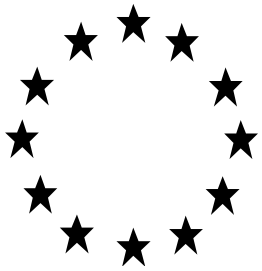
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

Evaluation of active substances

Assessment Report



Permethrin

Product-Type 8

(Wood Preservative)

Rapporteur: Ireland

April 2014

Permethrin PT8

Assessment report

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 Permethrin as product-type 8 (wood preservative), carried out in the context of the work programme for the review of existing active substances provided for in Article 89 of Regulation (EU) No 528/2012, with a view to the possible approval of this substance.

Permethrin (CAS no. 52645-53-1) was notified separately as an existing active substance, by Bayer Environmental Science/Sumitomo Chemicals (UK) Ltd. and Tagros Chemicals India Ltd, hereafter referred to as the applicants, in product-type 8.

Commission Regulation (EC) No. 1451/2007 of 4 December 2007[1] lays down the detailed rules for the evaluation of dossiers and for the decision-making process.

In accordance with the provisions of Article 7(1) 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. The deadline for submission of a complete dossier for Permethrin as an active substance in product-type 8 was 28 March 2004, in accordance with Annex V of Regulation (EC) No. 1451/2007.

On 24 March 2004, the Irish competent authority received a dossier from the applicant Bayer Environmental Science/Sumitomo Chemical (UK) Ltd. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation on 24 September 2004.

On 24 March 2004, the Irish competent authority received a dossier from the applicant Tagros Chemicals India Ltd. On 20 December 2006 and 21 December 2007, updates to the dossier were received by the Irish competent authority from the applicant Tagros Chemicals India Ltd, as requested. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation on 26 June 2008.

On 21 June 2010, the Rapporteur Member State submitted to the Commission and the applicant a copy of the evaluation report, hereafter referred to as the competent authority report.

In accordance with Article 16 of Regulation (EC) No 1451/2007, the Commission made the competent authority report publicly available by electronic means on 22 June 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 as well as BPC meetingts and the competent authority report was amended accordingly.

1.2. PURPOSE OF THE ASSESSMENT REPORT

The aim of the assessment report is to support the opinion of the Biocidal Products Committee and a decision on the approval of Permethrin for product-type 8, and, should

[1] 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.

it be approved, to facilitate the authorisation of individual biocidal products. In the evaluation of applications for product-authorisation, the provisions of Regulation (EU) No 528/2012 shall be applied, in particular the provisions of Chapter IV, as well as the common principles laid down in Annex VI.

For the implementation of the common principles of Annex VI, the content and conclusions of this assessment report, which is available from the Agency web-site shall be taken into account.

However, where conclusions of this assessment report are based on data protected under the provisions of Regulation (EU) No 528/2012, such conclusions may not be used to the benefit of another applicant, unless access to these data for that purpose has been granted to that applicant.

2. OVERALL SUMMARY AND CONCLUSIONS

2.1. PRESENTATION OF THE ACTIVE SUBSTANCE

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

CAS No.: 52645-53-1
EC No.: 258-067-9

Other No. (CIPAC, ELINCS): 331 (CIPAC)

IUPAC Name: 3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate

CA Name: (3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate

Common name, synonym: Permethrin

Molecular formula: $C_{21}H_{20}Cl_2O_3$

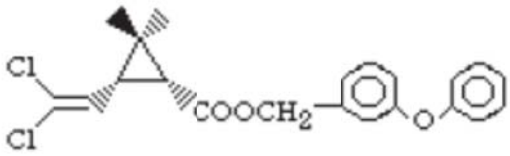
Purity: Permethrin has four stereoisomers:
1Rcis, 1Scis, 1Rtrans, and 1Strans.
Two pairs of diastereomers (each consisting of a non-racemic pair of enantiomers) are present in a ratio of *ca.* 25:75

Specification ≥93.0% w/w sum of all permethrin isomers.

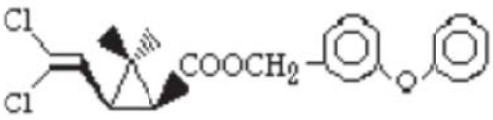
Permethrin is a reaction mass of four stereoisomers
1Rcis permethrin content = 5.0 – 10.0% w/w.
1Scis permethrin content = 15.0 – 20.0% w/w.
1Rtrans permethrin content = 45.0 – 55.0% w/w.
1Strans permethrin content = 17.0 – 27.0% w/w.

