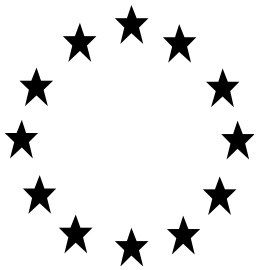
Directive 98/8/EC concerning the placing of biocidal products on the market

Inclusion of active substances in Annex I to Directive 98/8/EC

Assessment Report



1R-trans phenothrin

Product-type 18 (Insecticides, acaricides and products to control other arthropods)

March 2013

Annex I
RMS: Ireland

1R-trans phenothrin PT18

Assessment Report

Finalised in the Standing Committee on Biocidal Products at its meeting on 1 March 2013 in view of its inclusion in Annex I to Directive 98/8/EC

CONTENTS

1. STATEMENT OF SUBJECT MATTER AND PURPOSE

1.1. PROCEDURE FOLLOWED

This assessment report has been established as a result of the evaluation of 1R-trans phenothrin as product-type 18 (insecticides, acaricides and products to control other arthropods), carried out in the context of the work programme for the review of existing active substances provided for in Article 16(2) of Directive 98/8/EC concerning the placing of biocidal products on the market[1], with a view to the possible inclusion of this substance into Annex I or IA to the Directive.

Originally d-Phenothrin was notified as an existing active substance by two separate applicant companies, Sumitomo Chemical (UK) Plc and Endura SpA, under product-type 18.

Commission Regulation (EC) No. 2032/2003 of 4 November 2003[2] lays down the detailed rules for the evaluation of dossiers and for the decision-making process in order to include or not an existing active substance into Annex I to the Directive.

In accordance with the provisions of Article 5(2) of that Regulation, Ireland was designated as Rapporteur Member State to carry out the assessment on the basis of the dossier submitted by the applicant(s). The deadline for submission of a complete dossier for d-Phenothrin as an active substance in Product Type 18 was 30th April 2006 in accordance with Annex V of Regulation (EC) No 2032/2003.

On 26th April 2006, the Irish competent authority received dossiers from the applicants Sumitomo Chemical (UK) Plc and Endura SpA in support of d-Phenothrin as a product-type 18. It was adjudged by the Rapporteur Member State that efforts were made by the applicants to avoid duplicate animal testing in accordance with Article 6 (6) of Commission Regulation (EC) No 2032/2003. The Rapporteur Member State concluded that the dossier supplied by Endura SpA was incomplete for the purpose of the evaluation as a result of substantial critical data gaps in the toxicology section of their application on 31st July 2006. The Rapporteur Member State accepted the dossier supplied by Sumitomo Chemical (UK) Plc as complete for the purpose of the evaluation on 31st July 2006. Sumitomo Chemical (UK) Plc is hereafter referred to as the applicant.

On 29th July 2010, the Rapporteur Member State submitted, in accordance with the provisions of Article 14(4) and (6) of Regulation (EC) No. 1451/2007[3], to the Commission and the applicant a copy of the evaluation report, hereafter referred to as the competent authority report. The Commission made the report available to all Member States by electronic means on 23rd

[1] Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market. OJ L 123, 24.4.98, p.1.
[2] Commission Regulation (EC) No 2032/2003 of 4 November 2003 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market and amending Regulation (EC) No 1896/200. OJ L 307, 24.11.2003, p.1.
[3] Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. OJ L 325, 11.12.2007, p. 3

August 2010. The competent authority report included a recommendation for the inclusion of d-Phenothrin in Annex I to the Directive for PT 18.
In accordance with Article 16 of Regulation (EC) No 1451/2007, the Commission made the competent authority report publicly available by electronic means on 31 August 2010. This report did not include such information that was to be treated as confidential in accordance with Article 19 of Directive 98/8/EC.

In order to review the competent authority report and the comments received on it, consultations of technical experts from all Member States (peer review) were organised by the Commission. Revisions agreed upon were presented at technical and competent authority meetings and the competent authority report was amended accordingly. In particular, the all Member State peer review at the Technical Meeting concluded that the identity and name of the d-Phenothrin, based on the data submitted, should be revised in line with new guidance. As such, the competent authority report was amended accordingly to indicate that the substance recommended for inclusion in Annex I of Directive 98/8/EC was 1R-trans phenothrin. For further information please see the important note in Section 2.1 of this assessment report.

On the basis of the final competent authority report, the Commission proposed the inclusion of 1R-trans phenothrin in Annex I to Directive 98/8/EC and consulted the Standing Committee on Biocidal Product on 1 March 2013.

In accordance with Article 15(4) of Regulation (EC) No 1451/2007, the present assessment report contains the conclusions of the Standing Committee on Biocidal Products, as finalised during its meeting held on 1 March 2013.

1.2. PURPOSE OF THE ASSESSMENT REPORT

This assessment report has been developed and finalised in support of the decision to include 1R-trans phenothrin in Annex I to Directive 98/8/EC for product-type 18. The aim of the assessment report is to facilitate the authorisation in Member States of individual biocidal products in product-type 18 that contain 1R-trans phenothrin. In their evaluation, Member States shall apply the provisions of Directive 98/8/EC, in particular the provisions of Article 5 as well as the common principles laid down in Annex IV.

For the implementation of the common principles of Annex VI, the content and conclusions of this assessment report, which is available at the Commission website[4], shall be taken into account.

However, where conclusions of this assessment report are based on data protected under the provisions of 98/8/EC, such conclusions may not be used to the benefit of another applicant, unless access to these data has been granted.

[4] http://ec.europa.eu/comm/environment/biocides/index htm

1.3. OVERALL CONCLUSION IN THE CONTEXT OF DIRECTIVE 98/8/EC

The overall conclusion from the evaluation is that it may be expected that there are products containing 1R-trans phenothrin for the product-type 18, which will fulfil the requirements laid down in Article 10(1) and (2) of Directive 98/8/EC. This conclusion is subject to:

i. Compliance with the particular requirements in the following sections of this assessment report,

ii. The implementation of the provisions of Article 5(1) of Directive 98/8/EC, and

iii. The common principles laid down in Annex VI to Directive 98/8/EC.

Furthermore, these conclusions were reached within the framework of the uses that were proposed and supported by the applicant (see Appendix II). Extension of the use pattern beyond those described will require an evaluation at product authorisation level in order to establish whether the proposed extensions of use will satisfy the requirements of Article 5(1) and of the common principles laid down in Annex VI to Directive 98/8/EC.

2. OVERALL SUMMARY AND CONCLUSIONS

2.1. PRESENTATION OF THE ACTIVE SUBSTANCE

[IMPORTANT NOTE ON THE ACTIVE SUBSTANCE]:

The active substance originally identified and notified under the biocides review programme for active substances during 2002 was "d-Phenothrin" (CAS 188023-86-1). However, during the evaluation of the active substance and Technical Meeting peer review procedure it was identified that the data submitted in relation to the identity and physical-chemical characteristics of the substance allowed conclusions to be drawn on only a certain form of d-Phenothrin. The form of d-Phenothrin concluded during the review process indicated a substance containing at least 89% w/w of the 1R-trans isomer. Therefore, in accordance with the current ECHA guidance and practice for the identity and naming of substances it was determined that the active substance should be considered as a mono-constituent substance and named ***1R-trans phenothrin (CAS 26046-85-5)***. The evaluation of data during the review process utilised data generated with both d-phenothrin (CAS 188023-86-1) and 1R-trans phenothrin (CAS 26046-85-5) and it was agreed in the Technical Meeting that extrapolation of data from d-Phenothrin to 1R-trans phenothrin was possible for assessment. However, whilst both forms of d-Phenothrin were utilised in the assessment, the conclusion on the identity did not allow conclusions to be drawn regarding any other substance complying with the definition of d-phenothrin in the list of active substances in Regulation (EC) No 1451/2007. Therefore, only 1R-trans phenothrin was included in Annex I to Directive 98/8/EC.

This evaluation refers to the active substance of the form 1R-trans phenothrin (min. 89% w/w of the 1R-trans isomer). However, data were assessed that utilised both mono- and multi-consitiuent forms of the active substance .

2.1.1. Identity, Physico-Chemical Properties and Methods of Analysis

CAS-No.:	1Rtrans isomer: 26046-85-5 The "sum of all isomers": 26002-80-2
EINECS-No.:	1Rtrans isomer: 247-431-2 The "sum of all isomers": 247-404-5
CIPAC:	1Rtrans isomer: No CIPAC No. available. The "sum of all isomers": 356
IUPAC Name:	1Rtrans isomer: 3-phenoxybenzyl (1*R*,3*R*)-2,2-dimethyl- 3-(2-methylprop-1-enyl) cyclopropanecarboxylate

The "sum of all isomers":
(3-Phenoxyphenyl)methyl 2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropane-1-carboxylate

CA Name:

1Rtrans isomer:
Cyclopropanecarboxylic acid, 2,2-dimethyl- 3-(2-methyl-1-propenyl)-, (3-phenoxyphenyl)methyl ester, (1*R*,3*R*)-

The "sum of all isomers":
(3-phenoxyphenyl)methyl 2,2-dimethyl-3-(2-methyl-1-propen-1-yl)cyclopropanecarboxylate

Common name, synonym: (1R)-*trans* phenothrin

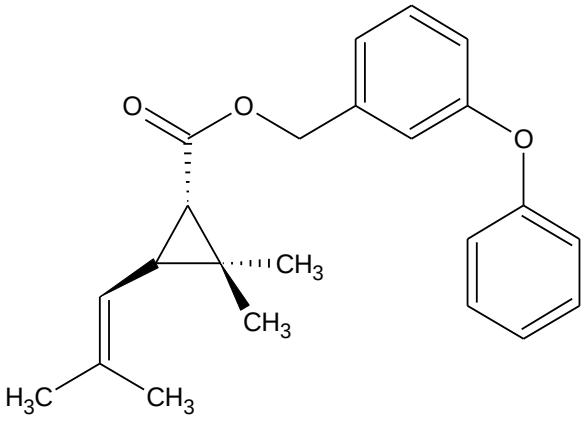
Molecular formula: $C_{23}H_{26}O_3$

Purity: The active substance shall comply with both the following minimum purities:

- Min. 89% w/w 1Rtrans isomer &
- Min. 95.5% w/w "sum of all isomers"

(Physical/chemical properties apply predominately to product containing min. 89% w/w 1-R-trans-Phenothrin and min. 95.5% w/w "sum of all isomers". Toxicological and Environmental studies were conducted on product containing 80% trans isomer mainly)

Structural formula:



(1R)-*trans* phenothrin

Molecular weight (g/mol): 350.46

The physical chemical properties of 1R-trans phenothrin have been determined and are considered to be acceptable for the proposed uses. 1R-trans phenothrin is a pale yellow oily liquid with slight petrol odour. It is virtually insoluble in water and is moderately soluble in organic solvents, both polar and non-polar. The partition data submitted indicates that the molecule will be fat-soluble. The molecule exhibits Newtonian behaviour. The molecule will not classify as flammable, explosive or oxidising.

1R-trans phenothrin is not reactive towards the container material. Physical/chemical properties apply predominately to product containing 89% w/w 1R-trans isomer. The toxicological and environmental studies were predominantly conducted on product containing 80% trans isomer.

The representative product is Sumithrin® 10 SEC and contains 10.5% w/w "sum of all isomers".

2.1.1.1. Analysis of the active substance as manufactured

There are four methods of analysis available for the analysis of the active substance in the technical material as manufactured:

(1) CIPAC 356 consists of two individual methods. The first method is capable of determining the "sum of all isomers" (GC-FID) and the second method is capable of determining the optical isomers (HPLC-UV).
(2) A second GC-FID method is also available for the determination of the "sum of all isomers".
(3) A third GC-FID method is available for the determination of geometric isomers.

Impurities in the technical material were analysed by GC-FID.

2.1.1.2. Formulation analysis

An acceptable validated GC method using MS detection was supplied for analysis of the "sum of all isomers" in the product Sumithrin 10 SEC. The applicant will have to provide a validated method of analysis that is capable of determining (1R)-*trans* phenothrin at the product authorisation stage.

2.1.1.3. Residue analysis

An acceptable validated method using GC with MS detection was supplied for the analysis of residues of d-phenothrin in drinking water to a LOQ of 0.10µg/L. The method has been validated using three ions with an m/z > 100. The method determines the "sum of all isomers".

The applicant needs to provide a method of analysis for surface water. The method should be provided before product authorisation.

An acceptable validated GC method using MS detection was supplied for analysis of residues of d-phenothrin in air to a LOQ of 0.001mg/m^3. The method has been validated using three ions with an m/z > 100. The method determines the "sum of all isomers".

A GC-MS method of analysis for soil has also been provided. However, the GC-MS method has only been validated using two ions with an m/z > 100. The method needs to be validated using a 3rd ion with m/z > 100. The method determines geometric isomers and the "sum of all isomers".
The applicant should provide a fully validated method of analysis for residues in soil before product authorisation.

It is considered that methods for residues of 1R-trans phenothrin in food of plant and animal origin and in body fluids and tissues are not applicable for this submission. No data required.

2.1.2. Intended Uses and Efficacy

The assessment of the biocidal activity of the active substance demonstrates that it has a sufficient level of efficacy against the target organism(s) and the evaluation of the summary data provided in support of the efficacy of the accompanying product, establishes that the product may be expected to be efficacious.

In addition, in order to facilitate the work of Member States in granting or reviewing authorisations, and to apply adequately the provisions of Article 5(1) of Directive 98/8/EC and the common principles laid down in Annex VI of that Directive, the intended uses of the substance, as identified during the evaluation process, are listed in Appendix II.

2.1.2.1. Field of use envisaged / Function and organism(s) to be controlled

Insecticide (Product-Type 18).

1R-trans phenothrin is intended for indoor use only by professional operators, to control crawling and flying insects in areas such as trains, trucks, hospitals, hotels and other public buildings.

Used for control of crawling insects: Cockroaches; *e.g*. German cockroaches *(Blattella germanica)*, American cockroaches *(Periplaneta Americana)* and Oriental Cockroaches *(Blatta Orientalis)*. Used for control of flying insects: House flies (*Musca domestica)* and mosquitoes (*Culicidae)*

2.1.2.2. Effects on target organism(s)

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.

Submitted efficacy data on d-Phenothrin, in support of 1R-trans phenothrin, indicates effects on different species with different exposure scenarios at a proposed maximum concentration range of 10-33 mg a.i./m^2. Efficacy was demonstrated against cockroaches at the maximum proposed application rate of 33 mg a.i./m^2. Lethality (knockdown) and flushing out are the only recognised effects, and *in situ* concentration-dependence of the effect has been demonstrated; however the threshold concentration is species dependant. Should Annex I inclusion be granted, comprehensive confirmatory data in relation to the minimum effective dose level required to exert the desired effect on the target organisms must be provided at the product authorisation stage.

2.1.2.3. Humaneness

Not applicable.

2.1.2.4. Resistance

The applicant has provided comment on resistance development to pyrethroid insecticides in general and 1R-trans phenothrin (See Doc IIA). The product should only be used when there is a crawling and flying insect infestation and should be used in areas where cockroaches are sighted. These conditions and a range of risk mitigation measures coupled with professional use should limit any potential for resistance to occur. The possible development of resistance should be considered at the product authorisation stage with appropriate risk management strategies.

2.1.3. Classification and Labelling

2.1.3.1. Proposal for the classification and labelling of the active substance

Directive 67/548/EEC

Hazard symbol: (for labelling)	N	Dangerous for the environment
Indication of danger:	Dead Fish and Tree	
Risk Phrases: (for labelling)	R50/53	Very toxic to aquatic organisms, and may cause long-term adverse effects in the aquatic environment
Safety Phrases: (for labelling)	S57 S60 S61	Use appropriate containment to avoid environmental contamination This material and/or its container must be disposed of as hazardous waste Avoid release to the environment. Refer to special instructions/Safety data sheets.

CLP Reg No. (EC) 1272/2008

Pictogram: (for labelling)	Acute 1 and Chronic 1 based on aquatic endpoints. 
Signal word:	Warning
Hazard Statements:	H410: Very toxic to aquatic life with long lasting effects.

(for labelling)	
Precautionary Statements: (for labelling)	P273: Avoid release to the Environment P391: Collect spillage P501: Dispose of contents/container to hazardous waste
M Factors	M factor 100 acute ($0.001<L(E)C_{50}\leq 0.01$) M factor 10 chronic ($0.001<NOEC\leq 0.01$) not rapidly degradable

Justification for the proposal:

Physical-Chemical Properties:
The molecule will not classify as flammable, explosive or oxidising for classification under either Directive 67/548/EEC or Regulation No. (EC) 1272/2008. No classification required.

Human Health:
No classification required for classification under either Directive 67/548/EEC or Regulation No. (EC) 1272/2008.

Environment:
Based on the toxicity of d-Phenothrin to aquatic organisms ($LC_{50}/EC_{50} \leq 1$ mg/L in fish, invertebrates and algae) 1R-trans phenothrin is proposed to classify as R50/53, very toxic to aquatic organisms, and may cause long-term adverse effects in the aquatic environment. The lowest acute ecotoxicity endpoint was the 96-h LC_{50} of 0.0027mg/l in rainbow trout.

Based on the toxicity of d-Phenothrin to aquatic organisms ($LC_{50}/EC_{50} \leq 1$ mg/L in fish, invertebrates and algae) 1R-trans phenothrin is proposed to classify as H410: Very toxic to aquatic life with long lasting effects. The lowest acute ecotoxicity endpoint: fish 96h LC_{50} 0.0027 mg/L. The lowest chronic ecotoxicity endpoint: Algae 72h NOErC 0.0036 mg/L.

2.1.3.2. Proposal for the classification and labelling of the product(s)

Directive 99/45/EC

Hazard symbol: (for labelling)	Xi, N	Irritant, Dangerous for the environment
Indication of danger:	Xi, Dead Fish and Tree	
Risk Phrases: (for labelling)	R41 R50/53*	Risk of serious damage to eyes Very toxic to aquatic organisms, and may cause long-term adverse effects in the aquatic environment
Safety Phrases: (for labelling)	S26 S39 S57	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Wear eye/face protection Use appropriate containment to avoid environmental

	S60 S61	contamination This material and/or its container must be disposed of as hazardous waste Avoid release to the environment. Refer to special instructions/Safety data sheets.
* LC50 or EC50 value ("L(E)C50") of substance classified as N, R50-53 (mg/l)	Classification of the preparation	

CLP Reg No. (EC) 1272/2008

Pictogram: (for labelling)	
Signal word:	Warning
Hazard Statements: (for labelling)	H410: Very toxic to aquatic life with long lasting effects. H318: Causes serious eye damage
Precautionary Statements: (for labelling)	P280: Wear eye/face protection P305+351+313: IF IN EYES: Rinse continuously with water for several minutes. Get medical advice/attention. P273: Avoid release to the Environment P391: Collect spillage P501: Dispose of contents/container to hazardous waste

Justification for the proposal:

Physical-Chemical Properties:
The molecule when formulated into the representative product Sumithrin 10 SEC will not classify as flammable, explosive or oxidising for classification under either Directive 99/45EC or Regulation No. (EC) 1272/2008. No classification required.

Human Health
In the rabbit eye irritation study Sumithrin® 10 SEC caused persistent corneal opacity evident on day 21 of the study. On the basis of ocular lesions still evident at the end of the observation period the product requires classification R41 (Risk of serious damage to eyes) or H318 (Causes serious eye damage).

Environment
Sumithrin contains 10.5% w/w 1R-trans phenothrin, which classifies as R50/53, very toxic to aquatic organisms, and may cause long-term adverse effects in the aquatic environment, based on its acute toxicity to aquatic organisms ($LC_{50}/EC_{50} \leq 1$ mg/L in fish, invertebrates and algae). No acute toxicity studies on the formulation were submitted, therefore classification of the product is based on the methods outlined in Directive 2006/8/EC, which indicates that because Sumithrin contains ≥0.25% w/w active ingredient, it warrants classification as N, R50/53.

Sumithrin contains 10.5% w/w 1R-trans phenothrin, which classifies as H410: Very toxic to aquatic life with long lasting effects, based on its acute and chronic toxicity to aquatic organisms and the proposed M-factors.

Additional labelling:
This product should have a label stipulating the following:

- Wear suitable protective clothing and gloves and eye/face protection (when diluting).
- Wear suitable protective clothing (coveralls) and spray mask when applying through power of knapsack sprayer.
- Wear approved respiratory equipment and eye protection (goggles) when applying through the 'Microgen' to conform to BS 2091 (or equivalent ULV equipment).
- Do not breathe spray mist. Otherwise wear respiratory protective equipment and eye protection (see HSE Guidance Booklet HS (G) 53: "Respiratory Protective Equipment - a practical guide for users"). However, engineering controls may replace personal protective equipment if a COSHH assessment shows they provide an equal or higher standard of protection.
- Do not contaminate foodstuffs, eating utensils or food contact surfaces. Cover water storage tanks before application.
- This material and its container must be disposed of in a safe way.
- When using do not eat, drink or smoke.
- Unprotected persons and animals should be kept away from treated areas until surfaces are dry.
- Do not apply directly to animals.
- Remove or cover all fish tanks and bowls before application.
- Do not contaminate ground, water bodies or watercourses with chemicals or used container.

Directive 1999/45/EEC may not allow a sufficient description of the special risks which may arise during the use of biocidal products. Thus, in addition to the phrases listed above, labelling, as specified in Article 20(3) of Directive 98/8/EC, might become necessary at Member State level.

2.2. SUMMARY OF THE RISK ASSESSMENT

2.2.1. Human Health Risk Assessment

2.2.1.1. Hazard Identification and Effects Assessment

Evaluator's Note:
The technical material supported by the notifier (Sumitomo) relates to 1R-trans phenothrin containing ~98% of the *trans* isomers and 2% the *cis* isomers. Studies were conducted with 1R-trans phenothrin or with a mixture of *trans* and *cis* d-phenothrin isomers with a *trans*:*cis* isomeric ratio of 80:20 or 98:2. With regard to the rate of toxicological metabolism, studies performed with the 80:20 *trans*:*cis* isomeric mix were deemed acceptable to support 1R-trans phenothrin products with a *trans* isomer content greater than or equal to 80% and a *cis* isomer content less than or equal to 20%, since the information available in the dossier shows that the *trans* isomer degraded more rapidly than the *cis* isomer. Therefore environmental exposure calculations for the 98:2 isomeric ratio that use degradation rate data pertaining to the 80:20 isomeric ratio would be conservative, since the 98:2 composition would be expected to degrade more rapidly than the 80:20 composition due to its higher *trans* content.

1R-trans phenothrin is a class 1 pyrethroid. It 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 that leads to repetitive firing of sensory nerve endings that may progress to hyperexcitation of the entire nervous system. At high pyrethroid concentrations conduction block can occur and the insects die.

Toxicokinetics
Following single or repeat oral administration, (1R,*trans*)- and (1R,*cis*)-[benzyl-^{14}C]-Phenothrin showed rapid and complete elimination. Tissue residues were generally very low, however, ^{14}C-concentrations in fat were slightly higher as compared with those in other tissues. The major metabolic reactions for both isomers were oxidation at 4'-position of the alcohol moiety and at methyl groups of the acid moiety, cleavage of the ester linkage, and conjugation with glucuronic acid, sulphuric acid and glycine. Ester metabolites were found in faeces, while the ester-cleaved metabolites were found mainly in urine. The sulphate of 3-(4'-hydroxyphenoxy) benzoic acid (4'-OH-PBacid) was a major metabolite. No remarkable sex-difference was observed in the ^{14}C-excretion profiles, ^{14}C-tissue residues and amounts of metabolites. There was no substantial difference in metabolism between the single dose group and the repeated dose group. Oral absorption of 1R-trans phenothrin is estimated to be 60%.

Dermal penetration
The absorption of 1R-trans phenothrin (Sumithrin) from a nominal 1% w/v formulation, (actual content 10g 1R-trans phenothrin/l) has been measured *in vitro* through human epidermis. The formulation was applied to the epidermal membranes at a rate of 20 µl/cm^2; all applications were left unoccluded for an exposure period of 24 hours. The amount of test material found in the receptor fluid after 24 hours (0.86%) and the amount of test material remaining in the skin after 24 hours (3.65%) are added to give a worst case dermal absorption of 4.5% of the applied dose.

