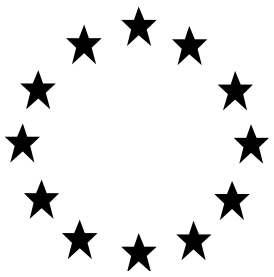
Regulation (EU) n°528/2012 concerning the making available on the market and use of biocidal products

Evaluation of active substances

Assessment Report



Etofenprox

Product-type 18 (Insecticide)

September 2013

Austria

Etofenprox (PT 18)

Assessment report

Finalised in the Standing Committee on Biocidal Products at its meeting on 27 September 2013

CONTENTS

1. STATEMENT OF SUBJECT MATTER AND PURPOSE

1.1. Principle of evaluation

This assessment report has been established as a result of the evaluation of Etofenprox as product-type 18 (insecticides, acaricides and products to control other arthropods), carried out in the context of the work programme for the review of existing active substances provided for in Article 16(2) of Directive 98/8/EC concerning the placing of biocidal products on the market1, with the original view to the possible inclusion of this substance into Annex I or IA to that Directive.

The evaluation has therefore been conducted in the view to determine whether it may be expected, in light of the common principles laid down in Annex VI to Directive 98/8/EC, that there are products in product-type 18 containing Etofenprox that will fulfil the requirements laid down in Article 5(1) b), c) and d) of that Directive.

1.2. Purpose of the assessment

The aim of the assessment report is to support a decision on the approval of Etofenprox for product-type 18, and should it be approved, to facilitate the authorisation of individual biocidal products in product-type 18 that contain Etofenprox. In the evaluation of applications for product-authorisation, the provisions of Regulation (EU) No 528/2012 shall be applied, in particular the provisions of Chapter IV, as well as the common principles laid down in Annex VI.

The conclusions of this report were reached within the framework of the uses that were proposed and supported by the applicant (see Appendix II). Extension of the use pattern beyond those described will require an evaluation at product authorisation level in order to establish whether the proposed extensions of use will satisfy the requirements of Regulation (EU) No 528/2012.

For the implementation of the common principles of Annex VI, the content and conclusions of this assessment report shall be taken into account.

However, where conclusions of this assessment report are based on data protected under the provisions of Regulation (EU) No 528/2012, such conclusions may not be used to the benefit of another applicant, unless access to these data has been granted.

1.3. Procedure followed

This assessment report has been established as a result of the evaluation of Etofenprox as product-type 18 (Insecticide), carried out in the context of the work programme for the review of existing active substances provided for in Article 16(2) of Directive 98/8/EC concerning the placing of biocidal products on the market.

Etofenprox (CAS no. 80844-07-1) was notified as an existing active substance, by LKC UK Ltd, hereafter referred to as the applicant, in product-type PT 18.

1 Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing biocidal products on the market. OJ L 123, 24.4.98, p.1

Commission Regulation (EC) No 1451/2007 of 4 December 2007[2] lays down the detailed rules for the evaluation of dossiers and for the decision-making process in order to include or not an existing active substance into Annex I or IA to the Directive.

In accordance with the provisions of Article 7(1) of that Regulation, Austria was designated as Rapporteur Member State to carry out the assessment on the basis of the dossier submitted by the applicant. The deadline for submission of a complete dossier for Etofenprox as an active substance in Product Type 18 was 30 April 2006, in accordance with Article 9 (c) of Regulation (EC) No 1451/2007.

On 26 April 2006, Austrian competent authorities received a dossier from the applicant. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation on 30 October 2006. Evaluation was suspended between 29 October 2007 and 29 July 2008 since data in the field of efficacy were missing. Within this time period, e-consultations with the Competent Authorities of other EU-Member States showed the need for additional testing. On 9 July 2008, the applicant asked for a further time period of 8 months to carry out the additional tests. Therefore, the Austrian Competent Authority suspended the time period until 30 April 2009.

On 9 August 2011, the Rapporteur Member State submitted, in accordance with the provisions of Article 14(4) and (6) of Regulation (EC) No 1451/2007, to the Commission and the applicant a copy of the evaluation report, hereafter referred to as the competent authority report. The Commission made the report available to all Member States by electronic means on 17 August 2011. The competent authority report included a recommendation for the inclusion of Etofenprox in Annex I to the Directive for product-type PT18.

In accordance with Article 16 of Regulation (EC) No 1451/2007, the Commission made the competent authority report publicly available by electronic means on 17 August 2011. This report did not include such information that was to be treated as confidential in accordance with Article 19 of Directive 98/8/EC.

In order to review the competent authority report and the comments received on it, consultations of technical experts from all Member States (peer review) were organised by the Commission. Revisions agreed upon were presented at technical and competent authority meetings and the competent authority report was amended accordingly.

In accordance with Article 15(4) of Regulation (EC) No 1451/2007, the present assessment report contains the conclusions of the Standing Committee on Biocidal Products, as finalised during its meeting held on 27 September 2013.

2 Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. OJ L 325, 11.12.2007, p. 3

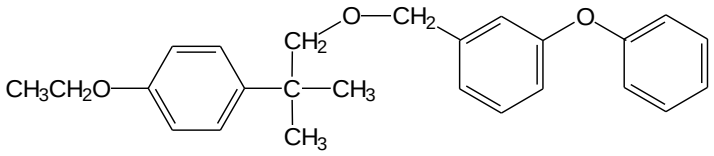
2. OVERALL SUMMARY AND CONCLUSIONS

2.1. Presentation of the Active Substance

2.1.1. Identity, Physico-Chemical Properties & Methods of Analysis

Active substance:

The active substance Etofenprox is attributed the CAS-No 80844-07-1 and the EC-No 407-980-2. The molecular formula is $C_{25}H_{28}O_3$, and the molecular weight is 376.47 g/mol. The minimum degree of purity is 97%w/w. Structural formula:



The structure of Etofenprox is confirmed by all spectra (IR, NMR, UV/VIS and MS).

The physico–chemical properties are studied for the purified active substance of stated specification (min. 97.0%w/w Etofenprox) according to the demands of the data requirements.

Etofenprox is a supercooled liquid (crystalline solid / viscous paste) and has an aromatic odour. Its melting point is 37.4°C, the boiling point is not determinable, degradation occurs at about 200°C.

The relative density is 1.172 at 20.7°C. The vapour pressure of the active substance is 8.13×10^{-7} Pa at 25°C, 2.16×10^{-3} Pa at 80°C and 7.01×10^{-3} Pa at 90°C. The calculated Henry's law constant is 0.0136 Pa x m^3 / mol at 25°C.

The water solubility of Etofenprox in test buffer (pH 4) is 5.2 µg/L (20°C), in test buffer (pH 9) it is 12.0 µg/L (20°C) and in bidistilled water it is 22.5 µg/L (20°C). The dissociation constant (pKa) cannot be determined. Etofenprox has no sites which can either be protonated or dissociate at pH 3 to 10.

The solubility of Etofenprox is in Methanol 49 g/L; in Ethanol 98 g/L; in Acetone 877 g/L; in Ethylacteate 837 g/ L; in Hexane 667 g/L; in Heptane 621 g/L; in Xylene 856 g/L; in Toluene 862 g/L and 924 g/L in Dichloromethane, all at 20°C. The active substance as manufactured is stable in organic solvents. The partition coefficient octanol-water is 6.9 at 20.1°C

The substance is regarded not to be surface active (surface tension is 68.12 mN/m at 20.1°C). The viscosity is not required (not liquid).

The active substance Etofenprox displays neither explosive nor oxidizing properties based on its structure.

No flash is recorded at temperatures up to 110°C and Etofenprox is not auto-flammable. It is not considered to be reactive to container material. (The containers are made from mild steel (i.e. low carbon steel) plate, tinned for corrosion protection. On the inside they are treated with a zinc phosphate based anti-corrosive.)

The identification and quantification of Etofenprox in the active substance as well as in the biocidal product Etofenprox 10% EW is performed by using a GC system with FID detection. The method has been validated and shown to be sufficiently specific, accurate and sensitive.

The compliance of the test substance with the specification derived from the 5-Batch analysis has been taken into consideration for each evaluated toxicological and ecotoxicological study and, if necessary, commented.

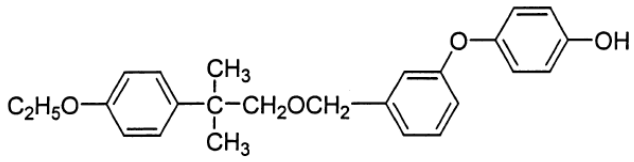
Metabolites:

Major metabolites are formed through degradation (for details please see chapter 2.2.3 Environmental risk assessment.) They are:

4'-OH

chemical name: 2-(4-ethoxyphenyl)-2-methylpropyl 3-(4-hydroxyphenoxy)benzylether

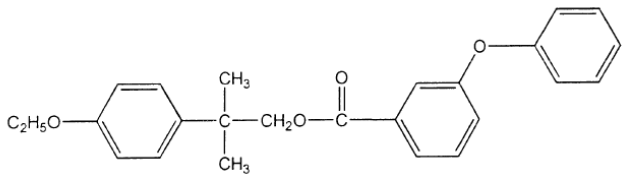
chemical structure:



α-CO

chemical name: 2-(4-ethoxyphenyl)-2-methylpropyl 3-phenoxybenzoate

chemical structure:



There is no evidence indicating that these metabolites have an increased human hazard compared to the parent molecule, Etofenprox.

The physico–chemical properties of the major metabolites

[^{14}C]-α –CO

The vapour pressure (calculated with EPI Suite 4.0 Modified Grain method) of the metabolite [^{14}C]-α –CO is 3.02 x 10^{-7} Pa x m^3/mole at 25°C.The Henry´s Law constant (calculated with EPI Suite 4.0 bond method) is 1.14 x 10^{-3} Pa x m^3/mole and is 3.93 x 10^{-3} Pa x m^3/mole. (calculated with EPI Suite 4.0 group method).

The water solubility of [^{14}C]-α –CO in bidistilled water is 42.5 µg/L at 20°C; and the Partitions coefficient n-octanol/water is log Pow = 6.5 at 22°C.

4'-OH

The structure of 4'-OH is confirmed by UV/VIS spectra; the absorption maxima are at 215-222 nm.

The vapour pressure (calculated with EPI Suite 4.0 Modified Grain method) of the metabolite 4'-OH is 6.8 x 10^{-9} Pa x m^3/mole at 25°C.The Henry´s Law constant (calculated with EPI Suite 4.0 bond method) is 2.38 x 10^{-7} Pa x m^3/mole and is 1.71 x 10^{-7} Pa x m^3/mole (calculated with EPI Suite 4.0 group method)

The water solubility of 4'-OH in purified water is 217 µg/L at 20°C; and the Partitions coefficient n-octanol/water is log Pow = 5.3 at 25°C.

The identification and quantification of Etofenprox and the metabolite α-CO in environmental matrices (soil, air and water) and in food/feedstuff of plant origin (oil seed rape, cabbage and cucumber) and food of animal origin (meat, fat, milk and egg), is performed by GC/MS-methods. The methods have been validated and shown to be sufficiently accurate and sensitive.

2.1.2. Intended Uses and Efficacy

The assessment of the biocidal activity of the active substance demonstrates that it has a sufficient level of efficacy against the target organisms (Target species: cockroaches belonging to the *Blattidae* and *Blattelidae*) and the evaluation of the summary data provided in support of the efficacy of the accompanying product, establishes that the product may be expected to be efficacious.

Etofenprox is an insecticide acting by direct contact and ingestion. It acts on sodium channels of the insect nervous system by disturbing the normal neurotransmittance. It has been evaluated for its use as an insecticide (Product Type 18) for use by professionals (PT 18.01). The representative formulation is Etofenprox 10%EW, containing 10% of active substance, and the proposed application rate is 70 mg a.s./m^2.

The efficacy of Etofenprox 10% EW as a surface spray has been tested against cockroaches (*Blattella germanica*) on carpet tiles as a model surface (Waters H. 2009). The experimental setup reflected real life conditions as only half of the test arena surface was treated and roaches were not confined to that part of the cage. This study demonstrates the efficacy of Etofenprox. The data suggest that the rate of 70 mg a.i./m^2 corresponds to the minimum effective dose on carpet tiles. Further usages with specific application rates will be applied for at the product authorization stage. The data included in this dossier have not been submitted to statistical testing. Given the number of experimental replicates (20) for each treatment the Austrian CA nevertheless assumes Etofenprox to efficiently kill cockroaches. The CA also assumes the minimum efficient dose to be 70 mg a.i./m^2. .

However, the applicant must, at the product authorisation stage, justify this decision by providing the results of adequate statistical tests demonstrating (i) that the observed mortality rates at lower doses are significantly different compared to the mortality at 70 mg a.i./m^2 and (ii) that there is no significant difference when comparing mortalities after application of 70 or 140 mg a.i./m^2, respectively.

For resistance management purposes, Etofenprox is an IRAC Mode of Action group 3A insecticide. Any insect population may contain individuals naturally resistant to Etofenprox and other group 3A insecticides. If these insecticides are used repeatedly, the resistant individuals may eventually

dominate the pest insect population. These resistant insects may not be controlled by Etofenprox or by other group 3A insecticides.

To delay the development of resistance:

- Avoid exclusive repeated use of insecticides from the same chemical subgroup which for Etofenprox is IRAC subgroup 3A.
- Alternate with products from other IRAC Mode of Action groups.
- Integrate other control measures such as chemical, cultural and biological, into insect control programs.

Specific strategies to prevent the development of resistance will be outlined at the product authorisation stage.

The intended uses of the substance, as identified during the evaluation process, are listed in Appendix II of this document.

2.1.3. Classification and Labelling

2.1.3.1. Proposed classification and labelling for the active substance – Etofenprox

Table 2.1.3.1-1: Proposed classification and labelling according to Reg. (EC) No 1272/2008, Annex VI, Table 3.2 (proposed by RMS)

Classification		Justification
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 **SCL:** N; R50-53: $C_n \geq 0.25\%$; N; R51-53: $0.025\% \leq C_n < 0.25\%$; R52-53: $0.0025\% \leq C_n < 0.025\%$;	All acute toxicity values are ≤1 mg/L and the substance is not rapidly biodegradable. Lowest available EC_{50} value =0.0012 mg/L.
	No classification for R64 (May cause harm to breastfeed babies), since R64 may only be applied in addition to other human health R phrases. No other human health R phrases are applicable.	
Safety phrases:	**S60-61** This material and its container must be disposed of as hazardous waste. Avoid release to the environment. Refer to special instructions /safety data sheets.	According to the classification with N; R50-53 and the labelling with N; R50/53 S-phrases S60-61 have to be on the label.

Table 2.1.3.1-2: Proposed classification according to Reg. (EC) No 1272/2008, Annex VI, Table 3.1 and Reg. (EU) No 286/2011(proposed by RMS)

Classification		Justification
Classification	Aquatic acute 1 (M=100)	L(E)C_{50} values ≤1 mg/L for all three trophic levels. Lowest available EC_{50} value =0.0012 mg/L.
	Aquatic chronic 1 (M=1000)	Not rapidly biodegradable and chronic NOECs for all three trophic levels ≤0.1 mg/L. Lowest available chronic NOEC value =0.000054 mg/L.
Hazard statements	H362 – May cause harm to breast-fed children	Potential for accumulation in fat and haemorrhage effect in lactated rats observed in reproduction toxicity studies. However the observed effects are not considered to be specific developmental toxic effects but due to the naturally high ratio of milk uptake to bodyweight
	H400 - Very toxic to aquatic life	See above (classification)
	H410 – Very toxic to a aquatic life with long lasting effects	See above (classification)

Table 2.1.3.1-3: Proposed labelling according to Reg. (EC) No 1272/2008, Annex VI, Table 3.1 and Reg. (EU) No 286/2011(proposed by RMS)

Labelling		
GHS Pictograms		 GHS09
Signal words		Warning
Hazard statements		H362 – May cause harm to breast-fed children H410 – Very toxic to aquatic life with long lasting effects
Precautionary statement	Prevention	P201 - Obtain special instructions before use. P260 - Do not breathe dust/fume/gas/mist/vapours/spray. P263 - Avoid contact during pregnancy/while nursing. P264 - Wash thoroughly after handling P270 - Do not eat, drink or smoke when using this product P273 – Avoid release to the environment P308 + 313 - IF exposed or concerned: Get medical advice/attention
	Response	P391 – Collect spillage
	Storage	
	Disposal	P501 - Dispose of contents/container in accordance with local/regional/ national/international regulation (to be specified).

2.1.3.2. Proposed classification and labelling for the biocidal product - Etofenprox 10EW

Table 2.1.3.2-1 Classification and labelling according to Regulation (EC) No 1272/2008, Annex VI, Table 3.2 (proposed by the RMS)

Hazard symbol		Justification
Class of danger	N	
R phrases	R 50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment	L(E)C_{50} values of Etofenprox in the range between 0.001 and 0.01 mg/L (-> SCL: N; R50-53: $C_n \geq 0.25\%$) and concentration in the product >10%.
S phrases	S60 This material and its container must be disposed of as hazardous waste. S61 Avoid release to the environment. Refer to special instructions / safety data sheet.	
Classification	N: R 50-53	
Labelling	N R: 50/53 S: 60-61	

Table 2.1.3.2-2 Classification according to Regulation (EC) No 1272/2008, Annex VI, Table 3.1 and according to Reg. (EU) No 286/2011 (proposed by the RMS)

Classification		Justification
Classification	Aquatic acute 1	M=100 and Etofenprox content in biocidal product >10%
	Aquatic chronic 1	M=1000 and Etofenprox content in biocidal product >10%
Hazard statements	H362 – May cause harm to breast-fed children	Etofenprox content in biocidal product ≥ 0.3%
	H400 - Very toxic to aquatic life	See above (classification)
	H410 – Very toxic to a aquatic life with long lasting effects	See above (classification)

Table 2.1.3.2-3: Labelling according to Regulation (EC) No 1272/2008, Annex VI, Table 3.1 and Reg. (EU) No 286/2011 (proposed by the RMS)

Labelling		
GHS Pictograms		 GHS09
Signal word		Warning
Hazard statements		H362 – May cause harm to breast-fed children
		H410 – Very toxic to aquatic life with long lasting effects
Precautionary Statements	General	
	Prevention	P201 - Obtain special instructions before use. P260 - Do not breathe dust/fume/gas/mist/vapours/spray. P263 - Avoid contact during pregnancy/while nursing. P264 - Wash thoroughly after handling P270 - Do not eat, drink or smoke when using this product P273 – Avoid release to the environment P308 + 313 - IF exposed or concerned: Get medical advice/attention
	Response	P391 – Collect spillage
	Storage	
	Disposal	P501 - Dispose of contents/container in accordance with local/regional/ national/international regulation (to be specified).

2.2. Summary of the Risk Assessment

2.2.1. Risk arising from physico-chemical properties

No physico-chemical hazards could be identified neither for the active substance nor for the biocidal product. Therefore there is no risk arising from physico-chemical properties.

2.2.2. Human Health Risk Assessment

2.2.2.1. Hazard identification

After gavage application in PEG at 30 mg/kg bw Etofenprox was estimated to have been absorbed in the rat by approximately 30%. From the available in vivo dermal absorption studies with 30% Etofenprox in product, 14% Etofenprox in methylcellulose and 0.01% Etofenprox in in-use dilution a dermal absorption value of 16% was estimated. Excretion proceeds rapidly, predominantly via the faeces (about 85% with 30 mg/kg bw), and is almost complete within 5 days of administration. Bile seems to be an important excretion-route (ca. 15% to 30% with 30 mg/kg bw day). Tissue distribution is extensive after multiple low doses but brain levels are uniformly low relative to blood plasma concentration. Tissue concentrations peak 4 hours after the last of 7 daily doses, and are highest in fat, but significant amounts are found in the adrenals, liver, ovaries, and thyroid gland. Tissue concentrations decline rapidly in all tissues except fat in which estimated half-lives of 5 to 8.5 days occur (males, females). Since this half-life-time in fat is significantly longer than 24 hours Etofenprox shows a potential for accumulation. Etofenprox is transferred via the placenta to the fetus but placental and fetal concentrations are low relative to maternal plasma concentration and elimination from these tissues is rapid. Unchanged Etofenprox is actively secreted into maternal milk and is ingested by pups producing a concentration ratio of >20 (pup stomach contents / maternal plasma). However, transfer to milk decreases markedly on cessation of dosing. On the basis of metabolism studies a metabolic pathway in rats is can be proposed. A toxicokinetic and metabolism study with dogs also indicates dominant bile and faeces excretion that is almost complete within 5 days after application. Also fat tissue affinity is observed, but no fat specific (terminal) half-live is explicit.

The acute oral and dermal LD50 values in rats are > 2000 mg/kg and no deaths or adverse clinical signs occur at this limit dose level. In the dog the acute oral LD50 is estimated as > 5000mg/kg. The acute 4-hour inhalation LC50 value in the rat is > 5.88 mg/L for a respirable aerosol in air. Etofenprox is neither a skin irritant nor an eye irritant and not skin sensitizing (negative GPMT) according to EU criteria.

The liver and thyroid gland are target organs in the rat following sub-chronic dietary exposure. The hepatic response is characterised by hepatocyte enlargement and clinical evidence suggestive of liver dysfunction affecting fat metabolism and, in males only, the synthesis of blood clotting factors. The effect on the thyroid gland is characterised by an increase in the number of thyroid microfollicles in both sexes and reduced levels of circulating thyroxine in males. Similar histomorphological effects in the liver and thyroid occur after inhalation administration, but there is no clinical evidence of effects on blood clotting time or circulating thyroxine levels. The NAOEL for liver and thyroid effects in the rat sub-chronic dietary study is about 20 mg/kg bw day.

