WHO SPECIFICATIONS AND EVALUATIONS

FOR PUBLIC HEALTH PESTICIDES

S-BIOALLETHRIN *

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

World Health Organization

* The ISO common name, allethrin, applies to a recemate of 8 enantiomers. *S*-bioallethrin is used here, in the absence of an ISO common name, for a mixture which is predominantly comprised of the (*S*)(1*R*,3*R*) enantiomer.

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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.

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 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/quality/en/).

PART ONE

SPECIFICATIONS

S-BIOALLETHRIN

INFORMATION

ISO common name

none

Synonyms

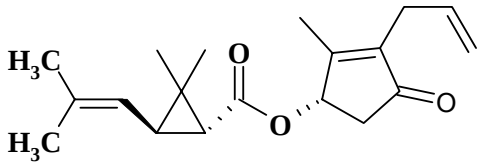
S-bioallethrin*; esdepalléthrine (France AFNOR); esbiol; bioallethrin *S*-cyclopentenyl isomer

Chemical names

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

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

Structural formula



Empirical formula

$C_{19}H_{26}O_3$

Relative molecular mass

302.4

CAS Registry number

28434-00-6

CIPAC number

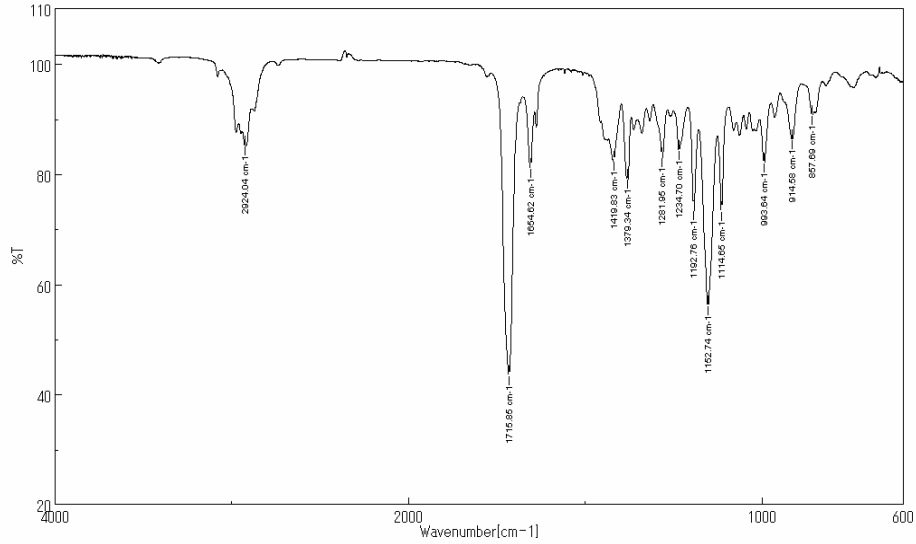
750

Identity tests

GC retention time and IR spectrum (see below) may be used to confirm the identity as allethrin isomers but the HPLC peak pattern (specification clause 2.3) is required to confirm the identity as *S*-bioallethrin.

* The ISO common name, allethrin, applies to a recemate of 8 enantiomers. *S*-bioallethrin is used here, in the absence of an ISO common name, for a mixture which is predominantly comprised of the (*S*)(1*R*,3*R*) enantiomer.

IR spectrum of *S*-bioalletrhin



S-BIOALLETHRIN TECHNICAL MATERIAL

WHO specification 750/TC (April 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 (750/2005). 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 750/2005, as PART TWO, forms an integral part of this publication.

1 Description

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

2 Active ingredient

2.1 **Identity tests** (750/TC/M/2, CIPAC Handbook L, Notes 1 and 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 ***S*-bioallethrin content** (750/TC/M/3, CIPAC Handbook L, Notes 1 and 2)

The *S*-bioallethrin content shall be declared (not less than 950 g/kg) and, when determined, the average measured content shall not be lower than the declared minimum content.

2.3 ***S*-bioallethrin isomer composition** (750/TC/M/3, CIPAC Handbook L, Notes 1 and 2)

The proportion of *trans*-isomer in the acid moiety of the active ingredient shall be declared (not less than 98.0%) and, when determined, the average measured *trans*-isomer proportion shall not be lower than the declared minimum.

The proportion of 1*R*-isomer content in the acid moiety of the active ingredient shall be declared (not less than 98.0%) and, when determined, the average measured 1*R*-isomer proportion shall not be lower than the declared minimum.

