# WHO SPECIFICATIONS AND EVALUATIONS FOR PUBLIC HEALTH PESTICIDES

# **ETOFENPROX**

2-(4-ethoxyphenyl)-2-methylpropyl 3-phenoxybenzyl ether



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## Disclaimer<sup>1</sup>

WHO specifications are developed with the basic objective of promoting, as far as practicable, the manufacture, distribution and use of pesticides that meet basic quality requirements.

Compliance with the specifications does not constitute an endorsement or warranty of the fitness of a particular pesticide for a particular purpose, including its suitability for the control of any given pest, or its suitability for use in a particular area. Owing to the complexity of the problems involved, the suitability of pesticides for a particular purpose and the content of the labelling instructions must be decided at the national or provincial level.

Furthermore, pesticides which are manufactured to comply with these specifications are not exempted from any safety regulation or other legal or administrative provision applicable to their manufacture, sale, transportation, storage, handling, preparation and/or use.

WHO disclaims any and all liability for any injury, death, loss, damage or other prejudice of any kind that may be arise as a result of, or in connection with, the manufacture, sale, transportation, storage, handling, preparation and/or use of pesticides which are found, or are claimed, to have been manufactured to comply with these specifications.

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<sup>&</sup>lt;sup>1</sup> This disclaimer applies to all specifications published by WHO.

#### INTRODUCTION

WHO establishes and publishes specifications\* for technical material and related formulations of public health pesticides with the objective that these specifications may be used to provide an international point of reference against which products can be judged either for regulatory purposes or in commercial dealings.

From 2002, the development of WHO specifications has followed the **New Procedure**, described in the 1st edition of Manual for Development and Use of FAO and WHO Specifications for Pesticides (2002) and amended with the supplement of this manual (2006), which is available only on the internet through the FAO and WHO web sites. This **New Procedure** follows a formal and transparent evaluation process. It describes the minimum data package, the procedure and evaluation applied by WHO and the experts of the "FAO/WHO Joint Meeting on Pesticide Specifications" (JMPS).

WHO Specifications now only apply to products for which the technical materials have been evaluated. Consequently, from the year 2002 onwards the publication of WHO specifications under the **New Procedure** has changed. Every specification consists now of two parts, namely the specifications and the evaluation report(s):

Part One: The <u>Specification</u> of the technical material and the related formulations of the pesticide in accordance with chapters 4 to 9 of the 1<sup>st</sup> edition of the "FAO/WHO Manual on Pesticide Specifications."

Part Two: The Evaluation Report(s) of the pesticide, reflecting the evaluation of the data package carried out by WHO and the JMPS. The data are provided by the manufacturer(s) according to the requirements of chapter 3 of the "FAO/WHO Manual on Pesticide Specifications" and supported by other information sources. The Evaluation Report includes the name(s) of the manufacturer(s) whose technical material has been evaluated. Evaluation reports on specifications developed subsequently to the original set of specifications are added in a chronological order to this report.

WHO specifications under the **New Procedure** do <u>not</u> necessarily apply to nominally similar products of other manufacturer(s), nor to those where the active ingredient is produced by other routes of manufacture. WHO has the possibility to extend the scope of the specifications to similar products but only when the JMPS has been satisfied that the additional products are equivalent to that which formed the basis of the reference specification.

Specifications bear the date (month and year) of publication of the current version. Dates of publication of the earlier versions, if any, are identified in a footnote. Evaluations bear the date (year) of the meeting at which the recommendations were made by the JMPS.

\* Footnote: The publications are available on the Internet under (http://www.who.int/whopes/quality/en/).

# **PART ONE**

# **SPECIFICATIONS**

# **ETOFENPROX**

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## **ETOFENPROX**

## **INFORMATION**

ISO common name

Etofenprox (ISO 1750 approved)

Synonyms

MTI-500, Trebon

Chemical names

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

CA: 1-[[2-(4-ethoxyphenyl)-2-methylpropoxy]methyl]-3-phenoxybenzene

Structural formula

$$CH_3CH_2O$$
 $CH_2$ 
 $CH_3$ 
 $CH_3$ 
 $CH_3$ 

Empirical formula

 $C_{25}H_{28}O_3$ 

Relative molecular mass

376.5

CAS Registry number

80844-07-1

CIPAC number

471

Identity tests

GC relative retention time; IR spectrum.

#### WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

### **ETOFENPROX TECHNICAL MATERIAL**

WHO specification 471/TC (July 2007\*)

This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturer whose name is listed in the evaluation reports (471/2006). It should be applicable to TC produced by this manufacturer but it is not an endorsement of those products, nor a guarantee that they comply with the specifications. The specification may not be appropriate for TC produced by other manufacturers. The evaluation report (471/2006), as PART TWO, forms an integral part of this publication.

# 1 **Description**

The material shall consist of etofenprox, together with related manufacturing impurities, and shall be a white crystalline solid or yellowish liquid or paste (Note 1), free from visible extraneous matter and added modifying agents.

# 2 Active Ingredient

2.1 Identity tests (471/TC/M/2, CIPAC Handbook K, p. 58, 2003)

The active ingredient shall comply with an identity test and, where the identity remains in doubt with at least one additional test.

2.2 Etofenprox content (471/TC/M/3, CIPAC Handbook K, p. 58, 2003)

The etofenprox content shall be declared (not less than 980 g/kg) and, when determined, the average measured content shall not be lower than the declared minimum content.

## 3 Relevant impurities

3.1 Water (MT 30.5, CIPAC Handbook J, p.120, 2000)

Maximum: 5.0 g/kg.

3.2 Insolubles in acetone (MT 27, CIPAC Handbook F, p.88, 1995)

Maximum: 1.0 g/kg.

## 4 Physical properties

4.1 **pH range** (MT 75.3, CIPAC Handbook J, p.131, 2000)

pH range: 5.5-7.0.

