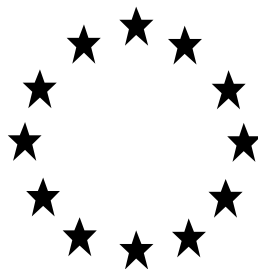


Directive 98/8/EC concerning the placing of biocidal products on the market

Inclusion of active substances in Annex I or IA to Directive 98/8/EC

Assessment Report



Etofenprox
Product-type 8
(Wood preservatives)

13 September 2007

Annex I - Austria

Etofenprox (PT 8)**Assessment report**

Finalised in the Standing Committee on Biocidal Products at its meeting on 13 September 2007 in view of its inclusion in Annex I to Directive 98/8/EC

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1. STATEMENT OF SUBJECT MATTER AND PURPOSE

1.1. Procedure followed

This assessment report has been established as a result of the evaluation of etofenprox as product-type 8 (wood preservatives), 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 a view to the possible inclusion of this substance into Annex I or IA to the Directive.

Etofenprox (CAS No 80844-07-1) was notified as an existing active substance, by Landis Kane Consulting, hereafter referred to as the applicant, in product-type 8.

Commission Regulation (EC) No 2032/2003 of 4 November 2003² lays down the detailed rules for the evaluation of dossiers and for the decision-making process in order to include or not to include an existing active substance into Annex I or IA to the Directive.

In accordance with the provisions of Article 5(2) 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 8 was 28 March 2004, in accordance with Annex V of Regulation (EC) No 2032/2003.

On 25 March 2004 the Austrian Competent Authority received a dossier from the applicant. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation on 23 June 2004.

On 11 October 2005, the Rapporteur Member State submitted, in accordance with the provisions of Article 10(5) and (7) of Regulation (EC) No 2032/2003, 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 11 October 2005. The competent authority report included a recommendation for the inclusion of etofenprox in Annex I to the Directive for product-type 8.

In accordance with Article 12 of Regulation (EC) No 2032/2003, the Commission made the competent authority report publicly available by electronic means on 11 October 2005. 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

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

2 Commission Regulation (EC) No 2032/2003 of 4 November 2003 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 and amending Regulation (EC) No 1896/2000. OJ L 307, 24.11.2003, p. 1

Commission. Revisions agreed upon were presented at Technical and Competent Authority Meetings and the competent authority report was amended accordingly.

On the basis of the final competent authority report, the Commission proposed the inclusion of etofenprox in Annex I to Directive 98/8/EC and consulted the Standing Committee on Biocidal Products on 13 September 2007.

In accordance with Article 11(4) of Regulation (EC) No 2032/2003, the present assessment report contains the conclusions of the Standing Committee on Biocidal Products, as finalised during its meeting held on 13 September 2007.

1.2. Purpose of the assessment report

This assessment report has been developed and finalised in support of the decision to include etofenprox in Annex I to Directive 98/8/EC for product-type 8. The aim of the assessment report is to facilitate the authorisation in Member States of individual biocidal products in product-type 8 that contain etofenprox. In their evaluation, Member States shall apply the provisions of Directive 98/8/EC, in particular the provisions of Article 5 as well as the common principles laid down in Annex VI.

For the implementation of the common principles of Annex VI, the content and conclusions of this assessment report, which is available at the Commission website³, shall be taken into account.

However, where conclusions of this assessment report are based on data protected under the provisions of Directive 98/8/EC, such conclusions may not be used to the benefit of another applicant, unless access to these data has been granted.

1.3. Overall conclusion in the context of Directive 98/8/EC

The overall conclusion from the evaluation is that it may be expected that there are biocidal products of product-type 8 containing etofenprox as active substance, which will fulfil the requirements laid down in Article 10(1) and (2) of Directive 98/8/EC. This conclusion is however subject to:

- i. compliance with the particular requirements in the following sections of this assessment report,
- ii. the implementation of the provisions of Article 5(1) of Directive 98/8/EC, and
- iii. the common principles laid down in Annex VI to Directive 98/8/EC.

³ <http://ec.europa.eu/comm/environment/biocides/index.htm>

Furthermore, these conclusions 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 Article 5(1) and of the common principles laid down in Annex VI to Directive 98/8/EC.

2. OVERALL SUMMARY AND CONCLUSIONS

2.1. Presentation of the Active Substance

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

Summary information on the identity and physico-chemical properties of etofenprox can be found in Appendix I to this document (List of Endpoints).

The method of analysis for the active substance as manufactured and for structurally related impurities in technical grade etofenprox has been validated and shown to be sufficiently specific, accurate and sensitive.

The methods for analysis of etofenprox and the metabolite α -CO in environmental matrices (soil, air and water) as well as in food/feedstuff of plant origin (oil seed rape, cabbage and cucumber) and food of animal origin (meat, fat, milk and egg) have been validated and shown to be sufficiently accurate and sensitive.

2.1.2. Intended Uses and Efficacy

Etofenprox has been evaluated for its use as wood preservative (product-type 8) for preventive application by industrial techniques, i.e. vacuum pressure in Use Classes 1 to 3 and dipping treatments in Use Classes 1 and 2. For both types of wood treatment, etofenprox is applied in a formulation (SPU-01990-I, soluble concentrate) containing 0.1% of active substance. The application rates proposed by the applicant are 2.5 g a.s./m³ wood for vacuum pressure and range from 0.03 to 0.04 g a.s./m² wood for dipping treatment.

The treated wood is placed on the market only after it is completely dry and only industrial uses are intended. Therefore the general public is only exposed to the active ingredient by emissions from treated wood (e.g. dermal uptake via direct contact) and when processing (e.g. sanding wood).

The assessment of the biocidal activity of the active substance applied by dipping treatment demonstrates that it has a sufficient level of efficacy against the target organism(s) 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.

In order to facilitate the work of Member States in granting or reviewing authorisations, and to apply adequately the provisions of Article 5(1) of Directive 98/8/EC and the common principles laid down in Annex VI of that Directive, the intended uses of the substance, as identified during the evaluation process, are listed in Appendix II.

Etofenprox is an insecticide acting by direct contact and ingestion. There are indications that etofenprox acts on the insect nerve system by disturbing the normal neurotransmittance. The preventive action of the active substance etofenprox for vacuum pressure treated wood in Use Classes 1-3 has been tested in four efficacy trials against wood destroying insects, e.g. larvae of the house longhorn beetle (*Hylotrupes bajulus*) and termites (*Reticulitermes santonensis*) according to EN testing methods, with and without an accelerated ageing procedure.


Based on the submitted studies no significant resistance against etofenprox has been found. Because of the wide alternation of generations (e.g. house longhorn beetle) no formation of resistance is to be expected.

2.1.3. Classification and Labelling

Etofenprox is currently not classified according to Annex I of Council Directive 67/548/EEC. The manufacturing impurities are not of potentially toxicological, ecotoxicological and environmental concern and therefore do not pose a risk to humans or the environment.

The proposed classification and labelling of etofenprox is presented below.

Table 2.1.3: The proposed classification and labelling of etofenprox

Classification	N; R50-53
Hazard symbol	N
Indication of danger:	<i>Dangerous for the environment</i>
Labelling symbol:	
Risk phrases	R50/53
Safety phrases	S36-60-61

2.2. Summary of the Risk Assessment

2.2.1. Risk arising from physico-chemical properties

There is not an unacceptable risk to users from the physico-chemical properties, as etofenprox and the etofenprox containing wood preservative product SPU-01990-I are thermally stable, non-flammable, non-explosive and non-oxidising.

2.2.2. Human Health Risk Assessment

2.2.2.1. Human primary exposure

Industrial wood treatment

There are no industry generated experimental data available for the exposure of humans to etofenprox when used in wood preservative products. The estimation of the exposure is therefore based on modelling and follows the recommendations given in the TNsG on human exposure⁴. Only preventive application by trained industrial workers in an industrial

⁴ European Commission (2002): Technical Notes for Guidance on human exposure to biocidal products; Guidance on exposure estimation.

environment is intended and has therefore been evaluated. A typical industrial work cycle consists of loading, treating, unloading and removal of the timber to storage. Workers are exposed through direct contact with the partially wet surface of the treated objects and through contact with ancillary equipment. Further exposure may arise from a contamination of the process plant, control room, previously used protective garment, etc.

Dermal exposure is by far more significant than inhalation exposure. The calculated exposure values for the inhalation route are very low for both the product and its active substance during the industrial wood treatment phase. This is in agreement with the initial expectations based on the low volatility of etofenprox and the low tendency for aerosol formation during industrial timber treatment.

2.2.2.2. Risk characterisation for human health for the industrial wood treatment (primary exposure)

The results of the exposure assessment and the relevant toxicological endpoints are compared in Table 2.2.2.2.

Table 2.2.2.2: Human exposure and risk characterisation for human health – primary exposure

exposure scenario		estimated total uptake [mg/kg bw day]	toxicity reference value [mg/kg bw day]	assessment factor = acceptable MOE	MOE ^a	exposure / AOEL ^a
Dipping Application of biocidal product	Reasonable worst = normal use^b case 1 (Based on highest data point of HSE distribution, 12% penetration through PPE, 100% dermal absorption)	0.066	NOAEL sub-chronic 13	100	197	0.51
			NOAEL chronic 2	100	30	3.30
			NOAEL develop 18.5	100	280	n.a.
	Reasonable worst = normal use^b case 2 (Based on highest data point of HSE distribution, 12% penetration through PPE, 13.8% dermal absorption)	0.009	NOAEL sub-chronic 13	100	1444	0.07
			NOAEL chronic 2	100	222	0.45
			NOAEL develop 18.5	100	2056	n.a.
Vacuum Pressure Application of biocidal product	Normal use case 1 (Based on 95th percentile of HSE distribution, 12% penetration through PPE, 100% dermal absorption)	0.05626	NOAEL sub-chronic 13	100	232	0.43
			NOAEL chronic 2	100	36	2.80
			NOAEL develop 18,5	100	330	n.a.
	Normal use case 2 (Based on 95th percentile of HSE distribution, 12% penetration through PPE, 13.8% dermal absorption)	0.00780	NOAEL sub-chronic 13	100	1659	0.06
			NOAEL chronic 2	100	255	0.39
			NOAEL develop 18.5	100	2361	n.a.

a.....The derivation of the MOE and the exposure/AOELs ratio is based on identical NOAELs and exposure estimates but since Member States could not agree on one of these approaches the Biocides Technical Meeting decided to describe both ratios in parallel.

b.....For dipping application the (normal use) 95th percentile is not applicable, indicative exposures are based upon maximum values, since model 1 for dipping application contains only 5 data points. Thus for risk assessment the exposure values for normal use are numerically identical to the exposure values for the reasonable worst case.

n.a....not applicable

Conclusion

Application of the wood preservative product

If exposure is compared to the subchronic NOAEL the respective MOE or exposure/AOEL ratio indicates an acceptable risk ($MOE > 100$, $exposure/AOEL < 1$). If exposure is compared to the chronic NOAEL the respective MOE or exposure/AOEL ratio indicates an unacceptable risk for the normal use case 1 assumptions that imply a default dermal uptake rate of 100%. If a dermal uptake study for the biocidal product would be available indicating a dermal uptake rate of far less than 100% (e.g. 13.8%, normal use case 2) also the respective MOE or exposure/AOEL ratio for chronic exposure might indicate an acceptable risk.

The comparison of the exposure estimates with the unspecific developmental NOAEL (ocular lesions of lactated F1 pups) would indicate that the risk for weanlings by exposure via lactation is acceptable. However since the toxicokinetic data indicate for lactating females a high degree of excretion via milk (see Hawkins et al. 1985a), it would be considered appropriately precautionous to exclude lactating women from the professional biocidal application processes. This would be in line with the fact that pesticide residues in infant formula and follow on formula are considered unacceptable above the very low level of 0.01mg/kg formula irrespective of classification and labelling decisions and irrespective of any risk assessment (Directive 99/50/EC). However, the final C/L decision is needed in order to confirm the hazard evaluation and select the respective risk management options adequately

In summary it is concluded that the treatment of wood with the wood preservative product SPU-01990-I implies an acceptable risk for workers if they are exposed for a shorter period than 3 months per year (seasonal and discontinuous exposure).

Since the assumption of seasonal and discontinuous wood treatment depends on the climate and on local work practice, the Member States would have to evaluate individually within the national product authorisation process if the risk due to professional application of etofenprox is acceptable. In order to support product authorisation a dermal absorption study with the biocidal product is required to refine the risk assessment prior to a decision on the national authorisation.

2.2.2.3. Risk characterisation for general public in contact with treated wood (secondary exposure)

Wooden articles treated with wood preservative product SPU-01990-I are intended for Use Classes 1 to 3 (vacuum pressure) and 1 to 2 (dipping treatment). The treated wood is not placed on the market until the wood is dry. Secondary exposure is therefore only calculated for the active substance as ingredient of the product.

The scenarios for secondary exposure assessment represent realistic worst cases that can occur, but are not likely to be exceeded. One reason is that the habits of children and infants change as they grow and long term exposure via mouthing or playing on the same playground structure is unlikely.

Based on realistic Tier 2 exposure estimates, all the MOEs are above 100 and acceptable. The tier 2 MOEs to the unspecific developmental NOAEL are above 1.2×10^5 . It can, therefore,

be concluded that secondary exposure of general public to etofenprox from wood treated with SPU-01990-I implies an acceptable risk.

No risk management measures are required.

