WHO SPECIFICATIONS AND EVALUATIONS

FOR PUBLIC HEALTH PESTICIDES

PRALLETHRIN

(*S*)-2-methyl-4-oxo-3-prop-2-ynylcyclopent-2-enyl(1*R*)-
cis,*trans*-2,2-dimethyl-3-(2-methylprop-1-enyl)
cyclopropanecarboxylate

WORLD HEALTH ORGANIZATION
GENEVA

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PRALLETHRIN

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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.

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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.

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[1] 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 follows the **New Procedure**, described in the 1st edition of Manual for Development and Use of FAO and WHO Specifications for Pesticides (2002). 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 Specification of the technical material and the related formulations of the pesticide in accordance with chapters 4 to 9 of the 1st 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 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. 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).

PART ONE

SPECIFICATIONS

PRALLETHRIN

PRALLETHRIN

INFORMATION

Common name

Prallethrin (E-ISO) is the common name for the racemic mixture of 8 stereoisomers

Chemical names

CA: (*S*)-2-methyl-4-oxo-3-(2-propynyl)-2-cyclopent-1-yl (1*R*)-*cis*,*trans*-2,2-dimethyl-3-(2-methyl-1-propenyl)cyclopropanecarboxylate (proposed CAS name)

IUPAC: (*S*)-2-methyl-4-oxo-3-prop-2-ynylcyclopent-2-enyl (1*R*)-*cis,trans*-2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate

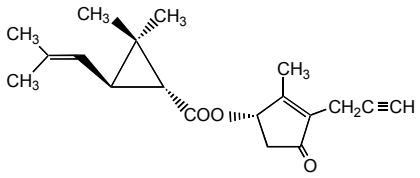
CAS Registry number

23031-36-9 (established for a mixture of 8 isomers)

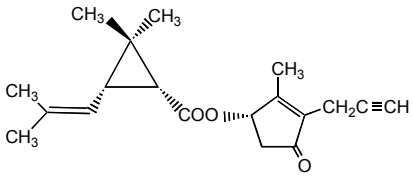
CIPAC number

743

Structural formula



1R,trans; S



1R,cis; S

Note: prallethrin, as defined in the accompanying specification, consists mainly of [1*R*,*trans*; *S*] and [1*R*,*cis*; *S*] isomers in a ratio of approximately 4:1. The E-ISO common name and CAS Registry number define prallethrin as the racemic mixture of the 8 possible stereoisomers implied by the structure. WHO recognizes that this use of the ISO common name is potentially confusing but, in the absence of an internationally accepted alternative, the name prallethrin is applied to the mixture defined by the WHO specification.

Molecular formula

$C_{19}H_{24}O_3$

Relative molecular mass

300.40

Identity tests

GC retention time, IR spectrum, stereo-selective HPLC (stereoisomer composition)

PRALLETHRIN TECHNICAL MATERIAL

WHO Specification 743/TC (November 2004*)

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 (743/2002). 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 specifications. The specification may not be appropriate for the products of other manufacturers. The evaluation report (743/2002) as PART TWO forms an integral part of this publication.

1 Description

The material shall consist of prallethrin, together with related manufacturing impurities. It shall be a yellowish-brown to brown oil, substantially odourless, free from visible extraneous matter and added modifying agents, except the stabilizer (Note 1).

2 Active ingredient

2.1 **Identity tests** (CIPAC 743/TC/M/2, Note 2)

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 **Total prallethrin isomers content** (CIPAC 743/TC/M/3, Note 3)

The total prallethrin isomers content shall be declared (not less than 900/kg) and, when determined, the average measured content shall not be lower than the declared minimum content.

2.3 **Isomer composition** (Note 3)

The range of the *trans*-isomers content of the prallethrin shall be declared (not less than 75% and not more than 85%) and, when determined, the average measured content shall not be lower than the declared minimum value nor higher than the declared maximum value.

The 1*R*-isomer content (in the acid moiety of the prallethrin isomers) shall be declared (not less than 95%) and, when determined, the average measured 1*R*-isomer content shall not be lower than the declared minimum content.

The *S*-isomer content (in the alcohol moiety of the prallethrin isomers) shall be declared (not less than 92%) and, when determined, the average measured *S*-isomer content shall not be lower than the declared minimum content.

Note 1 The stabilizer, 2,6-di-*tert*-butyl-*p*-cresol (BHT), is added in the concentration range 10–20 g/kg.

* 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/.

Note 2 GC retention time and IR spectrum may be used to confirm the identity as prallethrin isomers but the HPLC peak pattern (clause 2.3) is required to confirm the identity as prallethrin as defined by the specification.

