

**Section 7.5.1.3**                      **Terrestrial plant toxicity**  
**Annex Point IIIA-XIII.3.4**

morphology on Day 10 and 14. The plants recovered and did not show any morphological traits, that could be classified as visual injury like chlorosis, necrosis, wilting, leaf or stem deformation

4.1.4 Plant height                      Vegetative vigour test: no visual phytotoxicity symptoms for any of the 6 test species.  
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.

4.1.5 Plant dry weights                      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.

4.1.5 Plant dry weights                      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): EC<sub>50</sub>, EC<sub>25</sub> and LOEC > 200 g a.i./ha, > 200 g a.i./ha, NOEC ≥ 200 g a.i./ha.  
- Lettuce: EC<sub>50</sub>, EC<sub>25</sub> > 200 g a.i./ha, > 200 g a.i./ha, NOEC < 200 g a.i./ha, LOEC = 200 g a.i./ha.

4.1.8 Effect data                      Vegetative vigour test: see table A7\_5\_1\_3-7.  
All 6 species: EC<sub>50</sub>, EC<sub>25</sub> 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

**Section 7.5.1.3 Terrestrial plant toxicity**  
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and September, 2003),  
Proposal for a new guideline OECD 227  
OPPTS 850.4100  
OPPTS 850.4150  
No deviations.

**5.2 Results and discussion**

- 5.2.1 EC<sub>25</sub> > 200 g a.i./ha (all 6 species, both tests)
- 5.2.2 EC<sub>50</sub> > 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
- 5.3.2 Deficiencies No

x

x

Table A7\_5\_1\_3-I: Test plants.

	Family	Species	Common name	Source (seed/plant)
<b>Dicotyledonae</b>	<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
<b>Monocotyledonae</b>	<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 (spray volume equivalent to 200 /ha)
Dose rates	
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 $\mu\text{mol.m}^{-2}.\text{s}^{-1}$ - Vegetative vigour test : 2 to 633 $\mu\text{mol.m}^{-2}.\text{s}^{-1}$
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><b>3.1.4 Composition of Product</b></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 &gt; 295.8 g technical a.i./ 1000ml Etofenprox which corresponds to &gt;287.5 g pure a.i./ 1000 ml Etofenprox; Tolerance: <math>\pm 25</math> g/1000 ml;</p> <p><b>3.4 Testing procedure</b></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><b>4.1.8.Effect data and 5.2, correction:</b></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 &gt; 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><b>5.3.1. Reliability:</b></p> <p>typing error: 1</p>
Conclusion	See below
Reliability	1
Acceptability	Acceptable
Remarks	-

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

				Official use only
		<b>1 REFERENCE</b>		
<b>1.1</b>	<b>Reference</b>	<p>██████████ (1996): MTI-500 – Effects on reproduction in Bobwhite quail after dietary administration; ██████████                      ██████████ unpublished report no. MTC 270/962282                      (October 29, 1996).                      Dates of experimental work: October 06, 1995 – May 27, 1996</p>		
<b>1.2</b>	<b>Data protection</b>	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.		
		<b>2 GUIDELINES AND QUALITY ASSURANCE</b>		
<b>2.1</b>	<b>Guideline study</b>	Yes EPA, Subdivision E, Series 71, § 71-4		
<b>2.2</b>	<b>GLP</b>	Yes		
<b>2.3</b>	<b>Deviations</b>	No		
		<b>3 METHOD</b>		
<b>3.1</b>	<b>Test material</b>	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 <sup>-7</sup> 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).		
<b>3.2</b>	<b>Administration of the test substance</b>	Corn oil (see table A7_5_3_1_2-1)		
<b>3.3</b>	<b>Testing procedure</b>			
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 /    see table A7\_5\_3\_1\_2-3  
Observation

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 was performed  
**Range finding test**

4.1.1    Concentration    0, 100, 300 and 1000 ppm

4.1.2    Number/ percentage    No evidence for any treatment related effects  
of animals showing  
adverse effects

4.1.3    Nature of adverse    See 4.1.3  
effects

**4.2      Results test**  
**substance**

4.2.1    Applied    Dietary inclusion at 0, 30, 300 and 1000 ppm  
concentrations

4.2.2    Effect data    see table A7\_5\_3\_1\_3-5;  
(Mortality and    NOEC = 1000 ppm (95 % c.l. could not be determined due to the  
reproductivity)    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    Not performed  
analysis

4.2.6    Other effects    no other observations differentiating organisms in tests and controls

**4.3      Results of controls**

4.3.1    Number/ percentage    No adverse effects were observed in control and treated animals  
of animals showing  
adverse effects

4.3.2    Nature of adverse    effects

**5      APPLICANT'S SUMMARY AND CONCLUSION**

**5.1      Materials and**    Guideline: EPA, Subdivision E, Series 71, § 71-4  
**methods**    Valid study

**5.2      Results and**    Dietary administration of up to 1000 ppm etofenprox to the Bobwhite  
**discussion**    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**

<b>5.3</b>	<b>Conclusion</b>	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 <sup>2</sup> /bird]	2 (1 male/1 female) → ca. 600 cm <sup>2</sup> /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
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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	



<b>Evaluation by Competent Authorities</b>	
	<b>EVALUATION BY RAPPORTEUR MEMBER STATE</b>
<b>Date</b>	27.05.2005
<b>Materials and methods</b>	<p><b>3.1.2 Specification</b> 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><b>3.1.4 Purity:</b> 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>
<b>Conclusion</b>	Agree with the applicant's version
<b>Reliability</b>	1
<b>Acceptability</b>	Acceptable
<b>Remarks</b>	-

**Section A7.5.3.2/01 Non Target Arthropods, test on artificial substrates**  
**Annex Point IIIA-XIII.3.2**

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		<b>1 REFERENCE</b>
<b>1.1 Reference</b>		Feije, I.R. (2005a): Etofenprox: An acute oral toxicity test to evaluate the effect on survival of the honeybee <i>Apis mellifera</i> L. MITOX, Amsterdam, The Netherlands; unpublished report no. LK004AMO (July 26, 2005). Dates of experimental work: May 31, 2005 – June 4, 2005
<b>1.2 Data protection</b>		Yes
1.2.1 Data owner		<span style="background-color: black; color: black;">[REDACTED]</span> 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.
		<b>2 GUIDELINES AND QUALITY ASSURANCE</b>
<b>2.1 Guideline study</b>		Yes EPPO 170 OECD 213 (1998)
<b>2.2 GLP</b>		Yes
<b>2.3 Deviations</b>		No
		<b>3 MATERIALS AND METHODS</b>
<b>3.1 Test material</b>		etofenprox
3.1.1 Lot/Batch number		53045
3.1.2 Specification		As given in section 2
3.1.3 Description		White crystalline solid
3.1.4 Purity		99.6 %
3.1.5 Stability		No information in the report.
3.1.6 Further relevant properties		No information in the report.
3.1.7 Method of analysis		No information in the report.
<b>3.2 Reference substance</b>		Yes: dimethoate 400 g/l tested parallel
3.2.1 Method of analysis for reference substance		Not given in the report.
<b>3.3 Testing procedure</b>		



**Section A7.5.3.2/01**      **Non Target Arthropods, test on artificial substrates**  
**Annex Point IIIA-XIII.3.2**

- 3.3.1 Preparation of the test substance
- Etofenprox: a stock test solution was prepared by solving 250 mg test product in 100 ml solution (solvent: sugar water 50%, after 1 ml acetone). Test solutions were prepared as follows:
- 1.00 µg a.i./bee: 1 ml stock dissolved in 50% sugar water up to 25 ml
  - 0.30 µg a.i./bee: 0.3 ml stock dissolved in 50% sugar water up to 25 ml (=solution A)
  - 0.10 µg a.i./bee: 0.1 ml stock dissolved in 50% sugar water up to 25 ml (=solution B)
  - 0.03 µg a.i./bee: 5 ml of solution A dissolved in 50% sugar water up to 50 ml
  - 0.01 µg a.i./bee: 5 ml of solution B dissolved in 50% sugar water up to 50 ml
- Toxic reference: A stock solution of dimethoate was prepared by dissolving 250 µl product in 100 ml solution (solvent: sugar water 50%). Test solutions were prepared as follows:
- 0.1 µg a.i./bee: 250 µl stock dissolved in 50% sugar water up to 25 ml
  - 0.2 µg a.i./bee: 500 µl stock dissolved in 50% sugar water up to 25 ml
  - 0.3 µg a.i./bee: 750 µl stock dissolved in 50% sugar water up to 25 ml
- Control: the sugar-solution used as the solvent
- 3.3.2 Application of the test substance
- After ca. 2 hours starvation, application started by adding a small plate with the test item/sugar solution.
- 3.3.3 Test organisms
- Apis mellifera* L., from the outer broodless frames, mainly occupied by workers of at least 21 days old.
- 3.3.4 Test system
- Test unit: before application bees were collected in transparent plastic aquarium cages with approximate dimensions 19 cm \* 34 cm and 19 cm high. Then the bees were briefly anesthetized with CO<sub>2</sub> and distributed over various so-called Lieberfelder cages (i.e. wooden boxes with glass plates at the front and the rear; internal dimensions: 9 cm \* 10,5 cm \* 4 cm). The roof has two holes, one for a feeding bottle with 50 % sugar solution, the other for introducing/removing the bees – the latter is closed with a cork. After finishing of the test solutions, feeding bottles with Bee Fit were added.
- Food: commercially produced 73 % (dry weight) sugar solution Bee Fit® HM, diluted with demineralised water to approximately 50 % sugar. Bee Fit® HM is composed of Bee Fit enriched and High Maltose corn syrup that is enzymatically obtained from cereals. The sugar spectrum in the high-maltose corn syrup resembles that of nectar. It contains saccharose, fructose, glucose, maltose and higher sugars.
- 3.3.5 Test conditions
- 25 ± 2°C, 50-70 % relative humidity, in continuous darkness.
- 3.3.6 Test duration
- 96 hours