Table 2.2.2.3: Human exposure and risk characterisation for human health – secondary exposure (Tier 2)

exposure scenario	estimated total uptake [mg/kg bw day]	toxicity reference value [mg/kg bw day]	assessment factor = acceptable MOE	MOE ^a	exposure / AEL ^a
Uptake during sanding of treated wood by adult	0.00015	NOAEL subacute 13	100	86667	0.00
		NOAEL chronic 2	100	13333	0.01
		NOAEL develop 18,5	100	123333	n.a.
Acute oral ingestion by infant chewing wood	0.00045	NOAEL subacute 13	100	28889	0.00
Chronic inhalation of volatile residues indoors by adult	0.00000046	NOAEL chronic 2	100	4347826	0.00
		NOAEL develop 18,5	100	40217391	n.a.
Chronic dermal uptake by child playing on playground structures outdoors	0.0023	NOAEL chronic 2	100	870	0.12
Chronic dermal and ingestion uptake by infant playing on weathered structure and mouthing	0.004	NOAEL chronic 2	100	500	0.20

a.....The derivation of the MOE and the exposure/AELs ratio is based on identical NOAELs and exposure estimates but since Member States could not agree on one of these approaches the Biocides Technical Meeting decided to describe both ratios in parallel

n.a....not applicable

2.2.2.4. Combined exposure

Combined exposure to etofenprox used as a component in a wood preservative can not occur frequently, since only industrial use is envisaged. One reasonable scenario would be an operator who is exposed during the day by applying the product professionally and at home by inhalation of volatile residues indoors. Because of the low vapour pressure of etofenprox, exposure via inhalation of volatile residues is very low and does not increase the risk significantly. Combined exposure to etofenprox coming from products other than wood preservatives was not evaluated at present. Considering the sufficient margins of safety in this risk assessment, a combined exposure of the etofenprox containing SPU-01990-I will not lead to an unacceptable risk, when the other single exposure source has also a large margin of safety.

2.2.3. Environmental Risk Assessment

The overall environmental fate and ecotoxicological profile indicate that etofenprox is of short persistence in the environment. Exposure of fish and aquatic invertebrates are the areas of concern, the active substance is less toxic to algae. Etofenprox is classified as “not readily biodegradable”. It has no inhibitory effect on the respiration rate of activated sludge. It has a potential for bioaccumulation.

The surface water metabolite α -CO is less acutely toxic to fish, daphnids or algae than the active ingredient itself. The metabolite 4'-OH shows lower toxicity to chironomids than etofenprox.

The concentrations of etofenprox in the environment were estimated following the recommendations given in the currently available Guidance Documents^{5,6}. For vacuum pressure, the stages of the wood life considered are wood treatment, storage of treated wood and wood in-service. Wood, which is treated by dipping, is intended for use classes 1 and 2, i.e. indoor, and is also stored under cover. Therefore for dipping scenarios only wood treatment would have to be considered.

The emissions to the environment from the stages of storage and wood in-service were calculated on the basis of the results of a leaching test with wood in direct and continuous contact with water to determine the quantity of etofenprox leached out of the treated wood due to rainfall, per wood surface area and per day.

The risk characterisation for the environment shows that etofenprox used as intended will not pose an unacceptable risk to the sewage treatment plants (STP) micro-organisms, to the aquatic, sediment and terrestrial organisms.

Furthermore, the predicted concentrations in groundwater are all well below the trigger value of 0.1 $\mu\text{g/L}$.

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

As for the parent compound etofenprox, the PEC/PNEC ratios for the metabolites α -CO and 4'-OH indicate that an acceptable risk is expected for aquatic and sediment dwelling organisms exposed to degradation products of etofenprox for the treatment and wood in-service stages.

The PEC/PNEC ratios are presented in Tables 2.2.3-1 and 2.2.3-2 for etofenprox and the metabolites, respectively.

5 European Commission (2003): Technical Guidance Document on Risk Assessment, Part II.

6 OECD (2003): Emission Scenario Document for Wood Preservatives Part 1, Part 2, Part 3 and Part 4. OECD Series on Emission Scenario Documents, Number 2.

Table 2.2.3-1: Environmental risk characterisation for etofenprox (PEC/PNEC ratios)

Application Scenario	Dipping	Vacuum-pressure		In-service (vacuum pressure)	
	Process	Process	Storage	Noise barrier	House
STP micro-organisms	3.60×10^{-6}	1.69×10^{-6}	n.a.	$5.39 \times 10^{-9(a)}$	n.a.
Aquatic organisms	$0.422^{(a)}$	$0.244^{(a)}$		$1.2 \times 10^{-4(e)}$	n.a.
Sediment dwelling organisms	$7.37 \times 10^{-1(f)}$	$4.25 \times 10^{-1(f)}$		$1.72 \times 10^{-4(e)}$	n.a.
Terrestrial organisms	$3.09 \times 10^{-2(c)}$	$1.45 \times 10^{-2(c)}$	$0.16^{(d)}$	$4.0 \times 10^{-3(d,e)}$	$1.11 \times 10^{-2(d,e)}$
Aquatic food chain	$7.29 \times 10^{-4(a)}$	$4.21 \times 10^{-4(a)}$		$1.4 \times 10^{-6(a)}$	n.a.
Terrestrial food chain	$2.79 \times 10^{-3(b)}$	$1.31 \times 10^{-3(b)}$	n.a.	$3.74 \times 10^{-5(b)}$	n.a.

n.a. = not applicable

- (a) Based on annual average
- (b) Based on agricultural soil and 180 days
- (c) Agricultural soil averaged over 30 days
- (d) Based on Tier 2 concentrations
- (e) Based on 10 years
- (f) Tier 1

Table 2.2.3-2: Environmental risk characterisation for the metabolites α -CO and 4'-OH (PEC/PNEC ratios)

Application Scenario	Dipping	Vacuum-pressure	Vacuum-pressure In-service	
	Process	Process and storage	Noise barrier	House
aquatic organisms (α -CO)	$3.3 \times 10^{-2(a)}$	$1.91 \times 10^{-2(a)}$	$3.57 \times 10^{-5(b)}$	n.a.
sediment dwelling organisms (4'-OH)	$1.57 \times 10^{-2(c)}$	$6.79 \times 10^{-3(c)}$	$3.67 \times 10^{-5(b)}$	n.a.

n.a. = not applicable

- (a) Values based on annual average concentrations
- (b) Based on 10 years
- (c) Tier 1

2.2.4. List of endpoints

In order to facilitate the work of Member States in granting or reviewing authorisations, and to apply adequately the provisions of Article 5(1) of Directive 98/8/EC and the common principles laid down in Annex VI of that Directive, the most important endpoints, as identified during the evaluation process, are listed in [Appendix I](#).

2.2.5. Overall conclusions of the evaluation

There is not an unacceptable risk to users from the physico-chemical properties, as etofenprox and the etofenprox containing wood preservative product SPU-01990-I are thermally stable, non-flammable, non-explosive and non-oxidising.

Validated analytical methods are available for the determination of etofenprox and the impurities in the active substance as manufactured and for the determination of etofenprox and the metabolite α -CO in air, soil, water, plant and animal matrices.

The available data on the mammalian toxicity, mutagenicity and animal metabolism are considered adequate to support the risk evaluation of etofenprox and SPU-01990-I for humans. All core data and additional studies necessary according to Directive 98/8/EC and further studies required by other regulations, have been evaluated. The studies are scientifically defensible, and the quality of the data is sufficient to support individual study conclusions. From the studies available it is concluded that etofenprox has a low acute oral and dermal toxicity, is not irritant to the skin and eyes, is not a skin sensitizer, and is not neurotoxic, mutagenic, teratogenic or carcinogenic. Therefore, there are no indications for specific concerns.

Proposed internal chronic A(O)EL: 0.02 mg/kg bw/day, based on the combined chronic and carcinogenicity study in the mouse and a safety factor of 100.

Proposed internal subchronic and subacute A(O)EL: 0.13 mg/kg bw/day, based on the subchronic toxicity study in the rat and a safety factor of 100.

It is concluded that the industrial dipping or vacuum pressure treatment of wood with etofenprox imply an acceptable risk for workers if the workers involved in the wood treatment processes are exposed for a shorter period than 3 months per year (seasonal and discontinuous exposure). Since the assumption of seasonal and discontinuous wood treatment depends on the climate and on local work practice, the Member States would have to evaluate individually within the national product authorisation process if the risk due to industrial application of etofenprox is acceptable. In order to support product authorisation a dermal absorption study with the biocidal product is required to refine the risk assessment prior to a decision on the national authorisation.

The risk characterisation indicates an acceptable risk for secondary exposure of adults and infants via contact with etofenprox treated wood.

A detailed and scientifically sound dataset is available to allow good prediction of the environmental fate of etofenprox.

Etofenprox is “not readily biodegradable”. Simulation tests in different media show that it will not persist in the environment. It degrades in soil under aerobic conditions. In laboratory

water/sediment studies the degradation rate of etofenprox is similar to that seen in aerobic soil but the metabolite 4'-OH occurs at a significant level in the sediment.

Etofenprox is hydrolytically stable under relevant environmental conditions. It degrades photo-chemically in aqueous solution predominantly to α -CO. Photochemical degradation in soil is low. Mineralization and formation of bound residues in soil will be more rapid than photo-degradation. The photo-chemical degradation of etofenprox in air has been estimated to be very fast. Accumulation in air and contamination by wet or dry deposition is therefore not expected.

Etofenprox is not mobile in soil. It strongly adsorbs to soil and has a very low leaching potential.

Laboratory eco-toxicity studies show that etofenprox is of low order of toxicity to birds. Etofenprox is highly toxic to fish, daphnids and chironomids in standard laboratory aquatic tests and less toxic to algae. The metabolite α -CO is less acutely toxic to fish, daphnids or algae than the active ingredient itself. The metabolite 4'-OH shows lower toxicity to chironomids than etofenprox.

Etofenprox shows no effects on earthworms up to 16.1 mg/kg dry artificial soil. Plant emergence rate and plant dry weight were inhibited by 16% and the mean plant height was reduced by 11% in one out of 6 species at the highest concentration tested (0.234 mg/kg dry artificial soil). Inhibition of soil micro-organisms was not considered relevant up to the highest concentration tested (2.024 mg/kg artificial soil).

The overall environmental fate and eco-toxicity profile for etofenprox indicate that it is of short persistence in the environment and potential effects of exposure of fish and aquatic invertebrates are the main areas of concern.

The environmental risk assessment indicated that the risk of the intended use is acceptable.

3. DECISION

3.1. Background to the Decision

On the basis of the proposed and supported uses and the evaluation conducted as summarised in chapter 2.1 – 2.3 of this document, it can be concluded that under the conditions listed in chapter 3.2 etofenprox fulfils the requirements laid down in Article 5(1) (b), (c), and (d) of Directive 98/8/EC.

3.2. Decision regarding Inclusion in Annex I

The substance etofenprox shall be included in Annex I to Directive 98/8/EC as an active substance for use in product-type 8 (wood preservatives), subject to the following specific provisions:

Common name: Etofenprox

IUPAC name: 2-(4-ethoxyphenyl)-2-methylpropyl 3-phenoxybenzyl ether

CAS No.: 80844-07-1

EC No.: 407-980-2

Minimum degree of purity of the active substance:

The active substance as manufactured shall have a minimum purity of 970 g/kg.

Product types:

Wood preservative (product-type 8)

Specific provisions:

When assessing, in accordance with Article 5 and Annex VI, the application for authorisation of a product, Member States shall assess those use and/or exposure scenarios and/or populations that have not been representatively addressed in the Community level risk assessment and that may be exposed to the product. When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels.

Member States shall ensure that authorisations are subject to the following condition:

In view of the risk identified for workers, products cannot be used year round unless dermal absorption data is provided to demonstrate that there are no unacceptable risks from chronic exposure. In addition, products intended for industrial use must be used with appropriate personal protective equipment.

3.3. Elements to be taken into account by Member States when authorising products

At product authorisation level, the elements described in this section shall be respected:

- a) Authorisation of etofenprox containing products to be used especially for vacuum pressure application will require a demonstration of sufficient efficacy, as the evaluation of etofenprox has not shown sufficient efficacy at the tested concentrations for vacuum pressure application. The test protocols and the test results are reliable. However, the threshold levels for efficacy against wood boring beetles, e.g. *Hylotrupes bajulus*, and against termites, e.g. *Reticulitermes santonensis*, were not achieved according to the information of the applicant. Therefore, authorisation of etofenprox containing products shall require a demonstration of sufficient efficacy.
- b) In case authorisation is requested for an etofenprox containing product differing from the solvent based formulation (20% etofenprox in 80% organic solvent), a new leaching test shall be provided. As leaching from treated wood is a complex process which is influenced by application and formulation of the product (e.g.: water or solvent based) there is a clear need for leaching tests reflecting realistic situations.
- c) Since the risk assessment for industrial use is based on an exposure reduction by 88% by suitable personal protective equipment the use of suitable protective gloves, footwear and coverall is obligatory for the dipping and for the vacuum pressure application. New gloves should be used each working day.
- d) Workers involved in the treatment of wood by the dipping or the vacuum pressure method must not be exposed for more than 3 months per year, which is expected from just seasonal and discontinuous work practice. Since the assumption of seasonal and discontinuous wood treatment depends on the climate and on local work practice, the Member States would have to evaluate individually within the national product authorisation process if the risk due to industrial application of etofenprox is acceptable. In order to support product authorisation a dermal absorption study with the biocidal product is required to refine the risk assessment prior to a decision on the national authorisation.

The risk for daily exposure is not acceptable based on the available exposure data, because the ratios between the proposed AOEL, derived from the 2-years combined chronic/carcinogenicity study, and the exposure data are for both application procedures below one (and the respective MOEs are above 100). The risk characterisations indicate that a dermal uptake rate of 13.8% would result in an acceptable exposure/AOEL ratio (and acceptable MOE).

- e) The fact that Etofenprox is excreted via the milk should be considered as a toxicological alert for infants. Therefore it would be consistent and appropriately precautionous to regard it as an unacceptable risk that lactating women are exposed to etofenprox during the industrial application process in case this would lead to etofenprox levels in maternal milk above the general pesticide residue limit for infant formula. However, the final C/L decision is needed in order to confirm the hazard evaluation and select the respective risk management options adequately. In any case the responsibility of the

employer according to Article 4.1 of Directive 92/85/EC (OJ L 348, 28.11.1992, p. 1) should be addressed.

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 inclusion of etofenprox in Annex I to Directive 98/8/EC.

The conditions and restrictions proposed are considered reasonable, and no further information is required.