Note 3 Methods for the identification and determination of prallethrin in TC and LV were adopted by CIPAC in 2004 but are not yet published. Prior to publication, copies of the methods may be obtained through the CIPAC website, http://www.cipac.org or from the Secretary, Dr László Bura, Central Service for Plant Protection and Soil Conservation, Budaörsi út. 141-145, 1118 Budapest, Hungary.

PART TWO

EVALUATION REPORTS

PRALLETHRIN

WHO SPECIFICATIONS AND EVALUATIONS
FOR PUBLIC HEALTH PESTICIDES

PRALLETHRIN[1]

EVALUATION REPORT WHO/743/2002

Explanation

The data for prallethrin were evaluated in support of a new WHO specification for the TC only.

The data on prallethrin had not been evaluated by the FAO/WHO Joint Meeting on Pesticide Residues (JMPR) nor the WHO Programme on Chemical Safety (WHO/PCS). The data on prallethrin had been evaluated by the United States Environmental Protection Agency (EPA 2000) and by the UK Advisory Committee on Pesticides (ACP 1995).

Prallethrin is not under patent.

The draft specification and supporting data on prallethrin were provided by Sumitomo Chemical Company Limited, Japan, in October, 2001.

Uses

Prallethrin is a synthetic pyrethroid with fast knock-down activity against household insect pests. It is used in household insecticide products against mosquitoes, houseflies and cockroaches (Matsunaga *et al*. 1987). Prallethrin also has veterinary uses in the treatment of domestic pets.

Identity

Common name

prallethrin (E-ISO, [f] F-ISO, BSI), stereochemistry unspecified

Synonyms

ETOC, S-4068SF

Chemical names

IUPAC: (*S*)-2-methyl-4-oxo-3-prop-2-ynylcyclopent-2-enyl(1*R*)-*cis*,*trans*-2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate[2]

CA: (*S*)-2-methyl-4-oxo-3-(2-propynyl)-2-cyclopenten-1-yl 2,2-dimethyl-3-(2-methyl-1-propenyl) cyclopropanecarboxylate[2]

CAS Registry number

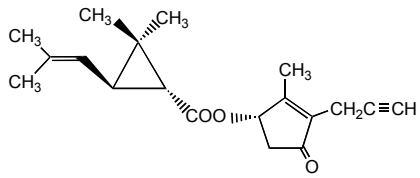
23031-36-9 (racemic)

[1] Prallethrin (E-ISO) is the common name for a racemic mixture of 8 stereoisomers, whereas the draft specification is for a product composed mainly of 2 of the 8 possible stereoisomers. For convenience, and in the absence of an internationally accepted alternative name, the ISO common name is applied here to a mixture with isomer composition as defined in Table 2 of the evaluation.

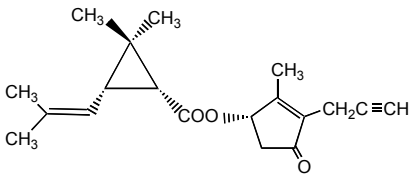
CIPAC number

743

Structural formula



1R,trans; S



1R,cis; S

Note: prallethrin, as defined in the draft specification, consists mainly of [1R,trans; S] and [1R,cis; S] isomers in a ratio of approximately 4:1. The ISO common name and CAS Registry number define prallethrin as the racemic mixture of the 8 possible stereoisomers implied by the structure. For convenience, and in the absence of an internationally accepted alternative name, the ISO common name is applied here to a mixture with isomer composition as defined in Table 2 of the evaluation.

Molecular formula

$C_{19}H_{24}O_3$

Relative molecular mass

300.40

Identity tests

GC retention time, IR spectrum, stereo-selective HPLC (stereoisomer composition)

Physical and chemical properties of prallethrin

Table 1. Physico-chemical properties of pure prallethrin.

Parameter	Value(s) and conditions	Purity %	Method reference
Vapour pressure:	<1.33 x 10^{-5} Pa at 23.1°C	99.4	EPA Guideline 63-9
Melting point and temperature of decomposition:	Melting point: liquid at room temperature Decomposition temperature: not stated	- -	- -
Solubility in water:	0.00803g/l at 25°C at pH5.5-5.6	99.4	EPA Guideline CG-1500
Octanol / water partition coefficient:	log P_{OW} = 4.49 at 25°C at pH 5.6-5.9	99.4	OECD 107
Hydrolysis characteristics:	Half-life = 118 hours at 23.5-25°C at pH 9. Significant degradation was not observed during 30 days at pH 5 and 7	Radiochem. purity 98.5	EPA Guideline 161-1

