

WHO SPECIFICATIONS AND EVALUATIONS FOR PUBLIC HEALTH PESTICIDES

BIOALLETHRIN ^{1/}

(*RS*)-3-allyl-2-methyl-4-oxocyclopent-2-enyl (1*R*,3*R*)-
2,2-dimethyl-3-(2-methylprop-1-enyl)
cyclopropanecarboxylate



WORLD HEALTH ORGANIZATION
GENEVA

^{1/} Bioallethrin is the BSI common name for a mixture of two of the allethrin isomers, [1*R*,*trans*;1*R*] and [1*R*,*trans*;1*S*] in an approximate ratio of 1:1.

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Disclaimer¹

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.

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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 has followed 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 developed 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 at
<http://www.who.int/whopes>

PART ONE
SPECIFICATIONS

BIOALLETHRIN

PART ONE

SPECIFICATIONS FOR BIOALLETHRIN

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WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

BIOALLETHRIN

INFORMATION

Common name: Bioallethrin (BSI, New Zealand) a mixture of two of the allethrin isomers, [1*R*,*trans*;1*R*] and [1*R*,*trans*;1*S*] in an approximate ratio of 1:1. No ISO common name.

Synonyms: Depalléthrine ((f) France, AFNOR); *d-trans*-allethrin (ESA)

Chemical name:

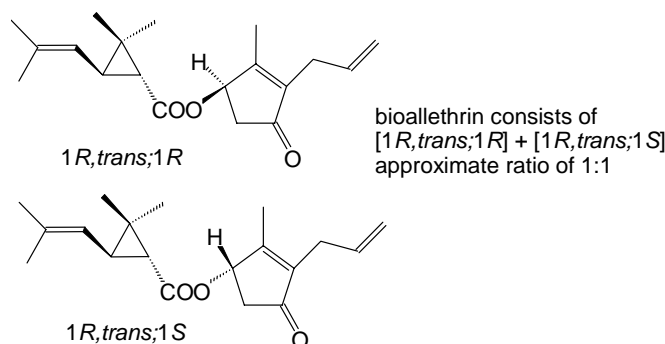
IUPAC: (*RS*)-3-allyl-2-methyl-4-oxocyclopent-2-enyl (1*R*, 3*R*)-2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate.

CA: None. CAS name for allethrin is: 2-methyl-4-oxo-3-(2-propenyl)-2-cyclopent-1-yl 2,2-dimethyl-3-(2-methyl-1-propenyl)cyclopropanecarboxylate.

CAS No: CAS number for allethrin is 584-79-2

CIPAC No: 203

Structural formula:



Molecular formula: $C_{19}H_{26}O_3$

Relative molecular mass:

302.41

Identity tests: Retention time by capillary GC-FID (analytical method for active ingredient content); chiral HPLC retention time and peak pattern (analysis method for isomer ratio); IR spectrum.

BIOALLETHRIN TECHNICAL MATERIAL

WHO Specification 203/TC (May 2005*)

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 (203/2003). 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 specifications. The specification may not be appropriate for the products of other manufacturers. The evaluation report (203/2003) as PART TWO forms an integral part of this publication.

1 Description

The material shall consist essentially of bioallethrin, with related manufacturing impurities. It shall be a yellow to brown oil, substantially odourless and free from extraneous materials or added modifying agents.

2 Active ingredient

2.1 Identity tests (Note 1)

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 Bioallethrin content (Note 2)

The bioallethrin content shall be declared (not less than 930 g/kg) and, when determined, the mean measured content shall not be lower than the declared minimum content.

2.3 Bioallethrin isomer composition (Note 2)

The *trans*-isomer content in the active ingredient in the material shall be declared (not less than 98.5%) and, when determined, the mean measured *trans*-isomer content in the active ingredient shall not be lower than the declared minimum value.

The 1*R*-isomer content at the acid moiety in the active ingredient in the material shall be declared (not less than 98%) and, when determined, the mean measured 1*R*-isomer content in the active ingredient shall not be lower than the declared minimum content.