The proportion of *S*-isomer content in the alcohol moiety of the active ingredient shall be declared (not less than 96.0%) and, when determined, the average measured *S*-isomer proportion shall not be lower than the declared minimum.

Note 1 Methods for the identification and determination of *S*-bioallethrin content and isomer composition 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/prepubme.htm or from the CIPAC Secretary, Dr László Bura (mail to bura.laszlo@ntksz.ontsz.hu).

* 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 *S*-bioallethrin is quantified as a mixture of allethrin isomers, though predominantly comprised of the (*S*)(1*R*,3*R*) enantiomer. Identification of the active ingredient as *S*-bioallethrin requires compliance with clause 2.3.

PART TWO

EVALUATION REPORTS

S-BIOALLETHRIN

WHO SPECIFICATIONS AND EVALUATIONS FOR
PUBLIC HEALTH PESTICIDES

_S_-BIOALLETHRIN

EVALUATION REPORT 750/2005

Recommendation

The Meeting recommended that:

(i) the specification proposed by Sumitomo for *S*-bioallethrin TC should be adopted by WHO.

Appraisal

The data for *S*-bioallethrin were evaluated in support of a new WHO specification for TC. The draft specification and supporting data were provided by Sumitomo Chemical Co. Ltd, in 2004.

S-bioallethrin was evaluated by IPCS as part of an evaluation of all allethrins (IPCS 1989). It is registered for use in various countries in North and South America, Europe, Asia and Australasia. *S*-bioallethrin is used in public health and domestic pest control applications, not for plant protection. In Europe, *S*-bioallethrin is registered as a biocide under directive 98/8/EC, to be evaluated in 2006. *S*-bioallethrin is not under patent.

The allethrin molecule has 3 chiral centres and can exist in the form of 8 enantiomers. The ISO common name, allethrin, applies to a racemic mixture of all 8 enantiomers but various pesticides have been developed which are in specific enantiomers. The term *S*-bioallethrin (a name of convenience, not an ISO common name) is usually applied to a single enantiomer [(*S*)(1*R*,3*R*)] of allethrin. However, although *S*-bioallethrin is the most highly enantio-enriched of the allethrin family of active ingredients, analytically, *S*-bioallethrin must be determined and identified indirectly, using measurements which do not permit the [(*S*)(1*R*,3*R*)] isomer to be completely distinguished from other allethrin enantiomers which may be present. As indicated by the specification, other allethrin enantiomers are present in *S*-bioallethrin in very low proportions and are quantified as *S*-bioallethrin. Thus it is important to recognize that the specification defines *S*-bioallethrin as a mixture of allethrins, in which the [(*S*)(1*R*,3*R*)] enantiomer is by far the most abundant component.

Like many other pyrethroids, *S*-bioallethrin has low solubility in water, more or less stable under mildly acidic-neutral conditions but rather rapidly hydrolyzed at pH 9. It is prone to photolysis, with a half-life of 19 h in water exposed to natural sunlight during November-February at 37ºN.

The Meeting was provided with confidential information on the manufacturing process and 5-batch analysis data and manufacturing limits for all impurities ≥1 g/kg. Mass balances were acceptable, 98.5-98.9%, with no unknowns detected. These data were confirmed as similar to those provided to the Ministry of Health in Spain in

support of registration in that country. The manufacturer confirmed that the data also relate to current production.

The Meeting agreed that none of the impurities should be regarded as relevant, for the purposes of specifications.

Analytical methods for the identification and determination of *S*-bioallethrin, as defined by the specification, are full CIPAC methods.

A draft specification was submitted only for TC, which required no clauses to limit physical properties. The specification was in accordance with the requirements of the manual (FAO/WHO 2002). The Meeting noted that *S*-bioallethrin is usually considered to be a single enantiomer but accepted that the limitations of available analytical technology mean that *S*-bioallethrin [(*S*)(1*R*,3*R*)] must be measured and defined as a mixture of allethrin isomers which is predominantly comprised of this enantiomer.