**Section A7.5.3.2/01 Non Target Arthropods, test on artificial substrates**  
**Annex Point IIIA-XIII.3.2**

- |       |  |   |
|-------|--|---|
| 3.3.7 | Test parameter / Examination               | mortality   |
| 3.3.8 | Monitoring of test substance concentration | No  |
| 3.3.9 | Statistics                                 | Mortality data were analysed statistically using Fisher's exact test. Calculation of LD <sub>50</sub> values was established through Probit analysis. |

**4 RESULTS**

**4.1 Results of test substance**

- |       |  |   |
|-------|--|---|
| 4.1.1 | Initial concentrations of test substance | 0.01, 0.03, 0.10, 0.30 and 1.00 µg a.i./bee |
| 4.1.2 | Effect data (Mortality / Fecundity)      | See table 4.1.                              |

**4.2 Results of controls**

- |       |                       |  |
|-------|-----------------------|--|
| 4.2.1 | Mortality / Fecundity | Mortality assessed 4, 24, 48, 72 and 96 hours after application. |
|-------|-----------------------|--|

**4.3 Test with reference substance**

- |       |                |                              |
|-------|----------------|------------------------------|
|       |                | Performed                    |
| 4.3.1 | Concentrations | 0.1, 0.2 and 0.3 µg a.i./bee |
| 4.3.2 | Results        | See table 4.1.               |

**5 APPLICANT'S SUMMARY AND CONCLUSION**

**5.1 Materials and methods**

Approximately 2 hours before application of etofenprox, bees were collected from the outer broodless frames of the colony. After the bees were shortly anesthetized with CO<sub>2</sub> and distributed over the various test units (10 bees per replicate; 4 replicates for each treatment). After a 2-hour starvation period test products were offered on a small plate (diameter ca. 2cm) filled with 100 µl sugar water 50% (10 µl per bee) in which the test product was solved. After approximately 2 hours the bees had consumed all test solution. Application were under ambient laboratory conditions.

**5.2 Results and discussion**

- |       |                       |  |
|-------|-----------------------|--|
| 5.2.1 | LD <sub>50</sub>      | 0.0238 µg a.i./bee after 96 hours of exposure. |
| 5.2.2 | Reproductive capacity | not assessed.                                  |

**5.3 Conclusion**




<b>Evaluation by Competent Authorities</b>	
	<b>EVALUATION BY RAPPORTEUR MEMBER STATE</b>
<b>Date</b>	March 2011
<b>Materials and methods</b>	Agree with the applicant's version
<b>Conclusion</b>	Agree with the applicant's version
<b>Reliability</b>	1
<b>Acceptability</b>	Acceptable
<b>Remarks</b>	-

Section A7.5.3.2/02  
Annex Point IIIA-XIII.3.2

Non Target Arthropods, test on artificial substrates

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		<b>1 REFERENCE</b>
<b>1.1 Reference</b>		Feije, I.R. (2005b): Etofenprox: An acute contact toxicity test to evaluate the effect on survival of the honeybee <i>Apis mellifera</i> L. MITOX, Amsterdam, The Netherlands; unpublished report no. LK006AMT (October 4, 2005). Dates of experimental work: September 12, 2005 – September 15, 2005
<b>1.2 Data protection</b>		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.
		<b>2 GUIDELINES AND QUALITY ASSURANCE</b>
<b>2.1 Guideline study</b>		Yes EPPO 170 OECD 214 (1998)
<b>2.2 GLP</b>		Yes
<b>2.3 Deviations</b>		No
		<b>3 MATERIALS AND METHODS</b>
<b>3.1 Test material</b>		etofenprox
3.1.1 Lot/Batch number		53045
3.1.2 Specification		As given in section 2
3.1.3 Description		White crystalline solid
3.1.4 Purity		99.6 %
3.1.5 Stability		No information in the report.
3.1.6 Further relevant properties		No information in the report.
3.1.7 Method of analysis		No information in the report.
<b>3.2 Reference substance</b>		Yes: dimethoate 400 g/l tested parallel
3.2.1 Method of analysis for reference substance		Not given in the report.
<b>3.3 Testing procedure</b>		

**Section A7.5.3.2/02**      **Non Target Arthropods, test on artificial substrates**  
**Annex Point IIIA-XIII.3.2**

- 3.3.1 Preparation of the test substance
- Etofenprox: a stock test solution was prepared by solving 200 mg test product in 200 ml acetone. Test solutions were prepared as follows:
- 0.005 µg a.i./bee: 125 µl stock dissolved acetone up to 25 ml
  - 0.015 µg a.i./bee: 375 µl stock dissolved acetone up to 25 ml
  - 0.05 µg a.i./bee: 1.25 ml stock dissolved acetone up to 25 ml
  - 0.15 µg a.i./bee: 3.75 ml stock dissolved acetone up to 25 ml
  - 0.5 µg a.i./bee: 12.5 ml stock dissolved acetone up to 25 ml
- Toxic reference: A stock solution of dimethoate was prepared by dissolving 250 µl product in 100 ml acetone. Test solutions were prepared as follows:
- 0.03 µg a.i./bee: 750 µl stock dissolved in acetone up to 25 ml
  - 0.10 µg a.i./bee: 2.5 ml stock dissolved in acetone up to 25 ml
  - 0.30 µg a.i./bee: 7.5 ml stock dissolved in acetone up to 25 ml
- Control: acetone, the used solvent
- 3.3.2 Application of the test substance
- The test products were applied using a calibrated Arnold Micro-applicator. For application each bee was picked up by gently grabbing a leg with a pair of forceps. Subsequently the bee was positioned such that a 1 µl droplet could be applied to the ventral part of the thorax between the base of the 2<sup>nd</sup> and 3<sup>rd</sup> pair of legs. To facilitate application the bees were anaesthetized with CO<sub>2</sub> for a short period (10-20 seconds) just before application.
- 3.3.3 Test organisms
- Apis mellifera* L., from the outer broodless frames, mainly occupied by workers of at least 21 days old.
- 3.3.4 Test system
- Test unit: before application bees were collected in transparent plastic aquarium cages with approximate dimensions 19 cm \* 34 cm and 19 cm high. After application, the bees were transferred into Lieberfelder cages (i.e. wooden boxes with glass plates at the front and the rear; internal dimensions: 9 cm \* 10,5 cm \* 4 cm). The roof has two holes, one for a feeding bottle with 50 % sugar solution, the other for introducing/removing the bees – the latter is closed with a cork.
- Food: commercially produced 73 % (dry weight) sugar solution Bee Fit® HM, diluted with demineralised water to approximately 50 % sugar. Bee Fit® HM is composed of Bee Fit enriched and High Maltose corn syrup that is enzymatically obtained from cereals. The sugar spectrum in the high-maltose corn syrup resembles that of nectar. It contains saccharose, fructose, glucose, maltose and higher sugars.
- 3.3.5 Test conditions
- 25 ± 2°C, 50-70 % relative humidity, in continuous darkness
- 3.3.6 Test duration
- 72 hours
- 3.3.7 Test parameter / Examination
- mortality

**Section A7.5.3.2/02 Non Target Arthropods, test on artificial substrates**  
**Annex Point IIIA-XIII.3.2**

- 3.3.8 Monitoring of test substance concentration No
- 3.3.9 Statistics Mortality data were analysed statistically using Fisher's exact test. Calculation of LD<sub>50</sub> values was established through Probit analysis.

**4 RESULTS**

**4.1 Results of test substance**

- 4.1.1 Initial concentrations of test substance 0.005, 0.015, 0.05, 0.15 and 0.5 µg a.i./bee
- 4.1.2 Effect data (Mortality / Fecundity) See table 4.1.

**4.2 Results of controls**

- 4.2.1 Mortality / Fecundity Mortality assessed 4, 24, 48 and 72 hours after application.

**4.3 Test with reference substance**

- 4.3.1 Concentrations Performed  
0.03, 0.10 and 0.30 µg a.i./bee
- 4.3.2 Results See table 4.1.

**5 APPLICANT'S SUMMARY AND CONCLUSION**

**5.1 Materials and methods**

*Apis mellifera* L. was exposed in groups of 10 per unit to the test solutions. There were 3 units for all treatments. A 1 µl droplet of the test substance was applied (using an Arnold Micro-applicator) to the ventral part of the thorax between the base of the 2<sup>nd</sup> and 3<sup>rd</sup> pair of legs. To facilitate application the bees were anaesthetized with CO<sub>2</sub> for a short period (10-20 seconds) just before application.

**5.2 Results and discussion**

- 5.2.1 LD<sub>50</sub> 0.0145 µg a.i./bee after 72 hours of exposure.
- 5.2.2 Reproductive capacity not assessed.

