**WHO SPECIFICATIONS AND EVALUATIONS FOR PUBLIC HEALTH PESTICIDES**

1\textit{R}-\textit{trans-}PHENOTHрин$^*$

3-фенилэтилэтоксифенил (1\textit{R},3\textit{R})-2,2-диметил-3-(2-метилпроп-1-ен-1-ил)циклопропанкарбоксилат

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$^*$ \textit{1R-trans-}фенофрин is the name given by the manufacturer, in the absence of an ISO common name.
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Disclaimer\textsuperscript{1}

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.

\textsuperscript{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 Manual for Development and Use of FAO and WHO Specifications for 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 9 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. 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.** Evaluations bear the date (year) of the meeting at which the recommendations were made by the JMPS.


## PART ONE  

### SPECIFICATIONS

<table>
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<tr>
<th>1R-trans-PHENOTHrin</th>
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WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

1R-trans-PHENOTHIRIN

INFORMATION

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

Synonyms
S-1712, Sumithrin®

Structural formula

\[
\begin{align*}
&\text{O} \quad \text{O} \\
&\text{H}_3 \text{C} \text{CH}_3 \\
&\text{H}_3 \text{C} \text{CH}_3
\end{align*}
\]

1R-trans-phenothrin

Molecular formula
C_{23}H_{26}O_3

* The ISO common name phenothrin refers to a racemic mixture of cis- and trans phenothrin in a nondefined ratio. The name “1R-trans-phenothrin” is used in lieu of a common name and stands for a material where the 1R-trans-phenothrin enantiomer is enriched and has a minimum of 890 g/kg in the TC. The CIPAC Code Number 356 refers to the racemic phenothrin with an undefined diastereomeric ratio.
Relative molecular mass
350.46

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

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

Identity tests
GC and HPLC retention time
WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

1R-trans-PHENOTHрин TECHNICAL MATERIAL
WHO specification 356/TC (September 2015)

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 (356/2015). 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 report (356/2015), as PART TWO, form an integral part of this publication.

1 Description

The material shall consist of 1R-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 1R-trans-Phenothrin content (356/TC/(M)/2.2 & 356/TC/(M)/3, CIPAC Handbook L, p. 97 & p. 99, 2005) (Note 2)

The 1R-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.

Note1 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 1R-trans phenothrin chromatographic signal (provided by the CIPAC method 356/TC/(M)/2.2).

Note2 1R-trans-phenothrin content is calculated by the following equation:

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

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### PART TWO

**EVALUATION REPORTS**

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**1 R-trans-PHENOTHRIN**

<table>
<thead>
<tr>
<th>Year</th>
<th>FAO/WHO evaluation report based on data submitted by Sumitomo Chemical Co. Ltd (TC)</th>
<th>Pages</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td></td>
<td>10</td>
</tr>
</tbody>
</table>

**Supporting Information**

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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 $1R$-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 $1R$-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 $1R$-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.

It was reviewed under the Environmental Health Criteria 243, Aircraft Disinsection Insecticides (WHO 2013). Aircraft disinfection is considered to be one of the main areas of use for $d$-phenothrin and $1R$-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 $1R$-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 $1R$-trans-phenothrin and all impurities detected; the limit of quantification was 1 g/kg.

The designation $1R$-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 $1R$-trans-phenothrin is derived from phenothrin and should indicate that the compound consists mainly of the $1R$-trans
enantiomer when the Rothamstead nomenclature (Elliott, 1975) is used. The minimum purity of the $1R$-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 $1R$-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 $1R$-trans-phenothrin TC.