The *S*-isomer content at the alcohol moiety in the active ingredient in the material shall be declared (not less than 48% and not more than 52%) and, when determined, the mean measured *S*-isomer content in the active

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

ingredient shall not be lower than the declared minimum content or higher than the declared maximum content.

Note 1 GC retention time and IR spectrum may be used to confirm the identity as allethrin isomers but the peak pattern obtained from chiral HPLC (clause 2.3) is required to confirm the identity as bioallethrin.

Note 2 Methods for the identification and determination of bioallethrin content were adopted by CIPAC in 2003 but are not yet published in a Handbook. Prior to publication of the Handbook, 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

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WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

BIOALLETHRIN

FAO/WHO EVALUATION REPORT 203/2003

Explanation

The data and draft specification for bioallethrin were submitted in support of a new WHO specification.

Bioallethrin is out of patent.

Bioallethrin had been evaluated by the WHO/IPCS (IPCS, 1989) and reviewed by the US EPA in 1976.

The draft specification and the supporting data were provided by Sumitomo Chemical Company Ltd., Japan, in 2002.

Uses

Bioallethrin is a synthetic pyrethroid with fast knock-down activity against household pest insects. It is used in public health against mosquitoes, houseflies and cockroaches.

Identity

Common name: Bioallethrin (BSI, New Zealand) a mixture of two of the allethrin isomers, [1*R*,*trans*;1*R*] and [1*R*,*trans*;1*S*] in an approximate ratio of 1:1. No ISO common name.

Synonyms: Depalléthrine ((f) France, AFNOR); *d-trans*-allethrin (ESA)

Chemical name:

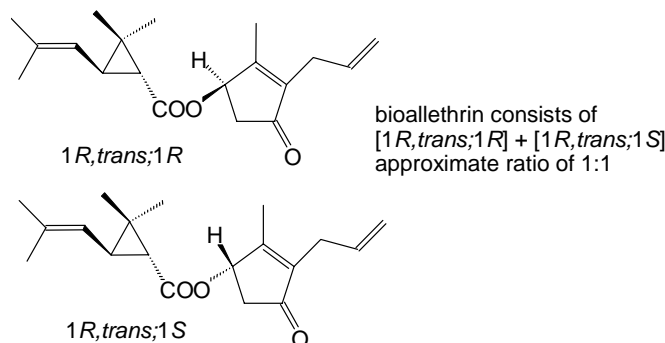
IUPAC: (*RS*)-3-allyl-2-methyl-4-oxocyclopent-2-enyl (1*R*, 3*R*)-2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate.

CA: None. CAS name for allethrin is: 2-methyl-4-oxo-3-(2-propenyl)-2-cyclopent-1-yl 2,2-dimethyl-3-(2-methyl-1-propenyl)cyclopropanecarboxylate.

CAS No: CAS number for allethrin is 584-79-2

CIPAC No: 203

Structural formula:



Molecular formula: C₁₉H₂₆O₃

Relative molecular mass:

302.41

Identity tests: Retention time by capillary GC-FID (analytical method for active ingredient content); chiral HPLC retention time and peak pattern (analysis method for isomer ratio); IR spectrum.

Notes on the isomer composition of related pesticides:

- allethrin consists of a racemic mixture of 8 stereoisomers;
- *d*-allethrin consists of [1*R*,*trans*;1*R*] + [1*R*,*trans*;1*S*] + [1*R*,*cis*;1*R*] + [1*R*,*cis*;1*S*] isomers in an approximate ratio of 4:4:1:1;
- bioallethrin consists of [1*R*,*trans*;1*R*] + [1*R*,*trans*;1*S*] isomers in an approximate ratio of 1:1;
- esbiothrin consists of [1*R*,*trans*;1*R*] + [1*R*,*trans*;1*S*] isomers in an approximate ratio of 1:3;
- *S*-bioallethrin (esbiol) consists of the [1*R*,*trans*;1*S*] isomer.

Physical and chemical properties of bioallethrin

Table 1. Physico-chemical properties of pure bioallethrin (note that *d-trans*-allethrin is bioallethrin).