SUPPORTING INFORMATION

FOR

EVALUATION REPORT 750/2005

Uses

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

Identity of the active ingredient

ISO common name

none

Synonyms

S-bioallethrin*; esdepalléthrine (France AFNOR); esbiol; bioallethrin *S*-cyclopentenyl isomer

Chemical names

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

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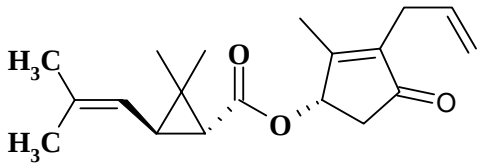
Structural formula



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Identity tests

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Physico-chemical properties of *S*-bioallethrin

Table 1. Physico-chemical properties of pure *S*-bioallethrin

Parameter	Value(s) and conditions	Purity %	Method	Reference
Vapour pressure:	2.59 x 10^{-2} Pa at 25°C	95.5	EC method A.4	C003257
Melting point	Liquid after storage for 1 week at -20°C	Not reported	EC method A.1	C03783
Boiling point	165-170^{o}C at 0.15 mm Hg	Not reported	EC method A.1	C03783
Temperature of decomposition	Not determined	-	-	-
Solubility in water	4.6mg/l at 20°C and pH 6.4-7.8	95.5	EC method A.6	C003142
Octanol / water partition coefficient	Log K P_{OW} = 5.0 at 22.0-22.5°C and pH 7.8	95.5	EC method A.8	C003141
Hydrolysis characteristics at 25°C	No measurable hydrolysis after 31 days at pH5. Estimated half-life approx 500 days at pH7. Half-life = 4.3 days at pH9.	Radiochemical purity: 99.3	EPA Guideline 161-1	KM-0007
Photolysis characteristics in water under natural sunlight	Half life: 49 experiment h or 19 sunlight h at 25.5°C and pH 5, latitude 37.45N, experimental period November-February	Not reported	EPA Guideline 161-3	KM-0006
Dissociation characteristics	Does not dissociate	-	-	-

Table 2. Chemical composition and properties of technical *S*-bioallethrin (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 98.5-98.9%, with no reported.
Declared minimum *S*-bioallethrin content:	950 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 temperature range	Liquid after storage for 1 week at -20°C

Background information on toxicology/ecotoxicology

S-bioallethrin was evaluated by IPCS in 1989. The WHO hazard classification is Class II, moderately hazardous (WHO 2002, listed as esbiol/bioallethrin). *S*-bioallethrin is being evaluated in the EU in 2006, under directive 98/8/EC.

Formulations and co-formulated active ingredients

S-bioallethrin is formulated only for use in public health and domestic pest control applications. The main formulation types available are LV. *S*-bioallethrin may be co-formulated with other pesticides. These formulations are registered and sold in many countries throughout the world, including the USA, Brazil, Mexico, China, Korea, Taiwan, Indonesia, Malaysia, Thailand, the Philippines, Singapore, India, Australia, New Zealand and some European countries.

Methods of analysis and testing

The analytical method for the active ingredient (including identity tests) is carried out by capillary GC with FID and internal standardization with *m*-terphenyl. Robust methods for the separate determination of the 8 allethrin enantiomers do not exist. Although the analytical methods for identification and determination of *S*-bioallethrin include the [(*S*)(1*R*,3*R*)] enantiomer and other enantiomers in the measurements, the proportions of the other enantiomers are very small and limited by the specification. There is no practical alternative to this analytical approach. The methods were adopted by CIPAC in 2003.

Impurities in *S*-bioallethrin were determined by capillary GC with FID detection.

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

Physical properties

No specifications are proposed for the formulations and therefore it is not necessary to consider their physical properties.

Containers and packaging

No special requirements for containers and packing have been identified.

Expression of the active ingredient

The active ingredient is expressed as *S*-bioallethrin. *S*-bioallethrin is not defined here as a single enantiomer [(*S*)(1*R*,3*R*)] of allethrin but as a mixture comprised almost wholly of the [(*S*)(1*R*,3*R*)] isomer, in which other allethrin isomers may occur in small proportions.

ANNEX 1

HAZARD SUMMARY PROVIDED BY THE PROPOSER

Note: The proposer provided written confirmation that the toxicological and ecotoxicological data included in the following summary were derived from *S*-bioallethrin having impurity profiles similar to those referred to in Table 2, above.