The liver is also a target organ in the mouse with sub-chronic dietary exposure. It exhibits a similar response to the rat, but at substantially higher dose levels. In addition the kidneys and haemolymphoreticular system have been identified as target organs in the mouse at high dose

levels. The kidneys exhibit cortical scarring, tubular dilatation and widespread tubular basophilia, accompanied by elevated plasma urea nitrogen concentration, suggestive of renal dysfunction. Effects on the haemolymphoreticular system comprise mildly reduced RBC count, haemoglobin concentration and haematocrit values, increased cellularity of the splenic white pulp, lymph node reactivity and reduced thymic cellularity. The NAOEL for all effects in the mouse sub-chronic dietary study is about 375 mg/kg bw/day.

Dermal application of 1000mg/kg bw/day Etofenprox for 28 days does not produce any evidence of systemic toxicity, but mild local skin irritation occurs, which shows evidence of reversibility.

Etofenprox does not produce gene mutations in bacterial or mammalian cells in vitro. It is also not clastogenic in an in vitro cytogenetics assay in peripheral human lymphocytes or in the in vivo mouse micronucleus test. Etofenprox does not influence unscheduled DNA synthesis in cultured human HeLa cells. All in vitro tests were carried out with and without metabolic activation. The in vitro cytogenicity assay and the micronucleus assay were not fully compliant with the OECD TGs. However considering within a Weight of Evidence evaluation all the data and uncertainties and the fact that there are no contradictive results it is concluded that the concern for potential genotoxic effects of Etofenprox is sufficiently low and the data basis is acceptable.

The liver is a target organ in the dog, but hepatic effects are minimal and reversible, and occur only at oral dose levels of at least 339 mg/kg bw/day for 52 weeks. The effect comprises minor changes in serum clinical chemistry parameters, increased liver weight and, in some females, swelling of centrilobular hepatocytes. Since no other treatment-related adverse effects occur after 52 weeks of treatment, a NAOEL value of about 32 mg/kg bw day has been established.

No further target organs are identifiable in chronic/carcinogenicity studies in rats and mice that have not been identified in short-term toxicity studies. In the rat, the liver and thyroid gland are confirmed as target organs for non-neoplastic effects with an overall NOAEL of about 3.7 mg/kg bw/day. In the mouse, the kidney is the main target organ and an overall mouse NOAEL of about 3.1 mg/kg bw day has been established.

Etofenprox does not induce frank carcinogenic effects in either the rat or the mouse, but in the rat, there is at 187 / 249 mg/kg bw/day (males / females) an increased incidence of thyroid follicular cell adenoma. Though with pair-wise comparison of treated to control animals the incidence for males was borderline to statistical significance, it is prudent to assume that at these high doses there is some probability of thyroid tumour development for both sexes: This conclusion is based on the significant trend test for males, the significant though benign effect with females and the thyroid organ weight as well as marcroscopic and histological alterations. The respective NOEL values in the rat are 26 and 34 mg/kg bw day (males and females). In the mouse study three males at 547 and one male at 75 mg/kg bw day showed a renal neoplasm. Since two of the neoplasms at the highest dose level were benign and based on statistical considerations, it was concluded that there was no evidence of carcinogenic potential in the mouse. Consequently the NOAEL values for carcinogenic effects in the mouse are >547 mg/kg bw/day.

Since Etofenprox produces increased liver weight and hepatic hypertrophy in the rat after short- and long-term administration, the most likely etiology of the observed increased incidence of thyroid adenoma is considered to be based on a primary effect of hepatic microsomal enzyme induction and a sequence of secondary events, as enhanced elimination of circulating thyroid hormone and -as a physiological control consequence- enhanced thyroid cell proliferation. An investigative study (Smith, 2003b - document IIIA6.10) provides consistent evidence to support this proposed mechanism: 1) increased hepatic microsomal enzyme induction, specifically UDPGT activity (UDPGT is known to be a major route of metabolism and elimination of circulating T4, Curran and DeGroot, 1991), 2) though no effect on circulating T4 concentration at least increased circulating TSH concentration and 3) a mild stimulation of thyroid cell proliferation at least in males (not females). There is evidence in the literature that a sustained elevation in circulating TSH

concentration can lead initially to hypertrophy of thyroid follicular cells, followed by hyperplasia and ultimately a greater risk of increased incidence of thyroid adenomas (McClain et al. 1988; Marquart & Schäfer 2004). Based on these data it is concluded that the increased incidence of thyroid adenomas in female rats was mediated by an indirect, non-genotoxic mechanism with a clear NOEL for the primary effect on the liver of 81.2 mg/kg bw day. Furthermore the increased incidence of thyroid adenomas in rats is considered less relevant to humans, since the human plasma levels of T4 are much higher and the turn over slower leading to a much more stable T4 concentration and therefore to a reduced positive feedback on TSH synthesis and hypertrophy of thyroid follicular cells.

Furthermore the increased incidence of thyroid adenomas in rats is considered less relevant to humans, since the human plasma levels of T4 are much higher and the turn over slower leading to a much more stable T4 concentration and therefore to a reduced positive feedback on TSH synthesis and hypertrophy of thyroid follicular cells.

The results of reproductive toxicity testing are not considered to be of concern. Possibly adverse effects were discussed, that are ocular lesions at 79 mg/kg bw/day (starting between days 16-21 of age with the majority occurring after weaning; at termination days 63-67; 238/79/28,4/0 mg/kg bw/day: 13/5/2/1 pups of ca. 180 each) and subcutaneous haemorrhagic lesions at 238 mg/kg bw/day (developmental neurotoxicity study, at termination days 63-67; 238/79/28,4/0 mg/kg bw/day: 11/5/1/2 pups of ca. 180 each) and at 5000 mg/kg bw/day (peri-/post natal study, before weaning, around nose) and functional neurological effects within F1 adults at 238 mg/kg bw/day (higher mean auditory startle response amplitudes and reduced habituation in female offspring and a clustering of differences in motor activity and latency to peak startle response in males) and liver/thyroid/renal histopathological effects at 279 mg/kg bw/day in F1 adults (minor hepatocyte enlargement and vacuolisation and increased height of the thyroid columnar epithelium and renal lesions like primarily cystic collecting ducts, focal fibrosis, cortical scarring and mineral deposits.)

The above described effects were not observed within the F0 generation within the reproductive toxicity studies. However reduced clotting times, hepatocyte enlargement and other histopathological thyroid effects have been observed in rat adults at even lower concentrations of 187 mg/kg bw/day in the 110- week dietary study (Green et al. 1986a) and in the subchronic dietary rat study (Green et al. 1983a) at 120 (hepatocyte enlargement) and 734 mg/kg bw/day (thyroid effects and prolonged clotting time). Severe renal effects were observed in adult mice at 10,4 mg/kg bw/day in the 110- week dietary study (Green et al. 1986b) and at 1975 mg/kg bw/day in the 13-week dietary study. Therefore the above discussed effects are not considered to be specific developmental toxic effects but due to the naturally high ratio of milk uptake to bodyweight. The haemorragic effects, histological liver and thyroid effects and the functional neurological effects are considered minimal. Furthermore all discussed effects were observed only at relatively high doses (above 237 mg/kg bw/day for all effects except ocular haemorrhage at 79 mg/kg bw/day). Thus the described effects are not considered sufficient for classification for developmental toxicity. The acceptable exposure levels (AEL) are derived from NOAELs below these, thus they cover the discussed effects.

2.2.2.2. Effects assessment

AELs are developed for short, medium and long term exposure. In the toxicokinetic study in the rat systemic availability was estimated as 30% of the applied dose. However this toxicokinetic study was carried out with gavage application of Etofenprox in PEG at 30 mg/kg bw to bile duct cannulated rats. In contrast the repeated dose NOAELs used for AEL derivation were derived from feeding studies (without bile duct cannulation) and NOAELs were below the dose of 30 mg/kg bw. Thus absorption rates higher than 30% are to be expected in the critical toxicological studies. However in order to err on the conservative side the external NOAELs were corrected for oral absorption by 30%. The standard assessment factors of 10 times 10, for interspecies and intraspecies uncertainty were applied: The AEL short term was derived from the rat developmental neurotoxicity study NOAEL of 28.4 mg/kg bw day (haemorrhage effects) multiplied by 0.3 and divided by 100 = 0.085 mg/kg bw day; the AEL medium term from the rat sub-chronic study NOAEL of 20 mg/kg bw day (liver and thyroid effects) multiplied by 0.3 and divided by 100 = 0.06 mg/kg bw day; the AEL long term from the rat 2-year study NOAEL of 3.7 mg/kg bw day (liver and thyroid effects) multiplied by 0.3 and divided by 100 = 0.011 mg/kg bw day.

Considering the potential for accumulation in fat and the haemorrhage effects in lactated rats observed in the reproduction studies classification for lactation effects (H362) was agreed by ECHA and RAC.

2.2.2.3. Exposure assessment

Human exposure towards the active substance from its use in the biocidal product can take place via different "routes of exposure", i.e. via inhalation, dermal contact and/or ingestion (see table 2.2.2.3-1).

Table 2.2.2.3-1: Main paths of human exposure to Etofenprox from the product "Etofenprox 10% EW"

Exposure path	**Primary (direct) exposure, during use of the b.p.[1]**			**Secondary (indirect) exposure Incidental contact after application**	**Via the environment**
	Industrial use	**Professional use**	**General public**	**General Public**	**General Public**
Inhalation	No	Yes	No	Not relevant	Not relevant[2]
Dermal	No	Yes	No	Yes	Not relevant[2]
Oral	No	Not relevant	No	Yes	Not relevant[2]

[1] Exposure resulting from the production of the active substance and of the biocidal product are not considered, as these manufacture processes are not performed in the EU.

[2] From TNsG on Human Exposure, 2007: "Exposure via the environment is an element of secondary exposure. It includes bystanders and consumers, including children, who are inadvertently exposed to biocides by inhalation of plumes drifting off-site and ingesting contaminated food." Those scenarios are not considered relevant in this case.

The assessment of human exposure to the active substance Etofenprox follows the recommendations of TNsG on Human Exposure, 2002[3] and, where applicable, in the User Guidance 2002[4] as well as in the TNsG on Human Exposure, 2007[5].

The biocidal product is intended to be applied as surface spray indoors for treatment of cracks and crevices in room perimeters by professional users (Application with hand-held pressurized or knapsack sprayers, 1-3 bars. For details on the intended use, please see Appendix II of this document.) Thereby dermal and inhalative exposure may occur. Oral exposure is considered not relevant. The professionals are expected to be trained and skilled in the main tasks of their occupation. Furthermore, they should have experience and skill in the use of personal protective equipment (PPE). The use of coveralls granting min. 80% protection as well as suitable gloves (to be disposed in an environmentally safe manner) is obligatory.

Subsequent to the use of the biocidal product, exposure to the general public is possible via the dermal and the oral route. Dermal and oral exposure could be relevant for infants and small children, when they crawl over a floor after treatment. Considering this case, direct dermal contact and oral ingestion by hand-to-mouth contact are conceivable for infants. It is expected that secondary exposure is usually not relevant for adults as intense dermal and oral contacts with contaminated surfaces are less likely than for infants.

Regarding inhalation exposure, Etofenprox 10% EW is intended to be applied by spraying and could be inhaled as aerosol during application (primary exposure of professionals). As the spraying jet is directed to surfaces (no use as space spray), the droplets of the mists settle down soon after application. As Etofenprox reveals also a low vapour pressure (8.13×10^{-7} Pa of the pure substance

[3] "Technical Notes for Guidance on Human Exposure to Biocidal Products", European Commission, 2002

[4] "Human Exposure to Biocidal Products User guidance version 1", European Commission, 2002

5 "Human Exposure to Biocidal Products User guidance version 2", European Commission, 2007

at 25°C), inhalation exposure of the active substance (via gaseous releases respectively mists) is expected to be not relevant for secondary exposure.

Also combined exposure (in the sense of total exposure via all exposure routes arising from individual tasks through different phases of use) was assessed. Aggregate exposure (in the sense of exposure to a single chemical from multiple sources i.e. through primary exposure and secondary exposure) and cumulative exposure (in the sense of concurrent exposure to the same active substance from different biocidal products) was not evaluated at present for Etofenprox.

Dietary exposure is considered as not relevant, as the biocidal product should not be applied in areas where food for human consumption is prepared, consumed or stored, or where feedingstuff for livestocks is prepared, consumed or stored.

The exposure values relevant for risk characterisation are presented in chapter 2.2.2.4 of this document.

2.2.2.4. Risk characterisation

The risk characterization for human health considers the exposure during the professional application of the product (Etofenprox 10% EW). The product is applied by knapsack sprayer to cracks and crevices in room perimeters. Details of the exposure assessment are provided in Doc IIB4.5.

The exposure from application without of personal protective equipment (PPE, gloves, coveralls) results unacceptably high if compared with the medium and long term acceptable exposure levels (AEL). However the use of personal protective equipment (PPE, gloves, coveralls) is recommended as a standard precautionary measure for professionals and only professional application is foreseen. Consequently tier 2 estimates including PPE protection factors are taken into consideration here. Tier 2 exposure estimates were calculated for 6h/day working shifts (2A) and for 2h/day working shifts (2B). The risk for the 2h/day working shift (2B scenario) appears acceptable when respective exposure is compared to the medium term AEL.

This scenario is considered to represent a reasonable worst case assessment for the following reasons: The intended use is described as spot treatment of cracks and crevices in room perimeters for maximal 2 hours per day and maximal 2 treatments per year per site. The assumption of 2 hours treatment per day appear as reasonable estimate since spot treatment is necessarily interrupted by moving from spot to spot and may be considered to be of low duration due to the low total surface treated. If more than one object per day is visited travelling times between the objects will also reduce the chance of exposure for more than 2 hours per day.

It is assumed that professionals will treat cock-roaches not on a daily long term basis, but rather interrupted by other work. Therefore the medium term AEL appears as appropriate toxicological reference point.

However even the long term AEL is only a factor of 2.4 below the exposure estimated form this spraying model and the spraying model is considered as very conservative: It includes also spraying overhead which is not relevant to spot treatment of cracks and crevices in room perimeters. In addition also the AELs are very conservative, since a low oral absorption of 30% was taken into consideration for calculating internal AELs though this 30% value was derived from bolus application to bile duct cannulated rats and the critical NOAELs were derived from feeding studies. In addition the dose applied was 10 fold above the critical long term NOAEL used for respective AEL derivation.

In summary one reasonable exposure scenario appears clearly acceptable (2B) and the overall uncertainties for the exposure assessment and the AEL derivation tend to overestimate the risk which supports the conclusion that the risk from application of Etofenprox by the described intended is acceptable.

Table 2.2.2.4.-1. Risk characterisation for the application of the biocidal product

Exposure Scenario:		Estimated Internal Exposure [mg/kg bw/day]				$AEL_{medium\ term}$ / $AEL_{long\ term}$ [mg/kg b.w/day]	$AF_{MOE\ ref}$	MOE	Exposure / AEL
Application of the biocidal product		Estim. oral uptake	Estim. dermal uptake	Estim. Inhal. uptake	Estim. total uptake (combined exposure)				
Tier 2A	Exposure via spraying; (mixing and loading included): duration: 6h/day; PPE: coverall (20% penetration), gloves, but no RPE	n r.	0.049	0.028	0.077	0.06	100	78	1.3
						0.011		14	7
Tier 2B	Exposure via spraying; (mixing and loading included): duration: 2h/day; PPE: coverall (20% penetration), gloves, but no RPE	n r.	0.016	0.009	0.026	0.06	100	230	0.4
						0.011		42	2.4

n r. = not relevant

Secondary exposure to the product via treated areas should be considered for infants crawling over the floor as reasonable worst case assessment. However due to the intended use “spot treatment of cracks and crevices in room perimeters” the potential for secondary exposure is considered unlikely or very low: cracks and crevices in room perimeters are probably often hardly accessible, especially if below furniture; they represent a very minor and peripheral surface of the room with consequently reduced probability of infants to crawl on. In addition as further risk mitigation measure the product should be labelled with the warning: “Use only in positions inaccessible to children and animals”.

However in order to further confirm that the risk is acceptable the exposure of a child touching the treated area once with his bare hands and licking his hands as well as respiring volatised Etofenprox was estimated (for details see doc IIB.4) and compared with the short term and medium term AEL. As described in the table below the risk appears as clearly acceptable.

Table 2.2.2.4-2 Risk characterisation for exposure to treated areas

Exposure Scenario: Exposure of infants to treated areas		Estimated oral absorption [mg/kg bw/day]	Estimated dermal absorption [mg/kg bw/day]	Estimated total absorption [mg/kg bw/day]	$AEL_{short\ term}$ / $AEL_{medium\ term}$ [mg/kg b.w/day]	AF MOE_{ref}	MOE	Exposure / AEL
Tier 2	**Infant crawling over treated floor** Infant: 10kg bw Total dermal or total oral uptake Disolodgable fraction: 10.6% Touched surface: 240 cm^2	0.005	0.003	0.003 - 0.005	0.06 / 0.085	100	> 1200	< 0.08

u ... upper limit of range estimate

Similarly to the exposure assumptions of infants crawling over treated areas also the potential exposure of companion animals may need to be considered at product authorisation stage.

So far it is recommended that the product should be labelled with the warning: “Use only in positions inaccessible to children and animals”.

According to the intended use, Etofenprox 10% EW respectively the diluted product (0.175%) should not be applied for areas where food for human consumption or feeding stuff for livestock is prepared, consumed or stored. Therefore, dietary exposure and risk assessment is considered to be not relevant.

2.2.3. Environmental Risk Assessment

2.2.3.1. Fate and distribution in the environment

Biodegradation:

Ready biodegradability:

Etofenprox is classified as "not readily biodegradable" (17% mineralisation after 28 days). Polar metabolites were identified.

Degradation in STP:

In an aerobic degradation study in activated sludge Etofenprox showed a DT_{50} for degradation of 1.3 days and a DT_{90} of 4.4 days after 30 days at 20.1°C in the dark (single first order, k =0.527, r^2 =0.8928). Conversion to standard European conditions gives a DT_{50} value of 2.5 days at 12°C.

In the aqueous phase only 3% AR were found one hour after application, AR reached a maximum of 27% after 2 days and then decreased to 5.5% after 30 days. With the exception of day 2 (0.1% AR) no parent compound was detected in the aqueous phase. Extractable residues in sludge decreased rapidly from 94.6% AR after 1 hour to 2.7% AR after 30 days. Non-extractable residues increased from 1.4% AR after 1 hour to a maximum of 60.5% AR after 30 days.

11 metabolites were found in addition to $^{14}CO_2$. One metabolite (M3) once exceeded 10% of AR with 24.8% after 2 days of incubation. However it was degraded rapidly to 1.0% after 7 days and to 0.1% after 14 and 30 days of incubation. Another metabolite (M10) reached 5% of AR at two consecutive sampling times (7.7% after 7 days and 6.3% after 14 days), but degraded thereafter to 3.9% at day 30. Metabolites M1, M4 and M8 were identified as PENA, 4'-OH and α-CO, respectively, only reaching <5% of AR. At day 30 none of these 11 metabolites were found, except M3 and M10 with 0.1% and 3.9% of AR, respectively. Identification of M3 and M10 was not possible due to the low concentrations (initially 1.63 µg/L parent compound). From its polarity it was guessed that Etofenprox split and M3 is one part of the molecule. From the available data a degradation half-life of 0.9 days was calculated for M3. Because of its transient property and since M3 was not found in any of the other degradation studies this explanation was accepted, taking into account 6 h mean hydraulic retention time.

Mineralisation reached 35.9% AR after 30 days. Only minor amounts of volatile products other than $14CO_2$ were found.

Degradation in a water/sediment system:

In a water/sediment system Etofenprox showed dissipation DT_{50} values of 2.1 and 10.4 days at 20°C in the water phase in a pond and in a lake, respectively. In the sediment phase dissipation DT_{50} values of 17.9 and 32.2 days were found. For the entire system the first order, degradation DT_{50} values were 6.5 and 20.1 days for pond and lake. Degradation may have been enhanced by the high carbon content, while the low sediment content may have lowered degradation. The higher value was chosen for risk characterisation. Conversion to standard European conditions therefore give a DT_{50} value of 38.1 days for degradation in the entire system at 12°C, a DT_{50} value for dissipation in the water phase of 19.7 days and a DT_{50} value for dissipation in the sediment phase of 61.1 days.

One major metabolite (4'-OH) was mainly found in the sediment phase, at a maximum of 14.4 – 21.4% AR at day 7 and 14 and thereafter decreased to ≤10% of AR. Non extractable residues were formed up to 30.8% TAR after 99 days (lake) and up to 28.9% AR after 30 days (pond) and

decreased slowly thereafter. Mineralization to CO_2 was up to 17.8% AR (lake) and 28.2% AR (pond).

The major metabolite 4'-OH dissipated with DT_{50} values of 55.8 days (pond) and 26.4 days (lake) in the sediment phase at 20°C. In the entire system it degraded with DT_{50} values of 29.7 days (pond) and 21.8 days (lake). Choosing again the higher values gives DT_{50} values at 12°C for degradation in the whole system of 56.3 days and for dissipation in the sediment phase of 105.8 days.

Degradation in soil:

In an aerobic degradation study in soil Etofenprox degraded with a mean DT_{50} value of 12 days at 20°C (n=4), corresponding to a DT_{50} value of 22.8 days at 12°C.

