

**FAO SPECIFICATIONS AND EVALUATIONS
FOR AGRICULTURAL PESTICIDES**

PROPOXUR

2-isopropoxyphenyl methylcarbamate



FOOD AND AGRICULTURE ORGANIZATION *of* THE UNITED NATIONS

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DISCLAIMER¹

FAO 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.

FAO disclaims any and all liability for any injury, death, loss, damage or other prejudice of any kind that may 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.

Additionally, FAO wishes to alert users to the fact that improper storage, handling, preparation and/or use of pesticides can result in either a lowering or complete loss of safety and/or efficacy.

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¹ This disclaimer applies to all specifications published by FAO.

INTRODUCTION

FAO establishes and publishes specifications* for technical material and related formulations of agricultural 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.

Since 1999 the development of FAO specifications follows the **New Procedure**, described in the 5th edition of the “Manual on the development and use of FAO specifications for plant protection products” (FAO Plant Production and Protection Page No. 149). This **New Procedure** follows a formal and transparent evaluation process. It describes the minimum data package, the procedure and evaluation applied by FAO and the Experts of the FAO/WHO Joint Meeting on Pesticide Specifications (JMPS). [Note: prior to 2002, the Experts were of the FAO Panel of Experts on Pesticide Specifications, Registration Requirements, Application Standards and Prior Informed Consent, which now forms part of the JMPS, rather than the JMPS.]

FAO Specifications now only apply to products for which the technical materials have been evaluated. Consequently from the year 2000 onwards the publication of FAO 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 Specification of the technical material and the related formulations of the plant protection product in accordance with chapter 4, 5 and 6 of the 5th edition of the “Manual on the development and use of FAO specifications for plant protection products”.

PART Two: The Evaluation Report(s) of the plant protection product reflecting the evaluation of the data package carried out by FAO and the JMPS. The data are to be provided by the manufacturer(s) according to the requirements of Appendix A, annex 1 or 2 of the “Manual on the development and use of FAO specifications for plant protection products” 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.

FAO specifications under the **New Procedure** do not necessarily apply to nominally similar products of other manufacturer(s), nor to those where the active ingredient is produced by other routes of manufacture. FAO 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.

* NOTE: PUBLICATIONS ARE AVAILABLE ON THE INTERNET AT
(<http://www.fao.org/ag/agp/agpp/pesticid/>)

OR IN HARDCOPY FROM THE PLANT PROTECTION INFORMATION OFFICER.

PART ONE

SPECIFICATIONS

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PROPOXUR

INFORMATION

Common name

Propoxur (E-ISO, F-ISO)

Synonyms

Bay 9010, Baygon, Bayer 39007, Blattanex, Bolfo, BO Q 5812315, OMS 33, PHC (JMAF), Pillargon, UN Carbamate, Tugon, Unden, Undene.

Chemical names

IUPAC: 2-isopropoxyphenyl methylcarbamate

CA: 2-(1-methylethoxy)phenyl methylcarbamate

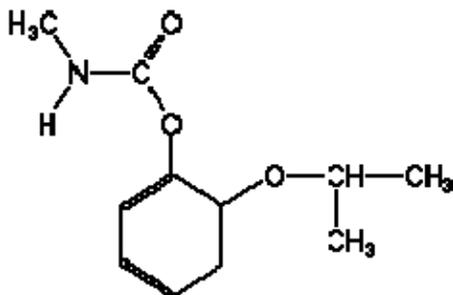
CAS Registry number

114-26-1

CIPAC number

80

Structural formula



Solid propoxur can exist in two crystal forms (modifications I and II) but the technical material usually contains >95% of modification I.

Empirical formula

C₁₁H₁₅NO₃

Relative molecular mass

209.25

Identity tests

HPLC retention time, with detection at 280 nm (CIPAC Handbook D, p. 155, 1988); IR and mass spectra; melting point (87.5-90°C).

PROPOXUR TECHNICAL MATERIAL

FAO specification 80/TC (FEBRUARY 2006*)

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 report 80/2003. It should be applicable to relevant products of this manufacturer but it 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. The evaluation report 80/2003, as PART TWO, forms an integral part of this publication.

1 Description

The material shall consist of propoxur together with related manufacturing impurities, in the form of colourless to pale yellow crystals with a phenolic odour, free from visible extraneous matter and added modifying agents.

2 Active ingredient

2.1 Identity tests (80/TC/M2/2, CIPAC Handbook D, p. 155, 1988)

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 Propoxur content (80/TC/M2/3, CIPAC Handbook D, p. 155, 1988)

The propoxur 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: 2.0 g/kg.

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

Maximum: 1.0 g/kg

4 Physical properties

4.1 Acidity and alkalinity (MT 31, CIPAC Handbook F, p. 96, 1995)

Maximum acidity: 0.5 g/kg calculated as H₂SO₄.

Maximum: 0.1 g/kg calculated as NaOH.

* Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at: <http://www.fao.org/ag/agp/agpp/pesticid/>.

