 7.4% Mefenpyr (Hoe 107892). Adult Eisenia fetida (4x10 animals per concentration) were exposed for 14 days to the nominal test concentrations (mixed into soil) of 100, 180, 320, 560 and 1000 mg product/kg substrate (dw). Chosen concentrations were based on a range finding test previously performed. The artificial soil consisted of 69.7% fine quartz sand, 10% sphagnum peat, 20% kaolin clay and calcium carbonate to adjust the pH value to 6.4. The test conditions were 20 ± 1°C, 70 ± 5% relative humidity and constant light. Seven and 14 days after the start of the study the number of surviving worms was determined, cocoon production and intoxication symptoms were recorded. At the end of testing the weight differences of the animals between start and end of testing were determined.

The no observed effect concentration (NOEC) was determined by statistical analysis, employing Analysis of Variance, General Linear Models, Duncan's Multiple Range Test and Fisher's Least Significant difference Test Procedures (SAS, 1979).

Findings:

For the reference substance chloroacetamide the LC50 value with 95% confidence limits was found after 7 days test duration at 27 (18-32) mg/kg and after 14 days at 24 (18-23) mg/kg.

At the start of testing the moisture content of the control substrate was 27.1% and at the end of testing 26.1%. Details of the results are presented in the table below:

Table B. 9.7.1-1: Effects of Hoe 046360 24 EW14 A203 on Eisenia fetida (mean of four replicates) in an acute toxicity study

Test concentration (mg/kg)	*% mortality*		*Production of cocoons*		*% difference between start and end weight*
Test duration	*7 d*	*14 d*	*7 d*	*14 d*	*14 d*
Control	*0*	*0*	*low*	*low*	*3.47*
100	*0*	*0*	*low*	*low*	*1.32*
180	*0*	*0*	*low*	*low*	*4.31*
320	*100*	*100*	*No*	*No*	-
560	*100*	*100*	*No*	*No*	-
1000	*100*	*100*	*No*	*No*	-

Conclusions:

In a 14-day artificial soil test with Fenoxaprop-P-ethyl, oil in water emulsion, 69 g/l (code: Hoe 046360 24 EW14 A203; 7.1% Fenoxaprop-P-ethyl + 7.4% Mefenpyr) the LC_{50} value lay at 240 (95% confidence limits 180-320) mg product/kg substrate (dw.). The NOEC was found to be 180 mg product/kg substrate (dw.).

For the first EU approval of the active substance no earthworm reproduction study with the formulated active substance had been triggered. In order to address new data requirements according to Regulation (EC) No. 1107/2009, additional studies on chronic exposure to earthworms have been performed with FPP + MPR EW 144.

Reference:	**Fenoxaprop-P-ethyl + mefenpyr-diethyl EW 144 (69+75) G: Sublethal toxicity to the earthworm *Eisenia fetida* in artificial soil**
Author(s), year:	Friedrich, S., 2016e
Report/Doc. number:	Study no. 16 10 48 015 S, Reference no. M-548492-01-1
Guideline(s):	OECD 222 (2004), ISO 11268-2 (1998)
GLP:	Yes
Deviations:	None
Validity:	Acceptable

Material and methods:

Test substance:	Fenoxaprop-P-ethyl + mefenpyr-diethyl EW 144 (69+75) G, Batch no.: EFKH003528, 70.37 g/L Fenxoaprop-P-ethyl (analysed),74.03 g/L mefenpyr-diethyl (analysed), density: 1.055 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: 301 - 498 mg/worm, adults with clitellum, approximately 3 months
Type of test, duration:	Laboratory sub-lethal test, 8 weeks (4 weeks adult mortality, 4 weeks juvenile development)
Applied concentrations:	Nominal: 0 (control, quartz sand), 18, 32, 56, 100 178, 316, 562, and 1000 mg test item/kg soil dw
Solvent:	None
Toxic standard:	Carbendazim 500 SC, tested in a separate study at concentrations of 5 and 10 mg prod./kg soil dw
Test substrate:	Artificial soil, 10 % sphagnum peat, 20 % kaolin clay, 69.5 % industrial quartz sand, 0.5 % calcium carbonate
Substrate/test vessel:	500 g dry weight/test container
Temperature:	18.8 – 22.0 °C
Light regime:	16 hours light (570 lx) / 8 hours dark
Water content:	Test start: 34.9-35.1 % (equivalent to 55.7-56.0 % of WHC) Test end: 34.1-35.1 % (equivalent of 54.4-56.0 % of WHC)
pH:	Test start: 6.02 – 6.11 Test end: 5.7 – 5.85
Feeding:	Finely ground horse manure was used as food; 5 g per replicate was added each week for the first 4 weeks.
Test parameters:	Temperature and air humidity were recorded continuously during the whole test period. The moisture content and the pH of the artificial soil were determined at the start and the end of the test. Mortality of adults (assessed after 28 days), mean body weight of adults (measured at day 0 and after 28 days), morphological and behavioural changes of adults (observed at day 28), number of juvenile earthworms (counted after 8 weeks) and condition and behaviour of juveniles (observed after 8 weeks)
Statistics:	The endpoints were mortality, change of biomass (difference in fresh weight of surviving worms between test start and four weeks after treatment) and reproduction (the number of juveniles present). The arithmetic mean and the standard deviation per treatment and per control for reproduction, mortality and biomass were calculated. The statistical analysis was performed with the software ToxRat Professional 3.2.1 (Ratte 2015). The EC_{10} and EC_{20} values (number of juveniles) were estimated by Probit analysis using linear max. likelihood regression. Confidence limits (95 %) of the ECx values were computed by normal approximation. 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. For statistical evaluation of the biomass change, the changed mean fresh weight of surviving worms per replicate was used.

Findings:

Biological results: Fenoxaprop-P-ethyl + mefenpyr-diethyl EW 144 (69+75) G showed statistically significantly adverse effects on mortality of the earthworm *Eisenia fetida* in artificial at 562 and 1000 mg test item/kg d.w. Statistically significant effects on biomass compared to the control group were recorded at a concentration of 562 mg test item/kg d.w. The test item showed statistically significantly adverse effects on reproduction at 316, 562 and 1000 mg test item/kg d.w.

Table B. 9.7.1-2: Observations

Fenoxaprop-P-ethyl + mefenpyr-diethyl EW 144 (69+75) G [mg test item/kg d.w.]									
	Control	18	32	56	100	178	316	562	1000
Mortality of adult worms after 4 weeks									
Mortality (%)	0.0	0.0	2.5	0.0	0.0	0.0	0.0	45.0*	100.0*
Biomass change (change in fresh weight after 4 weeks relative to initial fresh weight)									
Mean (mg)	95.3	91.6	105.8	91.8	104.4	83.4	88.4	15.9	-
Mean (%)	24.4	23.3	27.1	23.4	26.6	21.4	22.8	4.1*	-
Number of juveniles per surviving adult worm after 8 weeks									
Mean	14.6	13.9	15.1	14.5	13.3	12.5	3.7	0.04	-
Number of juveniles per replicate after 8 weeks									
Mean	146.0	138.8	147.8	144.5	132.8	125.0	37.3*	0.3*	0.0*
Reproduction compared to control (%)									
% to control	100	95.0	101.2	99.0	90.9	85.6	25.5	0.2	0.0

*: statistically significantly different from control (Multiple Sequentially-rejective Fisher Test After Bonferroni-Holm for mortality, α = 0.05, one-sided greater, Williams-t-test for biomass, α = 0.05, two-sided, Williams-t-test for reproduction,α = 0.05, one-sided smaller)

Table B. 9.7.1-3: Effects on mortality, growth and reproduction of *Eisenia fetida* in a sub-chronic test

Test item Test object Exposure	**Fenoxaprop-P-ethyl + mefenpyr-diethyl EW 144 (69+75) G** ***Eisenia fetida*** **Artificial soil**		
	Mortality	Biomass change	Reproduction
	[mg test item/kg d.w.]		
NOEC	316	316	178
LOEC	562	562	316
EC_{10} [1)] (95% confidence limits)	-	-	164 (138 – 194)
EC_{20} [1)] (95% confidence limits)	-	-	190 (167 – 217)

[1)] based on Probit analysis

Validity criteria:

Validity Criteria	**Recommended**	**Obtained**
Adult mortality	≤ 10%	0 %
Number of juveniles per replicate	≥ 30	103, 175, 151, 157, 114, 164, 138 and 166
Coefficient of variation of	≤ 30%	17.6 %

reproduction		

Reference item: In a reference test, the number of juveniles was reduced by 46 and 100 % by the toxic standard Nutdazim 50 FLOW (Carbendazim, SC 500) at concentrations of 5 and 10 mg/kg d.w. in comparison to the control. Therefore, the observed effects assure a high sensitivity of the test system.

Conclusion: The No-Observed-Effect-Concentration (NOEC) for reproduction was determined to be 178 mg test item/kg d.w., and the Lowest-Observed-Effect-Concentration (LOEC) for reproduction was determined to be 316 mg test item/kg d.w.