**5.3 Conclusion**

- 5.3.1 Other Conclusions At the end of the test exposure to etofenprox, the doses of 0.005, 0.015, 0.05, 0.15, 0.5 µg a.i./bee had statistically effect on survival of *Apis mellifera* compared to the control.
- 5.3.2 Reliability 1

**Section A7.5.3.2/02 Non Target Arthropods, test on artificial substrates**  
**Annex Point IIIA-XIII.3.2**

5.3.3 Deficiencies No

*Table 4.1. Mortality (M) and Abbott's corrected mortality (A) of honeybees after 4 days.*

Treatment	4 hours		24 hours		48 hours		72 hours	
	M (%)	A (%)	M (%)	A (%)	M (%)	A (%)	M (%)	A (%)
Control	0	-	0	-	0	-	0	-
Dimethoate								
0.03 (µg a.i./bee)	0	0	0	0	0	0	0	0
0.10 (µg a.i./bee)	0	0	7	7	20	20	20	20
0.30 (µg a.i./bee)	0	0	100	100	100	100	100	100
Etofenprox								
0.005 (µg a.i./bee)	0	0	0	0	33	33	33	33
0.015 (µg a.i./bee)	0	0	27	27	60	60	60	60
0.050 (µg a.i./bee)	7	7	50	50	57	57	57	57
0.150 (µg a.i./bee)	30	30	73	73	80	80	80	80
0.500 (µg a.i./bee)	50	50	90	90	97	97	97	97



<b>Evaluation by Competent Authorities</b>	
	<b>EVALUATION BY RAPPORTEUR MEMBER STATE</b>
<b>Date</b>	March 2011
<b>Materials and methods</b>	Agree with the applicant's version
<b>Conclusion</b>	Agree with the applicant's version
<b>Reliability</b>	1
<b>Acceptability</b>	Acceptable
<b>Remarks</b>	-

**Section A7.5.3.2/03 Non Target Arthropods, test on artificial substrates**  
**Annex Point IIIA-XIII.3.2**

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		<b>1 REFERENCE</b>
<b>1.1 Reference</b>		Bakker, F.M. (2001a): A laboratory dose-response study to evaluate the effects of MTL-500 30% EC on survival and reproduction of the parasitoid wasp <i>Aphidius rhopalosiphi</i> (DeStephani-Perez) (Hymenoptera: Braconidae). MITOX, Amsterdam, The Netherlands; unpublished report of study no. LK001ARL (December 18, 2001a). Dates of experimental work: November 6, 2001 – November 19, 2001
<b>1.2 Data protection</b>		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.
		<b>2 GUIDELINES AND QUALITY ASSURANCE</b>
<b>2.1 Guideline study</b>		Yes Mead-Briggs (1992): A laboratory method for evaluating the side-effects of pesticides on the cereal aphid parasitoid <i>Aphidius rhopalosiphi</i> (DeStephani-Perez). Mead-Briggs <i>et al.</i> (2000): A laboratory test for evaluating the effects of plant protection products on the parasitic wasp, <i>Aphidius rhopalosiphi</i> (DeStephani-Perez) (Hymenoptera, Braconidae). Polgar (1988): Guideline for testing the effect of pesticides on <i>Aphidius matricariae</i> Hal/Hym., Aphididae. Barrett <i>et al.</i> (1994): Guidance document on regulatory testing procedures for pesticides with non-target arthropods.
<b>2.2 GLP</b>		Yes
<b>2.3 Deviations</b>		No deviations to SETAC-ESCORT 2
		<b>3 MATERIALS AND METHODS</b>
<b>3.1 Test material</b>		TREBON 30% EC
3.1.1 Lot/Batch number		MA-0135
3.1.2 Specification		As given in section 2
3.1.3 Description		Light yellow clear liquid.
3.1.4 Purity		Etofenprox, 30% w/w
3.1.5 Stability		No information in the report.
3.1.6 Further relevant properties		No information in the report.
3.1.7 Method of analysis		Not applicable (TS concentration not tested)
<b>3.2 Reference substance</b>		Yes: dimethoate 400 g/L EC formulation tested parallel
3.2.1 Method of analysis for reference substance		Not applicable (concentration of reference substance not tested)

**Section A7.5.3.2/03 Non Target Arthropods, test on artificial substrates**  
**Annex Point IIIA-XIII.3.2**

**3.3 Testing procedure**

- 3.3.1 Preparation of the test substance See enclosed table A7\_5\_1\_2-1
- 3.3.2 Application of the test substance Applications were done with a calibrated laboratory sprayer (Schachtner track sprayer with a Teejet 80015 EVS spray nozzle) at a volume of 200 L water/ha
- 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
- 3.3.5 Test conditions See enclosed table A7\_5\_1\_2-4
- 3.3.6 Test duration Mortality phase: 48 hours  
Parasitism phase: 1 day  
Mummy development phase: 10 days
- 3.3.7 Test parameter / Examination The parasitoid condition (alive, affected, moribund or dead) was assessed after 48 hours of exposure  
The condition of the females was recorded after the 24 hours parasitisation  
Fecundity was assessed after 10 days by counting the number of mummies
- 3.3.8 Monitoring of test substance concentration No
- 3.3.9 Statistics The mean mortality was corrected for control mortality according to ABBOTT (1925)  
Mortality data were analyzed statistically using Fisher's Exact test ( $\alpha=0.05$ )  
The LR<sub>50</sub> values were calculated by Probit analysis  
Reproduction data were analyzed for significance using analysis of variance (ANOVA), followed by Fisher's Least Significant Difference test

**4 RESULTS**

**4.1 Results of test substance**

- 4.1.1 Initial concentrations of test substance 3.4, 5.0, 8.4, 15 and 25 µL/L TREBON 30EC (equivalent to application rates of 0.2, 0.3, 0.5, 0.9 and 1.5 g a.i./ha)
- 4.1.2 Effect data (Mortality / Fecundity) Mortality and fecundity data: see enclosed table A7\_5\_1\_2-5  
LR<sub>50</sub> value: see enclosed table A7\_5\_1\_2-5

**4.2 Results of controls**

- 4.2.1 Mortality / Fecundity Mortality and fecundity data: see enclosed table A7\_5\_1\_2-5

**4.3 Test with reference substance** Performed

- 4.3.1 Concentrations 120 mg dimethoate/ha in 200 L/ha corresponding to 1.5 µL/L

**Section A7.5.3.2/03 Non Target Arthropods, test on artificial substrates**  
**Annex Point IIIA-XIII.3.2**

4.3.2 Results see enclosed table A7\_5\_1\_2-5

**5 APPLICANT'S SUMMARY AND CONCLUSION**

**5.1 Materials and methods** As given in section 2 and 3

**5.2 Results and discussion**

5.2.1 LR<sub>50</sub> 0.42 g a.i./ha (95% confidence limits: 0.39 – 0.46 g a.i./ha)

5.2.2 Reproductive capacity not significantly affected at an application rate equivalent to 0.2 g x a.i./ha, in comparison to the control

**5.3 Conclusion**

5.3.1 Other Conclusions The mortality and the reproductive capacity of *Aphidius rhopalosiphi* were not significantly affected at an application rate equivalent to 0.2 g a.i./ha, in comparison to the control. Based on the mortality results, the 48-hour LR<sub>50</sub> of TREBON 30EC was calculated to be 0.42 g a.i./ha (95% confidence limits: 0.39 – 0.46 g a.i./ha).

5.3.2 Reliability 1

5.3.3 Deficiencies No

Table A7\_5\_1\_2-1: Preparation of TS solution.

Criteria	Details
Vehicle	Yes: deionised water
Concentration of vehicle	Stock solution was prepared in water by dissolving 0.250 ml of product in a final volume of 100 ml.
Vehicle control performed	Yes. the control was treated with deionised water with an amount of 200 L/ha

Table A7\_5\_1\_2-2: Test organisms.

Criteria	Details
Species/strain	<i>Aphidius rhopalosiphi</i> (DeStephani-Perez)
Source of the initial stock	PK Nützlingszuchten, Welzheim, Germany
Age	1-2days old adult wasps
Pre-treatment	Not applicable

Table A7\_5\_1\_2-3: Test system.

Criteria	Details
Test units	Mortality phase: cages with the 2 sprayed glass plates (12.5 x 12.5 cm) and a square metal frame (12.5 x 12.5 x 1.5 cm) Reproduction phase: acrylic cylinders (height of 20 cm tall and diameter of 11 cm covered with nylon gauze) containing untreated cereal plants ( <i>Hordeum</i> sp.; about 20-30 stems per pot) infested with aphid ( <i>Rhopalosiphum padi</i> ; approximately 50-100 aphids per plant)
Number of replicates/test concentration	4 replicates for the control (deionised water) and the test substance. 2 replicates for the reference substance.
Number of adult wasps/test concentration	15
Test performed in closed vessels due to significant volatility of test substrate	No

Table A7\_5\_1\_2-4: Test conditions.

Criteria	Mortality phase	Fecundity phase
Test temperature	25 ± 2°C	20-25°C
relative humidity	60-90%	60-90%
Light photoperiod	16 hours light / 8 hours darkness	16 hours light / 8 hours darkness
Light intensity	2650-4000 Lux	1200-1400 Lux

Table A7\_5\_1\_2-5: Mortality and reproductive capacity following treatment.