Note 1 Depending on the storage conditions, etofenprox can exist as white crystalline solid (melting point 37.4°C), a yellowish liquid or a yellowish viscous paste.

<sup>\*</sup> Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at: http://www.who.int/guality/en/.

#### WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

### **ETOFENPROX WETTABLE POWDER**

WHO specification 471/WP (July 2007\*)

This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturer whose name is listed in the evaluation reports (471/2006). It should be applicable to relevant products of this manufacturer, and those of any other formulators who use only TC from the evaluated source. The specification is not an endorsement of those products, nor a guarantee that they comply with the specification. The specification may not be appropriate for the products of other manufacturers who use TC from other sources. The evaluation report (471/2006), as PART TWO, forms an integral part of this publication.

# 1 Description

The material shall consist of a homogeneous mixture of technical etofenprox, complying with WHO specification 471/TC (July 2007), together with filler(s) and any other necessary formulants. It shall be in the form of a fine powder free from visible extraneous matter and hard lumps.

## 2 Active ingredient

2.1 Identity tests (471/WP/M/2, CIPAC Handbook K, p 60, 2003)

The active ingredient shall comply with an identity test and, where the identity is in doubt, shall comply with one additional test,

2.2 **Etofenprox content** (471/WP/M/3, CIPAC Handbook K, p.60, 2003)

The etofenprox content shall be declared (200 g/kg) and, when determined, the average content measured shall not differ from that declared by more than  $\pm$  6%.

# 3 Relevant impurities

3.1 Water (MT 30.5, CIPAC Handbook J, p.120, 2000)

Maximum: 40 g/kg.

## 4 Physical Properties

4.1 **pH range** (MT 75.3, CIPAC Handbook J, p.131, 2000)

pH range: 5.5 to 9.0.

4.2 Wet sieve test (MT 185, CIPAC Handbook K, p.149, 2003)

Maximum: 1% retained on a 75 μm test sieve.

<sup>\*</sup> Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at: <a href="http://www.who.int/whopes/quality/en/">http://www.who.int/whopes/quality/en/</a>.

4.3 **Suspensibility** (MT 15.1,CIPAC Handbook F, p.45, 1995) (Notes 1 & 2)

A minimum of 70% of the etofenprox content found under 2.2 shall be in suspension after 30 min in CIPAC standard water D at 30  $\pm$  2°C (Note 3).

4.4 Persistent foam (MT 47.2, CIPAC Handbook F, p.152, 1995) (Note 4)

Maximum: 10 ml after 1 min.

4.5 **Wettability** (MT 53.3, CIPAC Handbook F, p.165, 1995)

The formulation shall be completely wetted in 1 min without swirling.

## 5 Storage stability

5.1 **Stability at elevated temperature** (MT 46.3, CIPAC Handbook J, p.128, 2000)

After storage at  $54 \pm 2^{\circ}$ C for 14 days, the determined active ingredient content must not be lower 95%, relative to the determined average content found before storage (Note 5), and the formulation shall continue to comply with the clauses for:

- pH range (4.1);
- wet sieve test (4.2),
- suspensibility (4.3);
- wettability (4.5).
- Note 1 The formulation should be tested at the highest and lowest rates of use recommended by the supplier, provided this does not exceed the conditions given in method MT 15.1.
- Note 2 This test will normally only be carried out after the heat stability test, 5.1.
- Note 3 Chemical assay is the only fully reliable method to measure the mass of active ingredient still in suspension. However, the simpler gravimetric method, MT 168, may be used on a routine basis provided that it has been shown to give equal results to those of chemical assay. In case of dispute, chemical assay shall be the "referee method".
- Note 4 The mass of sample to be used in the test should be at the highest rate of use recommended by the supplier. The test is to be conducted in CIPAC standard water D.
- Note 5 Samples of the formulation taken before and after the storage stability test should be analyzed concurrently after the test in order to reduce the analytical error.

#### WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

## ETOFENPROX EMULSION, OIL IN WATER

WHO specification 471/EW (July 2007\*)

This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturer whose name is listed in the evaluation reports (471/2006). It should be applicable to relevant products of this manufacturer, and those of any other formulators who use only TC from the evaluated source. The specification is not an endorsement of those products, nor a guarantee that they comply with the specification. The specification may not be appropriate for the products of other manufacturers who use TC from other sources. The evaluation report (471/2006), as PART TWO, forms an integral part of this publication.

# 1 Description

The formulation shall consist of an emulsion of technical etofenprox. complying with the requirements of WHO specification 471/TC (July 2007), in an aqueous phase together with suitable formulants. After gentle agitation, the formulation shall be homogeneous (Note 1) and suitable for dilution in water.

## 2 Active ingredient

2.1 **Identity tests** (471/EW/M/2, CIPAC Handbook K, p.62, 2003)

The active ingredient shall comply with an identity test and, where the identity remains in doubt, shall comply with at least one additional test.

2.2 **Etofenprox content** (471/EW/M/3, CIPAC Handbook K, p 62, 2003)

The etofenprox content shall be declared (100 g/kg) and, when determined, the average content measured shall not differ from that declared by more than ± 10%.

## 3 Physical properties

3.1 **pH range** (MT 75.3, CIPAC Handbook J, p.131, 2000)

pH range: 6.0 to 8.0.

3.2 **Pourability** (MT 148.1, CIPAC Handbook F, p.348, 1995)

Maximum "residue": 2%.

Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at: http://www.who.int/whopes/quality/en/.

3.3 **Emulsion stability and re-emulsification** (MT 36.3, CIPAC Handbook J, p.137, 2000)

The formulation, when diluted at  $30 \pm 2^{\circ}$ C (Note 2) with CIPAC standard waters A and D, shall comply with the following:

Time after dilution	Limits of stability
0 h	Initial emulsification complete
0.5 h	Cream: none visible Oil: none visible Sediment: none visible
2 h	Cream: none visible Oil: none visible Sediment: none visible
24 h	Re-emulsification complete
24.5 h	Cream: none visible Oil: none visible Sediment: none visible
Note: in applying MT 36.3, tests after 24 h are required only where results at 2 h are in doubt	

3.4 **Persistent foam** (MT 47.2, CIPAC Handbook F, p.152, 1995) (Note 3)

Maximum: 10 ml after 1 min.

