

Acceptability	
Remarks	

Section 7.4.3.4**Annex Point IIIA-XIII.2.4****Effects on reproduction and growth rate with an invertebrate species***Daphnia magna*

		Official use only
1 REFERENCE		
1.1 Reference	Groeneveld A.H.C., Berends A.G., van der Laan J.M.Th., van Dijk N.R.M. (1993): The chronic toxicity of ¹⁴ C-etofenprox to <i>Daphnia magna</i> ; Solvay Duphar B.V., Environmental Research Department, The Netherlands; unpublished report no. C.DNL.51.007 (October 26, 1993) Dates of experimental work: June 02, 1993 – August 11, 1993 (incl. analytical work)	
1.2 Data protection	Yes	
1.2.1 Data owner	[REDACTED] Mitsui Chemicals Agro, Inc.	
1.2.2 Criteria for data protection	Data submitted to the MS after May 13, 2000 on existing a.s. for the purpose of its entry into Annex I.	
2 GUIDELINES AND QUALITY ASSURANCE		
2.1 Guideline study	Yes: OECD guideline 202 (OECD, 1984 and 1991)	
2.2 GLP	Yes	
2.3 Deviations	No	
3 METHOD		
3.1 Test material	¹⁴ C-etofenprox (radiolabelled test substance)	
3.1.1 Lot/Batch number	MRH/MTC 277/29	X
3.1.2 Specification	As given in section 2 Deviating from specification given in section 2 as follows	
3.1.3 Description		
3.1.4 Purity	96.5% (radiochemical purity)	X
3.1.5 Specific activity	27.3 µCi/mg	
3.1.6 Position of radiolabel	α- ¹⁴ C-benzyl	
3.1.7 Further relevant properties	Solubility in water: 22.5 µg/L at 20 ± 0.5°C Vapour pressure: 8.13 x 10 ⁻⁷ Pa at 25°C Stability in water: hydrolytically stable at pH 4, 7 and 9	
3.1.8 Method of analysis	<u>LSC</u> : Radioactivity was measured with a Packard liquid scintillation counter (TRI-CARB 1600 CR) using Ultimate Gold XR (Packard) scintillation fluid. Secondary stock solutions and test solutions were analysed with LSC. <u>HPLC</u> : Mobile phase was acetonitrile/water (v/v = 75/25), 100 x 4.6, 3 µm particles Microspher C18, Chrompack column, flow rate at 1.0 ml/minute, UV detection (210 nm). Seven fractions were obtained with a Gilson 202 collector and were analysed with LSC. The highest stock solution and the highest concentrated test solution were analysed with HPLC/LSC.	

Section 7.4.3.4
Annex Point IIIA-XIII.2.4**Effects on reproduction and growth rate with an invertebrate species*****Daphnia magna***

3.2	Preparation of TS solution for poorly soluble or volatile test substances	A primary stock solution was prepared in acetone containing 0.1 mg ¹⁴ C-etofenprox/ml solvent. Secondary stock solutions were prepared from this stock solution by further dilution with acetone to reach concentrations of 0.64, 1.1, 2.0, 3.4 and 6.0 µg/ml. See also table A7_4_3_4-1
3.3	Reference substance	No
3.3.1	Method of analysis for reference substance	
3.4	Testing procedure	
3.4.1	Dilution water	see enclosed table A7_4_3_4-2
3.4.2	Test organisms	see enclosed table A7_4_3_4-3
3.4.3	Handling of offspring	Young daphnids were counted daily and thereafter removed from the test solutions using a glass pipette.
3.4.4	Test system	see enclosed table A7_4_3_4-4
3.4.5	Test conditions	see enclosed table A7_4_3_4-5
3.4.6	Duration of the test	21 days
3.4.7	Test parameter	<ul style="list-style-type: none">- Immobility (e.g. mortality) of adult daphnids- Number of living young daphnids- Number of dead young daphnids- Appearance and behaviour of adult daphnids at test termination
3.4.8	Examination / Sampling	Daily examination for the parameters described above
3.4.9	Monitoring of TS concentration	Yes <ul style="list-style-type: none">- LSC analysis of all secondary stock solutions at all renewal days- HPLC/LSC analysis of the highest secondary stock solutions at days 0, 7, 14 and 21- LSC analysis of test solutions at renewal days (from day 7 onwards, results are given in table A7_4_3_4-6)- HPLC/LSC analysis of the highest test concentration on days 2, 9 and 16
3.4.10	Statistics	William's test for determination of NOEC for reproduction

4 RESULTS

4.1	Range finding test	Not performed, test substance concentrations were selected based on a previous study conducted under GLP.
4.1.1	Concentrations	
4.1.2	Number/ percentage of animals showing adverse effects	
4.1.3	Nature of adverse effects	

Section 7.4.3.4 Effects on reproduction and growth rate with an invertebrate species

Annex Point IIIA-XIII.2.4

Daphnia magna

4.2 Results test substance

4.2.1 Initial concentrations of test substance 0.064, 0.11, 0.20, 0.34 and 0.60 µg/L (nominal concentrations)

4.2.2 Actual concentrations of test substance see enclosed table A7_4_3_4-6

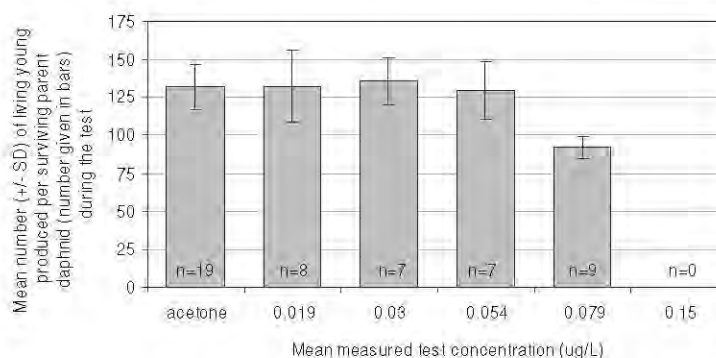
X

4.2.3 Effect data

- Mortality of parent animals: see enclosed table A7_4_3_4-7
- Reproduction data of surviving parent animals: see enclosed table A7_4_3_4-8
- The NOEC for reproduction was determined to be 0.054 µg/L.

X

4.2.4 Concentration / response curve



4.2.5 Other effects No other observations differentiating organisms in tests and controls were realised

4.3 Results of controls Acetone control mortality at test termination was 5% (see table A7_4_3_4-7)

4.4 Test with reference substance Not performed

4.4.1 Concentrations

4.4.2 Results

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

OECD 202 (1984, 1991)

Valid study

The study was conducted with ¹⁴C-etofenprox for analytical reasons (low solubility in water).

5.2 Results and discussion

Complete mortality occurred at the highest mean measured concentration of 0.15 µg/L.

The reproduction data of the daphnids, which were still alive at test termination, were used to determine a NOEC. The NOEC, based on William's test, was 0.054 µg/L. At a concentration of 0.079 µg/L the reproduction was reduced at 30%.

The NOEC for survival during an acute toxicity test was 0.089 µg/L (see Section A.7.4.1.2/02), which is in the same range as the chronic NOEC for reproduction that was determined in this study.

Section 7.4.3.4 **Effects on reproduction and growth rate with an**
Annex Point IIIA-XIII.2.4 **invertebrate species**
Daphnia magna

5.2.1	NOEC (21-days)	0.054 µg/L for reproduction	X
5.2.2	LOEC		
5.2.3	EC ₁₀₀	0.15 µg/L	X
5.3	Conclusion	Validity criteria can be considered as fulfilled. (see validity criteria summarized in table A7_4_3_4-9)	X
5.3.1	Reliability	I	
5.3.2	Deficiencies	No	

Table A7_4_3_4-1: Preparation of TS solution for poorly soluble or volatile test substances

Criteria	Details
Dispersion	No
Vehicle	Yes: acetone
Concentration of vehicle	0.01% (v/v)
Vehicle control performed	Yes: 10 µl acetone/100 ml test medium, 20 replicates (e.g. beakers)
Other procedures	

Table A7_4_3_4-2: Dilution water

Criteria	Details
Source	Reconstituted dilution water (Elendt M4 medium) based on deionised water
Alkalinity	Elendt M4 medium
Hardness	Elendt M4 medium
pH	6.9 – 8.3
Ca / Mg ratio	Elendt M4 medium
Na / K ratio	Elendt M4 medium
Oxygen content	8.8 – 10.1 mg/L
Conductance	Elendt M4 medium
Holding water different from dilution water	No

Table A7_4_3_4-3: Test organisms

Criteria	Details
Species/strain	<i>Daphnia magna</i> (Crustacea)
Source	Solvay Dulphar B.V., Environmental Research Department, The Netherlands
Age	0-24 hours at start of the test
Breeding method	
Kind of food	Algal suspension of <i>Chlorella vulgaris</i> (10 ⁹ cells/ml)
Amount of food	Day 1 – 6: 21 µl Day 7 – 14: 42 µl Day 15 onward: 21 µl
Feeding frequency	Daily
Pretreatment	acclimatisation
Feeding of animals during test	Yes (see above)

Table A7_4_3_4-4: Test system

Criteria	Details
Test type	Semi-static
Renewal of test solution	3 x/week (Monday, Wednesday, Friday)
Volume of test vessels	250 ml glass beakers, containing 100 ml Elendt M4 medium
Volume/animal	100 ml
Number of animals/vessel	1
Number of vessels/ concentration	10 (except solvent control: 20 replicates)
Test performed in closed vessels due to significant volatility of TS	No (however, test beakers were covered with Perspex plates)

Table A7_4_3_4-5: Test conditions

Criteria	Details
Test temperature	20.0 – 20.5°C
Dissolved oxygen	8.8 – 10.2 mg/L
pH	8.0 – 8.5
Adjustment of pH	No
Aeration of dilution water	No
Quality/Intensity of irradiation	800 lux
Photoperiod	16 h light, 8 h dark

Table A7_4_3_4-6: Measured concentrations of ¹⁴C-etofenprox equivalents in the test solutions based on LSC.

Day	Nominal concentration [$\mu\text{g/L}$]					
	0	0.064	0.11	0.20	0.34	0.60
7 ^a	< 0.033 ^c	0.055	0.090	0.16	0.26	n.d. ^d
9 ^b	< 0.033 ^c	0.055	0.090	0.14	0.22	0.51
9 ^a	< 0.033 ^c	0.060	0.080	0.16	0.21	0.37
12 ^b	< 0.033 ^c	0.050	0.090	0.15	0.23	0.49
12 ^a	< 0.033 ^c	0.057	0.080	0.15	0.23	0.43
14 ^b	< 0.033 ^c	0.070	0.100	0.16	0.26	0.49
14 ^a	< 0.033 ^c	0.059	0.086	0.16	0.26	0.46
16 ^b	< 0.033 ^c	0.060	0.110	0.18	0.25	0.54
16 ^a	< 0.033 ^c	0.035	0.085	0.19	0.26	0.44
19 ^b	< 0.033 ^c	0.089	0.110	0.21	0.28	0.54
19 ^a	< 0.033 ^c	0.085	0.110	0.19	0.26	0.50
21 ^b	< 0.033 ^c	0.062	0.093	0.19	0.28	n.d. ^d
Mean ^a	< 0.033 ^c	0.059	0.089	0.17	0.25	0.44
Mean ^b	< 0.033 ^c	0.064	0.099	0.17	0.25	0.51
Mean ^c	< 0.033 ^c	0.061	0.094	0.17	0.25	0.48

^a after renewal

^b before renewal

^c limit of detection

^d n.d. = not determined

^e mean of all values

Table A7_4_1_2-7: Survival of *Daphnia magna* during the chronic toxicity test with ¹⁴C-etofenprox.

Mean measured test concentration [$\mu\text{g/L}$] ^a	Number of surviving daphnids				Percentage [%] mortality after 21 days
	Day 0	Day 7	Day 14	Day 21	
0 (acetone control)	20	19	19	19 ^b	5
0.019	10	9	9	8 ^b	20
0.030	10	9	9	8 ^c	20
0.054	9 ^d	7	7	7 ^b	22
0.079	10	9	9	9 ^b	10
0.150	10	3	2	0	100

^a the results of the LSC analysis showed good agreement between the nominal and measured concentrations of ¹⁴C-etofenprox in the test solutions during the test period (see Table A7_4_1_2-6). However, the results of the HPLC/LSC analysis showed a decrease in ¹⁴C-etofenprox concentration between two renewals. For this reason all results were based on mean measured ¹⁴C-etofenprox concentrations.

^b no aberrant behaviour or appearance.

^c one daphnid was very small and was probably a male. The other daphnids appeared and behaved normal.

^d one glass beaker with a daphnid fell down during handling on day 8. the data of this daphnid were not used for statistical analyses.

Table A7_4_1_2-8: Number of living young produced per surviving daphnia during the test

Replicate number	Mean measured test concentration [$\mu\text{g/L}$]					
	Acetone control ^a		0.019	0.030	0.054	0.079
1	115	139		151		92
2	116	135	141	125	111	92
3	129	146	129	142		86
4	118	131	127	129		90
5	151	126	86		146	77
6	107		155	109	110	102
7	140	108	135	0 ^a	136	99
8	147	146	123	140	109	99
9	137	154			155	92
10	148	116	164	154	141	
Mean	132		133	136	130	92

^a data of the second row represent values for replicates 11-20

^b the parent daphnid was probably a male. For this reason the zero value is not included in the statistical analysis.

Table A7_4_3_4-9: Validity criteria for invertebrate reproduction test according to OECD Guideline 211

Criteria	fulfilled	not fulfilled
Mortality of parent animals < 20% at test termination	X	
Mean number of live offspring produced per parent animal surviving at test termination ≥ 60	X	
Concentration of dissolved oxygen in all test vessels >3 mg/l	X	
Concentration of test substance $\geq 80\%$ of initial concentration during test	X	

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	27.05.2005
Materials and methods	<p>3.1.2 Specification According to document A3 the physical state changes from white crystals to amber liquid with decreasing purity from 99,8 % to 99,3%.</p> <p>3.1.4 Purity: Within the 5 batch analysis a purity between 97,2 % and 99,6% is indicated. MRH/MTC 277/29 contained the same main impurities as later production batches (e.g. 5 batch analysis) at comparable percentages. The concentration of etofenprox used in this test is 95,6% and is only slightly lower than in the 5 batch analysis. Therefore the deviations to the specification are not considered to be ecotoxicologically relevant.</p> <p>4.2.2 Actual concentrations of test substance: The results of LCS analysis are expressed in ¹⁴C–etofenprox equivalents and no decrease in ¹⁴C concentrations was found between two renewals. HPLC/LSC analyses shows that only 10 % of the radioactivity in the old test solution (before renewal) represents ¹⁴C–etofenprox Based on these results a recalculation can be made: The mean measured concentration before renewal (see table A 7.4.1.2-6) was divided by a factor of 10. Assuming an exponential decrease of the ¹⁴C–etofenprox concentration between the two renewals, the mean measured concentration is equal to the geometric mean of the concentrations before and after renewal. This results in mean measured concentrations during the study period of 0.019, 0.030, 0.054, 0.079 and 0.15 µg/L</p> <p>5.3 Conclusion, Table A7_4_3_4-9: Mortality of parent animals equal or less 20% at test termination, criteria fulfilled</p>
Conclusion	<p>4.2.3 Effect data, 5.2.1. NOEC and 5.2.3 LC₁₀₀ are given in mean measured concentrations The Validity criteria for invertebrate reproduction test according to OECD Guideline 211 (see Table A7_4_3_4-9): Concentration of test substance ≥80% of initial concentration during test is not fulfilled. For this reason the results are given in mean measured concentrations</p>
Reliability	1
Acceptability	Acceptable
Remarks	-
	COMMENTS FROM...
Date	

Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Section A7.4.3.5.1/01 Effects on sediment dwelling organisms
Annex Point IIIA-XIII.3.4 *Chironomus riparius*

		1 REFERENCE	
1.1 Reference		Memmert U. (2002a): Effects of MTI-500 on larvae of <i>Chironomus riparius</i> in a 10-day toxicity test; RCC Ltd, Environmental Chemistry & Pharamalytics Division, Itingen, Switzerland; unpublished report no. 803777 (February 20, 2002). Dates of experimental work: June 29, 2001 – September 05, 2001	
1.2 Data protection		Yes	
1.2.1 Data owner		[REDACTED] Mitsui Chemicals Agro, Inc.	
1.2.2 Criteria for data protection		Data submitted to the MS after May 13, 2000 on existing a.s. for the purpose of its entry into Annex I.	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study		Yes OECD 219 (Draft, 2001)	
2.2 GLP		Yes	
2.3 Deviations		No	
		3 MATERIALS AND METHODS	
3.1 Test material		Etofenprox	
3.1.1 Lot/Batch number		MR-9301	
3.1.2 Specification		As given in section 2 Deviating from specification given in section 2 as follows	
3.1.3 Description		Solid (white crystal)	
3.1.4 Purity		99.70%	
3.1.5 Stability		No information in the report.	
3.1.6 Further relevant properties		Solubility in water: 22.5 µg/L at 20 ± 0.5°C Vapour pressure: 8.13 x 10 ⁻⁷ Pa at 25°C Stability in water: hydrolytically stable at pH 4, 7 and 9 n-Octanol/water partition coefficient: log Pow = 6.9	
3.1.7 Method of analysis		Samples of the application solutions were diluted with N,N-Dimethylformamide (DMF) and analysed on a high performance liquid chromatographic (HPLC) system using ultraviolet (UV/VIS) detection.	
3.2 Preparation of TS solution for poorly soluble or volatile test substances		A primary stock solution was prepared in N,N-Dimethylformamide (209 mg a.s./100 mL DMF) and used to produce secondary stock solutions in concentrations of 0.6, 3.8 and 20.9 µg a.s./100 µl DMF. 25 µl of the secondary stock solutions (or DMF alone for the solvent control) were applied into 250 ml test media just below the water surface (spiked water). See also enclosed table A7_4_3_5_1_01-1	
3.3 Reference substance		No	

Official
use only

Section A7.4.3.5.1/01 Effects on sediment dwelling organisms**Annex Point IIIA-XIII.3.4 *Chironomus riparius***

3.3.1 Method of analysis for reference substance

3.4 Testing procedure

- 3.4.1 Dilution water See enclosed table A7_4_3_5_1_01-2
- 3.4.2 Sediment See enclosed table A7_4_3_5_1_01-3
- 3.4.3 Test organisms See enclosed table A7_4_3_5_1_01-4
- 3.4.4 Test system See enclosed table A7_4_3_5_1_01-5
- 3.4.5 Test conditions See enclosed table A7_4_3_5_1_01-6
- 3.4.6 Duration of the test 10 days
- 3.4.7 Test parameter Survival and growth of the larvae: assessment after 10 days of exposure (larvae were washed out of the sediment, inspected for health and the dry weight of the pooled surviving larvae per vessel was determined)
- 3.4.8 Sampling At end of the study (no sampling of animals during the study)
- 3.4.9 Monitoring of TS concentration No monitoring of TS concentration in the test solutions (only application solutions were analysed for etofenprox content)
- 3.4.10 Statistics EC₅₀ could not be calculated due to the low toxic effects
Body weight data were analysed using multivariate Williams test, one-way ANOVA and Student t-test

4 RESULTS**4.1 Limit Test**

Not performed

- 4.1.1 Concentration
- 4.1.2 Number/ percentage of animals showing adverse effects
- 4.1.3 Nature of adverse effects

4.2 Results test substance

- 4.2.1 Initial concentrations of test substance 0.6, 3.8 and 20.9 µg a.s./L
- 4.2.2 Actual concentrations of test substance TS concentration was not monitored
- 4.2.3 Effect data
- Mortality data: see table A7_4_3_5_1_01-8
- Dry weight data of surviving larvae: see table A7_4_3_5_1_01-9
- 4.2.4 Concentration / response curve Effects were observed only at the highest test concentration of 20.9 µg a.s./L, where the body weight of the test animals was significantly reduced. Mortality in this group was not significantly affected.
- 4.2.5 Other effects No other effects observed

4.3 Results of controls

No adverse effects observed in control and solvent control

X

Section A7.4.3.5.1/01 Effects on sediment dwelling organisms**Annex Point IIIA-XIII.3.4 *Chironomus riparius***

4.4 Test with reference substance Not performed

4.4.1 Concentrations

4.4.2 Results

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

Guidelines: OECD 219 (Draft, 2001)
No deviations to guidelines

5.2 Results and discussion

5.2.1 EC₅₀ (10-day)

Survival: > 20.9 µg/L
Body weight: > 20.9 µg/L

5.2.2 NOEC (10-day)

3.8 µg/L

5.2.3 LOEC (10-day)

20.9 µg/L

5.3 Conclusion

Validity criteria can be considered as fulfilled. (see validity criteria summarized in table A7_4_3_5_1_01-10)

5.3.1 Reliability

1

5.3.2 Deficiencies

No

Table A7_4_3_5_1_01-1: Preparation of TS solution for poorly soluble or volatile test substances.