Parameter	Value(s) and conditions	Purity %	Method reference
Vapour pressure:	0.044 Pa (3.3 × 10 ⁻⁴ mm Hg) at 25°C (extrapolated) 0.104 Pa (7.8 × 10 ⁻⁴ mm Hg) at 30°C (measured)	≥99%	Gas saturation method. Roussel Uclaf, 1992.
Melting point and temperature of decomposition:	Melting point: not applicable Decomposition temperature: not available		Not applicable
Solubility in water:	4.6 ± 0.3 mg/l at 25 ± 0.2°C	≥99%	Under-saturation-over-saturation method, Roussel Uclaf, 1992.

Parameter	Value(s) and conditions	Purity %	Method reference
Octanol / water partition coefficient:	$P_{OW} = 48000 \pm 4600$ at 25°C (log $P_{OW} = 4.7$)	≥99%	Shake flask method, Roussel Uclaf, 1992
Hydrolysis characteristics: <i>d-trans</i> -allethrin ¹	No measurable hydrolysis after 31 days at 25 °C and pH 5. Estimated half-life approx. 500 days at 25 C and pH 7. Half life: 4.3 days at 25°C and pH 9.	Radiochem. purity: 99.3	EPA Guideline 161-1 (Estigoy <i>et al.</i> , 1990)
Photolysis ² characteristics: <i>d-trans</i> -allethrin	Photodegradation in water under natural sunlight. Half life: 49 experiment hours or 19 sunlight hours at 25.5°C and pH 5.	Radiochem. purity: 99.3	EPA Guideline 161-2 (Chari <i>et al.</i> , 1990)
Dissociation characteristics:	Does not dissociate.	-	-

Table 2. Chemical composition and properties of bioallethrin technical material (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 99.0-99.6%, including 2.5-2.9% of "unknowns".
Declared minimum bioallethrin content:	930g/kg
Relevant impurities ≥ 1 g/kg and maximum limits for them:	None
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	Boiling point: 165-170°C at 0.15 mm Hg

1 Hydrolysis rates were measured at 0.5 mg/l in 1% aqueous acetonitrile in sterile dark conditions for 1 month at pH 5 and pH 7 and for 16 days at pH 9. Hydrolysis products identified after pH 9 hydrolysis were allethrolone and two isomeric bicyclic ketones.

2 Photolysis rates were measured at 0.5 mg/l in 1% aqueous acetonitrile in sterile buffer at pH 5 and 25.5°C. Quartz tubes of solution were exposed to sunlight at 37.45°N (Richmond, California) for 5 days in January. Photolysis products were identified as allethrolone, dihydroxyallethrolone and carbon dioxide. *Cis-trans* isomerization was not observed under the conditions.

Hazard summary

Notes.

(i) The proposer provided written confirmation that the toxicological and ecotoxicological data included in the summary below were derived from bioallethrin 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 bioallethrin technical material, based on acute toxicity, irritation and sensitization.

Species	Test	Duration and conditions	Result	Purity	Reference
Rat M/F	Oral	EPA Guideline 81-1	Males: LD ₅₀ = 709 mg/kg bw (95% confidence limits, 398-1756), Females: LD ₅₀ = 1040 mg/kg bw (95% confidence limits, 806-1349)	not reported	Audegond <i>et al.</i> , 1981 IPCS, 1989, p 38
Rabbit M/F	Dermal	EPA Guideline 81-2	Males: LD ₅₀ = >3000 mg/kg bw, Females: LD ₅₀ = >3000 mg/kg bw	92.1%	Glaza, 1991a
Rat M/F	Inhalation	EPA Guideline 81-3	Males: LC ₅₀ = 2.51 mg/l, Females: LC ₅₀ = 2.51 mg/l	93.0% (note 1)	Jackson <i>et al.</i> , 1991
Rabbit M/F	Skin irritation	EPA Guideline 81-5	Slightly irritating (not irritant under EU criteria)	92.1%	Glaza, 1991b
Rabbit M/F	Eye irritation	EPA Guideline 81-4	Mildly irritating (not irritant under EU criteria)	92.1%	Glaza, 1991c
Guinea pig	Skin sensitization	Buehler method, EPA Guideline 81-6	Not sensitizing	92.1%	Glaza, 1991d

Note 1: chrysanthemic acid + anhydride = 1% w/w.