Test substance concentration (nominal)	<i>Aphidius rhopalosiphii</i>			
	Mortality after 2 days		Reproduction after 10 d	
	%	% corrected	Mummies/female/day	Reduction relative to the control
Control (deionised water)	3	-	6.6	-
0.2 g a.i./ha	5	2	5.8	13
0.3 g a.i./ha	24	22*	3.1	53*
0.5 g a.i./ha	56	54*	n.a.	n.a.
0.9 g a.i./ha	100	100*	n.a.	n.a.
1.5 g a.i./ha	100	100*	n.a.	n.a.
Reference substance	100	-	n.a.	n.a.
LR <sub>50</sub> g a.i./ha	0.42 (0.36 – 0.46)			

n.a. not assessed

\* statistically significantly different from the control (mortality: Fisher's exact test; reproduction: ANOVA/Fisher's LSD test)

( ) 95% confidence limits

<b>Evaluation by Competent Authorities</b>	
	<b>EVALUATION BY RAPPORTEUR MEMBER STATE</b>
<b>Date</b>	March 2011
<b>Materials and methods</b>	Agree with the applicant's version
<b>Conclusion</b>	<b>5.2 Results and discussion</b> 5.2.2 Reproductive capacity Significantly affected at an application rate equivalent to 0.3 g a.i/ha in comparison to the control
<b>Reliability</b>	1
<b>Acceptability</b>	Acceptable
<b>Remarks</b>	-

**Section A7.5.3.2/04**      **Non Target Arthropods, test on artificial substrates**  
**Annex Point IIIA-XIII.3.2**

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**1**      **REFERENCE**

- 1.1**      **Reference**      Bakker, F.M. (2001b): A laboratory dose-response study to evaluate the effects of MTI-500 30% EC on survival and reproduction of the predaceous mite *Typhlodromus pyri* Scheuten (Acari: Phytoseiidae). MITOX, Amsterdam, The Netherlands; unpublished report of study no. LK002TPL (December 18, 2001b).  
Dates of experimental work: November 9, 2001 – November 23, 2001

- 1.2**      **Data protection**      Yes
- 1.2.1      Data owner      XXXXXXXXXX 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  
Blümel *et al.* (2000): Laboratory residual contact test with the predatory mite *Typhlodromus pyri* Scheuten (Acari: Phytoseiidae) for regulatory testing of plant protection products.  
Bakker *et al.* (1992): Side-effects test for Phytoseiids and their rearing methods.  
Overmeer (1988): Laboratory method for testing side-effect of pesticides on the predacious mites *Typhlodromus pyri* and *Amblyseius potentillae* (Acari: Phytoseiidae).  
Barrett *et al.* (1994): Guidance document on regulatory testing procedures for pesticides with non-target arthropods.
- 2.2**      **GLP**      Yes
- 2.3**      **Deviations**      No deviations to SETAC-ESCORT 2

**3**      **MATERIALS AND METHODS**

- 3.1**      **Test material**      TREBON 30% EC
- 3.1.1      Lot/Batch number      MA-0135
- 3.1.2      Specification      As given in section 2
- 3.1.3      Description      Light yellow clear liquid.
- 3.1.4      Purity      Etofenprox 30% w/w
- 3.1.5      Stability      No information in the report.
- 3.1.6      Further relevant properties      No information in the report.
- 3.1.7      Method of analysis      Not applicable (TS concentration not tested)
- 3.2**      **Reference substance**      Yes: dimethoate 400g/L EC formulation tested parallel
- 3.2.1      Method of analysis for reference substance      Not applicable (concentration of reference substance not tested)

**Section A7.5.3.2/04**      **Non Target Arthropods, test on artificial substrates**  
**Annex Point IIIA-XIII.3.2**

**3.3 Testing procedure**

- 3.3.1 Preparation of the test substance      See enclosed table A7\_5\_1\_2-1
- 3.3.2 Application of the test substance      Applications were done with a calibrated laboratory sprayer (Schachtner track sprayer with a Teejet 80015 EVS spray nozzle) at a volume of 200 L water/ha
- 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
- 3.3.5 Test conditions      See enclosed table A7\_5\_1\_2-4
- 3.3.6 Test duration      Mortality phase: 7 days  
Reproduction phase: 7 days
- 3.3.7 Test parameter / Examination      Mortality was assessed after the 7-day exposure period. On day 7 the sex of the surviving adult mites was determined  
Reproduction phase: on days 0, 3, 5 and 7 of the reproduction period, the number of eggs and juveniles produced per surviving female were counted and removed. The total number of offspring produced per female (R) and the effect on the reproduction relative to the control were calculated.
- 3.3.8 Monitoring of test substance concentration      No
- 3.3.9 Statistics      The mean mortality was corrected for control mortality according to ABBOTT (1925).  
Mortality data were analyzed statistically using Fisher's Exact test ( $\alpha=0.05$ ).  
Reproduction data were analyzed in a one-way analysis of variance (ANOVA), followed by Fisher's Least Significant Difference test.

**4 RESULTS**

**4.1 Results of test substance**

- 4.1.1 Initial concentrations of test substance      3.4, 5.0, 8.4, 15 and 25  $\mu\text{L/L}$  TREBON 30EC (equivalent to application rates of 0.2, 0.3, 0.5, 0.9 and 1.5 g a.i./ha)
- 4.1.2 Effect data (Mortality / Reproduction)      Mortality and reproduction data: see enclosed table A7\_5\_1\_2-5  
LR<sub>50</sub> value: see enclosed table A7\_5\_1\_2-5

**4.2 Results of controls**

- 4.2.1 Mortality / Fecundity      Mortality and fecundity data: see enclosed table A7\_5\_1\_2-5

**4.3 Test with reference substance**      Performed

- 4.3.1 Concentrations      96 mg a.i./ha in 200 L/ha corresponding to 1.2  $\mu\text{L/L}$
- 4.3.2 Results      see enclosed table A7\_5\_1\_2-5



**Section A7.5.3.2/04 Non Target Arthropods, test on artificial substrates**  
**Annex Point IIIA-XIII.3.2**

**5 APPLICANT'S SUMMARY AND CONCLUSION**

<b>5.1</b>	<b>Materials and methods</b>	As given in section 2 and 3.
<b>5.2</b>	<b>Results and discussion</b>	
5.2.1	LR <sub>50</sub>	0.70 g a.i./ha (95% confidence limits: 0.58 – 0.84 g a.i./ha)
5.2.2	Reproductive capacity	not significantly affected at an application rate equivalent to 0.2 g a.i./ha, in comparison to the control x
<b>5.3</b>	<b>Conclusion</b>	
5.3.1	Other Conclusions	The mortality and the reproductive capacity of <i>Typhlodromus pyri</i> were not significantly affected at an application rate equivalent to 0.2 g a.i./ha, in comparison to the control. Based on the mortality results, the 7-day LR <sub>50</sub> of TREBON 30EC was calculated to be 0.70 g a.i./ha (95% confidence limits: 0.58 – 0.84 g a.i./ha).
5.3.2	Reliability	1
5.3.3	Deficiencies	No

Table A7\_5\_1\_2-1: Preparation of TS solution.

Criteria	Details
Vehicle	Yes: deionised water
Concentration of vehicle	Stock solution was prepared in water by dissolving 0.200 ml of product in a final volume of 250 ml.
Vehicle control performed	Yes: the control was treated with deionised water with an amount of 200 l/ha

Table A7\_5\_1\_2-2: Test organisms.

Criteria	Details
Species/strain	<i>Typhlodromus pyri</i> (Scheuten)
Source of the initial stock	MITOX, reared since 1978
Age	1 day old protonymphs
Pre-treatment	Not applicable

Table A7\_5\_1\_2-3: Test system.

Criteria	Details
Test units	Mortality phase: bottom glass plate (10 x 5 x 0.3 cm), a top glass plate (10 x 5 x 0.15 cm) and a middle part of inert material (10 x 5 x 0.3 cm). Reproduction phase: upturned glass Petri-dishes (diameter of 9 cm) covered by a wet filter paper of the same size, with an inner exposure area (2.8 cm in diameter) defined by a barrier of glue
Number of replicates/test concentration	4 replicates for the control (deionised water) and for the test substance. 2 replicates for the reference substance
Number of protonymphs/test concentration	20
Test performed in closed vessels due to significant volatility of test substrate	No

Table A7\_5\_1\_2-4: Test conditions.

Criteria	Mortality and reproduction phases
Test temperature	25 ± 2°C
relative humidity	60-90%
Light photoperiod	16 hours light / 8 hours darkness
Light intensity	100-2000 Lux

Table A7\_5\_1\_2-5: Mortality and reproduction capacity following treatment.