Criteria	Details
Dispersion	No
Vehicle	Yes: N,N-Dimethylformamide (DMF)
Concentration of vehicle	0.01% (v/v)
Vehicle control performed	Yes (equal concentration as in test solutions)
Other procedures (application)	Application: 25 µl of the respective application solution were applied into the 250 ml test media just below the water surface using a Hamilton syringe (spiked water). The water columns were then gently mixed to ensure homogeneous distribution, without disturbing the sediment

Table A7_3_5_1_01-2: Dilution water.

Criteria	Details
Source	Elendt M7 medium, prepared of purified water
Alkalinity	
Hardness	200 mg/L as CaCO ₃
pH	7.9 ± 0.3
Ca / Mg ratio	
Na / K ratio	
Oxygen content	5.6 – 6.5 mg/L (measured before application of the test item)
Conductance	
Holding water different from dilution water	No

Table A7_4_3_5_1_01-3: Sediment.

Criteria	Details
Type/source	Artificial sediment
Composition (% w/w)	Sphagnum peat: 4% Kaolin clay (kaolinite content >30%): 20% Sand (Sihelco 36): 76% Calcium carbonate (CaCO ₃): 0.31%
Total organic carbon (TOC)	2.0% (based on dry weight)
pH adjustment	Yes, CaCO ₃ was added to the ground and moistened peat to reach a pH of 6.3 before clay and sand was added
pH of final sediment mixture	6.7

Table A7_4_3_5_1_01-4: Test organisms.

Criteria	Details
Species/strain	<i>Chironomus riparius</i>
Source	In-house laboratory cultures maintained at RCC Ltd, Environmental Chemistry & Pharamalytics Division, Itingen, Switzerland. The midge culture originated from Novartis Crop Protection AG, Basel, Switzerland.
Age	Fresh egg masses were used as source for test animals. At the date when test animals were placed into the test beakers the larvae were 2-3 days old (first-instar larvae)
Breeding method	Midge culture was bred under similar temperature and light conditions as in the test, in the same kind of test water as used in the test Six days before application fresh egg masses were taken from the test organism culture and deposited into small vessels in test water with a small amount of food (mixture of fresh green algae <i>Scenedesmus subspicatus</i> from a laboratory culture and Tetra Min fish food suspension)

Table A7_4_3_5_1_01-4: Test organisms (continued).

Criteria	Details
Kind of food	During test: Tetra Min fish food (TETRA MIN Hauptfutter, Tetra Werke, 49304 Melle, Germany); flakes were finely ground and suspended in test water
Amount of food	Days 0/1/3: 23 mg Tetra Min/vessel Days 6/8: 47 mg Tetra Min/vessel
Feeding frequency	See above
Pretreatment	
Feeding of animals during test	Yes, see above

Table A7_4_3_5_1_01-5: Test system.

Criteria	Details
Type of test	Spiked water test; water/sediment system
Renewal of test solution	No (single application of the test item to the water column one day after adding the larvae to the test vessels)
Volume of test vessels	600 ml glass beakers (approximately 8 cm in diameter)
Amount/volume of sediment per vessel	approximately 130 g wet weight (46% water content; corresponds to about 89 g dry sediment) approximately 15 mm thickness
Volume of test medium per vessel	250 ml (water column about 6 cm depth)
Volume/animal	12.5 ml
Number of animals/vessel	5
Number of vessels/ concentration	4
Test performed in closed vessels due to significant volatility of TS	No (vessels were loosely covered with watch glasses)

Table A7_4_3_5_1_01-6: Test conditions.

Criteria	Details
Test temperature	See table A7_4_3_5_1_01-7
Dissolved oxygen	See table A7_4_3_5_1_01-7
pH	See table A7_4_3_5_1_01-7
Adjustment of pH	No
Aeration of dilution water	Yes, gentle aeration of the test media through a glass Pasteur pipette fixed 2-3 cm above the sediment layer (no aeration during the period from insertion of the larvae until immediately after application of the test medium)
Quality/Intensity of irradiation	600 – 680 Lux at water surface
Photoperiod	16 hours light/8 hours dark photoperiod (30 min transition period)

Table A7_4_3_5_1_01-7: Water quality criteria.

Parameter	Days of measurement	Nominal initial concentration of test item ($\mu\text{g/L}$)				
		Control	Solvent control	0.6	3.8	20.9
pH	0/6/10	8.0-8.3	8.1-8.4	8.0-8.4	8.1-8.4	8.0-8.4
Dissolved oxygen (mg/L)	0/1/3/6/8/10	5.6-8.0	6.1-8.1	6.1-8.7	6.0-8.6	6.4-8.6
Water temperature ($^{\circ}\text{C}$)	0/1/3/6/8/10	20.4-21.0	20.4-20.9	20.3-20.9	20.3-20.9	20.0-20.9
Total hardness (mmol/L)	0/10	3.0/3.2	3.2/3.2	–	–	3.0/3.2
Ammonium concentration (mg/L)	0/10	1.05/1.35	1.15/1.37	–	–	1.12/1.32

Table A7_4_3_5_1_01-8: Survival of larvae of *Chironomus riparius* after 10 days of exposure.

Nominal test item concentration ($\mu\text{g/L}$)	No. of larvae tested (per replicate)	No. of surviving larvae in replicate:				% survival (mean)
		1	2	3	4	
Control	20	20	18	18	20	95.0
Solvent control	20	20	19	20	19	97.5
0.6	20	20	20	20	17	96.3
3.8	20	19	20	17	20	95.0
20.9	20	16*	18*	18*	20*	90.0

* surviving larvae in the highest dosed group were smaller than those in the control/solvent control

Table A7_4_3_5_1_01-9: Dry weight of alive larvae at study termination after 10 days of exposure

Nominal test item concentration ($\mu\text{g/L}$)	Dry weight (mg) per surviving larva in replicate:				Mean (mg)	SD	STAT*
	1	2	3	4			
Control	1.39	1.60	1.47	1.68	1.54	0.13	n.s.**
Solvent control	1.54	1.52	1.28	1.54	1.47	0.12	–
0.6	1.53	2.00	1.34	1.38	1.56	0.30	n.s.
3.8	1.56	1.48	1.61	1.60	1.56	0.06	n.s.
20.9	0.92	1.35	1.17	1.15	1.15	0.18	s.

*STAT results of a Williams t-test ($\alpha = 0.05$, one-sided smaller)

n.s. statistically not significantly lower than in solvent control

s. statistically significantly lower than in solvent control

n.s.** mean value not significantly different from the solvent control (Student t-test, $\alpha = 0.05$, two-sided)

Table A7_4_3_5_1_01-10: Validity criteria for the sediment/water *Chironomus* toxicity test according to OECD Guideline 219.

Criteria	fulfilled	not fulfilled
Mortality in the controls <30% at the end of the test	X	
Emergence of adults (days after insertion in test vessels): - <i>C. riparius</i> , <i>C. yoshimatsui</i> : 12 – 23 days - <i>C. tentans</i> : 20 – 65 days	Not applicable	
Emergence in controls: 50 – 70%	Not applicable	
Concentration of dissolved oxygen: > 60% of the air saturation value of the temperature used	X	
pH of overlying water: 6 – 9	X	
Water temperature does not differ by more than $\pm 1.0^{\circ}\text{C}$ between test vessels, and is be maintained within the temperature ranges specified for the test species	X	

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	27.05.2005
Materials and methods	4.2.2 Actual concentrations of test substance: According OECD guideline 219 the concentration of the test substance must be analysed at the start and the end of the test at the highest concentration and a lower one as a minimum. Test substance concentration was not monitored in this test.
Conclusion	Agree with the applicant's version
Reliability	2
Acceptability	Acceptable
Remarks	-
	COMMENTS FROM...
Date	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Section A7.4.3.5.1/02 **Effects on sediment dwelling organisms**
Annex Point IIIA-XIII.3.4 **Metabolite 4'-OH; *Chironomus riparius***

		1 REFERENCE	
1.1	Reference	Memmert U. (2002b): Acute toxicity of 4'-OH to first-instar larvae of the midge <i>Chironomus riparius</i> ; RCC Ltd, Environmental Chemistry & Pharamanalytics Division, Itingen, Switzerland; unpublished report no. 841579 (August 19, 2002). Dates of experimental work: May 08, 2002 – May 30, 2002	
1.2	Data protection	Yes	
1.2.1	Data owner	[REDACTED] Mitsui Chemicals Agro Ltd.	
1.2.2	Criteria for data protection	Data submitted to the MS after May 13, 2000 on existing a.s. for the purpose of its entry into Annex I.	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	Guideline study	No: no official test guideline for an acute toxicity test with larvae of <i>C. riparius</i> is available; considered guidelines: Administration of test item: OECD 202 (Part 1, 1984) / EEC C.2 (1992) Species/age of test organisms: OECD 219 (Draft, 2001)	
2.2	GLP	Yes	
2.3	Deviations	Not applicable	
		3 MATERIALS AND METHODS	
3.1	Test material	4'-OH	
3.1.1	Chemical name (IUPAC)	2-(4-ethoxyphenyl)-2-methylpropyl 3-(4-hydroxyphenoxy) benzyl ether	
3.1.2	Lot/Batch number	043-011222-1	
3.1.3	Description	Solid, white	
3.1.4	Purity	96.0%	
3.1.5	Stability	No information in the report.	
3.1.6	Further relevant properties	Solubility in water: 217 µg/L at 20°C Stability in water: not indicated n-Octanol/water partition coefficient: log Pow = 5.3	
3.1.7	Method of analysis	Aqueous samples containing the test material were processed by liquid/liquid extraction and analysed on a high performance liquid chromatographic (HPLC) system using ultraviolet (UV/VIS) detection	
3.2	Preparation of TS solution for poorly soluble or volatile test substances	A primary stock solution was prepared in N,N-Dimethylformamide (50 mg 4'-OH/5 mL DMF) and used to produce secondary stock solutions in concentrations of 4.6, 10, 22, 46 and 100 µg 4'-OH/100 µl DMF. 5 µl of the secondary stock solutions (or DMF alone for the solvent control) were applied into 50 ml test media (spiked water) just before the introduction of the test organisms. See also enclosed table A7_4_3_5_1_02-1	

Official
use only

Section A7.4.3.5.1/02 Effects on sediment dwelling organisms**Annex Point IIIA-XIII.3.4 Metabolite 4'-OH; *Chironomus riparius***

3.3	Reference substance	No
3.3.1	Method of analysis for reference substance	
3.4	Testing procedure	
3.4.1	Dilution water	See enclosed table A7_4_3_5_1_02-2
3.4.2	Sediment	See enclosed table A7_4_3_5_1_02-3
3.4.3	Test organisms	See enclosed table A7_4_3_5_1_02-4
3.4.4	Test system	See enclosed table A7_4_3_5_1_02-5
3.4.5	Test conditions	See enclosed table A7_4_3_5_1_02-6
3.4.6	Duration of the test	48 hours
3.4.7	Test parameter	Survival of the larvae or abnormalities at the test organisms were determined visually by eye after 24 and 48 hours of exposure Water quality criteria were assessed at start and at the end of the test
3.4.8	Sampling	no sampling of animals during the study
3.4.9	Monitoring of TS concentration	Yes - before test start: stock solution, solvent control, each test medium - after 48 hours: solvent control, each test medium
3.4.10	Statistics	Probit analysis

4 RESULTS

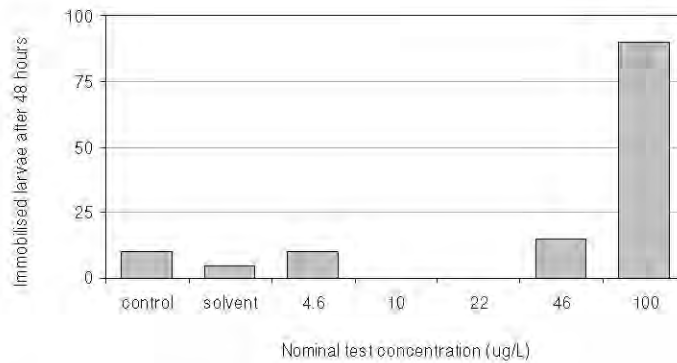
4.1	Limit Test	Not performed
4.1.1	Concentration	
4.1.2	Number/ percentage of animals showing adverse effects	
4.1.3	Nature of adverse effects	
4.2	Results test substance	
4.2.1	Initial concentrations of test substance	4.6, 10, 22, 46 and 100 µg 4'-OH/L

4.2.2	Actual concentrations of test substance	<table border="1"> <thead> <tr> <th>Nominal concentration [µg/L]</th> <th>Mean measured concentration [µg/L] (average over all measurements)</th> </tr> </thead> <tbody> <tr> <td>4.6</td> <td>not analysed (below NOEC)</td> </tr> <tr> <td>10</td> <td>not analysed (below NOEC)</td> </tr> <tr> <td>22</td> <td>17.6 (80% of nominal)</td> </tr> <tr> <td>46</td> <td>38.0 (83% of nominal)</td> </tr> <tr> <td>100</td> <td>70.7 (71% of nominal)</td> </tr> </tbody> </table>	Nominal concentration [µg/L]	Mean measured concentration [µg/L] (average over all measurements)	4.6	not analysed (below NOEC)	10	not analysed (below NOEC)	22	17.6 (80% of nominal)	46	38.0 (83% of nominal)	100	70.7 (71% of nominal)
Nominal concentration [µg/L]	Mean measured concentration [µg/L] (average over all measurements)													
4.6	not analysed (below NOEC)													
10	not analysed (below NOEC)													
22	17.6 (80% of nominal)													
46	38.0 (83% of nominal)													
100	70.7 (71% of nominal)													

4.2.3	Effect data	- Mortality (immobilisation) data: see table A7_4_3_5_1_02-8 - Effect data: see table A7_4_3_5_1_02-9
-------	-------------	--

Section A7.4.3.5.1/02 **Effects on sediment dwelling organisms**
Annex Point IIIA-XIII.3.4 **Metabolite 4'-OH; *Chironomus riparius***

4.2.4 Concentration /
response curve



4.2.5 Other effects No other effects observed

4.3 Results of controls No adverse effects observed in control and solvent control

4.4 Test with reference substance Not performed

4.4.1 Concentrations

4.4.2 Results

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

Guidelines considered: OECD 202, EEC C.2, OECD 219

Deviations: not applicable (no official test guideline exists for an acute toxicity test with larvae of the midge *Chironomus riparius*)

5.2 Results and discussion

5.2.1 LC₅₀ (95% c.l.) 24-hour: 53.6 µg/L (46.8 – 61.2 µg/L) 48-hour: 50.2 µg/L (43.9 – 57.3 µg/L)

5.2.2 LC₀ 24-hour: 17.6 µg/L 48-hour: 17.6 µg/L

5.2.3 LC₁₀₀ 24-hour: > 70.7 µg/L 48-hour: ~ 71.0 µg/L

5.2.4 NOEC 24-hour: – 48-hour: 17.6 µg/L

5.2.5 LOEC 24-hour: – 48-hour: 38.0 µg/L

5.3 Conclusion

Validity criteria of the considered study guidelines can be considered as fulfilled (see validity criteria summarized in tables A7_4_3_5_1_02-10 and A7_4_3_5_1_02-11)

A rather steep concentration-effect relationship of the acute toxicity of 4'-OH to first-instar larvae of *Chironomus riparius* was observed.

5.3.1 Reliability 1

5.3.2 Deficiencies No

Table A7.4.3.5.1.02-1: Preparation of TS solution for poorly soluble or volatile test substances.

Criteria	Details
Dispersion	No
Vehicle	Yes: N,N-Dimethylformamide (DMF)
Concentration of vehicle	0.01% (v/v)
Vehicle control performed	Yes (equal concentration as in test solutions)
Other procedures (application)	Application: 5 µl of the respective application solution were applied into the 50 ml test media (spiked water) just before test organisms were inserted.

Table A7.4.3.5.1.02-2: Dilution water.

Criteria	Details
Source	Elendt M7 medium, prepared of purified water
Alkalinity	0.9 mmol/L
Hardness	2.5 mmol/L (250 mg/L) as CaCO ₃
pH	7.9 ± 0.3
Ca / Mg ratio	
Na / K ratio	
Oxygen content	Before use, the test water was aerated until oxygen saturation
Conductance	
Holding water different from dilution water	No

Table A7.4.3.5.1.02-3: Sediment.

Criteria	Details
Type/source	No sediment was added in this acute test
Composition (% w/w)	
Total organic carbon (TOC)	
pH adjustment	
pH of final sediment mixture	

Table A7.4.3.5.1.02-4: Test organisms.

Criteria	Details
Species/strain	<i>Chironomus riparius</i>
Source	In-house laboratory cultures maintained at RCC Ltd, Environmental Chemistry & Pharamalytics Division, Itingen, Switzerland. The midge culture originated from Novartis Crop Protection AG, Basel, Switzerland.
Age	Fresh egg masses were used as source for test animals. At the date when test animals were placed into the test beakers the larvae were 2-3 days old (first-instar larvae)
Breeding method	Midge culture was bred under similar temperature and light conditions as in the test, in the same kind of test water as used in the test Six days before application fresh egg masses were taken from the test organism culture and deposited into small vessels in test water with a small amount of food (mixture of fresh green algae <i>Scenedesmus subspicatus</i> from a laboratory culture and a Tetra Min fish food suspension)
Kind of food	Mixture of fresh green algae <i>Scenedesmus subspicatus</i> from a laboratory culture and Tetra Min fish food suspension
Amount of food	5 mg carbon/L test water (measured by TOC analysis)
Feeding frequency	Once, at the start of the test (necessary to ensure a sufficient survival of the test animals during study duration)
Pretreatment	
Feeding of animals during test	Larvae were fed once at the start of the test

Table A7.4.3.5.1.02-5: Test system.

Criteria	Details
Type of test	Spiked water test
Renewal of test solution	No
Volume of test vessels	100 ml glass beakers
Amount/volume of sediment per vessel	No sediment added
Volume of test medium per vessel	50 ml
Volume/animal	10 ml
Number of animals/vessel	5
Number of vessels/concentration	4
Test performed in closed vessels due to significant volatility of TS	No (vessels were loosely covered with glass plates)

Table A7_4_3_5_1_02-6: Test conditions.

Criteria	Details
Test temperature	See table A7_4_3_5_1_02-7
Dissolved oxygen	See table A7_4_3_5_1_02-7
pH	See table A7_4_3_5_1_02-7
Adjustment of pH	No
Aeration of dilution water	Before use, test water was aerated until oxygen saturation. No aeration during the test
Quality/Intensity of irradiation	200 – 1200 Lux at water surface
Photoperiod	16 hours light/8 hours dark photoperiod

Table A7_4_3_5_1_02-7: Water quality criteria (pH, dissolved oxygen, temperature).

Nominal test item concentration (µg/L)	Start (0 hours)			End (48 hours)		
	pH	Oxygen (mg/L)	Temperature (°C)	pH	Oxygen (mg/L)	Temperature (°C)
Control	7.8	8.2	20	8.3	8.4	21
Solvent control	7.8	8.5	20	8.5	8.6	20
4.6	7.8	8.3	20	8.5	8.5	20
10	7.8	8.5	20	8.6	8.7	20
22	7.8	8.4	20	8.5	8.6	20
46	7.8	8.5	20	8.6	8.5	21
100	7.8	8.4	20	8.6	8.4	20

Table A7_4_3_5_1_02-8: Survival of larvae of *Chironomus riparius* after 24 and 48 hours of exposure to 4'-OH.

Nominal test item concentration (µg/L)	Mean measured test item concentration (µg/L)	No. of larvae tested	Immobilized larvae after 24 hours		Immobilized larvae after 48 hours	
			No.	%	No.	%
Control	–	20	1	5	2	10
Solvent control	–	20	1	5	1	5
4.6	n.a.	20	1	5	2	10
10	n.a.	20	0	0	0	0
22	17.6	20	0	0	0	0
46	38.0	20	2	10	3	15
100	70.7	20	17	85	18	90

n.a. not analysed (below the 48-hour NOEC)

Table A7.4.3.5.1.02-9: Effect data, based on measured concentrations

	24 hours	48 hours
LC ₅₀ [$\mu\text{g 4'-OH/L}$] (95 % c.l.)	53.6 (46.8 – 61.2)	50.2 (43.9 – 57.3)
LC ₀ [$\mu\text{g 4'-OH/L}$]	17.6	17.6
LC ₁₀₀ [$\mu\text{g 4'-OH/L}$]	> 70.7	approximately 71.0
NOEC [$\mu\text{g 4'-OH/L}$]		17.6
LOEC [$\mu\text{g 4'-OH/L}$]		38.0

Table A7.4.1.2.02-10: Validity criteria for acute daphnia immobilisation test according to OECD Guideline 202.

Criteria	fulfilled	not fulfilled
Immobilisation of control animals <10%	X	
Control animals not staying at the surface	X	
Concentration of dissolved oxygen in all test vessels >3 mg/l	X	
Concentration of test substance \geq 80% of initial concentration during test		X *

* results are therefore based on mean measured concentrations

Table A7.4.3.5.1.02-11: Validity criteria for the sediment/water *Chironomus* toxicity test according to OECD Guideline 219.