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 146.
- the coefficient of variation of reproduction to be ≤ 30 %: fulfilled, the coefficient of variation was 17.6 %.
- 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} = 251.33 mg/kg sdw (95% C.L. = not determined)

LC_{20}= 329.79 mg/kg sdw (95% C.L. = not determined)

LC_{50} = 554.57 mg/kg sdw (95% C.L. = not determined)

$NOEC_{mortality}$ = 316 mg/kg sdw

$EC_{10\ reproduction}$ = 170.015 mg/kg sdw (95% C.L. = 131.682; 219.507), Normalised width = 0.52, EC_{10} considered reliable

$EC_{50\ reproduction}$ = 257.101 mg/kg sdw (95% C.I. = 190.607; 346.629)

$NOEC_{reproduction}$ = 178 mg/kg sdw (Williams Multiple Sequential t-test)

$EC_{10\ weight\ change}$ = not determined

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

	$EC_{50\ weight\ change}$ = not determined $NOEC_{weight\ change}$ = 316 mg/kg sdw (Williams Multiple Sequential 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. A reliable EC_{10} could be identified in addition: $NOEC_{growth}$ = 316 mg test item/kg soil dw $NOEC_{reproduction}$ = 178 mg test item/kg soil dw $EC_{10\ reproduction}$ = 170.015 mg test item/kg soil dw $NOEC_{mortality}$ = 316 mg test item/kg soil dw **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:	**Fenoxaprop-P-ethyl + mefenpyr-diethyl EW 144 (69+75)G: Effects on the reproduction of the Collembola *Folsomia candida* tested in artificial soil**
Author(s), year:	Friedrich, F., 2016f
Report/Doc. number:	Study no. 16 10 48 013 S, Reference no. M-548494-01-1
Guideline(s):	OECD 232 (2009), ISO 11267 (1999)
GLP:	Yes
Deviations:	None
Validity:	Acceptable

Material and methods:

Test substance:	Fenoxaprop-P-ethyl (BCS-AI29196) + mefenpyr-diethyl (BCS-AF80757) EW 144 (69+75) G (FPP+MPR EW 144 (69+75)G), Batch no.: EFKH0003528, 70.37 g/L Fenxoaprop-P-ethyl (analysed), 74.03 g/L mefenpyr-diethyl (analysed)
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 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), 18, 32, 56, 100, 178, 316, 562 and 1000 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
Substrate/test vessel:	30 g wet weight, crumbly structured
Temperature:	19.8 – 21.5 °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: 24.3 – 24.6% (equivalent of 56.9 – 57.6% of WHC)
pH:	Test start: 6.02 – 6.06 Test end: 5.72 - 5.8
Feeding:	Approximately 2 mg of granulated dry yeast at the start of the test and after 14 days
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 Multiple Sequentially-rejective Welch-t-test After Bonferroni-Holm were used to compare the control with the independent test item group. The EC10 and EC20 values were calculated by Probit analysis using linear max. likelihood regression.

Findings:

Biological results:

Mortality:

Mortality rate of 1.3% were recorded in the test item treatment group. 1.3% parental mortality was observed in the control. No statistically significant effect (Fisher's Exact Binomial Test, $\alpha = 0.05$, one-sided greater) on parental mortality was found for the test item treatment group. No effects on behaviour of the collembolans were observed during the test.

Reproduction:

The mean number of juvenile collembolans counted four weeks after introduction of the parental collembolans into the test vessels was 1192 in the control and 1179 at 111.6 mg test item/kg soil d.w., respectively. No statistically significant effects (Student-t-test, $\alpha = 0.05$, one-sided smaller) on the number of juveniles compared to the control group was recorded at the test item treatment group.

Table B. 9.7.2-1: Effects on mortality and reproduction of *Folsomia candida* in a sub-chronic test

Test item Test object Exposure	**Fenoxaprop-P-ethyl + mefenpyr-diethyl EW 144 (69+75) G** *Folsomia candida* Artificial soil

mg test item/kg dry weight artificial soil (nominal concentrations)	Adult mortality (%)	Significance (**)	Mean number of juveniles per test vessel ± standard deviation			Reproduction (% of control)	Significance (*)
Control	6.3		734	±	87	-	
18	5.0	-	731	±	122	100	-
32	5.0	-	711	±	24	97	-
56	10.0	-	675	±	34	92	-
100	42.5	+	554	±	58	76	+
178	37.5	+	445	±	97	61	+
316	100	+	57	±	25	8	+
562	100	+	14	±	8	2	+
1000	100	+	0	±	-	0	+
						Mortality	**Reproduction**
NOEC (mg test item/kg dry weight artificial soil)						56	56
LOEC (mg test item/kg dry weight artificial soil)						100	100
						Reproduction	
EC_{10} (mg test item/kg dry weight artificial soil)[1)]						80	
95% confidence limits						(54 –119)	
EC_{20} (mg test item/kg dry weight artificial soil)[1)]						105	
95% confidence limits						(78 – 141)	

The calculations were performed with unrounded values
[1)] Probit analysis
(*) = (Multiple Sequentially-rejective Welch-t-test After Bonferroni-Holm, one-sided-smaller, α = 0.05, + = significant, - = not significant)
(**) = (Multiple Sequentially-rejective Fisher Test After Bonferroni-Holm, one-sided-greater, α = 0.05, + = significant, - = not significant)

Validity criteria:

Validity Criteria	Recommended	Obtained
Adult mortality	≤ 20%	6.3 %
Number of juveniles per replicate	≥ 100	734
Coefficient of variation of reproduction	≤ 30%	11.8 %

Reference item: In a separate study (BioChem project No. R 15 10 48 003 S, dated August 04, 2015), the EC_{50} (reproduction) of the reference item boric acid was calculated to be 103 mg/kg soil dry weight. The results of the reference test demonstrate the sensitivity of the test system.

Conclusion: The test item Fenoxaprop-P-ethyl + mefenpyr-diethyl EW 144 (69+75) G showed statistically significantly adverse effects on adult mortality of the collembolan *Folsomia candida* in artificial soil at concentrations including and above 100 mg test item/kg d.w.

The test item caused a significant reduction of reproduction of the collembolan *Folsomia candida* in artificial soil at concentrations including and above 100 mg test item/kg d.w. Therefore, the No-Observed-Effect-Concentration (NOEC) for reproduction was determined to be 56 mg test item/kg soil d.w. and the Lowest-Observed-Effect-Concentration (LOEC) for reproduction was determined to be

	100 mg test item/kg soil d.w
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 6.3% - The mean number of juveniles per vessel should be at least 100 at the end of the test: fulfilled, actual value in test was 733.5 - 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 = 11.8% **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 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} = 46.141 mg/kg sdw (95% C.L. = 66.486; 87.452) LC_{20} = 65.586 mg/kg sdw (95% C.L. = 23.505; 105.576) LC_{50} = 128.528 mg/kg sdw (95% C.L. = 74.091; 222.992) $NOEC_{mortality}$ = 56 mg/kg sdw $EC_{10\ reproduction}$ = 87.452 mg/kg sdw (95% C.L. = 66.486; 115.031), Normalised width = 0.6, EC_{10} considered reliable $EC_{20\ reproduction}$ = 112.402 mg/kg sdw (95% C.L. = 85.972; 147.102) $EC_{50\ reproduction}$ = 181.681 mg/kg sdw (95% C.L. = 130.543; 251.013) $NOEC_{reproduction}$ = 56 mg/kg sdw (Bonferroni Welch-test) EC_x concentrations were calculated by 3-parametric normal cumulative distribution function. Endpoints from the study report are acceptable: $NOEC_{reproduction}$ = 56 mg /kg soil dw $NOEC_{mortality}$ = 56 mg/kg soil dw **Conclusion of the RMS:** The study is considered to be valid.

Reference:	**Fenxoaprop-P-ethyl +mefenpyr-diethyl EW (69+75) G: Effects on reproduction of the predatory mite *Hypoaspis aculeifer* in artificial soil**
Author(s), year:	Schulz, L., 2016e
Report/Doc. number:	Report no. 16 10 48 014 S, Reference no. M-551052-01-1
Guideline(s):	OECD 226 (2008)
GLP:	Yes
Deviations:	None
Validity:	Acceptable

Material and methods:

Test substance:	Fenxoaprop-P-ethyl (BCS-AI29196) + mefenpyr-diethyl (BCS-AF80757) EW 144 (69+75) G, Batch no.: EFKH003528, Fenoxaprop-P-ethyl (sum of D+L ismoers) 70.37 g/L (analysed), mefenpyr-diethyl 74.03 g/L (analysed)
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 with 10 female adults.
Life stage, age:	Adults from a synchronised culture with an age difference of 3 days
Type of test, duration:	Laboratory sub-lethal test, 14 days
Applied concentrations:	Nominal: 0 (control), 18, 32, 56, 100, 178, 316, 562 and 1000 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:	19.7 – 21.5 °C
Light regime:	16 hours light (455 lx) / 8 hours dark
Water content:	Test start: 18.13 – 19.6% (equivalent to 44.86 – 48.50% of WHC) Test end: 17.39 – 18.86% (equivalent of 43.02 – 46.65% of WHC)
pH:	Test start: 5.9 – 6.1 Test end: 5.4 – 5.5
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:	The statistical analysis was performed with the software ToxRat Professional 2.10.06 (RATTE 2010). Fisher´s Exact Binominal test with Bonferroni correction and Williams-t-test were used to compare the control with the independent test item groups. Probit analysis was used for LCx and ECx calculation.

Findings:

Biological results: The test item Fenoxaprop-P-ethyl + mefenpyr-diethyl EW 144 (69+75) G showed no statistically significantly adverse effects on adult mortality of the predatory mite *Hypoaspis aculeifer* in artificial soil up to and including 316 mg test item/kg soil dry weight. At test concentrations of 562 and 1000 mg test item/kg soil dry weight statistically significant effects on mortality could be observed. The test item showed no statistically significantly adverse effects on reproduction of *Hypoaspis aculeifer* up to and including 56 mg test item/kg soil dry weight. At test concentrations of 100, 178, 316, 562 and 1000 mg test item/kg soil dry weight statistically significant effects on reproduction could be observed.

Table B. 9.7.2-2: Effects on mortality and reproduction of *Hypoaspis aculeifer* in a sub-chronic test

Test item Test object Exposure	**Fenoxaprop-P-ethyl + mefenpyr-diethyl EW 144 (69+75) G *Hypoaspis aculeifer* Artificial soil**						
mg test item/kg dry weight artificial soil (nominal concentrations)	**Adult mortality (%)**	**Significance (**)**	**Mean number of juveniles per test vessel ± standard deviation**			**Reproduction (% of control)**	**Significance (*)**
Control	7.5		292	±	35	100	
18	7.5	-	280	±	12	96	-
32	10.0	-	287	±	16	98	-
56	5.0	-	281	±	21	96	-
100	7.5	-	234	±	43	80	+
178	20.0	-	218	±	16	75	+
316	20.0	-	74	±	31	25	+
562	57.5	+	3	±	2	1	+
1000	100.0	+	0	±	0	0	+
						Mortality	**Reproduction**
NOEC (mg test item/kg dry weight artificial soil) LOEC (mg test item/kg dry weight artificial soil)						316 562	56 100
						Reproduction	
EC_{10} (mg test item/kg dry weight artificial soil)[1)] 95% confidence limits EC_{20} (mg test item/kg dry weight artificial soil)[1)] 95% confidence limits						69 (24 - 104) 104 (53 - 145)	

The calculations were performed with unrounded values

[1)] Probit analysis

(*) = (Williams-t-test, one-sided-smaller, $\alpha = 0.05$, + = significant, - = not significant)

(**) = (Fisher´s Exact Binominal Test with Bonferroni Correction, one-sided-greater, $\alpha = 0.05$, + = significant, - = not significant)

Validity criteria:

Validity Criteria	**Recommended**	**Obtained**
Adult mortality	≤ 20%	7.5 %
Number of juveniles per replicate	≥ 50	292

Coefficient of variation of reproduction	≤ 30%	11.9 %

Reference item: In a separate study (BioChem project No. R 15 10 48 001 S, experimental completion date: 2015-02-24), the EC_{50} (reproduction) of the reference item Dimethoate (analysed purity: 99.8 %, tolerance ± 1.0 %) was calculated to be 6.7 mg/kg soil d.w. The results of the reference test demonstrate the sensitivity of the test system.