Test substance concentration (nominal)	<i>Typhlodromus pyri</i>			
	Mortality after 7 days		Reproduction after 14 days	
	%	% corrected	eggs/female/7 days	Reduction relative to the control
Control (deionised water)	11	-	10.3	-
0.2 g a.i./ha	29	20*	9.5	8
0.3 g a.i./ha	28	18*	7.7	26
0.5 g a.i./ha	36	28*	8	23
0.9 g a.i./ha	66	62*	n.a.	n.a.
1.5 g a.i./ha	78	75*	n.a.	n.a.
Reference substance	65	61	n.a.	n.a.
LR <sub>50</sub> g a.i./ha	0.70 (0.58 – 0.84)			

n.a. not assessed

\* statistically significantly different from the control (mortality: Fisher's exact test; reproduction: ANOVA/Fisher's LSD test)

( ) 95% confidence limits

<b>Evaluation by Competent Authorities</b>	
	<b>EVALUATION BY RAPPORTEUR MEMBER STATE</b>
<b>Date</b>	March 2011
<b>Materials and methods</b>	Agree with the applicant's version
<b>Conclusion</b>	<b>5.2 Results and discussion</b> 5.2.2. Reproductive capacity and Table A7_5_1_2-5: Mortality and reproduction capacity following treatment. Significantly affected at an application rate equivalent to 0.3 g a.i/ha, and 0.5 g a.i/ha in comparison to the control
<b>Reliability</b>	1
<b>Acceptability</b>	Acceptable
<b>Remarks</b>	-

		<b>1 REFERENCE</b>	<b>Official use only</b>
<b>1.1</b>	<b>Reference</b>	Meinerling, M. and Lührs, U., 2011, Etofenprox: accumulation and elimination in earthworms ( <i>Eisenia fetida</i> ) in artificial soil, IBACON GmbH, report number 55641119, 02 February 2011, unpublished	
<b>1.2</b>	<b>Data protection</b>	Yes	
1.2.1	Data owner	Mitsui Chemicals Agro, Inc.	
1.2.2	Criteria for data protection	Data on existing a.s to maintain Annex I/IA entry	
		<b>2 GUIDELINES AND QUALITY ASSURANCE</b>	
<b>2.1</b>	<b>Guideline study</b>	Yes Guideline proposal for bioaccumulation in terrestrial oligochaetes, November 2009	
<b>2.2</b>	<b>GLP</b>	Yes	
<b>2.3</b>	<b>Deviations</b>	No	
		<b>3 METHOD</b>	
<b>3.1</b>	<b>Test material</b>	Etofenprox technical	
3.1.1	Lot/Batch number	K0561075	
3.1.2	Specification		
3.1.3	Purity	98.4%	
3.1.4	Stability	Expiration date: 26 June 2012	
3.1.5	Further relevant properties	None	
3.1.6	Method of analysis	LC-MS/MS	
<b>3.2</b>	<b>Reference substance</b>	Yes Etofenprox, 99.9% purity, (batch no. 5H0103) Provided by Sponsor	
3.2.1	Method of analysis for reference substance	No reference substance analysis is reported	
<b>3.3</b>	<b>Testing procedure</b>		
3.3.1	Preparation of the test substance	Stock solution prepared by dissolving 9 mg of etofenprox in 50 mL acetone, see Table A7_5_1_2-1.	
3.3.2	Application of the test substance	The test item was added to fine quartz sand as an aqueous dilution, the substrate was then dried to evaporate the solvent vehicle and then artificial soil was blended with the sand.	
3.3.3	Test organisms	Adult <i>Eisenia fetida</i> , see Table A7_5_1_2-2	
3.3.4	Test system	Plastic boxes, see Table A7_5_1_2-3	
3.3.5	Test conditions	See Table A7_5_1_2-4	
3.3.6	Test duration	42 days (21 days uptake phase; 21 days elimination phase)	
3.3.7	Test parameter	Mortality, behavioural abnormalities, weight change	

3.3.8 Examination

Behavioural abnormalities: each working day.

Sampling of earthworms: after 1, 2, 4, 7, 10, 14, 17 and 21 days exposure in the uptake phase. After transfer to untreated soil (start of elimination phase) worm were removed after 5 hours, and after 1, 2, 4, 7, 10, 14, 17 and 21 days after transfer to untreated soil. 3 replicates were destructively sampled at each sampling occasion for the test item group. 4 replicates of the control were sampled at the end of the uptake phase (day 21) and at the end of the elimination phase. The test substance was transferred into a tray and adult earthworms were collected. The fresh weight of the earthworms was determined as mean per test container. The supplementary replicates were not used as in all sampled replicates the 5 introduced earthworms were found.

Sampling of soil: soil specimens (approximately 100 g) were taken from each batch of prepared control and of the test item treated soil at start of the uptake phase (3 specimens) and the complete soil of all samples replicates at each sampling occasion during uptake phase.

Lipid content: the lipid content of the earthworms was determined of 3 control replicates at experimental start, i.e. introduction of the earthworms, at the end of the uptake phase, i.e. day 21 and at the end of the elimination phase.

Dry weight: the dry weight of the earthworms was determined from 3 control replicates at experimental star, i.e. introduction of the earthworms, at the end of the uptake phase, i.e. day 21 and at the end of elimination phase.

3.3.9 Monitoring of test substance concentration

At start of uptake phase, after 1, 2, 4, 7, 10, 14, 17 and 21 days exposure in the uptake phase.

3.3.10 Statistics

No statistics are reported for biological effects.

Statistical analysis and calculations are performed for bioaccumulation factor, kinetic bioaccumulation factor and elimination kinetics as summarised:

Bioaccumulation factor (BAF<sub>SS</sub>):

$$BAF_{SS} = \frac{c_a \text{ at steady state or end of uptake phase (mean)}}{c_s \text{ at steady state or end of uptake phase (mean)}}$$

Where:

$c_a$  = concentration of the substance in worm [ $g\ kg^{-1}$  wet or dry weight]

$c_s$  = concentration of the substance in soil [ $g\ kg^{-1}$  wet or dry weight]

Kinetic bioaccumulation factor:

The kinetic bioaccumulation factor (BAF<sub>k</sub>), the soil uptake rate constant and the elimination rate constant was determined using a non-linear parameter estimation method.

Elimination kinetics:

The elimination kinetics was modelled using the data from the elimination phase and applying the following model equation and a computer based non-linear parameter estimation method. A one compartment model was used to describe the time course of elimination.

## 4 RESULTS

### 4.1 Biological results

- 4.1.1 Mortality No mortality was observed in the treatment group or the control group, neither in the uptake nor the elimination phase.  
See Table A7\_5\_1\_2-5
- 4.1.2 Bodyweight changes The body weight changes of the earthworms during the uptake phase were +28.7% in the control, +17.5 to +39.5% for the worm samples taken during the uptake phase and +30.9% at transfer into the elimination phase.  
In the elimination phase, body weight changes were -16.4% in the control and -18.1 to +2.6% for the treated group.  
See Table A7\_5\_1\_2-5
- 4.1.3 Behavioural abnormalities No behavioural abnormalities were observed in the treatment group or the control group, neither in the uptake nor the elimination phase.

### 4.2 Analytical results

- 4.2.1 Analytical results During the uptake phase the measured concentration of etofenprox in soil samples decreased steadily. At test start the concentration in soil was 0.377 mg/kg soil wet weight (0.477 mg/kg soil dry weight). At the end of the uptake phase, the concentration in soil was determined to be 0.146 mg/kg soil wet weight.  
No etofenprox could be detected in the worm samples taken from untreated control samples. In the treated group, 24-hours after start of exposure, 0.147 µg etofenprox / g worm tissue (wet weight) was found. At the following sampling occasions, the concentration in worm tissues was determined to be 0.120 to 0.195 µg/g worm tissue (wet weight).  
After transferring the worm to untreated soil, the concentration in worm tissues decreased rapidly. After 5 hours, the concentration of etofenprox in worm tissues was 0.074 µg/g and decreased further. After 2 days, the concentration was below the LOQ of 0.05 µg/g worm tissue.
- 4.2.2 Bioaccumulation factor (steady state)  $BAF_{ss}$  An initial assessment of the concentration ratios in earthworms and soil was graphically evaluated. The evaluation appears to suggest that a concentration ratio around 0.8 (wet weight ratio) was approached in the course of the experiment. x
- 4.2.3 Uptake/depuration constants and bioaccumulation factor (kinetic)  $BAF_k$  The uptake rate constant ( $K_s$ ) was determined to be 0.1654.  
The elimination rate constant in worm tissues ( $K_e$ ) was determined to be 0.2253.  
The kinetic bioaccumulation factor  $BAF_k$  was determined as ratio between the uptake rate constant in worms ( $k_s$ ) and the elimination rate constant in worms ( $k_e$ ).  
 $BAF_k = 0.734$ .
- ### 4.3 Test with reference substance
- 4.3.1 Concentrations n.a.
- 4.3.2 Results n.a.

## 5 APPLICANT'S SUMMARY AND CONCLUSION

### 5.1 Materials and methods

Guidelines:

Proposal for a new guideline; OECD Guidelines for testing of chemicals: Bioaccumulation in terrestrial oligochaetes (November 2009)

Methods:

#### Uptake phase

21-day exposure in treated artificial soil prepared according to OECD 222 (5% peat only); one concentration of the test item was incorporated into the soil; 2 treatment groups (1 test item concentration, control); 54 replicates for the test item treatments and 22 replicates for the control with 5 worms in 250 g (dry weight) artificial soil each. Destructive samplings of 3 replicates of the test item treated group on day 1, 2, 4, 7, 10, 14, 17 and 21; destructive sampling of 10 replicates of the control on day 21 (3 replicates used for determination of earthworm dry mass, 3 used for determination of earthworm fat content).

#### Elimination phase

After 21 days of exposure, transfer of all remaining earthworms to untreated soil (start of elimination phase). Destructive samplings of 3 replicates of the test item group, 5 hours after transfer and on day 1, 2, 4, 7, 10, 14, 17 and 21; destructive sampling of 10 replicates of the control on day 21 (3 replicates used for determination of earthworm dry mass, 3 used for determination of earthworm fat mass).

Assessment of adult worm mortality and biomass development was carried out for each sampled replicate and for the transferred earthworms on day 21 of the uptake phase. Earthworm behaviour (surface check) was performed on each working day.

Soil specimens were taken from each batch of prepared control and of the test item treated soil at the start of uptake and at each sampling occasion during the uptake phase.

The earthworms of each sampling date were analysed directly after sampling. Only in the case of 2 sampling occasions, the worms were stored deep frozen for a maximum interval of 48 hours prior to analysis.