Criteria	fulfilled	not fulfilled
Mortality in the controls <30% at the end of the test	X	
Emergence of adults (days after insertion in test vessels): - <i>C. riparius</i> , <i>C. yoshimatsui</i> : 12 – 23 days - <i>C. tentans</i> : 20 – 65 days	Not applicable	
Emergence in controls: 50 – 70%	Not applicable	
Concentration of dissolved oxygen: > 60% of the air saturation value of the temperature used	X	
pH of overlying water: 6 – 9	X	
Water temperature does not differ by more than $\pm 1.0^\circ\text{C}$ between test vessels, and is maintained within the temperature ranges specified for the test species	X	

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	27.05.2005
Materials and methods	Agree with the applicant's version
Conclusion	Agree with the applicant's version
Reliability	1
Acceptability	Acceptable
Remarks	-
	COMMENTS FROM...
Date	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Section A7.4.3.5.1/03 Effects on sediment dwelling organisms**Annex Point IIIA-XIII.3.4*****Chironomus riparius***

		Official use only
1 REFERENCE		
1.1 Reference		<p>Memmert U. (2002c): Effects of MTI-500 on the development of sediment-dwelling larvae of <i>Chironomus riparius</i> in a water-sediment system; RCC Ltd, Environmental Chemistry & Pharamalytics Division, Itingen, Switzerland; unpublished report no. 803608 (February 20, 2002).</p> <p>Dates of experimental work: August 16, 2001 – October 15, 2001</p>
1.2 Data protection		Yes
1.2.1 Data owner		Mitsui Chemicals Agro, Inc.
1.2.2 Criteria for data protection		Data submitted to the MS after May 13, 2000 on existing a.s. for the purpose of its entry into Annex I.
2 GUIDELINES AND QUALITY ASSURANCE		
2.1 Guideline study		<p>Yes</p> <p>Proposal for BBA-Guideline (1995)</p> <p>OECD 219 (Draft, 2001)</p>
2.2 GLP		Yes
2.3 Deviations		No
3 MATERIALS AND METHODS		
3.1 Test material		Etofenprox
3.1.1 Lot/Batch number		MR-9301
3.1.2 Specification		As given in section 2
		Deviating from specification given in section 2 as follows
3.1.3 Description		Solid (white crystal)
3.1.4 Purity		99.70%
3.1.5 Stability		No information in the report.
3.1.6 Further relevant properties		<p>Solubility in water: 22.5 µg/L at 20 ± 0.5°C</p> <p>Vapour pressure: 8.13 x 10⁻⁷ Pa at 25°C</p> <p>Stability in water: hydrolytically stable at pH 4, 7 and 9</p> <p>n-Octanol/water partition coefficient: log Pow = 6.9</p>
3.1.7 Method of analysis		Samples of the application solutions were analysed on a high performance liquid chromatographic (HPLC) system using ultraviolet (UV/VIS) detection.
3.2 Preparation of TS solution for poorly soluble or volatile test substances		<p>A primary stock solution was prepared in N,N-Dimethylformamide (209 mg a.s./100 mL DMF) and used to produce secondary stock solutions in concentrations of 0.6, 3.8 and 20.9 µg a.s./100 µl DMF. 25 µl of the secondary stock solutions (or DMF alone for the solvent control) were applied into 250 ml test media just below the water surface (spiked water).</p> <p>See also enclosed table A7_4_3_5_1_03-1</p>

Section A7.4.3.5.1/03 Effects on sediment dwelling organisms**Annex Point IIIA-XIII.3.4 *Chironomus riparius***

3.3	Reference substance	No	
3.3.1	Method of analysis for reference substance		
3.4	Testing procedure		
3.4.1	Dilution water	See enclosed table A7_4_3_5_1_03-2	
3.4.2	Sediment	See enclosed table A7_4_3_5_1_03-3	
3.4.3	Test organisms	See enclosed table A7_4_3_5_1_03-4	
3.4.4	Test system	See enclosed table A7_4_3_5_1_03-5	
3.4.5	Test conditions	See enclosed table A7_4_3_5_1_03-6	
3.4.6	Duration of the test	25 days	
3.4.7	Test parameter	Survival and growth of the larvae: assessment after 10 days of exposure (larvae were washed out of the sediment, inspected for health and the dry weight of the pooled surviving larvae per vessel was determined)	X
3.4.8	Sampling	At end of the study (no sampling of animals during the study)	X
3.4.9	Monitoring of TS concentration	No monitoring of TS concentration in the test solutions (only application solutions were analysed for etofenprox content)	
3.4.10	Statistics	multivariate Williams test, one-way ANOVA and Student t-test	

4 RESULTS

4.1	Limit Test	Not performed	
4.1.1	Concentration		
4.1.2	Number/ percentage of animals showing adverse effects		
4.1.3	Nature of adverse effects		
4.2	Results test substance		
4.2.1	Initial concentrations of test substance	0.6, 3.8 and 20.9 µg a.s./L	
4.2.2	Actual concentrations of test substance	TS concentration was not monitored	X
4.2.3	Effect data	- Emergence ratio (fully emerged midges per number of inserted larvae): see table A7_4_3_5_1_03-8 - Development rate(1/development time): see table A7_4_3_5_1_03-9	
4.2.4	Concentration / response curve	Up to and including the highest test concentration of 20.9 µg a.s./L the mean emergence ratios of the midges were not significantly lower than in the solvent control. However the mean development rates of the male and the female midges were statistically significantly reduced at 20.9 µg a.s./L.	

Section A7.4.3.5.1/03 Effects on sediment dwelling organisms**Annex Point IIIA-XIII.3.4 *Chironomus riparius***

4.2.5	Other effects	No other effects observed
4.3	Results of controls	No adverse effects observed in control and solvent control
4.4	Test with reference substance	Not performed
4.4.1	Concentrations	
4.4.2	Results	

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	Materials and methods	Guidelines: OECD 219 (Draft, 2001) No deviations to guidelines
5.2	Results and discussion	
5.2.1	NOEC (25-day)	3.8 µg/L
5.2.2	LOEC (25-day)	20.9 µg/L
5.3	Conclusion	Validity criteria can be considered as fulfilled. (see validity criteria summarized in table A7_4_3_5_1_03-10)
5.3.1	Reliability	1
5.3.2	Deficiencies	No

Table A7_4_3_5_1_03-1: Preparation of TS solution for poorly soluble or volatile test substances.

Criteria	Details
Dispersion	No
Vehicle	Yes: N,N-Dimethylformamide (DMF)
Concentration of vehicle	0.01% (v/v)
Vehicle control performed	Yes (equal concentration as in test solutions)
Other procedures (application)	Application: 25 µl of the respective application solution were applied into the 250 ml test media just below the water surface using a Hamilton syringe (spiked water). The water columns were then gently mixed to ensure homogeneous distribution, without disturbing the sediment

Table A7_3_5_1_03-2: Dilution water.

Criteria	Details
Source	Elendt M7 medium, prepared of purified water
Alkalinity	
Hardness	200 mg/L as CaCO ₃
pH	7.9 ± 0.3
Ca / Mg ratio	
Na / K ratio	
Oxygen content	7.6 – 7.9 mg/L (measured before application of the test item, e.g. on day -1)
Conductance	
Holding water different from dilution water	No

Table A7_4_3_5_1_03-3: Sediment.

Criteria	Details
Type/source	Artificial sediment
Composition (% w/w)	Sphagnum peat: 4% Kaolin clay (kaolinite content >30%): 20% Sand (Sihelco 36): 76% Calcium carbonate (CaCO ₃): 0.31%
Total organic carbon (TOC)	2.0% (based on dry weight)
pH adjustment	Yes, CaCO ₃ was added to the ground and moistened peat to reach a pH of 6.3 before clay and sand was added
pH of final sediment mixture	7.4

Table A7_4_3_5_1_03-4: Test organisms.

Criteria	Details
Species/strain	<i>Chironomus riparius</i>
Source	In-house laboratory cultures maintained at RCC Ltd, Environmental Chemistry & Pharamalytics Division, Itingen, Switzerland. The midge culture originated from Novartis Crop Protection AG, Basel, Switzerland.
Age	Fresh egg masses were used as source for test animals. At the date when test animals were placed into the test beakers the larvae were 2-3 days old (first-instar larvae)
Breeding method	Midge culture was bred under similar temperature and light conditions as in the test, in the same kind of test water as used in the test Six days before application fresh egg masses were taken from the test organism culture and deposited into small vessels in test water with a small amount of food (mixture of fresh green algae <i>Scenedesmus subspicatus</i> from a laboratory culture and Tetra Min fish food suspension)

Table A7_4_3_5_1_03-4: Test organisms (continued).

Criteria	Details
Kind of food	During test: Tetra Min fish food (TETRA MIN Hauptfutter, Tetra Werke, 49304 Melle, Germany); flakes were finely ground and suspended in test water
Amount of food	Days 0/1/4/6: 23 mg Tetra Min/vessel Days 8/11/13/15/18/20/22: 47 mg Tetra Min/vessel
Feeding frequency	See above
Pretreatment	
Feeding of animals during test	Yes, see above

Table A7_4_3_5_1_03-5: Test system.

Criteria	Details
Type of test	Spiked water test; water/sediment system
Renewal of test solution	No (single application of the test item to the water column one day after adding the larvae to the test vessels)
Volume of test vessels	600 ml glass beakers (approximately 8 cm in diameter)
Amount/volume of sediment per vessel	approximately 130 g wet weight (46% water content; corresponds to about 89 g dry sediment) approximately 15 mm thickness
Volume of test medium per vessel	250 ml (water column about 6 cm depth)
Volume/animal	12.5 ml
Number of animals/vessel	5
Number of vessels/ concentration	4
Test performed in closed vessels due to significant volatility of TS	No (vessels were loosely covered with watch glasses, from day 8 on additionally with a mosquito net)

Table A7_4_3_5_1_03-6: Test conditions.

Criteria	Details
Test temperature	See table A7_4_3_5_1_03-7
Dissolved oxygen	See table A7_4_3_5_1_03-7
pH	See table A7_4_3_5_1_03-7
Adjustment of pH	No
Aeration of dilution water	Yes, gentle aeration of the test media through a glass Pasteur pipette fixed 2-3 cm above the sediment layer (no aeration during the period from insertion of the larvae until immediately after application of the test medium)
Quality/Intensity of irradiation	530 – 670 Lux at water surface
Photoperiod	16 hours light/8 hours dark photoperiod (30 min transition period)

Table A7.4.3.5.1.03-7: Water quality criteria.

Parameter	Days of measurement	Nominal initial concentration of test item ($\mu\text{g/L}$)				
		Control	Solvent control	0.6	3.8	20.9
pH	-1/0/8/15/22/25	8.1-8.5	8.1-8.5	8.0-8.5	8.0-8.5	8.0-8.5
Dissolved oxygen (mg/L)	-1/0/1/4/8/11/13/15/18/20/22/25	6.6-8.2	6.2-7.9	6.7-8.4	6.8-8.4	6.7-7.9
Water temperature ($^{\circ}\text{C}$)	-1/0/1/4/8/11/13/15/18/20/22/25	20.6-21.6	20.6-21.6	20.6-21.7	20.7-21.6	20.7-21.7
Total hardness (mmol/L)	0/25	3.2/3.6	3.4/3.9	–	–	3.2/3.4
Ammonium concentration (mg/L)	0/25	2.30/1.62	1.68/1.53	–	–	1.82/1.45

Table A7.4.3.5.1.03-8: Emergence ratio (ER; male and female midges pooled).

Parameter	Nominal initial concentration of test item ($\mu\text{g/L}$)				
	Control	Solvent control	0.6	3.8	20.9
Sum of inserted larvae	20	20	20	20	20
Sum of emerged midges	73	73	74	69	67
% of emerged midges (mean)	91.3	91.3	92.5	86.3	83.8
ER _{arc}					
mean	1.310	1.318	1.297	1.204	1.159
SD	0.1772	0.1948	0.0556	0.1259	0.0675
min	1.173	1.107	1.249	1.047	1.107
max	1.571	1.571	1.345	1.345	1.249
n	4	4	4	4	4
% of solvent control	99.4	100.0	98.4	91.4	87.9
STAT	n.s.*	–	n.s.	n.s.	n.s.

ER_{arc} arcsin-transformed emergence ratio

STAT results of a Williams t-test ($\alpha = 0.05$, one-sided smaller)

n.s. mean ER_{arc} not significantly lower than in solvent control

n.s.* mean ER_{arc} not significantly different from the solvent control (Student t-test, $\alpha = 0.05$, two-sided)

Table A7.4.3.5.1.03-9: Development rate (male and female midges pooled)

Parameter	Nominal initial concentration of test item (µg/L)				
	Control	Solvent control	0.6	3.8	20.9
Mean	0.074	0.072	0.073	0.072	0.064
SD	0.0011	0.0013	0.0019	0.0005	0.0017
min	0.073	0.070	0.071	0.072	0.063
max	0.076	0.073	0.075	0.073	0.067
n	4	4	4	4	4
% of solvent control	102.8	100.0	101.4	100.0	88.9
STAT	n.s.*	—	n.s.	n.s.	s.

STAT results of a Williams t-test ($\alpha = 0.05$, one-sided smaller)

n.s. mean development rate not significantly lower than in solvent control

n.s.* mean development rate not significantly different from the solvent control (Student t-test, $\alpha = 0.05$, two-sided)

s. mean development rate significantly lower than in solvent control

Table A7.4.3.5.1.03-10: Validity criteria for the sediment/water *Chironomus* toxicity test according to OECD Guideline 219.

Criteria	fulfilled	not fulfilled
Mortality in the controls <30% at the end of the test	X	
Emergence of adults (days after insertion in test vessels): - <i>C. riparius</i> , <i>C. yoshimatsui</i> : 12 – 23 days - <i>C. tentans</i> : 20 – 65 days	X	
Emergence in controls: 50 – 70%	X	
Concentration of dissolved oxygen: > 60% of the air saturation value of the temperature used	X	
pH of overlying water: 6 – 9	X	
Water temperature does not differ by more than $\pm 1.0^\circ\text{C}$ between test vessels, and is maintained within the temperature ranges specified for the test species	X	

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	27.05.2005
Materials and methods	<p>3.4.7 Test parameter: Development time/rate of midges and the emergence ratio as a number of fully emerged male and female midges</p> <p>3.4.8 Sampling: The number of emerged adults and their sex was recorded from Day 10 after application until Day 25 (7 days after emergence of the last test animals in the controls)</p> <p>4.2.2 Actual concentrations of test substance: According to OECD guideline 219 the concentration of the test substance must be analysed at the start and the end of the test at the highest concentration and a lower one as a minimum. The test substance concentration was not monitored in this test.</p>
Conclusion	Agree with the applicant's version
Reliability	2
Acceptability	Acceptable
Remarks	-
	COMMENTS FROM...
Date	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Section A7.5.1.1**Inhibition to microbial activity (terrestrial)****Annex Point IIA-VII.7.4**

		1 REFERENCE	
1.1	Reference	Kölzer U. (2003): Assessment of the side effects of etofenprox on the activity of the soil microflora; Arbeitsgemeinschaft GAB Biotechnologie GmbH & IFU Umweltanalytik GmbH, Niefern-Öschelbronn, Germany; unpublished report no. 20031050/01-ABMF (August 08, 2003). Dates of experimental work: March 20, 2003 – May 08, 2003	
1.2	Data protection	Yes	
1.2.1	Data owner	[REDACTED] Mitsui Chemicals Agro, Inc.	
1.2.2	Criteria for data protection	Data submitted to the MS after May 13, 2000 on existing a.s. for the purpose of its entry into Annex I.	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	Guideline study	Yes OECD 216 and 217 (2000)	
2.2	GLP	Yes	
2.3	Deviations	No	
		3 MATERIALS AND METHODS	
3.1	Test material	Etofenprox	
3.1.1	Lot/Batch number	87031	
3.1.2	Specification	As given in section 2 Deviating from specification given in section 2 as follows	x
3.1.3	Description	Oily liquid, white	
3.1.4	Purity	99.0%	
3.1.5	Stability	No information in the report.	
3.1.6	Further relevant properties	Solubility in water: 22.5 µg/L at 20 ± 0.5°C Vapour pressure: 8.13 x 10 ⁻⁷ Pa at 25°C Hydrolytic stability: hydrolytically stable at pH 4, 7 and 9	
3.1.7	Method of analysis	No analyses performed	
3.2	Reference substance	Yes: a toxic reference (dinoterb) was tested for each soil batch in the testing facility as a separate study to confirm the normal reaction of the soil against pesticides (unpublished report no. 20031050/01-ABMF). It is ensured that the latest study with the toxic reference did not start more than 1 year before the start of the study with etofenprox.	
3.2.1	Method of analysis for reference substance	-	
3.3	Testing procedure		
3.3.1	Soil sample	See enclosed table A7_5_1_1-1	
3.3.2	Test system	See enclosed table A7_5_1_1-2	x

Official
use only

Section A7.5.1.1 Inhibition to microbial activity (terrestrial)

Annex Point IIA-VII.7.4

3.3.3	Application of TS	See enclosed table A7_5_1_1-3	
3.3.4	Test conditions	See enclosed tables A7_5_1_1-4 and A7_5_1_1-5	
3.3.5	Test parameter	(A) Nitrogen turnover (B) Short term respiration (C) Soil dry weight (water content) (D) pH	
3.3.6	Analytical parameter	(A) Nitrogen concentration measured as the content of nitrate-N and ammonium-N (B) Measured as oxygen uptake (C) DIN ISO 11465 (D) DIN ISO 10390	
3.3.7	Duration of the test	28 days	
3.3.8	Sampling	Sampling at days 0, 7, 14 and 28	
3.3.9	Monitoring of TS concentration	No	
3.3.10	Controls	Control without test substance (untreated quartz sand added to a concentration identical to the treated samples, e.g. 1% of the soil dry weight)	
3.3.11	Statistics	Multiple t-test according to Dunnett	x

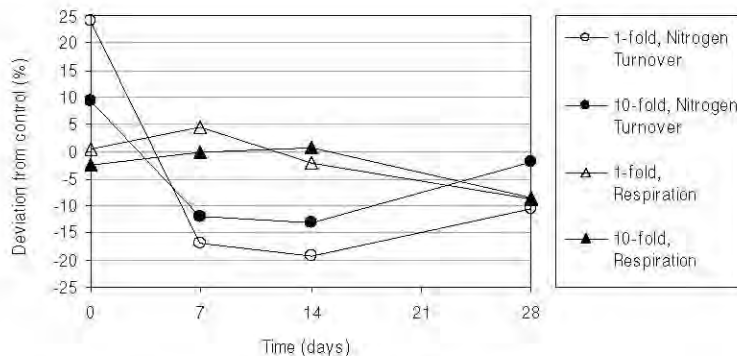
4 RESULTS

4.1	Range finding test	Not performed	
4.1.1	Concentration		
4.1.2	Effect data		
4.2	Results test substance		
4.2.1	Initial concentrations of test substance	0.0893 mg as/kg soil dry weight (corresponding to 0.067 kg as/ha, eg 1-fold maximum application rate) 0.893 mg as/kg soil dry weight (corresponding to 0.67 kg as/ha, eg 10-fold maximum application rate)	x
4.2.2	Actual concentrations of test substance	Monitoring of TS concentration not performed	
4.2.3	Growth curves	Not applicable	
4.2.4	Cell concentration data	Not applicable	

Section A7.5.1.1 Inhibition to microbial activity (terrestrial)

Annex Point IIA-VII.7.4

4.2.5 Concentration/
response curve



x

4.2.6 Effect data See enclosed tables A7_5_1_1-6 and A7_5_1_1-7

4.2.7 Other observed effects none

4.3 Results of controls See enclosed tables A7_5_1_1-6 and A7_5_1_1-7

4.4 Test with reference substance Performed

4.4.1 Concentrations 13.3 mg dinoterb/kg dry soil (10-fold field application rate); incubation for 28 days

4.4.2 Results Nitrogen turnover (measured as N-concentration):
 - control: 40 mg/kg soil DW (dry weight)
 - dinoterb 10-fold: 59.5 mg/kg soil DW (e.g. 48.8% of control)
 Short term respiration (measured as CO₂ release):
 - control: 2.78mg/h·kg soil DW
 - dinoterb 10-fold: 2.06 mg/ h·kg soil DW (e.g. -25.9% of control)

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods Guidelines: OECD 216 and 217 (2000)
No deviations to guidelines

x

Tested rates: 0.0893 and 0.893 mg etofenprox/kg dry soil, corresponding to 1-fold (= 0.067 kg as/ha) and 10-fold (= 0.67 kg as/ha) application rate, respectively

5.2 Results and discussion Nitrogen turnover: significant effect between control and 1-fold conc. of etofenprox observed at day 28. However, this difference was -10.6% and therefore below the threshold value given in OECD 216 (≤ 25% variation between the treatment and the control)

Short term respiration: no effects were observed for both concentrations of etofenprox.

