

WHO SPECIFICATIONS AND EVALUATIONS FOR PUBLIC HEALTH PESTICIDES

1*R-trans*-PHENOTHRIN*

3-phenoxybenzyl (1*R*,3*R*)-2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate



**World Health
Organization**

* 1*R-trans*-phenothrin is the name given by the manufacturer, in the absence of an ISO common name.

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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.

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

Additionally, WHO 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.

WHO is not responsible, and does not accept any liability, for the testing of pesticides for compliance with the specifications, nor for any methods recommended and/or used for testing compliance. As a result, WHO does not in any way warrant or represent that any pesticide claimed to comply with a WHO specification actually does so.

¹ This disclaimer applies to all specifications published by WHO.

INTRODUCTION

WHO establishes and publishes specifications² 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 “Manual on the development and use of FAO and WHO specifications for chemical pesticides.” 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 8 of the above-mentioned manual.

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 above-mentioned manual and supported by other information sources. Evaluation reports include 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 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.

² Publications available on the WHO Prequalification Unit – Vector Control Product Assessment Team (PQT/VCP) website: <https://extranet.who.int/pqweb/vector-control-products>

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Specifications bear the date (month and year) of publication of the current version. Evaluations bear the date (year) of the meeting at which the recommendations were made by the JMPS.

PART ONE: SPECIFICATIONS

1R-*trans*-PHENOTHRIN

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1R-*TRANS*-PHENOTHRIN* INFORMATION

ISO common name: Phenothrin (English), phénothrine (French) (ISO 1750 (published))

Chemical name(s):

IUPAC: 1R-trans isomer:

3-phenoxybenzyl (1*R*,3*R*)-2,2-dimethyl-3-(2-methylprop-1-enyl) cyclopropanecarboxylate

The unresolved mixture of stereoisomers:

(3-phenoxyphenyl)methyl 2,2-dimethyl-3-(2-methylprop-1-enyl) cyclopropane-1-carboxylate

CA: 1R-trans isomer:

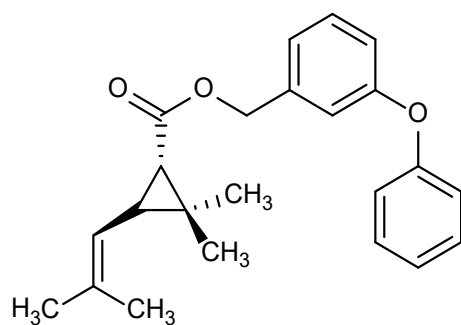
cyclopropanecarboxylic acid, 2,2-dimethyl-3-(2-methyl-1-propenyl)-, (3-phenoxyphenyl)methyl ester, (1*R*,3*R*)

The unresolved mixture of stereoisomers:

(3-phenoxyphenyl)methyl 2,2-dimethyl-3-(2-methyl-1-propen-1-yl) cyclopropanecarboxylate

Synonyms: S-1712, Sumithrin®

Structural formula:



1*R*-*trans*-phenothrin

Molecular formula: C₂₃H₂₆O₃

Relative molecular mass: 350.46

CAS Registry number: 1*R*-*trans* isomer: 26046-85-5
The "sum of isomers": 26002-80-2

CIPAC numbers: 1*R*-*trans*-phenothrin: Not allocated
d-phenothrin: 777
phenothrin: 356

Identity tests: GC and HPLC retention time

1R-*TRANS*-PHENOTHRIN TECHNICAL MATERIAL

WHO Specification 356/TC (September 2025*)

This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturer whose name is listed in the evaluation reports (356/2015, 356/2025). It should be applicable to TC produced by this manufacturer but it is not an endorsement of those products, nor a guarantee that they comply with the specification. The specification may not be appropriate for TC produced by other manufacturers. The evaluation reports (356/2015, 356/2025), as PART TWO, form an integral part of this publication.

1 Description

The material shall consist of 1*R-trans*-phenothrin together with related manufacturing impurities, in the form of pale yellowish oily liquid free from visible extraneous matter and added modifying agents.

2 Active ingredient

2.1 Identity tests (356/TC/(M)/2, CIPAC Handbook L, p. 97, 2005) (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 Total isomers content (356/TC/(M)/3, CIPAC Handbook L, p. 99, 2005)

The total isomers content shall be declared (not less than 955 g/kg), and when determined, the average measured content shall not be lower than the declared minimum content.

2.3 1*R-trans*-Phenothrin content (356/TC/(M)/2.2 & 356/TC/(M)/3, CIPAC Handbook L, p. 97 & p. 99, 2005) (Note 2)

The 1*R-trans*-phenothrin content shall be declared (not less than 890 g/kg), and when determined, the average measured content shall not be lower than the declared minimum content.