Acute toxicity
d-Phenothrin, used in tests to support of 1R-trans phenothrin, showed low acute oral, dermal and inhalation toxicity in the rat. In the rabbit d-Phenothrin produced no skin irritation and a minimal eye irritation potential. Under the conditions of the maximization method of Magnusson and Kligman, d-Phenothrin showed no potential to induce skin sensitisation in the Guinea-pig. As such it is considered that 1-trans phenothrin does not meet the criteria for classification according to Annex VI of Commission Directive 2001/59/EC.

Repeat dose toxicity
Repeat dose toxicity studies are available in the mouse, rat and dog. Consistent treatment related findings were seen in the liver. Changes, indicative of an adaptive response to repeat administration typically included increased liver weight and occasional hepatocellular hypertrophy and elevated alkaline phosphatase levels. Chronic administration of d-Phenothrin at very high dose levels (*ca.* 80 mg/kg bw) resulted in a mild anemia in dogs. There were no other consistent changes that could be directly attributed to d-Phenothrin toxicity.

The dog would appear to be slightly more sensitive to liver changes than the rat. An overall NOAEL of 8.2 mg/kg bw can be set from the chronic dog study.

No studies are available investigating repeat dose toxicity via the dermal route. As 1R-trans phenothrin has shown very low dermal acute toxicity it is considered appropriate to extrapolate from oral repeat dose toxicity data when assessing risk from dermal exposure.

No adverse effects of exposure were seen in rats exposed for 13 weeks to d-Phenothrin at achieved concentrations of up to 0.104 mg/1. Histological changes in thyroid, adrenal and nasal turbinates seen in rats exposed to 0.291 and 1.066 mg/1 d-Phenothrin were of unknown toxicological significance.

Genotoxicity
Results obtained from *in vitro* and *in vivo* test systems on d-Phenothrin indicate that the substance does not exhibit any mutagenic properties or cause chromosomal or DNA damage.

In a mutagenicity test with Escherichia coli (WP2 uvr) and Salmonella typhimurium (TA 1535, TA 1537, TA 1538, TA 98, and TA 100) with and without metabolizing enzyme system (S9 mix) d-Phenothrin was not mutagenic. In an *in vitro* cytogenicity test with Chinese hamster ovary cells with and without metabolic activation no significant increase in chromosomally aberrant cells was observed. In a mammalian system (V79 Chinese hamster cells) both in the presence and absence of S9 mix, the test compound did not induce any increases in the mutation frequency as compared with those of the vehicle controls. On the other hand, the positive control chemicals both induced marked increases in the mutation frequency.
In an *in vitro* cytogenicity test with Chinese hamster ovary cells with and without metabolic activation no significant increase in chromosomally aberrant cells was observed.
.

Carcinogenicity
Carcinogenicity and long term toxicity of d-Phenothrin have been investigated in the rat and the mouse. No treatment related change was seen in the incidence of tumours in either species.

The NOEL in the rat was 1000 ppm (equivalent to 47 mg/kg/day for males and 56 mg/kg/day for females). The NOEL in the mouse was at least 300 ppm in males (equivalent to ca. 40 mg/kg bw/day) and 1000 ppm in females (equivalent to 164 mg/kg bw/day). In both rats and mice increased liver weight and periacinar hepatocytic hypertrophy were seen; microscopic changes were evident in males only. In addition, male rats showed a higher incidence of cystic dilatation of the sinuses of the mesenteric lymph nodes and female rats showed an initial suppression in body weight development. The overall NOAEL for long term toxicity was 40 mg/kg bw/day.

Reproductive toxicity
Oral administration of d-Phenothrin at 3000 mg/kg bw/day to pregnant female rats from Day 6 to 15 of gestation was associated with reduced food intake and reduced maternal weight gain during treatment and with increased water intake both during and after treatment. Foetal weight was significantly reduced and placental weight was increased compared with both the concurrent controls and the background

control values. In this group 13.5% of foetuses from 10 litters had weights less than 2.7 g. In Groups 2 and 3 (300 and 1000 mg/kg bw/day), foetal and placental weights were not significantly different from the control values. A dose related increase in the incidence of 14th rib was seen from the low to high dose. This effect is in the presence of limited maternal toxicity at the top dose, and no maternal toxicity at the mid and low doses, suggests possible developmental effects of the test substance.

Oral administration of d-Phenothrin at 100, 300 and 500 mg/kg bw/day to pregnant female rabbits from Day 7 to 19 of gestation resulted in clear maternal toxicity. Slight maternal toxicity was evident at 300 mg/kg bw/day with clear maternal toxicity again evident in the 100 mg/kg bw/day group. This dose level was considered the LOAEL for maternal toxicity. Abortions, one in the controls, three at 100 mg/kg bw/day, one at 300 mg/kg bw/day and four at 500 mg/kg bw/day occurred in this study. Single incidences of spina bifida at 100 mg/kg bw/day and microphthalmia at 300 mg/kg bw/day also occurred. In addition, 4 incidences of hydrocephaly occurred in 3 litters at the highest dose. In historical controls microphthalmia was seen in 3 animals from 3 litters and spina bifida was seen in 7 animals from 7 litters by contract hydrocephaly was seen in 6 animals from 2 litters. Although serious malformations occurred in the historical control and abortions were seen in the historical and concurrent controls it cannot be conclusively stated the incidences in this study were not treatment related. The study is equivocal regarding embryotoxic / teratogenic effects.

In an additional, limited, rabbit developmental study submitted in 2009 pregnant rabbits were dosed at 0 and 750 mg/kg bw/d from day 6 to day 28 of gestation. Although the dose was high and elicited excessive maternal toxicity malformations and abortions noted in the previous study were not replicated. These findings suggest the malformations seen in the previous study may not have been treatment related.

The overall NOAEL for embryo toxicity, foetotoxicity and teratogenicity in rats was found to be 300 mg/kg bw/day. The NOAEL for embryo toxicity, foetotoxicity and teratogenicity in rabbits was found to be 30 mg/kg bw /day.

Continuous dietary administration of d-Phenothrin at up to 1000 ppm to male and female rats throughout two generations and up to maturation of a third generation had no adverse effect upon somatic growth, development and reproductive performance. At 3000 ppm, bodyweight and reproductive performances throughout the study showed no consistent, significant response to treatment, and selected F2 animals reared to maturation were in all respects comparable with the control group. However, F0 and F1 females and selected F2B male and female weanlings showed a slight, but consistent increase in relative liver weight. The overall NOEL in this 2 generation study was 1000 ppm (the lowest equivalent intake was seen in F1 females at first *pairing and was ca. 60 mg/kg bw/day).*

The maximum dose of 3000 ppm induced minimal toxicity (decreased body weight gain 4-6%). This result allied with the results from the sub-chronic /chronic and developmental studies suggest that a higher dose may have been appropriate to fully elucidate the substances possible effects of fertility.

Neurotoxicity

In a neurotoxicity study groups of 10 male and 10 female HannRcc: WIST(SPF) rats were administered one oral dose of 0 (control), 200, 600 and 2000 mg d-phenothrin /kg body weight in corn oil. Any toxic effects were recorded over a14 day observation period.

All animals survived their scheduled study period. General clinical observations, FOB evaluation including detailed clinical symptoms, Preyer's reflex, grip strength measurements in the fore- and hind paws, landing food splay, body temperature, and locomotor activity revealed no test item-related effects.

The single oral administration of Sumithrin at doses up to 2000 mg/kg resulted in no toxicologically significant findings. Food consumption and body weight development were not affected by treatment with test item. Examination of the selected nervous organs and tissues revealed no test item-related effects.

D-phenothrin was found not to illicit neurotoxicological effects after a single dose under the conditions tested.

Human data
Medical surveillance of manufacturing plant personnel revealed no occupation-related problems and there were no findings attributable to exposure with pyrethroids.

ARfD (acute reference dose) (AEL acute)
A review of the toxicological database indicates that developmental toxicity is a relevant endpoint for ARfD setting. In the rabbit oral development toxicity study clear maternal toxicity is evident at 100 mg/kg bw/day. In addition, an increased level of abortions is also apparent at this dose. The NOAEL for maternal embryo toxicity, foetotoxicity and teratogenicity in this study was found to be 30 mg/kg bw/day. A safety factor of 100 (10 for interspecies and 10 for intraspecies) is considered sufficient and an oral absorption value of 60% will apply in the case of the *AEL_{acute} However, oral absorption correction value is not normally applied to the ARfD* Therefore, a systemic ARfD of 0.3 mg/kg bw/day is proposed and a *AEL_{acute} of 0.18mg/kg bw/day.*

Acceptable operator exposure level (AOEL) AEL_{medium}
The NOAEL of 8.2 mg/kg bw/day from the dog 52 week chronic toxicity study is proposed as the basis of AOEL setting. The dog was shown to be the most sensitive species and the NOAEL in the study was the lowest NOAEL following repeat dose administration in mice, rats and dogs. Further, the liver finding seen at the LOAEL (diffuse hepatocellular enlargement) is considered characteristic for the type of toxicity after repeat administration. Given that the NOAEL was based on liver changes, a default safety factor of 100 is considered sufficiently conservative. An oral absorption value of 60% will apply. Therefore, a systemic AOEL of 0.05 mg/kg bw/day for subchronic exposure is proposed.

$AEL_{chronic}$
Although the $AEL_{chronic}$ is normally derived from rodent chronic or mulitigneration studies, however, the dog has proven more sensitive to the test substance in the studies provided. On this basis the NOAEL of 8.2 (mg/kg bw/day) from the dog 12 month study has been chosen. A safety factor of 100 is deemed appropriate and oral absorption value of 60% will apply. Therefore, a systemic $AEL_{chronic}$ of 0.05 mg/kg bw/day for chronic exposure is proposed.

Acceptable daily intake (ADI)
The acceptable daily intake for humans is normally derived from the NOAEL in long term toxicity/ carcinogenicity studies in rodents. However, as the dog was more sensitive than rodents to d-Phenothrin treatment and to avoid an ADI that is higher than the AOEL it is proposed that the NOAEL from the chronic dietary toxicity study in dogs (8.2 mg/kg bw /day) be used to set the ADI. Given that the NOAEL was based on adaptive liver changes a default safety factor of 100 is considered sufficiently conservative. Therefore, an ADI of 0.08 mg/kg bw/day is proposed.

Margin of Safety (MOS)
The margin of safety based on the subchronic internal systemic NOAEL, as discussed above, will be 8.2 mg/kg bw/day with a (MOS) of 100.

Drinking water limit
Exposure through drinking water should account for no more than 10% of the ADI. If it is assumed that the average daily consumption of water amounts to 2 liter per person (60 kg bw), a drinking water limit of ((60 kg bw x 0.08 mg/kg bw/d) / 10) / 2 litre = 0.24 mg/l can be established.

2.2.1.2. Exposure Assessment and Risk Characterisation

Product information in support of an evaluation of 1R-trans phenothrin for inclusion in Annex I to the 'Biocidal Products' Directive 98/8/EC, including an approach to exposure and risk assessment for 1R-trans phenothrin is presented within Documents IIB and IIC. The product characteristics may be summarised as follows;

Sumithrin® 10 SEC
Sumithrin® 10 SEC is a solubilised emulsion concentrate containing 10.5% 1R-trans phenothrin which is intended to be used by professional operators to control crawling and flying insects in areas such as trains, trucks, hospitals, hotels and other public buildings. Sumithrin® 10 SEC will not be in direct contact with food.

There is one substances of concern, Sorpol SM 100PM, to be taken into account in the human health risk assessment.

Professional exposure – Sumithrin 10 SEC
The scenarios assessed for the professional operator include both the mixing/loading and application phases and are based on reasonable worst case use with respect to duration and exposure range. Cleaning of the apparatus has not been included as it is not commonly performed. The application equipment is normally dedicated to one particular product with a range of uses (as stated in the TNsG Part 2 June 2002, page 112).

The risk assessments were conducted based on the TNsG Version 2002 and using ConsExpo Version 4.1.

Total systemic professional exposure MOE (TNsG Spray model 1, Misting model 2)

Assessment		**Default Values used**	**Systemic Exposure (mg/kg bw/day)**	**Systemic NOAEL (Adjusted) mg/kg bw/day**	**MOE**
TNsG models	Knapsack Sprayer Surface Application for Crawling Insects - Tier 1 (75th percentile)	Minimal Clothing (100%), no gloves, 4.5% dermal penetration	0.021	5.0	238
	Knapsack Sprayer Surface Application for Crawling Insects - Tier 2 (75th percentile)	Impermeable coveralls (5%), Gloves (PF10), 4.5% dermal penetration	0.0048	5.0	889
	ULV Sprayer Surface Application for Crawling Insects – Tier 1 (75th percentile)	Minimal Clothing (100%), no gloves, 4.5% dermal exposure	0.25	5.0	20
	ULV Sprayer Surface Application for Crawling Insects – Tier 2 (75th percentile)	Coveralls (20%), Gloves model default, RPE 4.5% dermal penetration	0.036	5.0	139

Total systemic exposure percentage of AOEL (TNsG Spray model 1, Misting model 2)

Assessment	**Default Values used**	**Systemic Exposure (mg/kg bw/day)**	**Systemic AOEL mg/kg bw/day**	**Exposure as a percentage of the AOEL**

TNsG models	Knapsack Sprayer Surface Application for Crawling Insects - Tier 1 (75th percentile)	Minimal Clothing (100%), no gloves, 4.5% dermal exposure	0.021	0.05	0.42
	Knapsack Sprayer Surface Application for Crawling Insects - Tier 2 (75th percentile)	Impermeable coveralls (5%), Gloves model default, 4.5% dermal penetration	0.0048	0.05	0.112
	ULV Sprayer Surface Application for Crawling Insects – Tier 1 (75th percentile)	Minimal Clothing (100%), Gloves model default, 4.5% dermal exposure	0.25	0.05	5
	ULV Sprayer Surface Application for Crawling Insects – Tier 2 (75th percentile)	Coveralls (20%), Gloves Model default, RPE 10, 4.5% dermal penetration	0.036	0.05	0.72

Non-Professional Exposure – Sumithrin 10 SEC

There should be no occurrence of non-professional exposure. The product should be allowed to dry before entry to the room is permitted.

Indirect Exposure as a Result of Use – Sumithrin 10 SEC

Indirect exposure could result from one of the following:-

- Inhalation of volatilised residues (acute/ sub-chronic)
- Dermal contact of contaminated surfaces (acute)
- Ingestion from hand to mouth contact (acute)
- Exposure from coveralls. This exposure was not assessed any further as the coveralls will be laundered or disposed on-site. No coveralls or PPE will be taken home.

As a worst case scenario the exposure to a child (1 year old; 10 kg) was evaluated using ConsExpo Version 4.1.

Child Exposure Following ULV Sprayer Surface Application for Crawling Insects Scenario, Child Exposure Following Knapsack Sprayer Air Space Application for Flying Insects, Child Exposure Following Knapsack Sprayer Air Space Application for Flying Insects

Child Exposure Following Crack and Crevice Application

Combined Indirect Exposure – Sumithrin 10 SEC

Exposure Scenario		Indirect exposure (ConExpo)							
		estimated inhalation uptake [mg/kg bw day]	estimated dermal uptake [mg/kg bw day]	estimated oral uptake [mg/kg bw day]	estimated total uptake [mg/kg bw day]	Relevant NOAEL/LOAEL [mg/kg.bw day] - Reference Value AEL (acute or medium or chronic)	AF MOEref	MOE	Exposure /AEL
- child exposure following ULV sprayer surface application for crawling insects (ConEXpo)	Intended use	0.0000	0.995	0.0696	1.06	18	100	17	6
- child exposure following knapsack sprayer space application for flying insects (ConExpo)	Intended use	0.0000	1.02×10^{-3}	5.44×10^{-7}	1.02×10^{-3}	18	100	17637	0.006
– Child Exposure Following Knapsack Sprayer Surface Application for Crawling Insects		0.0000	1.78×10^{-3}	1.24×10^{-5}	1.79×10^{-3}	18	100	10000	0.01
Tier 1 (Worst Case) - child exposure following trigger spray application for crack and crevice (ConEXpo)	Intended use	0.000	2.5×10^{-2}	2.3×10^{-5}	2.5×10^{-2}	0.18	18	720	0.14

Indirect exposure

Indirect/ Accidental Exposure					
		Route	Body dose (mg/kg bw/d)	Exposure as a percentage of AEL	Repeated dose toxicity (NOAEL = 30.0 mg/kg bw/day)

					adjusted MOE
Child Exposure Following ULV Sprayer Surface Application for Crawling Insects	No PPE or RPE; Dermal penetration 4.5%; Oral absorption 60%	Dermal and oral	1.06	588%	17
Child Exposure Following Knapsack Sprayer Air Space Application for Flying Insects	No PPE or RPE; Dermal penetration 4.5%; Oral absorption 60%	Dermal and oral	$1.02x10^{-3}$	0.6%	17637
Child Exposure Following Knapsack Sprayer Surface Application for Crawling Insects	No PPE or RPE; Dermal penetration 4.5%; Oral absorption 60%	Dermal and oral	$1.78x10^{-3}$	1%	10000
child exposure following trigger spray application for crack and crevice (ConEXpo)	No PPE or RPE; Dermal penetration 4.5%; Oral absorption 60%	Dermal and oral	$2.5x10^{-2}$	14%	720

*Compared to the (AEL_{acute}) 0.18 mg/kg bw

Conclusion

The potential for indirect exposure following application of Sumithrin 10 SEC to a child has been considered as a worst case. The product when limited to crack and crevice treatment yields a safe exposure level post application exposure to children and is not expected to represent a risk.

2.2.2. Environmental Risk Assessment

2.2.2.1. Fate and Distribution in the Environment

Evaluator's Note:
The technical material supported by the notifier (Sumitomo) relates to 1R-trans phenothrin containing ~98% of the *trans* isomers and 2% the *cis* isomers. Studies were conducted with 1R-trans phenothrin or with a mixture of *trans* and *cis* d-phenothrin isomers with a *trans*:*cis* isomeric ratio of 80:20 or 98:2. With regard to the rate of environmental degradation, studies performed with the 80:20 *trans*:*cis* isomeric mix were deemed acceptable to support 1R-trans phenothrin products with a *trans* isomer content greater than or equal to 80% and a *cis* isomer content less than or equal to 20%, since the information available in the dossier shows that the *trans* isomer degraded more rapidly than the *cis* isomer. Therefore environmental exposure calculations for the 98:2 isomeric ratio that use degradation rate data pertaining to the 80:20 isomeric ratio would be conservative, since the 98:2 composition would be expected to degrade more rapidly than the 80:20 composition due to its higher *trans* content.

Biodegradation

In a ready biodegradability study, conducted according to the requirements of OECD Test Guideline 301F, d-Phenothrin was found to be not biodegradable under the test conditions within the 28-day incubation period. d-Phenothrin at a concentration of 30 mg/l attained only 1% degradation after 28 days. The study is considered valid, with the toxicity control, containing both d-Phenothrin and the reference item sodium benzoate, showing no inhibitory effect on the activity of activated sludge microorganisms. In the procedure controls, the reference item sodium benzoate was biodegraded by an average of 87% on exposure Day 14, and reached an average biodegradation rate of 91% by the end of the test (Day 28). d-Phenothrin is not readily biodegradable.

d-Phenothrin biodegraded in soil under laboratory aerobic conditions. The weight of evidence from three soils supports a preferred biodegradation pathway involving hydrolytic cleavage of the ester linkage in d-phenothrin, as indicated by the detection of 3-phenoxybenzyl alcohol and 3-phenoxybenzoic acid. Concomitant metabolite formation from this pathway resulting in substances containing, or derived from, the cyclopropane ring portion of d-phenothrin would also be anticipated. However such metabolites were not detected. In some cases this was due to inappropriate radiolabelling of the parent molecule but in one case where [cyclopropyl-^{14}C]-d-*trans*-phenothrin was used there was an inexplicable absence of ester cleavage products. The longest measured DT_{50} value for d-phenothrin under aerobic conditions was equivalent to 27.2 days at 12 ºC.

Degradation was also investigated under flooded conditions in two of the soils used for the aerobic investigations. The metabolite detection pattern was identical to that observed in the same soils under aerobic conditions (formation of 3-phenoxybenzyl alcohol and 3-phenoxybenzoic acid), indicating that degradation of d-phenothrin under flooded conditions also proceeds via cleavage of the ester linkage. It was not possible to get information about possible ester cleavage products containing, or derived from, the cyclopropane ring portion of d-phenothrin due to the position of radiolabelling of the test substances at the methylene carbon adjacent to the phenoxybenzyl portion of the molecule.

The rate of degradation in soil under flooded conditions was much slower than in the same soils under aerobic conditions. DT_{50} values extrapolated to 12 ºC were 36.8 and 114.0 days for *trans*-phenothrin, and 57.2 and 200.9 days for *cis*-phenothrin.

Aquatic biodegradation of d-*trans*-phenothrin was investigated in a laboratory study using one water-sediment system obtained from a river. As was found to be the case in most of the soil studies, the degradation pathway proceeded via cleavage of the ester linkage in the test substance. Three main metabolites were detected, with 3-phenoxybenzoic acid exceeding 10% of applied radioactivity to

reach a maximum level in the total system of 18.6% of applied radioactivity. The other identified metabolites were 4'-OH-PBacid (3-(4-hydroxyphenoxy)benzoic acid) and 4'-OH-t-PHN (3-(4-hydroxyphenoxy)benzyl (1R,3R)-2,2-dimethyl-3-(2-methyl-1-propenyl)cyclopropanecarboxylate), which reached maximum respective whole-system levels of 9.7% and 7.9% of applied radioactivity. Potential metabolite formation deriving from the cyclopropane ring portion of d-phenothrin could not be detected due to the position of radiolabelling of the test substance in the benzyl ring of the phenoxyphenyl portion of the molecule.

The rate of degradation of d-*trans*-phenothrin in the aquatic system as a whole (water and sediment combined) clearly followed biphasic kinetics and was best described by the DFOP model (double first order parallel), giving an extrapolated DT_{50} value at 12 ºC of 19.15 days and a DT_{90} value >1000 days. The DFOP DT_{90} value is presented as >1000 days, since the actual value is extrapolated far beyond the duration of the study and cannot be reliably estimated. The rate of decline in the whole system slowed to almost a complete stop after about 20 days. With regard to metabolites, a DT_{50} value of 50.74 days (single first order) was derived for the degradation of 3-phenoxybenzoic acid in the whole system at 25 ± 2 ºC (corresponding to a DT_{50} value of 143.6 days at 12 ºC). It was not possible to derive reliable values for the other metabolites.

Abiotic degradation

Hydrolysis of the active substance, d-Phenothrin, is not expected to be a significant process in the environment. At pH 5 and 7 the test material is essentially stable as rate constants (and subsequent DT_{50} values) were determined by extrapolation way beyond the range of recorded data points observed during the test. Resultant r^2 values at pH 5 and 7 indicate the poor extrapolation beyond the data points. At pH 9 the DT_{50} for the test material was determined at 91 days and 120 days at 25 °C, with an r^2 of 0.8986 and 0.9000 for the benzyl and cyclopropyl-1 radiolabels, respectively. The corresponding normalised values at 12 °C are 257 and 340 days for the benzyl and cyclopropyl-1 radiolabels, respectively.[5] The main hydrolysis process involved the formation of d-t-CRA and PBalc. The other main process for the oxidation of d-trans-Phenothrin involved reactions on the propenyl group forming Cp2 or Bz2, which then underwent further degradation forming CHO-PH. Cp2/Bz2 and CHO-PH could both then undergo hydrolysis forming d-t-CRA/PBalc related components. CHO-PH was shown to be the major product in the dark controls, in pH 5 buffer, from an aqueous photolysis study of d-trans-Phenothrin.
d-Phenothrin is rapidly photolysed in sunlight with a DT_{50} of 9.1 hours and 13.9 hours for the benzyl and cyclopropyl radiolabelled test substance, respectively at 25 °C. Degradation proceeds from oxidative processes. When irradiated the major products form by reactions involving singlet oxygen and ozone. Cis/trans isomerization was not found to be a significant process. Overall, d-Phenothrin is readily degraded in aqueous solution under irradiated conditions, mainly by two pathways involving: a) cleavage of the propenyl double bond and b) by “ene” addition of singlet oxygen to carbon 1’ on the propenyl group. The primary degradates observed in light exposed samples were:

1. 3-phenoxybenzyl (1R, 3R)-2,2-dimethyl-3-formyl cyclopropanecarboxylate (CHO-PH) (5.9%),
2. 3-phenoxybenzyl (1R, 3R)-2,2-dimethyl-3-[(1RS)1-hydroperoxy-2-methylprop-2-enyl] cyclopropanecarboxylate (HOO-PHN) (3.3%),
3. 3- phenoxybenzyl (1R, 3R)-2,2-dimethyl-3-[(1RS)-hydroxy-2-methylprop-2-enyl]cyclopropanecarboxylate (HO-PHN) (21.1%),
4. 3-phenoxybenzyl (1R, 3R)-2,2-dimethyl-3-(2-methyl-l-oxo-prop-2-enyl)cyclopropanecarboxylate (Keto-PHN) (1.7%),
5. 3-Phenoxybenzyl alcohol (PBalc) (20.0%) and
6. Unknown 1 (23.3%).