Table A. Toxicology profile of technical *S*-bioallethrin, based on acute toxicity, irritation and sensitization

Species	Test	Duration and conditions or guideline adopted	Result	Reference
Rat (m,f)	oral	Not reported	LD_{50} = 574.5 mg/kg bw (m) LD_{50} = 412.9 mg/kg bw (f)	A95287
Rabbit (m,f)	dermal	EPA Guideline 81-2	LD_{50} >2000 mg/kg bw (m,f)	A95294
Rat (m,f)	inhalation	EPA Guideline 81-3	LC_{50} = 1260 mg/m^3 (m,f)	A95295
Rabbit (m,f)	skin irritation	EPA Guideline 81-5	Non-irritating	A95293
Rabbit (m,f)	eye irritation	EPA Guideline 81-4	Minimally irritating	A95292
Guinea pig	skin sensitization	Maximization method, EPA Guideline 81-6	Non-sensitizer	A95291

Table B. Toxicology profile of technical *S*-bioallethrin, based on repeated administration (sub-acute to chronic)

Species	Test	Duration and conditions or guideline adopted	Result	Reference
Rat (m,f)	feeding toxicity	90 d, EPA82-1	NOEL = 19.6 mg/kg bw/d	A96249
Dog (m,f)	feeding toxicity	90 d, EPA82-1	NOEL = 42.2 mg/kg bw/d	A96250
Rat (m,f)	dermal toxicity	28 d, EPA82-2	NOAEL >1000 mg/kg bw/d	A92648
Rat (m,f)	inhalation toxicity	28 d, in-house method close to OECD 412	NOAEL = 15 mg/m³ (equivalent to 3.3 mg/kg bw/d)	A92469; C003126
Mouse (m,f)	feeding carcinogenicity	EPA 83-5, 102 weeks, (test substance esbiothrin)	NOEL = 41.9 mg/kg bw/d (m) 49.7 mg/kg bw/d (f) Not carcinogenic	A95120
Rat (m,f)	feeding carcinogenicity	EPA 83-5, 104 weeks, (test substance esbiothrin)	NOEL = 27.0 mg/kg bw/d (m) 38.1 mg/kg bw/d (f) Not carcinogenic	A95123; C003950
Dog (m,f)	Feeding toxicity	EPA 83-1, 1 year, (test substance esbiothrin)	NOAEL = 13.7 mg/kg bw/d (m) 16.1 mg/kg bw/d (f)	A95121; C003952
Rat (m,f)	feeding, 2 generation reproduction	EPA Guideline 83-4, (test substance esbiothrin)	Reproduction NOEL = 1800 ppm Overall NOEL = 600 ppm	A95122
Rat (m,f)	oral, developmental toxicity	EPA Guideline 83-3	Maternal NOEL = 20 mg/kg bw/d Developmental NOEL = 80 mg/kg bw/d No evidence of embryo-foetal toxicity	C000719
Rabbit (m,f)	oral, developmental toxicity	EPA Guideline 83-3	Maternal NOEL = 50 mg/kg bw/d Developmental NOEL = 50 mg/kg bw/d Slight developmental delay and changes in morphology in some foetuses at highest dose (200 mg/kg bw/d), but no evidence of teratogenicity	C000728
Rat (m,f)	Oral, acute neurotoxicity	EPA Guideline 81-8	Temporary neuropharmacological signs but no histopathological lesions.	A92470

Table B. Toxicology profile of technical *S*-bioallethrin, based on repeated administration (sub-acute to chronic)

Species	Test	Duration and conditions or guideline adopted	Result	Reference
Rat (m,f)	sub-chronic neurotoxicity	EPA Guideline OPTTS 870 6200	NOEL = 144 mg/kg bw/d (m) 181 mg/kg bw/d (f) Not neurotoxic	C008385

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

Species	Test	Conditions	Result	Reference
Salmonella typhimurium, *Escherichia coli*	Gene mutation	Ames test *in vitro,* EPA Guideline 84-2	Negative	A96247
Mouse lymphoma cell	Mutagenic potential	*In vitro*, EPA Guideline 84-2	Negative	A92410
Mouse	Micronucleus assay	*In vivo*, EPA Guideline 84-2	Negative	A92411