PROPOXUR DUSTABLE POWDER

FAO specification 80/DP (FEBRUARY 2006*)

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 report 80/2003. It should be applicable to relevant products of this manufacturer but it 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. The evaluation report 80/2003, as PART TWO, forms an integral part of this publication.

1 Description

The material shall consist of an homogeneous mixture of technical propoxur, complying with the requirements of FAO specification 80/TC (FEBRUARY 2006), together with any other necessary carriers and any other necessary formulants. It shall be in the form of a fine, free-flowing, beige powder, free from visible extraneous matter and hard lumps.

2 Active ingredient

2.1 Identity tests (80/TC/M2/2, CIPAC Handbook D, p. 155, 1988)

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 Propoxur content (80/DP/M2/3, CIPAC Handbook D, p. 155, 1988)

The propoxur content shall be declared (g/kg) and, when determined, the average content measured shall not differ from that declared by more than the following tolerances.

Declared content in g/kg	Tolerance
Up to 25	± 15 % of the declared content
above 25 up to 100	± 10 % of the declared content
Note in each range the upper limit is included.	

3 Relevant impurities

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

Maximum: 15 g/kg.

4 Physical properties

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

pH range: 4 to 7 (1% in water).

* Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at: <http://www.fao.org/ag/agp/agpp/pesticid/>.

4.2 Dry sieve test (MT 59.1, CIPAC Handbook F, p. 177, 1995)

Maximum: 5% retained on a 75 µm test sieve.

Not more than $(0.005 \times X)\%$ of the mass of the sample used for the test shall be present as propoxur in the residue on the sieve, where X is the propoxur content (g/kg) found under 2.2 (Note 1).

5 Storage stability

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

After storage at $54 \pm 2^\circ\text{C}$ for 14 days, the determined average active ingredient content must not be lower than 97% relative to the determined average content found before storage (Note 2) and the formulation shall continue to comply with the clauses for:

- pH range (4.1);
- dry sieve test (4.2).

Note 1 For example, if the formulation has a determined content of 40 g/kg of propoxur and 20 g of sample is used in the test, then the amount of propoxur in the residue on the sieve should not exceed 0.040 g, i.e.

$$\frac{(0.005 \times 40) \times 20}{100} \text{ g}$$

Note 2 Samples of the formulation taken before and after the storage stability test should be analyzed together after the test in order to reduce the analytical error.

PROPOXUR WETTABLE POWDER

FAO specification 80/WP (FEBRUARY 2006*)

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 report 80/2003. It should be applicable to relevant products of this manufacturer but it 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. The evaluation report 80/2003, as PART TWO, forms an integral part of this publication.

1 Description

The material shall consist of an homogeneous mixture of technical propoxur, complying with the requirements of FAO specification 80/TC (FEBRUARY 2006). It shall be in the form of a fine, beige powder free from visible extraneous matter and hard lumps.

2 Active ingredient

2.1 Identity tests (80/TC/M2/2, CIPAC Handbook D, p. 155, 1988)

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

2.2 Propoxur content (80/WP/M2/3, CIPAC Handbook D, p. 155, 1988)

The propoxur content shall be declared (g/kg) and, when determined, the average content measured shall not differ from that declared by more than the following tolerances.

Declared content in g/kg	Tolerance
above 100 up to 250	± 6% of the declared content
above 250 up to 500	± 5% of the declared content
Note: in each range the upper limit is included	

3 Relevant impurities

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

Maximum: 20 g/kg.

4 Physical properties

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

pH range: 4 to 6 at 10% in water.

4.2 Wet sieve test (MT 59.3, CIPAC Handbook F, p. 179, 1995)

Maximum: 2% retained on a 75 µm test sieve.

* Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at: <http://www.fao.org/ag/agp/agpp/pesticid/>.

- 4.3 **Suspensibility** (MT 15.1, CIPAC Handbook F, p. 45, 1995; or MT 177, CIPAC Handbook F, p. 445, 1995) (Note 1)

A minimum of 60% of the propoxur content found under 2.2 shall be in suspension after 30 min in CIPAC Standard Water D at $30 \pm 2^\circ\text{C}$ (Note 2).

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

Maximum: 10 ml after 1 min.

- 4.5 **Wettability** (MT 53.3, CIPAC Handbook F, p. 164, 1995)

The formulation shall be completely wetted in 2 min without swirling.

5 Storage stability

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

After storage at $54 \pm 2^\circ\text{C}$ for 14 days, the determined average active ingredient content must not be lower than 97% relative to the determined average content found before storage (Note 4) 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 methods MT 15.1 or MT 177.

Note 2 Chemical assay is the only fully reliable method to measure the mass of active ingredient still in suspension. However, simpler methods such as gravimetric and solvent extraction determination may be used on a routine basis provided that these methods have been shown to give equal results to those of chemical assay. In case of dispute, chemical assay shall be the "referee method".

Note 3 The mass of sample to be used in the test should be at the highest rate of use recommended by the supplier.

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.

PROPOXUR EMULSIFIABLE CONCENTRATE

FAO specification 80/EC (FEBRUARY 2006*)

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 report 80/2003. It should be applicable to relevant products of this manufacturer but it 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. The evaluation report 80/2003, as PART TWO, forms an integral part of this publication.