[5] $DT_{50}(X\ °C) = DT_{50}(T)\ e^{(0\ 08.(T-X))}$ where X = 12 °C

Under field conditions, photolysis in water may only be relevant in the upper few centimetres of a water body. The active substance also exhibits a high K_{oc} (125,892.5 L/kg). Consequently, in water d-phenothrin is expected to bind to sediment and thus will not be photodegraded significantly.

d-Phenothrin will degrade quickly in the atmosphere based on the calculated DT_{50} value of 3.63 h, (24 hr day, 5 x 10^5 OH radicals per cm^3), determined using the US EPA AOPWIN model. Furthermore, volatilisation is unlikely to be a significant route of entry into the atmospheric compartment of the environment, based on a vapour pressure of 2.372×10^{-5} Pa (at 20 °C, 80:20 *trans*:*cis* d-phenothrin).

Distribution and mobility

The soil adsorption coefficient of d-trans-Phenothrin has been estimated by HPLC simulation in accordance with the OECD Guideline 121. The HPLC column was calibrated for distribution coefficient against retention time using calibration substances (e.g. linuron, aniline, DDT), which have known adsorption coefficients, dissolved in mobile phase. The adsorption coefficient on soil (K_{oc} and log K_{oc}) of d-trans-Phenothrin was estimated by HPLC simulation procedure to be 125,892.5 L/kg and 5.1, respectively, and was covered by a 95% confidence range of 25,118.9 to 7,943,282.3 and 4.4 to 6.9. The K_{oc} value of 125,892.5 L/kg indicates that d-phenothrin has a very low potential for mobility in soil.

Bioaccumulation

Measurements of aquatic and terrestrial bioaccumulation of d-Phenothrin have been performed. The bio-concentration factors for fish and earthworms have been calculated according to TGD:

BCF earthworm is = 75,716 l/kg
BCF fish (day 28 exposure phase) = 2506 l/kg and 3192 l/kg whole fish

A substance is considered to fulfil the B criterion when the bioconcentration factor (BCF) exceeds a value of 2,000 l/kg and the vB criterion (very bioaccumulative) when the BCF exceeds a value of 5,000 l/kg.

The technical material supported by the notifier (Sumitomo) related to the d-phenothrin containing ~98% of *trans* d-Phenothrin and 2% of *cis* d-Phenothrin.

Based on the available data (Saito *et al*. 1993 and Miayomoto *et al*. 1992), d-*cis*-phenothrin does not meet the B-criterion as investigated in both bluegill and carp. Lipid normalised BCF values are 877 L/kg (bluegill) and 934 (range 563-1246) L/kg (carp; the latter values corrected for actual water concentrations and lipid content).
Based on the data available, d-*cis*-phenothrin is not B and therefore not PBT, nor vPvB.

However, data for d-*trans*-phenothrin are different. In bluegill (despite shortcomings in the study, which need not necessarily have led to an overestimation of BCF) the B-criterion is met; with the k_1/k_2 estimates being 2506 and 3192 L/kg (5% lipid). In the Miyamoto study, the BCF in carp measured 635 L/kg (range 364-969) (corrected for actual concentrations and 5% lipid). In the Tanoue study (80% d-trans phenothrin) the BCF in carp were 399 L/kg and 424 L/kg. Based on the data available, d-*trans*-phenothrin is designated potentially B.

In the absence of experimental data, the BCF earthworm calculated is more an indication that d-Phenothrin could be considered as vB.

2.2.2.2. Effects Assessment

Effects on aquatic organisms

1R-trans phenothrin, applied as Sumithrin® is very acutely toxic to fish (96 h LC_{50} = 0.0027 mg/L), *Daphnia* (48 h EC_{50} i= 0.0043 mg/l) and algae (72 h E_bC_{50} = >0.011 mg/l) and thus classifies as R50/53, very toxic to aquatic organisms, and may cause long-term adverse effects in the aquatic environment.

Chronic toxicity studies indicted that daphnid reproduction was the most sensitive indicator of toxicity to Sumithrin. The chronic LOEC for Sumithrin following 21 days exposure to Daphnids was 0.81 µg ai./L, the NOEC was 0.47 µg a.i./L. The 21-day EC_{50} value, based on immobilisation, was estimated by non-linear interpolation to be 1.2 µg a.i./L (corresponding 95% confidence interval calculated by binomial probability of 0.81 to 2.1 µg a.i./L). An ELS study in rainbow trout found no adverse effects up to doses of 1.1 µg a.i./L. Thus, the chronic NOEC in fish is considered to be 1.1 µg a.i./L., the LOEC being >1.1 µg a.i./L.

d-Phenothrin data, in support of 1R-trans phenothrin, indicated no effect on STP microbial activity up to and including 100 mg a.s./L. No adverse effect is expected in wastewater treatment plants due to this finding.

Effects on terrestrial organisms

A short term (5 day) dietary test in bobwhite quail yielded an LC_{50} >5620 ppm (1.87 mg/mg food) indicating that d-Phenothrin is not toxic to birds. It was reported that when compared to the controls, there was no treatment related effect on body weights or feed consumption at any of the concentrations tested during the exposure period (Days 0 through 5).

However, an acute study in honeybees yielded an LD_{50} value for Sumithrin of approximately 0.005 µg a.i./bee following contact exposure indicating that d-Phenothrin is highly toxic upon contact to bees. Signs of toxicity included loss of equilibrium, lack of coordination and moribundity. A justification was accepted for non-submission of data on the acute toxicity to earthworms or other soil non-target organisms, as the proposed use of the test substance does not result in direct release to soil. The product is intended for indoor use only.

The use pattern of products that contain 1R-trans phenothrin will further act to ensure that the potential for secondary poisoning (e.g. from earthworm consumption) is negligible. Even in the rare event that accidental contamination does occur (for example in the event that contaminated sludge is spread on agricultural land), the infrequent nature of such emissions, will not give rise to a realistic possibility of significant bioconcentration in exposed organisms.

Metabolites in the Environment
The Q(S)AR model, ECOSAR was used to assess d-trans-Phenothrin and its major environmental metabolites, PBalc, PBacid and HO-trans-PHN with respect to the ecosystem. Fish 96h and 14 days, daphnia 48h, algae 96h and chronic fish, daphnia and algae were all assessed. The PBalc and PBacid metabolites are significantly (>100x) less toxic than the parent compound and the HO-trans-PHN metabolite is also less toxic than the parent compound. Therefore it is acceptable that the $PNEC_{aquatic}$ value derived for d-trans-Phenothrin will provide a sufficient level of protection.

2.2.2.3. PBT, POP and ED Assessment

PBT assessment

Persistence

A substance is considered to fulfil the persistence criterion (P) when the degradation half-life is –

> 60 days in marine water, or
> 40 days in freshwater or estuarine water, or
> 180 days in marine sediment, or
> 120 days in freshwater sediment or estuarine water sediment, or
> 120 days in soil.

The criteria for a substance to be considered as very persistent (vP) are when the degradation half-life is –

> 60 days in marine water or freshwater or estuarine water, or
> 180 days in marine or freshwater sediment or estuarine water sediment, or
> 180 days in soil.

It should be noted that the active substance has two chiral centres and can therefore have four possible stereoisomers (1*R,trans*, 1*S,trans*, 1*R,cis*, and 1*S,cis*). The overall degradation rate of the active substance in any medium would be expected to vary according to the proportions of the *cis* and *trans* isomers that are present. The information presented in the dossier for d-phenothrin shows that the *trans* isomer degraded more quickly than the *cis* isomer. The technical material being supported in this instance contains ~98% of *1R,trans* isomer and 2% of *1R,cis* isomer. From the point of view of persistence classification, technical material with a *cis* isomer content greater than 2% would be expected to degrade more slowly than 98:2 *trans*:*cis* 1R-trans phenothrin.

In a screening test for persistence d-phenothrin was found to be not ready biodegradable in a study conducted in accordance with the requirements of OECD Test Guideline 301F. Details of the biodegradation of d-phenothrin under less stringent conditions are summarised below for relevant environmental compartments.

With regard to biodegradation in the aquatic environment, data were presented for one freshwater system in a laboratory water-sediment study. No half-life data are available for d-Phenothrin in marine water or marine sediment. The water-sediment study investigated the behaviour of d-*trans*-phenothrin in one system obtained from a river. The test substance dissipated rapidly from the water phase with a half-life value equivalent to 0.84 day at 12 °C. It must be stressed that this half-life value for the water phase represents dissipation and not degradation. It reflects rapid removal from water due to strong partitioning to underlying sediment, as indicated by an estimated adsorption Koc value of 125,892.5 L/kg for d-phenothrin.

A degradation-only DT_{50} value for the water-sediment study was obtained for the whole system (water and sediment combined). Degradation of d-*trans*-phenothrin in the whole system clearly followed biphasic kinetics and was best described by the DFOP model (double first order parallel), giving a DT_{50} value of 6.77 days and a DT_{90} value >1000 days (25 °C). The equivalent best-fit DT_{50} value at 12 ºC is 19.15 days. The DFOP DT_{90} value is presented as >1000 days, since the actual value is extrapolated far beyond the duration of the study and cannot be reliably estimated. The rate of decline in the whole system slowed to almost a complete stop after about 20 days.

Due to the rapid and extensive partitioning of d-phenothrin to sediment, as evidenced by the fact that 83% of the applied radioactivity was extractable from the sediment phase one day after treatment, it is considered that the whole-system degradation values obtained are more representative of the degradation of d-phenothrin in sediment than in water. The observed biphasic degradation behaviour may be indicative of rapid adsorption to the upper parts of the sediment layer and slowing degradation within sediment as d-phenothrin moved deeper into the more anaerobic parts of the sediment compartment.

The whole-system DT_{50} value obtained (19.15 days at 12 ºC) doesn't technically fulfil the criterion for persistence in freshwater or in freshwater sediment. However, since the degradation pattern is biphasic, the DT_{90} value needs to be taken into account as well, in order to fully describe the potential for persistence. The biphasic whole-system degradation pattern observed in this study, with minimal degradation after 20 days, means that the possibility of overall slow degradation in sediment, and accumulation therein, cannot be excluded if repeated inputs to sediment were to occur (especially to anaerobic sediments). Since these conclusions are based on the results from only one water-sediment system, additional investigations with a range of water-sediment systems would be required to fully elucidate the degradation behaviour of d-phenothrin and establish if biphasic whole-system degradation is a general pattern or particular to this study only. Such studies, if well conducted, might allow for the determination of specific degradation-only DT_{50} values for the water compartment and for the sediment compartment, in addition to the whole-system DT_{50} value. At present, no precise degradation rate information is available for either compartment.

Biodegradation of d-*trans*-phenothrin in the water-sediment study resulted in a number of metabolites. Metabolite detection was limited due to the radiolabelling position used. Potential metabolite formation deriving from the cyclopropane ring portion of d-phenothrin could not be detected due to the test substance being labelled only in the benzyl ring of the phenoxyphenyl portion of the molecule.

Three main metabolites were detected, with 3-phenoxybenzoic acid exceeding 10% of applied radioactivity to reach a maximum level in the total system of 18.6% of applied radioactivity. The other identified metabolites were 4'-OH-PBacid (3-(4-hydroxyphenoxy)benzoic acid) and 4'-OH-t-PHN (3-(4-hydroxyphenoxy)benzyl (1R,3R)-2,2-dimethyl-3-(2-methyl-1-propenyl)cyclopropanecarboxylate), which reached maximum respective whole-system levels of 9.7% and 7.9% of applied radioactivity. A DT_{50} value of 50.74 days (single first order) was derived for the degradation of 3-phenoxybenzoic acid in the whole system at 25 ºC (corresponding to a DT_{50} value of 143.6 days at 12 ºC, fulfilling the P criterion for freshwater or estuarine water and for freshwater sediment or estuarine water sediment, and also fulfilling the vP criterion for freshwater or estuarine water). It was not possible to derive reliable values for the other metabolites.

Based on the metabolite kinetic analysis, 3-phenoxybenzoic acid could be adjudged to fulfil the P criterion in one freshwater aquatic system at 12 ºC, since its whole-system half-life value at this temperature exceeds the persistence thresholds for both freshwater and freshwater sediment. In order to accurately assess whether or not d-phenothrin and its aquatic metabolites have the potential to be persistent in water or sediment, specific degradation-only DT_{50} values would be required for these compartments from a number of aquatic test systems.

With regard to biodegradation in soil, data were presented for three soils tested under laboratory conditions – a sandy loam, a clay loam and a loamy sand. In the sandy loam soil, incubated under aerobic conditions at 25 ºC, [cyclopropyl-^{14}C]-d-*trans*-phenothrin and [benzyl-^{14}C]-d-*trans*-phenothrin degraded with DT_{50} (single first order) values of 9.2 and 9.6 days respectively, equivalent to corresponding values at 12 ºC of 26.0 and 27.2 days. There were no metabolites detected in excess of 10% of applied radioactivity.

In the clay loam and loamy sand soils, incubated under aerobic conditions at 25 ºC, the individual *trans* and *cis* isomers both degraded rapidly in each soil with half-life values in the range 1-2 days, corresponding to a range of 2.8 to 5.7 days at 12 ºC. It is not clear why these values are shorter than the values obtained for the degradation of 1R-trans phenothrin in the sandy loam soil. The metabolites 3-phenoxybenzyl alcohol and 3-phenoxybenzoic acid were detected at maximum respective levels of 12.9% and 8.1% of applied radioactivity but declined rapidly under the incubation conditions. 3-Phenoxybenzyl alcohol showed a decrease greater than 95% from its maximum level within 11 days, while 3-phenoxybenzoic acid showed a decrease greater than 50% from its maximum level within 2 days.

Degradation in the clay loam and loamy sand soils was also investigated under flooded conditions (at 25 ºC). Both *trans*- and *cis*- isomers degraded much more slowly in soil under flooded conditions than in the same soils under aerobic conditions, and the *cis* isomer degraded more slowly than the *trans* isomer. Under flooded conditions, *trans*-phenothrin degraded with DT_{50} values of 13.0 and 40.3 days and *cis*-phenothrin degraded with DT_{50} values of 20.2 and 71.0 days, corresponding to respective values at 12 ºC of 36.8 and 114.0 days for the *trans* isomer and 57.2 and 200.9 days for the *cis* isomer. A biphasic kinetics model was adjudged to give the best fit for degradation in the clay loam soil, with the DFOP model (double first order parallel) being used for *trans*-phenothrin in this soil (DT_{50} = 13.0 days, DT_{90} = 207 days) and the FOMC model (first order multicompartment) being used for *cis*-phenothrin in this soil (DT_{50} = 20.2 days, DT_{90} >1000 days). Degradation in the loamy sand soil is best described by single first order kinetics for both *trans*- and *cis*- phenothrin.

Degradation rates of metabolites in the flooded soils were not explicitly assessed, since no individual metabolite was detected in excess of 10% of applied radioactivity. 3-Phenoxybenzyl alcohol and 3-phenoxybenzoic acid appeared to decline more slowly than under aerobic conditions. The maximum observed levels of both substances occurred in the same soil (loamy sand) and at the same timepoint (day 30), with 3-phenoxybenzyl alcohol being detected at 4.7% AR and 3-phenoxybenzoic acid being detected at 7.5% AR. By day 120, 3-phenoxybenzyl alcohol had declined to 1.0% AR and 3-phenoxybenzoic acid had declined to 2.3% AR. The respective levels by day 180 were 0.3% AR and 1.3% AR.

Based on the information available for soil, neither d-phenothrin nor its individual *cis* and *trans* isomers fulfil the P criterion for soil under aerobic conditions. Under flooded conditions, the *cis*-isomer fulfils the P criterion, and also the vP criterion in one soil at 12 ºC. In the case of the flooded soil where a biphasic kinetics model was used, the DT_{50} values do not technically fulfil the P criterion but the DT_{90} values may need to be taken into account as well in order to fully describe the potential for persistence.

The pattern of significantly slower degradation in soil under more anaerobic conditions supports the suggestion made earlier that the biphasic whole-system degradation pattern observed in the water-sediment study might have been due in part to slowing degradation of d-phenothrin within sediment as it moved deeper into the more anaerobic parts of the system.

With regard to abiotic degradation, experimental evidence relevant to the consideration of persistence is available in the results from a hydrolysis study. Results from an aqueous photolysis study (showing rapid abiotic degradation under irradiated conditions with DT_{50} values at 25 °C ranging from 9.1 hours to 13.9 hours) are not considered relevant for the assessment of persistence in the environment. Under field conditions photolysis in water may only be relevant in the upper few centimetres of clear water bodies. The potential for aqueous photodegradation in the environment is also limited by the fact that the active substance is expected to partition extensively to sediment, as indicated by its very high Koc value.

In the hydrolysis study d-Phenothrin was effectively stable at pH 5 and 7. In the same study DT_{50} values of 91 days and 120 days at pH 9 (25 °C), equivalent to 257 days and 340 days at 12 °C, were determined for the benzyl and cyclopropyl radiolabelled test substance, respectively. On the basis of these results abiotic hydrolysis would not be expected to contribute significantly to the degradation of d-phenothrin under environmental conditions.

Conclusion of PBT assessment with respect to persistence

The overall degradation rate of d-phenothrin in any medium would be expected to vary according to the proportions of the *cis* and *trans* isomers that are present. The information presented shows that the *trans* isomer degrades more quickly than the *cis* isomer.

With regard to water and sediment, the tendency for persistence therein cannot be definitively established in the absence of compartment specific degradation-only DT_{50} values. The data presented

pertain to one aquatic system only and indicate biphasic whole-system degradation behaviour for d-*trans*-phenothrin, with quick initial degradation (DT_{50} of 19.15 days at 12 ºC) slowing such that there was minimal degradation after approximately 20 days (by which time d-*trans*-phenothrin accounted for 17% of the applied radioactivity). It is considered that the whole-system degradation data are more representative for sediment than for water due to rapid and extensive partitioning of the test substance to sediment. The observed biphasic degradation behaviour might reflect rapid adsorption to the upper parts of the sediment layer and slowing degradation within sediment as d-*trans*-phenothrin moved deeper into the more anaerobic parts of the sediment compartment.

It is not clear how to explicitly determine the P classification for situations where marked biphasic degradation occurs. Although the whole-system DT_{50} value of 19.5 days (12 ºC) doesn't technically fulfil the criterion for persistence in freshwater or in freshwater sediment, and approximately 80% of d-*trans*-phenothrin degraded within 20 days, the minimal degradation observed thereafter means that the possibility of overall slow degradation and persistent behaviour in sediment cannot be excluded. Additional investigations with a range of water-sediment systems could perhaps provide further insight and establish if biphasic whole-system degradation is a general pattern or particular to this study only.

It should also be noted that the metabolite 3-phenoxybenzoic acid fulfilled the P criterion for freshwater or estuarine water and for freshwater sediment or estuarine water sediment, and also fulfilled the vP criterion for freshwater or estuarine water, since in the one aquatic test system that was studied its whole-system half-life value at 12 ºC was 143.6 days.

With regard to soil, the information presented shows that neither d-phenothrin nor its individual *cis* and *trans* isomers (1R-trans phenothrin) fulfilled the P criterion under aerobic conditions. In two flooded soils with more anaerobic conditions 1R-trans phenothrin did not fulfil the P criterion in one of the soils but for the same soil *cis*-phenothrin fulfilled the P criterion, and also the vP criterion, based on a DT_{50} (12 ºC) value of 200.9 days. For the other flooded soil, DT_{90} values would need to be taken into account as well as DT_{50} values in order to fully describe the potential for persistence, due to possible biphasic degradation behaviour in this case for both *trans*- and *cis*- isomers.

Based on the information available, it appears that degradation of both *trans*- and *cis*- isomers is significantly slower under anaerobic conditions than under aerobic conditions. Therefore, while it may be expected that there are many aerobic situations where 1R-trans phenothrin and the *cis*-isomer would not fulfil the P criterion, the potential for persistence in anaerobic situations, such as within deeper sediment layers or in flooded soils, cannot be ruled out, especially for the *cis*- isomer.

On the basis of the available information, it is difficult to precisely categorise the persistence of d-phenothrin/1R-trans phenothrin with an all-encompassing statement. Persistency depends on the proportion of *cis* and *trans* isomers present and also on the degree to which anaerobic conditions are experienced. The situation is further complicated by biphasic degradation behaviour in some cases. Therefore it is recommended that the issue of persistence classification for the active substance be referred to the ECHA PBT working group for a full assessment. Such an assessment may require further data. In the interim, due to the fact that persistence may be exhibited under certain environmental conditions (such as anaerobic environments within deeper sediment layers or flooded soils), it is proposed that d-phenothrin be regarded as potentially persistent.

Bioaccumulation

Measurements of aquatic and terrestrial bioaccumulation of d-Phenothrin have been performed. The bio-concentration factors for fish and earthworms have been calculated according to Annex XIII of the REACH Regulation:

BCF fish (day 28 exposure phase) = 2506 l/kg and 3192 l/kg whole fish

A substance is considered to fulfil the B criterion when the bioconcentration factor (BCF) in aquatic organisms exceeds a value of 2,000 l/kg and the vB criterion (very bioaccumulative) when the BCF exceeds a value of 5,000 l/kg.

The technical material supported by the notifier (Sumitomo) related to the 1R-trans phenothrin containing ~98% of *trans* isomers and 2% of *cis* isomers.

Based on the available data (Saito *et al*. 1993 and Miayomoto *et al*. 1992), the *cis*- isomers do not meet the B-criterion as investigated in both bluegill and carp. Lipid normalised BCF values are 877 L/kg (bluegill) and 934 (range 563-1246) L/kg (carp; the latter values corrected for actual water concentrations and lipid content).

Based on the data available, the *cis*- isomers are neither B nor vPvB.

However, data for the *trans*- isomers are different. In bluegill (despite shortcomings in the study, which need not necessarily have led to an overestimation of BCF) the B-criterion is met; with the k_1/k_2 estimates being 2506 and 3192 L/kg (5% lipid). The depuration phase demonstrated the removal of residues from whole fish, with time to 50% depuration of 4.0-7.0 days. This depuration demonstrates that, in practice, any 1R-trans phenothrin taken up by an aquatic organism will be eliminated once exposure ceases. In carp, the B-criterion is not met with BCFs of 635 L/kg (range 364-969) (corrected for actual concentrations and 5% lipid) (Miyamoto study 1992) and 399 L/kg and 424 L/kg (Tanoue study 1990). Based on the data available, the *trans*- isomers may be potentially B.

The notifier provided the CA with bioaccumulation position papers explaining the uncertainty factors regarding the results obtained from the Ohshima study, see Doc IIA 4.1.4 Accumulation in organisms and summarised here:

- The study conducted using d-*cis*-Phenothrin (Saito S. *et al.* 1993) established a much lower bioconcentration value which was in keeping with the QSAR data, despite the fact that the *cis* isomer is expected to have a higher bioconcentration potential than the *trans* isomer.
  In mammalian species the residue levels in fat with the *cis*-isomer were 2 to 10 times higher than those with *trans*-isomer (Yoshitake A et al.,1987).This is due to differences in metabolism between mammals and fish.