## 5.2 Results and discussion

No mortality was observed in the treatment group or the control group, neither in the uptake nor the elimination phase.

The body weight changes of the earthworms during the uptake phase were +28.7% in the control, +17.5 to +39.5% for the worm samples taken during the uptake phase and +30.9% at transfer into the elimination phase.

In the elimination phase, body weight changes were -16.4% in the control and -18.1 to +2.6% for the treated group.

No behavioural abnormalities were observed in the treatment group or the control group, neither in the uptake nor the elimination phase.

During the uptake phase the measured concentration of etofenprox in soil samples decreased steadily. At test start the concentration in soil was 0.377 mg/kg soil wet weight (0.477 mg/kg soil dry weight). At the end of the uptake phase, the concentration in soil was determined to be 0.146 mg/kg soil wet weight.

No etofenprox could be detected in the worm samples taken from untreated control samples. In the treated group, 24-hours after start of exposure, 0.147 µg etofenprox / g worm tissue (wet weight) was found. At the following sampling occasions, the concentration in worm tissues was determined to be 0.120 to 0.195 µg/g worm tissue (wet weight).

After transferring the worm to untreated soil, the concentration in worm tissues decreased rapidly. After 5 hours, the concentration of etofenprox in worm tissues was 0.074 µg/g and decreased further. After 2 days, the concentration was below the LOQ of 0.05 µg/g worm tissue.

An initial assessment of the concentration ratios in earthworms and soil was graphically evaluated. The evaluation appears to suggest that a concentration ratio around 0.8 (wet weight ratio) was approached in the course of the experiment.

The uptake rate constant ( $K_s$ ) was determined to be 0.1654.

The elimination rate constant in worm tissues ( $K_e$ ) was determined to be 0.2253.

The kinetic bioaccumulation factor  $BAF_k$  was determined as ratio between the uptake rate constant in worms ( $k_s$ ) and the elimination rate constant in worms ( $k_e$ ).

$BAF_k = 0.734$ .

### 5.2.1 NOEC

0.45 mg etofenprox / soil dry weight

## 5.3 Conclusion

Validity criteria met

### 5.3.1 Reliability

1

### 5.3.2 Deficiencies

No

x

x

x

x

x



<b>Evaluation by Competent Authorities</b>										
	<b>EVALUATION BY RAPPOREUR MEMBER STATE</b>									
<b>Date</b>	May 2012									
<b>Materials and methods</b>	Agree with the applicant's version									
<b>Conclusion</b>	<p><b>4.2.2 Bioaccumulation factor (steady state) BAF<sub>ss</sub></b></p> <p><b>5.3 Results and discussion:</b> At the end of the 21 day exposure period a concentration ratio around 4 (dw, which is the relevant one) is approached.</p> <p>The uptake rate constant (K<sub>s</sub>) dry weight related: 0.8309 The elimination rate constant in worm tissues (K<sub>e</sub>) dry weight related: 0.2226 The kinetic bioaccumulation factor BAF<sub>k</sub> dry weight related: 3.733</p> <p><b>5.4 Conclusion: Validity criteria</b> Amended headline of Table A7_5_1_2-6: Validity criteria for testing the accumulation and elimination in earthworms test according to OECD 317.</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">Criteria</th> <th style="text-align: center;">fulfilled</th> <th style="text-align: center;">Not fulfilled</th> </tr> </thead> <tbody> <tr> <td>Overall mortality of animals &lt;10% (earthworms) 20% (Enchytraeidae)</td> <td style="text-align: center;">X</td> <td></td> </tr> <tr> <td>Mean mass loss as measured at the end of the uptake and at the end of the elimination phase &lt;20% compared to the initial fresh weight at start.</td> <td style="text-align: center;">X</td> <td></td> </tr> </tbody> </table>	Criteria	fulfilled	Not fulfilled	Overall mortality of animals <10% (earthworms) 20% (Enchytraeidae)	X		Mean mass loss as measured at the end of the uptake and at the end of the elimination phase <20% compared to the initial fresh weight at start.	X	
Criteria	fulfilled	Not fulfilled								
Overall mortality of animals <10% (earthworms) 20% (Enchytraeidae)	X									
Mean mass loss as measured at the end of the uptake and at the end of the elimination phase <20% compared to the initial fresh weight at start.	X									
<b>Reliability</b>	1									
<b>Acceptability</b>	Acceptable									
<b>Remarks</b>	-									

Table A7\_5\_1\_2-1: Preparation of test substance solution

Criteria	Details
<b>In case of the use of an organic solvent</b>	
Dispersion	No
Vehicle	Acetone
Concentration of vehicle	n.a.
Vehicle control performed	Yes Treated with same amount of acetone and sand per g substrate as the test substance treated group.
Other procedures	n.a.

n.a.: not applicable

Table A7\_5\_1\_1-2: Test organisms

Criteria	Details
Species/strain	<i>Eisenia fetida</i>
Source of the initial stock	Bred by IBACON
Culturing techniques	Bred under standardised conditions (according to OECD 207: in a breeding medium of cattle manure, peat, sand, calcium carbonate and straw, fed with cattle manure, stored at room temperature).
Age/weight	Age: 10 to 11 months, with well developed clitellum. Weight: 251 to 583 mg
Pre-treatment	Earthworms were acclimated for three days to the artificial soil and test temperature

Table A7\_5\_1\_1-3: Test system

Criteria	Details
Artificial soil test substrate	<ul style="list-style-type: none"> <li>5.0% Sphagnum-peat, air-dried and finely ground with no visible plant remains</li> <li>20.0% Kaolin clay (Kaolinite content &gt;30%)</li> <li>0.25% calcium carbonate (CaCO<sub>3</sub>) added to adjust pH to 6.0 ± 0.5</li> <li>74.75% fine quartz-sand (F34) (depending on the amount of CaCO<sub>3</sub> needed, more than 50% by mass of particle size 0.05 mm to 0.2 mm)</li> </ul>
Test mixture	Nominal: 0.45 mg etofenprox / kg soil Measured: 0.376 to 0.459 mg etofenprox / kg soil
Size, volume and material of test container	11.5 x 11.5 x 6.0 cm (L x W x H), 0.5L plastic boxes
Amount of artificial soil (g)/ container	250 g / container
Nominal levels of test concentrations	Nominal: 0.45 mg etofenprox / kg soil

Criteria	Details
Number of replicates/concentration	22 for the solvent control: <ul style="list-style-type: none"> <li>• 10 for the uptake phase</li> <li>• 10 for the elimination phase</li> <li>• 2 reserve replicates (not used)</li> </ul> 54 for the test substance group <ul style="list-style-type: none"> <li>• 24 for the uptake phase</li> <li>• 27 for the elimination phase</li> <li>• 3 supplementary replicates (not used)</li> </ul>
Number of earthworms/test concentration	5
Number of earthworms/container	5
Light source	Artificial light
Test performed in closed vessels due to significant volatility of test substrate	No, but perforated transparent lids used to enable exchange of air, to minimise evaporation from the artificial soil and to prevent worms from escaping.

Table A7\_5\_1\_2-4: Test conditions

Criteria	Details																																																
Test temperature	20 ± 2 °C																																																
Moisture content and pH	<table border="1"> <thead> <tr> <th>Treatment group</th> <th>pH</th> <th>Water content [%]</th> <th>% of WHC [%]</th> </tr> </thead> <tbody> <tr> <td colspan="4" style="text-align: center;">Determination at start of uptake phase</td> </tr> <tr> <td>Control</td> <td>5.8</td> <td>23.1</td> <td>51.3</td> </tr> <tr> <td>Test item</td> <td>5.8</td> <td>24.3</td> <td>54.0</td> </tr> <tr> <td colspan="4" style="text-align: center;">Determination at end of uptake phase</td> </tr> <tr> <td>Control</td> <td>5.9</td> <td>24.0</td> <td>53.3</td> </tr> <tr> <td>Test item</td> <td>5.9</td> <td>24.0</td> <td>53.3</td> </tr> <tr> <td colspan="4" style="text-align: center;">Determination at start of elimination phase</td> </tr> <tr> <td>Untreated soil<sup>1</sup></td> <td>5.9</td> <td>24.2</td> <td>53.8</td> </tr> <tr> <td colspan="4" style="text-align: center;">Determination at end of elimination phase</td> </tr> <tr> <td>Control (untreated soil)<sup>2</sup></td> <td>5.8</td> <td>22.2</td> <td>49.3</td> </tr> <tr> <td>Test item (untreated soil)<sup>2</sup></td> <td>5.8</td> <td>22.2</td> <td>49.4</td> </tr> </tbody> </table> <p>WHC: the maximum water holding capacity was 45%  <sup>1</sup>: mean of four samples  <sup>2</sup>: mean of three samples</p>	Treatment group	pH	Water content [%]	% of WHC [%]	Determination at start of uptake phase				Control	5.8	23.1	51.3	Test item	5.8	24.3	54.0	Determination at end of uptake phase				Control	5.9	24.0	53.3	Test item	5.9	24.0	53.3	Determination at start of elimination phase				Untreated soil <sup>1</sup>	5.9	24.2	53.8	Determination at end of elimination phase				Control (untreated soil) <sup>2</sup>	5.8	22.2	49.3	Test item (untreated soil) <sup>2</sup>	5.8	22.2	49.4
Treatment group	pH	Water content [%]	% of WHC [%]																																														
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Test item (untreated soil) <sup>2</sup>	5.8	22.2	49.4																																														
Adjustment of pH	Not reported																																																
Light intensity / photoperiod	400 to 800 lux; 16 hours light : 8 hours dark																																																
Relevant degradation products	No																																																

**Table A7\_5\_1\_2-5: Mortality and body weight changes during uptake and elimination phase**

	Uptake phase		Elimination phase	
	Mortality [%]	Mean body weight change [%]	Mortality [%]	Mean body weight change [%]
Control	0	28.7	0	-16.4
Test item <sup>1</sup>	0	17.5 to 39.5	-	-
Test item <sup>2</sup>	0	30.9	0	-18.1 to 2.6

<sup>1</sup>: sampled during uptake phase (replicates 1 to 24)  
<sup>2</sup>: sampled during elimination phase (replicates 25 to 54)

**Table A7\_5\_1\_2-6: Validity criteria for acute earthworm test**

	Fulfilled	Not fulfilled
Mortality of control animals < 10%	X	
Mean mass loss as measured at the end of the uptake and at the end of the elimination phase should not exceed 20% compared to the initial fresh weigh at start of each phase	X	

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**

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.