Note 1 Identity test may be based upon GC retention time (provided by the CIPAC method 356/TC/(M)/3) and LC retention time and intensities of the 1*R-trans* phenothrin chromatographic signal (provided by the CIPAC method 356/TC/(M)/2.2).

Note 2 1*R-trans*-phenothrin content is calculated by the following equation:

Content of 1*R-trans*-phenothrin = Total isomers content x (Trans isomer fraction percentage/100) x (1*R* isomer fraction percentage/100) 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/>.

PART TWO: EVALUATION REPORTS**1R-trans-PHENOTHRIN**

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FAO/WHO EVALUATION REPORT 356/2025

Recommendations

The Meeting recommended the following:

- (i) The 1R-*trans*-phenothrin TC as proposed by Endura S.p.A should be accepted as equivalent to the 1R-*trans*-phenothrin TC reference profile.
- (ii) The existing WHO specifications for 1R-*trans*-phenothrin TC, should be extended to encompass the technical material produced by Endura S.p.A.

Appraisal

The Meeting considered data and information submitted between November 2020 and March 2025 by Endura S.p.A in support of extension of the existing WHO specification 356 /TC for 1R-*trans*-phenothrin TC.

The data submitted met the requirements of the Manual on development and use of FAO and WHO specifications for chemical pesticides (2016, third revision of the first edition and 2022, second edition).

The manufacturer submitted confidential data on the manufacturing process, together with the manufacturing specification and batch analysis data on 1R-*trans*-phenothrin TC purity and all detectable impurities at or above 1 g/kg.

Endura S.p.A. stated that their 1R-*trans*-phenothrin TC has been registered in the European Union. A notice of approval has been received (ECHA, 23/12/2022).

The five batches analysed in the batch study were produced over 11 months in 2018 and 2019. The mass balance in the five batches analyzed ranged from 987.7 to 1004 g/kg. The specified minimum purity for the total isomers content in the TC is 955 g/kg, which is the same as the limit of 955 g/kg specified in the published TC specification. The specified minimum purity for 1R-*trans*-phenothrin content in the TC is 930 g/kg, which is higher than the limit of 890 g/kg specified in the published TC specification. The maximum limits for the impurities were supported by the batch data and were mostly statistically justified. The batch analysis study report indicates that no other significant impurities (each at or above 1 g/kg) were found in any of the five batches.

The batch analysis study was performed according to the principles of GLP. The CIPAC method 356/TC/M was used for the determination of active ingredient in the technical material. The CIPAC method consists of two techniques; the total phenothrin content is determined by GC-FID using m-terphenyl as an internal standard. The ratio of isomers is determined by HPLC-UV. In-house methods (GC with flame ionization and/or mass spectrometry detection) were used for the determination of other organic manufacturing impurities. Water was determined using CIPAC MT 30.5. All the analytical methods used in the batch analysis study were adequately validated with their specificity, linearity of response, accuracy, repeatability and limits of detection and quantification (for impurities).

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The manufacturing process for Endura S.p.A 1R-*trans*-phenothrin TC is similar to that of the reference profile; there are some differences in solvents and reagents used, however, the key reaction pathways are the same.

The impurity profile for the 1R-*trans*-phenothrin TC from Endura S.p.A. differed from the reference profile, with five new impurities at levels above 1 g/kg. Four other impurities were identified and quantified at levels below 1 g/kg (in some cases <LOQ of the method) in the batches but were declared in the proposed specification. Assessment of the relevance of all the new impurities identified indicated that two would be considered potentially relevant at the levels declared in the specification. In both these cases the analytical data for the batches and additional QC data provided by the proposer demonstrated that the impurities were found below levels at which they would be considered relevant, and that their levels can be controlled in the TC. The proposer revised their manufacturing specification to reflect that the impurities would not exceed that level at which they would become relevant.

Data on the melting point (OECD 102) and solubility in organic solvents (CIPAC MT 181) of the TC were submitted.

A bacterial reverse mutation test (OECD 471) with tester strains *Salmonella typhimurium* strains TA98, TA100, TA 102, TA1535 and TA1537 was submitted. The results of the study show that the 1R-*trans*-phenothrin TC produced by Endura S.p.A. does not induce bacterial reverse mutations under the conditions of this study.

On the basis of Tier-1 data provided by Endura S.p.A. (manufacturing process, purity/impurity profile, batch analysis data, mutagenicity profile), the Meeting concluded that the 1R-*trans*-phenothrin TC from Endura S.p.A. should be considered as equivalent to the reference profile supporting the existing WHO specification 356 /TC.