- Complementary data was provided to the CA from the applicant. This study Miyamoto *et. al.* (1992) (Doc IIIA A7.4.3.3.1(3)) supports the argument that d-*trans*-Phenothrin at 4.3ppb and 0.43 ppb in water (BCF at 42 days 667 L/kg and 405 L/kg respectively) is metabolised more quickly in carp than d-*cis*-Phenothrin at 4.3 ppb and 0.43 ppb (BCF at 42 days 950 L/kg and 817 L/kg respectively). Both with and without piperonyl butoxide (a microsomal monooxygenase inhibitor) the d-*trans*-Phenothrin BCF results were significantly lower than the d-*cis*-Phenothrin BCF results showing that the rate of metabolism is consistently quicker for d-*trans*-Phenothrin than for d-*cis*-Phenothrin in carp.

- The Tanoue A. 1990 study (Doc IIIA Section 7.4.3.3.1(4)) conducted on 80% *trans*-Phenothrin showed bioconcentration levels of 237-561L/kg at concentration Level No.1 (4.3 ppb Sumithrin), and 260-588 L/kg at concentration Level No.2 (0.43 ppb Sumithrin), once normalised to 5% for lipid content. The study did not meet the requirements of OECD Guideline 305 but does show that Sumithrin (containing 80% d-*trans*-Phenothrin) should not be considered to be classified as "Bioaccumulative" as the BCF values obtained are significantly lower than the classification threshold of 2000 L/kg.

- The fish used in the d-*trans*-phenothrin bioconcentration study had a low lipid content at 1.9% and low body weight. The equilibrium also seemed not to have been reached. In order to normalise the data, an extrapolation of the results to 5% was carried out, this may have introduced further error. The study conducted with d-*cis*-Phenothrin used fish with a lipid content of 4.3% therefore a much smaller extrapolation of the results was required and the Log K_{ow} was also likely to be within the applicability domain of the method guideline i.e. Log $K_{ow} \leq 6$.

- REACH Guidance Chapter R7.C (page 12) states, "The guideline [OECD 305] is most validly applied to substances with log K_{ow} values between 1.5 and 6. Practical experience suggests that if the aqueous solubility of the substance is low (i.e. below ~0.01 to 0.1 mg/L; d-Phenothrin is 0.002 mg/L), this test might not provide a reliable BCF because it is very difficult to maintain exposure concentrations (Verhaar *et al*., 1999)." The Log K_{ow} for d-trans-phenothrin is ca 6.8 (d-Phenothrin 98% *trans* isomer = LogP_{ow} 6.8; d-Phenothrin 80% *trans* isomer = LogP_{ow} 6.01) and acceptable aqueous concentration was maintained in both studies.

Based on these results, d-Phenothrin/1R-trans phenothrin may be potentially bioaccumulative.

The three major metabolites of 1R-trans phenothrin, PBalc, PBacid and HO-*trans*-PHN have low Q(S)AR calculated BCF values indicative of a low potentials to bioaccumulate. The Log BCF for PBalc, PBacidand HO-*trans*-PHN are 1.48, 0.5 and 2.84, respectively.

Taking the calculated BCF fish (mean =2849 L/kg) into consideration, the *trans*- isomers potentially meets the screening criterion B for bioaccumulation. However, on consideration of the uncertainty factors mentioned and additional/contradictory data that indicates the trans- isomers do not fulfil the B criterion the CA believes the active substance be referred to the ECHA PBT working group for a full assessment. Such an assessment may require further data. In the interim, d-phenothrin/1R-trans phenothrin may be considered potentially bioaccumulative.

Toxicity

The toxicity criterion used in Annex XIII of the REACH Regulation is a chronic NOEC for aquatic organisms of less than 0.01mg/l. For d-phenothrin the NOEC in the chronic toxicity study to Daphnia magna under flow-through conditions show the 21-day NOEC was 0.00047mg/l. The lowest acute ecotoxicity endpoint was the 96-h LC_{50} of 0.0027mg/l in rainbow trout.

Based on these results, d-Phenothrin/1R-trans phenothrin meets the criteria for Toxicity (T).

PBT Conclusion

d-Phenothrin/1R-trans phenothrin may be considered as a borderline candidate for PBT on the basis that it fulfils the toxicity criterion, it can be considered potentially persistent (under anaerobic conditions) and potentially bioaccumulative. Due to this borderline status and to the difficulties pertaining to the determination of the P classification, it is recommended that d-phenothrin should be further assessed by the ECHA PBT working group. Depending on the outcome of the ECHA PBT working group there may be a requirement for a comparative assessment of the active substance.

POP assessment

Persistence

In relation to the POPs persistence screening criteria as set out in Annex D to the Stockholm Convention (evidence that the half-life of the chemical in water is greater than two months, or that its half-life in soil is greater than six months, or that its half-life in sediment is greater than six months), it is considered that 1R-*trans*-phenothrin is generally unlikely to fulfil the criteria under aerobic conditions. The possibility of occasional manifestations of persistence under anaerobic conditions, such as might prevail within deeper sediment layers or in flooded soils, cannot be ruled out, especially for *cis* isomer.

Direct comparison against screening criteria is hampered by the lack of compartment specific degradation-only DT_{50} values for water and sediment, and also by possible biphasic degradation in some circumstances (in which cases DT_{90} values would need to be taken into account as well as DT_{50} values in order to fully describe the potential for persistence).

Although there is some ambiguity about how to apply the POP P criteria to the degradation behaviour of d-phenothrin/1R-trans phenothrin, and consequently about whether or not those criteria are fulfilled, further data on persistence are not required for the purpose of POP classification, since, as reported below, d-phenothrin/1R-trans phenothrin definitely does not have potential for long-range environmental transport, and, as such, is clearly not a POP substance.

Bioaccumulation

Based on the available data (Saito *et al*. 1993 and Miayomoto *et al*. 1992), *cis* isomer does not meet the B-criterion as investigated in both bluegill and carp. Lipid normalised BCF values are 877 L/kg (bluegill) and 934 (range 563-1246) L/kg (carp; the latter values corrected for actual water concentrations and lipid content).
Based on the data available, *cis* isomer of phenothrin does not show behaviour that suggests bioaccumulation in relation to POP criteria.

However, data for the *trans*- isomers are different. In bluegill (despite shortcomings in the study, which need not necessarily have led to an overestimation of BCF) the B-criterion is met; with the k_1/k_2 estimates being 2506 and 3192 L/kg (5% lipid). The depuration phase demonstrated the removal of residues from whole fish, with time to 50% depuration of 4.0-7.0 days. This depuration demonstrates that, in practice, any 1R-trans phenothrin taken up by an aquatic organism will be eliminated once exposure ceases. In carp, the B-criterion is not met with BCFs of 635 L/kg (range 364-969) (corrected for actual concentrations and 5% lipid) (Miyamoto study 1992) and 399 L/kg and 424 L/kg (Tanoue study 1990). Based on the data available, the *trans*- isomers may be potentially biocaccumulative.

The three major metabolites of 1R-trans phenothrin, PBalc, PBacid and HO-*trans*-PHN have low Q(S)AR calculated BCF values indicative of a low potentials to bioaccumulate. The Log BCF for PBalc, PBacidand HO-*trans*-PHN are 1.48, 0.5 and 2.84, respectively.

Conclusion:
The experimentally derived BCF for fish was 2506-3192 l/kg. The subsequent depuration phase demonstrated the removal of residues from whole fish, with time to 50% depuration of 4.0-7.0 days. This depuration demonstrates that, in practice, any 1R-trans phenothrin taken up by an aquatic organism is likely to be eliminated once exposure ceases. Taking the calculated BCF fish (mean =2849 L/kg) into consideration, *trans* isomers meets the screening criteria for bioaccumulation. However, on consideration of the uncertainty factors mentioned in the bioaccumulation assessment above, the CA believes *trans* isomers are a potentially bioaccumulative substance.

Long-range environmental transport

A calculated DT_{50} value for air was determined at 3.63 h (24 hr day, 5 x 10^5 OH radicals cm^{-3}), using the US EPA AOPWIN model. Whilst d-Phenothrin is likely to partition to some degree to air based on its method of application (i.e. spraying), its indoor use will limit atmospheric exposure and when in the atmosphere it is expected to rapidly degrade. The vapour pressure of 2.372 × 10^{-5} Pa (at 20 °C, 80:20 *trans*:*cis* d-phenothrin) indicates further that d-Phenothrin will not readily volatilise into the atmosphere at ambient temperature and pressure. It is not expected that the substance will fulfil the screening criteria for the potential for long-range environmental transport. Furthermore, there is no monitoring data available or other evidence indicating potential for long-range environmental transport.

Adverse Effects
The toxicity criterion used in the TGD is a chronic NOEC for aquatic organisms of less than 0.01mg/l. For d-phenothrin the NOEC in the chronic toxicity study to Daphnia magna under flow-through conditions show the 21-day NOEC was 0.00047mg/l. The lowest acute ecotoxicity endpoint was the 96-h LC_{50} of 0.0027mg/l in rainbow trout.

Endocrine Effects – please see the ED Assessment below.

POP Conclusion
d-Phenothrin does not fulfil the POP criteria.

ED Assessment

On the basis of the evaluation by the Irish CA for Biocides of toxicology/eco-toxicology studies using d-Phenothrin in support of 1R-trans phenothrin, no determination of endocrine disruption effects could be ascertained in the test organisms dosed with 1R-trans Phenothrin.

However, d-Phenothrin is listed in the Annexes of the EU Commission document on implementation of the Community Strategy for Endocrine Disruptors as a substance with the potential to be a substance that cause endocrine disruption in both humans and animals. With this in mind, further information may be required to assess the potential for endocrine disruption of both d-Phenothrin and 1R-trans phenothrin when EU harmonised guidelines are established for test methods and risk assessment.

2.2.2.4. Exposure Assessment

The environmental exposure of 1R-trans phenothrin was assessed in accordance with the OECD PT18 emission scenario document (ESD) for household and professional uses (OECD Series on Emission Scenario Documents, Number 18 (ENV/JM/MONO(2008)14), 17-Jul-2008 – Emission Scenario Document for Insecticides, Acaricides and Products to Control Other Arthropods for Household and Professional Uses). Sumithrin® 10 SEC is solely intended for indoor use through targeted spot application to cracks and crevices. Application is carried out using either a knapsack sprayer or ultra-low volume (ULV) sprayer. Three main release pathways are identified in the ESD – mixing/loading step, application step and cleaning step. The intermediate receiving compartments consist of indoor air, floors, applicator, treated surfaces, wastewater and wastes. Final receiving compartments in the environment are outdoor air (atmosphere), STPs, surface water, agricultural soil and groundwater. Emissions to these environmental compartments result from the cumulative emission from the mixing/loading, application and cleaning steps indoors following a treatment of the formulated

product Sumithrin® 10 SEC. From local initial emission rates and concentrations, local PEC values were generated using EUSES v.2.1.

Aquatic compartment

The main route of exposure of 1R-trans phenothrin to aquatic systems is considered to be through drains via STPs to surface water and associated aquatic sediment following a cleaning step after application. Local PEC outputs for STP microorganisms, surface waters and sediment from emissions to waste water are presented in **Table 2.2.2.4-1**. The maximum predicted environmental concentration of the active substance in STPs is 4.89 x 10^{-5} mg/L and in surface water 4.11 x 10^{-6} mg/L. The maximum PEC value for sediment was calculated at 0.0113 mg/kg wwt.

PEC groundwater values of 1R-trans phenothrin are also presented in **Table 2.2.2.4-1** and represent the soil porewater concentration of agricultural soil, resulting from the spreading of sewage sludge onto agricultural land and deposition of 1R-trans phenothrin to soil from the atmosphere. The maximum PEC value for groundwater is 2.72 x10^{-7} mg/L. In practice it is considered that there is no realistic potential for significant migration of 1R-trans phenothrin through the soil into groundwater because of the high K_{oc} value for the active substance.

Table 2.2.2.4-1: PEC values of 1R-trans phenothrin for STP, surface water, sediment and groundwater following the indoor control of crawling insects and subsequent emissions to waste water.

Compartment	Surface application Crawling insects	
	PEC	
	Knapsack	ULV
Micro-organisms in the STP [mg/L]	4.89E-05	1.48E-05
Surface water during emission episode (dissolved) [mg/L]	4.11E-06	1.25E-06
Fresh-water sediment during emission episode [mg/kg wwt]	1.13E-02	3.42E-03
Groundwater under agricultural soil [mg/L]	2.72E-07	8.26E-08

Maximum additive PEC values for the metabolites of 1R-trans phenothrin, HO-PHN, PBalc and PBacid, were also calculated for the aquatic compartments of the environment and are presented in **Table 2.2.2.4-2**.

Table 2.2.2.4-2: Additive PEC values of 1R-trans phenothrin metabolites (HO-PHN, PBalc and PBacid) for aquatic exposure (including groundwater) following the indoor control of crawling insects and subsequent emissions to the aquatic environment.

Compartment	Surface application Crawling insects	
	Knapsack	ULV
Total metabolites (HO-PHN + PBalc + PBacid) PEC_{STP} [mg/L]	2.20E-05	6.64E-06
Total metabolites (HO-PHN + PBalc + PBacid) PEC_{SW} [mg/L]	1.84E-06	5.61E-07
Total metabolites (HO-PHN + PBalc + PBacid) PEC_{SED} [mg/kg wwt]	5.06E-03	1.54E-03
Total metabolites (HO-PHN + PBalc + PBacid) PEC_{GW} [mg/L]	1.22E-07	3.70E-08

Atmospheric compartment

Exposure of 1R-trans phenothrin to the atmosphere is expected based on the means by which Sumithrin® 10 SEC is deployed for use (i.e. spray application). Exposure is likely to result from direct emission to air and indirectly from emission to the air from wastewater in an STP. However, based on the indoor application of 1R-trans phenothrin for the control of insects it is likely that emissions to the atmosphere will be limited. Annual average local PEC values for air were calculated at 1.57 x 10^{-12} mg/m^3 and 4.75 x 10^{-13} mg/m^3 respectively, for knapsack and ULV application to crawling insects (**Table 2.2.2.4-3)**. PEC values were also determined for the metabolites of 1R-trans phenothrin, HO-PHN, PBalc and PBacid, with additive annual average local PEC values for air calculated at 7.03 x 10^{-13} mg/m^3 and 2.13 x 10^{-13} mg/m^3 respectively, for knapsack and ULV application (**Table 2.2.2.4-4**).

Table 2.2.2.4-3: PEC values of 1R-trans phenothrin for air following the indoor control of crawling insects and subsequent emissions to waste water.

Outputs	Surface application Crawling insects	
	Knapsack	ULV
Annual average local PEC in air [mg/m^3]	1.57E-12	4.75E-13

Table 2.2.2.4-4: PEC values of 1R-trans phenothrin metabolites for air following the indoor control of crawling insects and subsequent emissions to waste water.

Outputs	Surface application Crawling insects	
	Knapsack	ULV
HO-PHN		
Annual average local PEC in air [mg/m^3]	3.46E-13	1.05E-13
PBalc		
Annual average local PEC in air [mg/m^3]	1.79E-13	5.43E-14
PBacid		
Annual average local PEC in air [mg/m^3]	1.78E-13	5.40E-14
Total metabolites PEC_{air} [mg/m^3]	7.03E-13	2.13E-13

Terrestrial compartment

Direct exposure of soil to 1R-trans phenothrin is not expected as a result of the Sumithrin® 10 SEC indoor use pattern; however, exposure to soil may arise indirectly from the use of sewage sludge in agriculture. PEC values for soil were determined for this indirect exposure route arising from emissions to a STP following cleaning after a targeted pest control operation indoors to control crawling insects. Local PEC outputs for soil following emissions to waste water are presented in **Table 2.2.2.4-5** for 1R-trans phenothrin and in **Table 2.2.2.4-6** for metabolites of 1R-trans phenothrin (HO-PHN, PBalc and PBacid).

Table 2.2.2.4-5: PEC values of 1R-trans phenothrin for soil following the indoor control of crawling insects and subsequent emissions to waste water in which contaminated sludge is spread onto soil.

Outputs	Surface application Crawling insects

	Knapsack	ULV
Local PEC in agric. soil averaged over 30 days [mg/kg wwt]	1.10E-03	3.34E-04
Local PEC in agric. soil averaged over 180 days [mg/kg wwt]	6.04E-04	1.83E-04

Table 2.2.2.4-6: Additive PEC values of 1R-trans phenothrin metabolites (HO-PHN, PBalc and PBacid) for terrestrial exposure following the indoor control of crawling flying insects and subsequent emissions to the environment.

Compartment	**Surface application Crawling insects**	
	Knapsack	**ULV**
HO-PHN		
Local PEC in agric. soil averaged over 30 days [mg/kg wwt]	2.43E-04	7.37E-05
Local PEC in agric. soil averaged over 180 days [mg/kg wwt]	1.33E-04	4.04E-05
PBalc		
Local PEC in agric. soil averaged over 30 days [mg/kg wwt]	1.26E-04	3.82E-05
Local PEC in agric. soil averaged over 180 days [mg/kg wwt]	6.90E-05	2.09E-05
PBacid		
Local PEC in agric. soil averaged over 30 days [mg/kg wwt]	1.25E-04	3.80E-05
Local PEC in agric. soil averaged over 180 days [mg/kg wwt]	6.87E-05	2.08E-05
Total metabolites PEC_{soil}		
Local PEC in agric. soil averaged over 30 days [mg/kg wwt]	4.94E-04	1.50E-04
Local PEC in agric. soil averaged over 180 days [mg/kg wwt]	2.71E-04	8.21E-05

Primary and secondary poisoning

Aquatic organisms:

The log octanol/water partition coefficient of d-Phenothrin (6.8) suggests that it may have significant potential for bioconcentration in the aquatic environment, with the possibility of bioaccumulation leading to secondary poisoning in fish eating predators (birds or mammals).

The concentration in fish is a result of uptake from the aqueous phase and intake of contaminated food (aquatic organisms). Thus, a $PEC_{oral,\ predator}$ was calculated from the bioconcentration factor (BCF) and a biomagnification factor (BMF) as:

$$PEC_{oral,\ predator} = 0.423 \text{ mg/kg}_{\text{ wet fish}}$$

Terrestrial organisms:

The log octanol/water partition coefficient of d-Phenothrin (6.8) suggests that it may have significant potential for bioconcentration in soil-dwelling organisms (e.g. earthworms) also, with the possibility

of bioaccumulation leading to secondary poisoning. As no study was conducted, the calculation method described in the TGD was used to determine the $PEC_{oral,\ predator}$ for earthworm eating predators as:

$$PEC_{oral,\ predator} = 1.63 \text{ mg/kg wet earthworm } (= C_{earthworm})$$

2.2.2.5. Risk Characterisation

Environmental risk in the aquatic compartment, including STP and sediment

PNEC derivation:

PNEC's relevant to risk characterisation in the aquatic compartment (hydrosphere) were as follows:

$PNEC_{STP\ micro\text{-}organisms}$ Assessment factor of 10 used = 10 mg/L

$PNEC_{aquatic\ (SW)}$ Assessment factor of 10 used = 0.000047 mg/l

$PNEC_{sediment}$ Assessment factor of 10 used = 0.129 mg/kg (wet weight) 0.59 mg/kg dry weight

$PNEC_{terrestrial}$ Assessment factor of 10 used = 0.0104 mg/kg (wet weight) 0.0117 mg/kg dry weight

Risk characterisation for the aquatic compartment:

The risk to the hydrosphere (STP, surface water, sediment and groundwater) following targeted spot application of Sumithrin® 10 SEC was characterised for both the parent material and the metabolites of 1R-trans phenothrin, HO-PHN, PBalc and PBacid.

PEC/PNEC ratios for 1R-trans phenothrin for STP, surface water, sediment and groundwater following the indoor control of crawling insects and subsequent emissions to waste water.

Compartment	PNEC	PEC		PEC/PNEC	
		Knapsack	ULV	Knapsack	ULV
Micro-organisms in the STP [mg/L]	10	4.89E-05	1.48E-05	0.0000049	0.0000015
Surface water during emission episode (dissolved) [mg/L]	0.000047	4.11E-06	1.25E-06	0.087	0.027
Fresh-water sediment during emission episode [mg/kg wwt]	0.129	1.13E-02	3.42E-03	0.88*	0.27*
Groundwater under agricultural soil [mg/L]	0.0001	2.72E-07	8.26E-08	0.0027	0.00083

* This ratio is increased by a factor of 10 in order to take into account the uptake via ingestion of sediment

The Q(S)AR model, ECOSAR contained within the US-EPA EPISuite program - version 4.10, has been used to assess d-*trans*-Phenothrin and its major environmental metabolites, PBalc, PBacid and HO-*trans*-PHN, with respect to the ecosystem. From the results summarised in the table below it can be seen that the PBalc and PBacid metabolites are significantly (>100x) less toxic than the parent compound and the HO-*trans*-PHN metabolite is also less toxic than the parent compound. Therefore it is considered that the $PNEC_{aquatic}$ value derived for d-*trans*-Phenothrin (0.000047 mg/L) will provide a sufficient level of protection. No further ecotoxicity testing was considered necessary.

Q(S)AR: ECOSAR data for metabolites and comparison with d-*trans*-phenothrin

Analyte	ECOSAR Class	Fish 96h LC50	Fish 14 d LC50	Daphnia 48h LC50	Algae 96h EC50	Fish 32/33 d ChV	Daphnia 21 d ChV	Algae ChV
d-*trans*-Phenothrin	Measured data	0.0027		0.0043	>0.011 (72 h)	>0.0011 (90 days)	0.00062	0.0047 (72 h)
d-*trans*-Phenothrin	Esters	0.033	0.00116	0.033	0.008	0.000772	0.005	0.012
	Pyrethroids	0.00032		0.00032	0.00032	3.15E-05	3.15E-05	3.15E-05
PBalc	Benzyl Alcohols	9.134		1.174		0.495	0.687	
	Neutral Organic SAR (baseline toxicity)	17.003		11.250	7.717	1.574	1.269	3.434
PBacid	Neutral organics - acid	33.033	34.455	24.780	27.203	3.917	3.901	14.342
HO-*trans*-PHN	Esters	0.233	0.074	0.283	0.078	0.008	0.062	0.074
	Vinyl/Allyl Alcohols	2.411		0.565	0.471	0.00166	0.003	0.175
	Neutral Organic SAR (baseline toxicity)	0.100		0.095	0.217	0.009	0.018	0.166

All values are in mg/L.

PEC/PNEC ratios for 1R-trans phenothrin metabolites (HO-PHN, PBalc and PBacid added together) for aquatic exposure (including groundwater) following the indoor control of crawling insects and subsequent emissions to the aquatic environment.

Compartment	PNEC (mg/L)	PEC (mg/L)		PEC/PNEC	
		Knapsack	ULV	Knapsack	ULV
Micro-organisms in the STP [mg/L]	10	2.20E-05	6.64E-06	0.0000022	0.00000066
Surface water during emission episode (dissolved) [mg/L]	0.000047	1.84E-06	5.61E-07	0.039	0.0119
Fresh-water sediment during emission episode [mg/kg wwt]	0.129	5.06E-03	1.54E-03	0.39*	0.119*
Groundwater under agricultural soil [mg/L]	0.0001	1.22E-07	3.70E-08	0.00122	0.00037

* This ratio is increased by a factor of 10 in order to take into account the uptake via ingestion of sediment

The PEC/PNEC ratios for aquatic scenarios indicate that there is no risk to the hydrosphere from the active ingredient 1R-trans phenothrin nor its metabolites following indoor targeted spot application of Sumithrin® 10 SEC for the control of crawling insects (and its subsequent release to wastewater). Overall, the risk to the aquatic environment from the use of Sumithrin® 10 SEC is considered acceptable.

Risk Characterisation for secondary poisoning via the aquatic food chain:

The risk to fish-eating organisms (mammals) was calculated as the ratio between the concentration in their food ($PEC_{oral,\ predator}$) and the no-effect-concentration for oral intake ($PNEC_{oral}$). The 52 week dog study (Cox R. (1987)) represents the most sensitive species (NOAEL=8.2 mg/kg bw/day) with a determined NOEC value of 300 mg/kg food. Applying an assessment factor of 30 to this value gives: **$PNEC_{oral,\ predator}$ of 10.0 mg/kg food**

The $PEC_{oral,\ predator}$ for fish-eating organisms was determined from the bioconcentration factor (BCF) and a biomagnification factor (BMF) as **$PEC_{oral,\ predator}$ = 0.423 mg/kg** $_{wet\ fish}$

The resulting risk quotient (**$PEC_{oral,\ predator}$/ $PNEC_{oral}$ = 0.423 / 100 = 0.042**) is less than 1, confirming the fact that there is no risk of secondary poisoning to fish-eating mammals, predators/scavengers, arising from 1R-trans phenothrin use.