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)

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.

**8.1.1 Methods and precautions concerning production, handling and use of the active substance and its formulations**

Technical measures:

- 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**

Storage conditions:

- Keep container tightly closed.
- Protect from direct sunlight.
- Store in cool, dark and well ventilated area.
- Store in a segregated and approved area.

Packaging material: Metal drums or cans with corrosion protection layer on surface.

**8.1.3 Methods and precautions concerning transport of the active substance and its formulations**

Transport information:

- UN Class: not regulated
- UN Number: none

x

x

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, CO<sub>2</sub> (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.

x

Section A8

Measures necessary to protect man, animals and the environment

8.6

**Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms (IIA-VIII.8.6)**

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)

8.7

**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



<b>Evaluation by Competent Authorities</b>	
<b>Date</b>	27.05.2005
<b>Evaluation of applicant's proposal</b>	<p><b>8.1.1</b> For details on the intended use and exposure as well as acceptable risk and personal protective equipment, please see Doc. II-B chapter 3 and 4 as well as Doc. II-C chapter 1.</p> <p><b>8.1.2</b> 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.</p> <p><b>8.1.3 Methods and precautions concerning transport of the active substance</b> UN Class, UN Number: This information was not reviewed, as under this point only "... transport must take into account any surface which could directly or indirectly come in contact with the product" is requested.</p> <p><b>8.3.1.</b> Do <u>not</u> induce vomiting, unless directed by medical personal</p> <p><b>8.4.3</b> Etofenprox is not persistent in soil, therefore for small amounts of Etofenprox decontamination is not necessary, since it will be degraded naturally (<math>DT_{50} &lt; 25</math> days).</p> <p><b>8.6</b> Etofenprox is highly toxic to aquatic organisms (fish, daphnia) and less toxic to green algae. Etofenprox is highly toxic to honeybees.</p>
<b>Conclusion</b>	
<b>Remarks</b>	For appropriate Precautionary Phrases for labelling see Doc IIA 1.6

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

<b>Evaluation by Competent Authorities</b>	
	<b>Evaluation by Rapporteur Member State</b>
<b>Date</b>	May 2011
<b>Evaluation of applicant's proposal</b>	<p><b>Safety phrases:</b></p> <p><b>S2 S13 S27/28 S36 S37 S39: label not necessary</b>, see Annex VI of 67/548/EEC (only classified as dangerous for the environment)</p> <p><b>S60 - 61: required:</b> 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><b>Risk phrases:</b></p> <p><b>R50/53:</b> The substance is classified as <u>not</u> readily biodegradable, since the mineralization of the substance only reached 17 - 32% after 28 days.</p> <p><b>SCL:</b></p> <p>N; R50-53: <math>C_n \geq 0.25\%</math>;</p> <p>N, R51-53: <math>0.025\% \leq C_n &lt; 0.25\%</math>;</p> <p>R52-53: <math>0.0025\% \leq C_n &lt; 0.025\%</math>;</p>
<b>Conclusion</b>	<p>Classification: N; R50-53</p> <p>Labelling:</p> <p>N; R50/53</p> <p>S60 - 61</p>
<b>Remarks</b>	Proposed classification according to Reg. 1272/2008/EC, Annex VI, Table 3.1 and Reg. (EU) No 286/2011: see Doc. II-A 1.6

## REFERENCE LIST – SORTED BY SECTION NUMBER

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	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 1.11 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 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.	1998	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.	1998	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 3.3.1/01	Shimono S.	1999	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.	2002	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. 06-alpha-74 Landis Kane Consulting, Document No. 500-2-87 Not GLP, unpublished	Y	
A 3.3.2/01	Shimono S.	1999	Color of etofenprox (MTI-500)	Y	Mitsui

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			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		Chemicals Agro., Inc.
A 3.3.2/02	Shimono S.	2002	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.	1999	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.	2002	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.	1998	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.	2002	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.	2002	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 3.5/01	Kunz C.	2000	Determination of the water solubility of <sup>14</sup> 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 [ <sup>14</sup> C]-Alpha-CO: water solubility Inveresk Research, Report No: 21386 Landis Kane Consulting, Document No. 500-2-12	Y	Mitsui Chemicals Agro., Inc.

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
			GLP, unpublished		
A 3.5/03	Matsumoto T.	2002	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.	2002	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.	2004	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	Tognucci A.	1998	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.
A 3.9/01	Tognucci A.	1998	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.	2002	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.	2002	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.	2002	1-Octanol/water partition coefficient test of PENA (HPLC method) Kurume Laboratory, Chemicals Evaluation and Research Institute, Report No. 82074	Y	Mitsui Chemicals Agro., Inc.

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
			Landis Kane Consulting, Document No. 500-2-19 GLP, unpublished		
A 3.10	Tognucci A.	1998	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.	1991	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.
A 3.11/02	Dublaski A.	1991	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.	2001	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.	1991	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.	2001	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.	2001	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. Mitsui Chemicals, Inc., Document No. not specified Landis Kane Consulting, Document No. 500-2-66 Not GLP, unpublished	N	Mitsui Chemicals Agro., Inc.
A 4.1/01	Ramsay N.	2002b	Etofenprox – Validation of analytical methods to support 5-batch analysis of Etofenprox to fulfil	Y	Mitsui Chemicals

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
			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		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 $\alpha$ -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 $\alpha$ -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 $\alpha$ -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 $\alpha$ -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 $\alpha$ -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 $\alpha$ -CO in cucumber RCC Ltd, Report No. 789377 Landis Kane Consulting, Document No. 500-4-03 GLP, unpublished	Y	Mitsui Chemicals Agro., Inc.
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	Y	Mitsui



Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
			analytical method for MTI-500 and $\alpha$ -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		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.
A 5.3/01	Schuma-cher 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	Schuma-cher 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	Schuma-cher 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	Schuma-cher 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.,	1985	Symptomatic and neurophysiological activities of	N	Public in-

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
	Koba-yashi T., Fujita T.		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		formation
A 6.1.1/01		2003a	Acute oral toxicity study of etofenprox in rats 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		1985a	Ethofenprox (MTI-500) acute limit test of toxicity to dogs following a single oral administration 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		1982a	Report on acute toxicity study of MTI-500 (ethofenprox) in rats 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		1982b	Report on Acute Toxicity Study of MTI-500 (ethofenprox) in Mice 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		2003b	Acute dermal toxicity study of etofenprox in rats 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		1982a	Report on acute toxicity study of MTI-500 (ethofenprox) in rats 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		1982b	Report on acute toxicity study of MTI-500 (ethofenprox) in mice 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		1983	MTI-500 Acute inhalation toxicity in rats 4 hour exposure Report No. MTC 60/821079 Landis Kane Consulting, Document No. 500-5-10 GLP, not published	Y	Mitsui Chemicals Agro., Inc.
A 6.1.4.s		1985a	MTI-500 Primary skin stimulation test in rabbits - Amendment No. 1 from October 28, 1991	Y	Mitsui Chemicals

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
			[REDACTED] Ltd., Report No. [REDACTED]-H-85-5 Landis Kane Consulting, Document No. 500-5-11 GLP, not published		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] Ltd., 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 <sup>14</sup> 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 <sup>14</sup> 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.
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 <sup>14</sup> C-ctofenprox in male rats (preliminary and definitive phases)	Y	Mitsui Chemicals

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			Report No. 6648-135 Landis Kane Consulting, Document No. 500-5-80 GLP, not published		Agro., Inc.
A 6.3.2		2000	A 28-day repeated dose dermal toxicity study in rabbits with technical MTI-500 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		1983a	Assessment of the toxicity of MTI-500 in rats during dietary administration for 13 weeks Re-issued amended pages on December 18, 1985 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		1983b	Assessment of the toxicity of MTI-500 to mice by dietary administration for 13 weeks Re-issued amended pages on December 18, 1985 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		1985	Ethofenprox (MTI-500) 90-day inhalation study in rats 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		1986a	Ethofenprox (MTI-500) Potential tumorigenic and toxic effects in prolonged dietary administration to rats Report No. MTC 59/85581 Landis Kane Consulting, Document No. 500-5-24 GLP, not published	Y	Mitsui Chemicals Agro., Inc.
A 6.5.1/02 and A6.7/02		1986b	Ethofenprox (MTI-500) Potential tumoregenic and toxic effects in prolonged dietary administration to mice 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		1985b	Ethofenprox (MTI-500) Toxicity to dogs by repeated dietary administration for 52 weeks followed by a recovery period of 8 weeks 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		1985	Reverse mutation in <i>Salmonella typhimurium</i>	Y	Mitsui

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			Report No. 162001-M-06185 Landis Kane Consulting, Document No. 500-5-19 GLP, not published		Chemicals Agro., Inc.
A 6.6.2		1985a	<i>In vitro</i> assessment of the clastogenic activity of MTI-500, etofenprox, in cultured human peripheral lymphocytes 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		1985a	Gene mutation in Chinese hamster V79 cells: test substance MTI-500 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		1985b	Unscheduled DNA synthesis in human cells cell line: Hela S3 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		1985c	MTI-500, etofenprox: Assessment of clastogenic action on bone marrow erythrocytes in the micronucleus test 85/MT0016/406 Landis Kane Consulting, Document No. 500-5-22 Not GLP, not published	Y	Mitsui Chemicals Agro., Inc.
A 6.6.7/01		1985a	MTI-500 $\alpha$ -CO: Acute oral toxicity in the rat 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		1985b	MTI-500 $\alpha$ -CO: Acute percutaneous toxicity in the rat 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		1987	MTI-500 $\alpha$ -CO Preliminary toxicity study in rats by dietary administration for 4 weeks 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		1988	MTI-500 $\alpha$ -CO Toxicity to rats by dietary administration for 13 weeks Report No. MTC 141/871458 Landis Kane Consulting, Document No. 500-5-41	Y	Mitsui Chemicals Agro., Inc.