However, authorisation of etofenprox containing products to be used especially for vacuum pressure application will require a demonstration of sufficient efficacy.

In case authorisation is requested for an etofenprox containing product differing from the solvent based formulation (20% etofenprox in 80% organic solvent), a new leaching test shall be provided.

In order to support product authorisation a dermal absorption study with the biocidal product is required to refine the risk assessment prior to a decision on the national authorisation

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 referred to in Articles 5 to 8, 10.4 and 14 of Directive 98/8/EC. Such adaptations will be examined and finalised in connection with any amendment of the conditions for the inclusion of etofenprox in Annex I to the Directive.

Appendix I: List of endpoints

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

Active substance (ISO Common Name)

Etofenprox

Product Type

Wood Preservative

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

CIPAC No

471

CAS No

80844-07-1

EEC No (EINECS or ELINCS)

407-980-2

FAO Specification (including year of publication)

not allocated

Minimum purity of the active substance as manufactured (g/kg)

970 g/kg

Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)

3 impurities >0.1 % w/w; confidential information

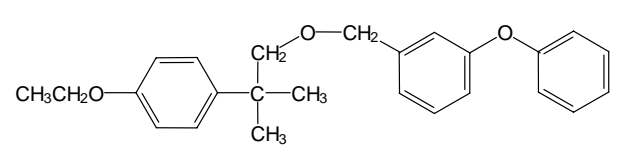
Molecular formula

 $C_{25}H_{28}O_3$

Molecular mass

376.5 g/mol

Structural formula



Physical and chemical properties

Melting point (state purity)	37.4 °C (purity > 99%)
Boiling point (state purity)	not applicable due to decomposition at about 200°C
Temperature of decomposition	approximately 200 °C (purity > 99%)
Appearance (state purity)	thermodynamically stable state: crystalline solid; metastable state: supercooled liquid; white to amber, aromatic odour (purity >99%)
Relative density (state purity)	1.172 g/cm ³ (at 20.7 °C, purity > 99%)
Surface tension	68.12 mN/m (90% saturated aqueous solution, at 20.1 °C)
Vapour pressure (in Pa, state temperature)	8.13 x 10 ⁻⁷ Pa at 25°C
Henry's law constant (Pa m ³ mol ⁻¹)	0.0136 Pa m ³ /mol at 25°C
Solubility in water (g/l or mg/l, state temperature)	pH 4: 0.0052 mg/l, at 20°C pH 7: 0.0225 mg/l, at 20°C pH 9: 0.012 mg/l, at 20°C
Solubility in organic solvents (in g/l or mg/l, state temperature) (Annex IIIA, point III.1)	methanol: 49 g/l (at 20 °C) ethanol: 98 g/l (at 20 °C) acetone: 877 g/l (at 20 °C) ethylacetate: 837 g/l (at 20 °C) hexane: 667 g/l (at 20 °C) heptane: 621 g/l (at 20 °C) xylene: 856 g/l (at 20 °C) toluene: 862 g/l (at 20 °C) dichloromethane: 924 g/l (at 20 °C)
Stability in organic solvents used in biocidal products including relevant breakdown products (IIIA, point III.2)	stable
Partition co-efficient (log P _{OW}) (state pH and temperature)	6.9 (HPLC method, at 20 °C)
Hydrolytic stability (DT ₅₀) (state pH and temperature) (point VII.7.6.2.1)	pH 4: stable (at 50 °C) pH 7: stable (at 50 °C) pH 9: stable (at 50 °C)
Dissociation constant (not stated in Annex IIA or IIIA; additional data requirement from TNsG)	does not dissociate
UV/VIS absorption (max.) (if absorption > 290 nm, state ε at wavelength)	maximum 273.5 nm in acidic and basic solution (acid methanol, pH 1 and basic methanol, pH 12) maximum 273.6 in neutral solution (methanol, pH 7)
Photostability (DT ₅₀) (aqueous, sunlight, state pH) (point VII.7.6.2.2)	buffer solution: DT ₅₀ =4.7 days (xenon arc lamp, pH 7.1) natural pond water: DT ₅₀ =7.9 days (xenon arc lamp, pH 8.1)
Quantum yield of direct phototransformation in water at Σ > 290 nm (point VII.7.6.2.2)	in buffer solution: Φ = 0.248

Flammability	natural pond water : $\Phi = 0.147$
	not flammable; no auto-flammability up to the melting point
Explosive properties	not explosive

Classification and proposed labelling

with regard to physical/chemical data	No classification
with regard to toxicological data	No classification
with regard to fate and behaviour data	No classification
with regard to ecotoxicological data	Classification: N; R50-53; Labelling: N; R50/53; very toxic to aquatic organisms, may cause long-term effects in the aquatic environment S36-60-61; Wear suitable protective clothing. - This material and its container must be disposed of as hazardous waste. - Avoid release to the environment. Refer to special instructions/safety data sheets.

Chapter 2: Methods of Analysis**Analytical methods for the active substance**

Technical active substance (principle of method) (Annex IIA, point 4.1)	CIPAC method 471/TC/M/3: Gas chromatography (GC) with flame ionisation detection (FID)
Impurities in technical active substance (principle of method) (Annex IIA, point 4.1)	confidential information

Analytical methods for residues

Soil (principle of method and LOQ) (Annex IIA, point 4.2)	Gas chromatography with MS detection LOQ=0.01 mg/kg, for etofenprox and its metabolite α -CO
Air (principle of method and LOQ) (Annex IIA, point 4.2)	Gas chromatography with MS detection LOQ=1.00 $\mu\text{g}/\text{m}^3$, for etofenprox and its metabolite α -CO
Water (principle of method and LOQ) (Annex IIA, point 4.2)	Gas chromatography with MS detection LOQ=0.05 $\mu\text{g}/\text{L}$, for etofenprox and its metabolite α -CO in drinking, ground and surface water
Body fluids and tissues (principle of method and LOQ) (Annex IIA, point 4.2)	Not evaluated
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)	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

(Annex IIIA, point IV.1)

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 based on urinary elimination, carcass residues and fecal metabolites:

~ 65% (30 mg/kg)

~ 52% (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%

Active substance via biocidal product: 100% (default value, since no study is available)

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 μ g/g compared to maternal plasma concentrations from 1.9 to 3.6 μ g/ml), but transfer decreases markedly on cessation of dosing.

Potential for accumulation:

Yes: Half-life time is 15 / 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

Toxicologically significant metabolite(s)

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.

≥ 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 LD₅₀ oral

> 2000 mg/kg bw

Rat LD₅₀ dermal

> 2000 mg/kg bw

Rat LC₅₀ inhalation

> 5.88 mg/L air /4h (> 95% particles < 5.5 μ m) 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

rat (oral, 13-weeks):liver, thyroid

rat (inhalation 13-weeks): liver, adrenal, thyroid

rabbit (dermal 4-weeks): no target organs

Lowest relevant oral NOAEL / LOAEL
 Lowest relevant dermal NOAEL / LOAEL
 Lowest relevant inhalation NOAEL / LOAEL

Rat (13-weeks) NOAEL: 20mg/kg bw/day
Rabbit (4-weeks) NOAEL: > 1000 mg/kg/day
Rat (13-weeks) NOAEL : 0.04 mg/L

Genotoxicity

No genotoxic potential in all <i>in vitro</i> and <i>in vivo</i> assays employed (Ames-Test, <i>in vitro</i> cytogenicity test with human lymphocytes, <i>in vitro</i> gene mutation test V79 cells, <i>in vitro</i> UDS, <i>in vivo</i> micronucleus test)

Long term toxicity and carcinogenicity

Target/critical effect
 Lowest relevant NOAEL / NOEL
 Carcinogenicity

Target/critical effect
Lowest relevant NOAEL / NOEL
Carcinogenicity

Reproductive toxicity

Species/ Reproduction target / critical effect
 Lowest relevant reproductive NOAEL / LOAEL

rats / minimally increased pub mortality at parentally toxic dose levels
--

<p>rat 2-generation:</p> <p><u>parental NOAEL</u>: 37 mg/kg bw day: ↓ weight gain, ↑ liver, kidney and thyroid weights</p> <p><u>reproductive NOAEL</u>: 37 mg/kg bw day: minimal ↑ pup mortality</p> <p><u>offspring NOAEL</u>: 37 mg/kg bw/day: pre-weaning tremors, abnormal gait, histopathological alterations in liver, kidneys and thyroid, ↑ heart weight</p>
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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

<p>rabbit</p> <p><u>maternal NOAEL</u>: 100 mg/kg bw: ↓ weight gain / food cons</p> <p><u>developmental NOAEL</u>: 100 mg/kg bw day: ↑ slight post-implantation loss and ↓ fetal weight gain.</p> <p>rat</p> <p><u>maternal NOAEL</u>: 28.4 mg/kg bw day: transiently reduced gestation weight</p> <p><u>developmental NOAEL</u>: 28.4 mg/kg bw day: ocular lesions (haemorrhage) in weanlings</p>
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Neurotoxicity / Delayed neurotoxicity

Species/ target/critical effect and lowest relevant developmental NOAEL / LOAEL.

rat, no neurotoxic effects were observed in the <u>acute neurotoxicity</u> or in the <u>13-week neurotoxicity study</u> 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

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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

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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
ADI (if residues in food or feed)	not relevant		
internal chronic A(O)EL	0,02 mg/kg day	Mouse 108-week	100
internal subchronic and subacute A(O)EL	0,13 mg/kg day	Rat 13-week	100
Drinking water limit	not relevant		
ARfD (acute reference dose)	not relevant		

Acceptable exposure scenarios

Professional users

The subchronic exposure scenarios for industrial application by vacuum pressure treatment or dipping are acceptable.

Non-professional users

Not relevant (only industrial use intended)

Indirect exposure as a result of use

The acute exposure scenarios for an adult sanding treated wood and an infant chewing treated wood and the subchronic exposure scenarios for adults sanding treated wood and the chronic exposure scenarios for adults and children inhaling evaporated product indoors and for children playing and mouthing on treated and weathered structures are acceptable without the need for risk mitigation measures.

Chapter 4: Fate and Behaviour in the Environment**Route and rate of degradation in water**Hydrolysis of active substance and relevant metabolites (DT₅₀) (state pH and temperature)Etofenprox:

pH 4: stable (50 °C)

pH 7: stable (50 °C)

pH 9: stable (50 °C)

Metabolite: [¹⁴C]- 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 DT₅₀: 9.6 days at 35°C (1st order, r²=0.977) and 2.4 days at 45°C (1st order, r²=0.985)Predicted DT₅₀: 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: DT₅₀ 4.7 days (1st order)Natural pond water, xenon arc lamp: DT₅₀ 7.9 days (1st order)

Dark control: Etofenprox was found to be stable.

Estimated DT₅₀ at 30°N: 7.8 – 21.8 days (spring – winter)Estimated DT₅₀ at 40°N: 8.4 – 44.2 days (spring – winter)Estimated DT₅₀ at 50°N: 9.5 – 131 days (spring – winter)Metabolites: after 15 days in pond water and buffer solution

α-CO: 37.8 and 63.6% AR

Readily biodegradable (yes/no)

NO;

Closed bottle test: 17 % degradation in 28 days;

Modified Sturm test: 32 % degradation in 28 days;

Biodegradation in seawater

Not evaluated

Degradation in water/sediment	
- DT ₅₀ water	Etofenprox: 2.1 - 10.4 days (n=2, r ² ≥ 0.999) DT ₅₀ of 10.4 days converted to standard European conditions: DT50 = 19.7 days
- DT ₉₀ water	Etofenprox: 7.1 – 34.5 days (n=2, r ² = 0.999)
- DT ₅₀ sediment (calculated)	Etofenprox: 17.9 – 32.2 days (n=2) 4'-OH: 26.4 – 55.8 days (n=2)
- DT ₉₀ sediment (calculated)	Etofenprox: 59.4 – 106.9 days (n=2) 4'-OH: 87.8 – 185.5 days (n=2)
- DT ₅₀ whole system	Etofenprox: 6.5 – 20.1 days (n=2, r ² = 0.994) 4'-OH: 21.8 – 29.7 days (n=2, r ² =0.798)
- DT ₉₀ whole system	Etofenprox: 23.8 – 71.0 days (n=2, r ² > 0.994) 4'-OH: 59.8 – 97.9 days (n=2)
Mineralization	17.8 – 28.2 % (n=2, after 0 - 99 days)
Non-extractable residues in sediment	0.1 – 30.8 % (n=2, after 0 - 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: only one metabolite (4'-OH) exceeded 10 % of AR; 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, (n=4) [α- ¹⁴ C-benzy] & [2- ¹⁴ C-propyl] labels
Non-extractable residues after 120 days	42.8-54.5% AR after 120 days, (n=4) [α- ¹⁴ C-benzy] & [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 (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 converted to standard European conditions: mean DT ₅₀ = 22.8 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	<p>Etofenprox, xenon arc lamp :</p> <p>DT₅₀ 19.3 days (1st order)</p> <p>DT₉₀ 64.0 days (1st order)</p> <p><u>Dark control:</u></p> <p>DT₅₀ 22.2 days (1st order)</p> <p>DT₉₀ 73.8 days (1st order)</p> <p><u>Etofenprox :</u></p> <p>Estimated DT50 at 30°N 26.1 days</p> <p>Estimated DT90 at 30°N 86.4 days</p> <p><u>Metabolites :</u> up to 10 minor metabolites < 7.7%; six characterised (α-CO, 4'-OH, DE, m-PB-acid, a mixture of PENA and EPMP and DP) ;</p>
Soil accumulation and plateau concentration	No data required
Adsorption/desorption	
K' (ml/g)	<p>196 – 343 (median 257.7, n=3, soil to aqueous phase ratio of 1:5)</p> <p>434 – 836 (median 596.4, n=3, soil to aqueous phase ratio of 1:25)</p>
K _{oc} (ml/g)	<p>8548 – 14923 (median 10 832, n=3, soil to aqueous phase ratio of 1:5)</p> <p>18968 – 33067 (median 24 681, n=3, soil to aqueous phase ratio of 1:25)</p>
K _d	Could not be determined (only 0.9% to 2.8% of the quantity adsorbed could be desorbed in the soil to aqueous phase ratio of 1:5; only 1.3% to 2.5% of the quantity adsorbed could be desorbed in the soil to aqueous phase ratio of 1:25)
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	
Photo-oxidative degradation in air	DT ₅₀ calculated=2.07 hours
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			
<i>Oncorhynchus mykiss</i>	96 h, flow-through	Mortality, LC ₅₀	0.0027
<i>Brachydanio rerio</i>	40 d, flow-through	Mortality and development, NOEC	0.025
Fish – Test substance: metabolite α-CO			
<i>Oncorhynchus mykiss</i>	96 h, flow-through	Mortality, LC ₅₀	> 0.048
Invertebrates – Test substance: etofenprox			
<i>Daphnia magna</i>	48 h, static renewal	Mortality, EC ₅₀	0.0012
<i>Daphnia magna</i>	21 d, semi-static	Reproduction, NOEC	0.000054
Invertebrates – Test substance: metabolite α-CO			
<i>Daphnia magna</i>	48 h, static	Mortality, EC ₅₀	> 0.044
Algae – Test substance: etofenprox			
<i>Pseudokirchneriella subcapitata</i>	72 h, static	Biomass, E _b C ₅₀	> 0.05625
<i>Pseudokirchneriella subcapitata</i>	72 h, static	Biomass, NOEC	0.05625
Algae – Test substance: : metabolite α-CO			
<i>Pseudokirchneriella subcapitata</i>	96 h, static	Biomass, E _b C ₅₀	> 0.053
Sediment dwelling organisms – Test substance: etofenprox			
<i>Chironomus riparius</i>	10 d, static water-sediment system	Mortality, EC ₅₀	> 0.0209
<i>Chironomus riparius</i>	25 d, static water-sediment system	Emergence, Development, NOEC	0.0038