The Meeting agreed that the new $1R$-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 $1R$-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.
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

Synonyms
S-1712, Sumithrin®
1\textit{R}-\textit{trans}-phenothrin

\textit{Molecular formula}
\[ \text{C}_{23}\text{H}_{26}\text{O}_{3} \]

\textit{Relative molecular mass}
350.46

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

\textit{CIPAC numbers}
- 1\textit{R}-\textit{trans}-phenothrin: Not allocated
- \textit{d}-phenothrin: 777
- phenothrin: 356

\textit{Identity tests}
- GC and HPLC retention time
### Physico-chemical properties of 1R-trans-phenothrin

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

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value(s) and conditions</th>
<th>Purity %</th>
<th>Method reference (and technique if the reference gives more than one)</th>
<th>Study number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vapour pressure</td>
<td>2.37 x 10^{-5} Pa at 20°C</td>
<td>99.8% (96.0% 1R isomer &amp; 96.9% trans-isomer)</td>
<td>OECD 104 (Knudsen effusion method) EEC Method A.4</td>
<td>[201] STP-0006</td>
</tr>
<tr>
<td>Melting point.</td>
<td>-41.4 °C</td>
<td>99.8% (93.8% 1Rtrans isomer)</td>
<td>EEC Method A.1</td>
<td>[202] STP-0003</td>
</tr>
<tr>
<td>Temperature of decomposition</td>
<td>&gt; 301 °C (boiling point)</td>
<td>99.4% (96.75% 1Rtrans isomer)</td>
<td>OECD 103</td>
<td>[203] EP-0121</td>
</tr>
<tr>
<td>Solubility in water</td>
<td>2 µg/l at 21 °C (pH 5 - 9)</td>
<td>99.4% (96.75% 1Rtrans isomer)</td>
<td>CIPAC method MT 157</td>
<td>[203] EP-0121</td>
</tr>
<tr>
<td>Octanol/water partition coefficient</td>
<td>log P_{OW} = 6.8 (pH 7)</td>
<td>99.4% (96.75% 1Rtrans isomer)</td>
<td>EEC Method A.8</td>
<td>[203] EP-0121</td>
</tr>
<tr>
<td>Hydrolysis characteristics</td>
<td>Half-life = 301 days at 25 °C at pH 5</td>
<td>radio-chemical purity 99.6%</td>
<td>EPA-FIFRA 161-1</td>
<td>[204], [205] EM-0037 EM-0038</td>
</tr>
<tr>
<td></td>
<td>Half-life = 495 -578 days at 25 °C at pH 7</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Half-life = 91 - 120 days at 25 °C at pH 9</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Photolysis characteristics</td>
<td>Half-life = 9.1 hours of natural sunlight at pH 5 and 24.5 °C (benzyl-label)</td>
<td>radio-chemical purity 95.6%</td>
<td>EPA-FIFRA 161-2</td>
<td>[206], [207] EM-91-0020 EM-91-0021</td>
</tr>
<tr>
<td></td>
<td>Half-life = 13.9 hours of natural sunlight at pH 5 and 24.5 °C (cyclopropyl-label)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Quantum yield: Not applicable as the absorbance wavelengths were &lt;280 nm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dissociation characteristics</td>
<td>Not applicable</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Solubility in organic solvents</td>
<td>&gt; 250 g/l methanol at 25 °C</td>
<td>99.4% (96.75% 1Rtrans isomer)</td>
<td>CIPAC method MT 181</td>
<td>[203] EP-0121</td>
</tr>
</tbody>
</table>
Table 2. Chemical composition and properties of 1R-trans-phenothrin technical material (TC)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value and conditions</th>
<th>Purity %</th>
<th>Method reference</th>
<th>Study number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Melting temperature range of the TC and/or TK</td>
<td>Not available, See Table 1. for the data on pure active ingredient</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Solubility in organic solvents</td>
<td>Not available, See Table 1. for the data on pure active ingredient</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

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 1R-trans-phenothrin in EU is shown below.
Clasification 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)
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. 1\(R\)-\(trans\)-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 1\(R\)-\(trans\)-phenothrin is determined by GC with
FID and internal standardisation with m-terphenyl. Evaluation of phenothrin isomers
is based on (1\(R\))-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 1\(R\)-\(trans\)-phenothrin is expressed as 1\(R\)-\(trans\)-phenothrin and is quantified as such.
ANNEX 1