1 Description

The material shall consist of technical Propoxur, complying with the requirements of FAO specification 80/TC (FEBRUARY 2006), dissolved in suitable solvents, together with any other necessary formulants. It shall be in the form of a stable, clear homogeneous, slightly yellow liquid, free from visible suspended matter and sediment, to be applied as an emulsion after dilution in water.

2 Active ingredient

2.1 Identity tests (80/TC/M2/2, CIPAC Handbook D, p. 155, 1988)

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 Propoxur content (80/EC/M2/3, CIPAC Handbook D, p. 155, 1988)

The propoxur content shall be declared (g/kg or g/l at $20 \pm 2^\circ\text{C}$, Note 1) and, when determined, the average content measured shall not differ from that declared by more than the following tolerance.

Declared content in g/kg or g/l at $20 \pm 2^\circ\text{C}$	Tolerance
above 100 up to 250	$\pm 6\%$ of the declared content
Note: the upper limit is included in the range	

3 Relevant impurities

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

Maximum: 10 g/kg.

4 Physical properties

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

pH range: 3.0 to 4.2 (at 1% in water)

* Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at: <http://www.fao.org/ag/agp/agpp/pesticid/>.

4.2 Emulsion stability and re-emulsification (MT 36.1.1, CIPAC Handbook F, p. 108, 1995) (Note 2)

The formulation, when diluted at $30 \pm 2^\circ\text{C}$ 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", maximum: 1 ml
2.0 h	"Cream", maximum: 2 ml "Free oil", maximum: 0 ml
24 h	Re-emulsification complete
24.5 h	"Cream", maximum: 1 ml "Free oil", maximum: 0 ml
Note: in applying MT 36.1, tests after 24 h are required only where results at 2 h are in doubt	

5 Storage stability

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

After storage at $0 \pm 1^\circ\text{C}$ for 7 days, the volume of solid and/or liquid which separates shall not be more than 0.3 ml.

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

After storage at $54 \pm 2^\circ\text{C}$ for 14 days, the determined average active ingredient content must not be lower than 97% relative to the determined average content found before storage (Note 3) and the formulation shall continue to comply with the clauses for:

- pH range (4.1);
- emulsion stability and re-emulsification (4.2).

Note 1 If the buyer requires both g/kg and g/l at 20°C , then in case of dispute the analytical results shall be calculated as g/kg.

Note 2 This test will normally only be carried out after the heat stability test, clause 5.2.

Note 3 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

PROPOXUR

Page

2003 **FAO/WHO evaluation report** based on submission of data from
Bayer CropScience (TC, DP, WP, EC)

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PROPOXUR

FAO/WHO EVALUATION REPORT 80/2003

Explanation

The data for propoxur were evaluated for review of existing FAO and WHO specifications for propoxur. Existing FAO full specifications for TC, DP, WP and EC (80/TC/S/F, 1991; 80/DP/S/F, 1992; 80/WP/S/F, 1991; 80/EC/S/F, 1991) were published as AGP: CP/332 in 1995. Existing WHO full specifications for TC and WP (WHO/SIT/18.R4 and WHO/SIF/30.R4, respectively) were published in 1999.

Propoxur is no longer under patent.

Propoxur was evaluated by the FAO/WHO JMPR in 1973, 1977, 1981, 1983 1989 and 1996. Propoxur has also been submitted to the EU as notification for the Biocidal Products Directive (Directive 98/8/EC) under notification no. N353.

The draft specification and the supporting data were provided by Bayer Crop Science AG, Germany, in 2002.

Uses

Propoxur is an *N*-methylcarbamate insecticide and acaricide. It is non-systemic is a contact and stomach poison, which does not accumulate. The mode of action is interference with nervous transmission across the synaptic gap through inhibition of acetylcholinesterase.

Propoxur is used both for agricultural and public health purposes, being applied by spraying or as a dust. It is used against insect pests such as chewing and sucking insects, ants, cockroaches, crickets, flies and mosquitoes. Agricultural crop applications include sugar cane, cocoa, grapes and other fruit, maize, rice, vegetables, cotton, lucerne, forestry and ornamentals.

Identity

ISO common name:

propoxur (E-ISO, F-ISO 1750)

Chemical names:

IUPAC: 2-isopropoxyphenyl methylcarbamate

CA: 2-(1-methylethoxy)phenyl methylcarbamate

CAS No:

114-26-1

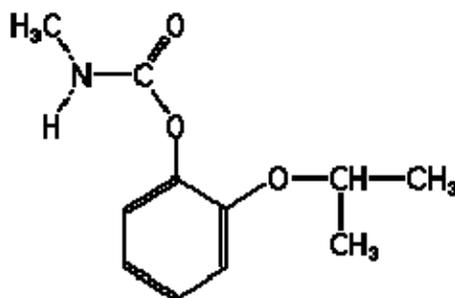
CIPAC No:

80

Synonyms:

Bay 9010, Baygon, Bayer 39007, Blattanex, Bolfo, BO Q 5812315, OMS 33, PHC (JMAF), Pillargon, UN Carbamate, Tugon, Unden, Undene

Structural formula:



Solid propoxur can exist in two crystal forms (modifications I and II) but the technical material usually contains >95% of modification I.