Conclusion: The No-Observed-Effect-Concentration (NOEC) and Lowest-Observed-Effect-Concentration (LOEC) for mortality were determined to be 316 and 562 mg test item/kg soil d.w., respectively. The NOEC and LOEC for reproduction were determined to be 56 and 100 mg test item/kg soil d.w., respectively.

The EC_{10} and EC_{20} values for reproduction were calculated to be 69 and 104 mg test item/kg soil dry weight, respectively.

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 = 7.5%).
- 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 = 292.
- the coefficient of variation of reproduction in the control should not exceed 30%: fulfilled, actual value in definitive test = 11.9 %.

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

Endpoints:

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} = 68.061 mg/kg sdw (95% C.L. = 1.498; 158.636)

LC_{20} = 125.017 mg/kg sdw (95% C.L. = 12.307; 279.660)

LC_{50} = 400.090 mg/kg sdw (95% C.L. = 175.597; 3260.703)

$NOEC_{mortality}$ = 178 mg/kg sdw

$EC_{10\ reproduction}$ = 122.912 mg/kg sdw (95% C.L. = 96.674; 156.271), Normalised width = 0.5, EC_{10} considered reliable

$EC_{20\ reproduction}$ = 153.562 mg/kg sdw (95% C.L. = 121.420; 194.495)

$EC_{50\ reproduction}$ = 235.106 mg/kg sdw (95% C.L. = 175.734; 312.377)

	$NOEC_{reproduction}$ = 56 mg/kg sdw (Bonferroni Welch-test) EC_x concentrations were calculated by 3-parametric normal cumulative distribution function. **RMS endpoints:** $NOEC_{mortality}$ = 178 mg a.s./kg soil $NOEC_{reproduction}$ = 56 mg/kg soil **Conclusion of the RMS:** The study is considered to be valid and appropriate for risk assessment purposes.

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	FPP+MPR EW 144 (69+75 g/L)	$EC_{10\ reproduction}$ = 170.015 mg/kg soil dw	Friedrich, S., 2016e
	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., 2016a
	HOPP acid	NOEC = 158 mg/kg soil dw	Friedrich, S., 2016b
Folsomia candida	FPP+MPR EW 144 (69+75 g/L)	NOEC = 56 mg /kg soil dw	Friedrich, F., 2016f
	Fenxoaprop-P-ethyl	NOEC ≥ 1000 mg/kg soil dw	Friedrich, S., 2015b
	Fenoxaprop-P-acid	NOEC ≥ 111.6 mg/kg soil dw	Friedrich, S., 2015a
	Fenoxaprop-P-ethyl-Benzoxazolone	NOEC ≥ 100 mg/kg soil dw	Friedrich, S., 2016c
	HOPP acid	NOEC ≥ 100 mg/kg sdw	Friedrich, S., 2016d
Hypoaspis aculeifer	FPP+MPR EW 144 (69+75 g/L)	NOEC = 56 mg/kg sdw	Schulz, L., 2016e
	Fenxoaprop-P-ethyl	NOEC ≥ 1000 mg/kg soil dw	Lopez, M. I. L., 2015
	Chlorobenzoxazolone	NOEC ≥ 100 mg/kg sdw	Schulz, L., 2016a
	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).

TER values for earthworms were calculated as the ratio between sublethal no observed effect concentrations (NOEC), and the maximum initial PEC_{soil}.

The predicted environmental concentrations in soil (PEC_{soil}) for the active substance Fenoxaprop-P-ethyl was

calculated based on a simple first tier approach (Microsoft® Excel spreadsheet) assuming even distribution of the compound in the upper 0-5 cm soil layer. A standard soil density of 1.5 g/cm^3 was assumed. The PEC_{soil} was calculated to be 0.111 mg a.s./kg soil (see fate section B.8).

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 (Fenoxaprop-P-ethyl has a logPOW of 4.58) 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
Eisenia fetida					
Cereals 1 x 1.2 L form./ha	Fenoxaprop-P-ethyl (technical)	NOEC ≥ 28*	0.111	≥ 252	5
	FPP+MPR EW 144 (69+75 g/L)	EC_{10} = 85 *	1.688	50	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	FPP+MPR EW 144 (69+75 g/L)	EC_{10} = 28 *	1.688	16	5
	Fenxoaprop-P-ethyl	NOEC ≥ 500 *	0.111	≥ 4504	5
	HOPP acid	NOEC ≥ 50 *	0.041	≥ 1219	5
	Chlorobenzoxazolone	NOEC ≥ 100	0.01	≥ 5000	5
	Fenoxaprop-P-acid	NOEC ≥ 111.6	0.097	≥ 1150	5

GAP use	Test substance	NOEC [mg/kg soil dw]	max PEC_{soil} [mg/kg soil dw]	TER_{LT}	Trigger
Hypoaspis aculeifer					
Cereals 1 x 1.2 L form./ha	FPP+MPR EW 144 (69+75 g/L)	NOEC = 28	1.688	16	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

Several studies on the effects of the active substance Fenxoaprop-P-ethyl on nitrogen transformation and carbon mineralisation were submitted for the first EU approval of the active substance.
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. Hence, the available studies on micro-flora respiration (carbon transformation) are given as additional information only. Please refer to RAR, Volume 3, B.9 (A.S.).

In addition to the studies with the active substance a new nitrogen and carbon mineralisation study with the representative formulation FPP + MPR EW 144 (69 + 75) was submitted. A summary of the study is provided below.

Reference:	**Fenoxaprop-P-ethyl, (oil in water emulsion) Hoe 046360 24 EW14 A203 investigating the effect on the nitrogen cycle (in accordance with BBA, VI, 1-1, 2nd edition)**

Author(s), year:	Baedelt, H. and Frings H., 1993a
Report/Doc. number:	Report no.: CW92/041, Reference no.: A51547
Guideline(s):	BBA guideline VI, 1-1
GLP:	Yes (not signed by authors)
Deviations:	One additional soil with horn meal was tested
Validity:	Not necessary

Material and methods:

Test substance: Hoe 046360 24 EW14 A203 (69 g/L Fenoxaprop-P-ethyl + 75 g/L mefenpyr-diethyl EW 144), Batch no.: not stated, content: Fenoxaprop-P-ethyl 7.1 % w/w, mefenpyr-diethyl 74 % w/w

Test species: Soil microorganisms

Type of test, duration: Nitrogen transformation test, 28 days,

Applied concentrations: Control, control with horn meal, 1.68, 8.40 and 16.80 mg/kg soil dry weight

Toxic standard: N-Serve 24 E nitrogen stabiliser (ready to use solution) with active substance nitrapyrin (applied concentration: 1 ppm (4.2 µl/kg soil))

Test substrate: Two standard soils from crop areas of Hoechst AG have been used (the area has not ben treated with pesticides for more than 2 years). Soil samples were taken from a depth of 0.20 cm at approx. 10 sites distributed over the area.

Soil (BBA classif.)	% sand	% silt	% clay	% OC	pH (CaCl2)	CEC (mVal/100g)	C/N ratio	MWHC (g/100 g)	Biomass (g C/100g)
Loamy sand Schwanheim	55	34	11	0.79	5.65	5.98	9.4	30.64	13.90
Silt loam Hattersheim	11.9	67.9	20	1.42	7.4	14.53	9.5	35.24	38.82

Substrate/test vessel: Aerated 2 L-stainless steel containers

Incubation: 20 °C

Water content 45 % of the max. water holding capacity. The water content was controlled twice weekly and evaporation losses compensated

pH: After 28 days: 5.9 – 6.40 (soil1), 5.2 – 6.07 (soil2)

Test parameters: Soil samples (40 g soil d.w. per replicate) were taken at intervals of 3 hours, 7, 14 and 28 days after application and the NH4-N-, NO3N- were determined. Ions were extracted with 200 ml extracting medium (1 % potassium aluminium sulphate solution) over a period of 1 hour and filtered.

Statistics: A statistical evaluation of the test results was not performed.

Findings:

Biological results: After rapid mineralization of the horn meal the ammonium and nitrate contents of the treated test plots deviated only insignificantly from those of the control after termination of the study. The results from the control plots without admixture of

horn meal show the microbial activity of the used standard soils.