Etofenprox was initially degraded to minor metabolites (α-CO, 4'-OH, DE and DP), which further degraded to CO_2. Bound residues were formed up to 47.9 – 57.0% TAR and decreased slowly by further mineralization to carbon dioxide to 42.8 -54.5% TAR after 120 days. Also the formation of PENA, EPMP and m-PB-acid (secondary metabolites) was shown. All detected metabolites were minor ones (<10% TAR). Mineralization to CO_2 reached 38.2 – 45.6% TAR after 120 days of incubation.

Degradation rates for the minor metabolites at 20°C were determined with DT_{50} values of 12 - 45 days (α-CO); 14 - 44 days (4'-OH); 17 - 66 days (DP) and 32 - 41 days (DE).

Abiotic degradation:

Hydrolysis:

Etofenprox is hydrolytically stable at pH 4, 7 and 9 at 50°C.

In a separate study the metabolite α-CO was hydrolytically stable at pH 4 and 7. It hydrolysed at pH 9 with a DT_{50} of 42.8 days at 25°C (extrapolation from measurements at 35 and 45°C) to two secondary metabolites (PENA, up to 44.1 % at 35°C and 45.3% at 45°C and m-PB-acid up to 38.4% at 35°C and up to 44.9% at 45°C).

These two metabolites were not considered further, since hydrolysis could only be observed at pH9. Under environmental conditions their generation is expected to be low. This is confirmed by the results of a water/sediment degradation test in which the only major metabolite was identified as 4'-OH. After application between 62-70% of Etofenprox were immediately associated with the sediment phase. In the water phase only 22–32% of Etofenprox were detected at the same point of time. This amount decreased further to ≤1% after 14 days. After application to a STP simulation test (OECD 314) up to 98% of Etofenprox was immediately associated to the sediment phase and only 1.6% were left in the water phase. α-CO and PENA were both identified as minor metabolites. Generation of α-CO and PENA reached a maximum of 4% (abiotic system) and 3.9% (biotic system), respectively. Therefore PENA and m-PBAcid are expected to be of minor importance under environmental conditions.

Hydrolysis is not expected to be a major degradation pathway.

Photolysis in water:

Etofenprox was photolytically degraded in sterile buffer solution with a DT_{50} value of 4.7 days at 25°C (corresponding to a DT_{50} value of 13.3 days at 12°C). Two major metabolites were formed during aqueous photolysis, α-CO (63.6% TAR) and the secondary metabolite PENA (12.0% TAR).

The photolysis study with α-CO showed no significant photo-degradation in sterile buffer solution after 48 – 72 h of incubation.

The contribution of photolysis to degradation in water is considered to be low. Additionally photolysis will only take place in the upper layers of the water phase. This is confirmed by the results of a water/sediment degradation test, in which the only major metabolite was identified as 4'-OH. After application between 62-70% of Etofenprox were immediately associated with the sediment phase. In the water phase only 22–32% of Etofenprox were detected at the same point of time. This amount decreased further to ≤1% after 14 days. After application to a STP simulation test (OECD 314) up to 98% of Etofenprox was immediately associated to the sediment phase and only 1.6% were left in the water phase. Generation of α-CO and PENA reached a maximum of 4% (abiotic system) and 3.9% (biotic system), respectively. Therefore PENA is expected to be of minor importance under environmental conditions.

Photo-oxidation in air:

An estimation of photochemical degradation of Etofenprox in air was calculated using the computer simulation software AopWin v1.92 and resulted in an overall OH rate constant of 62.16×10^{-12} cm^3/molecule·sec and in a half-life of 6.2 hours (24 hour day) at 25°C based on 5×10^5 OH/cm^3. According to these results, an accumulation of Etofenprox in air and a contamination by wet or dry deposition is not to be expected.

Photolysis in soil:

A direct photolysis rate constant of 0.0047 in soil was obtained, yielding in a DT_{50} of 147 days (20–22°C). Up to 10 minor degradation products were detected, six of which were characterised as α-CO, 4'-OH, DE, m-PB-acid, a mixture of PENA and EPMP and DP. None of the degradation compounds exceeded 7.7% of TAR. The mean recoveries of Etofenprox were 98.2% of TAR. The amount of non-extractable radioactivity increased up to 45% of the TAR at day 30. The amount of radioactivity evolved as $^{14}CO_2$ amounted to 7.4% after 30 days.

Therefore photolysis in soil is not expected to be a major degradation pathway for Etofenprox.

Distribution:

Etofenprox shows strong adsorption onto soil particles with an arithmetic mean K_{FOC} value of 28 524 L/kg (Freundlich coefficient).

The K_{OC} values for the major metabolites α –CO and 4'-OH were calculated with 36 870 and 11 090 L/kg, respectively (EPI Suite on the basis of their measured Log K_{ow}).

Therefore there is negligible likelihood for leakage of Etofenprox or its major metabolites to groundwater.

Accumulation:

Etofenprox has a potential for bioaccumulation as indicated by its high octanol/water partition coefficient (log K_{ow} of 6.9).

Bioaccumulation factors in a Bluegill sunfish were determined to be 1554, 7213 and 3951 L/kg in edibles, non-edibles and whole fish, respectively, at test concentrations of 0.18 and 1.08 µg/L. The BCF corrected for a whole body lipid content of 5% results in a whole body BCF in fish of 2565 L/kg. However, the accumulation was reversible with depuration half-life of 9 – 16 days and 95% depuration on day 69.

According to the TGD on risk assessment (Formula 82d), the $BCF_{earthworm}$ is 95281 L/kg.

The bio-concentration in terrestrial organisms was studied experimentally also (Study A 7.5.5.1, Doc. III-A 7.5.5.1). No mortality was observed in the treatment group or the control group, neither in the uptake nor the elimination phase. The uptake rate constant (K_s), wet weight related was determined to be 0.1654, the elimination rate constant in worm tissues (K_e) 0.2253 and in worms (k_e) 0.734, wet weight related. The determined kinetic bioaccumulation factor BAF_k (ratio between the uptake rate constant in worms) is lower than 1 (BAF_k=0.734) indicating that the concentration in earthworms is lower than in the surrounding environment.

2.2.3.2. Effects assessment

Etofenprox

Aquatic compartment (fish, daphnids, algae, micro-organisms, sediment dweller):

Fish:

In standard laboratory tests Etofenprox is highly acutely toxic to fish, as indicated by the LC_{50}-values of 2.7 and 13.0 µg/L for Rainbow trout (*Oncorhynchus mykiss*) and Bluegill sunfish (*Lepomis macrochirus*), respectively.

The chronic toxicity of Etofenprox was tested on the Rainbow trout over 21 days and the NOEC was determined to be 3.2 µg/L. The toxicity of Etofenprox on the early-life stage of fish was tested with the Zebra fish *(Brachydanio rerio)* and the NOEC determined to be 25 µg/L Zebra fish may well be less sensitive to the Etofenprox than rainbow trout, which shows an acute LC_{50}-value of 2.7 µg/L.

Based on the most sensitive endpoint (survival of F1 fish larvae), the overall NOEC for the fish life cycle study with zebrafish (*Danio rerio*) is 0.062 µg Etofenprox/L,

As invertebrates are more sensitive, the risk assessment is based on the chronic daphnia labor test (NOEC 0.054 µg/L).

Invertebrates:

Etofenprox is highly toxic to *Daphnia magna* with an acute EC_{50} of 1.2 µg/L.

The chronic toxicity to *Daphnia magna* was determined in a 21-day reproduction study and the NOEC was determined to be 0.054 µg a.s./L .

Algae:

Etofenprox is less toxic to algae than to invertebrates, as shown by E_rC_{50} and E_bC_{50} >56.25 µg a.i./L.

Micro-organisms:

Up to and including the highest tested concentration of 100 mg a.i./L (nominal) Etofenprox had no significant inhibitory effect on the respiration rate of activated sludge. However, at 50 and 100 mg a.i./L an increase of 3.4 and 10.3% oxygen consumption compared to the control could be detected.

All tested concentrations were far above the water solubility (0.0225 mg/L) of Etofenprox. Therefore the effect values are set equal to the water solubility. The 3 hour NOEC for STP micro-organisms is ≥0.0225 mg/L.

Sediment dwelling organisms:

The acute and the chronic toxicity of Etofenprox to *Chironomus riparius* were determined experimentally in static water-sediments systems, with application of the test item to the water column.

The nominal 10-day EC_{50}-value of Etofenprox for survival and body weight of larvae of *Chironomus riparius* was determined to be higher than 20.9 µg/L (the highest concentration tested) and the NOEC was 3.8 µg/L.

In the chronic study, conducted with spiked water, the nominal NOEC based on the development rate also was 3.8 µg/L.

A further sediment-water chironomid toxicity test was conducted in accordance with the OECD Guideline 218, using spiked sediment. The 28-day EC50, based on the percent survival of midges, was >6.4 mg a.i./kg and the NOEC for emergence and development was 2.9 and 6.4 mg. a.i./kg respectively.

Outdoor mesocosms study:

The fate and the effects of Etofenprox on natural communities of freshwater organisms were investigated in an outdoor mesocosms study. The taxonomic group which showed the greatest sensitivity in the enclosure systems is the zooplankton. So the lowest $NOEC_{community}$ (2.0 µg/l for the zooplankton) may be considered an initial Ecologically Acceptable Concentration (EAC) for Etofenprox to mixed zooplankton communities.

Degradation products

The 96-hour LC_{50} and NOEC-values of the metabolite α-CO for fish were found to be higher than or equal to the limit concentration of 48 µg/L.

The 48-hour EC_{50} and NOEC-values of the metabolite α-CO to daphnids were higher than or equal to the limit concentration of 44 µg/L.

The metabolite α-CO had no inhibitory effect on the growth of *Pseudokirchneriella subcapitata* up to its water solubility limit in test water (i.e. 42.5 µg/L at 20°C). The 96-hour EC_{50} values for the inhibition of the biomass and growth rate were higher the than the mean measured concentration of 53 µg/L.

Summed up, the surface water metabolite α-CO is less acutely toxic to fish, daphnids or algae than the active ingredient itself.

The sediment metabolite 4'-OH shows lower toxicity to chironomids than Etofenprox. . The 48-hour LC_{50} of 4'-OH was 50.2 µg/L and the 48-hour NOEC 17.6 µg/L.

Air compartment:

The vapour pressure of Etofenprox was determined to be 8.13 x 10^{-7} Pa at 25°C and the Henry's Law Constant 0.0136 Pa x m^3/mol at 25°C (Doc. III-A 3.2). Because of these low values, no volatilisation and thus no significant amounts of gaseous Etofenprox are expected to be in air.

The overall OH rate constant was determined to be 62.16 x 10^{-12} cm^3/molecule-sec (AopWin v1.92), resulting in an estimated half-life in air of 6.2 hours at 25°C (5 x 10^5 OH/cm^3) (Study A 7.3.1, Doc. III-A 7.3.1). According to these results, an accumulation of Etofenprox in the air is not expected.

Terrestrial compartment:

Earthworms:

Etofenprox showed no lethal effects on earthworms up to 47.2 mg a.i./kg soil, the highest concentration tested. Taking into account the high organic matter of the artificial substrate (10%) the LC_{50} for earthworms is >16.1 mg a.i./kg soil dry weight.

Micro-organisms:

Inhibition of microbial activity was tested in a study in which only 2 concentrations were tested. No significant inhibitory effects on short term respiration (8.68 and 8.44 %) were observed. However, Etofenprox showed significant inhibitory effects (10.6%) on nitrogen turnover at 0.0893 mg a.i./kg dry soil after 28 days. However at the 10-fold concentration no significant effects (-1.76%) were observed. Therefore it was decided to choose the higher value as NOEC. Converting this result to standard soil the NOEC is ≥2.024 mg/a.i./kg dry soil.

Plants:

In a limit test (0.234 mg/kg dry standard soil) the observed effects of Etofenprox on plants were 16% inhibition of the mean emergence rate and plant dry weight in only one species, 11% reduction of the mean plant height and change on leaf color from which the plants recovered during the test duration. Therefore the EC_{50} was considered to be >0.234 mg/kg dry standard soil.

Bees and arthropods:

Effect data are also available for bees and terrestrial arthropods.

The 96-hour acute oral and the 72-hour contact LD_{50} values of Etofenprox technical were 0.0238 and 0.0145 µg a.i./bee, respectively.

Laboratory tests with non-target arthropods (*Aphidius rhopalosiphi* and *Typhlodromus pyri* were conducted with TREBON 30EC (30% a.i. w/w). Etofenprox caused strong effects on the parasitic wasp *Aphidius rhopalosiphi* and the predatory mite *Typhlodromus pyri* when exposed to residues on glass plates in laboratory studies. The LR_{50} values were 0.42 g a.i./ha and 0.70 g a.i./ha to *Aphidius rhopalosiphi* and *Typhlodromus pyri*, respectively.

Birds:

Etofenprox is of low toxicity to birds as shown by an acute LD_{50} of >2000 mg/kg b.w. to mallard duck. The dietary LC_{50} of Mallard duck and Bobwhite quail is >5000 mg/kg diet. The reproduction toxicity NOEC is 1000 mg/kg diet in Bobwhite quail, the highest dose tested.

2.2.3.3. PBT assessment

Etofenprox

Persistence:

Ready biodegradability:

Etofenprox is not readily biodegradable (17% mineralization after 28 days in a Closed Bottle test; formation of polar metabolites up to 52.2% after 28 days).

Water/sediment:

In a water/sediment degradation study DT_{50} values (first order, degradation) for the entire system were 6.5 and 20.1 days at 20°C for pond and lake, respectively.

In both tested systems the organic carbon content was high (7.3% pond, 5.1% lake). Etofenprox dissipates very fast from the water phase with a DT_{50} value dissipation of 2.1 (pond) and 10.4 (lake). Therefore dissipation from the sediment phase with a DT_{50} of 17.9 days (pond) and 32.2 days (lake) was considered more relevant for the assessment of the P criterion than degradation in the water phase. The DT_{50} value (first order, dissipation) of 32.2 days for the sediment phase of the lake was therefore used for the assessment of persistence. Conversion to standard European conditions (12°C) resulted in a DT_{50} value of 61.1 days.

P-criterion: $T_{1/2}$ >120 days in fresh sediment – DT_{50} =61.1 days (12°C) => not P

Soil:

In an aerobic degradation study in soil Etofenprox degraded with a mean DT_{50} value of 12 days at 20°C, corresponding to a DT_{50} value of 22.8 days at 12°C.

P-criterion: $T_{1/2}$ >120 days in soil – DT_{50} =22.8 days (12°C) => not P

Etofenprox doesn't meet the P-criterion.

Bioaccumulation:

BCF_{fish} = 3951 L/kg (corrected for a whole body lipid content of 5%, the BCF is 2565 L/kg).

B-criterion: BCF >2000 => B

Etofenprox meets the B-criterion.

Toxicity:

The toxicological studies for genotoxicity, (sub)chronic toxicity, carcinogenicity and reproductive toxicity do not indicate concern for endocrine disruption or for CMR effects.

Fish: NOEC 0.025 mg/L

The chronic toxicity determined in the fish life cycle study with zebrafish is 0.000062 mg Etofenprox/L (NOEC).

Daphnia: NOEC was determined to be 0.000054 mg a.s./L .

Algae: NOEC: 0.056 mg a.i./L)

T-criterion: NOEC <0.01mg/L => T

Not listed in Annex 13 (List of 146 substances with endocrine disruption categorizations prepared in the Expert meeting) and 15 (List of 66 Category 1 substances with categorisation high, medium or low exposure concern) of the Endocrine disrupter website of the European Commission: http://ec.europa.eu/environment/endocrine/strategy/substances_en.htm#priority_list

Additionally, no negative impact on reproduction could be detected in the Life Cycle test with zebrafish.

There is no indication of endocrine potential of Etofenprox.

Because of the high toxicity of Etofenprox to invertebrates, the T-criterion is met.

Conclusion:

According to the available data Etofenprox isn't persistent in the environment, but it is bio-accumulative and toxic.

Therefore Etofenprox is neither a vPvB, nor a PBT substance.

Degradation products

Persistence:

Water/sediment:

Degradation in a water/sediment system showed one major metabolite (4'-OH) which was mainly found in sediment, at a maximum of 14.4 – 21.4% TAR. 4'-OH dissipated with DT_{50} values of 55.8 days (pond) and 26.4 days (lake) in the sediment phase at 20°C. As for the parent compound, the higher DT_{50} value (first order, dissipation) of 55.8 days was chosen for the assessment of the P criterion for the sediment phase. Conversion to standard European conditions results in a DT_{50} of 105.8 days at 12°C.

P-criterion: $T_{1/2}$ >120 days in fresh sediment – DT_{50} = 105.8 days (12°C) => not P

Soil:

In an aerobic degradation study in soil Etofenprox was initially degraded to several minor metabolites. Two of these minor metabolites (α-CO and 4'-OH) are also major metabolites in aquatic test systems. Therefore persistence for these two metabolites was assessed in soil on the basis of their mean DT_{50} values at 20°C; DT_{50} 22.6 days (α-CO) and DT_{50} 24.1 days (4'-OH). Conversion to standard European conditions (12°C) resulted in DT_{50} values of 42.9 days and 45.7 days, respectively.

P-criterion: $T_{1/2}$ >120 days in soil – α-CO: DT_{50} =42.9 days (12°C) => not P
P-criterion: $T_{1/2}$ >120 days in soil – 4'-OH: DT_{50} =45.7 days (12°C) => not P

Major metabolites, α-CO, 4'-OH, don't meet the P-criterion.

Bioaccumulation:

Based on a log K_{ow} of 6.5, the BCF calculated for the metabolite α-CO according to the TGD (Formula 75) gives a value of 43 651 L/kg.

Based on a log K_{ow} of 5.3, the BCF calculated for the metabolite 4'-OH according to the TGD (Formula 75) gives a value of 6 382 L/kg.

B-criterion: BCF >2000 => B
vB-criterion: BCF >5000 => vB

Major metabolites α-CO and 4'-OH, meet the B-criterion as well as the vB-criterion.

Toxicity:

The metabolite α-CO had no inhibitory effect on the growth of *Pseudokirchneriella subcapitata* up to its water solubility limit in test water (i.e. 0.0425 mg/L at 20°C). Accordingly, the 96-hour EC_{50} values for the inhibition of the biomass and growth rate were higher than the mean measured concentration of 0.053 mg/L.

The sediment metabolite 4'-OH is less toxic to the invertebrate *Chironomus riparius* than Etofenprox to the invertebrate daphia magna (the NOEC 198 times and the EC_{50} <42 times).

The 48-hour LC_{50} of 4'-OH was 0.502 mg/L and the 48-hour NOEC 17.6 µg/L.

T-criterion: Chronic NOEC <0.01mg/L => T

However, there is a lack of data: Chronic tests and tests conducted with higher test concentrations are not available.

In the ECHA "GUIDANCE on information requirements and chemical safety assessment" Part C, Chapter C.1.4.3, there is stated, if no chronic data are available, a substance could be also considered to meet the T-criterion based on L/EC_{50}-values:

T-criterion: L/EC_{50} <0.01mg/L => T
T-criterion: L/EC_{50} <0.1mg/L => potentially T

Because of the high toxicity to invertebrates and algae, α-CO might be considered to be potentially T. However, it should also be considered that the EC_{50} values of the acute toxicity testing of the metabolite α-CO are "greater than"- values and the substance is not P.

Because of the high toxicity to invertebrates, 4'-OH can be considered to be potentially T.

Conclusion:

Since the P-Criterion is not met, the available data indicate that the major metabolites α-CO and 4'-OH are neither vPvB nor PBT substances.

2.2.3.4. Exposure assessment

According to the intended use the biocidal product Etofenprox 10% EW is a spray to be applied by professionals indoors against cockroaches. The liquid product is to be diluted with water to obtain a solution containing 0.175%(w/w) Etofenprox, loaded into a sprayer and sprayed to cracks and crevices using a knapsack sprayer.

The process of formulation and the use of the insecticide Etofenprox 10% EW may lead to harmful emission to the environment. Therefore, an environmental exposure assessment has been performed in accordance with the Emission Scenario Document for insecticides, acaricides and products to control arthropods (PT18) for household and professional use (OECD, 2008)[6] as well as the results of the Workshop on ESD for PT18[7], outcome of TMI10 discussions8, the TGD II (EC 2003)[9] and the EUSES 2.1 Background report (EC 2008)[10] and is based on information relating to the intended use (Doc. II-B) of Etofenprox 10% EW. The exposure assessment has been performed for the substance Etofenprox.

In the ESD for PT18 it is generally assumed that insecticides used indoors will not reach directly the environmental compartments, but it is concluded that after the preparation of the biocidal product for application (dilution with water for example) and the application of the insecticide, the cleaning step will lead the releases to waste water through wet cleaning methods.

On this basis, the environmental exposure assessment has been performed for the active substance. Nevertheless, the potential environmental exposure to metabolites should also be considered. Since no clear recommendations are available for metabolites at the time of writing, the followed approach was to estimate the concentrations of relevant metabolites as a percentage of the concentrations of the parent compound Etofenprox.

The environmental exposure assessment was conducted for the local scale only.

Subsequent to the use of the biocidal product secondary poisoning may occur. Therefore, the concentration of contaminated food (e.g. earthworms or fish) via ingestion by birds and/or mammals is calculated according to the TGD II (EC 2003).

The exposure values relevant for risk characterization are presented in the following chapter.

---

6 ESD for PT18: OECD (2008) Series on Emission Scenario documents, Number 18, Emission Scenario Document for Insecticides, acaricides and products to control other arthropods for household and professional uses ENV/JM/MONO(2008)14, 30-Jun-2008.

[7] Workshop on ESD for PT18 (Brussels, Belgium, 11th of December 2007). Available via http://ecb.jrc.ec.europa.eu/documents/Biocides/EMISSION_SCENARIO_DOCUMENTS/ESD_PER_PRODUCT_TYPE/PT_18/PT18_Workshop_Environmental_Risk_Assessment_2007.pdf.