Structural formula

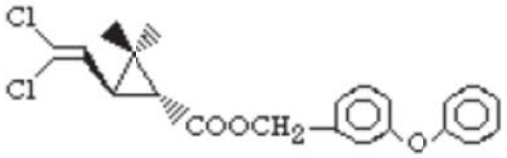
1Rcis isomer –



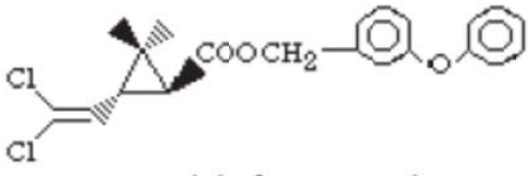
1Scis isomer –



1Rtrans isomer –



1Strans isomer –



Molecular weight (g/mol): 391.29 g/mol

Application in support of permethrin PT8 was received from two notifiers - Bayer Environmental Science/Sumitomo Chemicals (UK) Ltd and Tagros Chemicals India Ltd.

Permethrin technical (CAS number 52645-53-1) is manufactured by a toll manufacturer for Bayer Environmental Science/Sumitomo Chemicals (UK) Ltd. Tagros Chemicals India Ltd manufactures its' own source of Permethrin technical (see respective Confidential Sections for details).

The minimum purities of the Tagros and Bayer sources of technical material are based on representative batch data from the respective manufacturing facilities.

The minimum purity of the Tagros source is 93% w/w sum of all permethrin isomers.
Total cis range: 25 – 28% ratio
Total trans range: 72-75% ratio
1Rcis range: 7.9 – 8.3% w/w.
1Scis range: 15.8 – 16.7% w/w.
1Rtrans range: 45.4 – 46.1% w/w.
1Strans range: 22.5 – 23.0 % w/w.

The minimum purity of the Bayer source is 95% w/w sum of all permethrin isomers.
Total cis range: 22 – 28% ratio
Total trans range: 72-78% ratio
1Rcis range: 5.0 – 10.0% w/w.
1Scis range: 15-20% w/w.
1Rtrans range: 45 – 55% w/w.
1Strans range: 17 – 27 % w/w.
Following evaluation of the confidential data supplied by the two notifiers, Bayer/Sumitomo and Tagros Ltd., it is considered that the two sources of active substance are technically equivalent based on the technical equivalent guidance and following discussions at the Technical Meetings.

The overall minimum purity for Annex I inclusion is 93% w/w.
Cis:trans permethrin % ratio = 22-28:72-78 cis:trans.
1Rcis permethrin content = 5.0 – 10.0% w/w.
1Scis permethrin content = 15.0 – 20.0% w/w.
1Rtrans permethrin content = 45.0 – 55.0% w/w.
1Strans permethrin content = 17.0 – 27.0% w/w.

Permethrin is a yellow brown viscous liquid with a characteristic aromatic odour. The active substance is virtually insoluble in water (<0.00495 to 0.18 mg/l at 20°C), readily soluble in all solvent (>250g/l at both 20°C and 30°C). The data supplied indicate that the molecule is fat soluble with a Log Pow of 4.67 +/- 0.01 at 25°C. Permethrin does not absorb >290 nm which indicates that the molecule is not susceptible to breakdown by light. Results show that the molecule is non-volatile (2.155 x 10^{-6} Pa at 20°C).

Permethrin will not classify as being flammable, explosive or oxidising.

2.1.1.1. Analysis of the active substance as manufactured

Acceptable validated analytical methods were provided to determine the active substance content in the technical products.

Acceptable validated methods were provided to measure the cis/trans ratio and enantiomer content in technical products.

Acceptable validated methods were provided to determine impurities in the technical products.

2.1.1.2. Formulation analysis

Validated chiral methods of analysis for the active substance in formulations will be required at member state level six months before product authorization.

2.1.1.3. Residue analysis

Since the proposal is for non-crop use then analytical methods for residues in food of plant and animal origin are not required.

An acceptable validated method for residues of permethrin in soil was presented.

Acceptable validated methods were provided for residues of permethrin in water and in air.

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

Main Group: 2 – Preservatives
Product Type: 08 – Wood Preservatives

Permethrin is used in industrial preventive wood preservative applied in automated spraying, vacuum pressure, double vacuum pressure, flow coating or dipping treatment

plants. Timber treated with this active substance may be placed in Biological Hazard Classes 1, 2, 3 and 4a.

Permethrin containing products in Professional and Amateur use may be applied by brushing and spraying, and in professional use by remedial brushing and spraying and remedial injection.

The function of permethrin is insecticidal (including a termiticide) to control wood-destroying insects, such as *Hylotrupes bajulus* (Old-house borer), *Reticulitermes santonensis* (European subterranean termite), *Anobium punctatum* (Furniture beetle) *Lyctus brunneus* (Powderpost beetle), *Xestobium rufovillosum* (Deathwatch beetle), *Reticulitermes speriaus* (Japanese termite); *Coptotermes formosanus* (Formosan subterranean termite) during both larval and adult life-cycle stages.