## 4 Storage stability

4.1 Stability at 0°C (MT 39.3, CIPAC Handbook J, p.126, 2000)

After storage at  $0 \pm 2^{\circ}$ C for 7 days, no separation of particulate or oily matter shall be visible after gentle agitation.

4.2 **Stability at elevated temperature** (MT 46.3, CIPAC Handbook J, p.128, 2000)

After storage  $54 \pm 2^{\circ}$ C for 14 days, the determined average active ingredient content must not be lower than 95%, relative to the determined average content found before storage (Note 4), and the formulation shall continue to comply with the clauses for:

- pH range (3.1);
- emulsion stability and re-emulsification (3.3).
- Note 1 All physical and chemical tests listed in this specification are to be performed with a laboratory sample taken after the recommended homogenisation procedure. Before sampling to verify the formulation quality, the commercial container must be inspected carefully. On standing, emulsions may develop a concentration gradient which could even result in the appearance of a clear liquid on the top (sedimentation of the emulsion) or on the bottom (creaming up of the emulsion). Therefore, before sampling, the formulation must be homogenised according to the instructions given by the manufacturer or, in the absence of such instructions, by gentle shaking of the commercial container (for example, by inverting the closed container several times). Large containers must be opened and stirred adequately.
- Note 2 The formulation should be tested at the highest and lowest rates of use recommended by the supplier.

- $\frac{\text{Note 3}}{\text{by the supplier.}} \text{ The mass of sample to be used in the test should be at the highest rate of use recommended by the supplier. The test is to be conducted in CIPAC standard water D.}$
- Note 4 Samples of the formulation taken before and after the storage stability test should be analyzed concurrently after the test in order to reduce the analytical error.

# **PART TWO**

# **EVALUATION REPORTS**

# **ETOFENPROX**

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#### WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

### **ETOFENPROX**

## FAO/WHO EVALUATION REPORT 471/2006

#### Recommendations

The Meeting recommended the following.

- (i) The existing WHO specifications for etofenprox TC, EW and WP should be withdrawn.
- (ii) The specifications proposed by Mitsui Chemicals for etofenprox TC, WP and EW, as amended, should be adopted by WHO.
- (iii) The specifications proposed by Mitsui Chemicals for etofenprox TC and EC, as amended, should be adopted by FAO.

## **Appraisal**

The Meeting considered data and proposed specifications for etofenprox, submitted by Mitsui Chemicals in support of a revision of existing WHO specifications for TC (full specification WHO/SIT/34, 1999), WP (full specification WHO/SIF/63, 1999) and EW (interim specification WHO/IS/00.2, 1999) and in support of new FAO specifications for TC and EC.

Etofenprox was evaluated by the FAO/WHO JMPR and WHO/IPCS in 1993 (FAO 1993), 1999 (WHO 1999d) and 2003 (Hougart 2003). The use of etofenprox-containing formulations (20% WP, 10% EW) in public health was evaluated by WHOPES in 1999 (WHO, 1997 and 1999).

Etofenprox is a non-ester pyrethroid, so called because it acts on the chloride channel of insect nervous systems, as pyrethrins and pyrethroids do, though the molecule lacks the otherwise common structural moiety of these classes of insecticides: the ester bond between the acid and alcoholic moiety (Chamberlain *et al.* 1998). Unlike the pyrethrins and most pyrethroids, etofenprox does not contain centres of molecular asymmetry and therefore does not show stereoisomerism. It is an insecticide with contact and stomach action, with applications in agriculture, public health and animal health.

Confidential information on the manufacturing process and limits for all impurities occurring at or above 1 g/kg in the TC were provided to the Meeting. The manufacturing specification for minimum etofenprox content of the TC was 980 g/kg. Limits for impurities were supported by 5 batch analysis data. Though the original 5 batch data showed results of two out of five batches with etofenprox content slightly lower than 980 g/kg, more recent data supported a minimum purity of 980 g/kg. Mass balances were 98.1-100.6% and percentages of unidentified material were 0.08-0.14%. The information on the manufacturing process and impurities present in the TC was identical to that submitted in support of registration of etofenprox in Switzerland.

The TCs of 956-967 g/kg purity, tested in the majority of toxicological and ecotoxicological studies (Annex 1, Tables A-D), did not conform to the current

manufacturing specification (≥980 g/kg). In other hazard studies, TCs of 989-997 g/kg purity conformed to the ≥980 g/kg limit. Hence the various hazard data refer to one of two broad groups of impurity concentration: above or below the ≥980 g/kg limit. The manufacturer explained that the earlier hazard data reflect TC produced in the earliest phases of production and, over a period of 20 years, the manufacturing specification was gradually increased to the current minimum purity of 980 g/kg. The manufacturer provided information on the materials used in the tests and the Meeting agreed that the hazard data were acceptable.

The Meeting strongly supported the need to encourage manufacturers to produce technical grade active ingredients of the highest purity practicable and therefore accepted the proposed minimum of 980 g/kg for the FAO and WHO specifications. Nonetheless, it was acknowledged that this could create problems in future determinations of equivalence of etofenprox TCs, because, if another manufacturer's TC has a minimum active ingredient content lower than that of the FAO/WHO specification, non-equivalence by this criterion would normally indicate a requirement for data on acute toxicity. The Meeting recognized that such additional toxicology data may be necessary but concluded that decisions should be made on a case-bycase basis, to avoid unnecessary additional testing on animals. For example, equivalence with respect to particular hazards may be more or less predictable if the second manufacturer's TC specification is within the purity/impurity envelope of the material actually used to produce the reference data for those hazards.