Molecular formula:

$C_{11}H_{15}NO_3$

Relative molecular mass:

209.25

Identity tests:

HPLC retention time, with detection at 280 nm (CIPAC Handbook D, p. 155, 1988); IR and mass spectra; melting point (87.5-90°C).

Physico-chemical properties of propoxur

Table 1. Physico-chemical properties of pure propoxur

Parameter	Value(s) and conditions	Purity %	Method reference
Vapour pressure:	1.29 mPa at 20°C 2.78 mPa at 25°C (extrapolated)	99.9	OECD 104
Melting point and temperature of decomposition:	Melting point: Crystal modification I: 87.5°C Crystal modification II: 90.0°C Stable under ambient conditions, no decomposition occurs below 150°C Decomposition starts at about 220°C and the consequent multi-stage process evolves about 300 kJ/kg.	99.9	OECD 102/113
Solubility in water:	1.75 g/l at 20°C	99.8	US-EPA Guidelines
Octanol/water partition coefficient:	log P _{ow} = 1.56 at 20°C	99.8	US-EPA Guidelines
Hydrolysis characteristics:	Half-life at 22°C >1 year at pH 4 93.2 days at pH 7 30.1 hours at pH 9	Not reported	OECD 111
Dissociation characteristics:	Propoxur has no distinct acidic or basic properties in aqueous solution.	99.9	OECD 112

Parameter	Value(s) and conditions	Purity %	Method reference
Density	1.17 g/cm ³ at 20°C	99.9	OECD 109

Table 2. Chemical composition and properties of propoxur technical materials (TC)

Manufacturing process, maximum limits for impurities ≥ 1 g/kg, 5 batch analysis data.	Confidential information supplied and held on file by WHO. Mass balances were 99.9 to 100.1% with no unidentified impurities.
Declared minimum propoxur content:	980 g/kg
Crystal modification ratio of propoxur (discernible by IR)	Modification I: > 950 g/kg Modification II: < 50 g/kg
Relevant impurities ≥ 1 g/kg and maximum limits for them:	None
Relevant impurities < 1 g/kg and maximum limits for them:	None
Stabilisers or other additives and maximum limits for them:	None
Melting or boiling temperature range	87.5 to 90°C
Density	1.17 g/cm ³ at 20°C
Bulk density	0.52 kg/l

Hazard summary

Notes

(i) The Proposer confirmed that the toxicological and ecotoxicological data included in the summary below were derived from propoxur having impurity profiles similar to those referred to in the table above.

(ii) The conclusions expressed in the summary below are those of the proposer unless otherwise specified.

Table 3. Toxicology profile of propoxur technical material, based on acute toxicity, irritation and sensitization.

Species	Test	Duration and conditions	Purity	Result	Reference
Rat, Wistar, male, female	oral	60 animals, 14 days observation period, in polyethylene glycol 400, doses from 0 to 127.9 mg/kg bw	not stated	LD ₅₀ = Males: 89.7 mg/kg bw Females: 78.5 mg/kg bw	Sturdivant & Halliburton 1998
Rat, Wistar, male, female	oral	40 animals, in Lutrol, doses from 10 to 500 mg/kg bw	not stated	LD ₅₀ = Males: 196 mg/kg bw Females: 126 mg/kg bw	JMPR 1989, USEPA 1997, Flucke 1980
Rat, male, female	dermal	24 h, in Lutrol, applied to intact dorsal skin, observation period 14 days	99.6%	LD ₅₀ > 5000 mg/kg bw	JMPR 1989, USEPA 1997, Flucke 1980
Rat, male, female	inhalation	4 h, 40 animals, conc. in air from 0 to 912 mg/m ³	not stated	LC ₅₀ = 654 mg/m ³	Pauluhn 1993

Species	Test	Duration and conditions	Purity	Result	Reference
Rat, male, female	inhalation	4 h, 5 animals per sex, con. 28.7, 110.1, 330.4, 497.5 mg/m ³	99.6%	LC ₅₀ >0.5 mg/l	JMPR 1989, USEPA 1997, Pauluhn 1988
Rabbit	skin irritation	500 mg, 4 hours, 6 animals	not stated	No manifestations of irritation	USEPA 1997 Sheets & Fuss 1991
Rabbit, New Zealand White	skin irritation	Dose not recorded 24 or 72 hours	99.2%	No manifestations of irritation	JMPR 1989 Thyssen 1978
Rabbit, New Zealand White	eye irritation	0.1 g, 9 animals, examinations 1, 24, 48, 72 and 96 h	99.6%	No manifestations of irritation Severe miosis, which disappeared within 24 hours, no signs of irritation up to 96 hours post-application	JMPR 1989 Yamane 1986b
Rabbit, New Zealand White	Eye irritation	65 mg, 6 males, 48 h	99.8%	Instillation resulted in minor eye irritation (redness and discharge) which cleared within 48 h	USEPA 1997 Sheets, 1990a
Guinea-pig	skin sensitization	Magnusson and Kligman test, 30 animals	98.8%	No evidence of skin-sensitizing potential	JMPR 1989 Heimann 1982a
Wistar rat, male, female	acute neurotoxicity	14 days, groups of 12 male and female rats, doses of 0, 2, 10, 25mg/kg	99.4%	NOEL could not be determined, LOEL = 2mg/kg, based on brain CHE inhibition in both sexes 45 min after dosing	USEPA 1997 Dreist & Popp 1994