Sediment dwelling organisms – Test substance: metabolite 4'-OH			
<i>Chironomus riparius</i>	48 h, static	Mortality, LC ₅₀	0.0502
Microorganisms – Test substance: etofenprox			
<i>Activated sludge</i>	3h, static	Respiration rate, NOEC	≥ 100 mg/l or ≥ water solubility

Effects on earthworms or other soil non-target organisms

Acute toxicity to earthworms

LC₅₀ > 47.2 mg as / kg dry soil (measured value)
 LC₅₀ > 16.1 mg as / kg dry soil (converted to standard soil)

Reproductive toxicity to earthworms

No data required

Terrestrial plant toxicity

LC₅₀ > 200 g as / kg (measured value)
 LC₅₀ > 0.234 mg as / kg dry soil (converted to standard soil)

Effects on soil micro-organisms

Nitrogen mineralization

NOEC ≥ 0.893 mg as / kg dry soil (measured value)
 NOEC ≥ 2.024 mg as / kg dry soil (converted to standard 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 (measured value)
 NOEC ≥ 2.024 mg as / kg dry soil (converted to standard soil)

Effects on terrestrial vertebrates

Acute toxicity to mammals

No data required

Acute toxicity to birds

LD₅₀ > 2000 mg as/kg bw (mallard duck)

Dietary toxicity to birds

LC₅₀ > 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

No data required

Acute contact toxicity

No data required

Effects on other beneficial arthropods

Acute oral toxicity

No data required

Acute contact toxicity

No data required

Bioconcentration in fish

Bioconcentration factor (BCF)

edibles, BCF=1554
 in non-edibles, BCF=7213
 in whole fish, BCF=3951

Depuration time(DT₅₀)
 (DT₉₀)

CT₅₀ = 9-16 days (first-order kinetics)
 CT₉₅ = 39-69 days (first-order kinetics)

Level of residues (%) in organisms after the 14 day depuration phase

1.6% - 5.2% (after 62 days depuration phase)

Level of metabolites (%) in organisms accounting for > 10 % of residues

None

Appendix II: List of Intended Uses

Etofenprox is effective against major wood destroying insect pests, i.e. particularly house longhorn beetle (*Hylotrupes bajulus*) and termites (*Reticulitermes santonensis*).

Products containing etofenprox are intended to be used as a wood preservative (product-type 8) for preventive application by industrial techniques, i.e. vacuum pressure in use classes 1 to 3 and dipping treatments in use classes 1 and 2. The assessed biocidal product was an artificial product rather than a real one and was considered to be supplied as a soluble concentrate to be diluted down to the ready for use concentration. The formulations are not intended to contain more than 0.1% active substance. The application rates proposed by the applicant are 2.5 g a.s./m³ wood for vacuum pressure and range from 0.03 to 0.04 g a.s./m² wood for dipping treatment.

Designation of categories of users: industrial users

Summary of intended uses – Wood preservative

Object and/or situation (a)	Member State or Country	Product name / Product Type	Organisms controlled (b)	Formulation		Application			Applied amount		
				Type	Conc. of as	method kind / category of user	number min- max	interval between applications	g as/L application solution min max	g as/m ² wood min max	
Wood, use classes 1-3	EU	SPU-01990-I PT 8	Major wood destroying insect pests	SL Soluble concentrate	0.1%	vacuum pressure (industrial user)	1 cycle /article 2 cycles/day	-	0.01	0.04	1.
Wood, use classes 1-2	EU	SPU-01990-I PT 8			0.1%	dipping (industrial user)	1 cycle /article 3 cycles / day	-	0.05	0.15	1.

(a) Use class 1: wood under cover, dry; use class 2: wood under cover, damp; use class 3: wood not covered and not in contact with the ground

(b) Efficacy against house longhorn beetle (*Hylotrupes bajulus*) and termites (*Reticulitermes santonensis*);

(c) Conversion from g as/m³ wood to g as/m² wood is based on the assumption to 1 m³ wood corresponds to 40 m² wood

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. 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

Section No / Reference No	Author (s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/ N	Owner
A 2.7/01	Ramsay N.	2002a	Etofenprox 5-batch analysis of etofenprox to fulfill the requirements of OPPTS guidelines 830.1700, 830.1750 and 830.1800 and EC council directive 94/37/EEC article 1.9 and 1.11 Inveresk Research, Report No. 20852 Landis Kane Consulting, Document No. 500-1-01 GLP, unpublished	Y	Mitsui Chemicals, Inc.
A 2.10.1 → B 6.6	Mirbach M.	2004	Etofenprox: estimation of the human exposure to etofenprox used in the wood preservative product SPU-01990-I. Landis Kane Consulting, Report No. 04-alpha-02 Landis Kane Consulting, Document No.500-5-93 not GLP, not published	Y	Mitsui Chemicals, Inc.
A 2.10.2 → B 7.1/06	Rathey S.	2005b	Estimation of the predicted environmental concentrations of etofenprox used in the wood preservative product SPU-01990-I. Landis Kane Consulting, Report No. 04-alpha-04/03 Landis Kane Consulting, Document No.500-7-46 Not GLP, not published	Y	Mitsui Chemicals, Inc.
A 3.1.1	Tognucci A.	1999	Determination of the melting point / melting range of etofenprox RCC Ltd, Report No. 718830 Landis Kane Consulting, Document No: 500-2-01 GLP, unpublished	Y	Mitsui Chemicals, Inc.
A 3.1.2	Tognucci A.	1998a	Determination of the boiling point / boiling range of etofenprox RCC Ltd, Report No: 692730 Landis Kane Consulting, Document No. 500-2-02 GLP, unpublished	Y	Mitsui Chemicals, Inc.

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

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

Section No / Reference No	Author (s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/ N	Owner
A 3.4/05	Pouchert Ch.J., Behnke J.	1983	The Aldrich library of ¹³ C and ¹ H FT NMR spectra Aldrich Chemical Company 1983 Landis Kane Consulting, Document No. 500-2-61 Not GLP, published	N	Public information
A 3.4/06	Pouchert Ch.J.	1985	The Aldrich library of FT-IR spectra Aldrich Chemical Company 1985 Landis Kane Consulting, Document No. 500-2-62 Not GLP, published	N	Public information
A 3.4/07	Heller S.R., Milne G.W.A.	1978	EPA / NIH mass spectral data base U.S. Department of Commerce, National Bureau of Standards 1978 Landis Kane Consulting, Document No. 500-2-63 Not GLP, published	N	Public information
A 3.5/01	Kunz C.	2000	Determination of the water solubility of ¹⁴ C-etofenprox at three pH values and amendment dated October 04, 2000 RCC Ltd, Report No. 755515 Landis Kane Consulting, Document No. 500-2-11 GLP, unpublished	Y	Mitsui Chemicals, Inc.
A 3.5/02	McCorquodale G.Y.	2002a	Physico-chemical testing with [¹⁴ C]-Alpha-CO: water solubility Inveresk Research, Report No: 21386 Landis Kane Consulting, Document No. 500-2-12 GLP, unpublished	Y	Mitsui Chemicals, Inc.
A 3.5/03	Matsumoto T.	2002c	Determination of water solubility for 4'-OH by column elution method Kurume Laboratory, Chemicals Evaluation and Research Institute, Report No. 82070 Landis Kane Consulting, Document No. 500-2-13 GLP, unpublished	Y	Mitsui Chemicals, Inc.
A 3.5/04	Matsumoto T.	2002d	Determination of water solubility for PENA by flask method Kurume Laboratory, Chemicals Evaluation and Research Institute, Report No. 82073 Landis Kane Consulting, Document No. 500-2-14 GLP, unpublished	Y	Mitsui Chemicals, Inc.

Section No / Reference No	Author (s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/ N	Owner
A 3.5/05	Mirbach M.	2004a	Etofenprox: estimation of the temperature dependence of the solubility in water and organic solvents and of the partition coefficient octanol/water. Landis Kane Consulting, Report No. 04-alpha-18 Landis Kane Consulting, Document No.500-2-67 Not GLP, not published	Y	Mitsui Chemicals, Inc.
A 3.6	Schmiedel U.	1998	Expert statement on the dissociation of MTI-500 (etofenprox) in water RCC Ltd, Report No. 692741 Landis Kane Consulting, Document No. 500-2-26 Not GLP, unpublished	Y	Mitsui Chemicals, Inc.
A 3.7/01	Tognucci A.	1998d	Determination of the solubility of etofenprox in organic solvents RCC Ltd, Report No. 692752 Landis Kane Consulting, Document No. 500-2-15 GLP, unpublished	Y	Mitsui Chemicals, Inc.
A 3.7/02 → A 3.5/05	Mirbach M.	2004a	Etofenprox: estimation of the temperature dependence of the solubility in water and organic solvents and of the partition coefficient octanol/water. Landis Kane Consulting, Report No. 04-alpha-18 Landis Kane Consulting, Document No.500-2-67 Not GLP, not published	Y	Mitsui Chemicals, Inc.
A 3.9/01	Tognucci A.	1998e	Determination of the partition coefficient (N-octanol / water) of etofenprox and amendment dated October 13, 1999 RCC Ltd, Report No. 692763 Landis Kane Consulting, Document No. 500-2-16 GLP, unpublished	Y	Mitsui Chemicals, Inc.
A 3.9/02	McCorquodale G.Y.	2002b	Physico-chemical testing with [14C]-Alpha-CO: partition coefficient Inveresk Research, Report No. 21024 Landis Kane Consulting, Document No. 500-2-17 GLP, unpublished	Y	Mitsui Chemicals, Inc.
A 3.9/03	Matsumoto T.	2002e	1-Octanol/water partition coefficient test of 4'-OH (HPLC method) Kurume Laboratory, Chemicals Evaluation and Research Institute, Report No. 82071 Landis Kane Consulting, Document No. 500-2-18 GLP, unpublished	Y	Mitsui Chemicals, Inc.

Section No / Reference No	Author (s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/ N	Owner
A 3.9/04	Matsumoto T.	2002f	1-Octanol/water partition coefficient test of PENA (HPLC method) Kurume Laboratory, Chemicals Evaluation and Research Institute, Report No. 82074 Landis Kane Consulting, Document No. 500-2-19 GLP, unpublished	Y	Mitsui Chemicals, Inc.
A 3.9/05 → A 3.5/05	Mirbach M.	2004a	Etofenprox: estimation of the temperature dependence of the solubility in water and organic solvents and of the partition coefficient octanol/water. Landis Kane Consulting, Report No. 04-alpha-18 Landis Kane Consulting, Document No.500-2-67 Not GLP, not published	Y	Mitsui Chemicals, Inc.
A 3.10	Tognucci A.	1998f	Screening of the thermal stability in air of etofenprox RCC Umweltchemie AG, Report No. 692774 Landis Kane Consulting, Document No. 500-2-37 GLP, unpublished	Y	Mitsui Chemicals, Inc.
A 3.11/01	Dublaski A.	1991a	Determination of the flammability of etofenprox in accordance with EEC-Guideline A.10 Battelle Europe, Report No. BE-P-32-91-A10-02 Landis Kane Consulting, Document No. 500-2-29 GLP, unpublished	Y	Mitsui Chemicals, Inc.
A 3.11/02	Dublaski A.	1991b	Determination of the auto-flammability of etofenprox in accordance with EEC-Guideline A.16 Battelle Europe, Report No. BE-P-32-91-A16-02 Landis Kane Consulting , Document No. 500-2-30 GLP, unpublished	Y	Mitsui Chemicals, Inc.
A 3.12	Bates M.	2001a	MTI-500: determination of the flash point - Amended final report from January 31, 2001 Covance Laboratories Ltd., Report No. 719/8-D2141 Landis Kane Consulting, Document No. 500-2-31 GLP, unpublished	Y	Mitsui Chemicals, Inc.
A 3.13	Dublaski A.	1991c	Determination of the surface tension of etofenprox in accordance with EEC-Guideline A.05 Battelle Europe., Report No. BE-P-32-91-A05-02 Landis Kane Consulting, Document No. 500-2-33 GLP, unpublished	Y	Mitsui Chemicals, Inc.