The Meeting agreed that none of the impurities should be designated as relevant.

Etofenprox is a non-polar compound, of low vapour pressure. The compound is not ionized between pH 1 and 14 and its low water solubility is essentially unaffected by pH. Hydrolysis does not occur to a significant extent between pH 4 and 9. Due to the extended  $\pi$ -aromatic system in the molecule, there is some UV absorption above 290 nm (500-2-08) and hence direct photolysis contributes significantly to etofenprox degradation in water and on soil surfaces. Typical half live in water is 3 hours and in soil 6 days (Tsao & Eto 1990).

Two CIPAC methods for determination of etofenprox exist: an older one based on packed-column gas chromatography and a newer one based on capillary GC. The latter includes methods for the TC and formulations (WP, EC, EW).

Test methods for determination of physical-chemical properties of the technical active ingredient were OECD or EC, while those for the formulations were CIPAC, as indicated in the specifications.

The Meeting considered the proposed specifications, which were broadly in accordance with the requirements of the manual (FAO/WHO 2002) and thus certain clauses in the existing specifications, e.g. melting point and flash point, had been omitted and did not require further consideration.

## Issues common to 2 or more proposed specifications

Clauses for water content and pH were proposed for all specifications, although etofenprox has a very low affinity for water and is not prone to hydrolysis.

The Meeting accepted the need for a clause to limit water in the TC, because it is involved in the last step of synthesis and because the TC is used to prepare EC formulations. The manufacturer initially proposed a 1 g water/kg limit (in accordance with the existing specification) for the TC but then revised this to 5 g/kg. The

Meeting agreed to the higher limit on the basis that it had proven acceptable in practice. The Meeting accepted that water should be limited in the WP, to minimize to potential for clumping of the powder particles during storage of the formulation. The proposed limit of 40 g/kg was accepted, although this was higher than in the existing specification (30 g/kg), because it had proven acceptable in practice. In the absence of an existing specification for EC, the limit of 5 g/kg proposed for water was considered to be appropriate for this formulation.

The manufacturer proposed that pH should be controlled in etofenprox formulations to ensure the integrity of the formulations and their containers, which had been tested only in the specified pH ranges. The manufacturer accepted a proposal to specify a pH range of 5.5 to 7.0.for etofenprox TC, to ensure that acids and bases used in the production process have been carefully removed. The Meeting accepted that the proposed clauses for pH range provide a rapid and sensitive means for checking that concentrations of strong acids/bases are acceptably low. The proposed limits were similar to those in the existing specifications and were accepted.

The existing and proposed WHO specifications for WP and EW included three ranges for active ingredient content and the Meeting agreed that the active ingredient contents should be restricted to those tested by WHOPES (200 g/kg  $\pm$  6% for WP, 100 g/kg  $\pm$  10% for EW).

Existing limits for persistent foam in WP and EW specifications (there was no existing EC specification) were for 10 ml, maximum. The manufacturer proposed limits of 6, 3 and 2 ml. respectively. However, the Meeting considered that the lower values were more accurate than can be achieved reliably with method MT 47.2 and it was agreed with the manufacturer that 10 ml limits should be retained or instated.

#### Issues relating to TC only

The proposed minimum active ingredient content of the TC (980 g/kg) was slightly lower than that of the existing specification (985 g/kg) but the Meeting regarded the two values as analytically indistinguishable and therefore accepted the proposed value.

A clause to limit acetone insolubles in the TC was proposed and accepted, because the material is used to prepare EC formulations.

## Issues relating to WP only

The Meeting welcomed that the proposed limit of 1% for the wet sieve test, which was effectively more stringent than that of the existing specification.

The Meeting also welcomed the proposed limit of 70% for suspensibility, instead of the 60% limit in the existing specification.

The existing specification limit of 2 minutes for wettability was considered to be undesirably long by the Meeting and the manufacturer agreed to reduce the limit to 1 minute.

## Issues relating to EW only

The Meeting noted that the limits for emulsion stability in the existing specification required only testing at 2 hours, whereas the proposed specification (using method MT 36.3) included assessments at 0.5, 24 and 24.5 hours. The Meeting accepted the proposed stringent limits. Although not required for the specification, the

manufacturer stated that no cream or free oil, and only a maximum of 1 ml sediment, are expected to be visible before re-emulsification at 24 hours.

## Issues relating to EC only

The Meeting expressed concern that the limits initially proposed for emulsion stability permitted a maximum of 1 ml free oil at 2 and 24.5 hours. The manufacturer agreed that the formulation should produce no free oil when assessed at these times, although some creaming could not be avoided. The Meeting agreed with the manufacturer that it was not necessary to incorporate limits for foam in the test of emulsion stability, as persistent foam is specified separately.

The manufacturer stated that EC formulations may be used in both agriculture and public health applications. The Meeting agreed that the specification should be restricted agricultural products (i.e. FAO) because these formulations have not yet been assessed by WHOPES.

# SUPPORTING INFORMATION FOR EVALUATION REPORT 471/2006

#### Uses

Etofenprox is an insecticide, which disturbs insect nervous systems following direct contact or ingestion, and which is active against a broad spectrum of pests. It is used in agriculture, horticulture, viticulture, forestry, animal health and public health against many insect pests, for instance Lepidoptera, Hemiptera, Coleoptera, Diptera, Thysanoptera and Hymenoptera.

In agriculture, etofenprox is used on a broad range of crops such as rice, fruits, vegetables, corn, soybeans and tea. It is poorly absorbed by roots and little translocation occurs within plants.

In the public health sector, etofenprox is used for vector control either by direct application in infested areas or indirectly by impregnating fabrics, such as mosquito nets.