Effectiveness data demonstrating the effect of permethrin was provided for the following species; *Macrotermes bellicosus* (Sudanese warlike termite), *Pseudacanthotermes militaris* (Sugarcane termite), *Microtermes subhyalinus*, *Odontotermes pauperans*, *Ancistrotermes guineensis* and *Ancistrotermes spp.*, *Pissodes strobi* (Pine weevil), *Dendroctonus rufipennis* (Spruce beetle), *Hylotrupes bajulus* (Old-house borer), *Anobium punctatum* (Furniture beetle), *Lyctus brunneus* (Powderpost beetle) and *Reticulitermes santonensis* (Subterranean termite).

2.1.2.2. Effects on target organism(s)

The target organisms ingest a small amount of the treated wood which, once ingested, results in death of the target pests (see mode of action below).

As an insecticide, Permethrin when formulated as a wood preservative, is an axonic poison, binding to protein in nerves (voltage-gated sodium channel). Normally, this protein opens causing stimulation of the nerve and closes to terminate the nerve signal. Pyrethroids bind to this gate and prevent it from closing normally which results in continuous nerve stimulation. Efficacy data on permethrin-based products indicates effects on different species at different exposure scenarios at a concentration range in product of 0.01 to 0.5%. Lethality (knockdown) is the only recognised effect, and *in situ* concentration-dependence of the effect has been demonstrated; however the threshold concentration is species dependant. The toxic value for the *cis*-isomer is approximately 8 times lower than the *trans*-isomer, however different ratio isomer mixtures commercially available (typically 25:75 to 75:25) exhibit similar toxic values for wood-boring insects.

It should also be noted that permethrin may also exhibit a mild contact repellent effect in conjunction with the insecticidal effect. This contact repellence effect is also common to other pyrethroid insecticides (such as deltamethrin, cypermethrin, esfenvalerate and lamda-cyhalothrin) and is known as the "hot-foot effect" and may be relevant for some arthropods. The repellent effect is dose related and for insecticidal products the repellent effect of permethrin is considered as a side effect, since the toxic response of the insect is a delayed kill (insecticidal) effect.

No information was provide or available on the efficacy of the different permethrin isomers.

2.1.2.3. Humaneness

Not applicable.

2.1.2.4. Resistance

There are no reported cases of development of resistance involving the use of permethrin in wood preservation. However, cases of resistance have been documented in a wide variety of insects when permethrin has been used as a general insecticide as documented for the PT18 use of permethrin. The level of resistance is less than tenfold in some of the species but high levels of resistance have been observed such as in cockroaches. In general, pyrethroid resistance has been attributed to reduced neural sensitivity, enhanced metabolism, and reduced penetration ratio in many insects. A substantial degree of resistance remaining after synergism suggests the presence of other resistance mechanisms. As such it is good practice that authorization holders and professional end-users report any observed resistance incidents to the Competent Authorities or other appointed bodies involved in resistance management. Additionally, pest management strategies are advised in the use of permethrin for wood preservation in order to combat any potential for the onset of resistance.

2.1.3.Classification and Labelling

2.1.3.1. Current classification and labelling of the active substance

Directive 67/548/EEC

Hazard symbol: (for labelling)	Xn N	Harmful Dangerous for the environment
Indication of danger:		
Risk Phrases: (for labelling)	R20/22 R43 R50 R53	Harmful by inhalation and if swallowed May cause sensitisation by skin contact Very toxic to aquatic organisms May cause long-term adverse effects in the aquatic environment
Safety Phrases: (for labelling)	S 2 S 13 S 24 S 36/37/39 S 60 S 61	Keep out of the reach of children Keep away from food, drink and animal feedingstuffs Avoid contact with skin Wear suitable protective clothing, gloves and eye/face protection This material and its container must be disposed of as hazardous waste Avoid release to the environment. Refer to special instructions/Safety data sheets
Specific concentration limits	C ≥ 25 %: Xn, N; R20/22-43-50-53 1 % ≤ C < 25 %: N; R43-50-53 0,025 % ≤ C < 1 %: N; R50-53 0,0025 % ≤ C < 0,025 %: N; R51-53 0,00025 % ≤ C < 0,0025 %: R52-53	

Regulation (EC) No 1272/2008

Pictogram: (for labelling)	
Signal word:	Warning
Hazard Statements: (for labelling)	H410: Very toxic to aquatic life with long lasting effects. H302+H332: Harmful if inhaled and swallowed H317: May cause an allergic skin reaction
M-Factor	Acute M-Factor: 100, Chronic M-Factor: 10000 (based on 0.001<L(E)C50≤0.01) and (0.000001<NOEC≤0.00001, NRD)