Section No / Reference No	Author (s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/ N	Owner
A 3.15	Bates M.	2001b	MTI-500: evaluation of the explosive properties - Amended final report from January 31, 2001 Covance Laboratories Ltd., Report No. 719/9-D2141 Landis Kane Consulting. Document No. 500-2-32 GLP, unpublished	Y	Mitsui Chemicals, Inc.
A 3.16	Bates M.	2001c	MTI-500: determination of the oxidizing properties - Amended final report from January 31, 2001 Covance Laboratories Ltd., Report No. 719/11-D2141 Landis Kane Consulting, Document No. 500-2-34 GLP, unpublished	Y	Mitsui Chemicals, Inc.
A 3.17	Ohnuma K.	2004	Statement concerning the stability of etofenprox technical during storage and shipment. Mitsui Chemicals, Inc., Document No. not specified Landis Kane Consulting, Document No. 500-2-66 Not GLP, unpublished	N	Mitsui Chemicals, Inc.
A 4.1/01	Ramsay N.	2002b	Etofenprox – Validation of analytical methods to support 5-batch analysis of Etofenprox to fulfil the requirements of OPPTS Guidelines 830.1700, 830.1750 and 830.1800 and EC Council Directive 94/37/EEC Article 1.9 to 1.11. Inveresk Research, Report No. 21164 Landis Kane Consulting, Document No. 500-4-01 GLP, unpublished	Y	Mitsui Chemicals, Inc.
A 4.1/02	Dobrat W., Martijn A.	1995	CIPAC Handbook Volume G - Analysis of technical and formulated pesticides method etofenprox 471 Collaborative Int. Pesticides Analytical Council Ltd. 1995 Landis Kane Consulting, Document No. 500-4-02 Not GLP, published	N	Public information
A 4.2/01	Wolf S.	2003a	Validation of the residue analytical method for MTI-500 and α -CO in soil RCC Ltd, Report No. 811607 Landis Kane Consulting, Document No. 500-4-12 GLP, unpublished	Y	Mitsui Chemicals, Inc.
A 4.2/02	Wolf S.	2003b	Development and validation of the residue analytical method for MTI-500 and α -CO in air RCC Ltd, Report No. 811620 Landis Kane Consulting, Document No. 500-4-17 GLP, unpublished	Y	Mitsui Chemicals, Inc.

Section No / Reference No	Author (s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/ N	Owner
A 4.2/03	Wolf S.	2003c	Validation of the residue analytical method for MTI-500 and α -CO in drinking, ground and surface water RCC Ltd, Report No. 811618 Landis Kane Consulting, Document No. 500-4-15 GLP, unpublished	Y	Mitsui Chemicals, Inc.
A 4.3/01	Wolf S.	2001	Validation of the residue analytical method for MTI-500 and α -CO in oil seed rape RCC Ltd, Report No. 789390 Landis Kane Consulting, Document No. 500-4-08 GLP, unpublished	Y	Mitsui Chemicals, Inc.
A 4.3/02	Wolf S.	2002	Validation of the residue analytical method for MTI-500 and α -CO in cabbage RCC Ltd, Report No. 814588 Landis Kane Consulting, Document No. 500-4-07 GLP, unpublished	Y	Mitsui Chemicals, Inc.
A 4.3/03	Wolf S.	2003d	Validation of the residue analytical method for MTI-500 and α -CO in cucumber RCC Ltd, Report No. 789377 Landis Kane Consulting, Document No. 500-4-03 GLP, unpublished	Y	Mitsui Chemicals, Inc.
A 4.3/04	Class T.	2003a	Etofenprox: independent laboratory validation of analytical methods used for the determination of residues of etofenprox in plant materials PTRL Europe GmbH, Report No. P 692 G Landis Kane Consulting, Document No. 500-4-40 GLP, unpublished	Y	Mitsui Chemicals, Inc.
A 4.3/05	Wolf S.	2003e	Development and validation of the residue analytical method for MTI-500 and α -CO in meat (ruminant and chicken), milk, fat (ruminant) and egg RCC Ltd, Report No. 791245 Landis Kane Consulting, Document No. 500-4-19 GLP, unpublished	Y	Mitsui Chemicals, Inc.
A 4.3/06	Class T.	2003b	Etofenprox: independent laboratory validation of an analytical method used for the determination of residues of etofenprox in foodstuffs of animal origin PTRL Europe, Report No: P/B 701 G Landis Kane Consulting, Document No. 500-4-41 GLP, unpublished	Y	Mitsui Chemicals, Inc.

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

Section No / Reference No	Author (s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/ N	Owner
A 6.1.1/01	Oda S.	2003a	Acute oral toxicity study of etofenprox in rats Bozo Research Center Inc., Report No. B-5039 Landis Kane Consulting, Document No. 500-5-70, GLP, not published	Y	Mitsui Chemicals, Inc.
A 6.1.1/02	Harling R.J., Burford P., Heywood R.	1985a	Ethofenprox (MTI-500) acute limit test of toxicity to dogs following a single oral administration Huntingdon Research Centre Ltd., Report No. MTC 101/851185 Landis Kane Consulting, Document No. 500-5-07 GLP, not published	Y	Mitsui Chemicals, Inc.
A 6.1.1/03	Hashimoto K.	1982a	Report on acute toxicity study of MTI-500 (ethofenprox) in rats Hatano Research Institute, Food and Drug Safety Center, Report No. A-82-27~34 Landis Kane Consulting, Document No. 500-5-08 Not GLP, not published	Y	Mitsui Chemicals, Inc.
A 6.1.1/04	Hashimoto K.	1982b	Report on Acute Toxicity Study of MTI-500 (ethofenprox) in Mice Hatano Research Institute, Food and Drug Safety Center, Report No. A-82-35~42 Landis Kane Consulting, Document No. 500-5-09 Not GLP, not published	Y	Mitsui Chemicals, Inc.
A 6.1.2/01	Oda S.	2003b	Acute dermal toxicity study of etofenprox in rats Bozo Research Center Inc., Report No. B-5040 Landis Kane Consulting, Document No. 500-5-71 GLP, not published	Y	Mitsui Chemicals, Inc.
A 6.1.2/02 → A 6.1.1/03	Hashimoto K.	1982a	Report on acute toxicity study of MTI-500 (ethofenprox) in rats Hatano Research Institute, Food and Drug Safety Center, Report No. A-82-27~34 Landis Kane Consulting, Document No. 500-5-08 Not GLP, not published	Y	Mitsui Chemicals, Inc.
A 6.1.2/03 → A 6.1.1/04	Hashimoto K.	1982b	Report on acute toxicity study of MTI-500 (ethofenprox) in mice Hatano Research Institute, Food and Drug Safety Center, Report No. A-82-35~42 Landis Kane Consulting, Document No. 500-5-09 Not GLP, not published	Y	Mitsui Chemicals, Inc.
A 6.1.3	Jackson C.J., Hardy C.J., Clark G.C., Greg-son R.L., Lewis D.J., Gopinath C.	1983	MTI-500 Acute inhalation toxicity in rats 4 hour exposure Huntingdon Research Centre Ltd., Report No. MTC 60/821079 Landis Kane Consulting, Document No. 500-5-10 GLP, not published	Y	Mitsui Chemicals, Inc.

Section No / Reference No	Author (s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/ N	Owner
A 6.1.4.s	Kashima M., Ikeda H., Maru-yama Y., Ootsuka Y.	1985a	MTI-500 Primary skin stimulation test in rabbits - Amendment No. 1 from October 28, 1991 Haruna Laboratory Nippon Experimental Medical Research Institute, Ltd., Report No. NEMRI-H-85-5 Landis Kane Consulting, Document No. 500-5-11 GLP, not published	Y	Mitsui Chemicals, Inc.
A 6.1.4.e	Kashima M., Ikeda H., Maru-yama Y., Ootsuka Y.	1985b	MTI-500 Primary ophthalmic stimulation test in rabbits - Amendment No. 1 from October 28, 1991 Haruna Laboratory Nippon Experimental Medical Research Institute, Ltd., Report No. NEMRI-H-85-55 Landis Kane Consulting, Document No. 500-5-12 GLP, not published	Y	Mitsui Chemicals, Inc.
A 6.1.5	Kobayashi K.	1985	MTI-500 Skin sensitization test in guinea pigs - Correction to translation from October 21, 2003 Oizumi Laboratory Nippon Experimental Medical Research Institute, Ltd., Report No. not specified Landis Kane Consulting, Document No. 500-5-13 GLP, not published	Y	Mitsui Chemicals, Inc.
A 6.2/01	Hawkins D.R., Kirkpatrick D., Ewen B., Midgley I., Biggs S.R., Whitby B.R.	1985a	The biokinetics and metabolism of ¹⁴ C-ethofenprox in the rat Huntingdon Research Centre Ltd., Report No. HRC/MTC 68/84610 Landis Kane Consulting, Document No. 500-5-02 GLP, not published	Y	Mitsui Chemicals, Inc.
A 6.2/02	Burri R.	2001a	[¹⁴ C]-MTI-500: absorption, distribution, metabolism and excretion after single oral administration to male rats - amendment dated November 30, 2001 RCC Ltd, Report No. 801382 Landis Kane Consulting, Document No. 500-5-01 Not GLP, not published	Y	Mitsui Chemicals, Inc.
A 6.2/03	Burri R.	2001b	[¹⁴ C]-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	Mitsui Chemicals, Inc.
A 6.2/04	Hawkins D.R., Kirkpatrick D., Ewen B., Midgley I., Biggs S.R.	1985b	The metabolism of ¹⁴ C-ethofenprox in dogs Huntingdon Research Centre Ltd., Report No. HRC/MTC 69/84583 Landis Kane Consulting, Document No. 500-5-04 GLP, not published	Y	Mitsui Chemicals, Inc.

Section No / Reference No	Author (s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/ N	Owner
A 6.2/05	Tomoda K.	1986	Metabolism study of ethofenprox (MTI-500), metabolism in rat Mitsui Toatsu Chemicals, Inc., Report No. not specified Landis Kane Consulting, Document No. 500-5-03 Not GLP, not published	Y	Mitsui Chemicals, Inc.
A 6.2/06	Thalaker F.	1999	Dermal absorption of ¹⁴ C-ethofenprox in male rats (preliminary and definitive phases) Covance Laboratories Inc., Report No. 6648-135 Landis Kane Consulting, Document No. 500-5-80 GLP, not published	Y	Mitsui Chemicals, Inc.
A 6.3.2	Killeen J.C.	2000	A 28-day repeated dose dermal toxicity study in rabbits with technical MTI-500 Ricerca, LLC Toxicology & Metabolism, Report No. 011077-1 Landis Kane Consulting, Document No. 500-5-18 GLP, not published	Y	Mitsui Chemicals, Inc.
A 6.4.1/01	Green O.P., Street A.E., Heywood R., Gopinath C., Almond R.H.	1983a	Assessment of the toxicity of MTI-500 in rats during dietary administration for 13 weeks Re-issued amended pages on December 18, 1985 Huntingdon Research Centre Ltd., Report No. MTC 56/821067 Landis Kane Consulting, Document No. 500-5-14 GLP, not published	Y	Mitsui Chemicals, Inc.
A 6.4.1/02	Green O.P., Heywood R., Street A.E., Gopinath C., Almond R.H.	1983b	Assessment of the toxicity of MTI-500 to mice by dietary administration for 13 weeks Re-issued amended pages on December 18, 1985 Huntingdon Research Centre Ltd., Report No. MTC 55/821112 Landis Kane Consulting, Document No. 500-5-15 GLP, not published	Y	Mitsui Chemicals, Inc.
A 6.4.3.1	Coombs D.W., Hardy C.J., Clark G.C., Street A.E., Gipson W.A., Gopinath C., Reed L.E.	1985	Ethofenprox (MTI-500) 90-day inhalation study in rats Huntingdon Research Centre Ltd., Report No. MTC 81/841257 Landis Kane Consulting, Document No. 500-5-17 GLP, not published	Y	Mitsui Chemicals, Inc.
A 6.5.1/01 and A 6.7/01	Green O.P., Heaps C.J., Heywood R., Street A.E., Go-pinath C., Singh H., Gipson W.A.	1986a	Ethofenprox (MTI-500) Potential tumorigenic and toxic effects in prolonged dietary administration to rats Huntingdon Research Centre Ltd., Report No. MTC 59/85581 Landis Kane Consulting, Document No. 500-5-24 GLP, not published	Y	Mitsui Chemicals, Inc.

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A 6.5.1/02 and A 6.7/02	Green O.P., Heaps C.J., Heywood R., Street A.E., Go-pinath C., Imm S., Gipson W.A.	1986b	Ethofenprox (MTI-500) Potential tumoregenic and toxic effects in prolonged dietary administration to mice Huntingdon Research Centre Ltd., Report No. MTC 59/85582 Landis Kane Consulting, Document No. 500-5-25 GLP, not published	Y	Mitsui Chemicals, Inc.
A 6.5.2	Harling R.J., Burfort P., Street A.E., Heywood R., Majeed S.K., Gopinath C.	1985b	Ethofenprox (MTI-500) Toxicity to dogs by repeated dietary administration for 52 weeks followed by a recovery period of 8 weeks Huntingdon Research Centre Ltd., Report No. MTC 71/85234 Landis Kane Consulting, Document No. 500-5-16 GLP, not published	Y	Mitsui Chemicals, Inc.
A 6.6.1	Edwards C., Forster R.	1985	Reverse mutation in <i>Salmonella typhimurium</i> Life Science Research, Roma Toxicology Centre, Report No. 162001-M-06185 Landis Kane Consulting, Document No. 500-5-19 GLP, not published	Y	Mitsui Chemicals, Inc.
A 6.6.2	Bootman J., Hodson-Walker G., Dance C.A.	1985a	<i>In vitro</i> assessment of the clastogenic activity of MTI-500, ethofenprox, in cultured human peripheral lymphocytes Life Science Research Ltd., Report No. 85/MT0017/430 Landis Kane Consulting, Document No. 500-5-21 Not GLP, not published	Y	Mitsui Chemicals, Inc.
A 6.6.3/01	Seeburg A.H., Forster R.	1985a	Gene mutation in Chinese hamster V79 cells: test substance MTI-500 Life Science Research, Roma Toxicology Centre, report No. 162002-M-06985 Landis Kane Consulting, Document No. 500-5-20 GLP, not published	Y	Mitsui Chemicals, Inc.
A 6.6.3/02	Seeburg A.H., Forster R.	1985b	Unscheduled DNA synthesis in human cells cell line: Hela S3 Life Science Research, Roma Toxicology Centre, Report No. 162003-M-05785 Landis Kane Consulting, Document No. 500-5-23 GLP, not published	Y	Mitsui Chemicals, Inc.
A 6.6.4	Bootman J., Hodson-Walker G., Dance C.A.	1985c	MTI-500, ethofenprox: Assessment of clastogenic action on bone marrow erythrocytes in the micronucleus test Life Science Research, Report No. 85/MT0016/406 Landis Kane Consulting, Document No. 500-5-22 Not GLP, not published	Y	Mitsui Chemicals, Inc.
A 6.6.7/01	Cummins H.A., Gardner J.R.	1985a	MTI-500 α -CO: Acute oral toxicity in the rat Life Science Research Ltd, Report No. 85/MT0018/474 Landis Kane Consulting, Document No. 500-5-38 GLP, not published	Y	Mitsui Chemicals, Inc.