Table D. Ecotoxicology profile of technical *S*-bioallethrin

Species	Test	Duration and conditions	Result	Reference
Daphnia magna	Acute	EPA 72-2, flow through	EC_{50} (48 h) = 0.016 mg/l	A92347
Rainbow trout	Acute	Static, 4-d	LC_{50} (96h) = 0.0105 mg/l	A98540
Bluegill sunfish	Acute	Static, 4-d	LC_{50} (96h) = 0.0332 mg/l	A98540
Selenastrum capricornutum (alga)	Effect on growth	OECD 201	E_bC_{50} (72h) = 4.2 mg/l E_rC_{50} (72h) = 12.5 mg/l NOEC = 2.5 mg/l	A92346
Bobwhite quail	Acute feeding	8-d	LC_{50} >5000 ppm	A96239
Mallard duck	Acute feeding	8-d	LC_{50} >5000 ppm	A96238

Annex 2. References

Sumitomo document number, or other reference	Year and title of report, or publication details
A95295	1989. Esbiol acute inhalation toxicity in rats – 4 hour exposure.
A92346	1997. S-Bioallethrin: Algal inhibition test.
A92347	1997. S-Bioallethrin: Acute toxicity to Daphnia magna.
A92410	1995. Mutagenicity test on RUC #805 in the L5178Y TK +/- mouse lymphoma foward mutation assay.
A92411	1995. Mutagenicity test on RUC #805 in an in vivo mouse micronucleus assay.
A92469	1997. Esbiol Rat 28 day repeat dose inhalationtoxicity study.
A92470	1997. Esbiol: Rat acute oral neurotoxicity study.
A92648	1998. S-bioallethrin(Esbiol) Rat 28-day dermal toxicity.
A95120	1990. Esbiothrin: 102-week dietary carcinogenicity study in mice.
A95121	1987. Esbiothrin:Toxicity study in Beagle Dogs by repeated oral administrarion in diet for 52 weeks.
A95122	1990. Esbiothrin: Two generation reproduction toxicity study in rats.
A95123	1990. Esbiothrin: combinated chronic toxicity/oncogenicity study by repeated dietary administration to rats (104 weeks).
A95287	1980. Esbiol-Acute oral toxicity study in the rat.
A95291	1991. Dermal sensitisation study of Esbiol in guinea pigs – closed patch technique.
A95292	1991. Primary eye irritation study of Esbiol in rabbits.
A95293	1991. Primary dermal irritation study of Esbiol in rabbits.
A95294	1991. Acute dermal toxicity study of Esbiol in rabbits.
A96238	1973. 8-day dietary LC50 study with S-bioallethrin in Mallard ducks.
A96239	1973. 8-day dietary LC50 study with S-bioallethrin in Bobwhite quail.
A96247	1995. Mutagenicity test on RUC #805 in the salmonella/ mammalian-microsome reverse mutation assay (Ames test).
A96249	1996. S-bioallethrin(Esbiol): Rat 90 day dietary report dose study.
A96250	1996. S-bioallethrin(Esbiol): Dog 90 day dietary report dose study.
A98540	1973. Four-day static fish toxicity studies with S-bioallethrin in Rainbow trout and Bluegills.
C000719	1998. Esbiol: Rat oral developmental toxicity (teratogenicity) study.
C000728	1998. Esbiol: Rabbit oral developmental toxicity (teratogenicity) study.
C003126	1999. Esbiol Statement on the No-Adverse-Effect-Level(NOAEL) in the Rat 28 day inhalation study.
C003141	1999. Partition coefficient Esbiol Technical.
C003142	1999. Solubility in water Esbiol Technical.
C003257	1999. Vapour Pressure Esbiol Technical.
C003950	1990. Esbiothrin: combinated chronic toxicity/oncogenicity study by repeated dietary administration to rats (104 weeks).
C003952	1987. Esbiothrin:Toxicity study in Beagle Dogs by repeated oral administrarion in diet for 52 weeks.
C008385	2000. S-bioallethrin. Rat 90-day neurotoxicity study.
C03783	1999. Melting point Esbiol Technical.
FAO/WHO 2002	Manual on development and use of FAO and WHO specifications for pesticides. FAO plant production and protection paper 173. FAO, Rome, 2002.
IPCS 1989	Allethrins. Environmental Health Criteria 87. WHO, Geneva, 1989.
KM-0006	1990. Sunlight Photodegradation of [Alc-14C]-d-trans-Allethrin in a Buffered Aqueous Solution at pH5.
KM-0007	1990. Hydrolysis of [Alc-14C]-d-trans-Allethrin at pH 5, 7 and 9.

Sumitomo document number, or other reference	Year and title of report, or publication details
WHO 2002	The WHO recommended classification of pesticides by hazard and guidelines to classification. WHO, Geneva, 2002.