8 http://ecb.jrc.ec.europa.eu/documents/Biocides/MINUTES_TECHNICAL_MEETING/2010-TMI2010_open_session.pdf

[9] TGD II (2003)Technical Guidance Document in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. Part II.

10 EC (2004) European Union System for the Evaluation of Substances 2.0 (EUSES 2.0). Prepared for the European Chemicals Bureau by the National Institute of Public Health and the Environment (RIVM), Bilthoven, The Netherlands (RIVM Report no. 601900005). Available via http://ecb.jrc.ec.europa.eu/euses/.

2.2.3.5. Risk characterisation

Etofenprox

Aquatic compartment (including sediment):

STP:

Etofenprox will generally not directly reach the sewage system. However, wet cleaning methods applied after mixing/loading and application will lead to releases to sewage treatment plants, which are considered as the main receiving compartment for insecticides used indoors (see Doc. II-B, chapter 5.1.3).

The PEC_{STP} was calculated according to EUSES 2.1.1 (see Doc. II-B, chapter 5.2.2 PEC in STP).

The PNEC for aquatic micro-organisms was determined with $2.25x10^{-2}$ mg/L (see Doc. II-A, chapter 4.2.1 Aquatic compartment).

Table 2.2.3.5-1: PEC/PNEC ratios for STP micro-organisms

	PEC_{STP} (mg a.s./L)	**$PEC/PNEC_{STP}$**
	$PNEC_{STP\ micro\text{-}organisms}$= $2.25x10^{-2}$ mg a.s./L	
Wet cleaning	$6.18x10^{-3}$	$2.75x10^{-4}$

Conclusion

The PEC/PNEC ratios are all <1, indicating that the intended use of Etofenprox in the PT 18 product Etofenprox 10% EW poses an acceptable risk to STP micro-organisms.

Surface water incl. Sediment:

The PEC/PNEC ratio for the aquatic ecosystem was calculated taking into account the PEC_{SW} for the emission episode (see Doc. II-B) using the PNEC for aquatic organisms of $5.4x10^{-6}$ mg a.s./L (see Doc. II-A).

The PNEC for sediment dwelling organisms is $6.3x10^{-3}$ mg a.i./kg wwt (see Doc A-II). The PEC in sediment for the emission episode, is $1.69x10^{-3}$ mg a.s./kg dw (see Doc II-B).

Table 2.2.3.5-2: Local PEC/PNEC ratios for aquatic compartment

Exposure type	**$PEC_{surface\ water}$ (mg a.s./L)**	**$PEC/PNEC_{SW}$**
	$PNEC_{aquatic\ organisms}$= $5.4x10^{-6}$ mg a.s./L	
Emission episode	$5.93x10^{-7}$	0.11

Table 2.2.3.5-3: Local PEC/PNEC ratios for the sediment compartment

Exposure type	$PEC_{sediment}$ (mg a.s./kg wwt)	$PEC/PNEC_{sed}$
	$PNEC_{sed}$ = 6.3 x 10-3 mg a.i./kg wwt	
Emission episode	1.69 $x10^{-3}$	0.058

Conclusion

The PEC/PNEC ratio for surface water during and for the sediment compartment during the emission period is <1, thus the intended use of Etofenprox in the PT 18 product Etofenprox 10% EW will pose an acceptable risk to aquatic organisms.

Thus the intended use of Etofenprox in the PT 18 product Etofenprox 10% EW will not pose a risk to aquatic and benthic organisms.

Drinking water:

If surface water is intended for the abstraction of drinking water, the concentration calculation for Etofenprox is 0.0006 µg/L.

The concentration in pore water of an agricultural soil averaged over 180 days is taken as an indication for potential groundwater concentrations. The $PEC_{Groundwater}$ values is is $5.01x10^{-4}$ µg a.s./L.

Conclusion

In both cases, the drinking water concentrations are below the authorised limit value of 0.1 µg/L for drinking water (European Council Directive 98/83/EC on the quality of water intended for human consumption, 3 November 1998), showing that Etofenprox will not pose a risk to drinking water.

Air compartment:

The vapour pressure of Etofenprox was determined to be 8.13 x 10^{-7} Pa at 25°C and the Henry's Law Constant 0.0136 Pa x m^3/mol at 25°C (Doc. III-A 3.2). Because of these low values, no volatilisation and thus no significant amounts of gaseous Etofenprox are expected to be in air.

The overall OH rate constant was determined to be 62.16 x 10^{-12} cm^3/molecule-sec (AopWin v1.92), resulting in an estimated half-life in air of 6.2 hours at 25°C (5 x 10^5 OH/cm^3) (Study A 7.3.1, Doc. III-A 7.3.1). According to these results, an accumulation of Etofenprox in the air is not expected.

Terrestrial compartment:

According to the intended use direct emissions to the soil compartment are considered not relevant for indoor application. However, indirect exposure of agricultural soils through fertilization with sludge from a STP is considered relevant.

The PECs for the soil compartment were calculated according to TGD (2003) for arable soil and grassland as the average concentrations over certain time-periods in agricultural soil fertilized with sludge from a STP.

The PNEC for soil organisms is $2.024x10^{-2}$ mg a.s./kg_{dwt}.

Table 2.2.3.5-4: PEC/PNEC ratios for terrestrial organisms

Exposure scenario	PEC_{soil} (mg a.s./kg dry soil)	$PEC/PNEC_{soil}$
	$PNEC_{terrestrial\ organisms}$= $2.024x10^{-2}$ mg a.s./kg dry soil	
Arable land, 30 days (simple treat)	$4.38x10^{-3}$	0.22
Arable land, 30 days (simple treat, refined)	$3.99x10^{-4}$	0.02
Arable land, 180 days (simple treat)	$1.22x10^{-3}$	0.06
Arable land, 180 days (simple treat, refined)	$1.11x10^{-4}$	$5.48x10^{-3}$
Grassland, 180 days (simple treat)	$4.86x10^{-4}$	0.02
Grassland, 180 days (simple treat, refined)	$4.42x10^{-5}$	$2.18x10^{-3}$

Conclusion

The PEC/PNEC ratios are all <1, indicating that the intended use of Etofenprox in the PT 18 product Etofenprox 10% EW poses an acceptable risk to soil organisms.

Bees and arthropods:

As the representative product is used exclusively indoors against crack and crevices, the exposition and risk of bees and other arthropods is negligible.

Secondary poisoning (Non compartment specific effects relevant to the food chain):

Due to its high log K_{ow}, Etofenprox has a potential for bioaccumulation and is expected to enter the food chain. Therefore, a risk of secondary poisoning of birds and/or mammals via ingestion of contaminated food (e.g. earthworms or fish) could be expected.

The risk to the predators is calculated as the ratio between the concentration in their food and the predicted no-effect concentration for oral intake ($PNEC_{oral}$).

The concentration of Etofenprox in fish has been calculated from the PEC for surface water, the measured bioconcentration factor for fish and the biomagnification factor (see Doc II-B). The concentration of Etofenprox in earthworm has been calculated from the PEC in soil averaged over 180 days and the estimated bioconcentration factor for earthworm (see Doc. II-B).

The PNEC values for oral intake by birds and by mammals have been discussed in Doc II-A (see $PNEC_{oral.}$).

Table 2.2.3.5-5: PEC/PNEC ratios for non compartment specific effects (secondary poisoning)

Exposure scenario	PEC	PEC/PNEC
	$PNEC_{oral\ chron}$ = 24.7 mg a.s./kg diet	
Aquatic food chain	$4.17x10^{-6}$ mg a.s./kg $_{wet\ fish}$	$1.69x10^{-7}$
Terrestrial food chain	$2.19x10^{-21}$ mg a.s./kg $_{wet\ earthworm}$	$8.87x10^{-4}$

Conclusion

The PEC/PNEC ratios for secondary poisoning of fish- and earthworm-eating predators are well below 1 and thus acceptable.

Degradation products

Since there is no guidance available at the time of writing to calculate the predicted concentrations of degradation products in the environment, the approach followed in this dossier is to multiply the PEC values for Etofenprox by the highest percentage of the metabolite detected in laboratory studies in the corresponding compartment.

The metabolites considered for the risk assessment are α-CO for the water compartment and 4'-OH for the sediment compartment. None of the soil metabolites are considered for risk characterisation (none of these metabolites reached levels >5% of radioactivity of applied Etofenprox).

Aquatic compartment (including sediment):

The main metabolite in surface water is α–CO. The PECs of Etofenprox were multiplied by highest percentage of α–CO (63.6%) formed in the aqueous photolysis study to estimate the PECs of the metabolite α–CO (see Doc. II-B).

The highest level of 4'-OH detected in the sediment of the water/sediment study is 21.4% of the applied radioactivity. Thus the concentration of 4'-OH in sediment is calculated from the concentration of Etofenprox using the percentage of the metabolite (see Doc. II-B).

The PNECs of α–CO is 4.4 $x10^{-5}$ mg/L and the PNEC of 4'-OH for sediment dwelling organisms is 1.2 $x10^{-2}$ mg/kg wet sediment, respectively (see Doc. II-A).

Table 2.2.3.5-6: PEC/PNEC ratios for aquatic and benthic organisms for the metabolites α-CO and 4´-OH

Exposure type	**$PEC_{surface\ water}$ (mg a.s./L)/ $PEC_{sediment}$ (mg a.s./kg ww)**	**$PEC/PNEC_{SW}$ $PEC/PNEC_{sed}$**
	$PNEC_{aquatic\ organisms}$= $4.4x10^{-5}$ mg a.s./L	
Emission episode	$3.77x10^{-7}$	$8.57x10^{-3}$
	$PNEC_{sed}$ = $1.2x10^{-2}$ mg a.s./kg wwt	
Emission episode	$7.88x10^{-5}$	$6.57x10^{-3}$

Conclusion

The PEC/PNEC ratios of the metabolite α-CO and for 4´OH as well are below 1, indicating an acceptable risk for aquatic and sediment dwelling organisms from the intended use of Etofenprox in the PT 18 product Etofenprox 10% EW.

2.2.4. List of endpoints

In order to facilitate the work of Member States in granting or reviewing authorisations, the most important endpoints, as identified during the evaluation process, are listed in Appendix I.

3. PROPOSED DECISION

3.1. Background to the proposed decision

The assessment of the biocidal activity of the active substance demonstrated that it has a sufficient level of efficacy against the target organism. Target insects are knocked down and killed upon contact with the active ingredient. The toxic properties of Etofenprox are due to its effect on sodium channels in the insects nervous system. The target species are roaches belonging to the *Blattidae* and *Blatellidae.*

The evaluated application is by knapsack sprayer to cracks and crevices in room perimeters (spot application). The active substance has no hazardous physico-chemical properties.

The probability that the active substance has CMR or endocrine properties relevant to human health is low. A potential hazard concern for breast fed babies was identified. Human risk assessment was considered acceptable with the applications and PPE indicated in chapter 3.2. and 3.3.

The PBT assessment, based on the available data, showed that Etofenprox is not P, but is B and T. For the two major metabolites 4'OH and α-CO the assessment resulted in not P, vB and potentially T (due to lack of chronic data). Therefore Etofenprox is neither a vPvB, nor a PBT substance.

In the environmental risk assessment no risk to the air compartment, to the aquatic compartment (STP, Surface water including sediment and drinking water), to the soil compartment (including groundwater) as well as for secondary poisoning could be determined. For the two major metabolites α-CO and 4'OH no risk for surface water or, respectively, sediment was identified.

There is no indication of endocrine potential of Etofenprox. For instance, no negative impact on reproduction could be detected in the Life Cycle test with zebrafish.

3.2. Proposed decision

The overall conclusion from the evaluation of Etofenprox for use in product type 18 (insecticides, acaricides and products to control other arthropods), is that it may be possible to issue authorisations of products containing Etofenprox in accordance with the conditions laid down in Article 5(1) b), c) and d) of Dir. 98/8/EC.

It also appears from the report that the characteristics of etofenprox render it bioaccumulable (B) and toxic (T) in accordance with the criteria laid down in Annex XIII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council11. The period of approval should be 10 years in consistency with the current practice under Directive 98/8/EC, since the conditions of Article 90(2) of Regulation (EU) No 528/2012 are not met. However, for the purpose of authorising products in accordance with Article 23 of Regulation (EU) No 528/2012, etofenprox shall be considered as a candidate for substitution pursuant to Article 10(1)(d) of that Regulation.

11 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

It is therefore appropriate to approve Etofenprox for use in biocidal products for product-type 18, and subject to the following specific conditions:

1) Etofenprox is considered a candidate for substitution in accordance with article 10(1)(d) of Regulation (EU) No 528/2012.
2) The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance.
3) Authorisations are subject to the following conditions:
   a) For industrial or professional users, safe operational procedures and appropriate organizational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products shall be used with appropriate personal protective equipment.
   b) For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No 470/2009 or Regulation (EC) No 396/2005 shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.

3.3. Elements to be taken into account when authorising products

(1) For the purpose of authorising products in accordance with Article 23 of Regulation (EU) No 528/2012, etofenprox shall be considered as a candidate for substitution pursuant to Article 10(1)(d) of that Regulation.

(2) For authorisation of biocidal products, usages, application techniques, and rates different from the representative biocidal product that supports the approval additional efficacy tests will be necessary

(3) The applicant must submit results of adequate statistical test showing (i) that the observed mortality rates of the target organisms at lower doses are significantly different compared to the mortality at the minimum efficient dose (70 mg a.i./m^2) and (ii) that there is no significant difference when comparing mortalities after application of 70 or 140 mg a.i./m^2, respectively.

(4) An integrated resistance management strategy for Etofenprox is recommended at the Member States level, taking into account national specificities (climatic conditions, range of species use conditions, etc.) and the management strategy outline in this dossier.

(5) Use is limited to professional application by knapsack sprayer (1-3 bar) to cracks and crevices of room perimeters (spot application). The risk appeared acceptable with the assumption of 2 hours of work per day and use of the exposure model including overhead spraying. The latter is considered to overestimate exposure that will largely appear from treatment of cracks and crevices in the floor in room perimeters. If different uses are intended, a new exposure and risk assessment has to be provided.

(6) The intended use “professional application by knapsack sprayer to cracks and crevices (of room perimeters, spot application)”, once or twice a year per site was evaluated and considered as acceptable with regard to efficacy and human and environmental risk.

However according to the ESD gel applications are used for cracks and crevice treatment. The latter will probably lead to lower exposure. In addition risk management measures controlling that also practically only cracks and crevices are treated are more easily applicable. Therefore gel applications are preferable for cracks and crevice treatment. For the final product to be authorised the final product formulation, intended use, human and environmental risk as well as effective risk management options have to be carefully evaluated.

(7) A dermal absorption study is available for the representative product. Should other products be submitted for authorisation, dermal absorption values used in the applications for product authorisation should be justified, if available by the submission of specific dermal absorption data on the product, or by read-across to existing data if scientifically justified, or by using default values

(8) At product authorisation stage, a hazard and risk assessment for additional active substances and substances of concern contained in the biocidal product should be performed as far as applicable.

(9) The intended use "spot treatment by knapsack spraying to cracks and crevices in room perimeters" is likely to result in no or minimal and acceptable secondary exposure to infants and pets. Nevertheless in order to ensure this type of careful use a precautionary label is proposed: "Use only in positions inaccessible to children and animals".

(10) Etofenprox 10%EW respectively the diluted product (0.175%) should not be applied in areas where food for human consumption is prepared, consumed or stored, or where feedingstuff for livestocks is prepared, consumed or stored, as no respective risk assessment was provided. The applicant proposed a respective label.

3.4. Requirement for further information

It is considered that the evaluation has shown that sufficient data have been provided to verify the outcome and conclusions, and permit the proposal for the approval of Etofenprox

3.5. Updating this Assessment Report

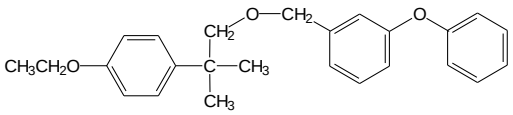
This assessment report may need to be updated periodically in order to take account of scientific developments and results from the examination of any of the information submitted in relation with Regulation (EU) No 528/2012. Such adaptations will be examined and finalised in connection with any amendment of the conditions for the approval of Etofenprox.

APPENDIX I: LIST OF ENDPOINTS

Chapter 1: Identity, Physical and Chemical Properties, Classification and Labelling

Active substance	Etofenprox
Product-type	18

Identity

Chemical name (IUPAC)	2-(4-ethoxyphenyl)-2-methylpropyl 3-phenoxybenzyl ether
Chemical name (CA)	Benzene, 1-[[2-(4-ethoxyphenyl)-2-methylpropoxy]methyl]-3-phenoxy
CAS No	80844-07-1
EC No	407-980-2
Other substance No.	CIPAC: 471
Minimum purity of the active substance as manufactured (g/kg or g/l)	970 g/kg
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	none
Molecular formula	$C_{25}H_{28}O_3$
Molecular mass	376.47 g/mol
Structural formula	

Physical and chemical properties

Melting point (state purity)	37.4 ± 0.1°C
Boiling point (state purity)	not determinable, degradation at about 200°C
Temperature of decomposition	no decomposition up to 150°C
Appearance (state purity)	solid (pure) or liquid (manufactured) white (pure) or amber (man.) slight aromatic odour (pure) or aromatic odour (manufactured)
Relative density (state purity)	1.172 g/cm^3 at 20.7°C ± 0.1°C
Surface tension	90% aqueous solution: 68.12 mN/m at 20.1°C
Vapour pressure (in Pa, state temperature)	8.13 x 10^{-7} Pa at 25°C 2.16 x 10^{-3} Pa at 80°C 7.01 x 10^{-3} Pa at 90°C
Henry's law constant (Pa m^3 mol $^{-1}$)	0.0136 Pa x m^3/mol at 25°C

Solubility in water (g/l or mg/l, state temperature)	- bidistilled water: 22.5 µg/L (20°C) - buffer at pH 4: 5.2 µg/L (20°C) - buffer at pH 9: 12.0 µg/L (20°C)
Solubility in organic solvents (in g/l or mg/l, state temperature)	Solubility (at 20°C): - Methanol: 49 g/L - Ethanol: 98 g/L - Acetone: 877 g/L - Ethylacetate: 837 g/L - Hexane: 667 g/L - Heptane: 621 g/L - Xylene: 856 g/L - Toluene: 862 g/L - Dichloromethane: 924 g/L
Stability in organic solvents used in biocidal products including relevant breakdown products	Etofenprox is stable in its biocidal products.
Partition coefficient (log P_{OW}) (state temperature)	Log P_{OW} = 6.9 / Log Pow
Dissociation constant	not applicable: Etofenprox has no sites which can either be protonated or dissociate at pH 3 to 10 (expert statement)
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	- UV/VIS absorption spectra: similar at pH values from 1 to 12; absorption maximum at 273 nm.
Flammability	not flammable
Explosive properties	not explosive

Classification and proposed labelling

with regard to physical/chemical data	-
with regard to toxicological data	Lakt., H362 – May cause harm to breast-fed children
with regard to ecotoxicological data and fate and behaviour	Aquatic acute 1 (M=100) Aquatic chronic 1 (M=1000) H400 – Very toxic to aquatic life H410 - Very toxic to aquatic life with long lasting effects P273 – Avoid release to the environment P391 – Collect spillage P501 – Dispose of contents/container in accordance with local/regional/national/international regulation (to be specified).