**Supporting Information
for
Evaluation Report 570/2025**

Table 1. Physico-chemical properties of pure 1R-trans-phenothrin

No data provided. Instead, data were provided for the TC.

Table 2. Chemical composition and properties of 1R-trans-phenothrin technical material (TC)

Manufacturing process, maximum limits for impurities ³ 1 g/kg, 5 batch analysis data	Confidential information supplied and held on file by WHO. Mass balances were 98.8 – 100.5 %, and percentages of unknowns were 0.0 – 1.2 %.			
Declared minimum phenothrin, sum of isomers content	955 g/kg			
Declared minimum 1R <i>trans</i> -phenothrin content	930 g/kg			
Relevant impurities ³ 1 g/kg and maximum limits	None			
Relevant impurities < 1 g/kg and maximum limits	None			
Stabilizers or other additives and maximum limits	None			
Parameter	Value(s) and conditions	Purity %	Method	Reference
Melting point	The freezing point was determined as -49.4°C.	98.7 (sum isomers) 95.7 % (1R- <i>trans</i>)	EEC Method A1 ASTM D5972	201401210
Solubility in organic solvents at 20°C	Heptane: > 250 g/L at 25°C > 250 g/L at 40°C Methanol: > 250 g/L at 25°C > 250 g/L at 40°C Xylene: > 250 g/L at 25°C > 250 g/L at 40°C n-octanol: > 250 g/L at 25°C > 250 g/L at 40°C	98.7 (sum isomers) 95.7 % (1R- <i>trans</i>)	CIPAC MT181	S-2014-00507

Annex 1: Hazard Summary Provided by the Proposer**Table 1. Toxicology profile of 1R-trans-phenothrin technical material, based on acute toxicity, irritation and sensitization**

Not provided.

Table 2. Mutagenicity profile of technical 1R-*trans*-phenothrin based on *in vitro* and *in vivo* tests

Species	Test	Purity %	Guideline, duration, doses, and conditions	Result	Study number
<i>Salmonella typhimurium</i> TA1535, TA1537, TA98, TA100, TA102	OECD 471 - Ames test , in vitro	96.7 %	OECD Guideline 471, 2020 1.6, 5, 16, 50, 160, 500, 1600 and 5000 µg/plate (with and without S9 mix)	-/+S9: Negative	AME02129

Notes:

- (i) The proposer confirmed that the toxicological data included in the summary below were derived from 1R-trans-phenothrin having impurity profile similar to those referred to in the table above.

Table 3. Ecotoxicology profile of technical 1R-*trans*-phenothrin

Not provided.

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Annex 2: References

Study number	Author(s)	Year	Study title. Study identification number. Report identification number. GLP [if GLP]. Company conducting the study
27209/2014	Zampieri L.	2014	Validation of an Analytical Method to Determine Impurities in 1R-trans Phenothrin TG. Study 27209/2014. Report number 27209. GLP. Contract Laboratory CHELAB Srl, Italy. Unpublished.
27209/2014	Zampieri L.	2014	Report number 27209-Amendment #1. Study 27209/2014. GLP. Contract Laboratory CHELAB Srl, Italy. Unpublished.
27209/2014	Zampieri L.	2014	Report number 27209-Amendment #2. Study 27209/2014. Report number 27209-Amendment #2. GLP. Contract Laboratory CHELAB Srl, Italy. Unpublished.
19.537572.0001	Zampieri L.	2020	Quantitative Determination of Assay of 1R-trans Phenothrin Technical Grade (5 BATCH ANALYSIS: R231/19, R232/19, R233/19, R234/19 AND R235/19). Report number 19.537572.0001. GLP. Contract Laboratory CHELAB Srl, Italy. Unpublished.
19.537572.0002	Zampieri L.	2020	Quantitative Determination of Stereoisomers in 1R-trans Phenothrin Technical Grade (5 BATCH ANALYSIS: R231/19, R232/19, R233/19, R234/19 AND R235/19). Report number 19.537572.0002. GLP. Contract Laboratory CHELAB Srl, Italy. Unpublished.
19.537572.0003	Zampieri L.	2020	Quantitative Determination of Impurities and Water in 1R-trans Phenothrin Technical Grade (5 BATCH ANALYSIS: R231/19, R232/19, R233/19, R234/19 AND R235/19). Report number 19.537572.0003. GLP. Contract Laboratory CHELAB Srl, Italy. Unpublished.
201401210	Mazzei N	2014	Determination of the freezing point and boiling point on the sample 1R-trans Phenothrin (pure active substance). Report 201401210. GLP. Innovhub Stazioni Sperimentali per L'industria. Unpublished.
S-2014-00507 AMI	Cassese S	2014	Determination of the solubility in organic solvents of the test item "1R-trans Phenothrin (pure active substance)". Report number S-2014-00507 AMI. GLP. Eurofins Biolab Srl, Italy. Unpublished.
1332	Ossani. E	2024	Integration of the analytical method validation to determine impurities in 1R-trans phenothrin TG. Report number 1332. Non GLP. Endura Analytical lab & QC, Unpublished
1339	Ossani. E	2024	Report number 1332. Non GLP. Endura Analytical lab & QC, Unpublished
AME02129	Mee C.	2023	1R-trans Phenothrin batch R1902051: Genetic Toxicity Evaluation using a Bacterial Reverse Mutation test with Salmonella typhimurium LT2 Strains TA1535, TA1537, TA98, TA100 and TA102. Report number AME02129. GLP. Gentronix Ltd, Cheshire, SK10 4TG, UK. Unpublished.