## Identity

ISO common name

etofenprox (ISO 1750 approved)

Chemical names

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

CA: 1-[[2-(4-ethoxyphenyl)-2-methylpropoxy]methyl]-3-phenoxybenzene

Synonyms:

MTI-500, Trebon

Structural formula

$$CH_3CH_2O \longrightarrow CH_2 \longrightarrow CH_3$$

Molecular formula:

 $C_{25}H_{28}O_3$ 

Relative molecular mass:

376.5 g/mol

CAS Registry number:

80844-07-1

CIPAC number:

471

Identity tests

GC relative retention time; IR spectrum.

## Physical and chemical properties

Table 1. Physico-chemical properties of pure etofenprox

Parameter	Value(s) and conditions	Purity %	Method	Reference
Vapour pressure	8.13 x 10 <sup>-7</sup> Pa at 25°C (extrapolated)	>99%	OECD 104, gas saturation	500-2-04
Melting point	37.4°C	>99%	OECD 102	500-2-01
Decomposition temperature	200°C	>99%	OECD 103	500-2-02
Solubility in water at 20°C	5.2 x 10 <sup>-6</sup> g/l at pH 4 22.5 x 10 <sup>-6</sup> g/l at pH 7 12.0 x 10 <sup>-6</sup> g/l at pH 9	>98%	OECD 105	500-2-11
Octanol/water partition coefficient	Log P <sub>OW</sub> = 6.9 at 25°C	>99%	EEC A8, OECD 117, HPLC	500-2-16
Hydrolysis characteristics	Hydrolytically stable at pH 4, 7, and 9	>98.9%	OECD 111	500-2-20
Photolysis Latitude 30° N, summer, $DT_{50} = 7.8 \text{ d}$ Latitude 40° N, summer, $DT_{50} = 8.4 \text{ d}$ Latitude 50° N, summer, $DT_{50} = 9.5 \text{ d}$ in pure water at pH 7 Quantum yield in pure water: 0.25 Quantum yield in pond water: 0.15		100%	OECD/GD (97) 21	500-2-21
Dissociation characteristics	Does not dissociate	-	Expert statement	500-2-26
Relative density	1.172 g/cm <sup>3</sup> at 20.7°C	>99%	OECD 109	500-2-03
UV/visible spectrum	Similar at pH 1 to 12; absorption maximum 273 nm.	>99%	OECD 101	500-2-08
Flammability	Not flammable	97.1%	EEC A.10	500-2-29
Auto-flammability	No self-ignition up to melting point	97.1%	EEC A16	500-2-30
Flash point	>110°C	99.3%	EEC A.9	500-2-31
Explosivity	Not explosive	99.3%	EEC A.14	500-2-32

Table 2. Chemical composition ar	nd properties of technical etofenprox (TC)
Manufacturing process, maximum limits for impurities ≥ 1 g/kg, 5 batch analysis data	Confidential information supplied and held on file by FAO and WHO. Mass balances were 98.1–100.6% and percentages of unknowns were 0.08–0.14%.
Declared minimum etofenprox content	980 g/kg
Relevant impurities ≥1 g/kg and maximum limits for them	Water, 5.0 g/kg Insolubles in acetone, 1.0 g/kg
Relevant impurities <1 g/kg and maximum limits for them	None
Stabilizers or other additives and maximum limits for them	None
Melting or boiling temperature range	Not stated

# **Hazard summary**

Etofenprox was evaluated for residues and toxicology by the FAO/WHO JMPR (JMPR 1993a, JMPR 1993b). MRLs were recommended for pome fruits and potatoes. An ADI of 0-0.03 mg/kg bw/day was allocated by the JMPR, based on a

long term study in mice and 100-fold safety factor. This estimate is in good agreement with the toxicological evaluation of the Swiss Office of Public Health (SOPH 2004).

The WHO hazard classification of etofenprox is "U: unlikely to present acute hazard in normal use" (WHO 2002).

The use of etofenprox-containing formulations (10 % EC, 10 % EW) in public health was evaluated by WHOPES (WHO 1997, 1999).

#### **Formulations**

The main formulation types of etofenprox available are:

- EC 100, 200 or 300 g/kg, used in agriculture and public health (note not yet evaluated by WHOPES for public health);
- WP 200 g/kg, used in public health and agriculture;
- EW 100 g/kg, used in public health and agriculture;
- DP 5 g/kg, used in agriculture;
- GR 10 or 15 g/kg, used in agriculture.

These formulations are registered for use and sold in many countries.

## Methods of analysis and testing

The analytical methods for determination of etofenprox (including identity tests) in TC, WP, EC and EW are full CIPAC methods, utilizing capillary GC with FID and internal standardization with dibutyl phthalate.

Two CIPAC methods exist for the determination of etofenprox (including identity tests): an older one based on packed-column gas chromatography (CIPAC G, pp. 56 and a newer one based on capillary GC (CIPAC K). The latter includes methods for the TC and formulations (WP, EC, EW) and has been accepted as full CIPAC method in 2002.

Test methods for determination of physical-chemical properties of the technical active ingredient were OECD or EC, while those for the formulations (Mitsui Chemicals 2005, Mitsui Chemicals 2006) were CIPAC or WHO, as indicated in the specifications.

## Physical properties

The physical properties, the methods for testing them and the limits proposed for the EC formulations, comply with the requirements of the Manual (FAO/WHO, 2002).

## **Containers and packaging**

No special requirements for containers and packaging have been identified.

## **Expression of the active ingredient**

The active ingredient is expressed as etofenprox.

## **ANNEX 1**

## HAZARD SUMMARY PROVIDED BY THE PROPOSER

Note: Mitsui Chemicals provided written confirmation that the toxicological and ecotoxicological data included in the following summary were derived from etofenprox having impurity profiles similar to those referred to in Table 2, above.