Chapter 2: Methods of Analysis

Analytical methods for the active substance

Technical active substance (principle of method)	CIPAC method 471/TC/M/3: Gas chromatography (GC) with flame ionisation detection (FID)
Impurities in technical active substance (principle of method)	confidential information

Analytical methods for residues

Soil (principle of method and LOQ)	Gas chromatography with MS detection LOQ=0.01 mg/kg, for Etofenprox and its metabolite α-CO
Air (principle of method and LOQ)	Gas chromatography with MS detection LOQ=1.00 µg/m^3, for Etofenprox and its metabolite α-CO
Water (principle of method and LOQ)	Gas chromatography with MS detection LOQ=0.05 µg/L, for Etofenprox and its metabolite α-CO in drinking, ground and surface water
Body fluids and tissues (principle of method and LOQ)	Not evaluated
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	Gas chromatography with MS detection LOQ= 0.01 mg/kg, for Etofenprox and its metabolite α-CO in oilseed rape, cabbage, cucumber
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Gas chromatography with MS detection LOQ=0.01 mg/kg, for Etofenprox and its metabolite α-CO in meat (ruminant and chicken) and egg LOQ=0.01 ml/l, for Etofenprox and its metabolite α-CO in milk

Chapter 3: Impact on Human Health

Absorption, distribution, metabolism and excretion in mammals

Rate and extent of oral absorption:	Rapid absorption (T_{max} values: 3 hrs [30mg/kg females]; 5 hrs 30 mg/kg males and 180mg/kg males and females]. Oral absorption with gavage application in PEG to bile-duct cannulated rats, based on content in urine, bile carcass and liver: ~ 30% (30 mg/kg) ~ 14% (180 mg/kg) $AUC_{180mg/kg}$ / $AUC_{30mg/kg}$ = 3.3 / 3.8 (M/F)
Rate and extent of dermal absorption:	Active substance: 13,8% Representative product for PT18: 16%
Distribution:	Extensive distribution after 7 doses with peak concentrations at 4 hours similar to, or lower than, peak plasma concentrations, except in fat (14 - 19-fold higher), adrenal (6 - 8-fold higher), liver (3.8 - 4.4-fold higher), ovary (2.7-fold higher), thyroid (2.4 - 2.7-fold higher) and GI tract (39 - 82-fold higher). Transferred via placenta to the fetus but placental and fetal concentrations are low relative to maternal plasma concentration (4.2-fold lower) and fetal elimination is rapid. Actively secreted into maternal milk (30 mg/kg bw dose for 7 days → radioactivity concentration in pup stomach from 41.3 to 88.3 µg/g compared to maternal plasma concentrations from 1.9 to 3.6 µg/ml), but transfer decreases markedly on cessation of dosing.
Potential for accumulation:	Yes: Half-life time is l5 / 8.5 days (M/F) in fat. No accumulation in other tissues, tissue concentrations decline rapidly in all tissues except fat. Concentrations in liver, kidney, fat and muscle after 7 daily doses are 2.7 - 5.5-fold higher than after one dose, except female fat (13-fold higher).
Rate and extent of excretion:	Extensive excretion, predominantly in the feces (~ 86 - 90% AD). Urinary excretion 6.3 - 10.7% AD, biliary excretion 15.2 - 29.6% AD at 30mg/kg and 9.9 - 10.3% AD at 180mg/kg. At least 90% of fecal excretion occurs within 72hrs and at least 88% of urinary excretion within 48 hours. Biliary excretion greatest at 3 - 15 hours.
Toxicologically significant metabolite(s):	≥ 63% AD metabolised, based on urinary and fecal metabolites. Two major metabolites (DE, 19.5 - 25.1% AD and 4'-OH, 7.2 - 13.8% AD) formed by O-deethylation of ethoxyphenyl moiety and ring hydroxylation of phenoxybenzyl moiety, subsequently eliminated in bile and urine as glucuronide or sulfate

	conjugates. Major liver components are unchanged parent (22.5 - 30.3% RD), DE (8.1 - 10.3% RD) and conjugates (24.1 - 43.3% RD). Major component of deconjugated bile is mixture of DE and 4'-OH (69 - 71% RD). Some evidence for the oxidative pathway forming very low levels of α-CO. Cleavage of parent molecule not a significant metabolic process. > 90% of the fat residue is unchanged parent molecule. DE = desethylEtofenprox 4'-OH = 4'-hydroxyEtofenprox α-CO = 2-(4-ethoxyphenyl)-2-methylpropyl 3-phenoxybenzoate AD = administered dose; RD = recovered dose in tissue

Acute toxicity

Rat LD_{50} oral	> 2000 mg/kg bw
Rat LD_{50} dermal	> 2000 mg/kg bw
Rat LC_{50} inhalation	> 5.88 mg/L air /4h (> 95% particles < 5.5 µm) by whole body exposure to a liquid aerosol.
Skin irritation	Non- irritant
Eye irritation	Non- irritant
Skin sensitization (test method used and result)	Non-sensitising (maximisation test)

Repeated dose toxicity

Species/ target / critical effect	rabbit (dermal 4-weeks): no target organs rat (feeding, 13-weeks): liver, thyroid rat (inhalation 13-weeks): liver, adrenal, thyroid rat (feeding, 110 weeks): liver, thyroid mouse (feeding, 108 weeks): liver, kidney
Lowest relevant oral NOAEL / LOAEL	Rat (feeding, 13-weeks): 20 / 120 mg/kg bw/day Rat (inhalation, 13 weeks): 12 / 60 mg/kg bw day (calculated from NOAEC / LOAEC, see below) Rat (feeding, 110 weeks): 3.7 / 25 mg/kg bw/day Mouse (feeding, 108 weeks): 3.1 / 10 mg/kg bw day
Lowest relevant dermal NOAEL / LOAEL	Rabbit (4-weeks): > 1000 mg/kg/day (for systemic effects; minor localized, reversible skin irritation observed)
Lowest relevant inhalation NOAEC / LOAEC	Rat (13-weeks): 0.04 / 0.21 mg/L

Genotoxicity	No genotoxic effects observed in all *in vitro* and *in vivo* assays employed (Ames-Test, in vitro cytogenicity test with human lymphocytes, in vitro gene mutation test

	V79 cells, in vitro UDS, in vivo micronucleus test).

Carcinogenicity

Species/type of tumour	Rat (2-year study)/thyroid follicular cell adenoma; MOA data support threshold and low relevance for humans
lowest dose with tumours	187 mg/kg bw day

Reproductive toxicity

Species/ Reproduction target / critical effect	rats / minimally increased pub mortality at parentally toxic dose levels
Lowest relevant reproductive NOAEL / LOAEL	**rat 2-generation:** parental: 37 / 246 mg/kg bw day: ↓ weight gain, ↑ liver, kidney and thyroid weights reproductive: 37 / 246 mg/kg bw day: minimal ↑ pup mortality offspring: 37 / 246 mg/kg bw/day: pre-weaning tremors, abnormal gait, histopathological alterations in liver, kidneys and thyroid, ↑ heart weight
Species/Developmental target / critical effect	rat and rabbit: no indication of teratogenic potency rat: ocular lesions (haemorrhage) in weanlings
Developmental toxicity	
Lowest relevant developmental NOAEL / LOAEL	**rabbit** maternal: 100 / 300 mg/kg bw: ↓ weight gain / food cons developmental: 100 / 300 mg/kg bw day: ↑ slight post-implantation loss and ↓ fetal weight gain. **rat** maternal: 28.4 / 79 mg/kg bw day: transiently reduced gestation weight developmental: 28.4 / 79 mg/kg bw day: ocular lesions (haemorrhage) in weanlings

Neurotoxicity / Delayed neurotoxicity

Species/ target/critical effect and lowest relevant developmental NOAEL / LOAEL	rat, no neurotoxic effects were observed in the acute neurotoxicity or in the 13-week neurotoxicity study at the highest doses tested, that were 2000 and 604 mg/kg bw, respectively. Delayed neurotoxicity: no data (a.i. has no chemical similarities to structures known or implicated in producing delayed neurotoxicity).

Other toxicological studies

.....	Rat 4-week investigative study: 1° target organ: liver 2° target organ: thyroid NOAEL (1° effect on liver) 1250 ppm (≡ 81.2mg/kg

bw/day) based on: ↑ hepatic UDPGT (M/F) at 5000 and 20000 ppm ↑ liver weight (M/F) at 5000 and 20000 ppm Also ↑ microsomal protein (M) and liver hypertrophy (M/F) at 20000 ppm ↑ serum TSH (M/F) at 5000 and 20000 ppm ↓ serum T4 (M) at 20000 ppm ↑ thyroid proliferation (M) at 20000 ppm Proposed mechanism leading to ↑ incidence of thyroid adenoma: ↑ hepatic UDPGT → ↓ serum T4 → ↑ serum TSH → ↑ thyroid proliferation → ↑ incidence of thyroid adenoma

Medical data

.....	Medical surveillance of production workers: no pattern of abnormalities in production operatives suggestive of adverse health risks due to exposure to Etofenprox. No clinical cases of poisoning incidents known to the applicant.

Summary	Value	Study	Assessment factor
systemic AEL $_{\text{human, short term}}$	0.085 mg/kg bw day	Rat developmental neurotoxicity feeding study	100 and correction for 30% oral absorption estimate
systemic AEL $_{\text{human, medium term}}$	0.06 mg/kg bw day	Rat subchronic feeding study	100 and correction for 30% oral absorption estimate
systemic AEL $_{\text{human, long term}}$	0.011 mg/kg bw day	Rat 2-year feeding study	100 and correction for 30% oral absorption estimate

Acceptable exposure scenarios (including method of calculation)

Production of active substance	Produced outside the EU.
Formulation of biocidal product	Produced outside the EU.
Application of biocidal product (user: trained/licensed professional)	Dermal and inhalative exposure (model "Spraying model 1 TNsG part 2, page 143)
Indirect exposure as a result of use	Dermal and oral exposure of infants
Exposure of pets	Exposure of pets needs to be prevented by labelling.
Dietary Exposure	Considered as not relevant, as the biocidal product should not be applied in areas where food for human consumption is prepared, consumed or stored, or where

feedingstuff for livestocks is prepared, consumed or stored.

Chapter 4: Fate and Behaviour in the Environment

Route and rate of degradation in water

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	Etofenprox: pH 4: stable (50°C)
	pH 7: stable (50°C)
	pH 9: stable (50°C)
	Metabolite: [^{14}C]- α-CO pH 4 and 7: stable in acetonitrile solution (9:1, v/v) at 50°C pH 9: hydrolysed to PENA and m-PBAcid at 35°C and 45°C Calculated DT_{50}: 9.6 days at 35°C (1st order, r^2=0.977) and 2.4 days at 45°C (1st order, r^2=0.985) Predicted DT_{50}: 42.8 days at 25°C (Arrhenius equation)
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	Etofenprox: Buffer solution pH 7, xenon arc lamp: DT_{50} 4.7 days (1st order) Natural pond water, xenon arc lamp: DT_{50} 7.9 days (1st order) Dark control: Etofenprox was found to be stable. Estimated DT_{50} at 30°N: 7.8 – 21.8 days (spring – winter) Estimated DT_{50} at 40°N: 8.4 – 44.2 days (spring – winter) Estimated DT_{50} at 50°N: 9.5 – 131 days (spring – winter) Metabolites: Formation of α-CO after 15 days: 37.8% AR in pond water 63.6% AR in buffer solution
Readily biodegradable (yes/no)	No; Closed bottle test: 17% degradation in 28 days; Modified Sturm test: 32% degradation in 28 days;
Biodegradation in seawater in STP	
DT_{50} whole system	1.3 days at 20°C
DT_{90} whole system	4.4 days at 20°C
Mineralisation	35.9% at 20°C (after 30 days)
Non-extractable residues	60.5% at 20°C (after 30 days)
Distribution in water / sediment systems (active substance)	after 1 days, water phase: 1.6% AR (no Etofenprox identified) after 1 days, sediment phase: 98.2% AR (almost exclusively Etofenprox) after 30 days, water phase: 5.5% AR (no Etofenprox identified) after 30 days, sediment phase: 63.2% AR (no Etofenprox identified)
Degradation in water/sediment	
DT_{50} water	Etofenprox, dissipation: 2.1 - 10.4 days at 20°C (n=2, r^2

	≥ 0.999)
DT_{90} water	Etofenprox, dissipation: 7.1 – 34.5 days at 20°C (n=2, r^2 = 0.999)
DT_{50} sediment (calculated)	Etofenprox, dissipation: 17.9 – 32.2 days at 20°C (n=2) 4'-OH, dissipation: 26.4 - 55.8 days at 20°C (n=2)
DT_{90} sediment (calculated)	Etofenprox, dissipation: 59.4 – 106.9 days at 20°C (n=2) 4'-OH, dissipation: 87.8 – 185.5 days at 20°C (n=2)
DT_{50} whole system	Etofenprox, degradation: 6.5 – 20.1 days at 20°C (n=2, r^2 =0.994) 4'-OH, degradation: 21.8 – 29.7 days at 20°C (n=2, r^2 =0.798)
DT_{90} whole system	Etofenprox, degradation: 23.8 - 71.0 days at 20°C (n=2, r^2 >0.994) 4'-OH, degradation: 59.8 – 97.9 days at 20°C (n=2)
Mineralisation	17.8 – 28.2% at 20°C (n=2, after 99 days)
Non-extractable residues	22.6 – 30.8 % at 20°C (n=2, after 99 days)
Distribution in water / sediment systems (active substance)	after 0 days, water phase: 22.3 - 32.1% (n=2) after 0 days, sediment phase: 63.1- 70.1% (n=2) after 99 days, water phase: not detected (n=2) after 99 days, sediment phase: 7.6-7.8% (n=2)
Distribution in water / sediment systems (metabolites)	water phase: max. 2.2% (4'-OH, after 14 days) other metabolites in water phase: each <2%
	sediment phase: max. 21.4% (4'-OH after 7 days) other metabolites in sediment phase: each <5%

Route and rate of degradation in soil

Mineralization after 120 days (aerobic)	38.2 - 45.6% AR after 120 days, at 20°C (n=4) [α-^{14}C-benzyl] & [2-^{14}C-propyl] labels
Non-extractable residues after 120 days	42.8 - 54.5% AR after 120 days, at 20°C (n=4) [α-^{14}C-benzyl] & [2-^{14}C-propyl] labels Maximum: 47.9 – 57% AR after 55 and 92 days (n=4)
Relevant metabolites - name and/or code, % of applied active ingredient (range and maximum)	no metabolite occurred at > 10% of the applied dose (up to 12 different radioactive fractions detected; most important: α-CO, 4'-OH, DE and DP)
Laboratory studies (range or median, with number of measurements, with regression coefficient)	DT_{50lab} (20°C, aerobic): 7 - 25 days (n=4, average r^2=0.982) geometric mean DT_{50} = 12 days
	DT_{90lab} (20°C, aerobic): 22 - 84 days (n=4, average r^2=0.982)
	DT_{50lab} (10°C, aerobic): 13 days (n=1, r^2=0.977)
	DT_{50lab} (20°C, anaerobic): no data required
	degradation in the saturated zone: no data required
Field studies (state location, range or median with number of measurements)	no data required

Anaerobic degradation	no data required
Soil photolysis	Etofenprox, xenon arc lamp: DT_{50} 19.3 days (1st order) DT_{90} 64.0 days (1st order) Dark control: DT_{50} 22.2 days (1st order) DT_{90} 73.8 days (1st order) Etofenprox: Estimated DT_{50} at 30°N 26.1 days Estimated DT_{90} at 30°N 86.4 days Metabolites: up to 10 minor metabolites <7.7%; six characterized (α-CO, 4'-OH, DE, DP, m-PB-acid, a mixture of PENA, EPMP and DP);
Non-extractable residues	no data required
Relevant metabolites - name and/or code, % of applied active ingredient (range and maximum)	no data required
Soil accumulation and plateau concentration	no data required

Adsorption/desorption

$K_{ads, F}$, $K_{des F}$ (ml/g)	$K_{ads\ F}$: 2.5 – 871.9, (n=5, soil to aqueous phase ratio of 1:25) $K_{des\ F}$: 42.8 – 818.0, (n=5, soil to aqueous phase ratio of 1:25)
$K_{ads, Foc}$, $K_{des Foc}$ (ml/g)	Etofenprox: $K_{ads, Foc}$: 1 546 – 100 214, arithmetic median 28 524, (n=5, soil to aqueous phase ratio of 1:25, all Freundlich coefficients) $K_{des\ Foc}$: 3661 - 96 029, arithmetic median 42 299, (n=5, soil to aqueous phase ratio of 1:25, all Freundlich coefficients) Metabolites: (EPI Suite estimation based on measured Log K_{ow}) α –CO: 36 870 4'-OH: 11 090
pH dependence (yes / no) (if yes type of dependence)	no

Fate and behaviour in air

Direct photolysis in air	Guideline not yet available
Quantum yield of direct photolysis	0.248 in buffer solution at pH 7 0.147 in natural pond water
Photo-oxidative degradation in air	Overall OH rate constant = 61.16×10^{-12} cm^3/molecule·sec DT_{50} calculated = 6.2 hours (5×10^5 OH/cm)
Volatilization	Not expected (vapour pressure = 8.13×10^{-7} Pa at 25°C and Henry's Law constant = 0.0136 Pa m^3/mol at 25°C)

Monitoring data, if available

Soil (indicate location and type of study)	Not available
Surface water (indicate location and type of study)	Not available
Ground water (indicate location and type of study)	Not available
Air (indicate location and type of study)	Not available

Chapter 5: Effects on Non-target Species

Toxicity data for aquatic species (most sensitive species of each group)

Species	Time-scale	Endpoint	Toxicity (mg/L)
Fish – Test substance: Etofenprox			
Oncorhynchus mykiss	96 h, flow-through	Mortality, LC_{50}	0.0027
Brachydanio rerio	40 d, flow-through	Mortality and development, NOEC	0.025
Fish – Test substance: metabolite α-CO			
Oncorhynchus mykiss	96 h, flow-through	Mortality, LC_{50}	>0.048
Invertebrates – Test substance: Etofenprox			
Daphnia magna	48 h, static renewal	Mortality, EC_{50}	0.0012
Daphnia magna	21 d, semi-static	Reproduction, NOEC	0.000054
Invertebrates – Test substance: metabolite α-CO			
Daphnia magna	48 h, static	Mortality, EC_{50}	>0.044
Algae – Test substance: Etofenprox			
Pseudokirchneriella subcapitata	72 h, static	Biomass, E_bC_{50}	>0.05625
Pseudokirchneriella subcapitata	72 h, static	Biomass, NOEC	0.05625
Algae – Test substance: : metabolite α-CO			
Pseudokirchneriella subcapitata	96 h, static	Biomass, E_bC_{50}	>0.053
Sediment dwelling organisms – Test substance: Etofenprox			
Chironomus riparius	10 d, static water-sediment system	Mortality, EC_{50}	>0.0209
Chironomus riparius	25 d, static water-sediment system, spiked water	Emergence, Development, NOEC	0.0038
Chironomus riparius	28 d, static water-sediment system, spiked sediment	Emergence, Development, NOEC	2.9 mg/kg dwt
Sediment dwelling organisms – Test substance: metabolite 4'-OH			
Chironomus riparius	48 h, static	Mortality, LC_{50}	0.0502
Microorganisms - Test substance: Etofenprox			

Activated sludge	3h, static	respiration rate, NOEC	≥0.0225

Effects on earthworms or other soil non-target organisms

Acute toxicity to earthworms	LC_{50} >47.2 mg as/kg dry soil Conversion to standard soil: LC_{50} >16.1 mg as/kg dry soil
Reproductive toxicity to earthworms	No data required

Terrestrial plant toxicity

Acute toxicity to plants	LC_{50} >200 g as/ha dry soil Conversion to 10 cm deep soil: LC_{50} >0.117 mg as/kg dry soil Conversion to standard soil: LC_{50} >0.234 mg as/kg dry soil
Reproductive toxicity to plants	No data required

Effects on soil micro-organisms

Nitrogen mineralization	NOEC ≥0.893 mg as/kg dry soil Conversion to standard soil: NOEC ≥2.024 mg as/kg dry soil (10.6% inhibition at 0.0893 mg as/kg, but no significant inhibition at 0.893 mg as/kg)
Carbon mineralization	NOEC ≥0.893 mg as/kg dry soil Conversion to standard soil: NOEC ≥ 2.024 mg as/kg dry soil

Effects on terrestrial vertebrates

Acute toxicity to mammals	No data required
Acute toxicity to birds	LD_{50} >2000 mg as/kg bw (mallard duck)
Dietary toxicity to birds	LC_{50} >5000 mg as/kg diet (mallard duck and bobwhite quail)
Reproductive toxicity to birds	NOEL 1000 mg as/kg diet (bobwhite quail)

Effects on honeybees

Acute oral toxicity	LD_{50}: 0.0238 µg a.i./bee (96 hr)
Acute contact toxicity	LD_{50}: 0.0145 µg a.i./bee (72 hr)

Effects on other beneficial arthropods

Acute oral toxicity	-
Acute contact toxicity	LR_{50}: 0.42 g a.i./ha (*Aphidius rhopalosiphi*)
Acute toxicity to ……..	LR_{50}: 0.70 g a.i./ha (*Typhlodro-mus pyri*)

Bioconcentration

Bioconcentration factor (BCF)	edibles, BCF=1554 L/kg in non-edibles, BCF=7213 L/kg whole fish, BCF=3951 L/kg (corrected for a whole body lipid content of 5%, the BCF is 2565 L/kg).
Depration time (DT_{50}) (DT_{90})	CT_{50} = 9-16 days (first-order kinetics) CT_{95} = 39-69 days (first-order kinetics)
Level of residues (%) in organisms after the 14 day Depurationphase	34% - 67% (after 14 days depuration phase) 1.6% - 5.2% (after 62 days depuration phase)
Level of metabolites (%) in organisms accounting for > 10 % of residues	None

Chapter 6: Other End Points

none

APPENDIX II: LIST OF INTENDED USES

Etofenprox is an insecticide acting by direct contact and ingestion. It acts on sodium channels of the insect nervous system by disturbing the normal neurotransmittance. It has been evaluated for its use as an insecticide (Product Type 18) for use by professionals (PT 18.01). The representative formulation is Etofenprox 10%EW, containing 10% of active substance, and the proposed application rate is 70 mg a.s./m^2.

The efficacy of Etofenprox 10% EW as a surface spray has been tested against cockroaches (*Blattella germanica*) on carpet tiles as a model surface (Waters H. 2009). The experimental setup involved surface treatment of half of the test arena thus allowing roaches freedom from being confined to that specific part of the cage. This study demonstrates the efficacy of Etofenprox. The data suggest that the rate of 70 mg a.i./m^2 corresponds to the minimum effective dose on carpet tiles. Further usages with specific application rates will be applied for at the product authorization stage. The data included in this dossier have not been submitted to statistical testing. Given the number of experimental replicates (20) for each treatment the Austrian CA nevertheless assumes Etofenprox to efficiently kill cockroaches. The CA also assumes the minimum efficient dose to be 70 mg a.i./m^2. .

However, the applicant must, at the product authorisation stage, justify this decision by providing the results of adequate statistical tests demonstrating (i) that the observed mortality rates at lower doses are significantly different compared to the mortality at 70 mg a.i./m^2 and (ii) that there is no significant difference when comparing mortalities after application of 70 or 140 mg a.i./m^2, respectively.

For resistance management purposes, Etofenprox is an IRAC Mode of Action group 3A insecticide. Any insect population may contain individuals naturally resistant to Etofenprox and other group 3A insecticides. If these insecticides are used repeatedly, the resistant individuals may eventually dominate the pest insect population. These resistant insects may not be controlled by Etofenprox or by other group 3A insecticides.
To delay the development of resistance:

- Avoid exclusive repeated use of insecticides from the same chemical subgroup which for Etofenprox is IRAC subgroup 3A.
- Alternate with products from other IRAC Mode of Action groups.
- Integrate other control measures such as chemical, cultural and biological, into insect control programs.