Applica- tion rate	Etofenprox [mg/kg dry soil]	N-turnover (deviation from control after 28 days) [%]	Respiration (deviation from control after 28 days) [%]
1-fold	0.0893	-10.6	-8.68
10-fold	0.893	-1.76	-8.44

5.2.1 NOEC Not applicable

x

5.2.2 EC₁₀ Not applicable

Section A7.5.1.1 Inhibition to microbial activity (terrestrial)**Annex Point IIA-VII.7.4**

5.2.3	EC ₅₀	Not applicable	x
5.3	Conclusion	Based on the results of the summarised study and in accordance with the OECD guidelines 216 and 217, etofenprox has no long-term effects on the nitrogen turnover and the short-term respiration in a field soil tested up to a concentration of 0.67 kg etofenprox/ha (corresponding to a 10-fold application rate).	x
5.3.1	Reliability	I	x
5.3.2	Deficiencies	No	

Table A7_5_1_1-1: Microbial sample/inoculum

Criteria	Details
Soil batch	F230403
Soil texture	Loamy sand
Sampling site:	“Im Bildgarten”, Nr. 587, 76877 Offenbach, Germany
Geographical reference on the sampling site	latitude 49°12'8N, longitude 8°10'52E
Data on the history of the site	Not cultured (no plant protection products applied for at least 1 year, no organic and mineral fertiliser applied for 6 and 3 months, respectively, prior to soil sampling)
Use pattern	Agricultural soil
Depth of sampling [cm]	0 – 20 cm
Clay [%] < 0.002 mm	9.40
Silt [%] 0.063 – 0.002 mm	34.8
Sand [%] ≥ 0.063 – 2 mm	55.8
pH	6.15
Organic carbon content [% dry weight]	0.86
Nitrogen content [% dry weight]	0.06
Cation exchange capacity [mval/100 g]	8.9
Initial microbial biomass (% of total organic C)	1.11
Collection / storage of samples	Soil sampling: January 22, 2003 Soil sieving: January 28, 2003 Start of storage: February 03, 2003 End of storage: April 04, 2003 Storage temperature (avg./min./max.): 4°C, 3.6°C, 5°C
Preparation of inoculum for exposure	Soil was sieved to a particle size of 2 mm Deionised water (284 ml/kg test soil) was added to bring the soil moisture content to 40% of the maximum water holding capacity (WHC _{max})
Pretreatment	<u>Nitrogen turnover</u> : dried Lucerne meal was added to the soil to a final concentration of 0.5% of the soil dry weight <u>Short term respiration</u> : prior to the beginning of the test, the amount of glucose needed to obtain maximal short-term rates of respiration was determined (400 mg glucose/100 g soil wet weight).

Table A7_5_1_1-2: Test system

Criteria	Details
Culturing apparatus	Glass bottles
Number of vessels / concentration	3
Aeration device	none
Measuring equipment	<p><u>Nitrogen turnover</u>: Nitrogen content of aqueous soil extracts was determined by measuring NH₄⁺ and NO₃⁻ concentrations by means of calibrated ion sensitive electrodes (Models 9300, 95-12, and 90-02; Orion Research Inc., Cambridge, MA, USA) and an Orion expandable Ionanalyser (Model EA 940).</p> <p><u>Short term respiration</u>: O₂ consumption was determined by measurement of the decrease of pressure in sealed incubation vessels as a result of the oxygen consumption by microbial activities (OxiTop Control OC100; WTW Wissenschaftlich-Technische Werkstätten GmbH, Weilheim, Germany)</p>
Test performed in closed vessels	No, incubation in non-sealed vessels (loosely closed with screw caps). Deionised water was added weekly to compensate for water loss.

Table A7_5_1_1-3: Application of test substance

Criteria	Details
Application procedure	<p>Stock solution: 26.7 mg etofenprox/ml acetone.</p> <p>Application: stock solution was applied to quartz sand at rates of 0.10 and 1.00 ml (nitrogen turnover) and 0.182 and 1.82 ml (short-term respiration) for the low and high treatment, respectively, which was added to samples of 3300 g (nitrogen turnover) and 6000 g (short-term respiration) moist test soil (final amount of quartz sand: 1% of the soil dry weight)</p>
Carrier	Acetone/quartz sand
Concentration of test item	<p>1-fold maximum field application rate of 0.067 kg ai/ha: 0.0893 mg ai/kg soil dry weight (1-fold)</p> <p>10-fold maximum field application rate of 0.670 kg ai/ha: 0.893 mg ai/kg soil dry weight (10-fold)</p>
Concentration of liquid carrier [% v/v]	Acetone was completely evaporated from the quartz sand prior to the application to the test soil
Liquid carrier control	No (untreated quartz sand was applied to the soil of the control samples)
Other procedures	

Table A7_5_1_1-4: Test conditions

Criteria	Details
Organic substrate	Ground Lucerne meal (nitrogen turnover) and glucose (short-term respiration); see table A7_5_1_1-1
Incubation temperature	20 ± 2°C (in the dark)
Soil moisture	See table A7_5_1_1-5; give measurements conducted at start and during test
Method of soil incubation	as bulk
Aeration	No

Table A7_5_1_1-5: Soil moisture content (%) and pH.

Samples	Nitrogen Turnover				Short term respiration			
	0 d	7 d	14 d	28 d	0 d	7 d	14 d	28 d
Soil moisture content (%)								
Control	12.9	12.5	12.8	13.0	12.2	12.5	11.6	12.4
Etofenprox 1-fold	13.2	12.0	12.8	12.4	12.8	12.9	13.2	13.0
Etofenprox 10-fold	13.0	12.5	12.8	12.5	12.5	13.1	12.4	12.7
pH								
Control	6.73	6.29	6.24	6.16	6.15	6.03	6.02	6.10
Etofenprox 1-fold	6.52	6.31	6.28	6.21	5.97	5.92	6.06	6.03
Etofenprox 10-fold	6.55	6.32	6.28	6.21	5.98	5.93	6.03	6.01

Table A7_5_1_1-6: Results of nitrogen turnover measurements. Effect data are given as total nitrogen measured (mg/kg soil dry weight) and relative to the results of the control samples (% values in brackets)

Time	Control	Etofenprox 1-fold		Etofenprox 10-fold	
	[mg/kg soil]	[mg/kg soil]	[%]	[mg/kg soil]	[%]
0-days	7.87	9.76	(24.0)	8.62	(-9.53)
7-days	16.7	13.9	(-16.8)	14.7	(-12.0)
14-days	23.4	18.9	(-19.2)	20.3	(-13.2)
28-days	34.1	30.5	(-10.6)	33.5	(-1.76)

Table A7_5_1_1-7: Results of short term respiration measurements. Effect data are given as CO₂ release (mg/h·kg soil dry weight) and relative to the results of the control samples (% values in brackets)

Time	Control	Etofenprox 1-fold		Etofenprox 10-fold	
	[mg/h·kg soil]	[mg/h·kg soil]	[%]	[mg/h·kg soil]	[%]
0-days	6.43	6.45	(0.311)	6.27	(-2.49)
7-days	4.22	4.41	(4.50)	4.22*	(0.00)
14-days	4.69	4.59	(-2.13)	4.72	(0.64)
28-days	4.03	3.68	(-8.68)	3.69	(-8.44)

* value was calculated based on 2 instead of 3 measured values due to a defect in the measuring device.

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	27.05.05
Materials and methods	<p>3.1.2 Specification No deviation from specification in section 2, batch 87031 was used in the 5 batch analyses.</p> <p>3.3.2 Test system Pre-incubation of the soil at 20°C at 30-40% WHC_{max}</p> <p>3.3.11 Statistics p ≤ 0.05, two-sided</p> <p>4.2.1 Initial concentrations of test substance The conversion of the test concentration to the application rate is not relevant. Values are based on nominal concentrations, no analytical measurements were performed.</p> <p>4.2.5 Concentration/response curve Graph refers to time/response curve at 2 concentration levels.</p>
Conclusion	<p>5.1 Materials and method Tested concentrations are not recommended in the OECD guidelines 216 and 217. If non-agrochemicals are tested, a geometric series of <u>at least five</u> concentrations should be used.</p> <p>5.2 Results and discussion Validity criteria for the test guidelines are met (variation between replicate controls less than ± 15%). The threshold value of ≤ 25% is not valid for regulatory purposes for biocides. Etofenprox shows significant inhibitory effects (11% compared to the control) on nitrogen turnover at 0.0893 mg ai/kg after 28 days. However at the 10-fold concentration no significant effect could be observed. The test design meets the needs for plant protection products, but not for biocides.</p> <p>5.2.1 NOEC, 5.2.3 EC50 Concrete values were not determined in the current test protocol, but are relevant for biocides.</p> <p>5.3 Conclusion Based on the results of the current study no concrete effect values were determined. Etofenprox showed significant effects on nitrogen turn-over (11% compared to the untreated control) at the lower tested concentration level. These findings could not be approved at a 10-fold concentration level. According to the chosen test design no concentration response curve could be established. Taking a conservative approach it is assumed that the NOEC is ≤ 0.0893 mg/kg and the EC50 > 0.0893 mg ai/kg.</p>
Reliability	1
Acceptability	Acceptable
Remarks	-
	COMMENTS FROM...
Date	

Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Section A7.5.1.2 Earthworm, acute toxicity test

Annex Point IIIA-XIII.3.2

		Official use only	
1 REFERENCE			
1.1 Reference	Roberts N.L., Hakin B. (1989): The subacute toxicity (LC ₅₀) of etofenprox (MTI-500) to the earthworm (<i>Eisenia foetida</i>); Huntingdon Research Centre Ltd., Huntingdon, England; unpublished report no. MTF 2/881276 (June 21, 1989). Dates of experimental work: April 19, 1988 – May 03, 1988		
1.2 Data protection	Yes		
1.2.1 Data owner	[REDACTED] Mitsui Chemicals Agro, Inc.		
1.2.2 Criteria for data protection	Data submitted to the MS after May 13, 2000 on existing a.s. for the purpose of its entry into Annex I.		
2 GUIDELINES AND QUALITY ASSURANCE			
2.1 Guideline study	Yes Revised UK Pesticides Safety Precautions Schemes (PSPS) Guidelines for testing of chemicals, Appendix D, Guidance on wildlife and environmental data requirements, working document D6, Laboratory and field testing of pesticide products for effect on soil macro-organisms, § 4. Tests for toxicity to earthworms (1983) OECD Guideline No. 207 (1984)		
2.2 GLP	Yes		
2.3 Deviations	No deviations to Directive 87/302/EEC, Part C		x
3 MATERIALS AND METHODS			
3.1 Test material	Etofenprox		
3.1.1 Lot/Batch number	ST-103		
3.1.2 Specification	As given in section 2 Deviating from specification given in section 2 as follows		x
3.1.3 Description	Yellow crystalline solid		
3.1.4 Purity	96.3%		x
3.1.5 Stability	No information in the report.		
3.1.6 Further relevant properties	Solubility in water: 22.5 µg/L at 20 ± 0.5°C Vapour pressure: 8.13 x 10 ⁻⁷ Pa at 25°C Stability in water: hydrolytically stable at pH 4, 7 and 9		
3.1.7 Method of analysis	Not applicable (TS concentration not tested)		
3.2 Reference substance	Yes: chloroacetamide tested in a separate study (conducted between May 15 and May 29, 1985)		
3.2.1 Method of analysis for reference substance	Not applicable (concentration of reference substance not tested)		
3.3 Testing procedure			
3.3.1 Preparation of the test substance	See enclosed table A7_5_1_2-1		

Section A7.5.1.2 Earthworm, acute toxicity test

Annex Point IIIA-XIII.3.2

3.3.2	Application of the test substance	See enclosed table A7_5_1_2-1	
3.3.3	Test organisms	See enclosed table A7_5_1_2-2	
3.3.4	Test system	See enclosed table A7_5_1_2-3	x
3.3.5	Test conditions	See enclosed table A7_5_1_2-4	
3.3.6	Test duration	14 days	
3.3.7	Test parameter	Mortality (assessed by testing the reaction of each worm to a mechanical stimulus at either end) Weights (expressed as replicate and group, e.g. treatment level, mean weight)	
3.3.8	Examination	Mortality: day 7 and 14 Weight: day 0 and 14	
3.3.9	Monitoring of test substance concentration	No	
3.3.10	Statistics	None applied	
4 RESULTS			
4.1	Filter paper test	Not performed	
4.1.1	Concentration		
4.1.2	Number/ percentage of animals showing adverse effects		
4.1.3	Nature of adverse effects		
4.2	Soil test		
4.2.1	Initial concentrations of test substance	0.0, 0.5, 1.4, 4.7, 14.2 and 47 mg etofenprox/kg dry weight artificial soil	x
4.2.2	Effect data (Mortality)	Mortality data: see enclosed table A7_5_1_2-5 LC ₀ , LC ₅₀ and LC ₁₀₀ values: see enclosed table A7_5_1_2-6	
4.2.3	Concentration / effect curve	Only one worm was found dead on day 7 at 14.2 mg etofenprox/kg dry weight artificial soil	
4.2.4	Other effects	no other observations differentiating organisms in tests and controls (e.g. weight loss, behavioural symptoms, pathological symptoms and changes in appearance)	
4.3	Results of controls		
4.3.1	Mortality	No mortalities observed in the negative control group	
4.3.2	Number/ percentage of earthworms showing adverse effects	No adverse effects observed in the negative control group	
4.3.3	Nature of adverse effects	No adverse effects observed in the negative control group	

Section A7.5.1.2 Earthworm, acute toxicity test

Annex Point IIIA-XIII.3.2

4.4 Test with reference substance Performed

4.4.1 Concentrations 0, 5, 10, 20, 40 and 80 mg chloroacetamide/kg dry soil

4.4.2 Results

Treat- ment *	No. of worms	Cumulative number of dead worms			
		Day 7		Day 7	
		absolute	(%)	absolute	(%)
Control	40	0	0	1	2.5
5	40	2	5	2	5
10	40	0	0	2	5
20	40	3	7.5	8	20
40	40	18	45	34	85
80	40	34	85	40	100

* mg chloroacetamide/kg dry soil

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

Guidelines: OECD 207

Revised UK Pesticides Safety Precautions Schemes (PSPS) Guidelines for testing of chemicals, Appendix D, Guidance on wildlife and environmental data requirements, working document D6, Laboratory and field testing of pesticide products for effect on soil macro-organisms, § 4. Tests for toxicity to earthworms (1983)

No deviations to guidelines

x

5.2 Results and discussion

5.2.1 LC₀ 47.2 mg/kg dry soil

5.2.2 LC₅₀ > 47.2 mg/kg dry soil

5.2.3 LC₁₀₀ > 47.2 mg/kg dry soil

5.3 Conclusion

Validity criteria can be considered as fulfilled (see enclosed table A7_5_1_2-7)

5.3.1 Other Conclusions Etofenprox is of low toxicity to earthworms at concentrations of 0.5 to 47.2 mg/kg dry soil, equivalent to application rates of 0.3 to 30.0 kg ai/ha. Since the maximum dose level represents an application rate equivalent to 100 x the maximum recommended application rate, etofenprox is not considered to represent a significant toxic hazard to earthworms.

x

5.3.2 Reliability 1

5.3.3 Deficiencies No

Table A7_5_1_2-1: Preparation of TS solution.

Criteria	Details
Dispersion	No
Vehicle	Yes: acetone
Concentration of vehicle	Stock solutions in acetone were applied to and thoroughly mixed with a small pre-mix of weighted dried soil, and the vehicle was allowed to evaporate off prior to incorporation with the main soil bulk
Vehicle control performed	Yes (same volume of acetone applied to the soil pre-mixtures in the control and all dose level treatments)
Other procedures	

Table A7_5_1_2-2: Test organisms.

Criteria	Details
Species/strain	<i>Eisenia foetida</i>
Source of the initial stock	HRC (Huntingdon Research Centre) breeding stock
Culturing techniques	Environmental conditions of the breeding stock were similar to the test conditions. Thus it was not considered necessary to include a pre-treatment acclimatisation period
Weight	162 – 178 mg (average weight for replicates of 10 worms)
Pre-treatment	

Table A7_5_1_2-3: Test system.

Criteria	Details
Artificial soil test substrate	Composition (all values in %w/w): - Calcium carbonate: 1% - Sphagnum peat: 10% - Kaolinite clay: 20% - Industrial sand: 69% pH of soil = 7.8 Moisture: after application of the test item, water was gradually mixed with the treated soil to give a moisture content equivalent to 35% of the dry weight.
Test mixture	Give the relationship test substance : artificial soil (mg/kg) per concentration level
Size, volume and material of test container	1 L polythene containers, lined with polythene bags
Amount of artificial soil (kg)/container	Not reported
Nominal levels of test concentrations	0.0, 0.5, 1.4, 4.7, 14.2 and 47.2 mg/kg artificial soil)
Number of replicates/test concentration	4
Number of earthworms/test concentration	40
Number of earthworms/container	10
Light source	Continuous illumination
Test performed in closed vessels due to significant volatility of test substrate	No

Table A7_5_1_2-4: Test conditions.

Criteria	Details
Test temperature	20 – 21°C
Moisture content	35% of the dry weight
pH	7.8
Adjustment of pH	No
Light intensity / photoperiod	Continuous illumination
Relevant degradation products	Not assessed

Table A7_5_1_2-5: Cumulative mortalities following treatment.

Test substance concentration (nominal) [mg etofenprox/kg artificial soil]	Mortality			
	Number		Percentage	
	7 d	14 d	7 d	14 d
0.0 (negative control)	0	0	0	0
0.5	0	0	0	0
1.4	0	0	0	0
4.7	0	0	0	0
14.2	1	1	2.5	2.5
47.2	0	0	0	0
Temperature [°C]	not reported	not reported		
pH	not reported	not reported		
Moisture content	not reported	not reported		

Table A7_5_1_2-6: Effect data based on nominal test item concentrations.

Endpoint	14 d [mg/kg soil]	95 % c.l.
LC ₀	47.2	n.d.
LC ₅₀	> 47.2	n.d.
LC ₁₀₀	> 47.2	n.d.

n.d. not determinable

Table A7_5_1_2-7: Validity criteria for acute earthworm test according to OECD 207.