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A 6.6.7/02	Cummins H.A., Gardner J.R.,	1985b	MTI-500 α -CO: Acute percutaneous toxicity in the rat Life Science Research Ltd, Report No. 85/MT0019/473 Landis Kane Consulting, Document No. 500-5-39 GLP, not published	Y	Mitsui Chemicals, Inc.
A 6.6.7/03	Powell L.A.J., Coleman M., Hey-wood R., Gopinath C., Gibson W.A.	1987	MTI-500 α -CO Preliminary toxicity study in rats by dietary administration for 4 weeks Huntingdon Research Centre Ltd., Report No. MTC 140/87194 Landis Kane Consulting, Document No. 500-5-40 GLP, not published	Y	Mitsui Chemicals, Inc.
A 6.6.7/04	Powell L.A.J., Coleman M., Crock D., Gopi-nath C., Gibson W.A., Read R.M., An-derson A.	1988	MTI-500 α -CO Toxicity to rats by dietary administration for 13 weeks Huntingdon Research Centre Ltd., Report No. MTC 141/871458 Landis Kane Consulting, Document No. 500-5-41 GLP, not published	Y	Mitsui Chemicals, Inc.
A 6.6.7/05	Bootman J., May K.	1985a	MTI-500 α -CO: Assessment of its mutagenic potential in amino-acid auxotrophs of <i>Salmonella typhimurium</i> and <i>Escherichia coli</i> to comply with the testing guidelines of the Japanese Ministry of Agriculture, Forestry and Fisheries (1985) Life Science Research, Report No. 85/MT0020/433 Landis Kane Consulting, Document No. 500-5-42 GLP, not published	Y	Mitsui Chemicals, Inc.
A 6.6.7/06	Bootman J., May K.	1985b	MTI-500 α -CO: Assessment of its ability to cause lethal DNA damage in strains of <i>Escherichia coli</i> Life Science Research Limited, report No. 85/MT0022/504 Landis Kane Consulting, Document No. 500-5-44 GLP, not published	Y	Mitsui Chemicals, Inc.
A 6.6.7/07	Bootman J., Hodson-Walker G., Dance C.A.	1985b	<i>In vitro</i> assessment of the clastogenic activity of MTI-500 α -CO in cultured human peripheral lymphocytes Life Science Research Limited, Report No. 85/MT0021/711 Landis Kane Consulting, Document No. 500-5-43 GLP, not published	Y	Mitsui Chemicals, Inc.
A 6.8.1.1 /01	Cozens D.D., Hughes E.W., Clark R., Anderson A.	1985a	Effect of ethofenprox (MTI-500) on fertility and pregnancy of the rat Huntingdon Research Centre Ltd., Report No. MTC 66/84668 Landis Kane Consulting, Document No. 500-5-33 GLP, not published	Y	Mitsui Chemicals, Inc.

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A 6.8.1.1 /02	Cozens D.D., Hughes E.W., Anderson A.	1985b	Effect of ethofenprox (MTI-500) on pregnancy of the rat with rearing to maturation of the F1 generation Huntingdon Research Centre Ltd., Report No. MTC 64/85422 Landis Kane Consulting, Document No. 500-5-34 GLP, not published	Y	Mitsui Chemicals, Inc.
A 6.8.1.1 /03	Cozens D.D., Hughes E.W., Offer J., Anderson A.	1985c	Effect of ethofenprox (MTI-500) on the peri and post natal period of the rat with rearing to maturation of the F1 offspring Huntingdon Research Centre Ltd., Report No. MTC 65/85423 Landis Kane Consulting, Document No. 500-5-35 GLP, not published	Y	Mitsui Chemicals, Inc.
A 6.8.1.2 /01	Bottomley A., Barton S.J., Masters R.E., Offer J., Parker C.A., Anderson A., Dawe I.S.M.	1985	Effect of etofenprox (MTI-500) on pregnancy of the rabbit Re-issued amended pages on December 20, 1985 Huntingdon Research Centre Ltd., Report No. MTC 85(84)/85444 Landis Kane Consulting, Document No. 500-5-36 GLP, not published	Y	Mitsui Chemicals, Inc.
A 6.8.1.2 /02	Fisher B.J.	2000	Rabbit developmental toxicity study with etofenprox Covance Laboratories Inc., Report No. 6648-146 Landis Kane Consulting, Document No. 500-5-37 GLP, not published	Y	Mitsui Chemicals, Inc.
A 6.8.2/01	Cozens D.D., Barton S.J., Offer J.M., Parker C.A., Anderson A.	1985d	Effect of ethofenprox (MTI-500) on multiple generations of the rat Re-issued amended pages on January 07, 1985 Huntingdon Research Centre Ltd., Report No. MTC 67/85706 Landis Kane Consulting, Document No. 500-5-32 GLP, not published	Y	Mitsui Chemicals, Inc.
A 6.9/01	Smith P.B.	2002	Acute oral gavage neurotoxicity study with MTI-500 in rats Covance Laboratories Inc., Report No. 6648-154 Landis Kane Consulting, Document No. 500-5-06 GLP, not published	Y	Mitsui Chemicals, Inc.
A 6.9/02	Smith P.B.	2003a	13-week dietary neurotoxicity study with MTI-500 in rats Covance Laboratories Inc., Report No. 6648-153 Landis Kane Consulting, Document No. 500-5-47 GLP, not published	Y	Mitsui Chemicals, Inc.
A 6.9/03	Myers D.P.	2003	Etofenprox developmental neurotoxicity study in the rat by oral (dietary) administration Huntingdon Life Sciences, Report No. MTU 215/032731 Landis Kane Consulting, Document No. 500-5-48 GLP, not published	Y	Mitsui Chemicals, Inc.

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A 6.9/04	Burton D.A.	2002	Etofenprox – Validation of an analytical method for the determination of Etofenprox in UAR VRF1 (VRF1) Diet Huntingdon Life Sciences Ltd., Report No. MTU/222/1023183 Landis Kane Consulting, Document No. 500-5-05 GLP, not published	Y	Mitsui Chemicals, Inc.
A 6.10	Smith P.B.	2003b	4-week dietary investigative study on thyroid function and hepatic microsomal enzyme induction with MTI-500 in rats Covance Laboratories Inc., Report No. 6648-156 Landis Kane Consulting, Document No. 500-5-83 GLP, not published	Y	Mitsui Chemicals, Inc.
A 6.11/03	Kamiya J., Yoshiwara K., Saito S., Takahashi Y., Oseki K., Shimizu H., Kawa-zura H., Shiga Y., Yoshida M., Haya-kawa M.	1985	General pharmacology of MTI-500 Institute of Biological Sciences, Mitsui Pharmaceuticals Inc., Japanese Pharmacology & Therapeutics, Vol.13 (11), 229-244 (1985) Landis Kane Consulting, Document No. 500-5-46 Not GLP, published	N	Public information
A 6.12.1	Yamazaki Y.	1992	Health report from the Industrial Hygiene Section, Ohmuta Factory Mitsui Toatsu Chemicals, Inc., Report No. not specified Landis Kane Consulting, Document No. 500-5-49 not GLP, not published	Y	Mitsui Chemicals, Inc.
A 7.1.1.1.1 /01	van der Gaauw A.	2001	¹⁴ C-etofenprox: hydrolysis at three different pH values RCC Ltd, Report No. 731158 Landis Kane Consulting, Document No. 500-2-20 GLP, unpublished	Y	Mitsui Chemicals, Inc.
A 7.1.1.1.1 /02	Clayton M.A., McCorquodale G.Y., Paterson K.	2003	Hydrolytic stability of [¹⁴ C]-alpha-CO in buffered aqueous solution Inveresk Research, Report No. 21993 Landis Kane Consulting, Document No. 500-7-09 GLP, unpublished	Y	Mitsui Chemicals, Inc.
A 7.1.1.1.2 /01	van der Gaauw A.	2003	Aqueous photolysis of [¹⁴ C]-etofenprox under laboratory conditions and determination of quantum yield RCC Ltd, Report No. 755526 Landis Kane Consulting, Document No. 500-2-21 GLP, unpublished	Y	Mitsui Chemicals, Inc.

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A 7.1.1.1.2 /02	Clayton M.A., McCorquodale G.Y.	2003	Artificial sunlight photodegradation of [¹⁴ C]-alpha-CO in buffered aqueous solution Inveresk Research, Report No. 21971 Landis Kane Consulting, Document No. 500-7-10 Not GLP, unpublished	Y	Mitsui Chemicals, Inc.
A 7.1.1.2.1	Thus J.L.G., van der Laan-Straathof J.M.Th., Keetelaar-Jansen W.A.J.	1993	Biodegradation of ¹⁴ C-etofenprox in an adapted modified Sturm test Solvay Duphar B.V., Report No. C.DNL.62.002 Landis Kane Consulting, Document No. 500-7-12 GLP, unpublished	Y	Mitsui Chemicals, Inc.
A 7.1.1.2.1 /02	Thus J.L.G., van der Laan-Straathof J.M.Th	1992	Determination of the biodegradability of etofenprox in a closed bottle test Solvay Duphar B.V., Report No. C.DNL.62.001 Landis Kane Consulting, Document No. 500-7-11 GLP, unpublished	Y	Mitsui Chemicals, Inc.
A 7.1.2.2.2 /01	Lewis C.J.	2001	(¹⁴ C)-MTI-500: degradation and retention in water-sediment systems and amendment dated July 22, 2002 Covance Laboratories Ltd., Report No. CLE 719/6-D2142 Landis Kane Consulting, Document No. 500-7-13 GLP, unpublished	Y	Mitsui Chemicals, Inc.
A 7.1.2.2.2 /02	Lewis C.J.	2002	(¹⁴ C)-MTI-500: recovery of radioactivity, isolation and analysis of a degradation product from a water-sediment system Covance Laboratories Ltd., Report No. CLE 719/14-D2149 Landis Kane Consulting, Document No. 500-7-14 GLP, unpublished	Y	Mitsui Chemicals, Inc.
A 7.1.2.2.2 /03	Mirbach M.	2005	Etofenprox: estimation of the degradation in sediment Landis Kane Consulting, Report No. 05-alpha-31 Landis Kane Consulting, Document No. 500-7-44 Not GLP, unpublished	Y	Mitsui Chemicals, Inc.
A 7.1.3	Völkel W.	1999	Adsorption / desorption of MTI-500 (etofenprox) on three soils RCC Ltd, Report no: 663175 Landis Kane Consulting, Document No. 500-7-06 GLP, unpublished	Y	Mitsui Chemicals, Inc.

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A 7.2.2.1	Völkl S.	2001	¹⁴ C-etofenprox: degradation and metabolism in four soils incubated under aerobic conditions - first amendment dated February 26, 2002 - second amendment dated June 03, 2003 RCC Ltd, Report No. 728987 Landis Kane Consulting, Document No. 500-7-01 GLP, unpublished	Y	Mitsui Chemicals, Inc.
A 7.2.2.4	Mamouni A	2002b	Photolysis of ¹⁴ C-MTI-500 on soil surface under laboratory conditions RCC Ltd, Report No. 800616 Landis Kane Consulting, Report No. 500-7-04 GLP, unpublished	Y	Mitsui Chemicals, Inc.
A 7.2.3.2	Warncke U.	1998	Leaching behaviour of etofenprox after application of Trebon 30 EC Urania Agrochem GmbH, Chemical Laboratories, Report No. C96VSI03 Landis Kane Consulting, Document No. 500-7-07 GLP, unpublished	Y	Spiess-Urania Chemicals GmbH
A 7.3.1	Bates M.	2001d	MTI-500: estimation of the photochemical oxidative degradation - Amended final report from January 31, 2001 Covance Laboratories Ltd., Report No. 719/12-D2141 Landis Kane Consulting, Document No. 500-2-27 Not GLP, unpublished	Y	Mitsui Chemicals, Inc.
A 7.4.1.1 /01	Machado M.W.	1995a	Etofenprox technical - acute toxicity to Rainbow trout (<i>Oncorhynchus mykiss</i>) under flow-through conditions Springborn Laboratories Inc., Report No. 94-12-5625 Landis Kane Consulting, Document No. 500-8-05 GLP, unpublished	Y	Mitsui Chemicals, Inc.
A 7.4.1.1 /02	Machado M.W.	1995b	Etofenprox technical - acute toxicity to Bluegill sunfish (<i>Lepomis macrochirus</i>) under flow-through conditions Springborn Laboratories Inc., Report No. 95-1-5653 Landis Kane Consulting, Document No. 500-8-07 GLP, unpublished	Y	Mitsui Chemicals, Inc.
A 7.4.1.1 /03	Bätscher R.	2002a	Acute toxicity of α -CO to Rainbow trout (<i>Oncorhynchus mykiss</i>) in a 96-hour flow-through test RCC Ltd., Report No. 841573 Landis Kane Consulting, Document No. 500-8-09 GLP, unpublished	Y	Mitsui Chemicals, Inc.