Specific strategies to prevent the development of resistance will be outlined at the product authorisation stage.

Table Appendix II-1: Acceptable intended uses of the biocidal product

PT	18
Formulation Type	Emulsion (EW)[1]
Conc. of a.s. in formulation	10%w/w
Conc. of a.s. in application solution	0.175%w/w (Dilution of the biocidal product with water)
Field of use envisaged	Spot treatment - use to treat hiding-places of cockroaches like cracks and crevices - for indoor use only
Target organisms	Adult cockroaches (i.e. *Blattella germanica* and *Blatta orientalis*)
User	Professional
Objects to be protected	Treatment of hiding-places of cockroaches like cracks and crevices (spot treatment)
Method of application	Application with knapsack sprayers (1-3 bars)
Applied amount of application solution	40 ml/m² surface
Application rate of a.s.	70 mg a.s./m² surface
Number of treatments per year	One application every 8 weeks. Maximum 2 applications per year and per site
Limitations	• Not for use outdoors • Not for use as a space spray • Not for area treatment- treatment of cracks and crevices in room perimeters only • Only for use with gloves and coveralls • Duration of use: Up to 2 hours per day. Not for use on surfaces where food for human consumption is prepared, consumed or stored, or where feedingstuff for livestock is prepared, consumed or stored. • Prevent contact of infants, children and companion animals with biocidal product during and after application (e.g. contamination via contaminated surfaces).

[1] Emulsion, oil in water

The term “indoors” is based on the scope of the guidance document OECD 2008[12] (household use).

12 “Emission scenario document for insecticides, acaricides and products to control other arthropods for household and professional uses”, OECD 2008

APPENDIX III: LIST OF STUDIES

Data protection is claimed by the applicant in accordance with Article 12.1(c) (i) and (ii) of Council Directive 98/8/EC for all study reports marked "Y" in the "Data Protection Claimed" column of the table below. For studies marked Yes(i) data protection is claimed under Article 12.1(c) (i), for studies marked Yes(ii) data protection is claimed under Article 12.1(c) (ii). These claims are based on information from the applicant. It is assumed that the relevant studies are not already protected in any other Member State of the European Union under existing national rules relating to biocidal products. It was however not possible to confirm the accuracy of this information.

LIST OF STUDIES FOR THE ACTIVE SUBSTANCE – SORTED BY SECTION NUMBER

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Date of 1st submission	Owner
A 2.7/01	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	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 2.7/02	2003a	MSDS of Etofenprox technical Mitsui Chemicals, Inc., MSDS No: 622141E2 Landis Kane Consulting, Report No. 500-3-02 Not GLP, published	N	Not applicable as no data protection claimed	Public in-formation
A 3.1.1	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	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 3.1.2	1998	Determination of the boiling point / boiling range of Etofenprox RCC Ltd, Report No: 692730	Y	March 2004 (PT	Mitsui Chemicals

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Date of 1st submission	Owner
		Landis Kane Consulting, Document No. 500-2-02 GLP, unpublished		8 and 18)	Agro., Inc.
A 3.1.3	1998	Determination of the relative density of Etofenprox RCC Ltd, Report No. 692728 Landis Kane Consulting, Document No. 500-2-03 GLP, unpublished	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 3.2	2000	Determination of the vapour pressure of Etofenprox RCC Ltd, Report No. 751803 Landis Kane Consulting, Document No. 500-2-04 GLP, unpublished	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 3.3.1/01	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	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 3.3.1/02	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	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 3.3.1/03	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	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 3.3.2/01	1999	Color of Etofenprox (MTI-500) Physical state of Etofenprox (MTI-500) Mitsui Chemicals, Inc., Life Science Laboratory, Report No.	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Date of 1st submission	Owner
		not specified Landis Kane Consulting, Document No. 500-2-06 Not GLP, unpublished			
A 3.3.2/02	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	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 3.3.3/01	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	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 3.3.3/02	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	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 3.4/01	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	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 3.4/02	2002	Measurement of UV-VIS absorption spectrum	Y	March 2004 (PT	Mitsui Chemicals

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Date of 1st submission	Owner
		of 4'-OH Kurume Laboratory, Chemicals Evaluation and Research Institute, Report No. 82072 Landis Kane Consulting, Document No. 500-2-09 GLP, unpublished		8 and 18)	Agro., Inc.
A 3.4/03	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	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 3.5/01	2000	Determination of the water solubility of ^{14}C-Etofenprox at three pH values and amendment dated October 04, 2000 RCC Ltd, Report No. 755515 Landis Kane Consulting, Document No. 500-2-11 GLP, unpublished	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 3.5/02	2002a	Physico-chemical testing with [14C]-Alpha-CO: water solubility Inveresk Research, Report No: 21386 Landis Kane Consulting, Document No. 500-2-12 GLP, unpublished	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 3.5/03	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	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 3.5/04	2002	Determination of water solubility for PENA by flask method Kurume Laboratory, Chemicals Evaluation and Research Institute, Report No. 82073	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Date of 1st submission	Owner
		Landis Kane Consulting, Document No. 500-2-14 GLP, unpublished			
A 3.5/05	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	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc
A 3.6	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	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 3.7	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	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 3.9/01	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	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 3.9/02	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	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Date of 1st submission	Owner
A 3.9/03	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	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 3.9/04	2002	1-Octanol/water partition coefficient test of PENA (HPLC method) Kurume Laboratory, Chemicals Evaluation and Research Institute, Report No. 82074 Landis Kane Consulting, Document No. 500-2-19 GLP, unpublished	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 3.10	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	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 3.11/01	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	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 3.11/02	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	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Date of 1st submission	Owner
A 3.12	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	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 3.13	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	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 3.15	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	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 3.16	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	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 3.17	2004	Statement concerning the stability of Etofenprox technical during storage and shipment. Mistui Chemicals, Inc., Document No. not specified Landis Kane Consulting, Document No. 500-2-66 Not GLP, unpublished	N	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Date of 1st submission	Owner
A 4.1/01	2002b	Etofenprox – Validation of analytical methods to support 5-batch analysis of Etofenprox to fulfil the requirements of OPPTS Guidelines 830.1700, 830.1750 and 830.1800 and EC Council Directive 94/37/EEC Article 1.9 to 1.11. Inveresk Research, Report No. 21164 Landis Kane Consulting, Document No. 500-4-01 GLP, unpublished	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 4.1/02	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	Not applicable as no data protection claimed	Public in-formation
A 4.2/01	2003a	Validation of the residue analytical method for MTI-500 and α-CO in soil RCC Ltd, Report No. 811607 Landis Kane Consulting, Document No. 500-4-12 GLP, unpublished	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 4.2/02	2003b	Development and validation of the residue analytical method for MTI-500 and α-CO in air RCC Ltd, Report No. 811620 Landis Kane Consulting, Document No. 500-4-17 GLP, unpublished	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 4.2/03	2003c	Validation of the residue analytical method for MTI-500 and α-CO in drinking, ground and surface water RCC Ltd, Report No. 811618 Landis Kane Consulting, Document No. 500-4-15 GLP, unpublished	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Date of 1st submission	Owner
A 4.3/01	2001	Validation of the residue analytical method for MTI-500 and α-CO in oil seed rape RCC Ltd, Report No. 789390 Landis Kane Consulting, Document No. 500-4-08 GLP, unpublished	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 4.3/02	2002	Validation of the residue analytical method for MTI-500 and α-CO in cabbage RCC Ltd, Report No. 814588 Landis Kane Consulting, Document No. 500-4-07 GLP, unpublished	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 4.3/03	2003d	Validation of the residue analytical method for MTI-500 and α-CO in cucumber RCC Ltd, Report No. 789377 Landis Kane Consulting, Document No. 500-4-03 GLP, unpublished	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 4.3/04	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	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 4.3/05	2003e	Development and validation of the residue analytical method for MTI-500 and α-CO in meat (ruminant and chicken), milk, fat (ruminant) and egg RCC Ltd, Report No. 791245 Landis Kane Consulting, Document No. 500-4-19 GLP, unpublished	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 4.3/06	2003b	Etofenprox: independent laboratory validation of an analytical method used for the determination of residues of	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Date of 1st submission	Owner
		Etofenprox in foodstuffs of animal origin PTRL Europe, Report No: P/B 701 G Landis Kane Consulting, Document No. 500-4-41 GLP, unpublished			
A 5.3/01	2003a	Determination of toxic values against *Reticulitermes santonensis* De Feytaud according to EN 117 (08/90) without accelerated ageing procedure – test material SPU-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	March 2004 (PT8)	Spiess-Urania Chemicals GmbH
A 5.3/02	2003b	Determination of toxic values against *Reticulitermes santonensis* De Feytaud according to EN 117 (08/90) after leaching procedure according to EN 84 (05/97) – test material SPU-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	March 2004 (PT8)	Spiess-Urania Chemicals GmbH
A 5.3/03	2003c	Determination of toxic values against larvae of *Hylotrupes bajulus* (L) according to EN 47 (08/90) without accelerated ageing procedure – test material SPU-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	March 2004 (PT8)	Spiess-Urania Chemicals GmbH

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Date of 1st submission	Owner
A 5.3/04	2003d	Determination of toxic values against larvae of *Hylotrupes bajulus* (L) according to EN 47 (08/90) after leaching procedure to EN 84 – test material SPU-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	March 2004 (PT8)	Spiess-Urania Chemicals GmbH
A 5.4	1985	Symptomatic and neurophysiological activities of new synthetic non-ester pyrethroids, Etofenprox, MTI-800, and related compounds Pesticide Biochemistry and Physiology Vol. 25, pp. 387 -395, 1986 Landis Kane Consulting, Document No. 500-3-01 Not GLP, published	N	Not applicable as no data protection claimed	Public in-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	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 6.1.1/02	1985a	Etofenprox (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	March 2004 (PT 8 and 18)	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	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Date of 1st submission	Owner
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	March 2004 (PT 8 and 18)	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	March 2004 (PT 8 and 18)	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	March 2004 (PT 8 and 18)	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	March 2004 (PT 8 and 18)	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	March 2004 (PT 8 and 18)	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 Report No. NEMRI-H-85-5 Landis Kane Consulting, Document No. 500-5-11 GLP, not published	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 6.1.4.e	1985b	MTI-500 Primary ophthalmic stimulation test in rabbits - Amendment No. 1 from October 28, 1991 Report No. NEMRI-H-85-55 Landis Kane Consulting,	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Date of 1st submission	Owner
		Document No. 500-5-12 GLP, not published			
A 6.1.5	1985	MTI-500 Skin sensitization test in guinea pigs - Correction to translation from October 21, 2003 Report No. not specified Landis Kane Consulting, Document No. 500-5-13 GLP, not published	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 6.2/01	1985a	The biokinetics and metabolism of ^{14}C-ethofenprox in the rat Report No. HRC/MTC 68/84610 Landis Kane Consulting, Document No. 500-5-02 GLP, not published	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 6.2/02	2001a	[14C]-MTI-500: absorption, distribution, metabolism and excretion after single oral administration to male rats - amendment dated November 30,2001 Report No. 801382 Landis Kane Consulting, Document No. 500-5-01 Not GLP, not published	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 6.2/03	2001b	[14C]-alpha-CO: absorption, distribution, metabolism and excretion after single oral administration to male rats RCC Ltd., Report No. 819832 Landis Kane Consulting, Document No. 500-5-45 Not GLP, not published	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 6.2/04	1985b	The metabolism of ^{14}C-ethofenprox in dogs Report No. HRC/MTC 69/84583 Landis Kane Consulting, Document No. 500-5-04 GLP, not published	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 6.2/05	1986	Metabolism study of ethofenprox (MTI-500), metabolism in rat Report No. not specifed Landis Kane Consulting,	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Date of 1st submission	Owner
		Document No. 500-5-03 Not GLP, not published			
A 6.2/06	1999	Dermal absorption of ^{14}C-Etofenprox in male rats (preliminary and definitive phases) Report No. 6648-135 Landis Kane Consulting, Document No. 500-5-80 GLP, not published	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals 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	March 2004 (PT 8 and 18)	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	March 2004 (PT 8 and 18)	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	March 2004 (PT 8 and 18)	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	March 2004 (PT 8 and 18)	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	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Date of 1st submission	Owner
		Report No. MTC 59/85581 Landis Kane Consulting, Document No. 500-5-24 GLP, not published			
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	March 2004 (PT 8 and 18)	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	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 6.6.1	1985	Reverse mutation in *Salmonella typhimurium* Report No. 162001-M-06185 Landis Kane Consulting, Document No. 500-5-19 GLP, not published	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 6.6.2	1985a	*In vitro* assessment of the clastogenic activity of MTI-500, ethofenprox, in cultured human peripheral lymphocytes Report No. 85/MT0017/430 Landis Kane Consulting, Document No. 500-5-21 Not GLP, not published	Y	March 2004 (PT 8 and 18)	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	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 6.6.3/02	1985b	Unscheduled DNA synthesis in human cells cell line: Hela S3 Life Science Research, Roma Toxicology Centre, Report No.	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Date of 1st submission	Owner
		162003-M-05785 Landis Kane Consulting, Document No. 500-5-23 GLP, not published			
A 6.6.4	1985c	MTI-500, ethofenprox: Assessment of clastogenic action on bone marrow erythrocytes in the micronucleus test Report No. 85/MT0016/406 Landis Kane Consulting, Document No. 500-5-22 Not GLP, not published	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 6.6.7/01	1985a	MTI-500 α-CO: Acute oral toxicity in the rat Report No. 85/MT0018/474 Landis Kane Consulting, Document No. 500-5-38 GLP, not published	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 6.6.7/02	1985b	MTI-500 α-CO: Acute percutaneous toxicity in the rat Report No. 85/MT0019/473 Landis Kane Consulting, Document No. 500-5-39 GLP, not published	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 6.6.7/03	1987	MTI-500 α-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	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 6.6.7/04	1988	MTI-500 α-CO Toxicity to rats by dietary administration for 13 weeks Report No. MTC 141/871458 Landis Kane Consulting, Document No. 500-5-41 GLP, not published	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 6.6.7/05	1985a	MTI-500 α-CO: Assessment of its mutagenic potential in amino-acid auxotrophs of *Salmonella typhimurium* and *Escherichia coli* to comply with the testing guidelines of the Japanese Ministry of Agriculture, Forestry and	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Date of 1st submission	Owner
		Fisheries (1985) Report No. 85/MT0020/433 Landis Kane Consulting, Document No. 500-5-42 GLP, not published			
A 6.6.7/06	1985b	MTI-500 α-CO: Assessment of its ability to cause lethal DNA damage in strains of *Escherichia coli* Report No. 85/MT0022/504 Landis Kane Consulting, Document No. 500-5-44 GLP, not published	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 6.6.7/07	1985b	*In vitro* assessment of the clastogenic activity of MTI-500 α-CO in cultured human peripheral lymphocytes Report No. 85/MT0021/711 Landis Kane Consulting, Document No. 500-5-43 GLP, not published	Y	March 2004 (PT 8 and 18)	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	March 2004 (PT 8 and 18)	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	March 2004 (PT 8 and 18)	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	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 6.8.1.1	1985b	Effect of ethofenprox (MTI-500) on pregnancy of the rat with	Y	March 2004 (PT	Mitsui Chemicals

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Date of 1st submission	Owner
/02		rearing to maturation of the F1 generation Report No. MTC 64/85422 Landis Kane Consulting, Document No. 500-5-34 GLP, not published		8 and 18)	Agro., Inc.
A 6.8.1.1 /03	1985c	Effect of ethofenprox (MTI-500) on the peri and post natal period of the rat with rearing to maturation of the F1 offspring Report No. MTC 65/85423 Landis Kane Consulting, Document No. 500-5-35 GLP, not published	Y	March 2004 (PT 8 and 18)	Mitsui 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 Report No. MTC 85(84)/85444 Landis Kane Consulting, Document No. 500-5-36 GLP, not published	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 6.8.1.2 /02	2000	Rabbit developmental toxicity study with Etofenprox Report No. 6648-146 Landis Kane Consulting, Document No. 500-5-37 GLP, not published	Y	March 2004 (PT 8 and 18)	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 Report No. MTC 67/85706 Landis Kane Consulting, Document No. 500-5-32 GLP, not published	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 6.9/01	2002	Acute oral gavage neurotoxicity study with MTI-500 in rats Report No. 6648-154 Landis Kane Consulting, Document No. 500-5-06 GLP, not published	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 6.9/02	2003a	13-week dietary neurotoxicity study with MTI-500 in rats	Y	March 2004 (PT	Mitsui Chemicals

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Date of 1st submission	Owner
		Report No. 6648-153 Landis Kane Consulting, Document No. 500-5-47 GLP, not published		8 and 18)	Agro., Inc.
A 6.9/03	2003	Etofenprox developmental neurotoxicity study in the rat by oral (dietary) administration Report No. MTU 215/032731 Landis Kane Consulting, Document No. 500-5-48 GLP, not published	Y	March 2004 (PT 8 and 18)	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 Huntingdon Life Sciences Ltd., Report No. MTU/222/1023183 Landis Kane Consulting, Document No. 500-5-05 GLP, not published	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 6.10	2003b	4-week dietary investigative study on thyroid function and hepatic micriosomal enzyme induction with MTI-500 in rats Report No. 6648-156 Landis Kane Consulting, Document No. 500-5-83 GLP, not published	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
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	March 2004 (PT 8 and 18)	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	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 6.11/03	1985	General pharmacology of MTI-500 Institute of Biological Sciences, Mitsui Pharmaceuticals Inc., Japanese Pharmacology &	N	Not applicable as no data protection	Public in-formation

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Date of 1st submission	Owner
		Therapeutics, Vol.13 (11), 229-244 (1985) Landis Kane Consulting, Document No. 500-5-46 Not GLP, published		claimed	
A 6.12.1	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	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 6.12.7 → A 2.7/02	2003a	MSDS of Etofenprox technical Mitsui Chemicals, Inc., MSDS No: 622141E2 Landis Kane Consulting, Report No. 500-3-02 Not GLP, published	N	Not applicable as no data protection claimed	Public in-formation
A 6.12.8 → A 2.7/02	2003a	MSDS of Etofenprox technical Mitsui Chemicals, Inc., MSDS No: 622141E2 Landis Kane Consulting, Report No. 500-3-02 Not GLP, published	N	Not applicable as no data protection claimed	Public in-formation
A 7.1.1.1.1 /01	2001	^{14}C-Etofenprox: hydrolysis at three different pH values RCC Ltd, Report No. 731158 Landis Kane Consulting, Document No. 500-2-20 GLP, unpublished	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 7.1.1.1.1 /02	2003	Hydrolytic stability of [^{14}C]-alpha-CO in buffered aqueous solution Inveresk Research, Report No. 21993 Landis Kane Consulting, Document No. 500-7-09 GLP, unpublished	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 7.1.1.1.2 /01	2003	Aqueous photolysis of [^{14}C]-Etofenprox under laboratory conditions and determination of quantum yield	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Date of 1st submission	Owner
		RCC Ltd, Report No. 755526 Landis Kane Consulting, Document No. 500-2-21 GLP, unpublished			
A 7.1.1.1.2 /02	2003	Artificial sunlight photodegradation of [^{14}C]-alpha - CO in buffered aqueous solution Inveresk Research, Report No. 21971 Landis Kane Consulting, Document No. 500-7-10 Not GLP, unpublished	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 7.1.1.2.1	1993	Biodegradation of ^{14}C-Etofenprox in an adapted modified Sturm test Solvay Duphar B.V., Report No. C.DNL.62.002 Landis Kane Consulting, Document No. 500-7-12 GLP, unpublished	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 7.1.1.2.1 /02	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	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 7.1.2.1.1	2012	^{14}C-Etofenprox – Biodegradation in activated sludge under aerobic conditions, IES Ltd, GLP, unpublished report No 20110163	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 7.1.2.2.2	2001	(^{14}C)-MTI-500: degradation and	Y	March	Mitsui

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Date of 1st submission	Owner
/01		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		2004 (PT 8 and 18)	Chemicals Agro., Inc.
A 7.1.2.2.2 /02	2002	(^{14}C)-MTI-500: recovery of radioactivity, isolation and analysis of a degradation product from a water-sediment system Covance Laboratories Ltd., Report No. CLE 719/14-D2149 Landis Kane Consulting, Document No. 500-7-14 GLP, unpublished	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 7.1.2.2.2 /03	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	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 7.1.3	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	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 7.1.3/02	2011	^{14}C-Etofenprox: Adsorption/Desorption on Soil,	Y	April 2006 (PT	Mitsui Chemicals