Table B. 9.9-1: Effect of Hoe 046360 24 EW14 A203 on mean (3 repl.) NH4+-N, NO3--N, and total mineral nitrogen (N-min) concentrations in two soils

Treatment		mg N/100 g soil (% variation from control)				
Loamy sand						
Control without horn meal		Day 0	Day 7	Day 14	Day 21	Day 28
	NO3-	0.57	1.67	2.17	2.03	2.32
	NH4+	0.16	0.14	0.01	0.20	0.22
	N-min	0.73	1.81	2.19	2.24	2.55
Control with horn meal	NO3-	0.59 (100)	4.94 (100)	6.48 (100)	6.65 (100)	7.85 (100)
	NH4+	0.84 (100)	0.50 (100)	0.02 (100)	0.19 (100)	0.24 (100)
	N-min	1.43 (100)	5.44 (100)	6.50 (100)	6.84 (100)	8.09 (100)
1.68 mg formul./kg	NO3-	0.61 (103.4)	4.97 (100.6)	6.60 (101.9)	6.67 (100.3)	7.98 (101.7)
	NH4+	0.82 (97.6)	0.48 (96.0)	0.01 (50.0)	0.18 (94.7)	0.24 (100)
	N-min	1.43 (100)	5.45 (100.2)	6.61 (101.7)	6.85 (100.1)	8.22 (101.6)
8.40 mg/kg	NO3-	0.64 (108.5)	4.72 (95.5)	6.60 (101.9)	6.76 (101.7)	7.37 (93.9)
	NH4+	0.78 (92.9)	0.63 (126.0)	0.02 (100)	0.17 (89.5)	0.20 (83.3)
	N-min	1.42 (99.3)	5.35 (98.3)	6.62 (101.8)	6.93 (101.3)	7.57 (93.6)
16.80 mg/kg	NO3-	0.63 (106.8)	4.43 (89.7)	6.74 (104)	6.92 (104.1)	7.57 (96.4)
	NH4+	0.62 (73.8)	1.02 (204)	0.02 (100)	0.23 (121.1)	0.22 (91.7)
	N-min	1.25 (87.4)	5.45 (100.2)	6.76 (104)	7.15 (104.5)	7.79 (96.3)
Sandy loam						
Control without horn meal		Day 0	Day 7	Day 14	Day 21	Day 28
	NO3-	0.39	0.66	0.95	1.16	1.17
	NH4+	0.33	0.19	0.16	0.33	0.46
	N-min	0.72	0.85	1.11	1.49	1.63
Control with horn meal	NO3-	0.44 (100)	5.76 (100)	6.86 (100)	6.92 (100)	7.15 (100)
	NH4+	0.90 (100)	0.24 (100)	0.18 (100)	0.22 (100)	0.45 (100)
	N-min	1.34 (100)	6.00 (100)	7.04 (100)	7.14 (100)	7.60 (100)
1.68 mg formul./kg	NO3-	0.45 (102.3)	5.73 (99.5)	6.88 (100.3)	7.02 (101.4)	7.22 (101)
	NH4+	0.89 (98.9)	0.24 (100)	0.16 (88.9)	0.21 (95.5)	0.42 (93.3)
	N-min	1.34 (100)	5.97 (99.5)	7.04 (100.3)	7.23 (101.3)	7.64 (100.5)
8.40 mg/kg	NO3-	0.45 (102.3)	4.71 (81.8)	6.65 (96.9)	7.04 (101.7)	7.34 (102.7)

Treatment		mg N/100 g soil (% variation from control)				
Loamy sand						
	NH4+	0.77 (85.6)	0.22 (91.7)	0.17 (94.4)	0.21 (95.5)	0.42 (93.3)
	N-min	1.22 (91.0)	4.93 (82.2)	6.82 (96.9)	7.25 (101.5)	7.76 (102.1)
16.80 mg/kg	NO3-	0.48 (109.8)	5.41 (94.0)	6.98 (101.7)	7.37 (106.5)	7.41 (103.7)
	NH4+	0.95 (105.6)	0.20 (83.3)	0.16 (88.9)	0.20 (89.4)	0.43 (95.6)
	N-min	1.43 (107.0)	5.61 (93.6)	7.14 (101.4)	7.57 (106)	7.84 (103.2)

Where the difference to the control was >25% the values are written in bold

Conclusion: The oil in water emulsion of Fenoxaprop-P-ethyl (Hoe 046360 24 EW14 A203) containing 7.1% w/w Fenoxaprop-P-ethyl + 7.4% w/w Hoe 107892 (safener) had no unacceptable impact on soil nitrogen turnover in a loamy sand and a sandy loam soil. After 28 days the difference to the control was between 1% and 6.1%. The concentrations tested were 1.68 mg test substance /kg soil, 8.40 mg/kg and 16.80 mg/kg soil (i.e. 0.12 mg a.s./kg soil, 0.58 mg a.s./kg soil and 1.06 mg a.s./kg + 0.13 mg safener/kg soil, 0.63 mg safener/kg soil and 1.26 mg safener/kg).

Comment RMS:	A study with the intended lead formulation is available therefore the study has been considered as not necessary.

Reference:	**Fenoxaprop-P-ethyl, (oil in water emulsion) Hoe 046360 24 EW14 A203 investigating the effect on aerobic soil respiration (in accordance with BBA, VI, 1-1, 2nd edition)**
Author(s), year:	Baedelt, H. and Frings H., 1993b
Report/Doc. number:	Report no.: CW92/027, Reference no.: A51545
Guideline(s):	BBA guideline VI, 1-1
GLP:	Yes (not signed by authors)
Deviations:	One additional soil with horn meal was tested
Validity:	Not evaluated, no data requirement

Reference:	**Fenoxaprop-P-ethyl + mefenpyr-diethyl EW 144 (69+75) G:Effects on the activity of soil microflora (Nitrogen transformation test)**
Author(s), year:	Schulz, L. 2016f
Report/Doc. number:	Report no.: EBFPN052, Reference no.: M-548480-01-1
Guideline(s):	OECD 216; adopted January 21, 2000, OECD Guideline for the Testing of Chemicals, Soil Microorganisms: Nitrogen Transformation
GLP:	Yes (not signed by authors)
Deviations:	none
Validity:	Acceptable

Material and methods:

Test substance:	Fenoxaprop-P-ethyl + mefenpyr-diethyl EW 144 (69+75) G, Batch no.: EFKH003528, content: Fenoxaprop-P-ethyl 6.67 % w/w, Fenoxaprop-P-ethyl D+L 6.88 % w/w, mefenpyr-diethyl 7.02 % w/w
Test species:	Soil microorganisms
Type of test, duration:	Nitrogen transformation test, 28 days,
Applied concentrations:	Control, 1.69 and 8.44 mg/kg soil dry weight
Toxic standard:	Dinoterb 98 % w/w, Batch no.: 20822 (application rates in the test: 5.1 kg/ha, 12 kg/ha and 20.25 kg/ha)
Test substrate:	Experimental soil: Biomass C (mg/100 g soil): 37.99, % organic matter: 2.3, pH: 6.2, particle size: sand: 52.3, silt: 36.6, clay: 11.1, classification: sandy loam
Substrate/test vessel:	Wide mouth glass flasks (500 mL
Incubation:	20 ± 2 °C
Water content	16.13 – 16.38 (test start) 15.81-16.07 (test end)
pH:	6.0 – 6.1 (test start) 6.1 – 6.2 (test end)
Test parameters:	Soil samples (10 g soil d.w. per replicate) were taken at intervals of 3 hours, 7, 14 and 28 days after application and the NH4-N-, NO3N- and NO2-N-contents were determined. Ions were extracted by shaking the soil with 50 mL 1M KCL solution for 60 minutes. The mixtures were centrifuged and stored deep-frozen prior to analysis. For the quantitative determination of the mineralized part of nitrogen the Autoanalyzer was used.
Statistics:	A statistical evaluation of the test results was performed by means of a 2-sided Student-t-test (for homogeneous variances at 5 % significance level).

Findings:

Biological results:	No adverse effects of Fenoxaprop-P-ethyl + mefenpyr-diethyl EW 144 (69+75) G on nitrogen transformation in soil could be observed at both test concentrations (1.69 mg test item/kg soil dry weight and 8.44 mg test item/kg soil dry weight) during the 28-day experiment. Differences from the control of +14.4% (test concentration 1.69 mg test item/kg soil dry weight) and +12.1 % (test concentration 8.44 mg test item/kg soil dry weight) were measured at the end of the 28-day incubation period (time interval 14-28).

Table B. 9.9-2: Effects on nitrogen transformation in soil after treatment with Fenoxaprop-P-ethyl + mefenpyr-diethyl EW 144 (69+75) G

Time Interval (days)	Control	1.69 mg test item/kg soil dry weight equivalent to 1.2 L test item/ha	8.44 mg test item/kg soil dry weight equivalent to 6.0 L test item/ha

	Nitrate-N[1)]			Nitrate-N[1)]			% difference to control	Nitrate-N[1)]			% difference to control
0-7	4.14	±	0.31	4.40	±	0.09	+6.3 [n.s.]	4.36	±	0.12	+5.3 [n.s.]
7-14	1.31	±	0.26	1.08	±	0.21	-18.1 [n.s.]	1.27	±	0.12	-3.3 [n.s.]
14-28	0.73	±	0.08	0.83	±	0.15	+14.4 [n.s.].	0.81	±	0.19	+12.1 [n.s.]

The calculations were performed with unrounded values
[1)] Rate: Nitrate-N in mg/kg soil dry weight/time interval/day, mean of 3 replicates and standard deviation
[n.s.] = No statistically significant difference to the control (Student-t-test for homogeneous variances, 2-sided, $p \leq 0.05$)

Validity criteria: The coefficients of variation in the control (NO_3-N) were maximum 4.1 % and thus fulfilled the demanded range (≤15 %).

Reference item: In the most recent test with the toxic standard (conducted from 06.01.2015 to 03.02.2015), Dinoterb caused an effect of +39.1 %, +62.5 % and +112.0 % (required ≥ 25 %) on the nitrogen transformation in a field soil at the tested concentrations of 6.80 mg, 16.00 mg and 27.00 mg Dinoterb per kg soil dry weight, respectively, 28 days after application (time interval 14-28) and thus demonstrates the sensitivity of the test system.

Conclusion: Fenoxaprop-P-ethyl + mefenpyr-diethyl EW 144 (69+75) G caused no adverse effects (difference to control < 25 %, OECD 216) on the soil nitrogen transformation (expressed as NO_3-N-production) at the end of the 28-day incubation period. The study was performed in a field soil at concentrations up to 8.44 mg test item/kg soil dry weight, which are equivalent to application rates up to 6.0 L test item/ha.

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%: the coefficient of variation was 4.1 %.

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 8.44 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
FPP+MPR EW 144 (69+75 g/L)	Nitrogen mineralisation	1.69 mg/kg soil dw	28 d	+ 14.4	Schulz, L. 2016f
		8.44 mg/kg soil dw		+ 12.1	
Fenoxaprop-P-ethyl	Nitrogen mineralisation	0.133 mg /kg dry soil	56 days	+ 0.3	McMurray A., 2002
		0.67 mg /kg dry soil		+ 5.4	
Fenoxaprop-P-ethyl	Nitrogen mineralisation	0.11 mg/kg soil dw	42 days	1.6%	Reis, K.-H.., 2008
		0.55 mg/kg soil dw		-19%	
Fenoxaprop-P-acid	Nitrogen mineralisation	0.1049 mg/kg soil dw	28 days	-3.7	Schulz, L., 2016b
		0.5244 mg/kg soil dw		+24.8	
Chlorobenzoxazolone	Nitrogen mineralisation	0.053 mg/kg soil dw	28 days	+2.1	Schulz, L., 2016c
		0.263 mg/kg soil dw		-12	
HOPP acid	Nitrogen mineralisation	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	$PEC_{soil, accumulation}$	Risk acceptable?
FPP+MPR EW 144 (69+75 g/L)	8.44 m/kg soil dw	1.688 mg/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 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 non-target plants are available.