1*R*-trans-PHENOTHRIN
FAO/WHO Evaluation Report 356/2015

Recommendation

The Meeting recommended the following:

- (i) The existing WHO specification for *d*-phenothrin TC (October 2004) should be withdrawn by WHO.
- (ii) The specification for 1*R*-trans-phenothrin TC, proposed by Sumitomo Chemical Co. Ltd, and as amended, should be adopted by WHO.

Appraisal

The Meeting considered data and information submitted by Sumitomo Chemical Co. Ltd (SCC) in 2014, in support of a new WHO specification for 1*R*-trans-phenothrin TC. The data submitted by SCC were broadly in accordance with the requirements of the Manual on development and use of FAO and WHO specifications for pesticides (November 2010 - second revision of the First Edition).

d-phenothrin and 1*R*-trans-phenothrin are not under patent.

d-phenothrin was evaluated by the FAO/WHO JMPR (1990) and WHO/IPCS (1984, 1988). It was reviewed by the US EPA in 1975 and by the UK Health and Safety Executive prior to 1984.

It was reviewed under the Environmental Health Criteria 243, Aircraft Disinsection Insecticides (WHO 2013). Aircraft disinsection is considered to be the one of the main areas of use for *d*-phenothrin and 1*R*-trans-phenothrin (beside the use as household insecticide). A generic risk assessment model was used to estimate the Tolerable Systemic Dose (TSD) for an aerosol formulation with 2 % *d*-phenothrin. The exposure under these scenarios were found to be less than 1 % of the TSD.

d-phenothrin was evaluated in the European Union for its proposed use as an insecticide under the Biocide Directive. However, the Rapporteur Member State (Ireland) "allowed conclusions to be drawn only regarding a certain form of *d*-phenothrin, i.e. a substance containing at least 89 % w/w of 1*R*-trans phenothrin." A letter of access was provided for comparison of the confidential data package submitted to Ireland and to JMPS. Written confirmation was received on the similarity of the data packages (e-mail communication from Dr. F. Brown, 2015).

The Meeting was provided with commercially confidential data on the manufacturing process, the manufacturing specification and 5-batch analysis data for 1*R*-trans-phenothrin and all impurities detected; the limit of quantification was 1 g/kg.

The designation 1*R*-trans-phenothrin is proposed by SCC in lieu of a proper ISO common name. The name is composed of phenothrin - a common name referring to a mixture of 4 stereoisomers where the *cis*- and *trans*- ratio is unstated and the diastereomers are considered racemic. The name 1*R*-trans-phenothrin is derived from phenothrin and should indicate that the compound consists mainly of the 1*R*-trans enantiomer when the Rothamstead nomenclature (Elliott, 1975) is used. The minimum purity of the 1*R*-trans enantiomer in the TC is 890 g/kg, and the maximum amount of the other enantiomers is 65 g/kg. The company indicated that the specification for 1*R*-

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trans-phenothrin TC should replace the WHO specification for *d*-phenothrin (WHO 2004). This existing specification should therefore be withdrawn and replaced by that for 1*R-trans*-phenothrin TC.

The Meeting agreed that the new 1*R-trans*-phenothrin TC specification cannot be accommodated into the existing *d*-phenothrin TC specification and is considered as a new reference profile. The new profile is supported by confidential data on manufacturing and impurity profile, physical-chemical-, analytical-, toxicity and ecotoxicity data package.