HAZARD SUMMARY PROVIDED BY THE PROPOSER

Note:

(i) The proposer confirmed that the toxicological and ecotoxicological data included in the summary below were derived from 1R-trans-phenothrin 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 A. Toxicology profile of 1R-trans-phenothrin technical material, based on acute toxicity, irritation and sensitization

<table>
<thead>
<tr>
<th>Species</th>
<th>Test</th>
<th>Purity % Note</th>
<th>Guideline, duration, doses and conditions</th>
<th>Result</th>
<th>Study number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat male/female</td>
<td>Oral</td>
<td>94.8</td>
<td>EPA-FIFRA 81-1 0, 5000 mg/kg</td>
<td>LD$_{50}$ = &gt;5000 mg/kg bw</td>
<td>[301] STT-0001</td>
</tr>
<tr>
<td>Rat male/female</td>
<td>Dermal</td>
<td>94.0</td>
<td>EPA-FIFRA 81-2 0, 5000 mg/kg</td>
<td>LD$_{50}$ = &gt;5000 mg/kg</td>
<td>[302] ET-0174</td>
</tr>
<tr>
<td>Rat male/female</td>
<td>Inhalation</td>
<td>93.8</td>
<td>EPA-FIFRA 81-3 4-hr exposure, 0, 2100 mg/m$^3$</td>
<td>LC$_{50}$ = &gt;2100 mg/m$^3$ (whole body)</td>
<td>[303] ET-0172</td>
</tr>
<tr>
<td>Rabbit male/female</td>
<td>Skin irritation</td>
<td>94.2</td>
<td>EPA-FIFRA (1982) 4-hr exposure</td>
<td>Non-irritating</td>
<td>[304] ET-80-0112</td>
</tr>
<tr>
<td>Guinea pig male</td>
<td>Skin sensitisation</td>
<td>94.2</td>
<td>Maximization test (Magnusson &amp; Kligman)</td>
<td>Non-sensitising</td>
<td>[305] ET-80-0113</td>
</tr>
</tbody>
</table>

* Note: Purity is the content of pure active ingredient in the technical material, expressed as a percentage.
<table>
<thead>
<tr>
<th>Species</th>
<th>Test</th>
<th>Purity %</th>
<th>Guideline, duration, doses and conditions</th>
<th>Result</th>
<th>Study number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat male/female</td>
<td>Sub-chronic / 90-d / inhalation</td>
<td>94.2</td>
<td>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/m³</td>
<td>NOEL: 104 mg/m³</td>
<td>[306] ET-91-0122</td>
</tr>
<tr>
<td>Dog male/female</td>
<td>Chronic / 1-y / diet</td>
<td>92.7</td>
<td>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)</td>
<td>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)</td>
<td>[307] ET-71-0108</td>
</tr>
<tr>
<td>Rat male/female</td>
<td>Chronic toxicity &amp; carcinogenicity / 2-y / diet</td>
<td>92.6</td>
<td>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</td>
<td>NOAEL: 1000 ppm (equivalent to:47 mg/kg bw/d for male, 56 mg/kg bw/d for female) LOAEL: 3000 ppm Not carcinogenic</td>
<td>[308] ET-71-0102</td>
</tr>
<tr>
<td>Mouse male/female</td>
<td>Chronic toxicity &amp; carcinogenicity / 2-y / diet</td>
<td>92.9</td>
<td>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</td>
<td>NOEL: 300 ppm (40 mg/kg bw/d) (male), 1000 ppm (164 mg/kg bw/d) (female) Not carcinogenic</td>
<td>[309] ET-71-0109</td>
</tr>
</tbody>
</table>

* Note: Purity is the content of pure active ingredient in the technical material, expressed as a percentage.
<table>
<thead>
<tr>
<th>Species</th>
<th>Test</th>
<th>Purity %</th>
<th>Guideline, duration, doses and conditions</th>
<th>Result</th>
<th>Study number</th>
</tr>
</thead>
</table>
| 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 |
Table C. Mutagenicity profile of 1R-trans-phenothrin technical material based on *in vitro* and *in vivo* tests