B.9.11.2. Testing on non-target plants

Seedling emergence and vegetative vigour studies have been conducted with the formulations Puma 120 Super (Fenoxaprop-P-ethyl 120 g/L + Mefenpyr-diethyl 33 g/L) and Ralon Super (Fenoxaprop-P-ethyl 69 g/L + Mefenpyr-diethyl 75 g/L) following the OECD test guidelines (OECD 208).

Reference: Roshon R. (2001a): Ecotoxicological Evaluation of Fenoxaprop-P-ethyl + Mefenpyr-diethyl Emulsifiable Concentrate (120 + 33 g/L) (Puma 120 Super), Terrestrial Plant Vegetative Vigour. Document No. B003327

Test guideline: Draft OECD 208; US EPA 850.4250 (1996)

GLP: Yes

Material and methods:

Six dicotyledonous species (i.e. soybean (Glycine max), carrot (*Daucus carota*), cucumber (*Cucumis sativa*), lettuce (*Lactuca sativa*), alfalfa (*Medicago sativa*), and tomato (*Lycopersicon esculentum*)) and four monocotyledonous species (i.e. corn (*Zea mays*), bluejoint marsh reed (*Calamagrostis canadensis*), Northern wheatgrass (*Agropyron dasystachyum*), and onion (*Allium cepa*)) were tested during this evaluation. The product Puma 120 Super coded AE F046360 24 EC 15 A3 containing 120 g/L Fenoxaprop-P-ethyl + 33 g/L safener Mefenpyr-diethyl was sprayed up to dose rates equivalent to 0.77 L product/ha corresponding to 92.4 g a.s./ha. The concentration range was selected in order to define the concentration-response curve between the expected NOAEC and IC_{50}. The type of soil used for the study was sandy loam. If an effect was observed during the range-finding test, a minimum of 5 and a maximum of seven test concentrations plus controls were used. If no effect was observed, only the maximum label rate (0.77 L/ha) plus control were tested. The number of replicates used for test concentrations and controls depended on seed size. The following endpoints were assessed, observations were conducted 7 and 14 d post-application: visual appearance, total number of living and/or dead plants, shoot height, shoot dry biomass, root length and root dry weight. The test duration was at minimum 14 days of growth after application. During the testing, chemical analysis for Fenoxaprop-P-ethyl and Mefenpyr-diethyl was conducted in the highest concentration of spray solution applied to the test plants; however nominal concentrations were used in calculations of all testing endpoints.

Findings:

There were no statistically significant effects at the maximum label rate of 0.77 L product/ha on growth or development of onion, Northern wheatgrass, soybean, cucumber, lettuce, tomato and alfalfa. Significant effects were noted on corn, bluejoint marsh grass and carrot. Of these, carrot was the least sensitive and corn the most sensitive. Bluejoint marsh grass was also affected by the test item, with an effect on shoot dry weight. The following table summarises the results of vegetative vigour tests for species that exhibited an inhibitory effect (based on nominal concentrations):

Table B. 9.11.2-1: Effects of Puma 120 on four plant species in the Vegetative Vigour Test

biological endpoint (L/ha)	shoot length	root length	shoot dry weight	root dry weight	phytotoxicity
Corn					
IC_{25} (mean (95% CL))	0.134 (0.127-0.142)	> 0.1925	0.092 (0.077-0.108)	0.06 (0.031-0.090)	0.109 (0.104-0.114)
IC_{50} (mean (95% CL))	0.188 (0.182-0.195)	> 0.1925	0.129 (0.113-0.145)	0.111 (0.083-0.138)	0.135 (0.130-0.140)
NOAEC	0.024	> 1925	0.024	0.024	0.006
Blue-joint marsh Grass					
IC_{25} (mean (95% CL))	0.427 (0.232-0.622)	0.412 (0.197-0.644)	0.223 (0.00-0.48)	0.204 (0.00-0.516)	> 0.77
IC_{50} (mean (95% CL))	> 0.77	> 0.77	0.512 (0.145-0.879)	0.547 (0.032-1.061)	> 0.77
NOAEC	0.1925	0.1925	not calculable	not calculable	> 0.77
Carrot					
IC_{25} (mean (95% CL))	> 0.77	> 0.77	> 0.77	0.476 (0.186-0.767)	> 0.77
IC_{50} (mean (95% CL))	> 0.77	> 0.77	> 0.77	> 0.77	> 0.77
NOAEC	> 0.77	> 0.77	> 0.77	> 0.77	> 0.77
Lettuce					
IC_{50} (mean (95% CL))	> 0.77	> 0.77	> 0.77	> 0.77	> 0.77
NOAEC	> 0.77	> 0.77	> 0.77	> 0.77	> 0.77
IC_{50}: the inhibiting concentration for 50 % effect; 95 % CL: 95 % confidence limits					

The monocotyledonous plants were more sensitive compared to dicotyls as shown by IC_{50} values (root/shoot weight) of 13.32 and 61.44 g a.s./ha in corn and bluejoint marsh reed, respectively. The lowest IC_{50} value of 13.32 g a.s./ha was found in corn, based on reduced biomass (root dry weight).

Comment (RMS): Because of discrepancies between the nominal and measured concentrations of Fenoxaprop-P-ethyl and Mefenpyr-diethyl in the spray solutions (measured concentrations being up to ca. 40 % lower), the study is considered not acceptable.

Comment RMS:	The study has been deemed as not acceptable during the Annex I inclusion process because of discrepancies between the nominal and measured concentrations of Fenoxaprop-P-ethyl and Mefenpyr-diethyl in the spray solutions (measured concentrations up to ca. 40% lower). This conclusion is still valid for the re-newal of Fenoxaprop-P-ethyl and consequently the study could not be used for risk assessment purposes.

Reference: Roshon R. (2001b): Ecotoxicological Evaluation of Fenoxaprop-P-ethyl + Mefenpyr-diethyl Emulsifiable Concentrate (120 + 33 g/L) (Puma 120 Super), Terrestrial Plant Seedling Emergence. Document No. B003326

Test guideline: US EPA 850.4225 (1996)

GLP: Yes

Material and methods:

Six dicotyledonous species (i.e., soybean (Glycine max), carrot (Daucus carota), cucumber (Cucumis sativa), lettuce (Lactuca sativa), alfalfa (Medicago sativa), and tomato (Lycopersicon esculentum)) and four monocotyledonous species (i.e. corn (Zea mays), bluejoint marsh reed (Calamagrostis canadensis), Northern wheatgrass (Agropyron dasystachyum), and onion (Allium cepa)) were tested during this evaluation. The test substance was Puma 120 Super coded AE F046360 24 EC 15 A3, containing 120 g /L Fenoxaprop-P-ethyl + 33 g/L safener AE F017892. The type of soil used for the study was sandy loam. For the preparation of test soils, a stock solution of the test item was prepared to provide a soil incorporation rate of 0.0084 µL/g soil dry weight, which is equivalent to the field dose rate of 0.77 L test item/ha. The number of concentrations tested was determined according to the observations made in the range-finding test. If an effect was observed during the range-finding test, a minimum of 5 and a maximum of seven test concentrations plus controls were used. If no effect was observed only the maximum soil concentration of 0.0084 µL test item/g dry soil plus control were tested. The following endpoints were assessed during the 14 d test duration: visual appearance, total number of living and/or dead plants, shoot length and dry biomass, and root length and dry weight. During the testing, chemical analysis for Fenoxaprop-P-ethyl and Mefenpyr-diethyl was conducted in the highest concentration of spray solution applied to the test plants.

Findings:

There were no statistically significant effects in any dicotyledonous plant species at the maximum soil concentration. Corn was the only monocotyledonous plant species affected. Based on reduced root dry weight an IC_{50} value of 2.4 nL/g dry soil was calculated, which is equivalent to a field dose rate of 26.4 g a.s./ha. The following table summarises the results of the seedling emergence test for corn (based on nominal concentrations).

Table B. 9.11.2-2: Results of Seedling Emergence Test in corn

biolog. endpoints (nL test item/g dry soil)	shoot length	root length	shoot dry weight	root dry weight	phytotoxicity
IC_{50} (mean (95% CL))	5.4 (4.8 – 6.0)	2.2 (1.9 – 2.4)	6.4 (4.8 – 8.1)	2.4 (2.0 – 2.8)	7.7 (7.2 – 8.2)
NOAEC	2.1	0.525	1.05	0.13125	1.05
IC_{50}: the inhibiting concentration for 50 % effect; 95 % CL: 95 % confidence limits					

No significant effects were noted in any dicotyledonous plant species up to and including a concentration equivalent to a field dose rate of 92.4 g a.s./ha. Of the monocotyledonous plants, corn was the only plant species affected. Based on reduced root dry weight an IC_{50} value of 2.4 nL/g dry soil was calculated, which is equivalent to a field dose rate of 26.4 g a.s./ha. The lowest IC_{50} value therefore was found in corn, based on reduced biomass (root dry weight).

Comment (RMS): Because of discrepancies between the nominal and measured concentrations of Fenoxaprop-P-ethyl and Mefenpyr-diethyl in the spray solutions (measured concentrations being up to ca. 80 % lower), the study is considered not acceptable

Comment RMS:	The study has been deemed as not acceptable during the Annex I inclusion process

	because of discrepancies between the nominal and measured concentrations of Fenoxaprop-P-ethyl and Mefenpyr-diethyl in the spray solutions (measured concentrations up to ca. 80% lower). This conclusion is still valid for the re-newal of Fenoxaprop-P-ethyl and consequently the study could not be used for risk assessment purposes.