Table 4. Toxicology profile of propoxur technical material based on repeated administration (sub-acute to chronic)

Species	Test	Duration and conditions	Purity	Result	Reference
Rat, Wistar male, female	oral, gavage	5 days, 5 animals per sex and , doses 0, 15, 30 mg/kg bw/day of propoxur of two different purities	98.6% technical and 99.2% recrystallized	Dose-related convulsions and apathy the only adverse effects, no difference between the two purities.	JMPR 1989 Heimann 1983
Wistar rat, female	Oral, feeding, toxicity	14 weeks, 100 rats, doses of 0, 8000 ppm via the feed	99.9%	NOAEL >8000 ppm	JMPR 1989 Hahnemann & Rühl-Fehlert 1988d

Species	Test	Duration and conditions	Purity	Result	Reference
Wistar rat, female	Oral, feeding, toxicity	104 weeks, 610 animals, doses from 0, 50, 250, 1000, 3000, 5000, 8000 ppm (0 to 348.46 mg/kg bw/day)	99.6-99.9%	NOAEL = 250 ppm (14.47 mg/kg bw/day) Growth retardation, ChE inhibition, urinary bladder alterations. Hyperplastic and neoplastic changes to bladder were diet-dependent and hyperplastic changes were reduced by administration of ammonium chloride	JMPR 1989 Hahnemann & Rühl-Fehlert 1988d
Mouse	Oral, feeding, toxicity	53 weeks, 50 female NMRI mice, diets containing 0, 3000, 8000 ppm	99.6-99.9%	Growth slightly decreased at 8000 ppm. Increased liver weight and fatty degeneration at 3000 and 8000 ppm. Relative lung weight increased at 8000 ppm only. No adverse effect on urinary bladder epithelium.	JMPR 1989 Hahnemann & Rühl-Fehlert 1988c
Hamster	Oral, feeding, toxicity	53 weeks, 50 female Syrian golden hamsters, diets containing 0, 3000, 8000 ppm.	99.6-99.9%	At both dose levels mortality incidence slightly increased, general state of animals impaired, growth retarded. Relative weights of kidneys and adrenals increased at 8000 ppm only. No adverse effect on urinary bladder epithelium.	JMPR 1989 Hahnemann & Rühl-Fehlert 1988a

Species	Test	Duration and conditions	Purity	Result	Reference
Dog	Oral, feeding, toxicity	52 weeks, 12 Beagle dogs (m/f), 0, 200, 600 ppm. Additional groups weeks 1-40, 1800 ppm; weeks 41-44, 3600 ppm; weeks 45-52, 5400 ppm	99.4%	Cholinergic symptoms observed at highest dose level, after elevation of dose to 5400 ppm and 1/6 animals died. The following were also increased in this group: thrombocyte, leucocyte and reticulocyte counts, incidence of Heinz bodies, ALAT and SAP, liver weight and thyroid weight; thymus weight decreased. At highest dose and at 600 ppm, growth was retarded and plasma cholesterol and liver <i>N</i> -demethylase increased. NOAEL = 200 ppm.	JMPR 1989 USEPA 1997 Hoffmann & Gröning, 1984
Rhesus monkey	Oral, feeding, (intubation), toxicity	13 weeks, 6 rhesus monkeys (m/f), doses of 40 mg/kg bw/day	99.6%	Cholinergic symptoms observed but no adverse effect on urinary bladder epithelium.	JMPR 1989 USEPA 1997 Hoffmann & Rühl, 1985
Mouse, male, female	Oral, feeding, carcinogenicity	SPF mice, strain CF1/W74, 2 years, groups of 50 male and 50 female rats, doses of 0, 700, 2000 or 6000 ppm in feed	99.6%	NOAEL = Males: 2000 ppm Females: 6000 ppm. No indications of oncogenic effects in any treatment group.	JMPR 1989 Bomhard & Löser 1981, Patterson 1980
Chinchilla rabbit, male, female	Dermal	5 male and 5 female rabbits, 14 applications, exposure period 24 hours, doses of 0 and 500 mg/kg bw/day	Not stated	Clinical, clinical chemical and haematological examinations did not detect any indications of damage or local irritant effects.	Kimmerle & Solmecke 1971
New Zealand white rabbit, male, female	Dermal	10 male, 10 female rabbits, 13 weeks, exposure period 6 hours/day, 5 days/week, doses of 0, 50, 250 and 1000 mg/kg bw/day in Cremophor	100%	NOAEL = 1000 mg/kg bw	USEPA 1997 Diesing & Flucke 1989