Criteria	fulfilled	Not fulfilled
Mortality of control animals < 10%	X	

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	27.05.2005
Materials and methods	<p>2.3 Deviations, 5.1 Materials and methods</p> <p>Deviations from the cited guidelines:</p> <ol style="list-style-type: none"> pH: 7.8 instead of 6 ± 0.5. The age of the test species was not reported. Taking into account the weights of the test species (162 – 178 mg per individual) the used earthworms were probably too young (300 – 600 mg weight recommended in OECD 207). Also individuals treated with chloroacetamid up to 40 ppm gained body weight. <p>3.1.2 Specification, 3.1.4 Purity</p> <p>According to document A3 the physical state changes from white crystals to amber liquid with decreasing purity from 99.8% to 99.3%.</p> <p>Within the 5 batch analysis a purity between 97.2% and 99.6% is indicated.</p> <p>ST-103 contained the same main impurities as later production batches (e.g. 5 batch analysis) at comparable percentages. The concentration of etofenprox is with 96.3% slightly lower than in the 5 batch analysis.</p> <p>Therefore the deviations to the specification are not considered to be ecotoxicologically relevant.</p> <p>3.3.4 Test system</p> <p>The amount of test substrate per test vessel was not reported.</p> <p>4.2.1 Initial concentrations of test substance</p> <p>The concentrations reflect the use of etofenprox for PPP and are not suitable to determine the LC50. Testing up to 1000 mg/kg is recommended in a pre-test to determine 0-100% mortality.</p>
Conclusion	<p>5.3.1 Other conclusions</p> <p>The reference made to the application rate kg ai/ha is not relevant for biocides.</p>
Reliability	1
Acceptability	Acceptable
Remarks	<p>The deviations from the OECD 207 guideline concerning the body weight of the test species and pH are acceptable for the determination of mortality (LC50). <i>Eisenia foetida</i> prefers neutral pHs. Therefore the pH of 7.8 can be considered as acceptable concerning the detection of lethal effects.</p>
	COMMENTS FROM...
Date	
Results and discussion	
Conclusion	
Reliability	
Acceptability	

Remarks	
----------------	--

Section 7.5.1.3 Terrestrial plant toxicity

Annex Point IIIA-XIII.3.4

		1 REFERENCE	Official use only
1.1	Reference	Büche, C. (2004); Terrestrial (non-target) plant test with MTI-500 30%EC: seedling emergence and seedling growth & vegetative vigour test; RCC Ltd., unpublished report no. 853515 (October 08, 2004) Dates of experimental work: May 18, 2004 – August 18, 2004	
1.2	Data protection	Yes	
1.2.1	Data owner	[REDACTED] Mitsui Chemicals Agro, Inc.	
1.2.2	Criteria for data protection	Data submitted to the MS after May 13, 2000 on existing a.s. for the purpose of its entry into Annex I.	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	Guideline study	Yes: OECD 208 (1984), and Proposals for updating this guideline (July, 2000 and September, 2003). Proposal for a new guideline OECD 227 OPPTS 850.4100 OPPTS 850.4150	
2.2	GLP	Yes	
2.3	Deviations	No	
		3 MATERIALS AND METHODS	
3.1	Test material	Trebon 30 EC, active substance: etofenprox	
3.1.1	Lot/Batch number	041-8027	
3.1.2	Specification	As given in section 2. Content of active substance 30.18%	
3.1.3	Purity	99.0%	
3.1.4	C	As given in section 2.	x
3.1.5	Further relevant properties	Not applicable.	
3.1.6	Method of analysis	Analysis of the application solutions by HPLC/MS (based on the GC-MS method validated in RCC Ltd. study No. RCC Study 811618 – see point A 4.2/03).	
3.2	Preparation of TS solution for poorly soluble or volatile test substances	Mixing of the test substance in purified water by intense stirring for 15 minutes at room temperature.	
3.3	Reference substance	Yes Blank formulation (Trebon 30 EC blank)	
3.3.1	Method of analysis for reference substance	Not applicable.	
3.4	Testing procedure		x

Section 7.5.1.3 Terrestrial plant toxicity

Annex Point IIIA-XIII.3.4

3.4.1	Dilution water	Purified water.
3.4.2	Test plants	See Table A7_5_1_3-1 - Monocotyledonous: corn and oat - Dicotyledonous: carrot, tomato, rape and lettuce
3.4.3	Test system	See Table A7_5_1_3-2 - Seedling emergence and seedling growth test : one spray application to soil - Vegetative vigour test : one spray application to plants Both types of test : limit test at a rate equivalent to 200 g a.i./ha. Six replicates (pots) per treatment and species, with 8 seeds per pot (except corn: 12 pots and 4 seeds per pot) 3 treatment group: water control, Trebon 30EC and Trebon 30EC blank formulation.
3.4.4	Test conditions	Greenhouse test. See table A7_5_1_3-3
3.4.5	Test duration	21 days
3.4.6	Test parameter	Observed endpoints : - Seedling emergence and seedling growth test : emergence rate, visual phytotoxicity symptoms, shoot dry weight and plant height - Vegetative vigour test : visual phytotoxicity symptoms, shoot dry weight and plant height
3.4.7	Sampling	Freshly prepared application solutions sampled at each application time
3.4.8	Method of analysis of the plant material	No analysis of plant material
3.4.9	Quality control	Yes
3.4.10	Statistics	Student's t-test ($\alpha=0.05$, one-sided)

4 RESULTS

4.1	Results test substance	
4.1.1	Applied initial concentration	86 to 94% of the nominal value (200 g a.i./ha)
4.1.2	Emergence rate	<u>Seedling emergence and seedling growth test</u> : see table A7_5_1_3-4 Treatment with Trebon 30EC: mean emergence rate not significantly different from the control group, except for lettuce (84% of control). Treatment with Trebon 30 EC blank formulation: mean plant height not significantly different from the control group.
4.1.3	Phytotoxicity rating	<u>Seedling emergence and seedling growth test</u> : no visual phytotoxicity symptoms during the test neither after treatment with the test item nor with the blank formulation, except in lettuce. Lettuce: 5 lettuce seedlings (i.e.15%) showed a slight brown coloration at the beginning of the observation period on Day 7. One lettuce seedling treated with the blank formulation control showed a similar morphology on Day 10 and 14. The plants recovered and did not show any morphological traits, that could be classified as visual injury like

Section 7.5.1.3 Terrestrial plant toxicity

Annex Point IIIA-XIII.3.4

- chlorosis, necrosis, wilting, leaf or stem deformation
- Vegetative vigour test: no visual phytotoxicity symptoms for any of the 6 test species.
- 4.1.4 Plant height Seedling emergence and seedling growth test : see table A7_5_1_3-4.
Treatment with Trebon 30EC: mean plant height not significantly different from the control group, except for lettuce (89% of control).
Treatment with Trebon 30 EC blank formulation: mean plant height not significantly different from the control group.
- Vegetative vigour test: see table A7_5_1_3-5.
Treatment with Trebon 30 EC or with the blank formulation: mean plant height not significantly different from the control group.
- 4.1.5 Plant dry weights Seedling emergence and seedling growth test : see table A7_5_1_3-4
Treatment with Trebon 30EC: mean dry weight not significantly different from the control group, except for lettuce (84% of control).
Treatment with Trebon 30 EC blank formulation: mean dry weight not significantly different from the control group.
- Vegetative vigour test: see table A7_5_1_3-5.
Treatment with Trebon 30 EC or with the blank formulation: mean dry weight not significantly different from the control group.
- 4.1.6 Root dry weights See point 4.1.5 above.
- 4.1.7 Number of dead plants None (for all 6 species, both tests).
- 4.1.8 Effect data Seedling emergence and seedling growth test : see table A7_5_1_3-6. x
- Corn, oat, tomato, carrot and rape (emergence, dry weight and plant height): EC₅₀, EC₂₅ and LOEC > 200 g a.i./ha, > 200 g a.i./ha, NOEC ≥ 200 g a.i./ha.
- Lettuce: EC₅₀, EC₂₅ > 200 g a.i./ha, > 200 g a.i./ha, NOEC < 200 g a.i./ha, LOEC = 200 g a.i./ha.
- Vegetative vigour test: see table A7_5_1_3-7.
All 6 species: EC₅₀, EC₂₅ and LOEC > 200 g a.i./ha, > 200 g a.i./ha, NOEC ≥ 200 g a.i./ha.
- 4.2 **Test with reference substance** Test with Trebon 30EC blank formulation: see point 4.1 above.

5 APPLICANT'S SUMMARY AND CONCLUSION

- 5.1 **Materials and methods** GLP study, according to guidelines: OECD 208 (1984), and Proposals for updating this guideline (July, 2000 and September, 2003).
Proposal for a new guideline OECD 227

Section 7.5.1.3 Terrestrial plant toxicity

Annex Point IIIA-XIII.3.4

		OPPTS 850.4100	
		OPPTS 850.4150	
		No deviations.	
5.2	Results and discussion		x
5.2.1	EC ₂₅	> 200 g a.i./ha (all 6 species, both tests)	
5.2.2	EC ₅₀	> 200 g a.i./ha (all 6 species, both tests)	
5.2.3	NOEC	≥ 200 g a.i./ha, except for lettuce in seedling emergence and seedling growth test (NOEC < 200 g a.i./ha.)	
5.2.4	LOEC	> 200 g a.i./ha, except for lettuce in seedling emergence and seedling growth test (LOEC = 200 g a.i./ha.)	
5.3	Conclusion		
5.3.1	Reliability	4	x
5.3.2	Deficiencies	No	

Table A7_5_1_3-1: Test plants.

	Family	Species	Common name	Source (seed/plant)
Dicotyledonae	<i>Umbelliferae</i>	<i>Daucus carota</i>	Carrot	Sativa Rheinau GmbH, CH-8462 Rheinau, Switzerland
	<i>Solanaceae</i>	<i>Lycopersicon esculentum</i>	Tomato	Sativa Rheinau GmbH, CH-8462 Rheinau, Switzerland
	<i>Brassicaceae</i>	<i>Brassica napus</i>	Rape	Landi Oberbaselbiet AG, CH-4460 Gelterkinden, Switzerland
	<i>Asteraceae</i>	<i>Lactuca sativa</i>	Lettuce	Sativa Rheinau GmbH, CH-8462 Rheinau, Switzerland
Monocotyledonae	<i>Gramineae</i>	<i>Zea mays</i>	Corn	Landi Oberbaselbiet AG, CH-4460 Gelterkinden, Switzerland
	<i>Gramineae</i>	<i>Avena sativa</i>	Oat	Sativa Rheinau GmbH, CH-8462 Rheinau, Switzerland

Table A7_5_1_3-2: Test system.

Criteria	Details
Test type	Greenhouse
Container type	Non-porous plastic pots (inner diameter 13 cm)
Seed germination potential	Germination rate (GR) of the seeds determined in non-GLP pre-tests: - rape: GR 100%, 4 days after sowing - lettuce: GR 100%, 4 days after sowing - tomato: GR 86%, 6 days after sowing - corn: GR 100%, 4 days after sowing - carrot: GR 96%, 6 days after sowing - oat: GR 90%, 5 days after sowing
Identification of the plant species	- rape: Lot No. D/KI 2129376A - lettuce: Lot No. VBZ 5808.04/05 - tomato: Lot No. BGH 6740.04/05 - corn: Lot No. FO 353 T 6080 01 T - carrot: Lot No. BGH 6719.04/05 - oat: Lot No. gr73/2062/04
Number of replicates	6 replicates (6 pots) per treatment, except corn: 12 replicates
Numbers of plants per replicate per dose	8 seeds per pot, i.e. 8 seeds per replicate (except corn: 4 seeds per pot)
Date of planting	May 19, 2004
Date of test substance application	- Seedling emergence and seedling growth test : one application to soil on June 08, 2004 - Vegetative vigour test : one application to plants, depending on species: June 08, 2004 (corn), June 15, 2004 (lettuce, tomato, oat) or June 24, 2004 (carrot, rape).
Height of plants at application	- rape: 7-10 cm - lettuce: 5-7 cm - tomato: 8-12 cm - corn: 14-43 cm - carrot: 9-15 cm - oat: 19-31 cm
Date of phytotoxicity rating or harvest	Observations for phytotoxicity symptoms: - Seedling emergence and seedling growth test : on Days 7, 10, 14 and 21 after 50% of the control plants emerged - Vegetative vigour test : on Days 7, 14 and 21 after application
Dates of analysis	June 08, 2004 – August 18, 2004

Table A7_5_1_3-3: Test conditions.

Criteria	Details
Test type	- Seedling emergence and seedling growth test - Vegetative vigour test
Method of application	Spray, 1 application, with calibrated track sprayer "Schachtner Spray Lab" (speed of conveyor belt: 2.0 km/h; type of nozzle: flat jet nozzle TEEJET 80015EVS; pressure: 2.32 bar)
Application levels	1 application level, equivalent to 660 g Trebon 30 EC/ha, i.e. 200 g a.i./ha
Dose rates	(spray volume equivalent to 200 l/ha)
Substrate characteristics	Standard soil Speyer 2.3, sandy loam. pH 6.3, 1% organic carbon, MWC 35.2/100 g dry soil, not sterilized.
Watering of the plants	Plants were bottom-watered every 1-5 days
Temperature	- Seedling emergence and seedling growth test : 15.4 to 40.1°C - Vegetative vigour test : 14.1 to 43.2°C
Light regime	8 hours darkness - 16 hours light (at the beginning of the test: 15 hours of natural light and 1 hour of artificial light). Mean daily photon fluence rate: - Seedling emergence and seedling growth test : 7 to 574 $\mu\text{mol}\cdot\text{m}^{-2}\cdot\text{s}^{-1}$ - Vegetative vigour test : 2 to 633 $\mu\text{mol}\cdot\text{m}^{-2}\cdot\text{s}^{-1}$
Relative humidity	- Seedling emergence and seedling growth test : 16.4 to 90.0% - Vegetative vigour test : 11.0 to 91.0%
Observation periods and duration of test	Duration of test: 21 days Observations: - Seedling emergence and seedling growth test : on Days 7, 10, 14 and 21 after 50% of the control plants emerged - Vegetative vigour test : on Days 7, 14 and 21 after application
Pest control	Beneficial organisms: <i>Steinernema feltia</i> (nematodes) against <i>Sciaridae</i> , applied on June 17, 2004 (day 9 of the seedling emergence and seedling growth test, day 30 of the vegetative vigour test). <i>Chrysoperla carnea</i> (larvae) against aphids, applied on June 28, 2004 (day 20 of the seedling emergence and seedling growth test, day 41 of the vegetative vigour test).
Any other treatments and procedures	Nutrients in irrigation water (need and timing assessed by observation of control plants): universal fertilizer, 10 to 40 mL nutrient solution per pot, at a concentration of 0.8 g nutrient powder/L.

Table A7_5_1_3-4: Results of the seedling emergence and seedling growth test (% of water control)

Plant species	Mean emergence rate		Mean plant height		Mean plant dry weight	
	Trebon 30EC	Blank formulation	Trebon 30EC	Blank formulation	Trebon 30EC	Blank formulation
Corn	104%	100%	98%	95%	95%	102%
Oat	82%	82%	102%	106%	99%	115%
Lettuce	84% *	100%	89% *	98%	84% *	95%
Tomato	90%	93%	101%	105%	107%	122%
Carrot	103%	95%	105%	108%	101%	116%
Rape	92%	105%	102%	99%	127%	93%

* significantly smaller than the control (student's t-test, one-sided smaller, $\alpha = 0.05$)

Table A7_5_1_3-5: Results of the vegetative vigour test (% of water control)

Plant species	Mean plant height		Mean plant dry weight	
	Trebon 30EC	Blank formulation	Trebon 30EC	Blank formulation
Corn	100%	100%	106%	113%
Oat	105%	102%	107%	97%
Lettuce	108%	101%	117%	89%
Tomato	98%	102%	119%	102%
Carrot	123%	100%	106%	91%
Rape	100%	94%	95%	89%

* significantly smaller than the control (student's t-test, one-sided smaller, $\alpha = 0.05$)

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	27.05.2005
Materials and methods	<p>3.1.4 Composition of Product</p> <p>Detailed information on the composition of the product is not included in section 2 but was submitted on request:</p> <p>TREBON 30EC contains > 295.8 g technical a.i./ 1000ml Etofenprox which corresponds to >287.5 g pure a.i./ 1000 ml Etofenprox; Tolerance: ± 25 g/1000 ml;</p> <p>3.4 Testing procedure</p> <p>The test item (660 g Trebon 30 EC/ha corresponding to 200 g ai/ha) was sprayed onto the soil or plant surface simulation typical spray tank application.</p> <p>The test design follows the approach for agricultural pesticides. The spraying application is a deviation from the OECD 208, 1984. In the proposal for updated 208 surface application is only mentioned for crop protection products reflecting the special application pattern for this products.</p> <p>Also the application concentration did not follow the current OECD 208 (3 test concentrations). In the new proposal it is stated, that in order to exclude phytotoxic properties a limit test of 1000 mg/kg and for crop protection products three times the recommended field application rate is appropriate for screening purposes.</p> <p>4.1.8.Effect data and 5.2, correction:</p> <p>Etofenprox shows phytotoxic effect in one of six tested species (lettuce) in seedling emergence and growth test. The effects were below 50% compared with the control. Because of the limit test (tested concentrations not in line with the recommendations of the guidelines) which can be considered as an initial screening test no LOEC and NOEC can be determined. The L(E)C50 is > 200 g ai/ha.</p> <p>Also by visual inspection phytotoxic symptoms on day 7 and 14 were observed (5 seedlings, cotyledons slightly brown coloured, reduced growth). The plants recovered during the remaining test period.</p> <p>5.3.1. Reliability:</p> <p>typing error: 1</p>
Conclusion	See below
Reliability	1
Acceptability	Acceptable
Remarks	-
	COMMENTS FROM...
Date	

Results and discussion

Conclusion

Reliability

Acceptability

Remarks

Section 7.5.3.1.3 Effects on reproduction of birds

Annex Point IIIA-XIII.1.3

			Official use only
		1 REFERENCE	
1.1	Reference	(1996): MTI-500 – Effects on reproduction in Bobwhite quail after dietary administration; unpublished report no. MTC 270/96282 (October 29, 1996). Dates of experimental work: October 06, 1995 – May 27, 1996	
1.2	Data protection	Yes	
1.2.1	Data owner	Mitsui Chemicals Agro, Inc.	
1.2.2	Criteria for data protection	Data submitted to the MS after May 13, 2000 on existing a.s. for the purpose of its entry into Annex I.	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	Guideline study	Yes EPA, Subdivision E, Series 71, § 71-4	
2.2	GLP	Yes	
2.3	Deviations	No	
		3 METHOD	
3.1	Test material	Etofenprox technical	
3.1.1	Lot/Batch number	56-067	
3.1.2	Specification	As given in section 2 Deviating from specification given in section 2 as follows	X
3.1.3	Description	Beige solid	
3.1.4	Purity	96.3%	X
3.1.5	Stability	No information in the report.	
3.1.6	Further relevant properties	Solubility in water: 22.5 µg/L at 20 ± 0.5°C Vapour pressure: 8.13 x 10 ⁻⁷ Pa at 25°C Stability in water: hydrolytically stable at pH 4, 7 and 9 Readily biodegradable	
3.1.7	Method of analysis	Test diet formulation containing the test material were extracted with acetonitrile, concentration of etofenprox was determined by high performance liquid chromatography (HPLC) using ultraviolet detection (UV, 225 nm).	
3.2	Administration of the test substance	Corn oil (see table A7_5_3_1_2-1)	
3.3	Testing procedure		
3.3.1	Test organisms	Bobwhite quail (<i>Colinus virginianus</i>) (see table A7_5_3_1_3-2)	
3.3.2	Test system	Dietary inclusion (see table A7_5_3_1_3-3)	
3.3.3	Diet	see table A7_5_3_1_3-3	
3.3.4	Test conditions	see table A7_5_3_1_2-4	

Section 7.5.3.1.3 Effects on reproduction of birds

Annex Point IIIA-XIII.1.3

- 3.3.5 Duration of the test Duration from start of pre-treatment period until last chick sacrifice: 29.4 weeks
Administration of diet containing the test material: 22 weeks
- 3.3.6 Test parameter
- 3.3.7 Examination / Observation see table A7_5_3_1_2-3
- 3.3.8 Statistics ANOVA (treatment effects); William's test (comparison of treated groups with the control group)

4 RESULTS

- 4.1 Limit Test / Range finding test** Range finding test was performed
- 4.1.1 Concentration 0, 100, 300 and 1000 ppm
- 4.1.2 Number/percentage of animals showing adverse effects No evidence for any treatment related effects
- 4.1.3 Nature of adverse effects See 4.1.3
- 4.2 Results test substance**
- 4.2.1 Applied concentrations Dietary inclusion at 0, 30, 300 and 1000 ppm
- 4.2.2 Effect data (Mortality and reproductivity) see table A7_5_3_1_3-5;
NOEC = 1000 ppm (95 % c.l. could not be determined due to the absence of any significant treatment related effects)
- 4.2.3 Body weight No significant treatment related effects
- 4.2.4 Food consumption No significant treatment related effects
- 4.2.5 Results of residue analysis Not performed
- 4.2.6 Other effects no other observations differentiating organisms in tests and controls
- 4.3 Results of controls**
- 4.3.1 Number/percentage of animals showing adverse effects No adverse effects were observed in control and treated animals
- 4.3.2 Nature of adverse effects

5 APPLICANT'S SUMMARY AND CONCLUSION

- 5.1 Materials and methods** Guideline: EPA, Subdivision E, Series 71, § 71-4
Valid study
- 5.2 Results and discussion** Dietary administration of up to 1000 ppm etofenprox to the Bobwhite quail has no adverse effect on the health, growth and reproductive performance of adult birds and their chicks.
- 5.2.1 NOEC 1000 ppm

Section 7.5.3.1.3 **Effects on reproduction of birds**
Annex Point IIIA-XIII.1.3

5.3	Conclusion	Validity criteria can be considered as fulfilled. (see validity criteria summarized in table A7_5_3_1_3-5)
5.3.1	Reliability	1
5.3.2	Deficiencies	No

Table A7_5_3_1_3-1: Method of administration of the test substance

Carrier / Vehicle	Details
Water	No
Organic carrier	Yes: corn oil
Concentration of the carrier [% v/v]	
Other vehicle	No
Function of the carrier / vehicle	solvent for test substance, facilitation of mixing with diet

Table A7_5_3_1_3-2: Test animals

Criteria	Details
Species/strain	Bobwhite quail (<i>Colinus virginianus</i>)
Source	[REDACTED]
Age (in weeks), sex and initial body weight (bw)	Age: approximately 22 weeks 84 male/84 female birds initial bodyweight range: 170 – 206 g
Age range within the test	
Breeding population	Birds were approaching their first breeding season
Amount of food	<i>Ad libitum</i> (food consumption was monitored)
Age at time of first dosing	approximately 22 weeks
Health condition / medication	All birds in good health
Pre-treatment	4 weeks acclimation period, no abnormal observations during pre-treatment