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Date of 1st submission	Owner
		Innovative Environmental Services (IES) Ltd., report no. 8180 015, unpublished		18)	Agro., Inc
A 7.2.2.1	2001	^{14}C-Etofenprox: degradation and metabolism in four soils incubated under aerobic conditions - first amendment dated February 26, 2002 - second amendment dated June 03, 2003 RCC Ltd, Report No. 728987 Landis Kane Consulting, Document No. 500-7-01 GLP, unpublished	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 7.2.2.4	2002b	Photolysis of ^{14}C-MTI-500 on soil surface under laboratory conditions RCC Ltd, Report No. 800616 Landis Kane Consulting, Report No. 500-7-04 GLP, unpublished	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals, Inc.
A 7.2.3.2	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	March 2004 (PT 8 and 18)	Spiess-Urania Chemicals GmbH
A 7.3.1	2001d	MTI-500: estimation of the photochemical oxidative degradation - Amended final report from January 31, 2001, Covance	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Date of 1st submission	Owner
		Laboratories Ltd., Report No. 719/12-D2141 Landis Kane Consulting, Document No. 500-2-27, Not GLP, unpublished			
A 7.4.1.1 /01	1995a	Etofenprox technical - acute toxicity to Rainbow trout (*Oncorhynchus mykiss*) under flow-through conditions Report No. 94-12-5625 Landis Kane Consulting, Document No. 500-8-05 GLP, unpublished	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 7.4.1.1 /02	1995b	Etofenprox technical - acute toxicity to Bluegill sunfish (*Lepomis macrochirus*) under flow-through conditions Report No. 95-1-5653 Landis Kane Consulting, Document No. 500-8-07 GLP, unpublished	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 7.4.1.1 /03	2002a	Acute toxicity of α-CO to Rainbow trout (*Oncorhynchus mykiss*) in a 96-hour flow-through test Report No. 841573 Landis Kane Consulting, Document No. 500-8-09 GLP, unpublished	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 7.4.1.2 /01	2003	Etofenprox technical: static renewal acute toxicity test with Daphnids (*Daphnia magna*) Springborn Smithers Laboratories (Europe) AG, Report No. 1045.000.110 Landis Kane Consulting, Document No. 500-8-51 GLP, unpublished	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 7.4.1.2 /02	2002b	Acute toxicity of α-CO to *Daphnia magn*a in a 48-hour immobilization test RCC Ltd, Report No. 841575 Landis Kane Consulting, Document No. 500-8-10 GLP, unpublished	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Date of 1st submission	Owner
A 7.4.1.3 /01	2003	Etofenprox technical: static toxicity test with the freshwater algae *Pseudokirchneriella subcapitata* Springborn Smithers Laboratories (Europe) AG, Report No. 1045.000.430 Landis Kane Consulting, Document No. 500-8-52 GLP, unpublished	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 7.4.1.3 /02	2002c	Toxicity of α-CO to *Pseudokirchneriella subcapitata* (formerly *Selenastrum capricornutum*) in a 96-hour algal growth inhibition test RCC Ltd, Report No. 841577 Landis Kane Consulting, Document No. 500-8-11 GLP, unpublished	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 7.4.1.4	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	March 2004 (PT 8 and 18)	Spiess-Urania Chemicals GmbH
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	March 2004 (PT 8 and 18)	Spiess-Urania & Mitsui Chemicals Agro., Inc.
A 7.4.3.2	2005	Toxic effects of MTI-500 (Etofenprox) to zebra fish (Brachydanio rerio) in an early-life stage toxicity test Report no. 853517 Landis Kane Consulting, Document No. 500-8-66 GLP, unpublished	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Date of 1st submission	Owner
A.7.4.3.2/02	2011	A Life Cycle test with the Zebrafish (*Danio rerio*) under flow through conditions, Fraunhofer-Institute for Molecular Biology and Applied Ecology (IME), report no. LKC-001/4-60/A, unpublished GLP	Y	April 2006 (PT 18)	Mitsui Chemicals Agro., Inc.
A 7.4.3.3.1	2002	Bioconcentration: flow-through fish test with MTI-500 (Trebon) in Bluegill sunfish Report No. 762254 Landis Kane Consulting, Document No. 500-8-15 GLP, unpublished	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 7.4.3.4	1993	The chronic toxicity of ^{14}C-Etofenprox to *Daphnia magna* Solvay Duphar B.V., Report No. C.DNL.51.007 Landis Kane Consulting, Document No. 500-8-18 GLP, unpublished	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 7.4.3.5.1 /01	2002a	Effect of MTI-500 on larvae of *Chironomus riparius* in a 10-day toxicity test RCC Ltd, Report No. 803777 Landis Kane Consulting, Document No. 500-8-21 GLP, unpublished	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 7.4.3.5.1 /02	2002b	Acute toxicity of 4'-OH to first - instar larvae of the midge *Chironomus riparius* RCC Ltd, Report No. 841579 Landis Kane Consulting, Document No. 500-8-12 GLP, unpublished	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 7.4.3.5.1 /03	2002c	Effect of MTI-500 on the development of sediment-dwelling larvae of *Chironomus riparius* in a water-sediment system RCC Ltd, Report No. 803608 Landis Kane Consulting, Document No. 500-8-22 GLP, unpublished	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A	2011	Etofenprox: A Prolonged	Y	April	Mitsui

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Date of 1st submission	Owner
7.4.3.5.1/04		Sediment Toxicity Test with *Chironomus riparius* Using Spiked Sediment. Wildlife International, Ltd., amended report no. 236A-133, unpublished GLP		2006 (PT 18)	Chemicals Agro., Inc
A7.4.3.5	2004	Assessment of the effects of Etofenprox (MTI-500) on natural communities of freshwater organisms in outdoor mesocosms. Cambridge Environmental Assessments (CEA), Boxworth, Cambridgeshire, England, unpublished report no. XEC003,unpublished	Y	April 2006 (PT 18)	Mitsui Chemicals Agro., Inc
A 7.5.1.1	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	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 7.5.1.2	1989	The subacute toxicity (LC50) of ethofenprox (MTI-500) to the earthworm (*Eisenia foetida*) Huntingdon Research Centre Ltd., Report No. MTF 2/881276 Landis Kane Consulting, Document No. 500-8-25 GLP, unpublished	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 7.5.1.3	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	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 7.5.3.1.1	1985	The acute toxicity (LD50) of MTI-500 (Etofenprox) to the Mallard duck Report No. MTC 77C/84793 Landis Kane Consulting,	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Date of 1st submission	Owner
		Document No. 500-8-01 GLP, unpublished			
A 7.5.3.1.2/01	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 Report No. MTC 77A/84795/2 Landis Kane Consulting, Document No. 500-8-02 GLP, unpublished	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 7.5.3.1.2/02	1984b	The subacute dietary toxicity (LC50) of MTI-500 (Etofenprox) to the Mallard duck - amended final report dated June 26, 1985 - signature pages added: August 21, 1985 Report No. MTC 77B/84795/2 Landis Kane Consulting, Document No. 500-8-03 GLP, unpublished	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 7.5.3.1.3	1996	MTI-500 Effects on reproduction in Bobwhite quail after dietary administration Report No. MTC 270/962282 Landis Kane Consulting, Document No. 500-8-04 GLP, unpublished	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A7.5.3.2/01	2005a	Etofenprox: An acute oral toxicity test to evaluate the effect on survival of the honeybee *Apis mellifera* L. MITOX, Report No. LK004AMO Landis Kane Consulting, Document No. 500-8-69 GLP, not published	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A7.5.3.2/02	2005b	Etofenprox: An acute contact toxicity test to evaluate the effect on survival of the honeybee *Apis mellifera* L.	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Date of 1st submission	Owner
		MITOX, Report No. LK006AMT Landis Kane Consulting, Document No. 500-8-70 GLP, not published			
A7.5.3.2/03	2001a	A laboratory dose-response study to evaluate the effects of MTI-500 30% EC on survival and reproduction of the parasitoid wasp *Aphidius rhopalosiphi* (DeStephani-Perez) (Hymenoptera: Braconidae) MITOX, Report No. LK001ARL Landis Kane Consulting, Document No. 500-8-39 GLP, not published	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A7.5.3.2/04	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, Report No. LK002TPL Landis Kane Consulting, Document No. 500-8-40 GLP, not published	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.
A 7.5.5.1	2011	Etofenprox: accumulation and elimination in earthworms (Eisenia fetida) in artificial soil, IBACON GmbH, report number 55641119, 02 February 2011, unpublished GLP	Y	April 2006 (PT 18)	Mitsui Chemicals Agro., Inc
A 7.5.6	2005	Insecticidal activity of the environmental metabolites of Etofenprox. Mitsui Chemicals, Inc. Landis Kane Consulting, Document No. 500-8-67 Not GLP, unpublished	Y	March 2004 (PT 8 and 18)	Mitsui Chemicals Agro., Inc.

LIST OF STUDIES FOR THE BIOCIDAL PRODUCT – SORTED BY SECTION NUMBER

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Date of 1st submission	Owner
B 2.2/11	2002	MSDS	N	Not applicable as no data protection claimed	Public in-formation
B 2.2/12	2003	MSDS	N	Not applicable as no data protection claimed	Public in-formation
B 2.2/13	2000	MSDS	N	Not applicable as no data protection claimed	Public in-formation
B 2.2/14	2003	MSDS	N	Not applicable as no data protection claimed	Public in-formation
B 2.2/16	2001	MSDS	N	Not applicable as no data protection claimed	Public in-formation
B 2.2/17	2003	MSDS	N	Not applicable as no data protection claimed	Public in-formation
B3.1.1/02	2006a	Etofenprox 10%EW: Physical state, colour, odor Landis Kane Consulting, Report No. 06-alpha-20 Landis Kane Consulting, Document No.500-2-74 Not GLP, published	Y	April 2006 (PT 18)	Mitsui Chemicals Agro., Inc.

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Date of 1st submission	Owner
B3.2/02	2006b	Etofenprox 10%EW: Explosive properties Landis Kane Consulting, Report No. 05-alpha-48 Landis Kane Consulting, Document No.500-2-75 Not GLP, not published	Y	April 2006 (PT 18)	Mitsui Chemicals Agro., Inc.
B3.3	2006c	Etofenprox 10%EW: Oxidising properties Landis Kane Consulting, Report No. 05-alpha-49 Landis Kane Consulting, Document No. 500-2-76 Not GLP, not published	Y	April 2006 (PT 18)	Mitsui Chemicals Agro., Inc.
B3.4/02	2006a	Determination of the flash point of Etofenprox 10%EW RCC Ltd, Report No. A52391 Landis Kane Consulting, Document No. 500-2-79 GLP, not published	Y	April 2006 (PT 18)	Mitsui Chemicals Agro., Inc.
B3.4/05	2006b	Determination of the auto-ignition temperature of Etofenprox 10% EW. RCC Ltd, Report No. A52402 Landis Kane Consulting, Document No. 500-2-82 GLP, not published	Y	April 2006 (PT 18)	Mitsui Chemicals Agro., Inc.
B3.6/02	2006d	Determination of the relative density of Etofenprox 10%EW RCC Ltd., Report No. A52413 Landis Kane Consulting, Document No. 500-2-77 GLP, not published	Y	April 2006 (PT 18)	Mitsui Chemicals Agro., Inc.
B3.7/03	2009	Determination of the storage stability of Etofenprox 10%EW Harlan Laboratories Ltd. Study Identification: Harlan Laboratories Study A52571 GLP, not published	Y	April 2006 (PT 18)	Mitsui Chemicals Agro., Inc.
B3.7/05	2006e	Low temperature stability of Etofenprox 10% EW. RCC Ltd, Report No. A52560 Landis Kane Consulting, Document No. 500-2-81 GLP, not published	Y	April 2006 (PT 18)	Mitsui Chemicals Agro., Inc.
B3.7/06	2006c	Accelerated storage stability of Etofenprox	Y	April	Mitsui

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Date of 1st submission	Owner
		10%EW RCC Ltd, Report No. A52424 Landis Kane Consulting, Document No. 500-2-89 GLP, not published		2006 (PT 18)	Chemicals Agro., Inc.
B3.10.1/02	2006f	Determination of the surface tension of an aqueous solution of Etofenprox 10%EW RCC Ltd, Report No. A52582 Landis Kane Consulting, Document No. 500-2-78 GLP, not published	Y	April 2006 (PT 18)	Mitsui Chemicals Agro., Inc.
B3.10.2/03	2006g	Determination of the viscosity of Etofenprox 10%EW RCC Ltd, Report No. A52593 Landis Kane Consulting, Document No. 500-2-84 GLP, not published	Y	April 2006 (PT 18)	Mitsui Chemicals Agro., Inc.
B 4.1/01 → see point B3.7/09	2006j	Determination of the storage stability of Etofenprox 1% Intermediate Concentrate (shelf life) and validation of the analytical method (Interim report) RCC Ltd, Report No. A59128 Landis Kane Consulting, Document No. 500-2-90 GLP, not published	Y	April 2006 (PT 18)	Mitsui Chemicals Agro., Inc.
B 4.1/02	2003	Analysis of technical and formulated pesticides, method Etofenprox emulsion, oil in water 471/EW/M/-; CIPAC Handbook Volume K (pp 57 – 63), Collaborative International Pesticides Analytical Council Limited 2003 Landis Kane Consulting, Document No. 500-4-48 Not GLP, published	N	Not applicable as no data protection claimed	Public in-formation
B 4.1/03	2001	Development and validation of an analytical method for the determination of MTI-500 (Active Ingredient) in MTI-500 30 % EC. RCC Ltd. Itingen, Switzerland, Report No. 806826 Landis Kane Consulting, Document No. 500-4-25 GLP, not published	Y	April 2006 (PT 18)	Mitsui Chemicals Agro., Inc.

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Date of 1st submission	Owner
B 5.10/01	2006a	Laboratory bioassay to assess the efficacy of Etofenprox 1% aerosol against houseflies, *Musca domestica* and mosquitoes, *Culex quinquefasciatus* (Final report). Insect Investigations Ltd, Cardiff, United Kingdom; Report No. 05/120 Landis Kane Consulting, Document No. 500-6-153 Not GLP, not published	Y	April 2006 (PT 18)	Mitsui Chemicals Agro., Inc.
B 5.10/02	2006b	Laboratory bioassays to determine the efficacy of Etofenprox 10% EW against German and Oriental cockroaches (Final report). Insect Investigations Ltd, Cardiff, United Kingdom; Report No. 05/119A Landis Kane Consulting, Document No. 500-6-154 Not GLP, not published	Y	April 2006 (PT 18)	Mitsui Chemicals Agro., Inc.
B 5.10/03	2006c	Laboratory bioassays to determine the efficacy of Etofenprox 10%EW against cat fleas, *Ctenocephalides felis* (Final report). Insect Investigations Ltd, Cardiff, United Kingdom; Report No. 05/119B Landis Kane Consulting, Document No. 500-6-155 Not GLP, not published	Y	April 2006 (PT 18)	Mitsui Chemicals Agro., Inc.
B 5.10/04	2006d	Laboratory bioassays to determine the efficacy of Trebon 30EC against German and Oriental cockroaches (Final report). Insect Investigations Ltd, Cardiff, United Kingdom; Report No. 05/119C Landis Kane Consulting, Document No. 500-6-156 Not GLP, not published	Y	April 2006 (PT 18)	Mitsui Chemicals Agro., Inc.
B 5.10/05	2009	Simulated use trial to determine the efficacy of Etofenprox 10EW against German cockroaches, *Blatella germanica*.	Y	April 2006 (PT 18)	Mitsui Chemicals Agro, Inc.

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Date of 1st submission	Owner
		I2LResearch Ltd, Cardiff, United Kingdom; Report No. 08/106 LKC, Document No. 500-6-169 Not GLP, not published			
B 5.10/06	1996	Susceptibility of German cockroaches (Blattella germanica), collected in hospitals, to selected carbamate and pyrethroid insecticides. Roczniki Panstwowego Zakladu Higieny, **47**, 333-341LKC, Document No. 500-6-170Not GLP, not published	N	Not applicable as no data protection claimed	Not applicable (published literature)
B 5.10/07	2007	Pyrethroids, knockdown resistance, and sodium channels. Abstracts of Papers, 233rd ACS National Meeting, Chicago, IL, United States, March 25-29, 2007. LKC, Document No. 500-6-171 Not GLP, not published	N	Not applicable as no data protection claimed	Not applicable (published literature)
B 6.1.1/01	1995a	An acute oral toxicity study in rats with 1% Etofenprox Report No. 3354.7 Landis Kane Consulting, Document No.500-5-97 GLP, not published	Y	April 2006 (PT 18)	Mitsui Chemicals Agro., Inc.
B 6.1.1/02	1988a	Test to evaluate the acute toxicity following a single oral administration (limit test) in the rat Report No. 808309 Landis Kane Consulting, Document No.500-5-73 GLP, not published	Y	April 2006 (PT 18)	Mitsui Chemicals Agro., Inc.
B 6.1.1/03	1991a	Etofenprox 30EC: acute oral toxicity study in rats Report No. 90-0150 Landis Kane Consulting, Document No.500-5-50 GLP, not published	Y	April 2006 (PT 18)	Mitsui Chemicals Agro., Inc.
B 6.1.2/01	1995b	An acute dermal toxicity study in rabbits with 1 % Etofenprox Report No. 3354.8 Landis Kane Consulting, Document No.500-5-98 GLP, not published	Y	April 2006 (PT 18)	Mitsui Chemicals Agro., Inc.

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Date of 1st submission	Owner
B 6.1.2/02	1988b	Test to evaluate the acute toxicity following a single cutaneous application (limit test) in the rat Report No. 808310 Landis Kane Consulting, Document No.500-5-72 GLP, not published	Y	April 2006 (PT 18)	Mitsui Chemicals Agro., Inc.
B 6.1.2/03	1991b	Ethofenprox 30EC, acute dermal toxicity study in rats Report No. 90-0152 Landis Kane Consulting, Document No.500-5-52 GLP, not published	Y	April 2006 (PT 18)	Mitsui Chemicals Agro., Inc.
B 6.1.3/01	1995c	An acute whole-body inhalation toxicity study in rats with 1 % Etofenprox Report No. 3354.9 Landis Kane Consulting, Document No.500-5-99 GLP, not published	Y	April 2006 (PT 18)	Mitsui Chemicals Agro., Inc.
B 6.1.3/02	2006	4-hour acute inhalation toxicity study in rats (Technical trials preceding a proposed 4-hour acute inhalation toxicity study in rats), Report No. A42254, Landis Kane Consulting Document No. 500-5-113 Not GLP, not published	Y	April 2006 (PT 18)	Mitsui Chemicals Agro., Inc.
B 6.1.3/03	1992	Acute (4-hour) inhalation toxicity study with Trebon EC-30 in rats Report No. V92.007 Landis Kane Consulting, Document No.500-5-53 GLP, not published	Y	April 2006 (PT 18)	Mitsui Chemicals Agro., Inc.
B 6.2.1/01	1995d	A primary skin irritation study in rabbits with 1% Etofenprox Report No. 3354.1 Landis Kane Consulting, Document No.500-5-101 GLP, not published	Y	April 2006 (PT 18)	Mitsui Chemicals Agro., Inc.
B 6.2.1/02	1988a	Test to evaluate acute cutaneous primary irritation and corrosivity, in the rabbit Report No. 807333 Landis Kane Consulting, Document No.500-5-78 GLP, not published	Y	April 2006 (PT 18)	Mitsui Chemicals Agro., Inc.

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Date of 1st submission	Owner
B 6.2.1/03	1991a	Primary dermal irritation to rabbits of Ethofenprox 30 EC Report No. NC-0136B Landis Kane Consulting, Document No.500-5-54 GLP, not published	Y	April 2006 (PT 18)	Mitsui Chemicals Agro., Inc.
B 6.2.2/01	1995e	A primary eye irritation study in rabbits with 1% Etofenprox Report No. 3354.10 Landis Kane Consulting, Document No.500-5-100 GLP, not published	Y	April 2006 (PT 18)	Mitsui Chemicals Agro., Inc.
B 6.2.2/02	1988b	Test to evaluate acute ocular irritation and reversibility in the rabbit Report No. 807333 Landis Kane Consulting, Document No.500-5-78 GLP, not published	Y	April 2006 (PT 18)	Mitsui Chemicals Agro., Inc.
B 6.2.2/03	1991b	Primary eye irritation to the rabbit of Ethofenprox 30EC Report No. NC-0136A Landis Kane Consulting, Document No.500-5-55 GLP, not published	Y	April 2006 (PT 18)	Mitsui Chemicals Agro., Inc.
B 6.3/01	1995f	A dermal sensitization study in guinea pigs with 1% Etofenprox – modified buehler design Report No. 3354.12 Landis Kane Consulting, Document No.500-5-102 GLP, not published	Y	April 2006 (PT 18)	Mitsui Chemicals Agro., Inc.
B 6.3/02	1989	Test to evaluate the sensitizing potential by topical applications in the guinea-pig “The Buehler Test” Report No. 908407, Landis Kane Consulting, Document No.500-5-110 GLP, not published	Y	April 2006 (PT 18)	Mitsui Chemicals Agro., Inc.
B 6.3/03	1991c	Ethofenprox 30 EC: dermal sensitization study in guinea pigs Report No. 90-0153 Landis Kane Consulting, Document No.500-5-56 GLP, not published	Y	April 2006 (PT 18)	Mitsui Chemicals Agro., Inc.