Reference:	**Fenoxaprop-P-ethyl + mefenpyr-diethyl; oil in water emulsion; 69 + 75 g/L (Code: AE F046360 24 EW14 A717) Effects on the vegetative vigour test of ten species of non-target plants**
Author(s), year:	Pallett K., Gosch, H. 2005a
Report/Doc. number:	Study no. C046048, Reference no. M-243579-01-1
Guideline(s):	OECD 208 (2000)
GLP:	Yes
Deviations:	Due to the proven graminicidal specifity of the test item a ratio of 1 monocotyledonous : 1 dicotyledonous species were tested
Validity:	Acceptable

Material and Methods:

Test substance:	Ralon Super (Fenoxaprop-P-ethyl 69 g/L + Mefenpyr-diethyl 75 g/L), Batch No.: AAKH02042
Type of test:	Vegetative vigour test
Test duration:	21 days
Test species:	5 monocotyledonous oats (*Avenia sativa*), ryegrass (*Lolium perenne L.*), corn (*Zea mays*), spring barley (*Hordeum vulgare*) and onion (*Allium cepa*)) and 5 dicotyledonous plant species oilseed rape (*Brassica napus*), soybean (*Glycine max*), cucumber (*Cucumis sativus*), sunflower (*Helianthus annuus*) and tomato (*Lycopersicon esculentum*))
Test soil:	Standard soil (silty loam) from Bayer CropScience GmbH. The soil was sieved to 2 mm.
Applied concentrations:	Control: Deionized water Test item: For corn, onion, ryegrass, barley and oats: 1200, 600, 300, 150, 75 and 37.5 mL prod./ha For oilseed rape, soybean, tomato, cucumber and sunflower: 1200 mL/ha
Replicates:	The plants of one pot represent one replicate. 8-10 pots per treatment group were used. Each pot contained 4-5 plants. In total 40 plants per treatment group were tested.
Exposure route:	The spray solution was applied once, at test initiation on the leaves and above-

ground portions of plant. Plants were grown from seed to the 2 to 4-leaf stage. The blank control spray solution was deionized water. The test item was dissolved in deionized water and was applied once with 200 L/h using an spray chamber equipped with an overhead nozzle (Lechner LU 367-02), with nozzle height set at 50 cm above the sprayed surface. The spray chamber volume was calibrated by weighing the amount of water applied to a known surface area.

Test conditions: Plants were grown and maintained under glasshouse conditions.

Temperature: 23±5°C during day, and 18±5°C at night. Minor deviations up to 36°C and down to 11°C occurred for short times and do not have effects on the plant growth.

Light Regime: Regulated at 16h light : 8 h dark

Test parameter: Plants were assessed for survival and for phytotoxicity on Day's 7, 14 and 21. Shoot dry weight was determined at the final assessment.

Statistics : Mortality and biomass (plant dry weight) were compared using the ToxRat software for statistical analysis (version 2.09)

Findings:

Analytical results: Analytical verification of the concentration of the test solution revealed it to be 113.2 % of the nominal.

Biological results: Adverse effects were only seen in the monocotyledonous species. In corn, oats and ryegrass phytotoxicity was apparent as leaf chlorosis, necrosis and there was also some leaf deformation in corn. Shoot biomass in corn was the most sensitive endpoint with the lowest EC_{50} of 108.7 mL product/ha, nominally equivalent to 8.14 g a.s./ha, taking into account the density of the product.

Table B. 9.11.2-3: Results of Vegetative Vigour Test in ten non-target plant species [mL product/ha]

species	survival			shoot dry weight		
	NOEC	EC_{25}	EC_{50}	NOEC	EC_{25}	EC_{50}
barley	1200	> 1200	> 1200	37.5	> 1200	> 1200
corn	75	97.2	128.9	37.5	82.5	108.7
oats	300	310.9	414.2	150	285.1	413.5
onion	1200	> 1200	> 1200	300	556.2	> 1200
ryegrass	600	889.2	> 1200	150	347.3	> 1200
cucumber	1200	> 1200	> 1200	1200	> 1200	> 1200
oilseed rape	1200	> 1200	> 1200	1200	> 1200	> 1200
soybean	1200	> 1200	> 1200	1200	> 1200	> 1200
sunflower	1200	> 1200	> 1200	1200	> 1200	> 1200
tomato	1200	> 1200	> 1200	1200	> 1200	> 1200

Comment RMS: **Validity:** The vegetative vigour test was conducted according to the OECD test guideline 208 B (July 2000). In order for the test to be considered valid, the following performance criteria must be met in the negative control:

- the mean seedling growth does not exhibit visible phytotoxic effects and
- the plant survival in the vegetative vigour test is at least 90% at the end of the

test.
The test is considered acceptable given the validity criteria regarding phytotoxic effects (no phytotoxic effects were observed in the control groups) and survival of the plants (97.5-100% survival at the end of the test). Hence, the study is considered acceptable according to the OECD guideline 208 B (July 2000).

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 also meet the given validity criteria according to the OECD test guideline 227 (2006).
100% of the prepared seedlings emerged. The lowest control mortality was 97.5% (onion).
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. In the present test the temperature ranged from 23±5°C during day, and 18±5°C at night. Minor deviations up to 36°C and down to 11°C occurred for short times. and do not have effects on the plant growth. Furthermore no detailed raw data on the humidity is given in the study report. However, under consideration of the observed effects on plant survival and plant phytotoxicity the influence of the humidity on the test plants is considered to be low. Additionally all other criteria are considered to be fulfilled.

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. EC_{50} = 108.7 mL product/ha, (8.14 g a.s./ha) **Conclusion of the RMS:** The study is considered to be valid and can be used for the risk assessment.

Reference:	**Fenoxaprop-P-ethyl + mefenpyr-diethyl; oil in water emulsion; 69 + 75 g/L (Code: AE F046360 24 EW14 A717) Effects on the seedling emergence and growth test of ten species of non-target plants**
Author(s), year:	Pallett, K., Gosch, H., 2005b
Report/Doc. number:	Study no. C046044 / M-243578-01-1
Guideline(s):	OECD 208 A (2000)
GLP:	Yes
Deviations:	None
Validity:	Acceptable

Material and Methods:

Test substance:	Ralon Super (Fenoxaprop-P-ethyl 69 g/L + Mefenpyr-diethyl 75 g/L), Batch No.: AAKH02042
Type of test:	Seedling emergence test
Test duration:	Test continued for 14 days following the emergence of 65% of the control seedlings
Test species:	6 dicotyledonous and 4 monocotyledonous plant species Seeds of ten species; barley (*Hordeum vulgare*) com (*Zea mays*), cucumber (*Cucumis sativa*), oats (*Avena sativa*), oilseed rape (*Brassica napus*), pea (*Pisum sativum*), ryegrass (*Lolium perenne*), soybean (*Glycine max*), sunflower (*Helianthus annuus*) and *tomato (Lycopersicum esculentum*) were treated after sowing with AE F046360 24 EW14 A717.
Test soil:	Standard soil (silty loam)
Applied concentrations:	Control: Deionized water Test item: 37.5, 75, 150, 300, 600 and 1200 mL prod./ha for barley, corn, oats and ryegrass Test item: 1200 mL prod./ha for cucumber, oilseed rape, pea, soybean, sunflower and tomato
Replicates:	The plants of one pot represent one replicate. 8 pots per treatment group. Each pot contained 5 seeds. In total 40 seeds per treatment group were tested
Exposure route:	Seeds were introduced manually in the soil. They were covered by about 5 mm of soil and top watered immediately to facilitate germination.

	The four monocotyledonous species were treated with solutions of the product and serial dilutions were sprayed with doses of the product ranging from 1200 mL/ha down to 37.5 mL/ha using a laboratory track sprayer. The six dicotyledonous species were treated with the highest rate of the product.
Test conditions:	Temperature: 25 ±3°C day, 18 ±5°C night; minor deviations up to 33°C occurred for short times and do not have effects on the plant growth. Light regime: Regulated at 16 h light : 8h dark
Test parameter:	Germination: Daily checks were made to identify the date when 65 % of the seedlings emerged in the controls for each species. Number of plants emerged were then be counted after 7 and 14 days after the emergence of 65 % of seeds in the control. Phytotoxicity Records: Visual phytotoxicity ratings of the living plants (e.g. chlorosis, necrosis, stunting, abnormal growth) 7 and 14 days after the emergence of 65 % of seeds in the controls. Phytotoxicity was assessed according to EPPO Standard 135. Phytotoxicity was recorded at each assessment time following a 0-100% rating system usually in 10% units. Mortality: Numbers of plants that died after application were recorded 7 and 14 days after the emergence of 65% of seeds in the controls. Plant biomass: The dry weight was determined at the final assessment.
Statistics :	Emergence, mortality and biomass (plant dry weight) were compared using the ToxRat software for statistical analysis (version 2.09) for the monocotyledonous species, tested with 6 rates. For the dicotyledonous species, tested with a single rate only biomass (plant dry weight) were compared using the ToxRat software for statistical analysis (version 2.09).
<u>Findings:</u>	
Analytical results:	Analytical verification of the concentration of the test solution revealed it to be 113.2 % of the nominal.
Biological results:	No visible symptoms of phytotoxicity were noted. There were marginal adverse effects on the growth of corn and oats. Phytotoxic symptoms visualised as growth suppression, abnormal growth or chlorosis were observed at application rates of 600 and 1200 mL/ha with 4 and 45 %, respectively in corn. The reduction in biomass in corn at the highest rate was statistically significant. Chlorosis was seen at the highest rate with 4 % in oilseed rape. In nine species there were no effects up to the highest rate tested and the EC_{25} and EC_{50} values for these species were therefore assumed to be > 1200 mL product/ha which is equivalent to 83 g a.s./ha. Table 9.9.1-4 summarises the results for the individual species.