Table A7_5_3_1_3-3: Test system

Criteria	Details
Test location	indoor in holding pens [REDACTED]
Holding pens	5 batteries of cages, each battery consisting of 4 tiers of 4 cages. Cages were constructed of polythene coated steel wire and measured approximately 0.31 x 0.39 x 0.30 m. Cages ha sloping floors with 0.1 m egg-catchers, and had externally attached food hoppers and automatic drinkers.
Number of animals (male/female)	160 (80/80)
Number of animals per pen [cm ² /bird]	2 (1 male/1 female) → ca. 600 cm ² /bird
Number of animals per dose	20 (3 dose groups/1 control group)
Pre-treatment / acclimation	Temperature: 21 – 23°C; relative humidity: 60%; lightning regime: 7 hours light/17 hours dark Diet: avian layer diet (Special Diets Services, Witham, Essex, England), offered <i>ad libitum</i> Water: domestic quality portable water (Anglian Water), offered <i>ad libitum</i>
Diet during test	Avian layer diet (Special Diets Services, Witham, Essex, England), offered <i>ad libitum</i> . Diet without any added antibiotics or other non-nutritional food additives. Test material was mixed with corn oil prior to incorporation in the diet. Pre-mixes were prepared weekly by mixing the required quantity of test substance with untreated basal diet (Turbula mixer, > 5 min). Test diet concentrations were prepared by direct dilution of the prepared pre-mix.
Dosage levels (of test substance)	0, 30, 300, 1000 ppm Test diets were offered <i>ad libitum</i>
Replicate/dosage level	20 replicates/dosing level (40 animals/dosing level)
Dosing method	Dietary inclusion
Dosing volume per application	Food consumption was monitored weekly
Frequency, duration and method of animal monitoring after dosing	- Mortality, clinical signs of adults and chicks: daily - Food consumption; see above - Bodyweight; see below - Reproductive parameters including number of eggs laid, number of eggs damaged, egg shell thickness, embryonic viability and chick survival: weekly
Time and intervals of body weight determination	- Individual adult bodyweights were recorded on weeks -2, 0 (immediately prior to introduction of test diets), 2, 4, 6, 8 and 22 (termination) - Individual chick bodyweights were determined twice, within 24 hours of hatching and again at the end of the observation period
Incubation, storing and hatching	Describe briefly the equipment for incubation, storing and hatching of eggs
Test period after egg-laying	Administration of test material during the whole 12 week egg laying period
Turning of eggs	Yes, during incubation, once every hour through 90° each side of the horizontal
Collection period for eggs	12 weeks

Table A7_5_3_1_3-4: Test conditions (housing)

Criteria	Details
Test temperature	Mean daily minimum temperature: 21°C Mean daily maximum temperature: 23°C
Shielding of the animals	No
Ventilation	Ventilation fans were adjusted as required
Relative humidity	60%
Photoperiod and lighting	Pre-treatment period and first 6 weeks of dosing: 7 hours light/17 hours dark. Photoperiod was then increased to 16 hours with a further half hour increase during week 9 and another during week 11. This 17 hour light/7 hour dark regime was kept until the end of egg production (week 22). Light intensity ranged from 90 to 200 lux.
Storing, incubation and hatching conditions for eggs	Eggs were labelled and stored at in a refrigerator at 16°C. At the end of each 7-day period eggs were removed from the refrigerator and allowed to reach room temperature (ca. 12 hours). Eggs were then candled and incubated (except those used for shell thickness measurement) in a La Nationale Sologne 36 incubator (37°C, 55% RH). After 21 days of incubation, eggs were transferred to a still air Bristol hatcher (37.5°C). Eggs were separated according to replicate and placed on wire mesh trays. Chicks which hatched were transferred to floor pens.
Environmental conditions for young birds	Wooden box floor pens, with an infra-red heat lamp suspended over each box. Photoperiod: 14 hour; temperature: 27 – 29°C; relative humidity: 36%. Feeding and water <i>ad libitum</i> (standard chick diet, Parker Brothers Ltd, Lark Mills, Suffolk, England)

Table A7_5_3_1_3-5: Values of reproduction ability

Reproductive parameter	Dose group [ppm]			
	0 (Control)	30	300	1000
Eggs laid per female	59.6	72.6	66.8	66.2
Eggs damaged (% of eggs laid)	0.9	1.1	2.0	1.1
Number of eggs set	1043	1317	1164	1150
Viable embryos	991	1189	1056	1103
Viable embryos (% of eggs set)	95	90	91	96
Live 3-week embryos	945	1139	1009	1039
Live 3-week embryos (% of viable embryos)	95	96	96	94
Hatchlings	849	1048	909	967
Hatchlings (% of viable embryos)	86	88	86	88
Hatchlings (% of live 3-week embryos)	90	92	90	93
14-day-old survivors	804	985	833	900
14-day-old survivors per female	42.8	49.9	44.1	48.3
14-day-old survivors (% of total hatchlings)	95	94	92	93
Mean eggshell thickness (mm)	0.21	0.21	0.21	0.21

Table A7_5_3_1_3-6: Validity criteria for bird reproduction test according to OECD 206

Criteria	Fulfilled	Not fulfilled
Mortality of control animals <10%	X	
Average number of 14-day-old survivors per hen in controls \geq 14, 12 and 24 for mallard duck, bobwhite quail and Japanese quail	X	
Average eggshell thickness for the control group \geq 0.34, 0.19 and 0.19 mm for mallard duck, bobwhite quail and Japanese quail	X	
Concentration of the test substance in the diet \geq 80 % of the nominal concentration throughout the test period	X	

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	27.05.2005
Materials and methods	<p>3.1.2 Specification According to document A3 the physical state changes from white crystals to amber liquid with decreasing purity from 99,8 % to 99,3%.</p> <p>3.1.4 Purity: Within the 5 batch analysis a purity between 97,2 % and 99,6% is indicated. 56067 contained the same main impurities as later production batches (e.g. 5 batch analysis) at comparable percentages. The concentration of etofenprox is with 96,3% slightly lower than in the 5 batch analysis. Therefore the deviations to the specification are not considered to be ecotoxicologically relevant.</p>
Conclusion	Agree with the applicant's version
Reliability	1
Acceptability	Acceptable
Remarks	-
	COMMENTS FROM...
Date	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Section A8**Measures necessary to protect man, animals and the environment**Official
use only**Subsection
(Annex Point)**

8.1		Recommended methods and precautions concerning handling, use, storage, transport or fire (IIA-VIII.8.1)
8.1.0	Methods and precautions concerning placing on the market	<p>On the basis of available information, etofenprox is not expected to produce any significant adverse health or environmental effects when the recommended use instructions are followed.</p> <p>No specific precautions have been taken by the producer/formulator to reduce emissions (e.g. special formulation of the active substance, technologies to prepare formulations including packaging)</p> <p>Etofenprox should not enter the (aquatic) environment (hazard symbol N: dangerous for the environment; risk phrase R50/53: very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment).</p>
8.1.1	Methods and precautions concerning production, handling and use of the active substance and its formulations	<p>Technical measures:</p> <ul style="list-style-type: none">• Use only with adequate ventilation.• Where there may be potential of fire or explosion hazard, use explosion-proof electrical equipment and take precautions against build-up of electrostatic charges.• Avoid contact with eyes, skin and clothing. Do not breathe dust.• Wear appropriate personal protective clothing and equipment (dust respirator, chemical cartridge respirator, protective gloves, safety glasses or goggles, safety helmet, protective clothing, safety boots).• Provide hand and eye wash station near work area. Wash thoroughly after handling.
8.1.2	Methods and precautions concerning storage of the active substance and its formulations	<p>Storage conditions:</p> <ul style="list-style-type: none">• Keep container tightly closed.• Protect from direct sunlight.• Store in cool, dark and well ventilated area.• Store in a segregated and approved area. <p>Packaging material: Metal drums or cans with corrosion protection layer on surface.</p>
8.1.3	Methods and precautions concerning transport of the active substance and its formulations	<p>Transport information:</p> <ul style="list-style-type: none">• UN Class: not regulated• UN Number: none

X

Section A8

Measures necessary to protect man, animals and the environment

Official
use only

8.1.4 Methods and precautions concerning fire of the active substance and its formulations

- Extinguishing media: water jet, water fog, foam, dry chemical, CO₂ (extinguishing media which must not be used; not defined)
- General hazard: no specific hazard for usual industrial or commercial handling
- Fire fighting instructions: keep unnecessary and unprotected personnel away. Shut off supply if possible. Remove containers to safe place if possible. Keep containers and surroundings cool by spraying with water. Fight fire from upwind position.
- Fire fighting equipment: respiratory and eye protection required for fire-fighting personnel. Full protective equipment and self-contained breathing apparatus (SCBA) should be used for all indoor fires and significant outdoor fires.
- Water used for fire fighting must be retained and treated before being released into natural water bodies

8.2

In case of fire, nature of reaction products, combustion gases, etc. (IIA-VIII.8.2)

- Hazardous combustion products: Carbon oxides
- Hazardous polymerisation: will not occur

Etofenprox does not contain halogens, therefore the formation of hydrohalogenic acids or polyhalogenated dibenzo-p-dioxins is not possible.

Etofenprox does not contain nitrogen, therefore the formation of hydrocyanic acid is not possible.

8.3

Emergency measures in case of an accident (IIA8.3)

8.3.1 Specific treatment in case of an accident, e.g. first-aid measures, antidotes, medical treatment if available

- Inhalation: remove persons feeling unwell immediately to fresh air. Get medical attention if cough or other symptoms develop.
- Eye contact: immediately flush eyes with plenty of water. Part eyelids with fingers to assure complete flushing. Check for and remove contact lenses if easily possible. Get medical attention if irritation persists.
- Skin contact: immediately remove contaminated clothing and shoes. Flush skin with large amount of water, clean off with soap and water. Get medical attention if symptoms develop.
- Ingestion: rinse mouth with water and give 1 or 2 glasses of water or milk. Get medical attention immediately. Induce vomiting as directed by medical personnel. Never give anything by mouth to an unconscious or convulsing person.

8.3.2 Emergency measures to protect the environment

- Personal precautions: keep unnecessary and unprotected personnel away. Wear appropriate personal protective equipment as specified in Section 8.1.1. Remove all sources of ignition. Stop leak if possible without personal risk.
- Environmental precautions: do not let this chemical enter the environment.
- Clean-up methods: use appropriate tools to put the spilled solid in a convenient waste disposal container.

X

Section A8

Measures necessary to protect man, animals and the environment

Official
use only

- 8.4** **Possibility of destruction or decontamination following release in or on the following: (a) Air; (b) Water, including drinking water; (c) Soil (IIA-VIII.8.4)**
- 8.4.1** **Possibility of destruction or decontamination following release in the air** Etofenprox has a very low vapour pressure; accidental release into the air does not lead to hazardous vapour concentrations. If clean-up should become necessary, air filters containing activated carbon, silica gel or polymer-based adsorptive materials are suited for clean-up.
- 8.4.2** **Possibility of destruction or decontamination following release in water, including drinking water** Etofenprox can be removed from water by treatment with activated carbon, silica gel or polymer based adsorbents. Biological treatment or uv photolysis are also possible remediation methods.
- 8.4.3** **Possibility of destruction or decontamination following release in or on soil** Small concentrations of etofenprox in soil are not persistent, but will be degraded naturally ($DT_{50} < 25$ days). Decontamination is not necessary. Large amounts of etofenprox in soil should be removed by incineration of the contaminated soil.
- 8.5** **Procedures for waste management of the active substance for industry or professional users e.g. possibility of re-use or recycling, neutralisation, conditions for controlled discharge, and incineration (IIA-VIII.8.5)**
- 8.5.1** **Possibility of re-use or recycling** Large amounts of etofenprox that are no longer approved for use, can be returned to the manufacturer for recycling. Small amounts or spills containing a large fraction of alien materials should be destroyed by incineration.
Etofenprox containing waste is not classified as hazardous waste, except if it contains other hazardous components.
- 8.5.2** **Possibility of neutralisation of effects** Spills of etofenprox are not hazardous, when removed by trained persons wearing protective clothes (gloves, boots, overall). Small and large spills can be removed by collecting the solid material in an appropriate container. Disposal should be by incineration. Pre-treatment or neutralisation is not necessary.
- 8.5.3** **Conditions for controlled discharge including leachate qualities on disposal** Diluted aqueous solutions (e.g. leachate) should be treated in a biological waste water treatment plant or by filtration through activated carbon. Etofenprox can be removed from aqueous suspensions by adsorbents, like activated carbon, silica or sand filters. Direct discharge of etofenprox containing solutions or suspensions into environmental waters must be avoided.
- 8.5.4** **Conditions for controlled incineration** No special precautions are required for the incineration of etofenprox or etofenprox containing waste. Etofenprox does not contain halogens, therefore the formation of polychlorinated dioxins and furans is not possible.
- 8.6** **Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms (IIA-VIII.8.6)**

Section A8

Measures necessary to protect man, animals and the environment

8.7

Etofenprox is highly toxic to aquatic organisms (fish, daphnia) with the exception of green algae.

Etofenprox is bioconcentrated in fish and earthworms. However, no secondary toxic effects on predatory birds or rodents have been observed or would be expected, because of the low toxicity of etofenprox to these species. (See Doc II-A, 4.2.4 for details)

Identification of any substances falling within the scope of List I or List II of the Annex to Directive 80/68/EEC on the protection of groundwater against pollution caused by certain dangerous substances (IIA-VIII,8.7)

Etofenprox and the other components of the formulations (except water) fall within List II of the Annex to Directive 80/68/EEC.

Official
use only

X

Evaluation by Competent Authorities	
1.1	2 EVALUATION BY RAPPORTEUR MEMBER STATE
Date	27.05.2005
Evaluation of applicant's proposal	8.1.2 The containers used are made from mild steel (i.e. low carbon) plate, tinned for corrosion protection. On the inside they are treated with a zinc based anti-corrosive. 8.3.1. Do <u>not</u> induce vomiting, unless directed by medical personal 8.6 Etofenprox is highly toxic to aquatic organisms (fish, daphnia) and less toxic to green algae.
Conclusion	Human exposure – agree with applicant's version Environmental exposure (soil, water, air compartment) – agree with applicant's version
2.1 REMARKS	-

Etofenprox

Insecticide for Use as Wood Preservative

Dossier According to Directive 98/8/EC

Document III, section A.9

**Proposals including Justification for the Proposals for the
Classification and Labelling of the Active Substance
according to Council Directive 67/548/EEC**

Section A9

Proposals including Justification for the Proposals for the Classification and Labelling of the Active Substance according to Council Directive 67/548/EEC

Applicant

[REDACTED]

Telephone no.: [REDACTED]
Telefax no.: [REDACTED]
E-mail: [REDACTED]

LKC UK Ltd
Carrick House
Lypiatt Road
Cheltenham
Gloucestershire
GL50 2QJ
United Kingdom

Person to contact

[REDACTED]

Telephone no.: [REDACTED]
Telefax no.: [REDACTED]
E-mail: [REDACTED]


LKC Switzerland Ltd.
Postfach 167
CH-44 Füllinsdorf
Switzerland

Person responsible for this summary

[REDACTED]

Switzerland
Telephone no.: [REDACTED]
Telefax no.: [REDACTED]
E-mail: [REDACTED]

LKC Switzerland Ltd.
Postfach 167
CH-44 Füllinsdorf
Switzerland

Classification and Labelling			Official use only
Hazard symbol:	N		
Indication of danger:	dangerous for the environment		
Labelling symbol:			
Risk phrases:	R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.	
Safety phrases:	S2	Keep out of the reach of children	X
	S13	Keep away from food, drink and animal feedingstuffs.	X
	S27/28	After contact with skin, take off immediately all contaminated clothing, and wash immediately with plenty of water.	
	S36/37/39	Wear suitable protective clothing, gloves and eye/face protection	X

Justifications for the Proposal

N	Substances and preparations which, were they to enter into the environment, would present or might present an immediate or delayed danger for one or more components of the environment.	
R50/53	Based on effects on aquatic organisms. The substance is acutely harmful to fish and <i>Daphnia</i> ($LC_{50} \leq 1$ mg/L) and has a $\log Pow \geq 3$ (i.e. 6.9). However, the substance is classified as readily biodegradable.	X
	No other risk phrases are applicable since the acute oral LD_{50} in the rat is > 2000 mg/kg and in the dog is > 5000 mg/kg, the acute dermal LD_{50} in the rat is > 2000 mg/kg, the 4-hour LC_{50} in the rat is > 5.9 mg/L, there is no evidence of skin irritation, no ocular irritation and no skin sensitisation.	
	No classification on the basis of physico-chemical properties since the substance is neither flammable, explosive nor has oxidising properties. Not corrosive.	
S2, 13	Required for all dangerous substances and preparations.	X
S27/28	Recommended for substances and preparations when water is not the most appropriate rinsing liquid.	X
S 36/37	Recommended for substances and preparations irritating to the skin.	X

S39	Required for corrosive substances and preparations, including irritants which give rise to risk of serious damage to the eyes. Recommended when it is necessary to draw the attention of the user to eye contact risks not mentioned in the risk phrases which have to be ascribed.	X
-----	---	---

Evaluation by Competent Authorities	
	Evaluation by Rapporteur Member State
Date	27.05.2005
Evaluation of applicant's proposal	<p>Safety phrases:</p> <p>S2: label not necessary, see Annex VI of 67/548/EEC (obligatory for all dangerous substances and preparations sold to the general public, except for those only classified as dangerous for the environment)</p> <p>S13: label not necessary, see Annex VI of 67/548 /EEC</p> <p>S27/28: label not necessary, see Annex VI of 67/548/EEC</p> <p>S36: required, see Annex VI of 67/548 (recommended for substances and preparations used in industry which are liable to damage health by prolonged exposure)</p> <p>S37: label not necessary, see Annex VI of 67/548/EEC</p> <p>S39: label not necessary, see Annex VI of 67/548 /EEC</p> <p>S60 - 61: required: According to the classification with N; R50-53 and the labelling with N; R50/53 the additional S-phrases S60-61 have to be put on the label.</p> <p>Risk phrases:</p> <p>R50/53: The substance is classified as not readily biodegradable, since the mineralization of the substance only reached 32% after 28 days.</p>
Conclusion	Classification: N; R50-53 Labelling: N; R50/53 S 36 – 60 - 61
Remarks	-
	Comments FROM...
Date	
Evaluation of applicant's justification	

Conclusion	
Remarks	

Etofenprox

Insecticide for Use as Wood Preservative

Dossier According to Directive 98/8/EC

Document III-A

**Appendix
Reference List**

Section A2, Identity of the Active Substance

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/N	Owner
A 2.7/01	Ramsay N.	2002a	Etofenprox 5-batch analysis of etofenprox to fulfill the requirements of OPPTS guidelines 830.1700, 830.1750 and 830.1800 and EC council directive 94/37/EEC article 1.9 and I.11 Inveresk Research, Report No. 20852 Landis Kane Consulting, Document No. 500-1-01 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 2.7/02	Anonymous	2003a	MSDS of etofenprox technical Mitsui Chemicals, Inc., MSDS No: 622141E2 Landis Kane Consulting, Report No. 500-3-02 Not GLP, published	N	Public information
A 2.10.1 → B 6.6	Mirbach M.	2004	Etofenprox: estimation of the human exposure to etofenprox used in the wood preservative product [REDACTED] 01990-I. Landis Kane Consulting, Report No. 04-alpha-02 Landis Kane Consulting, Document No.500-5-93 not GLP, not published	Y	Mitsui Chemicals Agro, Inc.
A 2.10.2 → B 7.1/06	Rathey S.	2005b	Estimation of the predicted environmental concentrations of etofenprox used in the wood preservative product [REDACTED] 01990-I. Landis Kane Consulting, Report No. 04-alpha-04/03 Landis Kane Consulting, Document No.500-7-46 Not GLP, not published	Y	Mitsui Chemicals Agro, Inc.

Section A3, Physical and Chemical Properties of the Active Substance

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/ N	Owner
A 3.1.1	Tognucci A.	1999	Determination of the melting point / melting range of etofenprox RCC Ltd, Report No. 718830 Landis Kane Consulting, Document No: 500-2-01 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 3.1.2	Tognucci A.	1998a	Determination of the boiling point / boiling range of etofenprox RCC Ltd, Report No: 692730 Landis Kane Consulting, Document No. 500-2-02 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 3.1.3	Tognucci A.	1998b	Determination of the relative density of etofenprox RCC Ltd, Report No. 692728 Landis Kane Consulting, Document No. 500-2-03 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 3.2	Tognucci A.	2000	Determination of the vapour pressure of etofenprox RCC Ltd, Report No. 751803 Landis Kane Consulting, Document No. 500-2-04 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 3.2.1 A 3.2	Tognucci A.	2000	Determination of the vapour pressure of etofenprox RCC Ltd, Report No. 751803 Landis Kane Consulting, Document No. 500-2-04 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 3.3.1/01	Shimono S.	1999a	Physical state of etofenprox (MTI-500) Mitsui Chemicals, Inc., LSL, Report No. not specified Landis Kane Consulting, Document No. 500-2-05 Not GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 3.3.1/02	Shimono S.	2002a	Physical state of manufactured etofenprox (MTI-500) Physical state of etofenprox (MTI-500) Mitsui Chemicals, Inc., Life Science Laboratory , Report No. not specified Landis Kane Consulting, Document No. 500-2-24 Not GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 3.3.1/03	Mirbach M.	2006	Comments on the Physical State of Etofenprox Landis Kane Consulting, Report No. not specified Landis Kane Consulting, Document No. not specified Not GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 3.3.2/01	Shimono S.	1999b	Color of etofenprox (MTI-500) Physical state of etofenprox (MTI-500) Mitsui Chemicals, Inc., Life Science Laboratory, Report No. not specified Landis Kane Consulting, Document No. 500-2-06 Not GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.