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

Note: Some test data in Table 4 were based on esbiothrin (isomer ratio 1:3), the same isomers as bioallethrin (isomer ratio 1:1), but in a different ratio.

Species	Test	Duration and conditions	Result	Purity	Reference
Rat M/F	Inhalation	EPA Guideline 82-4 10 days	Both sexes: NOEL = 125 mg/m ³	Bioallethrin 93.6%	Chesher and Malone, 1972; IPCS, 1989, p. 41 ¹
Rat M/F	Feeding, toxicity	3 months	Both sexes: NOEL = 135 mg/kg bw/day	Bioallethrin TC, 93%	Wallwork <i>et al.</i> , 1972; IPCS, 1989, p. 41
Dog M/F	Feeding, toxicity	EPA Guideline 83-1 6 months	Males: NOEL = 6.1 mg/kg bw/day, Females: NOEL = 7.2 mg/kg bw/day	Bioallethrin 92.5-93.5%	Spicer, 1982

¹ IPCS refers only to male rats.

Species	Test	Duration and conditions	Result	Purity	Reference
Rat M/F	Feeding, carcinogenicity (esbiothrin)	EPA 83-5 104 weeks	Males: NOEL = 27.0 mg/kg bw/day Females: NOEL = 38.1 mg/kg bw/day Carcinogenicity: negative	93.8% (esbiothrin)	Simmonard, 1990b
Mouse M/F	Feeding, carcinogenicity (esbiothrin)	EPA 83-5 102 weeks	Males: NOEL = 41.9 mg/kg bw/day Females: NOEL = 49.7 mg/kg bw/day Carcinogenicity: negative	93.8% (esbiothrin)	Simmonard, 1990a
Dog M/F	Feeding toxicity (esbiothrin)	EPA 83-1 1 year	Males: NOAEL = 13.7 mg/kg bw/day Females: NOEL = 16.1 mg/kg bw/day	93.8% (esbiothrin)	Petra, 1990
Rat M/F	Feeding, 2 generation reproduction	EPA Guideline 83-4	Reproduction NOEL = 58.7 mg/kg bw/day	93.8% (esbiothrin)	Savary, 1990
Rat M/F	Feeding, teratogenicity and embryotoxicity (esbiothrin)	EPA Guideline 83-3	Maternal NOAEL = 25 mg/kg bw/day Developmental NOAEL = 125 mg/kg bw/day (highest dose tested)	95.2% (esbiothrin)	Lochry, 1991
Rabbit M/F	Feeding, teratogenicity and embryotoxicity (esbiothrin)	EPA Guideline 83-3	Maternal NOAEL = 100 mg/kg bw/day, Developmental NOAEL = 300 mg/kg bw/day determined on esbiothrin	95.2% and 94.6% (esbiothrin)	Hoberman, 1991

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

Species	Test	Conditions	Result	Purity	Reference
Salmonella typhimurium, Escherichia coli	Gene mutation	Ames test <i>in vitro</i>	Negative	bioallethrin, purity not reported	Peyre <i>et al.</i> , 1980
Mouse hepatocytes	Micronucleus assay	EPA 84-2 <i>In vivo</i>	Negative	bioallethrin TC, purity not reported	Curry, 1998

Table 6. Ecotoxicology profile of bioallethrin technical material.