Table B. 9.11.2-4: Results of Seedling Emergence Test in ten non-target plant species [mL product/ha]

species	emergence			survival			shoot dry weight		
	NOEC	EC25	EC50	NOEC	EC25	EC50	NOEC	EC25	EC50
barley	1200	> 1200	> 1200	1200	> 1200	> 1200	1200	> 1200	> 1200
corn	1200	> 1200	> 1200	1200	> 1200	> 1200	600	> 1200	> 1200
oats	1200	> 1200	> 1200	1200	> 1200	> 1200	1200	> 1200	> 1200
ryegrass	1200	> 1200	> 1200	1200	> 1200	> 1200	1200	> 1200	> 1200
cucumber	1200	> 1200	> 1200	1200	> 1200	> 1200	1200	> 1200	> 1200
oilseed rape	1200	> 1200	> 1200	1200	> 1200	> 1200	1200	> 1200	> 1200
pea	1200	> 1200	> 1200	1200	> 1200	> 1200	1200	> 1200	> 1200
soybean	1200	> 1200	> 1200	1200	> 1200	> 1200	1200	> 1200	> 1200
sunflower	1200	> 1200	> 1200	1200	> 1200	> 1200	1200	> 1200	> 1200
tomato	1200	> 1200	> 1200	1200	> 1200	> 1200	1200	> 1200	> 1200

Comment RMS:	**Validity:** The seedling emergence test was conducted according to the OECD test guideline 208 A (July 2000). In order for the test to be considered valid, the following performance criteria must be met in the negative control: - a seedling emergence of at least 65% has to be observed and - the mean seedling growth does not exhibit visible phytotoxic effects. In the test the seedling emergence ranged from 97.5 to 67.5 %. In the control groups no phytotoxic effects were observed. The test is considered acceptable as the validity criteria are met. Taking into account the current valid) 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, except for soybean (67.5 %) which could be excluded because 10 species in total have been tested. 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. Plant mortality (< 10%) in the control groups was observed for all tested plants. 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. ER_{50} > 1200 mL product/ha (83 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

Table B. 9.12-1: Summary of non-target plant tests performed with the formulation Ralon Super (Fenoxaprop-P-ethyl 69 g/L + Mefenpyr-diethyl 75 g/L)

Test organisms	Study type	Test duration	Lowest ER_{50} [mL form./ha]	Reference
Terrestrial non-target plants (10 species)	Vegetative vigour (Tier 2)	21 days	ER_{50} = 108.7*	Pallett K., Gosch, H. 2005a
Terrestrial non-target plants (9 species)	Seedling emergence (Tier 2)	21 days	ER_{50} > 1200	Pallett, K., Gosch, H., 2005b

* maze has been the most senstitive species

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 maximal seasonal application rate of 1200 mL prod./ha (corresponding to 0.083 kg a.s./ha) with 1 application per season.

The corresponding off-field predicted environmental rate (PER) is 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 mL prod./ha 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

The following risk assessment is based on the findings of the vegetative vigour study. The lowest endpoint obtained from this study is 108.7 mL prod./ha (corn, shoot dry weight).

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} = 108.7	**3.3**
		50%	16.62		6.5
		75%	8.31		13
		90%	3.324		33
5 m	0.57%	-	6.84		16

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 mitigation or 5 meter buffer zone are considered.

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, KCP 10.1.2	Kley, C.	2002	Residues of Fenoxaprop-P-ethyl in cereal shoots: Initial residue levels and their dissipation Code: AE F046360; AE F088406; AE F054014 Bayer CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: C024368, Edition Number: M-216789-01-1 Date: 2002-08-29 GLP/GEP: no, unpublished	N	N		Bayer CropScience	In DAR (2005)
KCP 10.1.1.1	[redacted]	1991	Acute oral toxicity in the male and female Japanese quail (*Coturnix coturnix* Japonica) Fenoxaprop-P-ethyl oil in water emulsion 69 g/L Code: Hoe 046360 24 EW14 A203 [redacted] Report No.: A46612 Edition Number: M-130636-01-1 Date: 1991-09-13 GLP/GEP: Yes, unpublished	Y	N		Bayer	In DAR (2005)
KCP 10.1.1.1	[redacted]	1992	Acute oral toxicity in the male mallard duck (*Anas platyrhynchos*) Fenoxaprop-P-ethyl oil in water emulsion 69 g/L Code: Hoe 046360 24 EW14 A203 [redacted] Report No.: A47317 Edition Number: M-135735-01-1 Date: 1992-02-11 GLP/GEP: Yes, unpublished	Y	N		Bayer	In DAR (2005)
KCP 10.2.1	[redacted]	1992a	Effect to *Oncorhynchus mykiss* (rainbow trout) in a static-acute toxicity test (method OECD) Fenoxaprop-P-ethyl oil in water emulsion 69 g/L Code: Hoe 046360 24 EW14 A203 [redacted] Report No.: A48437	Y	N		Bayer	In DAR (2005)

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
			Edition Number: M-137461-01-1 Date: 1992-07-20 GLP/GEP: Yes, unpublished					
KCP 10.2.1	[redacted]	1992b	Effect to *Cyprinus carpio* (mirror carp) in a static-acute toxicity test (method OECD) Fenoxaprop-P-ethyl oil in water emulsion 69 g/L Hoe 046360 24 EW14 A203 [redacted] Report No.: A48253 Edition Number: M-137208-01-1 Date: 1992-07-02 GLP/GEP: Yes, unpublished	Y	N		Bayer	In DAR (2005)
KCP 10.2.1	Schaefers, C.	2002a	*Daphnia magna*, acute toxicity test Fenoxaprop-P-ethyl + mefenpyr-diethyl oil in water emulsion, 69 + 75 g/L Code: AE F046360 24 EW14 A716 Fraunhofer Institut, IME, Schmallenberg, Germany Bayer Report No.: C027502 Edition Number: M-213453-01-1 Date: 2002-12-05 GLP/GEP: Yes, unpublished	N	N		Bayer	In DAR (2005)
KCP 10.2.1	Heusel, R.	1991b	Effect to *Scenedesmus subspicatus* (green alga) in a growth inhibition test (method OECD) Fenoxaprop-P-ethyl oil in water emulsion 69 g/L Code: Hoe 046360 24 EW14 A203 Hoechst AG, Frankfurt am Main, Germany Bayer Report No.: A46487 Edition Number: M-130527-01-1 Date: 1991-08-26 GLP/GEP: Yes, unpublished	N	N		Bayer	In DAR (2005)
KCP 10.2.1	Wenzel, A.	2005	Alga, (*Pseudokirchneriella subcapitata*) growth inhibition test (OECD 201), static exposure (under consideration of proposal for updating OECD 201 of April 2004) AE F046360 24 EW14 A717 Fraunhofer Institut, IME, Schmallenberg, Germany Bayer	N	N		Bayer	In DAR (2005)

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
			Report No.: C046105 Edition Number: M-242775-01-1 Date: 2005-01-13 GLP/GEP: Yes, unpublished					
KCP 10.2.2	Heusel, R.	1994	Effect to *Daphnia magna* (waterflea) in a 21-day reproduction test (method OECD) Fenoxaprop-P-ethyl - oil in water emulsion 69 g/L Code: Hoe 046360 24 EW14 A703 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer Report No.: A53038 Edition Number: M-133804-01-1 Date: 1994-10-04 GLP/GEP: Yes, unpublished	N	N		Bayer	In DAR (2005)
KCP 10.2.2	Schaefers, C.	2002b	*Daphnia magna*, reproduction test, dosed at two life stages Part B: reproduction test Fenoxaprop-P-ethyl + mefenpyr-diethyl oil in water emulsion, 69 + 75 g/L Code: AE F046360 24 EW14 A716 Fraunhofer Institute for Molecular Biology and Applied Ecology (IME), Schmallenberg, Germany Bayer Report No.: C027503 Edition Number: M-213455-01-1 Date: 2002-12-06 GLP/GEP: Yes, unpublished	N	N		Bayer	In DAR (2005)
KCP 10.2.2	Bruns, E.	2008	Fenoxaprop-P-ethyl & mefenpyr-diethyl; oil in water emulsion; 69+75 g/l - *Daphnia magna* chronic toxicity test, dosed at two life stages in an uncovered static laboratory test system Bayer Report No.: EBFPX008 Edition Number: M-270407-01-2 MRID#: 47332701 Date: 2006-05-05 GLP/GEP: Yes, unpublished	N	Y	New study needed for refinement of risk assessment	Bayer	Submitted for the purpose of renewal
KCP 10.2.2	Hager, J.	2016i	Statement - EC10/EC20 calculation for chronic Daphnia	N	N		Bayer	Submitted

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
			toxicity test with fenoxaprop-P-ethyl & mefenpyr-diethyl; Oil in water emulsion; 69 + 75 g/L (M-270407-01-1, E. Bruns, 2006) Bayer Report No.: M-553439-01-1 Edition Number: M-270407-01-1 Date: 2016-04-27 GLP/GEP: n.a., unpublished					for the purpose of renewal
KCP 10.3.1.1.1	Waltersdorfer, A.	2000a	Oral toxicity (LD_{50}) to honey bees (*Apis mellifera* L.) Fenoxaprop-P-ethyl + AE F107892 oil in water emulsion 69 + 75 g/L Code: AE F046360 24 EW14 A715 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C010124 Edition Number: M-198464-01-1 Date: 2000-10-13 GLP/GEP: Yes, unpublished	N	N		Bayer	In DAR (2005)
KCP 10.3.1.1.1	Schmitzer, S.; Ehmke, A.	2013	Effects of fenoxaprop-P-ethyl + mefenpyr-diethyl EW 144 (69+75) G (Acute contact and oral) on honey bees (*Apis mellifera* L.) in the laboratory IBACON GmbH, Rossdorf, Germany Bayer Report No.: 81321035 Edition Number: M-472286-01-1 Date: 2013-11-25 GLP/GEP: Yes, unpublished	N	Y	Data requirement according to Regulation (EC) No 1107/2009 or 284/2013	Bayer	Submitted for the purpose of renewal
KCP 10.3.1.1.2	Waltersdorfer, A.	2000b	Contact toxicity (LD_{50}) to honey bees (*Apis mellifera* L.) fenoxaprop-P-ethyl + AE F107892 oil in water emulsion, 69 + 75 g/L Code: AE F046360 24 EW14 A715 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C010015 Edition Number: M-198222-01-1 Date: 2000-09-26 GLP/GEP: Yes, unpublished	N	N		Bayer	In DAR (2005)