Section A3, Physical and Chemical Properties of the Active Substance

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/ N	Owner
A 3.3.2/02	Shimono S.	2002b	Color of manufactured etofenprox (MTI-500) Physical state of etofenprox (MTI-500) Mitsui Chemicals, Inc., Life Science Laboratory, Report No. not specified Landis Kane Consulting, Document No. 500-2-54 Not GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 3.3.3/01	Shimono S.	1999c	Odor of etofenprox (MTI-500) Physical state of etofenprox (MTI-500) Mitsui Chemicals, Inc., Life Science Laboratory, Report No. not specified Landis Kane Consulting, Document No. 500-2-07 Not GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 3.3.3/02	Shimono S.	2002c	Odor of manufactured Etofenprox (MTI-500) Physical state of etofenprox (MTI-500) Mitsui Chemicals, Inc., Life Science Laboratory, Report No. not specified Landis Kane Consulting, Document No. 500-2-55 Not GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 3.4/01	Tognucci A.	1998c	Determination of the NMR-, IR-, UV/VIS absorption and mass spectra of etofenprox and amendment dated October 13, 1999 RCC Ltd, Report No. 692785 Landis Kane Consulting, Document No. 500-2-08 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 3.4/02	Matsumoto T.	2002a	Measurement of UV-VIS absorption spectrum of 4'-OH Kurume Laboratory, Chemicals Evaluation and Research Institute, Report No. 82072 Landis Kane Consulting, Document No. 500-2-09 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 3.4/03	Matsumoto T.	2002b	Measurement of UV-VIS absorption spectrum of PENA Kurume Laboratory, Chemicals Evaluation and Research Institute, Report No. 82075 Landis Kane Consulting, Document No. 500-2-10 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 3.4/04	Tognucci A.	2003	Determination of the NMR-, IR, UV/VIS absorption and mass spectra of CEP RCC Ltd, Report No. 845212 Landis Kane Consulting, Document No. 500-2-56 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 3.4/05	Pouchert Ch.J., Behnke J.	1983	The Aldrich library of ¹³ C and ¹ H FT NMR spectra Aldrich Chemical Company 1983 Landis Kane Consulting, Document No. 500-2-61 Not GLP, published	N	Public information

Section A3, Physical and Chemical Properties of the Active Substance

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/ N	Owner
A 3.4/06	Pouchert Ch.J.	1985	The Aldrich library of FT-IR spectra Aldrich Chemical Company 1985 Landis Kane Consulting, Document No. 500-2-62 Not GLP, published	N	Public information
A 3.4/07	Heller S.R., Milne G.W.A.	1978	EPA / NIH mass spectral data base U.S. Department of Commerce, National Bureau of Standards 1978 Landis Kane Consulting, Document No. 500-2-63 Not GLP, published	N	Public information
A 3.5/01	Kunz C.	2000	Determination of the water solubility of ¹⁴ C- etofenprox at three pH values and amendment dated October 04, 2000 RCC Ltd, Report No. 755515 Landis Kane Consulting, Document No. 500-2-11 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 3.5/02	McCorquodale G.Y.	2002a	Physico-chemical testing with [¹⁴ C]-Alpha-CO: water solubility Inveresk Research, Report No: 21386 Landis Kane Consulting, Document No. 500-2-12 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 3.5/03	Matsumoto T.	2002c	Determination of water solubility for 4'-OH by column elution method Kurume Laboratory, Chemicals Evaluation and Research Institute, Report No. 82070 Landis Kane Consulting, Document No. 500-2-13 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 3.5/04	Matsumoto T.	2002d	Determination of water solubility for PENA by flask method Kurume Laboratory, Chemicals Evaluation and Research Institute, Report No. 82073 Landis Kane Consulting, Document No. 500-2-14 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 3.5/05	Mirbach M.	2004a	Etofenprox: estimation of the temperature dependence of the solubility in water and organic solvents and of the partition coefficient octanol/water. Landis Kane Consulting, Report No. 04-alpha-18 Landis Kane Consulting, Document No.500-2-67 Not GLP, not published	Y	Mitsui Chemicals Agro, Inc.
A 3.6	Schmiedel U.	1998	Expert statement on the dissociation of MTI-500 (etofenprox) in water RCC Ltd, Report No. 692741 Landis Kane Consulting, Document No. 500-2-26 Not GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 3.7/01	Tognucci A.	1998d	Determination of the solubility of etofenprox in organic solvents RCC Ltd, Report No. 692752 Landis Kane Consulting, Document No. 500-2-15 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.

Section A3, Physical and Chemical Properties of the Active Substance

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/ N	Owner
A 3.7/02 A 3.5/05	Mirbach M.	2004a	Etofenprox: estimation of the temperature dependence of the solubility in water and organic solvents and of the partition coefficient octanol/water. Landis Kane Consulting, Report No. 04-alpha-18 Landis Kane Consulting, Document No.500-2-67 Not GLP, not published	Y	Mitsui Chemicals Agro, Inc.
A 3.9/01	Tognucci A.	1998e	Determination of the partition coefficient (N-octanol / water) of etofenprox and amendment dated October 13, 1999 RCC Ltd, Report No. 692763 Landis Kane Consulting, Document No. 500-2-16 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 3.9/02	McCorquodale G.Y.	2002b	Physico-chemical testing with [14C]-Alpha-CO: partition coefficient Inveresk Research, Report No. 21024 Landis Kane Consulting, Document No. 500-2-17 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 3.9/03	Matsumoto T.	2002e	1-Octanol/water partition coefficient test of 4'-OH (HPLC method) Kurume Laboratory, Chemicals Evaluation and Research Institute, Report No. 82071 Landis Kane Consulting, Document No. 500-2-18 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 3.9/04	Matsumoto T.	2002f	1-Octanol/water partition coefficient test of PENA (HPLC method) Kurume Laboratory, Chemicals Evaluation and Research Institute, Report No. 82074 Landis Kane Consulting, Document No. 500-2-19 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 3.9/05 A 3.5/05	Mirbach M.	2004a	Etofenprox: estimation of the temperature dependence of the solubility in water and organic solvents and of the partition coefficient octanol/water. Landis Kane Consulting, Report No. 04-alpha-18 Landis Kane Consulting, Document No.500-2-67 Not GLP, not published	Y	Mitsui Chemicals Agro, Inc.
A 3.10	Tognucci A.	1998f	Screening of the thermal stability in air of etofenprox RCC Umweltchemie AG, Report No. 692774 Landis Kane Consulting, Document No. 500-2-37 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 3.11/01	Dublaski A.	1991a	Determination of the flammability of etofenprox in accordance with EEC-Guideline A.10 Battelle Europe, Report No. BE-P-32-91-A10-02 Landis Kane Consulting, Document No. 500-2-29 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.

Section A3, Physical and Chemical Properties of the Active Substance

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/ N	Owner
A 3.11/02	Dublaski A.	1991b	Determination of the auto-flammability of etofenprox in accordance with EEC-Guideline A.16 Battelle Europe, Report No. BE-P-32-91-A16-02 Landis Kane Consulting, Document No. 500-2-30 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 3.12	Bates M.	2001a	MTI-500: determination of the flash point - Amended final report from January 31, 2001 Covance Laboratories Ltd., Report No. 719/8-D2141 Landis Kane Consulting, Document No. 500-2-31 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 3.13	Dublaski A.	1991c	Determination of the surface tension of etofenprox in accordance with EEC-Guideline A.05 Battelle Europe., Report No. BE-P-32-91-A05-02 Landis Kane Consulting, Document No. 500-2-33 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 3.15	Bates M.	2001b	MTI-500: evaluation of the explosive properties - Amended final report from January 31, 2001 Covance Laboratories Ltd., Report No. 719/9-D2141 Landis Kane Consulting, Document No. 500-2-32 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 3.16	Bates M.	2001c	MTI-500: determination of the oxidizing properties - Amended final report from January 31, 2001 Covance Laboratories Ltd., Report No. 719/11-D2141 Landis Kane Consulting, Document No. 500-2-34 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 3.17	Ohnuma K.	2004	Statement concerning the stability of etofenprox technical during storage and shipment. Mistui Chemicals, Inc., Document No. not specified Landis Kane Consulting, Document No. 500-2-66 Not GLP, unpublished	N	Mitsui Chemicals Agro, Inc.

Section A4, Analytical Methods

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/ N	Owner
A 4.1/01	Ramsay N.	2002b	Etofenprox – Validation of analytical methods to support 5-batch analysis of Etofenprox to fulfil the requirements of OPPTS Guidelines 830.1700, 830.1750 and 830.1800 and EC Council Directive 94/37/EEC Article 1.9 to 1.11. Inveresk Research, Report No. 21164 Landis Kane Consulting, Document No. 500-4-01 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 4.1/02	Dobrat W., Martijn A.	1995	CIPAC Handbook Volume G - Analysis of technical and formulated pesticides method etofenprox 471 Collaborative Int. Pesticides Analytical Council Ltd. 1995 Landis Kane Consulting, Document No. 500-4-02 Not GLP, published	N	Public information
A 4.2/01	Wolf S.	2003a	Validation of the residue analytical method for MTI-500 and α -CO in soil RCC Ltd, Report No. 811607 Landis Kane Consulting, Document No. 500-4-12 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 4.2/02	Wolf S.	2003b	Development and validation of the residue analytical method for MTI-500 and α -CO in air RCC Ltd, Report No. 811620 Landis Kane Consulting, Document No. 500-4-17 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 4.2/03	Wolf S.	2003c	Validation of the residue analytical method for MTI-500 and α -CO in drinking, ground and surface water RCC Ltd, Report No. 811618 Landis Kane Consulting, Document No. 500-4-15 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 4.3/01	Wolf S.	2001	Validation of the residue analytical method for MTI-500 and α -CO in oil seed rape RCC Ltd, Report No. 789390 Landis Kane Consulting, Document No. 500-4-08 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 4.3/02	Wolf S.	2002	Validation of the residue analytical method for MTI-500 and α -CO in cabbage RCC Ltd, Report No. 814588 Landis Kane Consulting, Document No. 500-4-07 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 4.3/03	Wolf S.	2003d	Validation of the residue analytical method for MTI-500 and α -CO in cucumber RCC Ltd, Report No. 789377 Landis Kane Consulting, Document No. 500-4-03 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.

Section A4, Analytical Methods

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/ N	Owner
A 4.3/04	Class T.	2003a	Etofenprox: independent laboratory validation of analytical methods used for the determination of residues of etofenprox in plant materials PTRL Europe GmbH, Report No. P 692 G Landis Kane Consulting, Document No. 500-4-40 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 4.3/05	Wolf S.	2003e	Development and validation of the residue analytical method for MTI-500 and α -CO in meat (ruminant and chicken), milk, fat (ruminant) and egg RCC Ltd, Report No. 791245 Landis Kane Consulting, Document No. 500-4-19 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 4.3/06	Class T.	2003b	Etofenprox: independent laboratory validation of an analytical method used for the determination of residues of etofenprox in foodstuffs of animal origin PTRL Europe, Report No: P/B 701 G Landis Kane Consulting, Document No. 500-4-41 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.

Section A5, Further Information on the Active Substance

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/ N	Owner
A 5.3/01	Schumacher P., Fennert E.-M.	2003a	Determination of toxic values against <i>Reticulitermes santonensis</i> De Feytaud according to EN 117 (08/90) without accelerated ageing procedure – test material [REDACTED] 01190-I; Material Testing Institute Brandenburg, Department 3 wood and wood protection, Germany; Report No. 3.2/03/8417/01 Landis Kane Consulting, Document No. 500-6-62 Not GLP, not published	Y	[REDACTED]
A 5.3/02	Schumacher P., Fennert E.-M.	2003b	Determination of toxic values against <i>Reticulitermes santonensis</i> De Feytaud according to EN 117 (08/90) after leaching procedure according to EN 84 (05/97) – test material [REDACTED] 01190-I; Material Testing Institute Brandenburg, Department 3 wood and wood protection, Germany; Report No. 3.2/03/8417/02 Landis Kane Consulting, Document No. 500-6-63 Not GLP, not published	Y	[REDACTED]
A 5.3/03	Schumacher P., Fennert E.-M.	2003c	Determination of toxic values against larvae of <i>Hylotrupes bajulus</i> (L) according to EN 47 (08/90) without accelerated ageing procedure – test material [REDACTED] 01190-I; Material Testing Institute Brandenburg, Department 3 wood and wood protection, Germany; Report No. 3.2/03/8417/03 Landis Kane Consulting, Document No. 500-6-64 Not GLP, not published	Y	[REDACTED]
A 5.3/04	Schumacher P., Fennert E.-M.	2003d	Determination of toxic values against larvae of <i>Hylotrupes bajulus</i> (L) according to EN 47 (08/90) after leaching procedure to EN 84 – test material [REDACTED] 01190-I; Material Testing Institute Brandenburg, Department 3 wood and wood protection, Germany; Report No. 3.2/03/8417/04 Landis Kane Consulting, Document No. 500-6-65 Not GLP, not published	Y	[REDACTED]
A 5.4	Nishimura K., Kobayashi T., Fujita T.	1985	Symptomatic and neurophysiological activities of new synthetic non-ester pyrethroids, etofenprox, MTI-800, and related compounds Pesticide Biochemistry and Physiology Vol. 25, pp. 387 -395, 1986 Landis Kane Consulting, Document No. 500-3-01 Not GLP, published	N	Public information

Section A6, Toxicological and Metabolism Studies on the Active Substance

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/N	Owner
A 6.1.1/01	[REDACTED]	2003a	Acute oral toxicity study of etofenprox in rats [REDACTED] Report No. B-5039 Landis Kane Consulting, Document No. 500-5-70 GLP, not published	Y	Mitsui Chemicals Agro, Inc.
A 6.1.1/02	[REDACTED]	1985a	Ethofenprox (MTI-500) acute limit test of toxicity to dogs following a single oral administration [REDACTED] Report No. MTC 101/851185 Landis Kane Consulting, Document No. 500-5-07 GLP, not published	Y	Mitsui Chemicals Agro, Inc.
A 6.1.1/03	[REDACTED]	1982a	Report on acute toxicity study of MTI-500 (ethofenprox) in rats [REDACTED] Report No. A-82-27~34 Landis Kane Consulting, Document No. 500-5-08 Not GLP, not published	Y	Mitsui Chemicals Agro, Inc.
A 6.1.1/04	[REDACTED]	1982b	Report on Acute Toxicity Study of MTI-500 (ethofenprox) in Mice [REDACTED] Report No. A-82-35~42 Landis Kane Consulting, Document No. 500-5-09 Not GLP, not published	Y	Mitsui Chemicals Agro, Inc.
A 6.1.2/01	[REDACTED]	2003b	Acute dermal toxicity study of etofenprox in rats [REDACTED] Report No. B-5040 Landis Kane Consulting, Document No. 500-5-71 GLP, not published	Y	Mitsui Chemicals Agro, Inc.
A 6.1.2/02 → A 6.1.1/03	[REDACTED]	1982a	Report on acute toxicity study of MTI-500 (ethofenprox) in rats [REDACTED] Report No. A-82-27~34 Landis Kane Consulting, Document No. 500-5-08 Not GLP, not published	Y	Mitsui Chemicals Agro, Inc.
A 6.1.2/03 → A 6.1.1/04	[REDACTED]	1982b	Report on acute toxicity study of MTI-500 (ethofenprox) in mice [REDACTED] Report No. A-82-35~42 Landis Kane Consulting, Document No. 500-5-09 Not GLP, not published	Y	Mitsui Chemicals Agro, Inc.
A 6.1.3	[REDACTED]	1983	MTI-500 Acute inhalation toxicity in rats 4 hour exposure [REDACTED] Report No. MTC 60/821079 Landis Kane Consulting, Document No. 500-5-10 GLP, not published	Y	Mitsui Chemicals Agro, Inc.

Section A6, Toxicological and Metabolism Studies on the Active Substance

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/ N	Owner
A 6.1.4.s	[REDACTED]	1985a	MTI-500 Primary skin stimulation test in rabbits - Amendment No. 1 from October 28, 1991 [REDACTED], Report No. [REDACTED] H-85-5 Landis Kane Consulting, Document No. 500-5-11 GLP, not published	Y	Mitsui Chemicals Agro, Inc.
A 6.1.4.e	[REDACTED]	1985b	MTI-500 Primary ophthalmic stimulation test in rabbits - Amendment No. 1 from October 28, 1991 [REDACTED] Report No. [REDACTED] H-85-55 Landis Kane Consulting, Document No. 500-5-12 GLP, not published	Y	Mitsui Chemicals Agro, Inc.
A 6.1.5	[REDACTED]	1985	MTI-500 Skin sensitization test in guinea pigs - Correction to translation from October 21, 2003 [REDACTED] Report No. not specified Landis Kane Consulting, Document No. 500-5-13 GLP, not published	Y	Mitsui Chemicals Agro, Inc.
A 6.2/01	[REDACTED]	1985a	The biokinetics and metabolism of ¹⁴ C-ethofenprox in the rat [REDACTED], Report No. [REDACTED] MTC 68/84610 Landis Kane Consulting, Document No. 500-5-02 GLP, not published	Y	Mitsui Chemicals Agro, Inc.
A 6.2/02	[REDACTED]	2001a	[14C]-MTI-500: absorption, distribution, metabolism and excretion after single oral administration to male rats - amendment dated November 30,2001 [REDACTED] Report No. 801382 Landis Kane Consulting, Document No. 500-5-01 Not GLP, not published	Y	Mitsui Chemicals Agro, Inc.
A 6.2/03	[REDACTED]	2001b	[14C]-alpha-CO; absorption, distribution, metabolism and excretion after single oral administration to male rats [REDACTED] Report No. 819832 Landis Kane Consulting, Document No. 500-5-45 Not GLP, not published	Y	Mitsui Chemicals Agro, Inc.
A 6.2/04	[REDACTED]	1985b	The metabolism of ¹⁴ C-ethofenprox in dogs [REDACTED], Report No. [REDACTED] MTC 69/84583 Landis Kane Consulting, Document No. 500-5-04 GLP, not published	Y	Mitsui Chemicals Agro, Inc.

Section A6, Toxicological and Metabolism Studies on the Active Substance

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/N	Owner
A 6.2/05	[REDACTED]	1986	Metabolism study of ethofenprox (MTI-500), metabolism in rat [REDACTED] Report No. not specified Landis Kane Consulting, Document No. 500-5-03 Not GLP, not published	Y	Mitsui Chemicals Agro, Inc.
A 6.2/06	[REDACTED]	1999	Dermal absorption of ¹⁴ C-ethofenprox in male rats (preliminary and definitive phases) [REDACTED] Report No. 6648-135 Landis Kane Consulting, Document No. 500-5-80 GLP, not published	Y	Mitsui Chemicals Agro, Inc.
A 6.3.2	[REDACTED]	2000	A 28-day repeated dose dermal toxicity study in rabbits with technical MTI-500 [REDACTED] Report No. 011077-1 Landis Kane Consulting, Document No. 500-5-18 GLP, not published	Y	Mitsui Chemicals Agro, Inc.
A 6.4.1/01	[REDACTED]	1983a	Assessment of the toxicity of MTI-500 in rats during dietary administration for 13 weeks Re-issued amended pages on December 18, 1985 [REDACTED] Report No. MTC 56/821067 Landis Kane Consulting, Document No. 500-5-14 GLP, not published	Y	Mitsui Chemicals Agro, Inc.
A 6.4.1/02	[REDACTED]	1983b	Assessment of the toxicity of MTI-500 to mice by dietary administration for 13 weeks Re-issued amended pages on December 18, 1985 [REDACTED], Report No. MTC 55/821112 Landis Kane Consulting, Document No. 500-5-15 GLP, not published	Y	Mitsui Chemicals Agro, Inc.
A 6.4.3.1	[REDACTED]	1985	Ethofenprox (MTI-500) 90-day inhalation study in rats [REDACTED], Report No. MTC 81/841257 Landis Kane Consulting, Document No. 500-5-17 GLP, not published	Y	Mitsui Chemicals Agro, Inc.
A 6.5.1/01 and A6.//01	[REDACTED]	1986a	Ethofenprox (MTI-500) Potential tumorigenic and toxic effects in prolonged dietary administration to rats [REDACTED] Report No. MTC 59/85581 Landis Kane Consulting, Document No. 500-5-24 GLP, not published	Y	Mitsui Chemicals Agro, Inc.