Species	Test	Duration and conditions	Purity	Result	Reference
Wistar rat, male, female	inhalation	12 weeks, (6 h per day, 5 days a week), groups of 10 male and 10 female rats, concentrations of 0, 5.7, 18.7 or 31.7 mg/m ³	98.9%	Only effect observed was depression of cholinesterase activity in plasma, erythrocytes and brain, at 31.7 mg/m ³ only.	JMPR 1989, Kimmerle & Iyatomi 1976
Wistar rat, male, female	feeding, 2 generation reproduction	groups of 25 male and 25 female rats, duration 330 days, pre-mating exposure 70 days both groups, 0, 30 and 80 ppm in feed for entire period (preparation, mating, gestation and rearing)	99.8%	NOAEL = Parent: 30 ppm Reproduction: 80 ppm	USEPA 1997, Suter 1990, Dotti 1992
Wistar rats, female	feeding, teratogenicity and embryotoxicity	25 mated females per group, exposure period from day 6 through 15 of gestation, in daily oral doses of 0, 3, 9 and 27 mg/kg bw, formulated in water/Cremoph or EL	99.4%	NOAEL = 3 mg/kg bw/day for maternal toxicity No evidence of embryotoxicity or teratogenicity even at the highest dose tested (27 mg/kg bw).	JMPR 1989 USEPA 1997 Becker <i>et al.</i> 1989b
Rabbit, female, Chinchilla strain	feeding, teratogenicity and embryotoxicity	4 groups, 16 females per group, from 6 th to 18 th day of gestation, in daily oral doses of 0, 3, 10 and 30 mg/kg bw, formulation agent water/Cremoph or EL	99.4%	NOAEL = 10 mg/kg bw/day for maternal toxicity and Embryotoxicity. Increased post-implantation losses at 30 mg/kg bw/day. Not teratogenic	JMPR 1989 USEPA 1997 Becker <i>et al.</i> 1989a

Species	Test	Duration and conditions	Purity	Result	Reference
Wistar rat, male, female	sub-chronic neurotoxicity	13 weeks, groups of 12 male and 12 female rats, doses of 0, 500, 2000 and 8000 ppm equivalent to 0, 39, 163 and 703 mg/kg bw/day for females and 0, 33, 132 and 543 mg/kg bw/day males	99.5%	NOEL (functional observation battery and motor and locomotor activity changes) = males: 543 mg/kg bw Females: 163 mg/kg bw	USEPA 1997, Dreist & Popp 1994
White leghorn hens	sub-chronic delayed neurotoxicity	8 hens, 30 days, doses of 0, 300, 1500, 3000 and 4500 ppm	Not stated	No evidence of delayed neurotoxicity during feeding or 4 weeks post-treatment.	Kimmerle 1966a Hobik 1967
B6C3F1 mice	Oncogenicity	2 groups of 50 males and 50 females in 0, 500, 2000, 8000 ppm, 2 years	99.6%	NOEL = 500 ppm, LOEL = 2000 ppm	USEPA 1997 Bomhard 1992

Table 5. Mutagenicity profile of propoxur technical material based on *in vitro* and *in vivo* tests

Species	Test	Conditions	Purity	Result	Reference
<i>Salmonella typhimurium</i> (TA 100, TA 98, TA1535, TA 1537, TA 1538)	Ames test, <i>in vitro</i>	Concentrations: 50 nmol/plate	95%	Negative	JMPR 1989, Blevins <i>et al.</i> 1977b
<i>Salmonella typhimurium</i> (TA 100, TA 98, TA1535, TA 1537, TA 1538)	Ames test, <i>in vitro</i>	Concentrations: 0.1-1000µg/plate, solvent DMSO	98%	Negative	JMPR 1989, Inukai & Iyatomi 1978
<i>Escherichia coli</i> (WP2 hcr. B/r try WP2)	Reverse mutation test, <i>in vitro</i>	Concentrations: 20 µl/disk	Not stated	Negative	JMPR 1989 Shirasu <i>et al.</i> 1976
<i>Saccharomyces cerevisiae</i> (D4)	Mitotic gene conversion test, <i>in vitro</i>	Concentrations: 2 ml of suspension (containing 1000 ppm a.i.) at 5 x 10 cells; solvent DMSO	99.8%	Negative	JMPR 1989, Siebert & Lemperle 1974, Siebert & Eisenbrand 1974
Male mice	Dominant lethal test, <i>in vivo</i>	Concentrations: 10 mg/kg bw; p.o.	99.2%	Negative	JMPR 1989 Herbold 1980a

Species	Test	Conditions	Purity	Result	Reference
Male and female NMRI-mice bone marrow cells	Micronucleus test, <i>in vivo</i>	2 x 5 mg/kg bw; 2 x 10 mg/kg bw; p.o.	99.2%	Negative	JMPR 1989 Herbold 1980b