Table A. Toxicology profile of etofenprox technical material, based on acute toxicity, irritation and sensitization

Species, strain, sex	Test	Duration, conditions/guideline and purity	Result	Reference
Rat, Sprague- Dawley, (m,f)	Acute oral	Single dose, 14 d observation, OECD 420 (1992), purity 99.0%	LD <sub>50</sub> >2000 mg/kg	500-5-70
Rat, Sprague- Dawley, (m,f)	Acute dermal	Single dose, 14 d observation, OECD 402 (1987), purity 99.0%	LD <sub>50</sub> >2000 mg/kg	500-5-71
Rat, Sprague- Dawley, (m,f)	Acute inhalation	4-h dose, 14 d observation, 92/60/EEC B.3, purity 96%	LC <sub>50</sub> >5.88 mg/l	500-5-10
Dog, beagle, (m,f)	Acute oral	Single dose, 14 d observation, no guideline, purity 96.3%	LD <sub>50</sub> >5.0 g/kg	500-5-07
Rabbit, Japanese White (m)	Skin irritation	6 animals, 72 h, 92/69/EEC B.4, purity 96.3%	Non-irritant	500-5-11
Rabbit, Japanese White (m)	Eye irritation	6 animals, 72 h, 92/69/EEC B.5, purity 96.3%	Non-irritant	500-5-12
Guinea pig, Hartley (m)	Skin sensitization, intradermal and topical	92/69/EEC B.6 (some deviations), purity 96.3%	Non-sensitizer	500-5-13

Table B. Toxicology profile of etofenprox technical material based on repeated administration (sub-acute to chronic)

Species, sex	Test	Duration, guideline, purity	Result	Reference
Rat (m,f)	dietary toxicity		NOAEL = 20, 23 mg/kg bw/d (m,f) LOEL = 120, 142 mg/kg bw/d (m,f)	500-5-14
Mouse (m,f)	dietary toxicity		NOAEL = 375, 390 mg/kg bw/d (m,f) LOEL = 1975, 2192 mg/kg bw/d (m,f)	500-5-15
Rat (m,f)	inhalation toxicity		NOAEL = 42 mg/m <sup>3</sup> (m,f) LOEL = 210 mg/m <sup>3</sup> (m,f)	500-5-17
Rabbit (m,f)	dermal toxicity		NOAEL >1000 mg/kg bw/d (m,f) LOEL = no adverse effects	500-5-18
Dog (m,f)	dietary toxicity		NOAEL = 33.4, 32.2 mg/kg bw/d (m,f) LOEL = 352, 339 mg/kg bw/d (m,f) Reversible minimal liver dysfunction, ↑ liver weight, minimal swelling of hepatocytes.	500-5-16
Rat (m,f)	dietary toxicity and carcinogenicity	110 weeks, 88/302/EEC, purity 96.3%	Carcinogenicity: NOAEL = 187, 249 mg/kg bw/d (m,f) (highest dose tested) All effects: NOAEL = 3.7, 4.8 mg/kg bw/d (m,f) LOEL = 25.5, 34.3 mg/kg bw/d (m,f)  ↓ weight gain, ↓ food consumption, ↑ liver, kidney, thyroid weights, hepatocyte enlargement, ↑ clotting time (m), ↑ thyroid cystic follicles (f)	500-5-24

Table B. Toxicology profile of etofenprox technical material based on repeated administration (sub-acute to chronic)

Species,	Test	Duration, guideline,	Result	Reference
sex	1031	purity	result	recicion
Mouse (m,f)	dietary toxicity and carcinogenicity	108 weeks, equivalent to 88/302/EEC B.26, purity 96.3%	Carcinogenicity: NOAEL = 547, 619 mg/kg bw/d (m,f) (highest dose tested) All effects: NOAEL = 3.1, 3.6 mg/kg bw/d (m,f) LOEL = 10.4, 11.7 mg/kg bw/d (m,f) Histopathological alterations in kidneys. At 4900ppm (highest dose tested): ↑ male mortality, ↓ weight gain, minor haematological effects, ↑ liver weight	500-5-25
Rat (m,f)	dietary investigative study	4 weeks mechanistic study, no guideline available, purity 99%	NOAEL = 81.2, 90.2 mg/kg bw/d (m,f) LOEL = 316, 380 mg/kg bw/d (m,f) 1° target organ: liver; 2° target organ: thyroid; $\uparrow$ microsomal protein (m); $\uparrow$ hepatic UDPGT (m,f); $\uparrow$ serum TSH (m,f); $\downarrow$ serum T4 (m) $\uparrow$ thyroid proliferation (m); $\uparrow$ liver weight (m,f); liver hypertrophy (m,f)	500-5-83
Rat (m,f)	oral, fertility	females treated 2 weeks prior to and up	All effects: NOAEL = 5000 mg/kg bw/d LOEL >5000 mg/kg bw/d Reproduction effects: NOAEL = 5000 mg/kg bw/d LOEL >5000 mg/kg bw/d	500-5-33
Rat (f)	oral, developmental toxicity	Treatment days 6-17 of gestation, equivalent to 88/302/EEC, Part B, purity 96.3%	All effects:  NOAEL = 250 mg/kg bw/d  LOEL = 5000 mg/kg bw/d  Reproduction effects:  NOAEL = 5000 mg/kg bw/d  LOEL >5000 mg/kg bw/d  Not teratogenic	500-5-34
Rat (m,f)	oral, peri-/post- natal study	Treatment day 17 gestation to day 21 post partum, no guideline available, purity 96.3%	All effects:  NOAEL = 250 mg/kg bw/d  LOEL = 5000 mg/kg bw/d  Reproduction effects:  NOAEL = 5000 mg/kg bw/d  LOEL >5000 mg/kg bw/d	500-5-35
Rat (m,f)	dietary, multi- generation study	$F_0$ : 25 weeks; $F_1$ : 28 weeks; $F_2$ : 13 weeks. No guideline available, purity 96.3%	All effects:  NOAEL = 37 mg/kg bw/d  LOEL = 246 mg/kg bw/d  Reproduction effects:  NOAEL = 37 mg/kg bw/d  LOEL = 246 mg/kg bw/d  Developmental effects:  NOAEL = 4.3 mg/kg bw/d  LOEL = 30 mg/kg bw/d	500-5-32