The risk to fish-eating organisms (birds) was calculated as the ratio between the concentration in their food ($PEC_{oral,\ predator,}$) and the no-effect-concentration for oral intake ($PNEC_{oral,\ predator\ bird}$). In this case, the $PNEC_{oral}$ was derived from the LC50 of 5620 ppm and the appropriate assessment factor of 3000 was then applied to this value resulting in a **$PNEC_{oral,\ predator}$ of 1.87 mg/kg food.**

The $PEC_{oral,\ predator}$ for fish-eating organisms was determined from the bioconcentration factor (BCF) and a biomagnification factor (BMF) as **$PEC_{oral,\ predator}$ = 0.423 mg/kg** $_{wet\ fish}$

The resulting risk quotient (**$PEC_{oral,\ predator}$/ $PNEC_{oral}$ = 0.423 / 1.87 = 0.23**) is less than 1, confirming the fact that there is no risk of secondary poisoning to fish-eating birds, predators/scavengers, arising from 1R-trans phenothrin use.

Summary aquatic risk assessment:

The results above indicate that there is no risk to the hydrosphere from the active ingredient 1R-trans phenothrin nor its metabolites following indoor targeted spot application of Sumithrin® 10 SEC for the control of crawling insects (and its subsequent release to wastewater).

d-Phenothrin data indicates a very high BCF values determined for fish (2506-3192 l/kg) suggesting that it may have significant potential for bioconcentration in the aquatic environment with the possibility of bioaccumulation leading to secondary poisoning. However, the $PEC_{oral,predator}/PNEC_{oral}$ ratios determined for fish-eating mammals and birds (0.042 and 0.23 respectively) and for earthworm eating mammals and birds (0.16 and 0.87 respectively) indicate that there is no risk of secondary poisoning following the appropriate use of Sumithrin® 10 SEC.

Overall, the risk to the aquatic environment from the use of Sumithrin® 10 SEC is considered acceptable.

Environmental risk in the terrestrial compartment

PNEC derivation:

No study was performed on the acute toxicity to earthworms or other soil non-target organisms, as the proposed use of the test substance does not result in direct release to soil. For the purposes of the risk assessment, the $PNEC_{terrestrial}$was derived using the TGD equilibrium partitioning method. An additional factor of 10 was required considering the logKow is 6.8, which is >5.0, resulting in a $PNEC_{terrestrial}$ of 0.0104 mg/kg wwt.

$PNEC_{terrestrial}$ = 0.0104 mg/kg (wet weight)

Risk characterisation for the terrestrial compartment:

The risk to the terrestrial compartment was characterised for both the parent material and the metabolites of 1R-trans phenothrin, HO-PHN, PBalc and PBacid. For the parent material, risk quotients were derived for the soil compartment following targeted spot application of Sumithrin® 10 SEC, assuming emissions to waste water in which contaminated sludge is then spread onto soil.

The PNEC value for the active substance was used for risk characterisation for the metabolites, together with the sum of the PEC values as determined in Doc II B (Section 3.3.4) for the metabolites.

PEC/PNEC ratios for 1R-trans phenothrin for soil following the indoor control of crawling insects and subsequent emissions to waste water in which contaminated sludge is spread onto soil.

Exposure scenario	PNEC [mg/kg wwt]	PEC [mg/kg wwt]		PEC/PNEC	
		Knapsack	ULV	Knapsack	ULV
Agric. soil (total), PEC averaged over 30 days [mg/kg wwt]	0.0104	1.10E-03	3.34E-04	0.106	0.032
Agric. soil (total), PEC averaged over 180 days [mg/kg wwt]	0.0104	6.04E-04	1.83E-04	0.058	0.018

PEC/PNEC ratios for 1R-trans phenothrin metabolites (HO-PHN, PBalc and PBacid added together) for terrestrial exposure following the indoor control of crawling insects and subsequent emissions to the environment.

Exposure scenario	PNEC (mg/l)	PEC (mg/l)		PEC/PNEC	
		Knapsack	ULV	Knapsack	ULV
Agric. soil (total), PEC averaged over 30 days [mg/kg wwt]	0.0104	4.94E-04	1.50E-04	0.048	0.014
Agric. soil (total), PEC averaged over 180 days [mg/kg wwt]	0.0104	2.71E-04	8.21E-05	0.026	0.008

For the active ingredient, no risk was identified for the soil compartment where contaminated sludge (via waste water emissions) is spread onto soil.

The PEC/PNEC ratios for the metabolites also indicate that there is no risk to the terrestrial compartment from 1R-trans phenothrin metabolites following indoor targeted spot application of Sumithrin® 10 SEC and its subsequent emissions to the terrestrial soil environment.

Risk Characterisation for secondary poisoning via the terrestrial food chain:

The risk to earthworm-eating mammals was calculated as the ratio between the concentration in their food ($PEC_{oral,\ predator}$) and the no-effect-concentration for oral intake ($PNEC_{oral}$).The 52 week dog study (Cox R. (1987)) represents the most sensitive species (NOAEL=8.2 mg/kg bw/day) with a determined NOEC value of 300 mg/kg food. Applying an assessment factor of 30 to this value gives: **$PNEC_{oral,\ predator}$ of 10.0 mg/kg food.**

The calculation method described in the TGD was used to determine the $PEC_{oral,\ predator}$ for earthworm eating predators of **$PEC_{oral,\ predator}$ = 1.63 mg/kg wet earthworm ($C_{earthworm}$)**

The resulting risk quotient (**$PEC_{oral,\ predator}/PNEC_{oral}$ = 1.63/ 100 = 0.16**) is less than 1, confirming the fact that there is no risk of secondary poisoning to earthworm-eating mammals arising from 1R-trans phenothrin use.

The risk to earthworm-eating birds was calculated as the ratio between the concentration in their food ($PEC_{oral,\ predator}$) and the no-effect-concentration for oral intake ($PNEC_{oral}$). In this case the PNEC oral was calculated based on the 5 day dietary study (Grimes J, 1988), using an assessment factor of 3000 was calculated to give a PNECoral of 1.87 mg/kg food.

$PEC_{oral,\ predator}$ derivation:
The calculation method described in the TGD was used to determine the $PEC_{oral,\ predator}$ for earthworm eating predators (see Doc IIB for details) as:

$PEC_{oral,\ predator}$ = 1.63 mg/kg wet earthworm ($C_{earthworm}$)

Risk characterisation for earthworm-eating birds:
The risk to the earthworm-eating birds is calculated as the ratio between the concentration in their food ($PEC_{oral,\ predator}$) and the no-effect-concentration for oral intake ($PNEC_{oral}$) as follows:

$PEC_{oral,\ predator}$/ $PNEC_{oral}$ = 1.63/ 1.87 = 0.87

Summary terrestrial risk assessment:
The risk characterization ratios determined for reasonable worst case scenarios in which 1R-trans phenothrin, and its metabolites, may enter the terrestrial environment (via emissions to waste water and subsequent spreading of contaminated sludge onto soil) as a result of the use of Sumithrin® 10 SEC indicate that there is no cause for concern in this case (i.e. all PEC/PNEC ratios were < 1.0).

The indoor use pattern of products that contain 1R-trans phenothrin will further act to ensure that the potential for secondary poisoning is negligible. When used as instructed on the label, there is essentially no potential for direct contamination of the soil compartment to occur. In the event of indirect exposure that could occur when contaminated sludge is spread on agricultural land, the infrequent nature of such emissions will not give rise to a realistic possibility of significant bioconcentration in exposed organisms.

A high log octanol/water partition coefficient (6.8) and very high BCF values were determined for earthworms (75,700 l/kg) suggesting that it may have significant potential for bioconcentration in soil-dwelling organisms, with the possibility of bioaccumulation leading to secondary poisoning. However, the $PEC_{oral,predator}$/$PNEC_{oral}$ ratios determined for earthworm eating mammals and birds (0.16 and 0.87 respectively) indicate that there is no risk of secondary poisoning following the use of Sumithrin® 10 SEC according to the proposed use instructions.

In conclusion, it is considered that there is no cause for concern following exposure of the terrestrial compartment to 1R-trans phenothrin resulting from the use of Sumithrin® 10 SEC.

2.2.3. List of Endpoints

In order to facilitate the work of Member States in granting or reviewing authorisations, and to apply adequately the Provisions of Article 5(1) of Directive 98/8/EC and the common principles laid down in Annex VI of that Directive, the most important endpoints, as identified during the evaluation process, are listed in Appendix I.

3. DECISION

3.1. BACKGROUND TO THE DECISION

The application by Sumitomo Chemical (UK) Plc in support of the active substance was for d-Phenothrin with the trans/cis isomeric ratio of 98:2 and which has been identified and renamed 1R-trans phenothrin (Please see Sections 1.1 and 2.1 of this document). However, a significant proportion of the information submitted by the applicant to support 1R-trans phenothrin was based on an isomeric mixture of trans/cis isomers in the ratio of 80:20. Some of the Sumitomo data provided, principally for the physical-chemical properties section was based on an isomeric mixture of trans/cis isomers in the ratio of 98:2. It was accepted that the 98:2 trans/cis isomeric mixture of the active substance was a safer mixture than the 80:20 trans/cis isomeric mixture. Consequently it was considered that the data supporting the 80:20 trans/cis mixture (identified in the text as "d-Phenothrin") could be extrapolated to support the 98:2 trans/cis mixture identified as 1R-trans phenothrin.

d-Phenothrin data used in support of 1R-trans phenothrin showed very low acute oral, dermal and inhalation toxicity in the rat. In the rabbit d-Phenothrin data produced no skin irritation and a minimal eye irritation potential. Under the conditions of the maximization method of Magnusson and Kligman, d-Phenothrin showed no potential to induce skin sensitisation in the Guinea-pig.

In repeated dose studies in the mouse, rat and dog consistent treatment related findings in the liver were seen. Changes indicative of a principally adaptive response were evident. Carcinogenicity and long-term toxicity of d-Phenothrin have been investigated in the rat and the mouse, in these studies increased liver weight and periacinar hepatocytic hypertrophy were seen. However, no treatment related change was seen in the incidence of tumours in either species. Results from *in vitro* and *in vivo* genotoxicity test systems indicate that d-Phenothrin does not exhibit any mutagenic properties or cause chromosomal or DNA damage.

In developmental and reproductive toxicity studies effects on the rabbit (increased rate of abortions and hydrocephaly) and rat (increased incidence of 14^{th} rib) were noted. However, a follow up study investigating the developmental effects of the substance in rabbits failed to confirm that abortions and hydrocephaly were substance related.

Safe uses have been modelled for d-phenothrin when used professionally, from a knapsack, for treatment of crawling insects and flying insects by crack and crevice application. Although the operator is to be protected via PPE when the product (10 Sec) is applied by an ultra low volume (ULV) application system.
Both knapsack and ULV application methods, when limited to crack and crevice treatment, yield a safe exposure level post application exposure to children and is not expected to represent a risk from secondary exposure.
Environment studies were conducted with d-*trans*-phenothrin or with a mixture of *trans* and *cis* d-phenothrin isomers with a *trans*:*cis* isomeric ratio of 80:20 or 98:2. With regard to the rate of environmental degradation, studies performed with the 80:20 *trans*:*cis* isomeric mix were deemed acceptable to support d-phenothrin products with a *trans* isomer content greater than or equal to 80% and a *cis* isomer content less than or equal to 20%, since the information available in the dossier shows that the *trans* isomer degraded more rapidly than the *cis* isomer. Therefore environmental exposure calculations for the 98:2 isomeric ratio that use degradation rate data pertaining to the 80:20 isomeric ratio would be conservative, since the 98:2 composition would be expected to degrade more rapidly than the 80:20 composition due to its higher *trans* content.

In a ready biodegradability study, conducted according to the requirements of OECD Test Guideline 301F, d-phenothrin was found to be not biodegradable under the test conditions within the 28-day incubation period. In laboratory simulation tests under less stringent conditions, biodegradation

occurred in soils, under aerobic and flooded conditions, and in a water-sediment system obtained from a river.

The weight of evidence from the simulation tests supports a preferred biodegradation pathway involving hydrolytic cleavage of the ester linkage in d-phenothrin, as indicated by the detection of 3-phenoxybenzyl alcohol (soil studies) and 3-phenoxybenzoic acid (soil studies and water sediment study). Concomitant metabolite formation from this pathway resulting in substances containing, or derived from, the cyclopropane ring portion of d-phenothrin would also be anticipated. However such metabolites were not detected. In some cases this was due to inappropriate radiolabelling of the parent molecule but in one soil study where [cyclopropyl-^{14}C]-d-*trans*-phenothrin was used there was an inexplicable absence of ester cleavage products.

The longest measured DT_{50} value for biodegradation of d-phenothrin in soil under aerobic conditions was equivalent to 27.2 days at 12 ºC. The rate of degradation in two soils incubated under flooded conditions was much slower than in the same soils under aerobic conditions. DT_{50} values for the flooded soils, extrapolated to 12 ºC, were 36.8 and 114.0 days for *trans*-phenothrin, and 57.2 and 200.9 days for *cis*-phenothrin.

Degradation rates of metabolites in soil were not explicitly assessed, since the metabolites generally formed at low levels and there was only one transient detection of an individual metabolite that was in excess of 10% of applied radioactivity. Under aerobic conditions 3-phenoxybenzyl alcohol was detected at a maximum level of 12.9% of applied radioactivity and showed a decrease from this level of greater than 95% within 11 days, while 3-phenoxybenzoic acid was detected at a maximum level of 8.1% of applied radioactivity and showed a decrease from this level of greater than 50% within 2 days.

Degradation of 3-phenoxybenzyl alcohol and 3-phenoxybenzoic acid appeared to be slower in the flooded soil incubations. Under flooded conditions the maximum observed levels of both substances occurred in the same soil (loamy sand) and at the same timepoint (day 30), with 3-phenoxybenzyl alcohol being detected at 4.7% AR and 3-phenoxybenzoic acid being detected at 7.5% AR. By day 120, 3-phenoxybenzyl alcohol had declined to 1.0% AR and 3-phenoxybenzoic acid had declined to 2.3% AR. The respective levels by day 180 were 0.3% AR and 1.3% AR.

In the water-sediment study degradation of d-*trans*-phenothrin in the whole system clearly followed biphasic kinetics and was best described by the DFOP model (double first order parallel), giving a DT_{50} value of 6.77 days and a DT_{90} value >1000 days (25 °C). The rate of decline in the whole system slowed to almost a complete stop after about 20 days. The equivalent best-fit DT_{50} value at 12 ºC is 19.15 days.

An attempt was made to determine metabolite degradation rates for the water-sediment study. A DT_{50} value of 50.74 days (single first order) was derived for the degradation of 3-phenoxybenzoic acid in the whole system at 25 ± 2 ºC (corresponding to a DT_{50} value of 143.6 days at 12 ºC). It was not possible to derive reliable values for other metabolites.

Abiotic degradation was investigated in hydrolysis and aqueous photolysis studies. d-Phenothrin was found to be hydrolytically stable at pH 5 and 7. At pH 9 the hydrolysis DT_{50} (25 °C) for the test material was determined at 91 days and 120 days, with an r^2 of 0.89 and 0.90 for the benzyl and cyclopropyl radiolabels, respectively, equivalent to 257 days and 340 days at 12 °C. The main hydrolysis process involved the formation of d-t-CRA and PBalc. Abiotic hydrolysis would not be expected to contribute significantly to the degradation of d-phenothrin under environmental conditions.

Aqueous photodegradation DT_{50} values (25 °C) were estimated at 9.1 hours and 13.9 hours for the benzyl and cyclopropyl radiolabelled test substance, respectively. The primary degradates observed in light exposed samples were 3-phenoxybenzyl(*1R,3R*)-2,2-dimethyl-3-[(*1RS*)-hydroxy-2-methylprop-

2enyl]-cyclopropanecarboxylate (HO-PHN) (21.1%), 3-phenoxybenzyl alcohol (PBalc) (20.0%) and an unidentified substance designated as Unknown 1 (23.3 %). Photolysis in water under field conditions may only be relevant in the upper few centimetres of clear water bodies. The potential for aqueous photodegradation in the environment is also limited by the fact that d-phenothrin is expected to partition extensively to sediment, as indicated by its very high K_{oc} value.

The adsorption coefficient on soil (K_{oc} and log K_{oc}) of d-*trans*-phenothrin was estimated by a HPLC simulation procedure to be 125,892.5 L/kg and 5.1, respectively, and was covered by a 95% confidence range of 25,118.9 to 7,943,282.3 and 4.4 to 6.9. The K_{oc} value of 125,892.5 L/kg indicates that d-phenothrin has a very low potential for mobility in soil.

With regard to the air compartment there is no potential for long range transport. d-Phenothrin would be expected to degrade quickly in the atmosphere based on the calculated DT_{50} value of 3.63 h (24 hr day, 5 x 10^5 OH radicals cm^{-3}), determined using the US EPA AOPWIN model.

In relation to assessing overall environmental persistence in comparison with PBT and POPs criteria it must be borne in mind that the degradation rate of d-phenothrin in any medium would be expected to vary according to the proportions of the *cis* and *trans* isomers that are present, since the *trans* isomer appears to degrade more quickly than the *cis* isomer. Based on the information presented it was concluded that for PBT d-Phenothrin is considered to be a borderline PBT candidate on the basis that it fulfils the toxicity criterion, is potentially persistent (under anaerobic conditions) and is potentially bioaccumulative. Due to this borderline status and to the difficulties pertaining to the determination of the P and B classification, it is recommended that d-phenothrin should be further assessed by the ECHA PBT working group. For the POP assessment it was concluded that d-Phenothrin does not fulfil the POP criteria.

d-phenothrin is very acutely toxic to fish, aquatic invertebrates and algae, with LC_{50}/EC_{50}'s ≤ 1 mg/L in all cases, warranting classification as R50/53, very toxic to aquatic organisms, and may cause long-term adverse effects in the aquatic environment. Chronic toxicity studies indicated that daphnid reproduction was the most sensitive indicator of toxicity to Sumithrin® (NOEC = 0.00047 mg a.i./L). An ELS study in rainbow trout found no adverse effects up to doses of 1.1 µg a.i./L. d-Phenothrin had no effect on respiration of micro-organisms up to and including 100 mg a.s./L. No adverse effect is expected in wastewater treatment plants due to this finding.

A short term (5 day) dietary test in bobwhite quail yielded an LC_{50} >5620 ppm (1.87 mg/mg food) indicating that d-Phenothrin is not toxic to birds. However, an acute study in honey bees yielded an LD_{50} value for Sumithrin of approximately 0.005 µg a.i./bee following contact exposure indicating that d-Phenothrin is highly toxic upon contact to bees. The risk to bees has been calculated for the substance based on the guideline that was available at the time of the decision. Further discussions and methodologies are expected to be available at the product authorisation stage that must be considered at that time. A justification was accepted for non-submission of data on the acute toxicity to earthworms or other soil non-target organisms, as the proposed use of the test substance does not result in direct release to soil.

The metabolites, HO-PHN, PBalc and PBacid, are less toxic than the parent material, d-Phenothrin, on the basis of a QSAR assessment conducted with the ECOSAR model. Therefore the toxic data for the active substance was applied in the risk assessment for the metabolites.

Despite its inherent observed toxicity to aquatic organisms and to honeybees, given the low level of environmental exposure expected in all compartments from the indoor use of d-Phenothrin as a targeted spot treatment application in cracks and crevices, it is considered that there is very limited risk to the environment and that safe uses of the formulated product, Sumithrin® 10 SEC, have been identified. The environmental risk assessment resulted in acceptable PEC/PNEC ratios (<1) in all cases for the use of Sumithrin® 10 SEC indoors as a targeted spot treatment application in cracks and

crevices. It is concluded at an environmental exposure level that at the proposed level of use and use pattern d-Phenothrin will not have any unacceptable effect on the environment.

In relation to efficacy, the active substance d-Phenothrin has been evaluated and has demonstrated its efficacy for use as an insecticide (product type – 18) for the use pattern "indoor use" for the control of crawling (German, American & Oriental cockroaches) and flying insects (house flies & mosquitoes), in areas such as trains, trucks, hospitals, hotels and other public buildings.

3.2. DECISION REGARDING INCLUSION IN ANNEX I

The substance 1R-trans phenothrin shall be included in Annex I to Directive 98/8/EC as an active substance for use in product-type 18 (insecticides, acaricides and products to control other arthropods), subject to the following specific provisions:

The data submitted for the purpose of the evaluation 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. In accordance with current practice for naming of substances, that substance should be considered as mono-constituent and named 1R-trans phenothrin. The evaluation did not allow conclusions to be drawn regarding any other substance complying with the definition of d-phenothrin in the list of active substances in Regulation (EC) No 1451/2007. Therefore, only 1R-trans phenothrin should be included in Annex I to Directive 98/8/EC based on the existing evaluation.

Identity:

1R-*trans* isomer (1R-trans phenothrin):

Chemical name (IUPAC)	: 3-phenoxybenzyl (1*R*,3*R*)-2,2-dimethyl-3-(2-methylprop-1-enyl) cyclopropanecarboxylate
Chemical name (CA)	: Cyclopropanecarboxylic acid, 2,2-dimethyl- 3-(2-methyl-1-propenyl)-, (3-phenoxyphenyl)methyl ester, (1*R*,3*R*)-
CAS No	: 26046-85-5
EINECS No	: 247-431-2
Purity	Min. 89% w/w 1Rtrans isomer

The "sum of all isomers":

Chemical name (IUPAC)	: (3-Phenoxyphenyl)methyl 2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropane-1-carboxylate
Chemical name (CA)	: (3-phenoxyphenyl)methyl 2,2-dimethyl-3-(2-methyl-1-propen-1-yl)cyclopropanecarboxylate
CAS No	: 26002-80-2
EINECS No	: 247-404-5
Purity	:Min. 95.5% w/w "sum of all isomers"

The Union level risk assessment did not address all potential uses and exposure scenarios; certain uses and exposure scenarios. When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI of the Biocidal Products Directive (98/8/EC), Member States shall assess exposure to populations and environmental compartments and uses or exposure scenarios that have not been representatively addressed in the risk assessments presented in the CAR.

Member States shall ensure that authorisations are subject to the following conditions unless it can be demonstrated in the application for product authorisation that the risks can be reduced to an acceptable level:

In view of the risks identified for human health, it is appropriate to require that safe operational procedures are established for the ultra low volume (ULV) application, and that products are used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks can be reduced to an acceptable level by other means

For products containing 1R-trans phenothrin that may lead to residues in food or feed, Member States shall verify the need to set new or to amend existing maximum residue levels (MRLs) according to Regulation (EC) No 470/2009 or Regulation (EC) No 396/2005, and take any appropriate risk mitigation measures ensuring that the applicable MRLs are not exceeded.

The risk of using the product shall be acceptable for bees and the conditions of the authorisation shall include, where appropriate, risk mitigation measures to protect them.

3.3. ELEMENTS TO BE TAKEN INTO ACCOUNT BY MEMBER STATES WHEN AUTHORISING PRODUCTS

1. Products must be labelled appropriately to ensure safe storage, handling, use and disposal in accordance with national arrangements.

2. The size of the package placed on the market should be proportionate to the duration of the treatment and appropriate to the pattern of use of particular user groups.

3. Product design and use restrictions should be optimised in order to ensure efficient insect pest control while at the same time minimizing the risk for non-target organisms, especially bees.

4. The amateur use of 1R-trans phenothrin was not assessed as a part of this Competent Authority Report. Member States should be aware to fully evaluate this pattern of use in relation to the risk posed to humans, animals and the environment if application for this use is made at product authorisation.

5. Whilst the efficacy data provided is sufficient to recommend Annex I inclusion, data demonstrating the efficacy of the product at the minimum application rate against the range of proposed target organisms for knapsack spraying and ULV must be provided at the product authorisation stage.