The 5-batch analysis study was performed according to GLP guidelines. The CIPAC method 356/TC/(M)/3 (capillary GC with flame ionization detection and internal standard) was used for determination of total phenothrin content. The CIPAC method 356/TC/(M)/2 was used to determine the *cis* and *trans* ratio and enantiomeric ratios. The phenothrin manufacturing impurities were determined by GC-FID, except for water and sulphated ash that were determined using the CIPAC Methods MT 30.5 and MT 29, respectively. The results clearly show that both water and ash are well below 1 g/kg and hence are not included in the TC specification. All the analytical methods used in the 5-batch analysis study were fully validated for their specificity, linearity of response, accuracy, repeatability and limits of detection and quantification (for impurities).

The minimum chemical purity of 1*R-trans*-phenothrin (sum of all isomers) in the TC is 955 g/kg. Mass balances are acceptable (98.0 to 98.8%), with no unknowns detected. None of the impurities was identified as relevant above or below 1 g/kg.

**Supporting Information
for
Evaluation Report 356/2015**

Explanation

The data for *d*-phenothrin (sum of isomers) were evaluated in support of review of existing WHO specifications (WHO/356/2002).

d-phenothrin and *1R-trans*-phenothrin are not under patent.

d-phenothrin was evaluated by the FAO/WHO JMPR (1990) and WHO/IPCS (1984, 1988). It was reviewed by the US EPA in 1975 and by the UK Health and Safety Executive prior to 1984.

The draft specification and the supporting data were provided by Sumitomo Chemical Company Ltd., Japan, in 2014.

Uses

1R-trans-phenothrin is a pyrethroid insecticide. *1R-trans*-phenothrin acts by being absorbed by invertebrate neuronal membranes and binding to the sodium channels. The prolonged opening of sodium channels produces a protracted sodium influx which leads to repetitive firing of sensory nerve endings which may progress to hyper-excitation of the entire nervous system. At high pyrethroid concentrations conduction block can occur and the insects will die. It is used in public health against cockroaches, house flies and mosquitoes.

Identity of the active ingredient

ISO common name: Phenothrin (English), phénothrine (French) (ISO 1750 (published))

Chemical name(s):

IUPAC: 1R-trans isomer:

3-phenoxybenzyl (*1R,3R*)-2,2-dimethyl-3-(2-methylprop-1-enyl)
cyclopropanecarboxylate

The unresolved mixture of stereoisomers:

(3-phenoxyphenyl)methyl 2,2-dimethyl-3-(2-methylprop-1-enyl)
cyclopropane-1-carboxylate

CA: 1R-trans isomer:

cyclopropanecarboxylic acid, 2,2-dimethyl-3-(2-methyl-1-propenyl)-,
(3-phenoxyphenyl)methyl ester, (*1R,3R*)

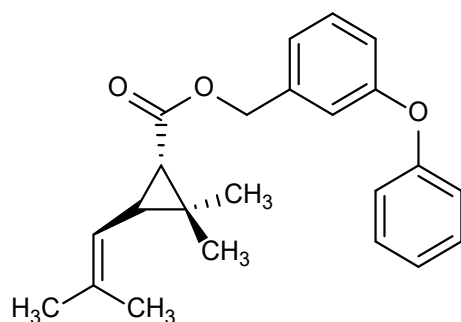
The unresolved mixture of stereoisomers:

(3-phenoxyphenyl)methyl 2,2-dimethyl-3-(2-methyl-1-propen-1-yl)
cyclopropanecarboxylate

WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

Synonyms: S-1712, Sumithrin®

Structural formula:



1*R*-*trans*-phenothrin

Molecular formula: C₂₃H₂₆O₃

Relative molecular mass: 350.46

CAS Registry number: 1*R*-*trans* isomer: 26046-85-5
The “sum of isomers”: 26002-80-2

CIPAC numbers: 1*R*-*trans*-phenothrin: Not allocated
d-phenothrin: 777
phenothrin: 356

Identity tests: GC and HPLC retention time

Physico-chemical properties of 1*R*-trans-phenothrin**Table 1. Physico-chemical properties of pure 1*R*-trans-phenothrin**