Species	Test	Duration and conditions	Result	Purity	Reference
Bobwhite quail	Acute dietary toxicity	8 days	LC ₅₀ = >5620 ppm	<i>d</i> -allethrin 93.4%	Fink and Beavers, 1978a
Mallard duck	Acute dietary toxicity	8 days	LC ₅₀ = >5620 ppm	<i>d</i> -allethrin 93.4%	Fink and Beavers, 1978b
Coho salmon	Acute flow-through toxicity	96 hr at 12°C	LC ₅₀ (96 hr) = 9.4 µg/l	<i>d-trans</i> allethrin 90%	Mauck <i>et al.</i> , 1976
Steelhead trout	Acute flow-through toxicity	96 hr at 12°C	LC ₅₀ (96 hr) = 9.7 µg/l	<i>d-trans</i> allethrin 90%	Mauck <i>et al.</i> , 1976

Species	Test	Duration and conditions	Result	Purity	Reference
Channel catfish	Acute flow-through toxicity	96 hr at 12°C	LC ₅₀ (96 hr) = 27 µg/l	<i>d-trans</i> allethrin 90%	Mauck <i>et al.</i> , 1976
Yellow perch	Acute flow-through toxicity	96 hr at 12°C	LC ₅₀ (96 hr) = 9.9 µg/l	<i>d-trans</i> allethrin 90%	Mauck <i>et al.</i> , 1976
<i>Daphnia magna</i>	Acute static toxicity	96 hr at 17-21°C	LC ₅₀ (96 hr) = 35.6 µg/l (95% CL = 2.2-87 µg/l)	<i>d-trans</i> allethrin	Preiss, 1979

Bioallethrin was evaluated by the WHO/IPCS in 1989, with the following conclusions (IPCS, 1989, p 54).

“General population: under recommended conditions of use, the exposure of the general population to allethrins is negligible and is unlikely to present a hazard.

Occupational exposure: with reasonable work practices, hygiene measures, and safety precautions, the use of allethrins is unlikely to present a hazard to those occupationally exposed to them.

Environment: under recommended conditions of use and application rates, it is unlikely that allethrins or their degradation products will attain significant levels in the environment. In spite of the high toxicity of these compounds for fish and honey bees, they are only likely to cause a problem in the case of spillage or misuse.”

The WHO hazard classification of bioallethrin is class II, moderately hazardous (WHO, 2002).

Formulations

The main formulation type available is MV (vaporizing mats), which is registered and sold in many countries throughout the world. A draft specification for MV was not submitted for consideration by the meeting.

Methods of analysis and testing

A CIPAC method (203/TC/M) was available for the analysis of bioallethrin TC, using packed-column GC-FID with dibutyl phthalate as an internal standard (CIPAC, 1998).

An improved analytical method for the determination of active ingredient content in technical and formulated *d*-allethrin, bioallethrin, esbiothrin or *S*-bioallethrin was validated and adopted by CIPAC in 2003. The content of *d*-allethrin, bioallethrin, esbiothrin or *S*-bioallethrin is determined by capillary gas chromatography (column 0.25 mm ID x 30 m, coated with a 0.25 µm film of cross-linked nitroterephthalic acid-modified polyethylene glycol e.g. DB-FFAP) using split injection, flame ionization detection and *m*-terphenyl as internal standard. The method was tested using *d*-allethrin TC, *d*-allethrin LV, bioallethrin TC, esbiothrin TC and *S*-bioallethrin TC. *d*-Allethrin analytical standard served as the reference standard for all analyses.

An analytical method for determination of the isomer composition of bioallethrin was also adopted by CIPAC as an identity test, which can be applied to all active ingredients based on allethrin stereoisomers. The optical isomer ratios are determined by HPLC, using a chiral stationary phase.

Test methods for determination of physical-chemical properties of technical active ingredient were OECD and EPA.

Containers and packaging

No special requirements for containers and packaging were identified.

Expression of the active ingredient

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

Appraisal

The data and draft specification were submitted in support of a new WHO specification and were in accordance with the requirements of the FAO/WHO Manual, 1st edition (FAO/WHO).

Bioallethrin is the BSI common name for an approximately 1:1 mixture of [1*R*,*trans*;1*R*] and [1*R*,*trans*;1*S*] allethrin isomers and it is one of a group of active ingredients based on various proportions of allethrin isomers. The CIPAC number for bioallethrin is 203. Bioallethrin is out of patent.