6. The use of insecticides containing 1R-trans phenothrin must take into specific account the aquatic compartment of the environment. The potential risk of direct emissions, via drains, to water bodies should be considered for each Member State’s product authorisation.

7. The potential for residues of 1R-trans phenothrin in food and feed was not assessed as part of this Competent Authority Report. Member States should be aware to fully evaluate, as part of a dietary risk assessment, the potential for food/feed residues of 1R-trans phenothrin if application at product authorisation is being sought where there is a risk of food/feed contamination, such as kitchens, food processing factories, restaurants and shops that sell food/feed.

8. Member States should encourage the application of Codes of Good Practices in pest control. In particular, since the potential resistance of target insects to 1R-trans phenothrin has been identified, resistance management measures should be included in the authorisation of products and could include (but should not be restricted to) the following factors:

- The population size of the target insect should be evaluated before a control campaign. The dose and frequency of applications and the timing of the control campaign should be in proportion to the size of the infestation.
- A complete elimination of insects in the infested area should be achieved.
- The use instruction of products should contain guidance on resistance management for insecticides.
- Resistant management strategies should be developed, and 1R-trans phenothrin should not be used in an area where resistance to this substance is suspected.
- The authorisation holder and professional end-users shall report any observed resistance incidents to the Competent Authorities or other appointed bodies involved in resistance management.

9 Appropriate risk mitigation measures must be taken to minimise the potential exposure of humans, of non-target species and of the aquatic environment. In particular, Member States should consider that labels and/or safety-data sheets of products authorised clearly indicate that:

1. Professional users must wear appropriate personal protective equipment.

2. Products should be used in a way that minimises release to the aquatic environment.

3. Used and unused products shall be disposed of properly and not washed.

4. Products shall not be placed in areas accessible to infants, children and companion animals.

5. Products should be used in a way that minimises release to anaerobic environments.

10. When assessing applications for product authorisation, Member states should consider the fact that it is considered that d-Phenothrin:

- meets the criteria to be considered as “T”
- may potentially meet the criteria to be considered as “P”
- may potentially meet the criteria to be considered as “B”

It has been agreed that 1R-trans phenothrin should be further assessed by the ECHA PBT working group, in order to have a formal conclusion on those properties. Those conclusions should be taken into consideration at the stage of product authorisation.

11. d-Phenothrin is listed in the Annexes of the EU Commission document on implementation of the Community Strategy for Endocrine Disruptors as a substance with the potential to be a substance that cause endocrine disruption in both humans and animals. With this in mind, further information may be required to assess the potential for endocrine disruption of 1R-trans phenothrin when EU harmonised guidelines are established for test methods and risk assessment.

3.4. REQUIREMENT FOR FURTHER INFORMATION

It is considered that the evaluation has shown that sufficient data have been provided to verify the outcome and conclusions, and permit the proposal for the inclusion of 1R-trans phenothrin in Annex I to Directive 98/8/EC with regard to the toxicology and environment sections of this Competent Authority Report.

However, the following data requirements have been identified for physical-chemical properties and methods of analysis:

Identity of the active substance

- No requirements

Physical and chemical properties of the active substance

- No requirements

Physical and chemical properties of the biocidal product

The following information should be provided at product authorisation stage:

- A two year storage stability study at ambient temperature is required for the product Sumithrin 10SEC. To be provided at the product authorisation stage.

- Emulsifiability, emulsion stability and re-emulsification should also be tested under storage (storage under low temperature at 0°C for 7 days and storage at ambient temperature for 2 years) concentrations that are representative of the intended use should be used in the study. To be provided at the product authorisation stage.

- Pourability should be tested before and after storage (ambient temperature for 2 years). To be provided at the product authorisation stage.

Methods of analysis

The following information should be provided at product authorisation stage:

- An acceptable validated method is required to analyse the impurity p-SUM to a level of 0.1% in Sumithrin technical product.

The following information should be provided post-Annex I inclusion. It should preferably be submitted to the original Rapporteur Member State (Ireland) at the latest 6 months before the date of inclusion of the active substance into Annex I of directive 98/8/EC:

- Method of analysis for soil.

- Method of analysis for surface water.
- A validated method of analysis for the 1Rtrans isomer in the biocidal product.

Human health

No further data required for human toxicology

Environment

A study to measure the dislodgeable residue from washed floors may be required at product authorisation level to support non-targeted (blanket) treatments to floors.

No further data required for ecotoxicology.

3.5. UPDATING THIS ASSESSMENT REPORT

This assessment report may need to be periodically updated in order to take account of scientific developments and results from the examination of any of the information referred to in Articles 7, 10.4 and 14 of Directive 98/8/EC. Such adaptations will be examined and finalised in connection with any amendment of the conditions for the inclusion of 1R-trans phenothrin in Annex I to the Directive.

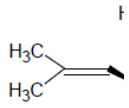
APPENDIX I: LIST OF ENDPOINTS

CHAPTER 1: IDENTITY, PHYSICAL AND CHEMICAL PROPERTIES, CLASSIFICATION AND LABELLING

Active substance (ISO Common Name)	1-R-trans-Phenothrin
Product-type	Main Group 3 (Pest control): Product type 18 (Insecticides, acaricides and products to control other arthropods)

Identity

Chemical name (IUPAC)	1Rtrans iomser: 3-phenoxybenzyl (1*R*,3*R*)-2,2-dimethyl- 3-(2-methylprop-1-enyl) cyclopropanecarboxylate The "sum of isomers": (3-Phenoxyphenyl)methyl 2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropane-1-carboxylate
Chemical name (CA)	1Rtrans iomser: Cyclopropanecarboxylic acid, 2,2-dimethyl- 3-(2-methyl-1-propenyl)-, (3-phenoxyphenyl)methyl ester, (1*R*,3*R*) The "sum of isomers": (3-phenoxyphenyl)methyl 2,2-dimethyl-3-(2-methyl-1-propen-1-yl)cyclopropanecarboxylate
CAS No.	1Rtrans isomer: 26046-85-5 The "sum of isomers": 26002-80-2
EC No.	1Rtrans isomer: 247-431-2 The "sum of isomers": 247-404-5
Other substance No.	1-R-trans isomer: No CIPAC No. available The "sum of isomers": CIPAC No. 356.
Minimum purity of the active substance as	The active substance shall comply with both the

manufactured (g/kg or g/l)	following minimum purities: 1Rtrans isomer: Min. 890 g/kg & The "sum of isomers": Min. 955 g/kg
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	None present
Molecular formula	$C_{23}H_{26}O_3$
Molecular mass	350.46
Structural formula	 1-R-trans-Phenothrin

Physical and Chemical Properties

Melting point (state purity)	-41.4 ºC (<231.6±0.5K) (93.8% w/w 1Rtrans- isomer & 99.8% w/w "sum of isomers")
Boiling point (state purity)	>301 ºC (96.75% w/w 1Rtrans- isomer & 99.4% w/w "sum of isomers")
Temperature of decomposition	> 301 °C (boiling point) (96.75% w/w 1Rtrans- isomer & 99.4% w/w "sum of isomers")
Appearance (state purity)	Liquid, oily; Pale yellow; slight petrol odour (90.04% w/w 1Rtrans- isomer & 97% w/w "sum of isomers")
Relative density (state purity)	1.06 at 20ºC (96.75% w/w 1Rtrans- isomer & 99.4% w/w "sum of isomers")
Surface tension	Not applicable (water solubility of the test substance is <1mg/l)
Vapour pressure (in Pa, state temperature)	2.37×10^{-5} Pa at 20°C ; 4.17×10^{-5} Pa at 25°C (96.75% w/w 1Rtrans- isomer & 99.4% w/w "sum of isomers")
Henry's law constant (Pa m^3 mol^{-1})	4.2 Pa m^3 mol^{-1} at 20°C
Solubility in water (g/l or mg/l, state temperature)	2 µg/l at 21°C (96.75% w/w 1Rtrans- isomer & 99.4% w/w "sum of isomers")
Solubility in organic solvents (in g/l or mg/l, state temperature)	Methanol >250 g/l; Acetone >250 g/l; Ethyl acetate >250 g/l; 1,2-dichloroethane >250 g/l; m-xylene >250 g/l; heptane >250 g/l (96.75% w/w 1Rtrans- isomer & 99.4% w/w "sum of isomers")
Stability in organic solvents used in biocidal products including relevant breakdown products	Not applicable as the product will not be formulated with organic solvents.
Partition coefficient (log P_{OW}) (state temperature)	pH 7 = logP_{ow} 6.8 It is accepted that d-phenothrin does not ionise in water therefore logP_{ow} 6.8 will apply at pH 5 and at pH 9. (96.75% w/w 1Rtrans- isomer & 99.4% w/w "sum of isomers")
Hydrolytic stability (DT_{50}) (state pH and temperature)	pH 5: at 25 ºC is 301 days
	pH 7: at 25 ºC is 495-578 days
	pH 9: at 25 ºC is 91-120 days

Dissociation constant	Not applicable.
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	UV/VIS absorbance max observed at 202.96, 202.37 & 217.27nm at acidic, neutral and alkaline pH. (93.8% w/w 1Rtrans- isomer & 99.8% w/w "sum of isomers")

Photostability (DT_{50}) (aqueous, sunlight, state pH)	9.1 hours of natural sunlight at pH 5 and 24.5ºC [^{14}C-benzyl]-*d-trans*-phenothrin 13.9 hours of natural sunlight at pH 5 and 24.5ºC [^{14}C-cyclopropyl]-*d-trans*-phenothrin
Quantum yield of direct phototransformation in water at Σ > 290 nm	Not applicable as the absorbance wavelengths were <290 nm (To be clarified)
Flammability	Autoflammability: 385ºC at 102.2kPa (90.04% w/w 1Rtrans- isomer & 97% w/w "sum of isomers") Flash Point: 130ºC at 101.2kPa (90.04% w/w 1Rtrans- isomer & 97% w/w "sum of isomers")
Explosive properties	No explosive properties based on the structure of the compound and the percentage oxygen balance.
Oxidising properties	Non-oxidising.

Classification and Proposed Labelling

With regard to physical/chemical data	No classification
With regard to toxicological data	Not applicable
With regard to fate and behaviour data	Not applicable
With regard to ecotoxicological data	R50/53: Very toxic to aquatic organisms, and may cause long-term adverse effects in the aquatic environment

CHAPTER 2: METHODS OF ANALYSIS

Analytical Methods for the Active Substance

Technical active substance (principle of method)	GC-FID (geometric isomers) GC-FID ("the sum of all isomers") HPLC-UV (enantiomers) .
Impurities in technical active substance (principle of method)	GC-FID.

Analytical Methods for Residues

Soil (principle of method and LOQ)	GC-MS The LOQ = 0.01 mg/kg.

	Two ions used for method validation (123 m/z for quantitation, and 183 m/z used for confirmation) The method determines geometric isomers and the "sum of all isomers". Data remains outstanding.
Air (principle of method and LOQ)	GC-MS The LOQ =0.001 mg/m^3 Three ions used for method validation (123 m/z for quantitation, 183, and 153 m/z used for confirmation) The method determines the "sum of all isomers".
Water (principle of method and LOQ)	<u>Drinking water -</u> GC-MS The LOQ = 0.1µg/L Three ions with m/z > 100 m/z used for method validation (183 m/z for quantitation, 350, and 123 m/z used for confirmation). The method determines the "sum of all isomers". <u>Surface water:</u> A method for surface water is required.
Body fluids and tissues (principle of method and LOQ)	Not applicable
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	Not applicable
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Not applicable

CHAPTER 3: IMPACT ON HUMAN HEALTH

Absorption, Distribution, Metabolism and Excretion in Mammals

Rate and extent of oral absorption:	Rapid, 60% based on urinary excretion.
Rate and extent of dermal absorption:	4.5% by 24 hrs (1% w/v formulation) Based on results of an *in vitro* human dermal absorption study.
Distribution:	Widely distributed, the highest residues in fat.
Potential for accumulation:	No potential for accumulation.
Rate and extent of excretion:	Rapid, ca. 90% within 24h days; almost complete within 7 days.
Toxicologically significant metabolite(s)	None

Acute Toxicity

Rat LD_{50} oral	> 5000 mg/kg bw
Rat LD_{50} dermal	> 5000 mg/kg bw
Rat LC_{50} inhalation	> 2.1 mg/l (whole body)
Skin irritation	Non-irritant
Eye irritation	Non-irritant
Skin sensitization (test method used and result)	Non sensitising (M&K)

Repeated Dose Toxicity

Species/ target / critical effect	Adaptive liver changes in the rat, mouse and dog: increased liver weight; occasional hepatocellular hypertrophy and elevated alkaline phosphatase levels.
Lowest relevant oral NOAEL / LOAEL	8.2 mg/kg bw/d (52 week, dog)
Lowest relevant dermal NOAEL / LOAEL	No study available
Lowest relevant inhalation NOAEL / LOAEL	0.104 mg/l (90 day, rat)

Genotoxicity	The overall body of toxicological data coming from a number of *in vivo* and *in vivo* assays indicates that there is no concern.

Carcinogenicity

Species/type of tumour	No tumours
Lowest dose with tumours	Not applicable

Reproductive Toxicity

Species/ Reproduction target / critical effect	Rat: F0 and F1 females and selected F2B male and female weanlings showed a slight, but consistent increase in relative liver weight.
Lowest relevant reproductive NOAEL / LOAEL	60 mg/kg bw/day

Species/Developmental target / critical effect	**Rat:** d-Phenothrin at 3000 mg/kg bw/day was associated with reduced food intake, reduced maternal weight gain during treatment and with increased water intake both during and after treatment. Foetal weight was significantly reduced and placental weight was increased compared with both the concurrent controls and the background control values. In Groups 2 and 3 (300 and 1000 mg/kg bw/day), foetal and placental weights were not significantly different from the control values. A dose related increase in the incidence of 14th rib was seen from the low to high dose. **Rabbit;** Abortions, one in the controls, three at 100 mg/kg bw/day, one at 300 mg/kg bw/day and four at 500 mg/kg bw/day occurred. Single incidences of spina bifida at 100 mg/kg bw/day and microphthalmia at 300 mg/kg bw/day also occurred. In addition, 4 incidences of hydrocephaly occurred in 3 litters at the highest dose. In a follow up study 1 incidence of hydrocephaly and 1 of microphthalmia was noted at a dose level of 750 mg/kg bw/d. This result suggests the incidences in the primary study may not have been due to treatment.
Developmental toxicity	
Lowest relevant developmental NOAEL / LOAEL	30 mg/kg bw/day

Neurotoxicity/Delayed Neurotoxicity

Species/ target/critical effect	No evidence of changes in sciatic nerves in rats.
Lowest relevant developmental NOAEL / LOAEL	Not applicable

Other Toxicological Studies

None

Medical Data

None

Summary

	Value	Study	Safety factor
ADI (acceptable daily intake, external long-term reference dose)	0.08 mg/kg bw	52 wk study in dog	100
AOEL-S (Operator Exposure) (AEL_{medium})	0.05 mg/kg bw	52 wk study in dog	100, 60% absorption correction
(AEL_{acute}) ARfD (acute reference dose)	0.18 mg/kg bw 0.3 mg/kg bw	The NOAEL for maternal embryo toxicity, foetotoxicity and teratogenicity in this study was found to be 30	100, 60% absorption correction (No absorption correction for ARfD)

		mg/kg bw/day	
Professional user ($AEL_{chronic}$)	0.05 mg/kg bw	52 wk study in dog	100, 60% absorption correction
Reference value for inhalation (proposed OEL)	None proposed	None proposed	None proposed
Dermal absorption	4.5%	I*n vitro* human dermal absorption study.	Not Applicable

Acceptable Exposure Scenarios (including method of calculation)

Professional users	Safe uses have been modelled using thespray ing model 1 and misting model 2from the TNsG 2002 for d-phenothrin when used professionally, from a knapsack or ULV sprayer, for treatment of crawling Insects and flying insects.
Production of active substance	Not evaluated
Formulation of biocidal product	Not evaluated
Intended uses	For use by professional operators to control crawling and flying insects in kitchens, food processing factories, trains, trucks, hospitals, restaurants, food shops, hotels and other public buildings.
Secondary exposure	Exposure scenarios have been assessed for indierct oral and dermal exposure to children. ULV surface application was found to yield unacceptable secondary exposure levels, when modelled using ConExpo and compared to the AEL_{acute} However, as use of the product will be limited to crack and crevice treatment and this use yields a safe exposure level post application exposure to children is not expected represent a problem.
Non-professional users	Not applicable
Indirect exposure as a result of use	Exposure scenarios have been assessed for indierct oral and dermal exposure to children. ULV surface application was found to yield unacceptable secondary exposure levels, when modelled using ConExpo and compared to the AEL_{acute} However, as use of the product will be limited to crack and crevice treatment and this use yields a safe exposure level post application exposure to children is not expected represent a problem.

CHAPTER 4: FATE AND BEHAVIOUR IN THE ENVIRONMENT

Route and Rate of Degradation in Water

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	pH 5: DT_{50} = 301 d at 25 °C ± 1 °C (equivalent to 852 d at 12 °C) [benzyl-^{14}C-d-*trans*-phenothrin, r^2 = 0.6859] pH 5: DT_{50} = 301 d at 25 °C ± 1 °C (equivalent to 852 d at 12 °C) [cyclopropyl-^{14}C-d-*trans*-phenothrin, r^2 = 0.8277]
	pH 7: DT_{50} = 578 d at 25 °C ± 1 °C (equivalent to 1,635 d at 12 °C) [benzyl-^{14}C-d-*trans*-phenothrin, r^2 = 0.1487] pH 7: DT_{50} = 495 d at 25 °C ± 1 °C (equivalent to 1,400 d at 12 °C) [cyclopropyl-^{14}C-d-*trans*-phenothrin, r^2 = 0.5163]
	pH 9: DT_{50} = 91 d at 25 °C ± 1 °C (equivalent to 257 d at 12 °C) [benzyl-^{14}C-d-*trans*-phenothrin, r^2 = 0.8986] pH 9: DT_{50} = 120 d at 25 °C ± 1 °C (equivalent to 339 d at 12 °C) [cyclopropyl-^{14}C-d-*trans*-phenothrin, r^2 = 0.9000]
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	pH 5: DT_{50} = 9.1 h at 25 °C ± 1 °C [benzyl-^{14}C]-d-*trans*-phenothrin pH 5: DT_{50} = 13.9 h at 25 °C ± 1 °C [cyclopropyl-^{14}C]-d-*trans*-phenothrin (Photodegradation rates could be enhanced in comparison to those that would be obtained under the conditions specified in the TNsG (latitude of 40 to 65 °N in spring or autumn), since results correspond to mid-summer conditions and more southerly latitudes.)
Readily biodegradable (yes/no)	No (OECD 301F)
Biodegradation in seawater	Not applicable.
Non-extractable residues	(water-sediment study – [benzyl-^{14}C]-d-*trans*-phenothrin, one test system only) 39.1% after 91 days
Distribution in water / sediment systems (active substance)	(water-sediment study – [benzyl-^{14}C]-d-*trans*-phenothrin, one test system only) 52.4% (water) / 44.3% (sediment) – day 0 0.3% (water) / 51.6% (sediment) – day 7 0.4% (water) / 14.2% (sediment) – day 91 Mineralisation: 43.7% after 91 days Non-extractable residues: 39.1% after 91 days It was only possible to determine a whole-system degradation rate. Degradation of d-*trans*-phenothrin in the whole system at an incubation temperature of 25 ± 2 ºC clearly followed biphasic kinetics and was best described by the DFOP model (double first order parallel), giving a DT_{50} value of 6.77 days and a DT_{90} value >1000 days. The rate of decline in the whole system slowed to almost a complete stop after about 20 days. The equivalent best-fit DT_{50} value at 12 ºC is 19.15 days.
Distribution in water / sediment systems (metabolites)	(water-sediment study – [benzyl-^{14}C]-d-*trans*-phenothrin, one test system only)

	Three main metabolites were detected – 3-phenoxybenzoic acid (PBacid), 3-(4-hydroxyphenoxy)benzoic acid (4'-OH-PBacid) and 3-(4-hydroxyphenoxy)benzyl (1R,3R)-2,2-dimethyl-3-(2-methyl-1-propenyl)cyclopropanecarboxylate (4'-OH-t-PHN) *PBacid* Whole-system maximum of 18.6% by day 30, declining to 3.5% by day 91 at the end of the incubation. Whole-system DT_{50}: 50.74 days (single first order) (equivalent to 143.6 days at 12 ºC) *4'-OH-PBacid* Whole-system maximum of 9.7% by day 14, declining to 0.4% by day 91. Not possible to derive a reliable degradation rate. *4'-OH-t-PHN* Whole-system maximum of 7.9% by day 2, declining to 2.7% by day 91. Not possible to derive a reliable degradation rate. Due to the position of radiolabelling in the test material it was only possible to see the formation of metabolites containing, or derived from, the phenoxyphenyl portion of the parent molecule. Potential additional metabolite formation deriving from the cyclopropane ring portion of d-phenothrin could not be detected by this study.

Route and Rate of Degradation in Soil

Mineralisation (aerobic)	Study 1 – [cyclopropyl-^{14}C]-d-*trans*-phenothrin, one soil (sandy loam) 51.6% after 120 days Non-extractable residues: 35.2% after 120 days Study 2 – [benzyl-^{14}C]-d-*trans*-phenothrin, one soil (sandy loam) 34.7% after 122 days Non-extractable residues: 51.5% after 122 days Study 3 – individual *trans* and *cis* isomers of phenothrin, two soils (clay loam and loamy sand) ~55-60% mineralisation by day 30 for *trans*-phenothrin, ~30-35% mineralisation by day 30 for *cis*-phenothrin Non-extractable residues: 20.3-31.7% by day 180 for *trans*-phenothrin, 31.5-45.8% by day 180 for *cis*-phenothrin
Laboratory studies (range or median, with number of measurements, with regression coefficient)	Study 1 – [cyclopropyl-^{14}C]-d-*trans*-phenothrin, one soil (sandy loam) DT_{50lab} (25 °C, aerobic): 9.2 days, equivalent to 26.0 days at 12 ºC (single first order, chi^2err% = 7.3812, r^2 = 0.9877) DT_{90lab} (25 °C, aerobic): 30.6 days No metabolites in excess of 10% of applied

radioactivity.

Study 2 – [benzyl-^{14}C]-d-*trans*-phenothrin, one soil (sandy loam)
DT_{50lab} (25 °C, aerobic): 9.6 days, equivalent to 27.2 days at 12 ºC (single first order, chi^2err% = 10.0913, r^2 = 0.9790)
DT_{90lab} (25 °C, aerobic): 31.7 days
No metabolites in excess of 10% of applied radioactivity.

Study 3 – individual *trans* and *cis* isomers of phenothrin, two soils (clay loam and loamy sand)
The *trans* and *cis* isomers each degraded rapidly in both soils with DT_{50} (25 ºC, aerobic) values in the range 1-2 days, corresponding to a range of 2.8 to 5.7 days at 12 ºC (DT_{50} values were determined from visual inspection of residue levels).
3-phenoxybenzyl alcohol was detected at a maximum level of 12.9% of applied radioactivity and declined rapidly, showing a decrease of greater than 95% from its maximum level within 11 days. No other metabolite was detected in excess of 10% of applied radioactivity.