Parameter	Value(s) and conditions	Purity %	Method reference (and technique if the reference gives more than one)	Study number
Vapour pressure	2.37 x 10 ⁻⁵ Pa at 20°C	99.8% (96.0% 1 <i>R</i> isomer & 96.9% trans-isomer)	OECD 104 (Knudsen effusion method) EEC Method A.4	[201] STP-0006
Melting point.	-41.4°C	99.8% (93.8% 1 <i>R</i> trans isomer)	EEC Method A.1	[202] STP-0003
Temperature of decomposition	> 301°C (boiling point)	99.4% (96.75% 1 <i>R</i> trans isomer)	OECD 103	[203] EP-0121
Solubility in water	2 µg/l at 21°C (pH 5 - 9)	99.4% (96.75% 1 <i>R</i> trans isomer)	CIPAC method MT 157	[203] EP-0121
Octanol/water partition coefficient	log P _{OW} = 6.8 (pH 7)	99.4% (96.75% 1 <i>R</i> trans isomer)	EEC Method A.8	[203] EP-0121
Hydrolysis characteristics	Half-life = 301 days at 25°C at pH 5 Half-life = 495 -578 days at 25°C at pH 7 Half-life = 91 - 120 days at 25°C at pH 9	radio-chemical purity 99.6%	EPA-FIFRA 161-1	[204], [205] EM-0037 EM-0038
Photolysis characteristics	Half-life = 9.1 hours of natural sunlight at pH 5 and 24.5°C (benzyl-label) Half-life = 13.9 hours of natural sunlight at pH 5 and 24.5°C (cyclopropyl-label)	radio-chemical purity 95.6%	EPA-FIFRA 161-2	[206], [207] EM-91-0020 EM-91-0021
	Quantum yield: Not applicable as the absorbance wavelengths were <290 nm			
Dissociation characteristics	Not applicable			
Solubility in organic solvents	> 250 g/l methanol at 25°C > 250 g/l acetone at 25°C > 250 g/l ethyl acetate at 25°C > 250 g/l 1,2-dichloroethane at 25°C > 250 g/l m-xylene at 25°C > 250 g/l heptane at 25°C	99.4% (96.75% 1 <i>R</i> trans isomer)	CIPAC method MT 181	[203] EP-0121

Table 2. Chemical composition and properties of 1*R-trans*-phenothrin 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 98.0-98.8 % and percentages of unknowns were 1.2-2 %.		
Declared minimum phenothrin (sum of isomers) content		955 g/kg		
Declared minimum 1 <i>R-trans</i> -phenothrin content		890 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		
Parameter	Value and conditions	Purity %	Method reference	Study number
Melting temperature range of the TC and/or TK	Not available, See Table1. for the data on pure active ingredient	-	-	-
Solubility in organic solvents	Not available, See Table1. for the data on pure active ingredient	-	-	-

Hazard summary

d-phenothrin was evaluated by the WHO IPCS (1990). The following is the conclusions of evaluation by WHO IPCS.

General population: The exposure of the general population to *d*-phenothrin is expected to be very low and is not likely to present a hazard when it is used as recommended.

Occupational exposure: With reasonable work practices, hygiene measures and safety precautions, *d*-phenothrin is unlikely to be an occupational hazard.

Environment: The rapid breakdown of *d*-phenothrin in sunlight and its use principally on stored grain imply that environmental exposure should be very low. Environmental effects of the compound are, therefore, extremely unlikely.

The IPCS hazard classification of *d*-phenothrin is: Unlikely to present acute hazard in normal use, class U.

The current classification of 1*R-trans*-phenothrin in EU is shown below.

Classification according to EU directive 67/548/EEC

Identification of Danger:



Dangerous for the environment (N)

Risk Phrases: R50/53 (Very toxic to aquatic organisms, and may cause long-term adverse effects in the aquatic environment)

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Classification according to Regulation 1272/2008

GHS Pictogram:



Aquatic Acute Cat 1,
Aquatic Chronic Cat 1

Signal word: Warning

Hazard Statement: H410 (Very toxic to aquatic life with long lasting effects.)

Formulations and co-formulated active ingredients

The main formulation types available are aerosols. *1R-trans*-phenothrin may be co-formulated with other pyrethroids. These formulations are registered and sold in mainly European countries.

Methods of analysis and testing

The analytical method for the active ingredient (including identity tests) is a CIPAC method published in Handbook L. The *1R-trans*-phenothrin is determined by GC with FID and internal standardisation with *m*-terphenyl. Evaluation of phenothrin isomers is based on (*1R*)-isomer and trans-isomer ratios. The isomer ratio is determined by HPLC using a chiral stationary phase.

The method(s) for determination of impurities are based on temperature programmed GC.

Test methods for determination of physico-chemical properties of the technical active ingredient were OECD, EPA and/or EC.

Physical properties

The physical properties, the methods for testing them and the limits proposed for the formulations, comply with the requirements of the FAO/WHO Manual (November 2010 - second revision of the first edition).

Containers and packaging

No special requirements for containers and packaging have been identified.

Expression of the active ingredient

The *1R-trans*-phenothrin is expressed as *1R-trans*-phenothrin and is quantified as such.