Table B. Toxicology profile of etofenprox technical material based on repeated administration (sub-acute to chronic)

Species, sex	Test	Duration, guideline, purity	Result	Reference
		(1999), purity 96.68%	All effects:  NOAEL = 100 mg/kg bw/d  LOEL = 300 mg/kg bw/d  Reproduction effects:  NOAEL = 100 mg/kg bw/d  LOEL = 300 mg/kg bw/d  Developmental effects:  NOAEL = 100 mg/kg bw/d  LOEL = 300 mg/kg bw/d  Not teratogenic	500-5-37

Table C. Mutagenicity profile of etofenprox technical material based on *in vitro* and *in vivo* tests

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Test system	Study type	Concentration range or doses tested, guideline, purity	Result	Reference	
S. typhimurium (5 strains)	In vitro gene mutation assay	0, 0 (solvent), 200-3200 μg/plate (±S9 in both assays), OECD 471 (1981), purity 96.3%	Negative, ±S9 activation	500-5-19	
Human lymphocytes	In vitro cytogenetics test; 24-h exposure	, , , , , , , , , , , , , , , , , , ,	Negative, ±S9 activation	500-5-21	
Chinese hamster V79 HGPRT <sup>+/-</sup> cells	In vitro gene mutation assay	0 (solvent), 9.75-156 μg/ml (±S9 in both assays), 79/831/EEC, Annex V, Part B, purity 96.3%	Negative, ±S9 activation	500-5-20	
HeLa S3 cells	In vitro UDS assay	0 (solvent), 9.75-156 μg/ml (-S9); 0 (solvent), 2.44-39.0 μg/ml (+S9), 79/831/EEC, Annex V, Part B, purity 96.3%	Negative, ±S9 activation	500-5-23	
Mouse	In vivo micronucleus test; 24, 48, 72-h sacrifices	24-hr: 0, 80, 400, 2000 mg/kg; 48-hr: 0, 2000 mg/kg; 72-hr: 0, 2000 mg/kg, equivalent to 92/69/EEC B.11, purity 96.3%	Negative	500-5-22	

Table D. Ecotoxicology profile of etofenprox technical material

Species	, 5	Duration, purity conditions	Result	Reference
	,		LC <sub>50</sub> = 2.7 μg/l * NOEC = 0.66 μg/l	500-8-05
			LC <sub>50</sub> = 13.0 μg/l NOEC = 6.90 μg/l	500-8-07

 $<sup>^*</sup>$  Other studies on rainbow trout, in water-sediment systems treated with etofenprox EC (as Trebon 30EC), produced LC  $_{50}$  values of >69  $\mu g/l$  and 32  $\mu g/l$  when applied as a surface spray or directly diluted into the water, respectively.

Table D. Ecotoxicology profile of etofenprox technical material

Species	Test, guideline	Duration, purity conditions	Result	Reference
Rainbow trout (Oncorhynchus mykiss)	chronic toxicity to juvenile fish, OECD 204	21 d, semi static, purity >99%	NOEC = 3.2 μg/l	500-8-13
Bluegill sunfish ( <i>Lepomis</i> <i>macrochirus</i> )	bioaccumulation, OECD 305	62 d application, 62 d depuration, purity 99.7%	BCF = 3951 Depuration occurs in 9-16 d	500-8-15
Water flea (Daphnia magna)	Chronic reproduction toxicity, OECD 202 & 211	21 d, semi static, purity 96.5%	NOEC = 0.05 μg/l	500-8-18
Chironimus riparius larvae	short-term toxicity, OECD 219, draft	10 d, static water; 25 d static water + sediment system, purity 99.7%	EC <sub>50</sub> >20.9 μg/l NOEL = 3.8 μg/l **	500-8-21; 500-8-22
Green alga (Pseudokirchneriella subcapitata)	acute toxicity, OECD 201	72 h, static, purity 98.86%	EC <sub>50</sub> >150 μg/l NOEC = 150 μg/l	500-8-52
Diverse community of aquatic species	outdoor mesocosm study	16 weeks, purity 99.16%	NOEC = 2 μg/l (for the community) ***	500-8-49
Earthworm ( <i>Eisenia</i> foetida)	sub-acute toxicity, OECD 207	2 weeks, 20-21°C, artificial soil, purity 96.3%	LC <sub>50</sub> >47.2 mg/kg dry soil	500-8-25
Soil microflora	Effects on activity, OECD 216 and 217	20°C, 28 d, purity 99%	no effect	500-8-53
Honey bee (Apis mellifera)	acute toxicity, EPPO 170	24 h, oral, contact dorsal, contact tarsal, purity 96%	$LD_{50}$ = 0.27 µg/bee $LD_{50}$ = 0.13 µg/bee $LD_{50}$ = 5.56 µg/bee	500-8-63
Mallard duck (Anas platyrhynchos)	acute oral toxicity, US EPA E 71-1	single application, gavage, purity 96.3%	LD <sub>50</sub> >2000 mg/kg bw	500-8-01
Bobwhite quail (Colinus virginianus)	short-term dietary toxicity, US EPA E 71-2	5 d, repeated dose, feeding, purity 96.3%	LD <sub>50</sub> >5000 mg/kg bw	500-8-02
Mallard duck (Anas platyrhynchos)	short-term dietary toxicity, US EPA E 71-2	5 d, repeated dose, feeding, purity 96.3%	LC <sub>50</sub> >5000 mg/kg bw	500-8-03
Bobwhite quail ( <i>Colinus virginianus</i> )	Reproduction toxicity, US EPA E 71-4 and OECD 206	22 weeks, dietary exposure, purity 96.3%	NOEL = 1000 mg/kg bw	500-8-04

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<sup>\*\*</sup> The chronic toxicity of etofenprox to larvae of *Chironomus riparius* was also assessed in a static study over an exposure period of 25 days and the NOEC, based on development rate, was similarly found to be 3.8 μg/l.