Degradation in the saturated zone: Not applicable

Field studies (state location, range or median with number of measurements)

Not applicable

Anaerobic degradation

Study with individual *trans* and *cis* isomers of phenothrin on two soils (clay loam and loamy sand) under flooded conditions

trans-Phenothrin (25 ± 2 ºC)			
clay loam - double first order parallel		loamy sand - single first order	
k1 (d^{-1})	0.1849	k (d^{-1})	0.0172
k2 (d^{-1})	0.0078	DT_{50} (d)	40.2999
g	0.4960	DT_{90} (d)	133.8732
DT_{50} (d)	13.0166	chi^2err%	8.7977
DT_{90} (d)	207.3215	r^2	0.9653
chi^2err%	4.7867		
r^2	0.9915		
cis-Phenothrin (25 ± 2 ºC)			
clay loam - first order multicompartment		loamy sand - single first order	
alpha	0.3302	k (d^{-1})	0.0098
beta	2.8238	DT_{50} (d)	70.9961
DT_{50} (d)	20.2130	DT_{90} (d)	235.8441
DT_{90} (d)	>1000	chi^2err%	6.5668
chi^2err%	6.8047	r^2	0.9646

	r^2 0.9697 Equivalent DT_{50} values at 12 ºC are 36.8 and 114.0 days for the *trans* isomer and 57.2 and 200.9 days for the *cis* isomer. Mineralisation: ~5-15% by day 30 for *trans*-phenothrin, ~2-5% mineralisation by day 30 for *cis*-phenothrin Non-extractable residues: 27.6-43.3% by day 180 for *trans*-phenothrin, 32.7-39.5% by day 180 for *cis*-phenothrin No individual metabolites were detected in excess of 10% of applied radioactivity.
Soil photolysis	Not applicable
Non-extractable residues	Not applicable
Relevant metabolites - name and/or code, % of applied a.i. (range and maximum)	Not applicable
Soil accumulation and plateau concentration	Not applicable

Adsorption/Desorption

Ka , Kd Ka_{oc} , Kd_{oc} pH dependence (yes / no) (if yes type of dependence)	K_{oc} = 125,892.5 L/kg (d-*trans*-phenothrin) Log K_{oc} = 5.1 [OECD method 121 – HPLC method] pH dependence: No

Fate and Behaviour in Air

Direct photolysis in air	Not applicable.
Quantum yield of direct photolysis	Not applicable.
Photo-oxidative degradation in air	DT_{50} = 3.63 hours, (24-hour day, 5 x 10^5 OH radicals per cm^3), US EPA AOPWIN model v.1.91.
Volatilisation	Not applicable.

Monitoring Data, if available

Soil (indicate location and type of study)	Relevant European data not available
Surface Water (indicate location and type of study)	Relevant European data not available
Groundwater (indicate location and type of study)	Relevant European data not available
Air (indicate location and type of study)	Relevant European data not available

CHAPTER 5: EFFECTS ON NON-TARGET SPECIES

Toxicity Data for Aquatic Species (most sensitive species of each group)

Species	Time-scale	Endpoint	Toxicity
Fish			
Fish	96h	LC_{50}	0.0027 mg/l
Invertebrates			
Daphnia	48h	EC_{50}	0.0043 mg/l
Algae			
Algae	72h	EbC_{50} NOErC	>0.011 mg/l 0.0036 mg/l
Micro-organisms			
Activated Sludge	3h	EC_{50}	>100 mg/l

Effects on Earthworms or other Soil Non-target Organisms

Acute toxicity to…	Not tested as this compound is for indoor use only.
Reproductive toxicity to…	Not required

Effects on Soil Micro-organisms

Nitrogen mineralisation	Not tested as this compound is for indoor use only.
Carbon mineralisation	Not tested as this compound is for indoor use only.

Effects on Terrestrial Vertebrates

Acute toxicity to mammals	>5000 mg/kg bw (Refer to Annex IIA, point 6.1)
Chronic toxicity to mammals	NOAEL 8.2 mg/kg bw/day 52 week dog study 300 mg/kg food
Acute toxicity to birds	Not tested as this compound is for indoor use only.
Dietary toxicity to birds	5620 ppm 1.87 mg/kg food
Reproductive toxicity to birds	Not tested as this compound is for indoor use only.

Effects on Honeybees

Acute oral toxicity	Not tested.
Acute contact toxicity	0.005 µg a.i./bee

Effects on other Beneficial Arthropods

Acute oral toxicity	Not tested as this compound is for indoor use only.
Acute contact toxicity	Data not required
Acute toxicity to…	Data not required

Bioconcentration

Bioconcentration factor (BCF) Fish	2506-3192- l/kg (measured value, mean value 2849 l/kg); 841-1032 l/kg (calculated using BIOFAC method)
Bioconcentration factor (BCF) Earthworm	75,716 l/kg (calculated using QSAR by Jager, 1998)
Depuration time in Fish (DT50) (DT90)	DT_{50} mean 4.7-7.0 days (measured);5.3-7.2 days (calculated). DT_{90} not calculated
Level of metabolites (%) in organisms accounting for > 10 % of residues	At 28 days an unknown metabolite accounted for 11-13.2% of the residue. All other metabolites were <10%.

CHAPTER 6: OTHER ENDPOINTS

Effects on reproduction and growth rate of fish

NOEC	0.0011 mg a.i./L
LOEC	>0.0011 mg a.i./L

Effects on reproduction and growth rate with an invertebrate species

NOEC	0.00047 mg a.i./L
LOEC	0.00081 mg a.i./L
EC_{50} (EC_x)	0.0012 mg a.i./L

APPENDIX II: LIST OF INTENDED USES

Product-type:

18 (insecticides, acaricides and products to control other arthropods).

Claim of the participant:

1R-trans phenothrin is intended for indoor use only by professional operators, to control crawling and flying insects in areas such as trains, trucks, hospitals, hotels and other public buildings.

Target organisms:

Used for the control of crawling and flying insects including:

- German cockroaches *(Blattella germanica)*,
- American cockroaches *(Periplaneta Americana)*
- Oriental Cockroaches *(Blatta Orientalis)*
- House fly (*Musca domestica*);
- Mosquitoes (*Culicidae*);

Concentration:

Sumithrin® 10 SEC containing 10.5% w/w 1R-trans phenothrin.

Crawling Insects
For the control of cockroaches use 1 part of Sumithrin® 10 SEC diluted with 150-250 parts of water and applied by knapsack or power sprayer at the rate of 50 ml/square metre to give a maximum of 33 mg a.s. per square metre (0.07% a.s.).

For the ultra low volume (ULV) application, Sumithrin® 10 SEC should be diluted with an equal quantity of water and applied at the rate of 20 ml per 100 square metres or 0.08 ml/cubic metre via microgen E2, G2, 67 or 69 ULV equipment to give a maximum of 10 mg a.s. per square metre (5.25% a.s.).

Flying Insects
For the control of flying insects (flies, mosquitoes) use 1 part of Sumithrin® 10 SEC diluted with 250-500 parts of water and apply by knapsack or power sprayer at a rate of 50 ml/square metre to give a maximum of 20 mg a.s. per square metre for flying insects (0.04% a.s.).

Categories of users:

Professionals

Type of application:

Spray application: targeted crack and crevice surface spray applications.

Presented below is the water emulsifiable concentrate product, Sumithrin® 10 SEC.

Summary of intended uses for the product Sumithrin® 10 SEC: soluble emulsifiable concentrate product

Object and/or situation	Member State or Country	Product name	Organisms controlled	Formulation		Application			Remarks:
(a)			(c)	Type (d-f)	Conc. of as (i)	type	Dose rate	method kind (f-h)	(m)
Insecticide (PT18)	EU	**Sumithrin® 10 SEC**	Crawling insects e.g. American cockroaches *(Periplaneta Americana)*	SEC	10.5% w/w	Curative	Knapsack: 33 mg/a.s/m^2 ULV: 10 mg/a.s/m^2	Targeted crack/crevice spray application – Knapsack, ULV Indoors Professional use	SEC = Soluble Emulsifiable Concentrate ULV = Ultra Low Volume
Insecticide (PT18)	EU	**Sumithrin® 10 SEC**	Flying insects e.g. Mosquitoes (*Culicidae*)	SEC	10.5% w/w	Curative	Knapsack: 20 mg/a.s/m^2	Targeted crack/crevice spray application - Knapsack Indoors Professional use	Soluble Emulsifiable Concentrate

(a) *e.g.* biting and suckling insects, fungi, molds; (b) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(c) GCPF Codes - GIFAP Technical Monograph No 2, 1989 ISBN 3-8263-3152-4); (d) All abbreviations used must be explained
(e) g/kg or g/l;(f) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench;
(g) Kind, *e.g.* overall, broadcast, aerial spraying, row, bait, crack and crevice equipment used must be indicated;
(h) Indicate the minimum and maximum number of application possible under practical conditions of use;
(i) Remarks may include: Extent of use/economic importance/restrictions

APPENDIX III: LIST OF STUDIES

Data protection is claimed by the applicant in accordance with Article 12.1(c) (i) and (ii) of Council Directive 98/8/EC for all study reports marked "Y" in the "Data Protection Claimed" column of the table below.

Physical-Chemical Properties

Author(s)	Section No./Reference No.	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data Protection Claimed (Yes/No)	Owner
Physical & Chemical Properties Of The Active Substance					
Cuthbert J.E., Mullee D.M.	A3_1_1	2002	Title: S-1712: Determination of Melting/Freezing Temperature. Company: Safepharm Laboratories Ltd. Report No: SPL Project No. 1430/009 GLP: Yes	Yes	Sumitomo Chemical Co., Ltd.
Chambers, J.G.	A3_1_2	2006	Title: Determination of Physical and Chemical Properties of d-Phenothrin Company: Synergy Laboratories Ltd. Report No: STP-0005 GLP: Yes	Yes	Sumitomo Chemical Co., Ltd.
Hoffman M.	A3	1989	Title: Determination of Boiling Point/ Boiling Range of Sumithrin®. Company: Hazleton Laboratories America Inc., Wisconsin. Report No: Hazleton Report No. HLA 6001-295 GLP: Yes	Yes	Sumitomo Chemical Co., Ltd.
Chambers, J.G.	A3_1_3	2006	Title: Determination of Physical and Chemical Properties of d-Phenothrin Company: Synergy Laboratories Ltd. Report No: STP-0005 GLP: Yes	Yes	Sumitomo Chemical Co., Ltd.
Furuta, R.	A3_1_3	1988	Title: Specific Gravity of Sumithrin®. Company: Laboratory of Biochemistry and Toxicology, Sumitomo Chemical Co., Ltd. Reference No: EP-80-0050 GLP: No	Yes	Sumitomo Chemical Co., Ltd.
Semann T.	A3_2	1989	Title: Vapour Pressure Determination of Sumithrin® Company: Hazleton Laboratories America Inc.,	Yes	Sumitomo Chemical Co., Ltd.

Author(s)	Section No./Reference No.	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data Protection Claimed (Yes/No)	Owner
Physical & Chemical Properties Of The Active Substance					
			Wisconsin. Report No: HLA Study No. 6001-260 GLP: Yes		
Okada Y.	A3_2_1	2000	Title: Henry's Law Constant for d-Phenothrin (Sumithrin®) Company: Environmental Health Science Laboratory, Sumitomo Chemical Co., Ltd., Takarazuka, Japan. Report No: EF-2000-006 GLP: No.	Yes	Sumitomo Chemical Co., Ltd.
Chambers, J.G.	A3_3_1	2006	Title: Determination of Physical and Chemical Properties of d-Phenothrin Company: Synergy Laboratories Ltd. Report No: STP-0005 GLP: Yes	Yes	Sumitomo Chemical Co., Ltd.
Chambers, J.G.	A3_3_2	2006	Title: Determination of Physical and Chemical Properties of d-Phenothrin Company: Synergy Laboratories Ltd. Report No: STP-0005 GLP: Yes	Yes	Sumitomo Chemical Co., Ltd.
Chambers, J.G.	A3_3_3	2006	Title: Determination of Physical and Chemical Properties of d-Phenothrin Company: Synergy Laboratories Ltd. Report No: STP-0005 GLP: Yes	Yes	Sumitomo Chemical Co., Ltd.
Inoue, H	A3_4	2000	Title: UV/VIS, IR, NMR and Mass Spectra of S-1712 Technical Substance Company: Environmental Health Science Laboratory, Sumitomo Chemical Co., Ltd Report No: Study No. 3497 GLP: Yes	Yes	Sumitomo Chemical Co., Ltd.
Chambers, J.G.	A3_5	2006	Title: Determination of Physical and Chemical Properties of d-Phenothrin Company: Synergy Laboratories Ltd. Report No: SYN/2201 GLP: Yes	Yes	Sumitomo Chemical Co., Ltd.
Chambers, J.G.	A3_7	2006	Title: Determination of Physical and Chemical	Yes	Sumitomo Chemical

Author(s)	Section No./Reference No.	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data Protection Claimed (Yes/No)	Owner
Physical & Chemical Properties Of The Active Substance					
			Properties of d-Phenothrin Company: Synergy Laboratories Ltd. Report No: SYN/2201 GLP: Yes		Co., Ltd.
Duescher R., Loken R.	A3_7	1989	Title: Determination of Solubility of Sumithrin® in Organic Solvents Company: Hazleton Laboratories America Inc., Wisconsin. Report No: HLA 6001-264B GLP: Yes	Yes	Sumitomo Chemical Co., Ltd.
Chambers, J.G.	A3_9	2006	Title: Determination of Physical and Chemical Properties of d-Phenothrin Company: Synergy Laboratories Ltd. Report No: SYN/2201 GLP: Yes	Yes	Sumitomo Chemical Co., Ltd.
Loken R.	A3_9	1989	Title: Octanol/ Water Partition Coefficient Determination of Sumithrin®. Company: Hazleton Laboratories America Inc., Wisconsin. Report No: HLA 6001-259 GLP: Yes	Yes	Sumitomo Chemical Co., Ltd.
Chambers, J.G.	A3_10	2006	Title: Determination of Physical and Chemical Properties of d-Phenothrin Company: Synergy Laboratories Ltd. Report No: SYN/2201 GLP: Yes	Yes	Sumitomo Chemical Co., Ltd.
Chambers, J.G.	A3_11	2006	Title: Determination of Physical and Chemical Properties of d-Phenothrin Company: Synergy Laboratories Ltd. Report No: SYN/2201 GLP: Yes	Yes	Sumitomo Chemical Co., Ltd.
Furuta R.	A3_11	1988	Title: Flammability of Sumithrin® Company: Laboratory of Biochemistry and Toxicology, Sumitomo Chemical Co., Ltd. Reference No: EP-80-0053 GLP: No	Yes	Sumitomo Chemical Co., Ltd.

Author(s)	Section No./Reference No.	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data Protection Claimed (Yes/No)	Owner
Physical & Chemical Properties Of The Active Substance					
Chambers, J.G.	A3_12	2006	Title: Determination of Physical and Chemical Properties of d-Phenothrin Company: Synergy Laboratories Ltd. Report No: SYN/2201 GLP: Yes	Yes	Sumitomo Chemical Co., Ltd.
Chambers, J.G.	A3_14	2006	Title: Determination of Physical and Chemical Properties of d-Phenothrin Company: Synergy Laboratories Ltd. Report No: SYN/2201 GLP: Yes	Yes	Sumitomo Chemical Co., Ltd.
Asada Y.	A3_17	2005	Title: Reactivity of Pyrethroids Technical Materials towards Container Materials Company: Environmental Health Division, Sumitomo Chemical Co., Ltd.Report Reference No: QAP-0036 GLP: No	Yes	Sumitomo Chemical Co., Ltd.

Author(s)	Section No./Reference No.	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data Protection Claimed (Yes/No)	Owner
Physical & Chemical Properties Of The Biocidal Product					
Wooley A.J, Mullee D.M.	B3.1.1	2006	Title: Sumithrin 10SEC:Determination of General Physico-chemical Properties, Company: Safepharm Laboratories Ltd., Report No: 0483/0048, 9 GLP: Yes	Y	Sumitomo Chemical Co., Ltd.
Wooley A.J, Mullee D.M.	B.3.1.2	2006	Title: Sumithrin 10SEC:Determination of General Physico-chemical Properties, Company: Safepharm Laboratories Ltd., Report No: 0483/0048, 9 GLP: Yes	Y	Sumitomo Chemical Co., Ltd.
Wooley A.J, Mullee D.M.	B.3.1.3	2006	Title: Sumithrin 10SEC:Determination of General Physico-	Y	Sumitomo Chemical Co., Ltd.

Author(s)	Section No./Reference No.	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data Protection Claimed (Yes/No)	Owner
			chemical Properties, Company: Safepharm Laboratories Ltd., Report No: 0483/0048, 9 GLP: Yes		
Anon	B.3.4	Unknown	Title: Composition and Physico-chemical Properties of Sumithrin, 10SEC. Company: Report No: EF-10-0024	N	Sumitomo Chemical Co., Ltd.
Wooley A.J., Mullee D.M.	B.3.5	2006	Title: Sumithrin 10SEC, Determination of accelerated storage stability, low temperature stability and physico-chemical Characteristics Company: Safepharm Laboratories Ltd. Report No: 0555/0048 GLP: Yes	Y	Sumitomo Chemical Co., Ltd.
Wooley A.J, Mullee D.M.	B.3.6	2006	Title: Sumithrin 10SEC:Determination of General Physico-chemical Properties, Company: Safepharm Laboratories Ltd., Report No: 0483/0048, 9 GLP: Yes	Y	Sumitomo Chemical Co., Ltd.
Wooley A.J., Mullee D.M.	B.3.7	2006	Title: Sumithrin 10SEC, Determination of accelerated storage stability, low temperature stability and physico-chemical Characteristics Company: Safepharm Laboratories Ltd. Report No: 0555/0048 GLP: Yes	Y	Sumitomo Chemical Co., Ltd.
White, D.F.	B.3.7	2006	Title: Long-term storage stability 6 months at 25±2^{o}C Summary (Interim report) Company: Safepharm Laboratories Ltd. Report No: 0555/0069(a) GLP: Yes	Y	Sumitomo Chemical Co., Ltd.
Wooley	B.3.8	2006	Title: Sumithrin 10SEC,	Y	Sumitomo

Author(s)	Section No./Reference No.	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data Protection Claimed (Yes/No)	Owner
A.J., Mullee D.M.			Determination of accelerated storage stability, low temperature stability and physico-chemical Characteristics Company: Safepharm Laboratories Ltd. Report No: 0555/0048 GLP: Yes		Chemical Co., Ltd.
Wooley A.J., Mullee D.M.	B.3.10.1	2006	Title: Sumithrin 10SEC: Determination of General Properties Company: Safepharm Laboratories Ltd. Report No: 0483/0048 GLP: Yes	Y	Sumitomo Chemical Co., Ltd.
Wooley A.J., Mullee D.M.	B.3.10.2	2006	Title: Sumithrin 10SEC: Determination of General Properties Company: Safepharm Laboratories Ltd. Report No: 0483/0048 GLP: Yes	Y	Sumitomo Chemical Co., Ltd.

Analytical Methods

Author(s)	Section No./Reference No.	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data Protection Claimed (Yes/No)	Owner
Methods Of Analysis For the Active Substance					
Minamide C.	IIA4.1	1997	Title: Enforcement Analytical Method for Sumithrin Technical Grade, Company: Sumitomo Chemical Co., Ltd. Report No: 2356 GLP: Yes	Yes	Sumitomo Chemical Co., Ltd.
Minamide C.	IIA4.1(2)	1997	Title: Enforcement Analytical Method for Sumithrin Technical Grade, Company: Sumitomo Chemical Co., Ltd. Report No: 2356 GLP: Yes	Yes	Sumitomo Chemical Co., Ltd.
Minamide C.	IIA4.1(3)	1997	Title: Enforcement Analytical Method for Sumithrin Technical Grade, Company: Sumitomo Chemical Co., Ltd. Report No: 2356 GLP: Yes	Yes	Sumitomo Chemical Co., Ltd.
	IIA4.1(6)	2002	Title: CIPAC Method 356 – d-Phenothrin, CIPAC/4271/m d-Phenothrin & Title: Furuta R. (2002), CIPAC Method 356 – d-Phenothrin Small Scale Collaborative Study on the Determination of d-Phenothrin in d-Phenothrin Technical by gas Chromatography, Environmental Health Science Laboratory, Sumitomo Chemical Co. Ltd., CIPAC/4272/R d-Phenothrin	No	CIPAC
Wimbush J., Corfield L.	IIA4.2(b)	2006	Title: Sumithrin (d-Phenothrin): Validation of an Analytical Method for the determination of residues in air Company: Covance Laboratories Limited, Otley Road, Harrogate, UK.	Yes	Sumitomo Chemical Co. Ltd.

Author(s)	Section No./Reference No.	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data Protection Claimed (Yes/No)	Owner
			Report No: 2282/022-D2149 GLP: Yes		
Schuster L.L.	IIA4.2(c)	1988	Title: Method validation for the analysis of sumithrin in aquatic test water. Company: Analytical Bio-Chemistry Laboratories, Inc. Missouri. Report No: 37081 GLP: Yes	Y	Sumitomo Chemical Co. Ltd.
Methods of Analysis For The Biocidal Product					
White D.F, Mullee D.M.	B.4.1	2006	Title: Sumithrin 10SEC: Determination of Analytical Method Validation Company: Safepharm Laboratories Ltd., Report No: 0555/0027 GLP: Yes	Y	Sumitomo Chemical Co. Ltd.

Author(s)	Section No./Reference No.	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data Protection Claimed (Yes/No)	Owner
Efficacy					
Anon	IIIA5.3/6	1974	Insecticidal efficacy of Sumithrin® and Bio-resmethrin against flying insects., Takarazuka Research Center, Sumitomo Chemical Co., Ltd., Report Reference EE-40-0102, April 1974	Y	Sumitomo Chemical Co., Ltd.
Anon	IIIA5.3/3	1980	Comparative Insecticidal Activities between Sumithrin® and Permethrin against household insect pests, Institute for Biological Science, Sumitomo Chemical Co., Ltd., Reference No. EE-00-0042, March 1980	Y	Sumitomo Chemical Co., Ltd.
Lukwa N., Manokore V.	IIIA5.3/2	1997	Biological Activity of Permethrin, Phenothrin/Allerthrin and d-Phenothrin on Periplaneta Americana and Blattella Germanica Cockroaches, East African Medical Journal Vol. 74, No. 4 April 1997	N	Publ.
Nishibe I., Itoh T.	IIIA5.3/1	1986	Flushing out Efficacy of Aircraft Use Aerosol Containing 2% (w/v) of Sumithrin Against German Cockroach, Pesticide Laboratory, Takarazuka Research Centre, Sumitomo Chemical Co., Ltd., Hyogo, Japan, Reference No. EE-60-0099, May 1986	Y	Sumitomo Chemical Co., Ltd.
Süss	IIIA5.3/5	1985	Laboratory Evaluation of the Efficacy of Sumithrin 10 SEC with Ultra Low Volume Sprayer, University of Milan, Report Reference EE-61-0131, 19 December 1985	Y	Sumitomo Chemical Co., Ltd.
Yoshida K.	IIIA5.3/4	1982	Insecticidal Efficacy of Red Earth Containing S-2703 Forte, Permethrin or Sumithrin Against German Cockroaches, Sumitomo Chemical Co., Ltd, Reference No.EE-20-0063, December 1982	Y	Sumitomo Chemical Co., Ltd.

Author(s)	Section No./Reference No.	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data Protection Claimed (Yes/No)	Owner
	B5	2006	Draft Label - Sumithrin 10 SEC, Sumitomo Chemical Co., Ltd, GLP: No, Unpublished.	Y	Sumitomo Chemical Co., Ltd.
Anon	B5_10/1	1984	Insecticidal Efficacy of Sumithrin 10 SEC against Housefly and German Cockroach, Sumitomo Chemical Co., Ltd, EE-50-0078, GLP: No, Unpublished	Y	Sumitomo Chemical Co., Ltd.