Annex 1: Hazard Summary Provided by the Proposer

Notes:

- (ii) The proposer confirmed that the toxicological and ecotoxicological data included in the summary below were derived from 1R-trans-permethrin having impurity profiles similar to those referred to in the table above.
- (iii) The conclusions expressed in the summary below are those of the proposer, unless otherwise specified.

Table 1. Toxicology profile of 1R-trans-phenothrin technical material, based on acute toxicity, irritation and sensitization

Species	Test	Purity % Note*	Guideline, duration, doses and conditions	Result	Study number
Rat male/female	Oral	94.8	EPA-FIFRA 81-10, 5000 mg/kg	LD ₅₀ = >5000 mg/kg bw	[301] STT-0001
Rat male/female	Dermal	94.0	EPA-FIFRA 81-20, 5000 mg/kg	LD ₅₀ = >5000 mg/kg bw	[302] ET-0174
Rat male/female	Inhalation	93.8	EPA-FIFRA 81-34-hr exposure 0, 2100 mg/m ³	LC ₅₀ = >2100 mg/m ³ (whole body)	[303] ET-0172
Rabbit male/female	Skin irritation	94.2	EPA-FIFRA (1982) 4-hr exposure	Non-irritating	[304] ET-80-0112
Rabbit male/female	Eye irritation	94.2	EPA-FIFRA (1982)	Non-irritating	[304] ET-80-0112
Guinea pig male	Skin sensitisation	94.2	Maximization test (Magnusson & Kligman)	Non-sensitising	[305] ET-80-0113

* Note: Purity is the content of pure active ingredient in the technical material, expressed as a percentage.

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Table 2. Toxicology profile of 1R-trans-phenothrin technical material, based on repeated administration (subacute to chronic)

Species	Test	Purity % Note*	Guideline, duration, doses and conditions	Result	Study number
Rat male/female	Sub-chronic / 90-d / inhalation	94.2	The study report makes no claims on guideline compliance. The study essentially meets the requirements of OECD Test Guideline 413 (adopted 12 May 1981). 13 weeks 0, 30, 100, 300, 1000 mg/m ³	NOEL: 104 mg/m ³	[306] ET-91-0122
Dog male/female	Chronic / 1-y / diet	92.7	EPA-FIFRA 83-1 1 year 0, 100, 300, 1000, 3000 ppm (equivalent to: 0, 2.69, 8.24, 27.66, 80.19 mg/kg bw/d for male, 0, 2.63, 7.07, 26.77, 79.83 mg/kg bw/d for female)	NOAEL: 8.24 mg/kg bw/d (male), 7.07 mg/kg bw/d (female) LOAEL: 27.66 mg/kg bw/d (male), 26.77 mg/kg bw/d (female)	[307] ET-71-0108
Rat male/female	Chronic toxicity & carcinogenicity / 2-y / diet	92.6	Section 163.83 (Parts 1 and 2) of the Environmental Protection Agency Proposed Guidelines for registering pesticides in the US: Hazard evaluation : Human and Domestic Animals (Federal Register, 43, Pages 37375-37382, August 22, 1978) 2 years 0, 300, 1000, 3000 ppm	NOAEL: 1000 ppm (equivalent to: 47 mg/kg bw/d for male, 56 mg/kg bw/d for female) LOAEL: 3000 ppm Not carcinogenic	[308] ET-71-0102
Mouse male/female	Chronic toxicity & carcinogenicity / 2-y / diet	92.9	No claims of guideline compliance are made in the study report. However, this study appears to comply with the requirements of OECD Test Guideline 453 (adopted 12 May 1981). 2 years 0, 300, 1000, 3000 ppm	NOEL: 300 ppm (40 mg/kg bw/d) (male), 1000 ppm (164 mg/kg bw/d) (female) Not carcinogenic	[309] ET-71-0109

* Note: Purity is the content of pure active ingredient in the technical material, expressed as a percentage.

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Species	Test	Purity % Note*	Guideline, duration, doses and conditions	Result	Study number
Rat male/female	Reproduction / two generation	92.9	The study report makes no claims on guideline compliance. Some deviations from OECD Test Guideline 416 (adopted 22 January 2001) were observed. 0, 300, 1000, 3000 ppm	Parental NOAEL: 1000 ppm Reproductive NOAEL: 3000 ppm Offspring NOAEL: 1000 ppm	[310] ET-61-0101
Rat female	Teratogenicity / oral	92.6	The study report makes no claims on guideline compliance. The study essentially meets the requirements of OECD Test Guideline 414 (adopted 22 January 2001). 0, 300, 1000, 3000 mg/kg bw/d	Maternal NOAEL: 300 mg/kg bw/d Developmental NOAEL: 300 mg/kg bw/d	[311] ET-31-0085
Rabbit female	Teratogenicity / oral	94.1	EPA-FIFRA 83-3 0, 30, 100, 300, 500 mg/kg bw/d	Maternal NOAEL: 300 mg/kg bw/d Developmental NOAEL: 300 mg/kg bw/d	[312] ET-91-0121