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			GLP, not published		
A 6.6.7/05		1985a	MTI-500 $\alpha$ -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) 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		1985b	MTI-500 $\alpha$ -CO: Assessment of its ability to cause lethal DNA damage in strains of <i>Escherichia coli</i> 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		1985b	<i>In vitro</i> assessment of the clastogenic activity of MTI-500 $\alpha$ -CO in cultured human peripheral lymphocytes Report No. 85/MT0021/711 Landis Kane Consulting, Document No. 500-5-43 GLP, not published	Y	Mitsui Chemicals Agro., Inc.
A 6.7/01 → A 6.5.1/01		1986a	Ethofenprox (MTI-500) Potential tumorigenic and toxic effects in prolonged dietary administration to rats 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		1986b	Ethofenprox (MTI-500) Potential tumoregenic and toxic effects in prolonged dietary administration to mice 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		1985a	Effect of ethofenprox (MTI-500) on fertility and pregnancy of the rat 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		1985b	Effect of ethofenprox (MTI-500) on pregnancy of the rat with rearing to maturation of the F1 generation 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		1985c	Effect of ethofenprox (MTI-500) on the peri and	Y	Mitsui

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/03			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		Chemicals Agro., Inc.
A 6.8.1.2 /01		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.
A 6.8.1.2 /02		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		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		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		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		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		2002	Etofenprox – Validation of an analytical method for the determination of Etofenprox in UAR VRF1 (VRF1) Diet [REDACTED] Report No. MTU/222/1023183 Landis Kane Consulting, Document No. 500-5-05 GLP, not published	Y	Mitsui Chemicals Agro., Inc.
A 6.10		2003b	4-week dietary investigative study on thyroid function and hepatic microsomal enzyme induction with MTI-500 in rats [REDACTED] Report No. 6648-156	Y	Mitsui Chemicals Agro., Inc.

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			Landis Kane Consulting, Document No. 500-5-83 GLP, not published		
A 6.11/01 → A 6.1.1/03		1982a	Report on acute toxicity study of MTI-500 (ethofenprox) in rats Report No. A-82-27-34 Landis Kane Consulting, Document No. 500-5-08 Not GLP, not published	Y	Mitsui Chemicals Agro., Inc.
A 6.11/02 → A 6.1.1/04		1982b	Report on acute toxicity study of MTI-500 (ethofenprox) in mice 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., Kawa-zura H., Shiga Y., Yoshida M., Haya-kawa 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
A 7.1.1.1.1 /01	van der Gaauw A.	2001	<sup>14</sup> 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 [ <sup>14</sup> 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 [ <sup>14</sup> C]-etofenprox under laboratory conditions and determination of quantum yield RCC Ltd, Report No. 755526	Y	Mitsui Chemicals Agro., Inc.



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			Landis Kane Consulting, Document No. 500-2-21 GLP, unpublished		
A 7.1.1.1.2 /02	Clayton M.A., McCorquodale G.Y.	2003	Artificial sunlight photodegradation of [ <sup>14</sup> 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 <sup>14</sup> 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 7.1.2.1.1	Völkel, W.	2012	<sup>14</sup> C-Etofenprox – Biodegradation in activated sludge under aerobic conditions, IES Ltd, GLP, unpublished report No 20110163	Y	Mitsui Chemicals Agro., Inc.
A 7.1.2.2.2 /01	Lewis C.J.	2001	( <sup>14</sup> 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	( <sup>14</sup> 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.
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 7.1.3/02	Völkel W.	2011	<sup>14</sup> C-Etofenprox: Adsorption/Desorption on Soil, Innovative Environmental Services (IES) Ltd., report no. 81801015, unpublished	Y	Mitsui Chemicals Agro., Inc.
A 7.2.2.1	Völkl S.	2001	<sup>14</sup> 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	Y	Mitsui Chemicals Agro., Inc.

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			GLP, unpublished		
A 7.2.2.4	Mamouni A	2002b	Photolysis of <sup>14</sup> 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-I-5653 Landis Kane Consulting, Document No. 500-8-07 GLP, unpublished	Y	Mitsui Chemicals Agro., Inc.
A 7.4.1.1 /03	[REDACTED]	2002a	Acute toxicity of $\alpha$ -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 $\alpha$ -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,	Y	Mitsui Chemicals Agro., Inc.

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			Report No. 1045.000.430 Landis Kane Consulting, Document No. 500-8-52 GLP, unpublished		
A 7.4.1.3 /02	Bätscher R.	2002c	Toxicity of $\alpha$ -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	
A 7.4.3.1		1997	Etofenprox technical: fish (rainbow trout), prolonged toxicity test, 21 days (semi-static) Report No. 970304SP Landis Kane Consulting, Document No. 500-8-13 GLP, unpublished	Y	Mitsui Chemicals Agro., Inc.
A 7.4.3.2		2005	Toxic effects of MTI-500 (Etofenprox) to zebra fish ( <i>Brachydanio rerio</i> ) in an early-life stage toxicity test ; Report no. 853517 Landis Kane Consulting, Document No. 500-8-66 GLP, unpublished	Y	Mitsui Chemicals Agro., Inc.
A 7.4.3.2-02		2011	Etofenprox: A Life Cycle test with the Zebrafish ( <i>Danio rerio</i> ) under flow through conditions GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
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 <sup>14</sup> C-etofenprox 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	Blake, N.	2004	Assessment of the effects of Etofenprox (MTI-500) on natural communities of freshwater organisms in outdoor mesocosms Landis Kane Consulting, Document No. XEC003 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.

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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 7.4.3.5.1 /04	Thomas S.T., Kendall T.Z., Krueger H.O	2011	Etofenprox: A Prolonged Sediment Toxicity Test with <i>Chironomus riparius</i> Using Spiked Sediment. Wildlife International, Ltd., amended report no. 236A-133 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.
A 7.5.3.1.1	[REDACTED]	1985	The acute toxicity (LD50) of MTI-500 (etofenprox) 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	Y	Mitsui Chemicals Agro., Inc.

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
			- signature pages added: August 21, 1985 [REDACTED] Report No. MTC 77B/84795/2 Landis Kane Consulting, Document No. 500-8-03 GLP, unpublished		
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.
A7.5.3.2/01	Feije, R.	2005a	Etofenprox: An acute oral toxicity test to evaluate the effect on survival of the honeybee <i>Apis mellifera</i> L. MITOX, Report No. LK004AMO Landis Kane Consulting, Document No. 500-8-69 GLP, not published	Y	Mitsui Chemicals Agro., Inc.
A7.5.3.2/02	Feije, R.	2005b	Etofenprox: An acute contact toxicity test to evaluate the effect on survival of the honeybee <i>Apis mellifera</i> L. MITOX, Report No. LK006AMT Landis Kane Consulting, Document No. 500-8-70 GLP, not published	Y	Mitsui Chemicals Agro., Inc.
A7.5.3.2/03	Bakker, F.M.	2001a	A laboratory dose-response study to evaluate the effects of MTI-500 30% EC on survival and reproduction of the parasitoid wasp <i>Aphidius rhopalosiphi</i> (DeStephani-Perez) (Hymenoptera: Braconidae) MITOX, Report No. LK001ARL Landis Kane Consulting, Document No. 500-8-39 GLP, not published	Y	Mitsui Chemicals Agro., Inc.
A7.5.3.2/04	Bakker, F.M.	2001b	A laboratory dose-response study to evaluate the effects of MTI-500 30% EC on survival and reproduction of the predaceous mite <i>Typhlodromus pyri</i> Scheuten (Acari: Phytoseiidae) MITOX, Report No. LK002TPL Landis Kane Consulting, Document No. 500-8-40 GLP, not published	Y	Mitsui Chemicals Agro., Inc.
A 7.5.5.1	Meinerling, M. Lührs, U.	2011	Final report (2 <sup>nd</sup> Original) Etofenprox: accumulation and elimination in earthworms ( <i>Eisenia fetida</i> ) in artificial soil, IBACON GmbH, report number 55641119_02 GLP, unpublished	Y	[REDACTED]
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, not published	Y	Mitsui Chemicals Agro., Inc.

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