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Date of 1st submission	Owner
B 6.4/02	2011	Etofenprox: the in vivo percutaneous absorption of [^{14}C]-Etofenprox in formulation (30EC) and in-use spray dilution in the rat (OECD 427) GLP , not published	Y	April 2006 (PT 18)	Mitsui Chemicals Agro., Inc.
B 6.5/02 → see point B 2.2/02	2005	MSDS of Etofenprox 10%EW Mitsui Chemicals Inc, MSDS No: 66044ES. Landis Kane Consulting, Document No. 500-3-25 Not GLP, published	N	Not applicable as no data protection claimed	Public in-formation
B 6.5/11 → see point B 2.2/11	2002	MSDS	N	Not applicable as no data protection claimed	Public in-formation
B 6.5/12 → see point B 2.2/12	2003	MSDS	N	Not applicable as no data protection claimed	Public in-formation
B 6.5/13 → see point B 2.2/13	2000	MSDS	N	Not applicable as no data protection claimed	Public in-formation
B 6.5/14 → see point B 2.2/14	2003	MSDS	N	Not applicable as no data protection claimed	Public in-formation
B 6.5/15 → see point B 2.2/15	2001	MSDS	N	Not applicable as no data protection claimed	Public in-formation
B 6.5/16 → see point B	2003	MSDS	N	Not applicable as no data protection	Public in-formation

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Date of 1st submission	Owner
2.2/16				claimed	
B 6.6/01	2006a	Estimation of the human exposure to Etofenprox used in a 10EW insecticidal professional product (PT 18.01) Landis Kane Consulting, Report No. 06-alpha-02 Landis Kane Consulting, Document No.500-5-111 Not GLP, not published	Y	April 2006 (PT 18)	Mitsui Chemicals Agro., Inc.
B 6.6/04	2003a	Temporal measurements of transfer of Etofenprox from carpet flooring treated with a total release fogger. Wildlife International Ltd, Report No. 236C-130. Landis Kane Consulting, Document No. 500-6-136 GLP, not published	Y	April 2006 (PT 18)	Mitsui Chemicals Agro., Inc.
B 6.6/05	2003b	Temporal measurements of transfer of Etofenprox from vinyl flooring treated with a total release fogger. Wildlife International Ltd, Report No. 236C-128. Landis Kane Consulting, Document No. 500-6-134 GLP, not published	Y	April 2006 (PT 18)	Mitsui Chemicals Agro., Inc.
B 6.6/06	2003c	Temporal measurements of airborne concentrations of Etofenprox released from a total release fogger. Wildlife International Ltd, Report No. 236C-129. Landis Kane Consulting, Document No. 500-6-135 GLP, not published	Y	April 2006 (PT 18)	Mitsui Chemicals Agro., Inc.
B 7.1/01	2010	Environmental Exposure for the Biocidal Product Etofenprox 10% EW (PT 18) LKC Report No. 10-alpha-19 LKC Document No. 500-7-55 not GLP, not published	Y	April 2006 (PT 18)	Mitsui Chemicals Agro., Inc.

APPENDIX IV-1: STANDARD TERMS AND ABBREVIATIONS

Note: The technical terms “active ingredient” and “active substance” are equivalent

Stand. Term / Abbreviation	Explanation
A	ampere
Ach	acetylcholine
AchE	acetylcholinesterase
ADI	acceptable daily intake
ADME	administration distribution metabolism and excretion
ADP	adenosine diphosphate
AE	acid equivalent
AF	assessment factor
AFID	alkali flame-ionisation detector or detection
A/G	albumin/globulin ratio
ai	active ingredient
ALD_{50}	approximate median lethal dose, 50%
ALT	alanine aminotransferase (SGPT)
Ann.	Annex
AOEL	acceptable operator exposure level
AMD	automatic multiple development
ANOVA	analysis of variance
AP	alkaline phosphatase
approx	approximate
ARC	anticipated residue contribution
ARfD	acute reference dose
as	active substance
AST	aspartate aminotransferase (SGOT)
ASV	air saturation value
ATP	adenosine triphosphate
BAF	bioaccumulation factor
BCF	bioconcentration factor
bfa	body fluid assay
BOD	biological oxygen demand
bp	boiling point
BP	Biocidal Product
BPD	Biocidal Products Directive

Stand. Term / Abbreviation	Explanation
BSAF	biota-sediment accumulation factor
BSE	bovine spongiform encephalopathy
BSP	bromosulfophthalein
Bt	*Bacillus thuringiensis*
Bti	*Bacillus thuringiensis israelensis*
Btk	*Bacillus thuringiensis kurstaki*
Btt	*Bacillus thuringiensis tenebrionis*
BUN	blood urea nitrogen
bw	body weight
c	centi- (x 10^{-2})
°C	degrees Celsius (centigrade)
CA	controlled atmosphere
CAD	computer aided design
CADDY	computer aided dossier and data supply (an electronic dossier interchange and archiving format)
CAS	Chemical Abstracts Service
cd	candela
CDA	controlled drop(let) application
cDNA	complementary DANN
CEC	cation exchange capacity
cf	confer, compare to
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CL	confidence limits
cm	centimetre
CNS	central nervous system
COD	chemical oxygen demand
CPK	creatinine phosphatase
cv	coefficient of variation
CSF	Confidential Statement of Formula
Cv	ceiling value
d	day(s)

Stand. Term / Abbreviation	Explanation
DES	diethylstilboestrol
DIS	draft international standard *(ISO)*
DFR	Dislodgeable Foliar Residue
DMSO	dimethylsulfoxide
DNA	deoxyribonucleic acid
dna	designated national authority
DO	dissolved oxygen
DOC	dissolved organic carbon
dpi	days post inoculation
DRES	Dietary Risk Evaluation System
DRP	detailed review paper *(OECD)*
DSC	Differential scanning calorimetry
$DT_{50(lab)}$	period required for 50 percent dissipation (under laboratory conditions) (define method of estimation)
$DT_{90(field)}$	period required for 90 percent dissipation (under field conditions) (define method of estimation)
dw	dry weight
DWEL	Drinking Water Equivalent Level
DWQG	drinking water quality guidelines
ε	decadic molar extinction coefficient
E_bC_{50}	median effective concentration, biomass
E_rC_{50}	median effective concentration, growth rate
EC_{50}	median effective concentration
ECD	electron capture detector
ED_{50}	median effective dose
EDI	estimated daily intake
EEC	Estimated Environmental Concentration
EINECS	European inventory of existing commercial substances
ELINCS	European list of notified chemical substances
ELISA	enzyme linked immunosorbent assay
e-mail	electronic mail
EMDI	estimated maximum daily intake
EN	European norm

Stand. Term / Abbreviation	Explanation
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
EPMA	electron probe micro-analysis
ERL	extraneous residue limit
ESPE46/51	evaluation system for pesticides
EUSES	European Union system for the evaluation of substances
F	field
F_0	parental generation
F_1	filial generation, first
F_2	filial generation, second
FBS	full base set
FDA	Food and Drug Administration
FELS	fish early-life stage
FIA	fluorescence immuno-assay
FID	flame ionisation detector
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
F_{mol}	fractional equivalent of the metabolite´s molecular weight compared to the active substance
FOB	functional observation battery
f_{oc}	organic carbon factor (compartment dependent)
fp	freezing point
FPD	flame photometric detector
FPLC	fast protein liquid chromatography
g	gram(s)
GAP	good agricultural practice
GC	gas chromatography
GC-EC	gas chromatography with electron capture detector
GC-FID	gas chromatography with flame ionisation detector
GC-MS	gas chromatography-mass spectrometry
GC-MSD	gas chromatography with mass-selective detection
GEP	good experimental practice

Stand. Term / Abbreviation	Explanation
GFP	good field practice
GGT	gamma glutamyl transferase
GI	gastro-intestinal
GIT	gastro-intestinal tract
GL	guideline level
GLC	gas liquid chromatography
GLP	good laboratory practice
GM	geometric mean
GMM	genetically modified micro-organism
GMO	genetically modified organism
GPC	gel-permeation chromatography
GPS	global positioning system
GRAS	Generally Recognized As Safe as designated by FDA
GSH	glutathione
GV	granulosevirus
h	hour(s)
H	Henry's Law constant (calculated as a unitless value)
ha	hectare(s)
HA	Health Advisory
Hb	haemoglobin
HC5	concentration which will be harmless to at least 95 % of the species present with a given level of confidence (usually 95 %)
HCG	human chorionic gonadotropin
Hct	haematocrit
HDT	highest dose tested
hL	hectolitre
HEED	high energy electron diffraction
HID	helium ionisation detector
HPAEC	high performance anion exchange chromatography
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography – mass spectrometry
HPPLC	high pressure planar liquid chromatography

Stand. Term / Abbreviation	Explanation
HPTLC	high performance thin layer chromatography
HRGC	high resolution gas chromatography
H_S	Shannon-Weaver index
Ht	haematocrit
HUSS	human and use safety standard
I	indoor
I_{50}	inhibitory dose, 50%
IC_{50}	median immobilisation concentration or median inhibitory concentration 1
ICM	integrated crop management
ID	ionisation detector
IEDI	international estimated daily intake
IGR	insect growth regulator
im	intramuscular
inh	inhalation
INT	2-p-iodophenyl-3-p-nitrophenyl-5-phenyltetrazoliumchloride testing method
ip	intraperitoneal
IPM	integrated pest management
IR	infrared
ISBN	international standard book number
ISSN	international standard serial number
IUCLID	International Uniform Chemical Information Database
iv	intravenous
IVF	*in vitro* fertilisation
k *(in combination)*	kilo
k	rate constant for biodegradation
K	Kelvin
Ka	acid dissociation constant
Kb	base dissociation constant
K_{ads}	adsorption constant
K_{des}	apparent desorption coefficient
kg	kilogram
K_H	Henry´s Law constant (in atmosphere per cubic metre per mole)
K_{oc}	organic carbon adsorption coefficient

Stand. Term / Abbreviation	Explanation
K_{om}	organic matter adsorption coefficient
K_{ow}	octanol-water partition coefficient
Kp	solid-water partition coefficient
kPa	kilopascal(s)
l, L	litre
LAN	local area network
LASER	light amplification by stimulated emission of radiation
LBC	loosely bound capacity
LC	liquid chromatography
LC-MS	liquid chromatography- mass spectrometry
LC_{50}	lethal concentration, median
LCA	life cycle analysis
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD	Lethal Dose-low
LD_{50}	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
LEL	Lowest Effect Level
ln	natural logarithm
LOAEC	lowest observable adverse effect concentration
LOAEL	lowest observable adverse effect level
LOC	Level of Concern
LOD	limit of detection
LOEC	lowest observable effect concentration
LOEL	lowest observable effect level
log	logarithm to the base 10
LOQ	limit of quantification (determination)
LPLC	low pressure liquid chromatography
LSC	liquid scintillation counting or counter
LSD	least squared denominator multiple range test
LSS	liquid scintillation spectrometry
LT	lethal threshold
m	metre
M	molar

Stand. Term / Abbreviation	Explanation
µm	micrometer (micron)
MAC	maximum allowable concentration
MAK	maximum allowable concentration
MATC	Maximum Acceptable Toxicant Concentration
MC	moisture content
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCLG	Maximum Contaminant Level Goal
MCV	mean corpuscular volume
MDL	method detection limit
MFO	mixed function oxidase
µg	microgram
mg	milligram
MHC	moisture holding capacity
MIC	minimum inhibitory concentration
min	minute(s)
MKC	minimum killing concentration
mL	millilitre
MLD	median lethal dose
MLT	minimum lethal time
mm	millimetre
MMAD	mass median aerodynamic diameter
mo	month(s)
MOE	margin of exposure
mol	mole(s)
MOS	margin of safety
Mp	melting point
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRE	maximum residue expected
MRID	Master Record Identification (number).
MRL	maximum residue level or limit
mRNA	messenger ribonucleic acid
MS	mass spectrometry
MSDS	material safety data sheet

Stand. Term / Abbreviation	Explanation
MTD	maximum tolerated dose
MT	material test
MW	molecular weight
n.a., N/A	not applicable
n-	normal (defining isomeric configuration)
N	number of observations
NAEL	no adverse effect level
nd	not detected
NEDI	national estimated daily intake
NEL	no effect level
NERL	no effect residue level
ng	nanogram
nm	nanometre
NMR	nuclear magnetic resonance
no, n°	number
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOE_rC	no observed effect concentration, growth rate
NOED	no observed effect dose
NOEL	no observed effect level
NOIS	notice of intent to suspend
NPD	nitrogen-phosphorus detector or detection
NPDES	National Pollutant Discharge Elimination System
NPV	nuclear polyhedrosis virus
NR	not reported
NTE	neurotoxic target esterase
OC	organic carbon content
OCR	optical character recognition
ODP	ozone-depleting potential
ODS	ozone-depleting substances
OEL	occupational exposure limit
OH	hydroxide
OJ	Official Journal

Stand. Term / Abbreviation	Explanation
OM	organic matter content
OP	Organophosphate
OPP	Office of Pesticide Programs
Pa	pascal
PAD	pulsed amperometric detection
2-PAM	2-pralidoxime
PADI	Provisional Acceptable Daily Intake
PAM	Pesticide Analytical Method
pc	paper chromatography
PC	personal computer
PCV	haematocrit (packed corpuscular volume)
PEC	predicted environmental concentration
PEC_A	predicted environmental concentration in air
PEC_S	predicted environmental concentration in soil
PEC_{SW}	predicted environmental concentration in surface water
PEC_{GW}	predicted environmental concentration in ground water
PED	plasma-emissions-detector
pH	pH-value
PHED	pesticide handler's exposure data
PIC	prior informed consent
pic	phage inhibitory capacity
PIXE	proton induced X-ray emission
pKa	negative logarithm (to the base 10) of the acid dissociation constant
pKb	negative logarithm (to the base 10) of the base dissociation constant
PNEC	predicted no effect concentration (compartment to be added as subscript)
po	by mouth
POP	persistent organic pollutants
ppb	parts per billion (10^{-9})
PPE	personal protective equipment
ppm	parts per million (10^{-6})
PPP	plant protection product

Stand. Term / Abbreviation	Explanation
ppq	parts per quadrillion (10^{-24})
ppt	parts per trillion (10^{-12})
PSP	phenolsulfophthalein
PrT	prothrombin time
PRL	practical residue limit
PRN	Pesticide Registration Notice
PT	product type
PT(CEN)	project team CEN
PTDI	provisional tolerable daily intake
PTT	partial thromboplastin time
Q*1	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
QA	quality assurance
QAU	quality assurance unit
(Q)SAR	quantitative structure-activity relationship
r	correlation coefficient
r^2	coefficient of determination
RA	risk assessment
RBC	red blood cell
RED	Reregistration Eligibility Decision
REI	restricted entry interval
RENI	Registry Nomenclature Information System
Rf	retardation factor
RfD	reference dose
RH	relative humidity
RL_{50}	median residual lifetime
RNA	ribonucleic acid
RP	reversed phase
rpm	revolutions per minute
rRNA	ribosomal ribonucleic acid
RRT	relative retention time
RS	Registration Standard
RSD	relative standard deviation
s	second
S	solubility

Stand. Term / Abbreviation	Explanation
SAC	strong adsorption capacity
SAP	serum alkaline phosphatase
SAR	structure/activity relationship
SBLC	shallow bed liquid chromatography
sc	subcutaneous
sce	sister chromatid exchange
SCAS	semi-continous activated sludge
SCTER	smallest chronic toxicity exposure ratio (TER)
SD	standard deviation
se	standard error
SEM	standard error of the mean
SEP	standard evaluation procedure
SF	safety factor
SFC	supercritical fluid chromatography
SFE	supercritical fluid extraction
SIMS	secondary ion mass spectroscopy
S/L	short term to long term ratio
SMEs	small and medium sized enterprises
SOP	standard operating procedures
sp	species (only after a generic name)
SPE	solid phase extraction
SPF	specific pathogen free
ssp	subspecies
SSD	sulphur specific detector
SSMS	spark source mass spectrometry
STEL	short term exposure limit
STER	smallest toxicity exposure ratio (TER)
STMR	supervised trials median residue
STP	sewage treatment plant
t	tonne(s) (metric ton)
$t_{½}$	half-life (define method of estimation)
T_3	tri-iodothyroxine
T_4	thyroxine
T_{25}	tumorigenic dose that causes tumours in 25 % of the test animals
TADI	temporary acceptable daily intake
TBC	tightly bound capacity

Stand. Term / Abbreviation	Explanation
TC	Toxic Concentration
TCD	thermal conductivity detector
TD	Toxic Dose
TDR	time domain reflectrometry
TG	technical guideline, technical group
TGD	Technical guidance document
TID	thermionic detector, alkali flame detector
TEP	Typical End-Use Product
TER	toxicity exposure ratio
TER_I	toxicity exposure ratio for initial exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
tert	tertiary (in a chemical name)
TEP	typical end-use product
TGAI	Technical Grade Active Ingredient
TGGE	temperature gradient gel electrophoresis
TIFF	tag image file format
TLC	thin layer chromatography
Tlm	median tolerance limit
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TMRC	theoretical maximum residue contribution
TMRL	temporary maximum residue limit
TNsG	technical notes for guidance
TOC	total organic carbon
Tremcard	transport emergency card
tRNA	transfer ribonucleic acid
TSH	thyroid stimulating hormone (thyrotropin)
TTC	2,3,5-triphenylterazoliumchloride testing method
TTC	Toxicological-Threshold-of-Concern
TWA	time weighted average
UDS	unscheduled DNA synthesis

Stand. Term / Abbreviation	Explanation
UF	uncertainty factor (safety factor)
ULV	ultra low volume
UR	unit risk
UV	ultraviolet
UVC	unknown or variable composition, complex reaction products
UVCB	undefined or variable composition, complex reaction products in biological material
v/v	volume ratio (volume per volume)
vis	visible
WBC	white blood cell
Wk	week
WP	Wettable Powder
WPS	Worker Protection Standard
wt	weight
w/v	weight per volume
ww	wet weight
w/w	weight per weight
XRFA	X-ray fluorescence analysis
Yr	year
<	less than
≤	less than or equal to
>	greater than
≥	greater than or equal to

APPENDIX IV-2: ABBREVIATIONS OF ORGANISATION AND PUBLICATIONS

Abbreviation	Explanation
ASTM	American Society for Testing and Materials
BA	Biological Abstracts (Philadelphia)
BART	Beneficial Arthropod Registration Testing Group
BBA	German Federal Agency of Agriculture and Forestry
CA(S)	Chemical Abstracts (System)
CAB	Centre for Agriculture and Biosciences International
CAC	Codex Alimentarius Commission
CAS	Chemical Abstracts Service
CCFAC	Codex Committee on Food Additives and Contaminants
CCGP	Codex Committee on General Principles
CCPR	Codex Committee on Pesticide Residues
CCRVDF	Codex Committee on Residues of Veterinary Drugs in Food
CE	Council of Europe
CEC	Commission of the European Communities
CEFIC	European Chemical Industry Council
CEN	European Committee for Normalisation
CEPE	European Committee for Paints and Inks
CIPAC	Collaborative International Pesticides Analytical Council Ltd
CMA	Chemicals Manufacturers Association
COREPER	Comite des Representants Permanents
COST	European Co-operation in the field of Scientific and Technical Research
DG	Directorate General
DIN	German Institute for Standardisation
EC	European Commission
ECB	European Chemicals Bureau
ECCO	European Commission Co-ordination
ECDIN	Environmental Chemicals Data and Information Network of the European Communities
ECDIS	European Environmental Chemicals Data and Information System
ECE	Economic Commission for Europe
ECETOC	European Chemical Industry Ecology and Toxicology Centre
EDEXIM	European Database on Export and Import of Dangerous Chemicals
EEC	European Economic Community
EHC	Environmental Health Criteria
EINECS	European Inventory of Existing Commercial Chemical Substances

Abbreviation	Explanation
ELINCS	European List of New Chemical Substances
EMIC	Environmental Mutagens Information Centre
EPA	Environmental Protection Agency
EPAS	European Producers of Antimicrobial Substances
EPFP	European Producers of Formulated Preservatives
EPO	European Patent Office
EPPO	European and Mediterranean Plant Protection Organization
ESCORT	European Standard Characteristics of Beneficials Regulatory Testing
EU	European Union
EUPHIDS	European Pesticide Hazard Information and Decision Support System
EUROPOEM	European Predictive Operator Exposure Model
EWMP	European Wood Preservation Manufacturers
FAO	Food and Agriculture Organization of the UN
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
FRAC	Fungicide Resistance Action Committee
GATT	General Agreement on Tariffs and Trade
GAW	Global Atmosphere Watch
GIFAP	Groupement International des Associations Nationales de Fabricants de Produits Agrochimiques (now known as GCPF)
IARC	International Agency for Research on Cancer
IATS	International Academy of Toxicological Science
ICBP	International Council for Bird Preservation
ICCA	International Council of Chemical Associations
ICES	International Council for the Exploration of the Seas
ILO	International Labour Organization
IMO	International Maritime Organisation
IOBC	International Organization for Biological Control of Noxious Animals and Plants
IPCS	International Programme on Chemical Safety
IRAC	Insecticide Resistance Action Committee
ISCO	International Soil Conservation Organization
ISO	International Organization for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JECFA FAO/WHO	Joint Expert Committee on Food Additives
JFCMP	Joint FAO/WHO Food and Animal Feed Contamination Monitoring Programme
JMP	Joint Meeting on Pesticides (WHO/FAO)
JMPR	Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)

Abbreviation	Explanation
MITI	Ministry of International Trade and Industry, Japan
NATO	North Atlantic Treaty Organization
NAFTA	North American Free Trade Agreement
NCI	National Cancer Institute (USA)
NCTR	National Center for Toxicological Research (USA)
NGO	non-governmental organisation
NTP	National Toxicology Program (USA)
OECD	Organization for Economic Co-operation and Development
OLIS	On-line Information Service of OECD
OPPTS	Office of Prevention, Pesticides and Toxic Substances (US EPA)
OSPAR	Oslo Paris Convention (Convention for the Protection of the Marine Environment of the North-East Atlantic)
PAN	Pesticide Action Network
RIVM	Netherlands National Institute of Public Health and Environmental Protection
RNN	Re-registration Notification Network
RTECS	Registry of Toxic Effects of Chemical Substances (USA)
SETAC	Society of Environmental Toxicology and Chemistry
SI	Système International d'Unitès
SITC	Standard International Trade Classification
TOXLINE	Toxicology Information On-line
UBA	German Environmental Protection Agency
UN	United Nations
UNEP	United Nations Environment Programme
WFP	World Food Programme
WHO	World Health Organization
WPRS	West Palearctic Regional Section
WTO	World Trade Organization