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A 7.4.1.2 /01	Gries T.	2003	Etofenprox technical: static renewal acute toxicity test with Daphnids (<i>Daphnia magna</i>) Springborn Smithers Laboratories (Europe) AG, Report No. 1045.000.110 Landis Kane Consulting, Document No. 500-8-51 GLP, unpublished	Y	Mitsui Chemicals, Inc.
A 7.4.1.2 /02	Bätscher R.	2002b	Acute toxicity of α -CO to <i>Daphnia magna</i> in a 48-hour immobilization test RCC Ltd, Report No. 841575 Landis Kane Consulting, Document No. 500-8-10 GLP, unpublished	Y	Mitsui Chemicals, Inc.
A 7.4.1.3 /01	Gries T., Purghart V.	2003	Etofenprox technical: static toxicity test with the freshwater algae <i>Pseudokirchneriella subcapitata</i> Springborn Smithers Laboratories (Europe) AG, Report No. 1045.000.430 Landis Kane Consulting, Document No. 500-8-52 GLP, unpublished	Y	Mitsui Chemicals, Inc.
A 7.4.1.3 /02	Bätscher R.	2002c	Toxicity of α -CO to <i>Pseudokirchneriella subcapitata</i> (formerly <i>Selenastrum capricornutum</i>) in a 96-hour algal growth inhibition test RCC Ltd, Report No. 841577 Landis Kane Consulting, Document No. 500-8-11 GLP, unpublished	Y	Mitsui Chemicals, Inc.
A 7.4.1.4	Czech P.	2002	Toxicity of etofenprox to activated sludge in a respiration inhibition test RCC Ltd, Report No. 841615 Landis Kane Consulting, Document No. 500-8-50 GLP, unpublished	Y	Spiess-Urania Chemicals GmbH
A 7.4.3.1	Wilhelmy H.	1997	Etofenprox technical: fish (rainbow trout), prolonged toxicity test, 21 days (semi-static) Dr. U. Noack-Laboratorium, Report No. 970304SP Landis Kane Consulting, Document No. 500-8-13 GLP, unpublished	Y	Spiess-Urania & Mitsui Chemicals, Inc.
A 7.4.3.2	Peither A.	2005	Toxic effects of MTI-500 (Etofenprox) to zebra fish (<i>Brachydanio rerio</i>) in an early-life stage toxicity test ; RCC Ltd., Report no. 853517 Landis Kane Consulting, Document No. 500-8-66 GLP, unpublished	Y	Mitsui Chemicals, Inc.

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A 7.4.3.3.1	van Dijk A.	2002	Bioconcentration: flow-through fish test with MTI-500 (Trebon) in Bluegill sunfish RCC Ltd, Report No. 762254 Landis Kane Consulting, Document No. 500-8-15 GLP, unpublished	Y	Mitsui Chemicals, Inc.
A 7.4.3.4	Groenefeld A.H.C., Berends A.G., van der Laan J.M.Th., van Dijk N.R.M.	1993	The chronic toxicity of ¹⁴ C-etofenprox to <i>Daphnia magna</i> Solvay Duphar B.V., Report No. C.DNL.51.007 Landis Kane Consulting, Document No. 500-8-18 GLP, unpublished	Y	Mitsui Chemicals, Inc.
A 7.4.3.5.1 /01	Memmert U.	2002a	Effect of MTI-500 on larvae of <i>Chironomus riparius</i> in a 10-day toxicity test RCC Ltd, Report No. 803777 Landis Kane Consulting, Document No. 500-8-21 GLP, unpublished	Y	Mitsui Chemicals, Inc.
A 7.4.3.5.1 /02	Memmert U.	2002b	Acute toxicity of 4'-OH to first - instar larvae of the midge <i>Chironomus riparius</i> RCC Ltd, Report No. 841579 Landis Kane Consulting, Document No. 500-8-12 GLP, unpublished	Y	Mitsui Chemicals, Inc.
A 7.4.3.5.1 /03	Memmert U.	2002c	Effect of MTI-500 on the development of sediment-dwelling larvae of <i>Chironomus riparius</i> in a water-sediment system RCC Ltd, Report No. 803608 Landis Kane Consulting, Document No. 500-8-22 GLP, unpublished	Y	Mitsui Chemicals, Inc.
A 7.5.1.1	Kölzer U.	2003	Assessment of the side effects of etofenprox on the activity of the soil microflora Arbeitsgemeinschaft GAB Biotechnologie GmbH & IFU Umweltanalytik GmbH, Report No. 20031050/01-ABMF Landis Kane Consulting, Document No. 500-8-53 GLP, unpublished	Y	Mitsui Chemicals, Inc.
A 7.5.1.2	Roberts N.L., Hakin B.	1989	The subacute toxicity (LC50) of etofenprox (MTI-500) to the earthworm (<i>Eisenia foetida</i>) Huntingdon Research Centre Ltd., Report No. MTF 2/881276 Landis Kane Consulting, Document No. 500-8-25 GLP, unpublished	Y	Mitsui Chemicals, Inc.

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A 7.5.1.3	Büche, C.	2004	Terrestrial (non-target) plant test with MTI-500 30%EC: seedling emergence and seedling growth & vegetative vigour test. RCC Ltd., Report No. 853515 Landis Kane Consulting, Document No. 500-8-64 GLP, unpublished	Y	Mitsui Chemicals, Inc.
A 7.5.3.1.1	Roberts N.L., Hakin B., Anderson A.	1985	The acute toxicity (LD50) of MTI-500 (ethofenprox) to the Mallard duck Huntingdon Research Centre plc, Report No. MTC 77C/84793 Landis Kane Consulting, Document No. 500-8-01 GLP, unpublished	Y	Mitsui Chemicals, Inc.
A 7.5.3.1.2/01	Roberts N.L., Hakin B.	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 Huntingdon Research Centre plc, Report No. MTC 77A/84795/2 Landis Kane Consulting, Document No. 500-8-02 GLP, unpublished	Y	Mitsui Chemicals, Inc.
A 7.5.3.1.2/02	Roberts N.L., Hakin B.	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 Huntingdon Research Centre plc, Report No. MTC 77B/84795/2 Landis Kane Consulting, Document No. 500-8-03 GLP, unpublished	Y	Mitsui Chemicals, Inc.
A 7.5.3.1.3	Rodgers M.H.	1996	MTI-500 Effects on reproduction in Bobwhite quail after dietary administration Huntingdon Life Sciences Ltd., Report No. MTC 270/962282 Landis Kane Consulting, Document No. 500-8-04 GLP, unpublished	Y	Mitsui Chemicals, Inc.
A 7.5.6	Tanaka T.	2005	Insecticidal activity of the environmental metabolites of etofenprox. Mitsui Chemicals, Inc. Landis Kane Consulting, Document No. 500-8-67 Not GLP, unpublished	Y	Mitsui Chemicals, Inc.

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B 3.1 → B 3.7/01	Warncke, U.	2004	Determination of the storage stability at 54°C of the test item SPU-01990-I-0-SL; Spiess-Urania Chemicals GmbH, Versuchsstation Christinenthal, Germany; Report No. U04PCI02 Landis Kane Consulting, Document No. 500-2-65 GLP, not published	Y	Spiess-Urania Chemicals GmbH
B 3.5 → B 3.7/01	Warncke, U.	2004	Determination of the storage stability at 54°C of the test item SPU-01990-I-0-SL; Spiess-Urania Chemicals GmbH, Versuchsstation Christinenthal, Germany; Report No. U04PCI02 Landis Kane Consulting, Document No. 500-2-65 GLP, not published	Y	Spiess-Urania Chemicals GmbH
B 3.6	Woolley A.J., Mullee D.M.	2003	MK-333: Determination of general physico-chemical properties; Safepharm Laboratories Limited, Shardlow DE74 2GD, England; SPL Project No. 1832/012 Landis Kane Consulting, Document No. 500-2-64 GLP, not published	Y	Lonza Ltd, Spiess-Urania Chemicals GmbH
B 3.7/01	Warncke, U.	2004	Determination of the storage stability at 54°C of the test item SPU-01990-I-0-SL; Spiess-Urania Chemicals GmbH, Versuchsstation Christinenthal, Germany; Report No. U04PCI02 Landis Kane Consulting, Document No. 500-2-65 GLP, not published	Y	Spiess-Urania Chemicals GmbH
B 3.8 → B 3.7/01	Warncke, U.	2004	Determination of the storage stability at 54°C of the test item SPU-01990-I-0-SL; Spiess-Urania Chemicals GmbH, Versuchsstation Christinenthal, Germany; Report No. U04PCI02 Landis Kane Consulting, Document No. 500-2-65 GLP, not published	Y	Spiess-Urania Chemicals GmbH
B 3.10 → B 3.6	Woolley A.J., Mullee D.M.	2003	MK-333: Determination of general physico-chemical properties; Safepharm Laboratories Limited, Shardlow DE74 2GD, England; SPL Project No. 1832/012 Landis Kane Consulting, Document No. 500-2-64 GLP, not published	Y	Lonza Ltd, Spiess-Urania Chemicals GmbH
B 3.11 → B 3.6	Woolley A.J., Mullee D.M.	2003	MK-333: Determination of general physico-chemical properties; Safepharm Laboratories Limited, Shardlow DE74 2GD, England; SPL Project No. 1832/012 Landis Kane Consulting, Document No. 500-2-64 GLP, not published	Y	Lonza Ltd, Spiess-Urania Chemicals GmbH

Section No / Reference No	Author (s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/N	Owner
B 4.1	Lüdke S.	2004	Validated method of analysis for the determination of etofenprox in SPU-01990-I-0-SL; Spiess-Urania Chemicals GmbH, Versuchsstation Christinenthal, 25593 Christinenthal, Germany; Report No. Wa-16-02-04-1990 Landis Kane Consulting, Document No. 500-4-44 Not GLP, not published	Y	Spiess-Urania Chemicals GmbH
B 5.10.2/01	Schumacher P., Fennert E.-M.	2004	Determination of the preventive action against recently hatched larvae of <i>Hylotrupes bajulus</i> (L.) (04/90) – test material VP 3257 A. Material Testing Institute Brandenburg, Department 3, Wood and wood protection, Eberswalde, Germany; Report No. 3.2/03/8517/01 Landis Kane Consulting, Document No. 500-6-66 Not GLP, not published	Y	Lonza Ltd, Spiess-Urania Chemicals GmbH
B 5.10.2/02	Fennert E.-M., Doblinski M.	2004	Determination of the preventive action against recently hatched larvae of <i>Hylotrupes bajulus</i> (L.) according to EN 46 (04/90) after leaching procedure according to EN 84 (05/97) – test material VP 3257 A. Material Testing Institute Brandenburg, Department 3, Wood and wood protection, Eberswalde, Germany; Report No. 3.2/03/8517/02 Landis Kane Consulting, Document No. 500-6-125 Not GLP, not published	Y	Lonza Ltd, Spiess-Urania Chemicals GmbH
B 5.10.2/03	Fennert, E.-M., Wessely, S.	2005a	Determination of the protective effectiveness against wood destroying basidiomycetes according to EN 113 (11/96) after leaching procedure according to EN 84 (05/97) – test material VP 3257 A. Material Testing institute Brandenburg, Department 3, Wood and wood protection, Eberswalde, Germany; Report no 32/04/8596/03 Landis Kane Consulting, Document No. 500-6-127 Not GLP, not published	Y	Lonza Ltd, Spiess-Urania Chemicals GmbH

Section No / Reference No	Author (s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/N	Owner
B 5.10.2/04	Fennert, E.-M., Doblinski, M.	2005a	Determination of the toxic values against recently hatched larvae of <i>Hylotrupes bajulus</i> (L.) according to EN 47(08/90) after leaching procedure according to EN 84 (05/97) - test material VP 3257 A. Material Testing Institute Brandenburg, Department 3, Wood and wood protection, Eberswalde, Germany; Report no. 32/04/8596/02 Landis Kane Consulting, Document No. 500-6-150 Not GLP, not published	Y	Lonza Ltd, Spiess-Urania Chemicals GmbH
B 5.10.2/05	Fennert, E.-M., Doblinski, M.	2005b	Determination of the toxic values against <i>Reticulitermes santonensis</i> De Feytaud according to EN 117 (08/90) after leaching procedure according to EN 84 (05/97) - test material VP 3257 A. Material Testing Institute Brandenburg, Department 3, Wood and wood protection, Eberswalde, Germany; Report no. 32/04/8596/01 Landis Kane Consulting, Document No. 500-6-146 Not GLP, not published	Y	Lonza Ltd, Spiess-Urania Chemicals GmbH
B 5.10.2/06	Fennert, E.-M., Doblinski, M.	2005c	Determination of the toxic values against recently hatched larvae of <i>Hylotrupes bajulus</i> (L.) according to EN 47(08/90) after evaporative ageing procedure according to EN 73 (04/90) - test material VP 3257 A. Material Testing Institute Brandenburg, Department 3, Wood and wood protection, Eberswalde, Germany; Report no. 32/04/8596/05 Landis Kane Consulting, Document No. 500-6-147 Not GLP, not published	Y	Lonza Ltd, Spiess-Urania Chemicals GmbH
B 5.10.2/07	Fennert, E.-M., Doblinski, M.	2005d	Determination of the toxic values against <i>Reticulitermes santonensis</i> De Feytaud according to EN 117 (08/90) after evaporative ageing procedure according to EN 73 (04/90) - test material VP 3257 A. Material Testing Institute Brandenburg, Department 3, Wood and wood protection, Eberswalde, Germany; Report no. 32/04/8596/04 Landis Kane Consulting, Document No. 500-6-149 Not GLP, not published	Y	Lonza Ltd, Spiess-Urania Chemicals GmbH