Parameter	Value(s) and conditions	Purity %	Method reference
Photolysis characteristics:	Photodegradation on soil: Half life: 24.8 days (acid-labelled) 26.9 days (alcohol-labelled) Photolysis at 0.51 ppm in sterile water containing 1% acetonitrile, at 22 to 27ºC, buffered to pH 5 in natural sunlight for a total of up to 192 hours test time (day and night) Half life: 13.6 hours (alcohol-labelled)	Radiochem. purity 98.0 98.5	EPA Guideline 161-3 not stated
Dissociation characteristics:	Does not dissociate.	-	-

Table 2. Chemical composition and properties of technical prallethrin.

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 98.4-98.9%.
Declared minimum prallethrin content:	900 g/kg
Isomer composition: *trans*-isomer content 1*R*-isomer in acid moiety *S*-isomer content in alcohol moiety	 Not less than 75% and not more than 85% Not less than 95% Not less than 92%
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:	BHT (2,6-di-*tert*-butyl-*p*-cresol) = not less than 2 g/kg and not more than 20g/kg
Melting or boiling temperature range	Boiling point: 313.5°C at 760mmHg

Toxicological summaries

Notes.

(i) In some cases, the proposer did not indicate the purity of materials used for the toxicological and ecotoxicological tests but provided written confirmation that the data included in summary below were derived from prallethrin having impurity profiles similar to those referred to in the Table 2, above.

(ii) The conclusions in the summary below are those of the proposer, except where identified as being derived from the USEPA evaluation[3], unless otherwise indicated.

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

Species	Test	Duration and conditions or guideline adopted	Result
Rats, male & female	oral	EPA Guideline 81-1	LD_{50} = (male) 640, (female) 460 mg/kg bw
Rats, male & female	dermal	EPA Guideline 81-2	LD_{50} = (male) >5000, (female) >5000 mg/kg bw
Rats, male & female	inhalation	EPA Guideline 81-3	LC_{50} (Nose exposure) = (male) 855, (female) 658 mg/m^3

Species	Test	Duration and conditions or guideline adopted	Result
Rabbits, male & female	skin irritation	EPA Guideline 81-5	Not irritant
Rabbits, male & female	eye irritation	EPA Guideline 81-4	Minimal irritant
Guinea pigs	skin sensitization	Maximization method, EPA Guideline 81-6	Not sensitizing

Prallethrin is moderately toxic when administered orally or by inhalation and is more toxic to female than male rats. It is of low toxicity via the dermal route. It is non-irritant to skin and a minimal irritant to the eyes of rabbit. It is not a skin sensitizer in guinea pigs.

Table 4 Toxicology profile of the technical prallethrin, based on repeated administration (sub-acute to chronic).

Species	Test	Duration and conditions or guideline adopted	Purity (%)	Result
Rats, male & female	inhalation	4 hours/day for 28 days	92.0	NOEL = 1.01 mg/m³
Rats, male & female	feeding, toxicity	3 months, EPA Guideline 82-1	92.0	NOAEL = 79.1 mg/kg/day*
Mice, male & female	feeding, toxicity	3 months, EPA Guideline 82-1	93.6	NOAEL = 374 mg/kg/day (both sexes)
Rats, male & female	Repeated dermal	10% of body surface 6 hours/day for 21 days	93.2	NOAEL = 30 mg/kg/day*
Dogs, male & female	feeding, toxicity	3 months, EPA Guideline 82-1	94.6	NOEL = 3 mg/kg/day (both sexes)
Dogs, male & female	feeding, toxicity	1 years, EPA Guideline 83-1	93.6	NOAEL = 2.5 mg/kg/day (both sexes)
Rats, male & female	feeding, carcinogenicity	EPA Guideline 83-2	92.0	NOAEL = Male:3.27mg/kg/day, Female : 4.00mg/kg/day Carcinogenicity: Negative
Mice, male & female	feeding, carcinogenicity	EPA Guideline 83-2		NOEL= Male: 600 ppm, Female: 120 ppm Carcinogenicity: Negative
Rats, male & female	feeding, 2 generation reproduction	EPA Guideline 83-4	93.6 92.9	Adult NOAEL = 120 ppm Offspring NOAEL = 600 ppm
Rats, male & female	feeding, teratogenicity and embryotoxicity	EPA Guideline 83-3	93.2	Maternal NOAEL = 10 mg/kg Developmental NOAEL = 300 mg/kg No developmental toxicity
Rabbits, male & female	feeding, teratogenicity and embryotoxicity	EPA Guideline 83-3	93.2	Maternal NOAEL = 30 mg/kg* Developmental NOAEL= 200 mg/kg No developmental toxicity*
Rats, Males and females	sub-chronic neurotoxicity	13 weeks	93.0	Systemic NOAEL Male: 74 mg/kg bw* Female: 88 mg/kg bw

* Conclusions from US EPA review[3].