Section A6, Toxicological and Metabolism Studies on the Active Substance

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/N	Owner
A 6.5.1/02 and A6.7/02	[REDACTED]	1986b	Ethofenprox (MTI-500) Potential tumoregenic and toxic effects in prolonged dietary administration to mice [REDACTED] Report No. MTC 59/85582 Landis Kane Consulting, Document No. 500-5-25 GLP, not published	Y	Mitsui Chemicals Agro, Inc.
A 6.5.2	[REDACTED]	1985b	Ethofenprox (MTI-500) Toxicity to dogs by repeated dietary administration for 52 weeks followed by a recovery period of 8 weeks [REDACTED] [REDACTED] Report No. MTC 71/85234 Landis Kane Consulting, Document No. 500-5-16 GLP, not published	Y	Mitsui Chemicals Agro, Inc.
A 6.6.1	[REDACTED]	1985	Reverse mutation in <i>Salmonella typhimurium</i> [REDACTED] Report No. 162001-M-06185 Landis Kane Consulting, Document No. 500-5-19 GLP, not published	Y	Mitsui Chemicals Agro, Inc.
A 6.6.2	[REDACTED]	1985a	<i>In vitro</i> assessment of the clastogenic activity of MTI-500, ethofenprox, in cultured human peripheral lymphocytes [REDACTED] Report No. 85/MT0017/430 Landis Kane Consulting, Document No. 500-5-21 Not GLP, not published	Y	Mitsui Chemicals Agro, Inc.
A 6.6.3/01	[REDACTED]	1985a	Gene mutation in Chinese hamster V79 cells: test substance MTI-500 [REDACTED] report No. 162002-M-06985 Landis Kane Consulting, Document No. 500-5-20 GLP, not published	Y	Mitsui Chemicals Agro, Inc.
A 6.6.3/02	[REDACTED]	1985b	Unscheduled DNA synthesis in human cells cell line: Hela S3 [REDACTED] Report No. 162003-M-05785 Landis Kane Consulting, Document No. 500-5-23 GLP, not published	Y	Mitsui Chemicals Agro, Inc.
A 6.6.4	[REDACTED]	1985c	MTI-500, ethofenprox: Assessment of clastogenic action on bone marrow erythrocytes in the micronucleus test [REDACTED] Report No. 85/MT0016/406 Landis Kane Consulting, Document No. 500-5-22 Not GLP, not published	Y	Mitsui Chemicals Agro, Inc.

Section A6, Toxicological and Metabolism Studies on the Active Substance

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/N	Owner
A 6.6.7/01	[REDACTED]	1985a	MTI-500 α -CO: Acute oral toxicity in the rat [REDACTED] Report No. 85/MT0018/474 Landis Kane Consulting, Document No. 500-5-38 GLP, not published	Y	Mitsui Chemicals Agro, Inc.
A 6.6.7/02	[REDACTED]	1985b	MTI-500 α -CO: Acute percutaneous toxicity in the rat [REDACTED] Report No. 85/MT0019/473 Landis Kane Consulting, Document No. 500-5-39 GLP, not published	Y	Mitsui Chemicals Agro, Inc.
A 6.6.7/03	[REDACTED]	1987	MTI-500 α -CO Preliminary toxicity study in rats by dietary administration for 4 weeks [REDACTED] Report No. MTC 140/87194 Landis Kane Consulting, Document No. 500-5-40 GLP, not published	Y	Mitsui Chemicals Agro, Inc.
A 6.6.7/04	[REDACTED]	1988	MTI-500 α -CO Toxicity to rats by dietary administration for 13 weeks [REDACTED] Report No. MTC 141/871458 Landis Kane Consulting, Document No. 500-5-41 GLP, not published	Y	Mitsui Chemicals Agro, Inc.
A 6.6.7/05	[REDACTED]	1985a	MTI-500 α -CO: Assessment of its mutagenic potential in amino-acid auxotrophs of <i>Salmonella typhimurium</i> and <i>Escherichia coli</i> to comply with the testing guidelines of the Japanese Ministry of Agriculture, Forestry and Fisheries (1985) [REDACTED] Report No. 85/MT0020/433 Landis Kane Consulting, Document No. 500-5-42 GLP, not published	Y	Mitsui Chemicals Agro, Inc.
A 6.6.7/06	[REDACTED]	1985b	MTI-500 α -CO: Assessment of its ability to cause lethal DNA damage in strains of <i>Escherichia coli</i> [REDACTED] report No. 85/MT0022/504 Landis Kane Consulting, Document No. 500-5-44 GLP, not published	Y	Mitsui Chemicals Agro, Inc.
A 6.6.7/07	[REDACTED]	1985b	<i>In vitro</i> assessment of the clastogenic activity of MTI-500 α -CO in cultured human peripheral lymphocytes [REDACTED] Report No. 85/MT0021/711 Landis Kane Consulting, Document No. 500-5-43 GLP, not published	Y	Mitsui Chemicals Agro, Inc.

Section A6, Toxicological and Metabolism Studies on the Active Substance

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/N	Owner
A 6.7/01 → A 6.5.1/01	[REDACTED]	1986a	Ethofenprox (MTI-500) Potential tumorigenic and toxic effects in prolonged dietary administration to rats [REDACTED] Report No. MTC 59/85581 Landis Kane Consulting, Document No. 500-5-24 GLP, not published	Y	Mitsui Chemicals Agro, Inc.
A 6.7/02 → A 6.5.1/02	[REDACTED]	1986b	Ethofenprox (MTI-500) Potential tumoregenic and toxic effects in prolonged dietary administration to mice [REDACTED], Report No. MTC 59/85582 Landis Kane Consulting, Document No. 500-5-25 GLP, not published	Y	Mitsui Chemicals Agro, Inc.
A 6.8.1.1 /01	[REDACTED]	1985a	Effect of ethofenprox (MTI-500) on fertility and pregnancy of the rat [REDACTED] Report No. MTC 66/84668 Landis Kane Consulting, Document No. 500-5-33 GLP, not published	Y	Mitsui Chemicals Agro, Inc.
A 6.8.1.1 /02	[REDACTED]	1985b	Effect of ethofenprox (MTI-500) on pregnancy of the rat with rearing to maturation of the F1 generation [REDACTED] Report No. MTC 64/85422 Landis Kane Consulting, Document No. 500-5-34 GLP, not published	Y	Mitsui Chemicals Agro, Inc.
A 6.8.1.1 /03	[REDACTED]	1985c	Effect of ethofenprox (MTI-500) on the peri and post natal period of the rat with rearing to maturation of the F1 offspring [REDACTED], Report No. MTC 65/85423 Landis Kane Consulting, Document No. 500-5-35 GLP, not published	Y	Mitsui Chemicals Agro, Inc.
A 6.8.1.2 /01	[REDACTED]	1985	Effect of etofenprox (MTI-500) on pregnancy of the rabbit Re-issued amended pages on December 20, 1985 [REDACTED] Report No. MTC 85(84)/85444 Landis Kane Consulting, Document No. 500-5-36 GLP, not published	Y	Mitsui Chemicals Agro, Inc.

Section A6, Toxicological and Metabolism Studies on the Active Substance

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/ N	Owner
A 6.8.1.2 /02	[REDACTED]	2000	Rabbit developmental toxicity study with etofenprox [REDACTED], Report No. 6648-146 Landis Kane Consulting, Document No. 500-5-37 GLP, not published	Y	Mitsui Chemicals Agro, Inc.
A 6.8.2/01	[REDACTED]	1985d	Effect of ethofenprox (MTI-500) on multiple generations of the rat Re-issued amended pages on January 07, 1985 [REDACTED], Report No. MTC 67/85706 Landis Kane Consulting, Document No. 500-5-32 GLP, not published	Y	Mitsui Chemicals Agro, Inc.
A 6.9/01	[REDACTED]	2002	Acute oral gavage neurotoxicity study with MTI-500 in rats [REDACTED], Report No. 6648-154 Landis Kane Consulting, Document No. 500-5-06 GLP, not published	Y	Mitsui Chemicals Agro, Inc.
A 6.9/02	[REDACTED]	2003a	13-week dietary neurotoxicity study with MTI-500 in rats [REDACTED] Report No. 6648-153 Landis Kane Consulting, Document No. 500-5-47 GLP, not published	Y	Mitsui Chemicals Agro, Inc.
A 6.9/03	[REDACTED]	2003	Etofenprox developmental neurotoxicity study in the rat by oral (dietary) administration [REDACTED] Report No. MTU 215/032731 Landis Kane Consulting, Document No. 500-5-48 GLP, not published	Y	Mitsui Chemicals Agro, Inc.
A 6.9/04	Burton D.A.	2002	Etofenprox – Validation of an analytical method for the determination of Etofenprox in UAR VRF1 (VRF1) Diet Huntingdon Life Sciences Ltd., Report No. MTU/222/1023183 Landis Kane Consulting, Document No. 500-5-05 GLP, not published	Y	Mitsui Chemicals Agro, Inc.
A 6.10	[REDACTED]	2003b	4-week dietary investigative study on thyroid function and hepatic microsomal enzyme induction with MTI-500 in rats [REDACTED] Report No. 6648-156 Landis Kane Consulting, Document No. 500-5-83 GLP, not published	Y	Mitsui Chemicals Agro, Inc.
A 6.11/01 → A 6.1.1/03	[REDACTED]	1982a	Report on acute toxicity study of MTI-500 (ethofenprox) in rats [REDACTED] Report No. A-82-27~34 Landis Kane Consulting, Document No. 500-5-08 Not GLP, not published	Y	Mitsui Chemicals Agro, Inc.

Section A6, Toxicological and Metabolism Studies on the Active Substance

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/N	Owner
A 6.11/02 → A 6.1.1/04	[REDACTED]	1982b	Report on acute toxicity study of MTI-500 (ethofenprox) in mice [REDACTED] Report No. A-82-35-42 Landis Kane Consulting, Document No. 500-5-09 Not GLP, not published	Y	Mitsui Chemicals Agro, Inc.
A 6.11/03	Kamiya J., Yoshiwara K., Saito S., Takahashi Y., Oseki K., Shimizu H., Kawazura H., Shiga Y., Yoshida M., Hayakawa M.	1985	General pharmacology of MTI-500 Institute of Biological Sciences, Mitsui Pharmaceuticals Inc., Japanese Pharmacology & Therapeutics, Vol.13 (11), 229-244 (1985) Landis Kane Consulting, Document No. 500-5-46 Not GLP, published	N	Public information
A 6.12.1	Yamazaki Y.	1992	Health report from the Industrial Hygiene Section, Ohmuta Factory Mitsui Toatsu Chemicals, Inc., Report No. not specified Landis Kane Consulting, Document No. 500-5-49 not GLP, not published	Y	Mitsui Chemicals Agro, Inc.
A 6.12.7 → A 2.7/02	Anony- mous	2003a	MSDS of etofenprox technical Mitsui Chemicals, Inc., MSDS No: 622141E2 Landis Kane Consulting, Report No. 500-3-02 Not GLP, published	N	Public information
A 6.12.8 → A 2.7/02	Anony- mous	2003a	MSDS of etofenprox technical Mitsui Chemicals, Inc., MSDS No: 622141E2 Landis Kane Consulting, Report No. 500-3-02 Not GLP, published	N	Public information

Section A7, Ecotoxicological Profile including Environmental Fate and Behaviour of the Active Substance

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/N	Owner
A 7.1.1.1.1 /01	van der Gaauw A.	2001	¹⁴ C-etofenprox: hydrolysis at three different pH values RCC Ltd, Report No. 731158 Landis Kane Consulting, Document No. 500-2-20 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 7.1.1.1.1 /02	Clayton M.A., McCorquodale G.Y., Paterson K.	2003	Hydrolytic stability of [¹⁴ C]-alpha-CO in buffered aqueous solution Inveresk Research, Report No. 21993 Landis Kane Consulting, Document No. 500-7-09 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 7.1.1.1.2 /01	van der Gaauw A.	2003	Aqueous photolysis of [¹⁴ C]-etofenprox under laboratory conditions and determination of quantum yield RCC Ltd, Report No. 755526 Landis Kane Consulting, Document No. 500-2-21 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 7.1.1.1.2 /02	Clayton M.A., McCorquodale G.Y.	2003	Artificial sunlight photodegradation of [¹⁴ C]-alpha-CO in buffered aqueous solution Inveresk Research, Report No. 21971 Landis Kane Consulting, Document No. 500-7-10 Not GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 7.1.1.2.1	Thus J.L.G., van der Laan-Straathof J.M.Th., Keetelaar-Jansen W.A.J.	1993	Biodegradation of ¹⁴ C-etofenprox in an adapted modified Sturm test Solvay Duphar B.V., Report No. C.DNL.62.002 Landis Kane Consulting, Document No. 500-7-12 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 7.1.1.2.1 /02	Thus J.L.G., van der Laan-Straathof J.M.Th.	1992	Determination of the biodegradability of etofenprox in a closed bottle test Solvay Duphar B.V., Report No. C.DNL.62.001 Landis Kane Consulting, Document No. 500-7-11 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 7.1.2.2.2 /01	Lewis C.J.	2001	(¹⁴ C)-MTI-500: degradation and retention in water-sediment systems and amendment dated July 22, 2002 Covance Laboratories Ltd., Report No. CLE 719/6-D2142 Landis Kane Consulting, Document No. 500-7-13 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 7.1.2.2.2 /02	Lewis C.J.	2002	(¹⁴ C)-MTI-500: recovery of radioactivity, isolation and analysis of a degradation product from a water-sediment system Covance Laboratories Ltd., Report No. CLE 719/14-D2149 Landis Kane Consulting, Document No. 500-7-14 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.

Section A7, Ecotoxicological Profile including Environmental Fate and Behaviour of the Active Substance

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/N	Owner
A 7.1.2.2.2 /03	Mirbach M.	2005	Etofenprox: estimation of the degradation in sediment Landis Kane Consulting, Report No. 05-alpha-31 Landis Kane Consulting, Document No. 500-7-44 Not GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 7.1.3	Völkel W.	1999	Adsorption / desorption of MTI-500 (etofenprox) on three soils RCC Ltd, Report no: 663175 Landis Kane Consulting, Document No. 500-7-06 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 7.2.2.1	Völkl S.	2001	¹⁴ C-etofenprox: degradation and metabolism in four soils incubated under aerobic conditions - first amendment dated February 26, 2002 - second amendment dated June 03, 2003 RCC Ltd, Report No. 728987 Landis Kane Consulting, Document No. 500-7-01 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 7.2.2.4	Mamouni A	2002b	Photolysis of ¹⁴ C-MTI-500 on soil surface under laboratory conditions RCC Ltd, Report No. 800616 Landis Kane Consulting, Report No. 500-7-04 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 7.2.3.2	Warncke U.	1998	Leaching behaviour of etofenprox after application of Trebon 30 EC Urania Agrochem GmbH, Chemical Laboratories, Report No. C96VSI03 Landis Kane Consulting, Document No. 500-7-07 GLP, unpublished	Y	[REDACTED]
A 7.3.1	Bates M.	2001d	MTI-500: estimation of the photochemical oxidative degradation - Amended final report from January 31, 2001 Covance Laboratories Ltd., Report No. 719/12-D2141 Landis Kane Consulting, Document No. 500-2-27 Not GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 7.4.1.1 /01	[REDACTED]	1995a	Etofenprox technical - acute toxicity to Rainbow trout (<i>Oncorhynchus mykiss</i>) under flow-through conditions [REDACTED] Report No. 94-12-5625 Landis Kane Consulting, Document No. 500-8-05 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 7.4.1.1 /02	[REDACTED]	1995b	Etofenprox technical - acute toxicity to Bluegill sunfish (<i>Lepomis macrochirus</i>) under flow-through conditions [REDACTED] Report No. 95-1-5653 Landis Kane Consulting, Document No. 500-8-07 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.

Section A7, Ecotoxicological Profile including Environmental Fate and Behaviour of the Active Substance

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/N	Owner
A 7.4.1.1 /03	[REDACTED]	2002a	Acute toxicity of α -CO to Rainbow trout (<i>Oncorhynchus mykiss</i>) in a 96-hour flow-through test [REDACTED] Report No. 841573 Landis Kane Consulting, Document No. 500-8-09 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 7.4.1.2 /01	Gries T.	2003	Etofenprox technical: static renewal acute toxicity test with Daphnids (<i>Daphnia magna</i>) Springborn Smithers Laboratories (Europe) AG, Report No. 1045.000.110 Landis Kane Consulting, Document No. 500-8-51 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 7.4.1.2 /02	Bätscher R.	2002b	Acute toxicity of α -CO to <i>Daphnia magna</i> in a 48-hour immobilization test RCC Ltd, Report No. 841575 Landis Kane Consulting, Document No. 500-8-10 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 7.4.1.3 /01	Gries T., Purghart V.	2003	Etofenprox technical: static toxicity test with the freshwater algae <i>Pseudokirchneriella subcapitata</i> Springborn Smithers Laboratories (Europe) AG, Report No. 1045.000.430 Landis Kane Consulting, Document No. 500-8-52 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 7.4.1.3 /02	Bätscher R.	2002c	Toxicity of α -CO to <i>Pseudokirchneriella subcapitata</i> (formerly <i>Selenastrum capricornutum</i>) in a 96-hour algal growth inhibition test RCC Ltd, Report No. 841577 Landis Kane Consulting, Document No. 500-8-11 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 7.4.1.4	Czech P.	2002	Toxicity of etofenprox to activated sludge in a respiration inhibition test RCC Ltd, Report No. 841615 Landis Kane Consulting, Document No. 500-8-50 GLP, unpublished	Y	[REDACTED]
A 7.4.3.1	[REDACTED]	1997	Etofenprox technical: fish (rainbow trout), prolonged toxicity test, 21 days (semi-static) [REDACTED] Report No. 970304SP Landis Kane Consulting, Document No. 500-8-13 GLP, unpublished	Y	[REDACTED]
A 7.4.3.2	[REDACTED]	2005	Toxic effects of MTI-500 (Etofenprox) to zebra fish (<i>Brachydanio rerio</i>) in an early-life stage toxicity test ; [REDACTED] Report no. 853517 Landis Kane Consulting, Document No. 500-8-66 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.

Section A7, Ecotoxicological Profile including Environmental Fate and Behaviour of the Active Substance

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/ N	Owner
A 7.4.3.3.1		2002	Bioconcentration: flow-through fish test with MTI-500 (Trebou) in Bluegill sunfish Report No. 762254 Landis Kane Consulting, Document No. 500-8-15 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 7.4.3.4	Groenefeld A.H.C., Berends A.G., van der Laan J.M.Th., van Dijk N.R.M.	1993	The chronic toxicity of ¹⁴ C-eto fenprox to <i>Daphnia magna</i> Solvay Duphar B.V., Report No. C,DNL.51,007 Landis Kane Consulting, Document No. 500-8-18 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 7.4.3.5.1 /01	Memmert U.	2002a	Effect of MTI-500 on larvae of <i>Chironomus riparius</i> in a 10-day toxicity test RCC Ltd, Report No. 803777 Landis Kane Consulting, Document No. 500-8-21 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 7.4.3.5.1 /02	Memmert U.	2002b	Acute toxicity of 4'-OH to first - instar larvae of the midge <i>Chironomus riparius</i> RCC Ltd, Report No. 841579 Landis Kane Consulting, Document No. 500-8-12 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 7.4.3.5.1 /03	Memmert U.	2002c	Effect of MTI-500 on the development of sediment-dwelling larvae of <i>Chironomus riparius</i> in a water-sediment system RCC Ltd, Report No. 803608 Landis Kane Consulting, Document No. 500-8-22 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 7.5.1.1	Kölzer U.	2003	Assessment of the side effects of etofenprox on the activity of the soil microflora Arbeitsgemeinschaft GAB Biotechnologie GmbH & IFU Umweltanalytik GmbH, Report No. 20031050/01-ABMF Landis Kane Consulting, Document No. 500-8-53 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 7.5.1.2	Roberts N.L., Hakin B.	1989	The subacute toxicity (LC50) of etofenprox (MTI-500) to the earthworm (<i>Eisenia foetida</i>) Huntingdon Research Centre Ltd., Report No. MTF 2/881276 Landis Kane Consulting, Document No. 500-8-25 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 7.5.1.3	Büche, C.	2004	Terrestrial (non-target) plant test with MTI-500 30%EC: seedling emergence and seedling growth & vegetative vigour test. RCC Ltd., Report No. 853515 Landis Kane Consulting, Document No. 500-8-64 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.

Section A7, Ecotoxicological Profile including Environmental Fate and Behaviour of the Active Substance

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/N	Owner
A 7.5.3.1.1	[REDACTED]	1985	The acute toxicity (LD50) of MTI-500 (ethofenprox) to the Mallard duck [REDACTED] Report No. MTC 77C/84793 Landis Kane Consulting, Document No. 500-8-01 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 7.5.3.1.2/01	[REDACTED]	1984a	The subacute dietary toxicity (LC50) of MTI-500 (etofenprox) to the Bobwhite quail - amended final report dated June 27, 1985 - signature pages added: August 21, 1985 [REDACTED], Report No. MTC 77A/84795/2 Landis Kane Consulting, Document No. 500-8-02 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 7.5.3.1.2/02	[REDACTED]	1984b	The subacute dietary toxicity (LC50) of MTI-500 (etofenprox) to the Mallard duck - amended final report dated June 26, 1985 - signature pages added: August 21, 1985 [REDACTED] Report No. MTC 77B/84795/2 Landis Kane Consulting, Document No. 500-8-03 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 7.5.3.1.3	[REDACTED]	1996	MTI-500 Effects on reproduction in Bobwhite quail after dietary administration [REDACTED] Report No. MTC 270/962282 Landis Kane Consulting, Document No. 500-8-04 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
A 7.5.6	Tanaka T.	2005	Insecticidal activity of the environmental metabolites of etofenprox. Mitsui Chemicals, Inc. Landis Kane Consulting, Document No. 500-8-67 Not GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.