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

* Note: Purity is the content of pure active ingredient in the technical material, expressed as a percentage.
Table D. Ecotoxicity profile of 1R-trans-phenothrin technical material

<table>
<thead>
<tr>
<th>Species</th>
<th>Test</th>
<th>Purity %</th>
<th>Guideline, duration, doses and conditions</th>
<th>Result</th>
<th>Study number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bobwhite quail (<em>Colinus virginianus</em>)</td>
<td>Dietary / 5-d</td>
<td>94.2</td>
<td>EPA-FIFRA 71-2, ASTM E857-81 5 days 0, 562, 1000, 1780, 3160, 5620 ppm</td>
<td>LC50: &gt;5620 ppm</td>
<td>[401] EW-81-0003</td>
</tr>
<tr>
<td>Rainbow trout (<em>Salmo gairdneri</em>)</td>
<td>Acute Flow-through</td>
<td>94.2</td>
<td>EPA-FIFRA 72-1 96 hours 0, 0.5, 1.0, 2.0, 4.0, 8.0 µg/L</td>
<td>LC50: 2.7 µg/L</td>
<td>[402] EW-81-0004</td>
</tr>
<tr>
<td>Bluegill sunfish (<em>Lepomis macrochirus</em>)</td>
<td>Acute Flow-through</td>
<td>94.2</td>
<td>EPA-FIFRA 72-1 96 hours 0, &lt;2.5, 3.2, 9.3, 27, 73 µg/L</td>
<td>LC50: 16 µg/L</td>
<td>[403] EW-81-0005</td>
</tr>
<tr>
<td>Neonate cladocrans (<em>Daphnia magna</em>)</td>
<td>Acute Flow-through</td>
<td>93.4</td>
<td>EPA-FIFRA 72-2 48 hours 0, 2.6, 4.3, 7.2, 12, 20 µg/L</td>
<td>EC50: 4.3 µg/L</td>
<td>[404] EW-41-0018</td>
</tr>
<tr>
<td>Green alga (<em>Pseudokirchneriella subcapitata</em>)</td>
<td>Chronic Static</td>
<td>96.6</td>
<td>OECD 201 72 hours 0, 0.00093, 0.0018, 0.0036, 0.0062 and 0.011 mg a.i./L</td>
<td>ErC50: &gt;0.011 mg a.i./L</td>
<td>[405] STW-0002</td>
</tr>
<tr>
<td>Activated sludge</td>
<td>Respiration inhibition test</td>
<td>96.6</td>
<td>OECD 209 3 hours 0, 4.6, 10, 22, 46, 100 mg/L</td>
<td>NOEC: &gt;100 mg/L</td>
<td>[406] STW-0001</td>
</tr>
<tr>
<td>Honey bee (<em>Apis mellifera</em>)</td>
<td>Acute contact</td>
<td>94.2</td>
<td>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</td>
<td>LD50: 0.005 µg a.i./bee</td>
<td>[407] EW-91-0009</td>
</tr>
</tbody>
</table>

* Note: Purity is the content of pure active ingredient in the technical material, expressed as a percentage.
## ANNEX 2: REFERENCES

### References for appraisal

<table>
<thead>
<tr>
<th>Author(s)</th>
<th>Year</th>
<th>Journal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr. Finbar Brown, Regulatory and Enforcement Unit (Biocides), Pesticide</td>
<td>2015</td>
<td>e-mail communication on 16. June 2015 confirming the similarity of confidential data submitted by Sumitomo to JMPS and Regulatory and Enforcement Unit (Biocides).</td>
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</table>

### References for non-confidential data (sorted by study number)

<table>
<thead>
<tr>
<th>Study number</th>
<th>Author(s)</th>
<th>Year</th>
<th>Study title. Study identification number. Report identification number. Company conducting the study.</th>
</tr>
</thead>
</table>