Section No / Reference No	Author (s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/N	Owner
B 5.10.2/08	Fennert, E.-M., Wessely, S.	2005b	Determination of the protective effectiveness against wood destroying basidiomycetes according to EN 113 (11/96) after evaporative ageing procedure according to EN 73 (04/90) – test material VP 3257 A. <i>Material Testing institute Brandenburg, Department 3, Wood and wood protection, Eberswalde, Germany; Report no 32/04/8596/06</i> Landis Kane Consulting, Document No. 500-6-148. Not GLP, not published	Y	Lonza Ltd, Spiess-Urania Chemicals GmbH
B 6.1.1	Sanders A.	2004a	MK-333: Acute oral toxicity in the rat – acute toxic class method. Safepharm Laboratories Ltd; Report No. 1832/013 Landis Kane Consulting, Document No.500-5-91 GLP, not published	Y	Lonza Ltd, Spiess-Urania Chemicals GmbH
B 6.1.2	Sanders A.	2004b	MK-333: Acute dermal toxicity (limit test) in the rat. Safepharm Laboratories Ltd; Report No. 1832/014 Landis Kane Consulting, Document No.500-5-92 GLP, not published	Y	Lonza Ltd., Spiess-Urania Chemicals GmbH
B 6.2.1	Sanders	2004c	MK-333: acute dermal irritation in the rabbit; Safepharm Laboratories Ltd, Shardlow, England; unpublished report no. 1832/019 (April 19, 2004)	Y	Lonza Ltd; Spiess-Urania Chemicals GmbH
B 6.2.2	Sanders	2004d	MK-333: acute eye irritation in the rabbit Safepharm Laboratories Ltd, Shardlow, England; unpublished report no. 1832/020 (April 19, 2004)	Y	Lonza Ltd; Spiess-Urania Chemicals GmbH
B 6.6	Mirbach M.	2004	Etofenprox: estimation of the human exposure to etofenprox used in the wood preservative product SPU-01990-I. Landis Kane Consulting, Report No. 04-alpha-02 Landis Kane Consulting, Document No.500-5-93 not GLP, not published	Y	Mistui Chemicals . Inc.
B 6.6/02	Anonymous	2006a	Exposure of workers during wood treatment Landis Kane Consulting, not GLP, not published	Y	Mitsui Chemicals , Inc.

Section No / Reference No	Author (s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/N	Owner
B 7.1/01	Kratz T., Rathey S.	2004a	Estimation of the predicted environmental concentrations of etofenprox used in the wood preservative product SPU-01990-I. Landis Kane Consulting, Report No. 04-alpha-04 Landis Kane Consulting, Document No.500-7-33 Not GLP, not published	Y	Mitsui Chemicals, Inc.
B 7.1/02	Wegner R., Sauer C.	2004a	Lignusal EP 20, vacuum impregnation – Estimation of emission from preservative treated wood to the environment: laboratory method for wood held in storage after treatment and for wooden commodities that are not covered and are not in contact with ground. Material Testing Institute Brandenburg, Report No. 31/04/7446/02. Landis Kane Consulting, Document No.500-7-41 Not GLP, not published	Y	Spiess-Urania Chemicals GmbH
B 7.1/03	Wegner R., Sauer C.	2004b	Lignusal EP 20, brushing – Estimation of emission from preservative treated wood to the environment: laboratory method for wood held in storage after treatment and for wooden commodities that are not covered and are not in contact with ground. Material Testing Institute Brandenburg, Report No. 31/04/7446/01. Landis Kane Consulting, Document No.500-7-42 Not GLP, not published	Y	Spiess-Urania Chemicals GmbH
B 7.1/04	Kratz T., Rathey S.	2004b	Estimation of the predicted environmental concentrations of etofenprox used in the wood preservative product SPU-01990-I. Landis Kane Consulting, Report No. 04-alpha-04/02 Landis Kane Consulting, Document No.500-7-43 Not GLP, not published	Y	Mitsui Chemicals, Inc.
B 7.1/05	Rathey S.	2005a	Use of etofenprox in a wood preservative product: estimation of the environmental concentrations in ground water. Landis Kane Consulting, Report No. 05-alpha-32 Landis Kane Consulting, Report No. 500-7-45 Not GLP, unpublished	Y	Mitsui Chemicals, Inc.

Section No / Reference No	Author (s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/N	Owner
B 7.1/06	Rathey S.	2005b	Estimation of the predicted environmental concentrations of etofenprox used in the wood preservative product SPU-01990-I. Landis Kane Consulting, Report No. 04-alpha-04/03 Landis Kane Consulting, Document No.500-7-46 Not GLP, not published	Y	Mitsui Chemicals, Inc.
B 7.1/07	Anonymous	2006b	Environmental exposure for the stage of manufacture of the wood preservative product SPU-01990-I. Landis Kane Consulting, not GLP, not published	Y	Mitsui Chemicals, Inc.
B 7.3/04 → B 2.2/07	Anonymous	2003d	Review report for the active substance propiconazole. European Commission, document SANCO/3049/99-Final Landis Kane Consulting, Document No. 500-3-09 Not GLP, published	N	Public information

Appendix IV: List of standard terms and abbreviations and List of abbreviations of organisation and publications

Standard terms and abbreviations

Stand. term / Abbreviation	Explanation
4'-OH	4'-hydroxyetofenprox
α -CO	2-(4-ethoxyphenyl)-2-methylpropyl 3-phenoxybenzoate (metabolite)
ACh	acetylcholine
AChE	acetylcholinesterase
ADI	acceptable daily intake
ADME	administration distribution metabolism and excretion
ADP	adenosine diphosphate
ai	active ingredient
ALT	alanine aminotransferase (SGPT)
AOEL	acceptable operator exposure level
ANOVA	analysis of variance
approx	approximate
ARfD	acute reference dose
as	active substance
AST	aspartate aminotransferase (SGOT)
ASV	air saturation value
ATP	adenosine triphosphate
BAF	bioaccumulation factor
BCF	bioconcentration factor
BOD	biological oxygen demand
BPD	Biocidal Products Directive
BUN	blood urea nitrogen
bw	body weight
c	centi- (x 10 ⁻²)
°C	degrees Celsius (centigrade)
EDI	estimated daily intake
EINECS	European inventory of existing commercial substances

Stand. term / Abbreviation	Explanation
ca.	circa
CEC	cation exchange capacity
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CL	confidence limits
cm	centimetre
COD	chemical oxygen demand
CPK	creatinine phosphatase
cv	coefficient of variation
Cv	ceiling value
d	day(s)
DES	diethylstilboestrol
DIS	draft international standard (<i>ISO</i>)
DMSO	dimethylsulfoxide
DNA	deoxyribonucleic acid
DO	dissolved oxygen
DOC	dissolved organic carbon
dpi	days post inoculation
DT _{50(lab)}	period required for 50 percent dissipation (under laboratory conditions)
DT _{90(lab)}	period required for 90 percent dissipation (under laboratory conditions)
dw	dry weight
DWQG	drinking water quality guidelines
ϵ	decadic molar extinction coefficient
EC ₅₀	median effective concentration
GSH	glutathione
GV	granulosevirus

Stand. term / Abbreviation	Explanation
ELINCS	European list of notified chemical substances
e-mail	electronic mail
EMDI	estimated maximum daily intake
EN	European norm
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
FELS	fish early-life stage
FID	flame ionisation detector
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
g	gram(s)
GAP	good agricultural practice
GC	gas chromatography
GC-MS	gas chromatography-mass spectrometry
I ₅₀	inhibitory dose, 50%
IC ₅₀	median immobilisation concentration or median inhibitory concentration 1
ID	ionisation detector
im	intramuscular
inh	inhalation
ip	intraperitoneal

Stand. term / Abbreviation	Explanation
h	hour(s)
H	Henry's Law constant (calculated as a unitless value)
ha	hectare(s)
Hb	haemoglobin
HCG	human chorionic gonadotropin
Hct	haematocrit
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography - mass spectrometry
HPPLC	high pressure planar liquid chromatography
HPTLC	high performance thin layer chromatography
HRGC	high resolution gas chromatography
H _s	Shannon-Weaver index
Ht	haematocrit
GEP	good experimental practice
GGT	gamma glutamyl transferase
GI	gastro-intestinal
GIT	gastro-intestinal tract
GLC	gas liquid chromatography
GLP	good laboratory practice
LC	liquid chromatography
LC-MS	liquid chromatography- mass spectrometry
LC ₅₀	lethal concentration, median
LC-MS-MS	liquid chromatography with

Stand. term / Abbreviation	Explanation	Stand. term / Abbreviation	Explanation
			tandem mass spectrometry
IR	infrared	LD ₅₀	lethal dose, median; dosis letalis media
ISBN	international standard book number	ln	natural logarithm
ISSN	international standard serial number	LOAEC	lowest observable adverse effect concentration
IUCLID	International Uniform Chemical Information Database	LOAEL	lowest observable adverse effect level
iv	intravenous	LOD	limit of detection
k (<i>in combination</i>)	kilo	LOEC	lowest observable effect concentration
k	rate constant for degradation	LOEL	lowest observable effect level
K	Kelvin	log	logarithm to the base 10
K _a	acid dissociation constant	LOQ	limit of quantification (determination)
K _b	base dissociation constant	LPLC	low pressure liquid chromatography
K _{ads}	adsorption constant	LSC	liquid scintillation counting or counter
K _{des}	apparent desorption coefficient	LSD	least squared denominator multiple range test
kg	kilogram	LSS	liquid scintillation spectrometry
K _{oc}	organic carbon adsorption coefficient	m	metre
K _{om}	organic matter adsorption coefficient	m ²	square metre
K _{ow}	octanol-water partition coefficient	m ³	cubic metre
K _p	solid-water partition coefficient	M	molar
kPa	kilopascal(s)	µm	micrometre (micron)
l, L	litre		
MAC	maximum allowable concentration	NOAEC	no observed adverse effect concentration
MAK	maximum allowable concentration	NOAEL	no observed adverse effect level
MC	moisture content	NOEC	no observed effect concentration
MCH	mean corpuscular haemoglobin	NOED	no observed effect dose
MCHC	mean corpuscular haemoglobin concentration	NOEL	no observed effect level
MCV	mean corpuscular volume	NR	not reported
MDL	method detection limit	NTE	neurotoxic target esterase
MFO	mixed function oxidase	OC	organic carbon content
µg	microgram	OH	hydroxide

Stand. term / Abbreviation	Explanation
mg	milligram
MHC	moisture holding capacity
min	minute(s)
mL	millilitre
mm	millimetre
MMAD	mass median aerodynamic diameter
MOE	margin of exposure
mol	mole(s)
MOS	margin of safety
MRE	maximum residue expected
MRL	maximum residue level or limit
mRNA	messenger ribonucleic acid
MS	mass spectrometry
MSDS	material safety data sheet
MW	molecular weight
n.a.	not applicable
n	number of observations
NAEL	no adverse effect level
nd	not detected
NMR	nuclear magnetic resonance
no, n°	number
RA	risk assessment
RBC	red blood cell
RfD	reference dose
RH	relative humidity
RL ₅₀	median residual lifetime
RNA	ribonucleic acid
RP	reversed phase
rRNA	ribosomal ribonucleic acid
RSD	relative standard deviation

Stand. term / Abbreviation	Explanation
OM	organic matter content
Pa	pascal
2-PAM	2-pralidoxime
PCV	haematocrit (packed corpuscular volume)
PEC	predicted environmental concentration
PED	plasma-emissions-detector
pH	pH-value
pKa	negative logarithm (to the base 10) of the acid dissociation constant
PNEC	predicted no effect concentration (compartment to be added as subscript)
ppb	parts per billion (10 ⁻⁹)
PPE	personal protective equipment
ppm	parts per million (10 ⁻⁶)
PPP	plant protection product
PrT	prothrombin time
PT	product type
PTT	partial thromboplastin time
QA	quality assurance
QAU	quality assurance unit
(Q)SAR	quantitative structure-activity relationship
r	correlation coefficient
r ²	coefficient of determination
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)
TLC	thin layer chromatography
TMDI	theoretical maximum daily intake
TNsG	technical notes for guidance
TOC	total organic carbon

Stand. term / Abbreviation	Explanation
s	second
SAP	serum alkaline phosphatase
SAR	structure/activity relationship
SD	standard deviation
se	standard error
SF	safety factor
SL	Soluble concentrate
SOP	standard operating procedures
sp	species (only after a generic name)
SPE	solid phase extraction
SPF	specific pathogen free
spp	subspecies
STP	sewage treatment plant
t	tonne(s) (metric ton)
t _{1/2}	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
TG	technical guideline, technical group
TGD	Technical guidance document

Stand. term / Abbreviation	Explanation
tRNA	transfer ribonucleic acid
TSH	thyroid stimulating hormone (thyrotropin)
TTC	2,3,5-triphenylterazoliumchloride testing method
TWA	time weighted average
UDS	unscheduled DNA synthesis
ULV	ultra low volume
UV	ultraviolet
v/v	volume ratio (volume per volume)
vis	visible
WBC	white blood cell
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

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)
CAS	Chemical Abstracts Service
CE	Council of Europe
CEC	Commission of the European Communities
CIPAC	Collaborative International Pesticides Analytical Council Ltd
DG	Directorate General
DIN	German Institute for Standardisation
EC	European Commission
ECB	European Chemicals Bureau
ECCO	European Commission Co-ordination
ECE	Economic Commission for Europe
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EPA	Environmental Protection Agency
EU	European Union
FAO	Food and Agriculture Organization of the UN

Abbreviation	Explanation
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GIFAP	Groupement International des Associations Nationales de
IARC	International Agency for Research on Cancer
IATS	International Academy of Toxicological Science
IMO	International Maritime Organisation
ISO	International Organization for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
OECD	Organization for Economic Co-operation and Development
OPPTS	Office of Prevention, Pesticides and Toxic Substances (US EPA)
RIVM	Netherlands National Institute of Public Health and Environmental Protection
SETAC	Society of Environmental Toxicology and Chemistry
UBA	German Environmental Protection Agency
UN	United Nations
WHO	World Health Organization