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 10.3.1.2	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, Monheim, Germany TF- BCS-CHA Report No.: 102000000715 Edition Number: M-577004-01-1 Date: 2017-01-12 GLP/GEP: Yes, unpublished	No	Yes	Data requirement according to Regulation (EC) No 1107/2009 or 283/2013	TF- BCS-CHA	Submitted for the purpose of renewal
KCP 10.3.1.3	Schmitzer, S.	2014	Fenoxaprop-P-ethyl + mefenpyr-diethyl EW 144 (69+75 g/L): Effects on honey bee brood (*Apis mellifera* L.) - Brood feeding test IBACON GmbH, Rossdorf, Germany Bayer Report No.: M-486086-01-1 Date: 2014-05-07 GLP/GEP: Yes, unpublished	N	Y	Data requirement according to Regulation (EC) No 1107/2009 or 284/2013	Bayer	Submitted for the purpose of renewal
KCP 10.3.1.5	Taenzler, V.	2016	Fenoxaprop-P-ethyl + mefenpyr-diethyl EW 144 (69+75 g/L): Effects on honey bee brood (*Apis mellifera* L.) under semi-field conditions - Tunnel test - Final report IBACON GmbH, Rossdorf, Germany TF- BCS-CHA Report No.: 98861033 Edition Number: M-553368-01-1 Date: 2016-02-25 GLP/GEP: Yes, unpublished	No	Yes	Data requirement according to Regulation (EC) No 1107/2009 or 283/2013	TF- BCS-CHA	Submitted for the purpose of renewal
KCP 10.3.2.1	Moll, M.; Groer, M.	2001	Effects of AE F046360 24 EW14 A715 on the parastoid *Aphidius rhopalosiphi* (hymenoptera, braconidae) in the laboratory -dose response test- Code: AE F046360 24 EW14 A715 IBACON GmbH, Rossdorf, Germany Bayer Report No.: C011097 Edition Number: M-200191-01-1 Date: 2001-01-16 GLP/GEP: Yes, unpublished	N	N		Bayer	In DAR (2005)
KCP 10.3.2.1	Waltersdorfer, A.	2000c	Toxicity to the predatory mite *Typhlodromus pyri* SCHEUTEN (Acari, phytoseiidae) in the laboratory	N	N		Bayer	In DAR (2005)

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
			fenoxaprop-P-ethyl + AE F107892 oil in water emulsion, 69 + 75 g/L Code: AE F046360 24 EW14 A715 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C010041 Edition Number: M-198274-01-1 Date: 2000-09-28 GLP/GEP: Yes, unpublished					
KCP 10.3.2.2	Roehlig, U.	2005	Dose-response toxicity (LR50) of AE F046360 24 EW14 A717 to the predatory mite *Typhlodromus pyri* (Scheuten) under extended laboratory conditions BioChem agrar GmbH, Gerichshain, Germany Bayer Report No.: 05 10 48 051 Edition Number: M-252427-01-1 Date: 2005-05-25 GLP/GEP: Yes, unpublished	No	Yes	Extended laboratory study submitted to answer RMS' question on the reproduction effects observed in the tier 1 glass plate study	Bayer	Submitted for the purpose of renewal
KCP 10.3.2.1	Waltersdorfer, A.	2000d	Toxicity to the foliage dwelling predator *Chrysoperla carnea* Steph. (Neuroptera, Chrysopidae) in the laboratory Fenoxaprop-P-ethyl + AE F107892 oil in water emulsion 69 + 75 g/L Code: AE F046360 24 EW14 A715 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C010123 Edition Number: M-198462-01-1 Date: 2000-10-13 GLP/GEP: Yes, unpublished	N	N		Bayer	In DAR (2005)
KCP 10.3.2.1	Petto, R.; Klepka, S.	1995	Effects on *Pardosa amentata* (Clerck) (Araneae, Lycosidae) in laboratory of Code: Hoe 046360 24 EW14 A203 RCC Umweltchemie GmbH & Co. KG, Rossdorf, Germany	No	No		Bayer	In DAR (2005)

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
			Bayer Report No.: A54209 Edition Number: M-134792-01-1 Date: 1995-03-03 GLP/GEP: Yes, unpublished					
KCP 10.3.2.1	Pietrzik, J.	1992	Side-effects on the ground beetle (*Poecilus cupreus* L.) in the laboratory of Code: Hoe 046360 24 EW14 A203 GAB Biotechnologie GmbH, Niefern-Oeschelbronn, Germany Bayer Report No.: A48217 Edition Number: M-136074-01-2 Date: 1992-04-01 GLP/GEP: Yes, unpublished	N	N		Bayer	In DAR (2005)
KCP 10.3.2.1	Kuehner, C.	1993	Side-effects on the staphylinid (*Aleochara bilineata* Gyll. Coleoptera, Staphylinidae) in the laboratory of Code: Hoe 046360 24 EW14 A203 GAB Biotechnologie GmbH, Niefern-Oeschelbronn, Germany Bayer Report No.: A51546 Edition Number: M-131452-01-2 Date: 1993-03-12 GLP/GEP: Yes, unpublished	N	N		Bayer	In DAR (2005)
KCP 10.3.2.1	Petto, R.	1992	Effects on the reproduction of *Aleochara bilineata* Gyll. (Coleoptera, Staphylinidae) in laboratory of Code: Hoe 046360 24 EW14 A203 RCC Umweltchemie GmbH & Co. KG, Rossdorf, Germany Bayer Report No.: A47601 Edition Number: M-136087-01-1 Date: 1992-03-30 GLP/GEP: Yes, unpublished	N	N		Bayer	In DAR (2005)
KCP 10.4.1	Heusel, R.	1991c	Effect to *Eisenia fetida* (earthworm) in a 14-day artificial soil test (method OECD) Fenoxaprop-P-ethyl oil in water emulsion 69 g/L Hoe 046360 24 EW14 A203	N	N		Bayer	In DAR (2005)

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
			Hoechst AG, Frankfurt am Main, Germany Bayer Report No.: A46759 Edition Number: M-130767-01-1 Date: 1991-09-12 GLP/GEP: Yes, unpublished					
KCP 10.4.1.1	Friedrich, S.	2016e	Fenoxaprop-P-ethyl + mefenpyr-diethyl EW 144 (69+75) G: Sublethal toxicity to the earthworm *Eisenia fetida* tested in artificial soil BioChem agrar GmbH, Gerichshain, Germany Bayer Report No.: 16 10 48 015 S Edition Number: M-548492-01-1 Date: 2016-02-16 GLP/GEP: Yes, unpublished	N	Y	Data requirement according to Regulation (EC) No 1107/2009 or 284/2013	Bayer	Submitted for the purpose of renewal
KCP 10.4.2.1	Friedrich, S.	2016f	Fenoxaprop-P-ethyl + mefenpyr-diethyl EW 144 (69+75) G: Effects on the reproduction of the collembolan *Folsomia candida* tested in artificial soil BioChem agrar GmbH, Gerichshain, Germany Bayer Report No.: 16 10 48 013 S Edition Number: M-548494-01-1 Date: 2016-02-15 GLP/GEP: Yes, unpublished	N	Y	Data requirement according to Regulation (EC) No 1107/2009 or 284/2013	Bayer	Submitted for the purpose of renewal
KCP 10.4.2.1	Schulz, L.	2016e	Fenoxaprop-P-ethyl + mefenpyr-diethyl EW 144 (69+75) G: Effects on the reproduction of the predatory mite *Hypoaspis aculeifer* tested in artificial soil BioChem agrar GmbH, Gerichshain, Germany Bayer Report No.: EBFPN054 Edition Number: M-551052-01-1 Date: 2016-03-10 GLP/GEP: Yes, unpublished	N	Y	Data requirement according to Regulation (EC) No 1107/2009 or 284/2013	Bayer	Submitted for the purpose of renewal
KCP 10.5	Baedelt, H.; Frings, H.	1993a	Effect on the nitrogen cycle (in accordance with BBA, VI, 1-1, 2nd edition) Fenoxaprop-P-ethyl oil in water emulsion Code: Hoe 046360 24 EW14 A203 Hoechst AG, Frankfurt am Main, Germany	N	N		Bayer	In DAR (2005)

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
			Bayer Report No.: A51547 Edition Number: M-131126-01-2 Date: 1993-03-25 GLP/GEP: No, unpublished					
KCP 10.5	Baedelt, H.; Frings, H.	1993b	Short-term effect on aerobic soil respiration (in accordance with BBA, VI, 1-1, 2nd edition) Fenoxaprop-P-ethyl oil in water emulsion Code: Hoe 046360 24 EW14 A203 Hoechst AG, Frankfurt am Main, Germany Bayer Report No.: A51545 Edition Number: M-227689-01-2 Date: 1993-02-03 GLP/GEP: No, unpublished	N	N		Bayer	In DAR (2005)
KCP 10.5	Schulz, L.	2016f	Fenoxaprop-P-ethyl + mefenpyr-diethyl EW 144 (69+75) G: Effects on the activity of soil microflora (nitrogen transformation test) BioChem agrar GmbH, Gerichshain, Germany Bayer Report No.: EBFPN052 Edition Number: M-548480-01-1 Date: 2016-02-19 GLP/GEP: Yes, unpublished	N	Y	Data requirement according to Regulation (EC) No 1107/2009 or 284/2013	Bayer	Submitted for the purpose of renewal
KCP 10.6.2	Roshon, R.	2001a	Ecotoxicological Evaluation of Fenoxaprop-p-ethyl + Mefenpyr-diethyl Emusifiable Concentrate (120 + 33 g/L) (Puma 120 Super), Terrestrial Plant Vegetative Vigour ESG International Inc., Guelph, Canada Bayer Report No.: B003327 Report includes Trial Nos.: S0497 Edition Number: M-240371-01-1 Date: 2001-05-31 GLP/GEP: Yes, unpublished	N	N		Bayer	In DAR (2005)
KCP 10.6.2	Roshon, R.	2001b	Ecotoxicological Evaluation of Fenoxaprop-p-ethyl + Mefenpyr-diethyl Emusifiable Concentrate (120 + 33 g/L)	N	N		Bayer	In DAR (2005)

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
			(Puma 120 Super), Terrestrial Plant Seedling Emergence ESG International Inc., Guelph, Canada Bayer Report No.: B003326 Report includes Trial Nos.: S0497 Edition Number: M-240370-01-1 Method Report No.: XEN00-29 Date: 2001-05-31 GLP/GEP: No, unpublished					
KCP 10.6.2	Pallett, K.; Gosch, H.	2005a	Effects on the vegetative vigour test of ten species of non-target plants Fenoxaprop-P-ethyl + mefenpyr-diethyl; oil in water emulsion; 69 + 75 g/l Code: AE F046360 24 EW14 A717 Bayer CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C046048 Edition Number: M-243579-01-1 Date: 2005-01-21 GLP/GEP: Yes, unpublished	N	N		Bayer	In DAR (2005)
KCP 10.6.2	Pallett, K.; Gosch, H.	2005b	Effects on the seedling emergence and growth test of ten species of non-target plants Fenoxaprop-P-ethyl + mefenpyr-diethyl; oil in water emulsion; 69 + 75 g/L Code: AE F046360 24 EW14 A717 Bayer CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C046044 Edition Number: M-243578-01-1 Date: 2005-01-21 GLP/GEP: Yes, unpublished	N	N		Bayer	In DAR (2005)