The vapour pressure of bioallethrin is higher than that of many other synthetic pyrethroids, being 0.044 Pa at 25°C. Like most other synthetic pyrethroids, bioallethrin has low water solubility (4.6 mg/l at 25°C) and the octanol-water partition coefficient ($\log P_{OW} = 4.7$ at 25°C) makes it a fat-soluble compound. It is stable to hydrolysis under neutral or slightly acid conditions, but hydrolyzes readily under basic conditions. In water, bioallethrin is quickly degraded by photolysis but *cis*-allethrin was not detected as a significant product.

The Meeting was provided with commercially confidential information on the manufacturing process and batch analysis data on all impurities present at or above 1 g/kg. Analyses of 5 batches of bioallethrin produced in 2002 accounted for 99.0-99.6% of the material, including 0.25-0.29 of high molecular weight "unknowns". There was no evidence to suggest that the "unknowns" posed additional hazards. Unlike the closely related *d*-allethrin, subtle differences in the manufacturing process meant that technical bioallethrin was not likely to contain chrysanthemic anhydride at or above 1 g/kg. The Meeting therefore agreed that none of the impurities present in bioallethrin technical material should be considered relevant.

Bioallethrin is of low mammalian toxicity. The IPCS evaluation in 1989 concluded that, under recommended conditions of use, the exposure of the general population to allethrins is negligible and is unlikely to present a hazard. Also, with the usual precautions, the use of allethrins was considered by IPCS as being unlikely to present a significant risk to those occupationally exposed to them. The WHO hazard classification of bioallethrin is: moderately hazardous. *d*-Allethrin is of low toxicity to birds and the Meeting considered that it was reasonable to translate that result to bioallethrin (bioallethrin constitutes about 80% of *d*-allethrin). Bioallethrin is very toxic to fish and *Daphnia*.

The manufacturing process and impurity profile data submitted to WHO were declared by the manufacturer to be identical to those submitted for registration in the USA. However, the Meeting was unable to confirm this due to circumstances beyond the control of the manufacturer. Thus, in lieu of the usual requirement for a full assessment of the acceptability of hazards and risks conducted by a national registration authority, the Meeting requested an assessment by WHO/PCS. The consequent assessment by WHO/PCS secretariat concluded that: (i) the toxicities of *d*-allethrin, bioallethrin, esbiothrin, and *S*-bioallethrin and allethrin, are similar; (ii) taken together, the data available indicated that the acute toxicity of bioallethrin is moderate, with no signs of carcinogenicity, reproduction toxicity, or remarkable organ toxicity; (iii) bioallethrin is at most slightly irritating and is unlikely to be sensitizing (WHO/PCS 2005).

A CIPAC/AOAC method (203/TC/M, CIPAC 1998), involving packed-column GC-FID was already available for the analysis of technical bioallethrin, using GC-FID with dibutyl phthalate as an internal standard. However, in 2003, a new capillary GC-FID analytical method, suitable for the determination of *d*-allethrin, bioallethrin, esbiothrin and *S*-bioallethrin was validated by collaborative study and adopted by CIPAC.

The specification for bioallethrin TC requires the determination of bioallethrin content and measurements of total *trans*-isomer, total 1*R*-isomer, and total *S*-isomer contents in the active ingredient, in order to distinguish bioallethrin from other mixtures of allethrin isomers. An analytical method for isomer composition of *d*-allethrin was available, as described in the evaluation of *d*-allethrin in 2002; and it may also be applied to bioallethrin. This method was adopted by CIPAC in 2003, as an identity test in support of the method for determination of active ingredient content. The optical isomer ratios are determined by HPLC using a chiral stationary phase. The method for isomer composition is recommended as the primary identity test; secondary identity tests based on IR spectrum and GC retention time provide only confirmation of the presence of allethrin isomers.

Recommendations

The Meeting recommended that the specification for bioallethrin TC, proposed by Sumitomo Chemical Company Ltd and amended as agreed between the proposer and the Meeting, should be adopted by WHO.

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