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

Species	Test	Conditions	Purity (%)	Result
Salmonella typhimurium, Escherischia coli	Gene Mutation (Ames):	EPA Guideline 84-2	91.3	Negative
V79 Chinese hamster lung cells	Gene Mutation (V79):	EPA Guideline 84-2	91.2	Negative
Bone marrow cells of mice	Micronucleus Test:	EPA Guideline 84-2	93.2	Negative
Rat hepatocytes	Unscheduled DNA Synthesis	EPA Guideline 84-4	91.2	Negative
Chinese hamster ovary cells	*in vitro* Chromosomal aberration test:	EPA Guideline 84-2	91.2	Positive with S9 mix

All assays conducted were negative, except in Chinese hamster ovary cell test where the *in vitro* chromosomal aberration test was positive with metabolic activation.

Table 6. Ecotoxicology profile of prallethrin technical material.

Species	Test	Duration and conditions	Result
Honey bees	Acute contact toxicity	EPA Guideline 141-1	LD_{50} (48 hr): 0.028 µg/bee
Bobwhite quail	Acute oral toxicity	EPA Guideline 71-1	LD_{50}: 1171 mg/kg
Mallard duck	Acute oral toxicity	EPA Guideline 71-1	LD_{50}: >2000 mg/kg
Bobwhite quail	Acute dietary toxicity	EPA Guideline 71-2	LC_{50}: >5620 ppm
Mallard duck	Acute dietary toxicity	EPA Guideline 71-2	LC_{50}: >5620 ppm
Bluegill sunfish	Acute flow-through toxicity	EPA Guideline 72-1	LC_{50} (96 hr): 22 µg/l
Rainbow trout	Acute flow-through toxicity	EPA Guideline 72-1	LC_{50} (96 hr): 12 µg/l
Daphnia	Acute flow-through toxicity	EPA Guideline 72-2	EC_{50} (48 hr): 6.2 µg/l
Rainbow trout	Early life-stage toxicity	EPA Guideline 72-4	NOEC: 3.0 µg/l,
Daphnia	Life cycle toxicity study	EPA Guideline 72-4	NOEC: 0.65 µg/l,
Bobwhite quail	Reproduction toxicity	EPA Guideline 71-4	NOEL: 360 ppm
Mallard duck	Reproduction toxicity	EPA Guideline 71-4	NOEL: 600 ppm

The WHO/PCS hazard classification of prallethrin is “Moderately hazardous, Class II [4].

Formulations

The main formulation types available are vaporizing mats (MV) and liquid vaporizers (LV), although they are not produced by the proposer. These formulations are registered and sold in Japan, Brazil, Argentina, Mexico, China, Thailand, Malaysia, India, Spain, Italy and South Africa[*].

Methods of analysis and testing

Chemical analysis methods for total active ingredient and isomer ratio

Validation of the analytical method for active ingredient is in progress under the auspices of CIPAC[**]. Prallethrin is determined by capillary GC with FID and the retention times provide the first identity test. A second identity test relies on the IR spectrum.

The analytical method for determination of the isomer composition of prallethrin is in process of peer validation[***]. Geometric and optical isomer ratios at the acid moiety, and optical isomer ratios at the alcohol moiety, are determined separately by HPLC using a chiral stationary phase, after hydrolysis of prallethrin.

Analytical methods for impurities were based on either GC-FID or, in the case of unkowns, by GPC with UV absorption detection.

Physical test methods

Test methods for determination of physical-chemical properties of technical active ingredient were OECD and EPA. The specification for prallethrin TC does not require testing of physical properties, and specifications were not proposed for formulations, so that physical test methods for support of the specifications were not considered in this evaluation.

Containers and packaging

No special requirements for containers and packaging have been identified.

Expression of active ingredient

The active ingredient is expressed as prallethrin, as defined by the draft WHO specification.

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[*] October 2004 footnote. The manufacturer confirmed that prallethrin formulations are registered and sold in the UK and the USA (Fujita 2004).

[**] August 2004 footnote. The method for determination of prallethrin content was adopted by CIPAC in June 2004, with provisional status.

[***] August 2004 footnote. The method for identification of prallethrin (isomer ratio) was adopted by CIPAC in June 2004, with tentative status.