Author(s)	Section No./Reference No.	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data Protection Claimed (Yes/No)	Owner
Chianella; Rossi	B5_10/2	1986	Semi-Field Residual Contact/Floor Tiles/ Cockroach, SIAPA Research Centre, Trial No. 705/I/87, EE-61-0106, GLP: No, Unpublished	Y	Sumitomo Chemical Co., Ltd.
Chianella; Rossi	B5_10/3	1986	Blatta Orientalis/Floor Tiles/Cockroach, SIAPA Research Centre, Trial No. 724/I/87, EE-61-0108, GLP: No, Unpublished	Y	Sumitomo Chemical Co., Ltd.
Anon	B5_10/4	1992	Comparison Efficacy Test Between Trigger Sprayer and Mistlon Sprayer against American Cockroach (Periplaneta americana) and German cockroach (Brattella germanica) using Emulsifiable Concentrate(EC) and Solubilized Emulsion Concentrate(SEC), Sumitomo Chemical Co., Ltd, EEE-20-0084, GLP: No, Unpublished	Y	Sumitomo Chemical Co., Ltd.
Anon	B5_10/5	1992	Comparison Efficacy Test Between Emulsifiable Concentrate(EC) and Solubilized Emulsion Concentrate(SEC) a certain type of sprayer against American Cockroach (Periplaneta americana) and German cockroach (Blattella germanica) using Trigger Sprayer and Mistlon Sprayer, Sumitomo Chemical Co., Ltd, EEE-20-0085, GLP: No, Unpublished	Y	Sumitomo Chemical Co., Ltd.
Chianella; Rossi	B5_10/6	1986	Semi-Field Residual Contact/Floor Tiles/ Cockroach, SIAPA Research Centre, Trial No. 712/I/87, EE-61-0107, GLP: No, Unpublished	Y	Sumitomo Chemical Co., Ltd.
Chianella; Fiorini	B5_10/7	1986	Blatta Orientalis (Cockroach), SIAPA Research Centre, Trial No. 810/I/86, EEE-61-0051, GLP: No, Unpublished	Y	Sumitomo Chemical Co., Ltd.
Senior L	B5_10/8	2006	Laboratory studies to assess Sumithrin 10 SEC, applied as a direct spray, for efficacy against cockroaches, Insect Investigations Ltd, Study Code 06/36, GLP: No, Unpublished	Y	Sumitomo Chemical Co., Ltd.
Senior L	B5_10/9	2006	Laboratory studies to assess Sumithrin 10SEC, applied as a residual spray, for efficacy against cockroaches, Insect Investigations Ltd, Study Code	Y	Sumitomo Chemical Co., Ltd.

Author(s)	Section No./Reference No.	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data Protection Claimed (Yes/No)	Owner
			06/37, GLP: No, Unpublished		
Süss	B5_10/10	1985	Laboratory Evaluation of the Efficacy of Sumithrin 10 SEC with Ultra Low Volume Sprayer, University of Milan, EE-61-0131, GLP: No, Unpublished	N	Sumitomo Chemical Co., Ltd.

Toxicology

Author(s)	Section No./Reference No.	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data Protection Claimed (Yes/No)	Owner
Toxicology					
Amyes S.J., Macrae S.M., Martin P.A., Whitney J.C.	IIIA6.3.1	1983	Sumithrin®: Five Week Range-Finding Toxicity Study in Mice Life Sciences Research Ltd., Eye, Suffolk. LSR No. 83/SUM006/024, GLP (Unpublished).	Y	Sumitomo Chemical Co., Ltd.
Amyes S.J., Martin P.A., Ashby R., Lee P., Brown P.M., Fowler J.S.L., Finn J.P.	IIIA6.7/2	1987	Sumithrin®: Oncogenicity and Toxicity Study in Mice. Life Sciences Research Ltd., Eye, Suffolk. Report No. 86/SUM007/166, GLP (Unpublished).	Y	Sumitomo Chemical Co., Ltd.
Anon	A8	2004	Safety Data Sheet SUMITHRIN TG; Issued: 19/03/2004 Revision 1	N	Sumitomo Chemical Co., Ltd.
Cox R.	IIIA6.5	1987	Chronic Toxicity Study in Dogs with Sumithrin®, T.G. Hazleton Laboratories America, Inc., Virginia. Study No. 343-173, GLP (Unpublished).	Y	Sumitomo Chemical Co., Ltd.
Hadfield N	IIIA6.2/02	2006	Sumithrin: In Vitro Absorption from a 1% Sumithrin Formulation through Human Epidermis Draft Report Syngenta Central Toxicology Laboratory Report Number: JV1898-REG, GLP (Unpublished).	Y	Sumitomo Chemical Co., Ltd.
Hoffman G.M.	IIIA6.1.3	1995	An Acute (4-hour) Inhalation Toxicity Study of Sumithrin® in the Rat via Whole-Body Exposure. Pharmaco LSR Inc., New Jersey. Study No. 95-5241, GLP (Unpublished).	Y	Sumitomo Chemical Co., Ltd.
Kenny T.J., Coombs D.,W., Hardy C.J., Clark G.C., Crook D., Gopinath C.	IIIA6.4.3	1989	Sumithrin T.G. 90 Day Inhalation Toxicity Study in the Rat Huntingdon Research Centre Ltd., Huntingdon, Cambridgeshire, England HRC Report No. SMO 314/89644	Y	Sumitomo Chemical Co., Ltd.
Khoda H., Nishimo K., Kadota T., Miyamoto J.	IIIA6.3.3	1973	Acute and Subacute Inhalation Toxicity Studies of S-2539 and S-2539 Forte in Rats and Mice. Research Department, Pesticides Division, Sumitomo Chemical Co., Ltd. , nonGLP (Unpublished).	Y	Sumitomo Chemical Co., Ltd.
Kishida F., Suzuki H.	IIIA6.6.4/2	1981a	Mutagenicity Test of Sumithrin® in Host-Mediated Assay.	Y	Sumitomo Chemical

Author(s)	Section No./Reference No.	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data Protection Claimed (Yes/No)	Owner
			Laboratory of Biochemistry and Toxicology, Research Department, Pesticides Division, Sumitomo Chemical Co., Ltd. , GLP (Unpublished). , nonGLP (Unpublished).		Co., Ltd.
Kishida F., Suzuki H.	IIIA6.6.1	1981b	Gene Mutation Test of Sumithrin® in Bacterial System. Laboratory of Biochemistry and Toxicology, Research Department, Pesticides Division, Sumitomo Chemical Co., Ltd. , GLP (Unpublished).	Y	Sumitomo Chemical Co., Ltd.
Martin P.A.	IIIA6.7/1	1987	Sumithrin®: Combined Toxicity and Oncogenicity Study in rats. Life Sciences Research Ltd., Eye, Suffolk. Report No. 85/SUM003/586, GLP (Unpublished).	Y	Sumitomo Chemical Co., Ltd.
Misaki Y.	IIIA6.1.1	1997	Acute Oral Toxicity Study of S-1712 in Rats. Environmental Health Science Laboratory, Sumitomo Chemical Co., Ltd. Study No. 3262, GLP (Unpublished).	Y	Sumitomo Chemical Co., Ltd.
Misaki Y.	IIIA6.1.2	1996	Acute Dermal Toxicity Study of Sumithrin® in Rats. Environmental Health Science Laboratory, Sumitomo Chemical Co., Ltd. Study No. 3146, GLP (Unpublished).	Y	Sumitomo Chemical Co., Ltd.
Murakami M., Hiromori T., Ito S., Hosokawa S.	IIIA6.4.1/2	1981	Six Month Oral Toxicity Study of S2539 Forte (Sumithrin®) in Rats Laboratory of Biochemistry and Toxicology, Research Department, Pesticides Division, Sumitomo Chemical Co. Ltd., Hyogo, Japan. , GLP (Unpublished).	Y	Sumitomo Chemical Co., Ltd.
Murli H.	IIIA6.6.2	1989	Mutagenicity Test on Sumithrin® T.G.in an In Vitro Cytogenetic Assay Measuring Chromosomal Aberration Frequencies in Chinese Hamster Ovary (CHO) Cells Hazleton Laboratories America Inc., Maryland. Study No. 10593-0-437, GLP (Unpublished).	Y	Sumitomo Chemical Co., Ltd.
Nakanishi T.	IIIA6.1.4/ 1	1988	Primary Eye and Skin Irritation Tests with Sumithrin® in Rabbits.	Y	Sumitomo Chemical

Author(s)	Section No./Reference No.	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data Protection Claimed (Yes/No)	Owner
			Laboratory of Biochemistry and Toxicology, Sumitomo Chemical Co., Ltd. Study No. 1536, GLP (Unpublished).		Co., Ltd.
Nakanishi T.	IIIA6.1.4/ 2	1988	Primary Eye and Skin Irritation Tests with Sumithrin® in Rabbits. Laboratory of Biochemistry and Toxicology, Sumitomo Chemical Co., Ltd. Study No. 1536, GLP (Unpublished).	Y	Sumitomo Chemical Co., Ltd.
Nakanishi T.	IIIA6.1.5	1988	Skin Sensitization Test with Sumithrin® in Guinea pigs. Laboratory of Biochemistry and Toxicology, Sumitomo Chemical Co., Ltd. Study No. 1555, GLP (Unpublished).	Y	Sumitomo Chemical Co., Ltd.
Nemec M.D.	IIIA6.8.1/2	1989	A Teratology Study in Rabbits with Sumithrin® WIL Research Laboratories, Ashland, OH. Project No.: WIL-118003, GLP (Unpublished).	Y	Sumitomo Chemical Co., Ltd.
Okuno Y., Kadota T.	IIIA6.9	1978	Neurotoxicity Study of d-Phenothrin (S-2539-Forte®) in Rats by Repeated Oral Administration. Institute for Biological Science, Hyogo, Japan. , GLP (Unpublished).	Y	Sumitomo Chemical Co., Ltd.
Pence D., Hagen W.H., Alsaker R.D., Hastings T.F., Dawkins B.G., Tacey R.L., Marshall P.M.	IIIA6.4.1/3	1981	Subchronic Toxicity Study in Dogs S2539-F Hazleton Laboratories America, Inc., Virginia. Project No. 343-128 , GLP (Unpublished).	Y	Sumitomo Chemical Co., Ltd.
Shono F	IIIA6.12.1	2005	Review on Medical Examination of Factory Workers Exposed to Pyrethroids Environmental Health Division, Sumitomo Chemical Co., Ltd. Report No SVT-009 , nonGLP (Unpublished).	N	Sumitomo Chemical Co., Ltd.
Suzuki H., Hara M., Miyamoto J.	IIIA6.6.4/1	1981	In Vivo Chromosomal Aberration Test of Sumithrin® on Bone Marrow Cells of Mice. Research Department, Pesticides Division, Sumitomo Chemical Co., Ltd. , GLP (Unpublished).	Y	Sumitomo Chemical Co., Ltd.

Author(s)	Section No./Reference No.	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data Protection Claimed (Yes/No)	Owner
Tesh J.M., Willoughby C.R., Fowler J.S.L.	IIIA6.8.2	1986	Sumithrin®: Effects Upon Reproductive Performance of Rats Treated Continuously Throughout Two Successive Generations. Life Sciences Research Ltd., Eye, Suffolk. Report No. 85/SUM009/331, GLP (Unpublished).	Y	Sumitomo Chemical Co., Ltd.
Tesh J.M., Willoughby C.R., Lambert E.P., Wilby O.K., Tesh S.A.	IIIA6.8.1/1	1983	Sumithrin®: Effects of Oral Administration Upon Pregnancy in the Rat (2.) Main Study. Life Sciences Research Ltd., Eye, Suffolk. Report No. 83/SUM005/084, GLP (Unpublished).	Y	Sumitomo Chemical Co., Ltd.
Yallup V.M., Ashby R., Whitney J.C.	IIIA6.4.1/1	1983	Sumithrin®:Toxicity in Dietary Administration over 13 Weeks. Life Science Research. Life Sciences Research Ltd., Eye, Suffolk. LSR Report No. 82/SUM002/222, GLP (Unpublished).	Y	Sumitomo Chemical Co., Ltd.
Yoshitake A., Nakatsuka I., Isobe N., Matsunaga H.	IIIA6.2/01	1987	Metabolism of (1R, trans)- and (1R, cis)- Isomers of Phenothrin in Rats. Laboratory of Biochemistry and Toxicology, Takarazuka Research Center, Sumitomo Chemical Co., Ltd. Study Nos.: 340, 341, 342, 343, 502, 503, GLP (Unpublished).	Y	Sumitomo Chemical Co., Ltd.

Author(s)	Section No./Reference No.	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data Protection Claimed (Yes/No)	Owner
Toxicology					
Kohda H., Kadota T., Miyamoto J.	IIIB6.1.1/1	1979	Acute Oral, Subcutaneous and Dermal Toxicity Studies of Sumithrin® 10% Solubilized Emulsion Concentrate in Rats and Mice Research Department, Pesticide Division, Sumitomo Chemical Co., Ltd. Non GLP (Unpublished).	Y	Sumitomo Chemical Co., Ltd.
Kohda H., Kadota T., Miyamoto J.	IIIB6.1.1/2	1979	Acute Oral, Subcutaneous and Dermal Toxicity Studies of Sumithrin® 10% Solubilized Emulsion Concentrate in Rats and Mice Research Department, Pesticide Division, Sumitomo Chemical Co., Ltd. Non GLP (Unpublished).	Y	Sumitomo Chemical Co., Ltd.

Author(s)	Section No./Reference No.	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data Protection Claimed (Yes/No)	Owner
Kohda H., Kadota T., Miyamoto J.	IIIB6.1.2/1	1979	Acute Oral, Subcutaneous and Dermal Toxicity Studies of Sumithrin® 10% Solubilized Emulsion Concentrate in Rats and Mice Research Department, Pesticide Division, Sumitomo Chemical Co., Ltd. Non GLP (Unpublished).	Y	Sumitomo Chemical Co., Ltd.
Kohda H., Kadota T., Miyamoto J.	IIIB6.1.2/2	1979	Acute Oral, Subcutaneous and Dermal Toxicity Studies of Sumithrin® 10% Solubilized Emulsion Concentrate in Rats and Mice Research Department, Pesticide Division, Sumitomo Chemical Co., Ltd. Non GLP (Unpublished).	Y	Sumitomo Chemical Co., Ltd.
N/A	IIIB8	2005	Safety Data Sheet Sumithrin 10 SEC Issued 08/06/2005 Revision No. 1 Sumitomo Chemical (UK) Plc	N	Sumitomo Chemical Co., Ltd.
N/A	IIIB5	2006	Draft Label - Sumithrin 10 SEC Sumitomo Chemical Co., Ltd	Y	Sumitomo Chemical Co., Ltd.
Okuno Y., Miyagawa H., Kadota T., Miyamoto J.	IIIB6.2/E	1975	Irritative effect of Sumithrin® solubilized emulsifiable concentrate on the rabbit eye and skin. Research Department, Pesticide Division, Sumitomo Chemical Co., Ltd. Non GLP (Unpublished).	Y	Sumitomo Chemical Co., Ltd.
Okuno Y., Miyagawa H., Kadota T., Miyamoto J.	IIIB6.2/S	1975	Irritative effect of Sumithrin® solubilized emulsifiable concentrate on the rabbit eye and skin. Research Department, Pesticide Division, Sumitomo Chemical Co., Ltd.	Y	Sumitomo Chemical Co., Ltd.
Okuno Y., Miyagawa H., Kadota T., Miyamoto J.	IIIB6.3	1975	Skin Sensitization Test with Sumithrin® Solubilized Emulsifiable Concentrate in Guinea-pigs Research Department, Pesticide Division, Sumitomo Chemical Co., Ltd.	Y	Sumitomo Chemical Co., Ltd.
Toho Chemical Industry Co., Ltd.	IIIB2	2005	Sorpol SM-100PM, MSDS No. 523310, Issued 22 July 2005 Toho Chemical Co., Ltd., Yokosuka-Shi, Kanagawa-Ken, Japan.	N	Toho Chemical Industry Co., Ltd.

Environment (incl. Eco-toxicology)

Author(s)	Section No./Reference No.	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data Protection Claimed (Yes/No)	Owner
Environmental Fate and Behaviour					
Bates, M.	IIIA, 7.1.3	1999	d-trans-Phenothrin: Evaluation of the Soil Adsorption Coefficient (Koc) by HPLC Simulation in Accordance with the Draft OECD Guideline (1997) "Estimation of the Adsorption Coefficient (Koc) on Soil and on Sewage Sludge using High Performance Liquid Chromatography (HPLC)". Covance Laboratories Ltd, Harrogate, England., Report No. 333/134-D2141, GLP (unpublished).	Y	Sumitomo Chemical Co., Ltd.
Grutzner I.	IIIA, 7.1.1.2.1/01	2002a	Ready Biodegradability of S-1712 in a Manometric Respirometry Test. RCC Ltd., Switzerland., Study No. 820596, GLP (unpublished).	Y	Sumitomo Chemical Co., Ltd.
Hatzenbeler C.J.	IIIA, 7.1.2.2.1	1999	Aerobic Aquatic Soil Metabolism of [Benzyl-^{14}C]-d-trans-Phenothrin Ricerca, Inc., 7528 Auburn Road, P.O. Box 1000, Painesville, OH, USA, Report No. 7430-98-0010-EF-001, GLP (unpublished).	Y	Sumitomo Chemical Co., Ltd.
Hatzenbeler C.J	IIIA, 7.1.1.1.1/01	2000a	A Hydrolysis Study of [Benzyl-14C] -d-trans-Phenothrin in Water. Environmental and Metabolic Fate, Ricerca, Painesville OH, Report No. 007782-1-1, GLP (unpublished).	Y	Sumitomo Chemical Co., Ltd.
Hatzenbeler C.J	IIIA, 7.1.1.1.1/02	2000b	A Hydrolysis Study of [Cyclopropyl-1-14C] -d-trans-Phenothrin in Water. Environmental and Metabolic Fate, Ricerca, Painesville OH, Report No.	Y	Sumitomo Chemical Co., Ltd.

Author(s)	Section No./Reference No.	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data Protection Claimed (Yes/No)	Owner
			007781-1-1, GLP (unpublished).		
Nambu K., Ohkawa H., Miyamoto J.	IIIA, 7.2.1/03	1980	Metabolic Fate of Phenothrin in Plants and Soils Research Department, Pesticides Division, Sumitomo Chemical Co., Ltd., Takarazuka, Hyogo 665, Japan Published paper (J. Pesticide Sci. 5, 177-197 (1980)), GLP status not reported.	N	Public domain
Nambu K., Ohkawa H., Miyamoto J.	IIIA, 7.2.1/04	1980	Metabolic Fate of Phenothrin in Plants and Soils Research Department, Pesticides Division, Sumitomo Chemical Co., Ltd., Takarazuka, Hyogo 665, Japan Published paper (J. Pesticide Sci. 5, 177-197 (1980)), GLP status not reported.	N	Public domain
Shepler K., Ruzo L.O., McGovern P.A.	IIIA, 7.1.1.1.2/01	1989a	Aqueous Solution Photolysis of [14C-benzyl]-d-trans-phenothrin in Natural Sunlight. Pharmacology and Toxicology Research Laboratory- Richmond, California, Report No. 160W-1, GLP (unpublished).	Y	Sumitomo Chemical Co., Ltd.
Shepler K., Ruzo L.O., McGovern P.A.	IIIA, 7.1.1.1.2/02	1989b	Aqueous Solution Photolysis of [14C-cyclopropyl]-d-trans-phenothrin in Natural Sunlight. Pharmacology and Toxicology Research Laboratory- Richmond, California, Report No. 159W-1, GLP (unpublished).	Y	Sumitomo Chemical Co., Ltd.
Takahashi N., Matsuda T., Mikami N.	IIIA, 7.1.1.1.2/03	1989	Hydrolysis and Photolysis of d-trans-Phenothrin in Aqueous Media (Preliminary Study) Biochemistry and Toxicology Laboratory, Sumitomo Chemical Co., Ltd., Technical Reference No. E-89-006, GLP (unpublished).	Y	Sumitomo Chemical Co., Ltd.
Takahashi N., Matsuda T., Mikami	IIIA, 7.1.1.1.2/04	1989	Hydrolysis and Photolysis of d-trans-Phenothrin in Aqueous Media (Preliminary	Y	Sumitomo Chemical Co., Ltd.

Author(s)	Section No./Reference No.	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data Protection Claimed (Yes/No)	Owner
N.			Study) Biochemistry and Toxicology Laboratory, Sumitomo Chemical Co., Ltd., Technical Reference No. E-89-006, GLP (unpublished).		
Williams, M.D., Bielefeld, T.A.	IIIA, 7.2.1/01	1991a	Aerobic Soil Metabolism Study of [Cyclopropyl-14C]-d-trans-Phenothrin ABC Laboratories Inc., 7200 East ABC Lane, P.O. Box 1097, Columbia, Missouri 65202, USA, ABC Final Report #38070, GLP (unpublished).	Y	*Sumitomo Chemical Co., Ltd.*
Williams, M.D., Bielefeld, T.A.	IIIA, 7.2.1/02	1991b	Aerobic Soil Metabolism Study of [Benzyl-14C]-d-trans-Phenothrin ABC Laboratories Inc., 7200 East ABC Lane, P.O. Box 1097, Columbia, Missouri 65202, USA, ABC Final Report #38289, GLP (unpublished).	Y	*Sumitomo Chemical Co., Ltd.*

Author(s)	Section No./Reference No.	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data Protection Claimed (Yes/No)	Owner
Ecotoxicology					
Anon	A8	2004	Safety Data Sheet SUMITHRIN TG; Issued: 19/03/2004 Revision 1	N	Public Domain
Bowman J.	A7_4_1_1/01	1988a	Acute Flow-Through Toxicity of Sumithrin® to Rainbow Trout (Salmo gairdneri).	Y	Sumitomo Chemical Co., Ltd.
Bowman J.	A7_4_1_1/02	1988b	Acute Flow-Through Toxicity of Sumithrin® to Bluegill Sunfish (Lepomis macrochirus)	N	Public Domain
Graves W.C., Swigert J.P.	A7_4_1_2	1994	Sumithrin®: A 48-hour Flow-Through Acute Toxicity Test with the Cladoceran (daphnia magna).	Y	Sumitomo Chemical Co., Ltd.
Grimes J., Jaber M.	A7_5_3_1_2	1988	A Dietary LC50 Study with the Bobwhite.	Y	Sumitomo Chemical Co., Ltd.

Author(s)	Section No./Reference No.	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data Protection Claimed (Yes/No)	Owner
Grutzner I.	A7_4_1_4	2002b	Toxicity of S-1712 to Activated Sludge in a Respiration Inhibition Test.	Y	Sumitomo Chemical Co., Ltd.
Hoberg J.R.	A7_4_1_2	2002	S-1712 Toxicity to the Freshwater Green Algae, Pseudokirchneriella subcapitata.	Y	Sumitomo Chemical Co., Ltd.
Hoxter K. A., Thompson M. M., Jaber M.	A7_5_4_1	1989	Sumithrin®: An acute contact toxicity study with the honey bee.	N	Public Domain
Miyamoto M., Saito S., Takimoto Y., Matatoshi M.	A7_4_3_3_1/03	1992	Effect of Metabolism on Bioconcentration of Geometric Isomers of d-Phenothrin in Fish Environmental Health Science Laboratory, Sumitomo Chemical Co., Ltd., 4-2-1, Takatsukasa, Takarazuka, Hyogo, 665 Japan Published paper (Chemosphere, Vol 24, No 12, pp2001-2007, 1992), GLP status not reported.	N	Public domain
Ohshima M., Takahasi N.	A7_4_3_3_1/01	1990	Accumulation and Metabolism of 14 C-d-trans-Phenothrin in Bluegill Sunfish (Lepomis macrochirus)	Y	Sumitomo Chemical Co., Ltd.
Putt A.E.	A7_4_3_4	1998	Sumithrin-The Chronic Toxicity to Daphnia magna under Flow-Through Conditions	Y	Sumitomo Chemical Co., Ltd.
Saito S., Yoshida S., Takimoto Y.	A7_4_3_3_1/02	1993	Accumulation and Metabolism of ^{14}C-d-cis-Phenothrin in Bluegill Sunfish (Lepomis macrochirus) Environmental Health Science Laboratory, Sumitomo Chemical Co., Ltd., Hyogo 665, Japan, Study No. ACC92003, GLP (unpublished).	Y	Sumitomo Chemical Co., Ltd.
Sousa J.V.	A7_4_3_2	1998	Sumithrin-Early Life-Stage Toxicity Test with Rainbow Trout (Oncorhynchus mykiss)	Y	Sumitomo Chemical Co., Ltd.
Tanoue A.	A7_4_3_3_1/04	1990	Bioconcentration Test of 3-Phenoxybenzyl (1R)-cis-trans-chrysanthemate (Commercial name: Sumithrin)	Y	Sumitomo Chemical Co., Ltd.

Author(s)	Section No./Reference No.	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data Protection Claimed (Yes/No)	Owner
			Environmental Health Science Laboratory, Sumitomo Chemical Co., Ltd., Hyogo 665, Japan., Study No. KSOP/REC/011 RS-1, GLP (unpublished - translated from Japanese to English 28 October 2011).		