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Table 3. Mutagenicity profile of 1*R*-trans-phenothrin technical material based on *in vitro* and *in vivo* tests

Species	Test	Purity % Note*	Guideline, duration, doses and conditions	Result	Study number
<i>Salmonella typhimurium</i>	Host-mediated assay <i>in vivo</i>	93.5	Method described by Legator and Malling 0, 2500, 5000 mg/kg	Negative	[313] ET-10-0067
<i>Salmonella typhimurium</i> / <i>Escherichia coli</i>	Ames test <i>in vitro</i>	93.5	Method described by Ames <i>et al.</i> and Yahagi <i>et al.</i> -/+S9: 0, 10, 50, 100, 500, 1000, 5000 µg/plate	-/+S9: Negative	[314] ET-10-0068
Chinese hamster ovary (CHO) cells	Chromosomal aberration <i>in vitro</i>	94.2	EPA-FIFRA 84-2 -S9: 0, 101, 151, 202, 252 µg/mL +S9: 0, 202, 303, 404, 505 µg/mL	-/+S9: Negative	[315] ET-91-0115

* Note: Purity is the content of pure active ingredient in the technical material, expressed as a percentage.

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Table 4. Ecotoxicity profile of 1*R*-trans-phenothrin technical material

Species	Test	Purity % Note*	Guideline, duration, doses and conditions	Result	Study number
Bobwhite quail (<i>Colinus virginianus</i>)	Dietary / 5-d	94.2	EPA-FIFRA 71-2, ASTM E857-81 5 days 0, 562, 1000, 1780, 3160, 5620 ppm	LC ₅₀ : >5620 ppm	[401] EW-81-0003
Rainbow trout (<i>Salmo gairdneri</i>)	Acute Flow-through	94.2	EPA-FIFRA 72-1 96 hours 0, 0.5, 1.0, 2.0, 4.0, 8.0 µg/L	LC ₅₀ : 2.7 µg/L	[402] EW-81-0004
Bluegill sunfish (<i>Lepomis macrochirus</i>)	Acute Flow-through	94.2	EPA-FIFRA 72-1 96 hours 0, <2.5, 3.2, 9.3, 27, 73 µg/L	LC ₅₀ : 16 µg/L	[403] EW-81-0005
Neonate cladocerans (<i>Daphnia magna</i>)	Acute Flow-through	93.4	EPA-FIFRA 72-2 48 hours 0, 2.6, 4.3, 7.2, 12, 20 µg/L	EC ₅₀ : 4.3 µg/L	[404] EW-41-0018
Green alga (<i>Pseudokirchneriella subcapitata</i>)	Chronic Static	96.6	OECD 201 72 hours 0, 0.00093, 0.0018, 0.0036, 0.0062 and 0.011 mg a.i./L	ErC ₅₀ : >0.011 mg a.i./L	[405] STW-0002
Activated sludge	Respiration inhibition test	96.6	OECD 209 3 hours 0, 4.6, 10, 22, 46, 100 mg/L	NOEC: >100 mg/L	[406] STW-0001
Honey bee (<i>Apis mellifera</i>)	Acute contact	94.2	EPA-FIFRA 141-1 48 hours 0, 0.00078, 0.00156, 0.00313, 0.00625, 0.0125, 0.025, 0.05 µg a.i./bee	LD ₅₀ : 0.005 µg a.i./bee	[407] EW-91-0009

* Note: Purity is the content of pure active ingredient in the technical material, expressed as a percentage.

Annex 2: References

References for appraisal

Author(s)	Year	Journal
Dr. Finbar Brown Regulatory and Enforcement Unit (Biocides), Pesticide Control Division, Department of Agriculture, Food and the Marine, Ireland	2015	e-mail communication on 16. June 2015 confirming the similarity of confidential data submitted by Sumitomo to JMPS and Regulatory and Enforcement Unit (Biocides).
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[307]		1987	Chronic toxicity study in dogs with Sumithrin, T.G. Hazleton Laboratories America, Inc., Study No. 343-173. Sumitomo Chemical Co., Ltd., Report No. ET-71-0108. GLP, Unpublished.
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Study number	Author(s)	Year	Study title. Study identification number. Report identification number. GLP [if GLP]. Company conducting the study.
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