<sup>\*\*\*</sup> Etofenprox had a short half-life in the water, with all concentrations below the limit of detection by day 7. Based on these data, it was considered that an initial Ecologically Acceptable Concentration (EACi) for etofenprox would be 2.0 μg/l.

# Annex 2. References

	THINGA II THORSE CONTROL
Mitsui Chemicals document number or other reference	Year and title of report or publication details
500-2-01	1999. Determination of the melting point / melting range of etofenprox.
500-2-02	1998. Determination of the holling point / holling range of etofenprox.
500-2-03	2000. Determination of the relative density of etofenprox.
500-2-03	2000. Determination of the vapour pressure of etofenprox.
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	1999. Determination of the NMR-, IR-, UV/VIS absorption and mass spectra of etofenprox and amendment.
500-2-11	2000. Determination of the water solubility of <sup>14</sup> C-etofenprox at three pH values and amendment.
500-2-16	1998. Determination of the partition coefficient (N-octanol / water) of etofenprox and amendment.
500-2-20	2001. <sup>14</sup> C-etofenprox: hydrolysis at three different pH values.
500-2-21	2003. Aqueous photolysis of [ <sup>14</sup> C]-etofenprox under laboratory conditions and determination of quantum yield.
500-2-26	1998. Expert statement on the dissociation of MTI-500 (etofenprox) in water.
500-2-29	1991. Determination of the flammability of etofenprox in accordance with EEC-Guideline A.10.
500-2-30	1991. Determination of the auto-flammability of etofenprox in accordance with EEC-Guideline A.16.
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500-2-32	2001. MTI-500: evaluation of the explosive properties - Amended final report.
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500-5-10	1983. MTI-500 Acute inhalation toxicity in rats 4 hour exposure.
500-5-11	1985. MTI-500 Primary skin stimulation test in rabbits - Amendment No. 1.
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500-5-13	1985. MTI-500 Skin sensitization test in guinea pigs - Correction to translation.
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500-5-15	1983. Assessment of the toxicity of MTI-500 to mice by dietary administration for 13 weeks, Re-issued amended pages.
500-5-16	1985. Ethofenprox (MTI-500) toxicity to dogs by repeated dietary administration for 52 weeks followed by a recovery period of 8 weeks.
500-5-17	1985. Ethofenprox (MTI-500) 90-day inhalation study in rats.
500-5-18	2000. A 28-day repeated dose dermal toxicity study in rabbits with technical MTI-500.
500-5-19	1985. Reverse mutation in Salmonella typhimurium.
500-5-20	1985. Gene mutation in chinese hamster V79 cells: test substance MTI-500.
500-5-21	1985. <i>In vitro</i> assessment of the clastogenic activity of MTI-500, ethofenprox, in cultured human peripheral lymphocytes.
500-5-22	1985. MTI-500, ethofenprox: Assessment of clastogenic action on bone marrow erythrocytes in the micronucleus test.
500-5-23	1985. Unscheduled DNA synthesis in human cells cell line: Hela S3.
500-5-24	1986. Ethofenprox (MTI-500) Potential tumorigenic and toxic effects in prolonged dietary administration to rats.
500-5-25	1986. Ethofenprox (MTI-500) Potential tumoregenic and toxic effects in prolonged dietary administration to mice.
500-5-32	1985. Effect of ethofenprox (MTI-500) on multiple generations of the rat, Reissued amended pages.
500-5-33	1985. Effect of ethofenprox (MTI-500) on fertility and pregnancy of the rat.

Mitsui Chemicals document number or other reference	Year and title of report or publication details
500-5-34	1985. Effect of ethofenprox (MTI-500) on pregnancy of the rat with rearing to maturation of the F1 generation.
500-5-35	1985. Effect of ethofenprox (MTI-500) on the peri and post natal period of the rat with rearing to maturation of the F1 offspring.
500-5-36	1985. Effect of etofenprox (MTI-500) on pregnancy of the rabbit, Re-issued amended pages.
500-5-37	2000. Rabbit developmental toxicity study with etofenprox.
500-5-70	2003. Acute oral toxicity study of etofenprox in rats.
500-5-71	2003. Acute dermal toxicity study of etofenprox in rats.
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500-8-04	1996. MTI-500 Effects on reproduction in Bobwhite quail after dietary administration.
500-8-05	1995. Etofenprox technical - acute toxicity to Rainbow trout ( <i>Oncorhynchus mykiss</i> ) under flow-through conditions.
500-8-07	1995. Etofenprox technical - acute toxicity to Bluegill sunfish ( <i>Lepomis macrochirus</i> ) under flow-through conditions.
500-8-13	1997. Etofenprox technical: fish (rainbow trout), prolonged toxicity test, 21 days (semi-static).
500-8-15	2002. Bioconcentration: flow-through fish test with MTI-500 (Trebon) in Bluegill sunfish.
500-8-18	1993. The chronic toxicity of <sup>14</sup> C-etofenprox to <i>Daphnia magna</i> .
500-8-21	2002. Effect of MTI-500 on larvae of <i>Chironomus riparius</i> in a 10-day toxicity test.
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500-8-25	1989. The subacute toxicity (LC50) of ethofenprox (MTI-500) to the earthworm ( <i>Eisenia foetida</i> ).
500-8-49	2004. Assessment of the effects of etofenprox (MTI-500) an natural communities of freshwater organisms in outdoor mesocosms.
500-8-51	2003. Etofenprox technical: static renewal acute toxicity test with Daphnids ( <i>Daphnia magna</i> ).
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500-8-63	1986. Report of investigation relative to the question of toxicity of Trebon to the honeybee <i>Apis mellifera</i> .
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