Table 6. Ecotoxicology profile of propoxur technical material

Species	Test	Duration and conditions	Purity	Result	Reference
<i>Daphnia magna</i> (water flea)	Acute toxicity	48 h	98.8%	EC ₅₀ = 0.011 ppm	USEPA 1997 Lamb 1981
<i>Lepomis macrochirus</i> (bluegill sunfish)	Short-term toxicity, flow-through	96h, concentrations from 2.2 to 10 ppm, temperature 22°C	98.8%	LC ₅₀ = 6.2 mg/l	USEPA 1997 Lamb 1981
Rainbow trout	Short-term toxicity, flow-through	96h, 5 concentrations: 2.2 to 10 ppm, temperature 22°C	98.8%	LC ₅₀ = 3.7 mg/l	USEPA 1997 Lamb 1981
<i>Scenedesmus subspicatus</i> (green algae)	Effect on growth, static water	72 h, Directive 92/69/EEC	99.6%	IC ₅₀ = 22 mg/l NOEC = 3.1 mg/l	Caspers 2001
Bobwhite quail	sub-acute toxicity	5 days, 10 birds per dietary level, doses of 500, 1000, 2000, 4000 and 8000 ppm	98.8%	LC ₅₀ = 2828 ppm NOEL = 1000 ppm	USEPA 1997 Lamb 1981

Propoxur was evaluated by WHOPES in 1976 and re-evaluated in 1999.

Propoxur was evaluated by the FAO/WHO JMPR in 1973, 1977, 1981, 1983, 1989, 1991 and 1996. with the toxicological reviews conducted in 1973 and 1989. The JMPR (JMPR 1989) concluded that propoxur showed moderate acute toxicity in the animal species examined. After reviewing all available data from *in vitro* and *in vivo* short-term tests, the JMPR concluded that there was no evidence of genotoxicity. The JMPR recommended an ADI of 0.02 mg/kg bw/day for propoxur.

The US EPA also evaluated propoxur (USEPA 1997) and concluded that it is likely to be moderately persistent under aerobic or anaerobic soil conditions (a metabolic half-life of several months), mobile (K_d values less than 1) and may potentially leach to groundwater. It is hydrolytically stable at acid or neutral pH (3-7) but degrades rapidly in alkaline conditions. Propoxur was categorized as very highly toxic to birds on an acute basis (some LD₅₀s are <10 mg/kg); highly toxic to birds on a sub-acute dietary basis (LC₅₀ in the range of 51-500 ppm); moderately toxic to freshwater fish (some LC₅₀s in the range >1-10 ppm); highly toxic to bees (<11 µg/bee) on an acute contact basis; and very highly toxic to freshwater invertebrates (daphnid EC₅₀ <1 ppm).

The WHO hazard classification of propoxur is: “moderately hazardous, class II” (WHO 2000) and the USEPA classification of acute toxicity is also class II (USEPA 1997).

Formulations

The main formulation types available are WP, DP and EC, which are registered and sold in more than 45 countries throughout the world.

Methods of analysis and testing

The analytical method for the active ingredient (which also provides an identity test) is CIPAC 80/TC/M/2/3. Propoxur is determined by HPLC, using internal standardization with butyrophenone and UV detection at 280 nm. Propoxur may be identified by HPLC retention time and by IR and mass spectra.

The methods for determination of impurities were based on HPLC.

Test methods for physico-chemical properties of technical active ingredient are OECD, EPA and EU, while those for the formulations are CIPAC, as indicated in the specifications.

Physical properties

The properties and limits proposed for the specifications for TC, WP and EC comply with the requirements of the WHO/FAO Manual (FAO/WHO 2002).

Containers and packaging

Propoxur should be packed in polyethylene or polyamide using additional outer packaging.

Expression of the active ingredient

The active ingredient is expressed as propoxur.

Appraisal

The Meeting considered data, provided by Bayer Crop Science AG, for the review of existing full FAO (TC, DP, WP, EC) and WHO (TC, WP) specifications for propoxur. Propoxur is no longer under patent, it is presently registered in more than 45 countries and has been used in agriculture and public health applications for many years. It is, however, not approved for use in agriculture in the USA and the proposer reported that registration of propoxur for crop applications in Europe would not be supported.

Propoxur has been registered for many years in numerous countries world-wide. Information including that related to toxicology and ecotoxicology on propoxur is available from publications/websites of the US EPA, JMPR, WHO and EXTNET (<http://extoxnet.orst.edu/pips/propoxur.htm>). The Proposer stated that the data provided for this evaluation were similar to those provided to the JMPR for evaluation

but was unable to state categorically that they were similar to those submitted to the US EPA (USEPA 1997).

Propoxur is an *N*-methyl carbamate insecticide which is fairly soluble in water, very soluble in polar organic solvents but only slightly soluble in non-polar organic solvents. It is hydrolyzed very slowly at pH 4, slowly at pH 7 but rather rapidly at pH 9.

Propoxur is of moderate mammalian toxicity, it is rapidly metabolized and does not accumulate in tissues. It is not sensitizing or irritant to skin and is not irritant to the eye, although transient severe miosis occurred following application to the eye. There is no evidence that propoxur is carcinogenic, teratogenic or embryotoxic (post-implantation loss occurred only at doses above the level at which maternal toxicity occurred). In a 5-day study on rats, comparing the toxicity of technical (purity 98.6%) and recrystallized (purity 99.2%) propoxur, no difference in toxicity was found. The JMPR has recommended an ADI of 0.02 mg/kg bw/day for propoxur.