Appraisal

Prallethrin is an active ingredient that had not previously been the subject of a WHO specification.

The ISO common name and CAS Registry number define prallethrin as the racemic mixture of the 8 possible stereoisomers implied by the structure. However, the prallethrin defined in the draft specification consists mainly of [1*R,trans; S*] and [1*R,cis; S*] isomers, in a ratio of approximately 4:1. The meeting noted that this application of the ISO common name could be confusing but considered that the name should be used for this purpose until an internationally accepted alternative name is developed.

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Prallethrin is almost insoluble in water but highly soluble in organic solvents, such as hexane, ethanol, acetone, toluene, etc. It is of low volatility and, whilst stable under acidic or neutral conditions, it is slowly hydrolysed in moderately alkaline conditions.

Confidential information on the manufacturing process and on all impurities present at or above 1 g/kg was provided to the meeting, together with manufacturing limits for impurities in the TC. Limits were supported by 5 batch analysis, in which unidentified impurities were the range 1.1 to 1.6% and mass balances were 98.4 to 98.9%. The impurity data submitted in support of the specification were not derived from the same batches as the corresponding data submitted for registration of prallethrin by the US EPA but the proposer provided both series of data. The results and manufacturing specifications were similar in most respects but, firstly, no manufacturing limit for three impurities was provided to the US EPA and, secondly, unidentified impurities were not measured in the batch data submitted to US EPA. The proposer stated that the additional data had been provided to WHO to ensure the highest accountability in the analytical data. The concentration of the unidentified compounds had not been determined in the batches for which data had been provided to US EPA but no change in manufacturing process had occurred. The declared minimum active ingredient content was 900 g/kg in both cases. The meeting concluded that the apparent differences in the impurity data did not represent real differences in the profiles. No relevant impurities were identified by the meeting. A stabilizer (2,6-di-*tert*-butyl-*p*-cresol, BHT) is required, in the range 2 to 20 g/kg.

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The active ingredient content is determined by a capillary GC method. The method was validated in a small scale collaborative trial and is now undergoing full-scale collaborative study under the auspices of CIPAC[*]. An analytical method for the determination isomer composition, based on HPLC with a chiral column, in process of peer validation[**].

Prallethrin is of low mammalian toxicity, with no evidence of carcinogenicity. No reproductive effects were observed at any dose level and no development toxicity was observed at the highest treated dose. In a 13-week, sub-chronic neurotoxicity study in rat there were no indications of neuropathology, although there were

[*] August 2004 footnote. The method for determination of prallethrin content was adopted by CIPAC in June 2004, with provisional status, based on acceptable validation by collaborative study.

[**] August 2004 footnote. The method for identification of prallethrin (isomer ratio) was adopted by CIPAC in June 2004, with tentative status, based on acceptable peer validation.

indications of a higher arousal rate in females at 6000 ppm. Prallethrin is not mutagenic.

Prallethrin is very toxic to bees and fish but of low toxicity to birds. As it is not intended for use in agriculture, adverse environmental effects and human dietary exposure are not expected. Prallethrin is used in public health against mosquitoes, houseflies, cockroaches. The main formulations are vaporizing mats and liquid vaporizers and hence human exposure should only occur through emissions from these products when in actual use. The US EPA evaluated prallethrin and concluded that there is a reasonable certainty that no harm will result from aggregate exposure in normal use (EPA 2000).

The IPCS hazard classification of prallethrin is moderately hazardous (WHO 2002).

Recommendations

The meeting recommended that the specification for prallethrin TC should be adopted by WHO, subject to validation and adoption of the analytical method for active ingredient content by CIPAC* and subject to satisfactory peer validation of the identity test based on the determination of the stereoisomer ratios**.

References

ACP 1995 — Evaluation of prallethrin, Issue No. 131. UK Advisory Committee on Pesticides. Pesticides Safety Directorate and Health and Safety Executive, UK, April 1995.

EPA 2000 — US EPA, Prallethrin [(RS)-2-methyl-4-oxo-3-(2-propynyl) cyclopent-2-enyl (1RS)-cis, trans-chrysanthemate]; Pesticide Tolerance. *The Federal Register*, June 26 2000, **65** (123) page IV.

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Matsunaga *et al*. 1987 — T. Matsunaga, T.M.Makita, A.Higo, I.Nishibe, K.Dohara and G.Shinjo. Studies on prallethrin, a new synthetic pyrethroid for indoor applications. I. The insecticidal activities of prallethrin. *Jpn. J. Sanit. Zool.*, **38**, 219-223 (1987).

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