As may be expected for such a carbamate insecticide, propoxur is highly toxic to honeybees, aquatic invertebrates and birds, though its toxicity varies according to the species. It is moderately to slightly toxic to fish. The reported 96-hour LC50 values are 3.7 mg/L in rainbow trout, and 6.6 mg/L in bluegill sunfish. Propoxur is highly toxic to freshwater invertebrates and very highly or highly toxic to birds, its toxicity varying according to species. Propoxur is rather persistent and mobile in soils, having characteristics which could produce leaching to groundwater.

The Meeting was provided with confidential information on the current manufacturing process, together with data from 5-batch analyses and the manufacturing specifications for all impurities ≥ 1 g/kg. Mass balances were high (99.9-100.1%) and no unidentified impurities were present. The current (2000-on) manufacturing process produces a higher purity TC than previously and no new impurities are found (Riegner 2005). The data were stated by the manufacturer to be identical to those submitted for registration in Mexico, Australia, the Philippines, Thailand, Venezuela and Malaysia. The data were confirmed as being essentially similar to those submitted to Australia (Sethi 2005).

The proposed specification for propoxur TC was in accordance with the requirements of the manual (FAO/WHO 2002), with the exception of the three clauses considered below. Meeting noted the proposed higher minimum purity of 980 g/kg (1991 FAO specification minimum 970 g/kg, 1999 WHO specification minimum 950 g/kg).

- (i) The manufacturer initially proposed a clause to control the crystal form ratio of propoxur TC, on the basis that crystal modification II has an adverse effect on the suspensibility of water dispersible formulations (Grohs 2004a). The two forms can apparently be distinguished by IR or x-ray diffraction methods but it was subsequently stated that the problem occurs only in WPs formulated with high concentrations (above 50%) of propoxur, which are no longer marketed (Grohs 2004b). The clause is not required for the low concentration and liquid formulations currently marketed and therefore the proposal was withdrawn.
- (ii) A proposed clause for melting point of the TC, with a range of 87.5-90°C (instead of 86-91.5°C in the existing FAO and WHO specifications) was not in accordance with current guidelines in the manual (FAO/WHO 2002). The

Meeting agreed that it should not be included but that it could be used as a supporting identity test.

(iii) The manufacturer explained (Grohs 2004a) that a proposed clause to limit acidity in the TC was necessary because, although propoxur is stable to hydrolysis in acid conditions, the TC is used to formulate water-based aerosols and the presence of excessive acid could initiate rapid rusting of the aerosol canister.

The proposed specifications for DP, WP and EC were broadly in accordance with the requirements of the manual (FAO/WHO 2002) but the following points were discussed and agreed with the manufacturer.

(i) The Meeting noted that the proposed minimum active ingredient content after the test of storage at elevated temperature was 95% (relative to the determined average content found before storage) compared to 97% in the existing FAO specification but the manufacturer subsequently confirmed that the limits should be 97% (Grohs 2004a).

(ii) The manufacturer initially specified the use of 63 µm sieve in the dry sieve test for the DP but agreed that the clause should be restricted to the standard 75 µm sieve (Grohs 2004a).

(iii) The manufacturer initially specified the use of a 40 µm sieve in the wet sieve test for the WP but agreed that the clause should be restricted to the standard 75 µm sieve (Grohs 2004a).

(iv) The Meeting questioned the long (2 min) wettability time specified for the WP. The manufacturer stated that propoxur is non-polar and therefore difficult to wet, that the 2 min limit is given in existing FAO and WHO specifications, and that the wettability had not given rise to practical problems in the field after many years of use (Grohs 2004a). Although it was noted that propoxur is not of exceptionally low polarity (it is slightly soluble in water), the Meeting agreed to accept the 2 min limit.

(v) The Meeting questioned the relatively high limit for water (10 g/kg) in the EC. The manufacturer stated that the EC is not turbid at <10 g/kg (Grohs 2004a) but that the water content must be kept below 10 g/kg in order to meet cold stability requirements. At temperatures below -5°C, ice crystals function as crystallization points and reduce the solubility of propoxur in the EC, causing sedimentation (Grohs 2004a). The Meeting noted that, although the proposed specification for propoxur WP (at the 500 g/kg level) is the same for both agricultural and public health applications, users should adhere to the label recommendations and not use the products interchangeably.

The analytical and physical test methods to be used in support of the proposed specifications are all CIPAC methods.

Recommendations

The Meeting recommended that:

- (i) the existing FAO specifications for propoxur TC, DP, WP and EC and the existing WHO specifications for propoxur TC and WP should be withdrawn;

- (ii) the proposed specifications (amended as described in the appraisal, above) for propoxur TC and WP should be adopted by FAO and WHO;
- (iii) the proposed specifications (amended as described in the appraisal, above) for propoxur DP and EC should be adopted by FAO.

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