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

Hazard Class and Category Codes Hazard Statement Code(s)	Acute Tox. 4 H302 Acute Tox. 4 H332 Skin Sens. 1 B H317 Aquatic Acute 1 H400 Aquatic Chronic 1 H410
Pictogram: (for labelling)	
Signal word:	Warning
Hazard Statements: (for labelling)	H410: Very toxic to aquatic life with long lasting effects. H302+H332: Harmful if inhaled and swallowed H317: May cause an allergic skin reaction
M-Factor	Acute M-Factor: 100, Chronic M-Factor: 10000 (based on 0.001<L(E)C50≤0.01) and (0.000001<NOEC≤0.00001, NRD)

Physical-Chemical Properties:
The active substance permethrin will not classify as being flammable, explosive or oxidising. No further data required.

Toxicology:
No changes proposed. However, under the CLP Regulation the classification of permethrin as a skin sensitizer needs to be distinguished between category 1A and 1B. This was not required under the previous dangerous substances legislation. On the basis of the data that comprises five studies three from the biocide process and two from the pesticide process. However, as the substance is currently classified sensitizer R43 and there are two positive studies we would advocate retaining the classification as sensitiser according to the CLP Regulation and propose the classification of permethrin as a skin sensitizer category 1B ('skin sens. Cat. 1B').

Environment:
Please note that a change is incurred according to the amendment No: 286/2011 of Commission Regulation (EU) No: 1272/2008.

H400 (Acute Cat 1) will be changed to H410 (Acute Cat 1; Chronic Cat 1): Very toxic to aquatic life with long lasting effects, in accordance with the principles of precedence for hazard statements outlined in Article 27 of the CLP Regulation.
M-Factor added: Acute M-Factor: 100 Chronic M-Factor: 10000 (based on 0.001<L(E)C50≤0.01) and (0.000001<NOEC≤0.00001, NRD).

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

The classification of biocidal products containing permethrin will require to be evaluated at Member State level when product authorisation is required.

Directive 99/45/EC

Symbols	
Classification	Xn: Harmful N: Dangerous for the environment
R phrases	R: 20/22, Harmful if swallowed and inhaled. R43: May cause skin sensitisation R65: Harmful: May cause lung damage if swallowed R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
S phrases	S2: Keep out of reach of children S24: Avoid contact with skin. S13: Keep away from food, drink and animal feedingstuffs S36/37/39: Wear suitable protective clothing, gloves and eye/face protection. S60: This material and its container must be disposed of as hazardous waste. S61: Avoid release to the environment. Refer to special instructions/safety data sheets. S62: If swallowed, do not induce vomiting: seek medical advice immediately and show this container or label

CLP Regulation (EC) No 1272/2008 and amendment No: 286/2011

Pictogram: (for labelling)	
Signal word:	Warning
Hazard Statements: (for labelling)	H410 (Acute Cat 1; Chronic Cat 1): Very toxic to aquatic life with long lasting effects. H332: Harmful if inhaled H302: Harmful if swallowed H304: May be fatal if swallowed and enters airways H317: May cause an allergic skin reaction

Precautionary Statements: (for labelling)	P280: Wear eye/face protection P302+352+313: IF ON SKIN: Wash with plenty of soap and water. P301+P310: IF SWALLOWED immediately call a POISON CENTER or doctor/physician P331: Do NOT induce vomiting P273: Avoid release to the Environment P391: Collect spillage P501: Dispose of contents/container to hazardous waste
M-Factor	Acute M-Factor: 100, Chronic M-Factor: 10000 (based on 0.001<L(E)C50≤0.01) and (0.000001<NOEC≤0.00001, NRD)

Justification for the proposal:

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

Human Health
The acute oral studies submitted by Applicant 1 and 2 had LD_{50} values ranging from 480 - 1623 mg/kg bw/day, respectively. Under CLP this results in H302; Harmful if swallowed. Permethrin did not classify as toxic or harmful by the dermal route. Although the inhalation studies submitted by Applicant 1 and 2 indicated it did not require classification for inhalation, Under CLP Permethrin is classified as H332; Harmful by inhalation.
The classification is based on the study (Brammer A., 1989) referenced in PPP DAR. Having one non-guideline negative study, one guideline positive study, one guideline negative study and an existing classification. The rationale of the RMS was to apply the precautionary principal and retain the classification.

The study submitted by applicant 1, Parcell (1991) was negative for skin sensitisation. However, two previously evaluated studies (Leah, 1989 & Thakkar, Bharat 1995) both recorded positive results for permentrhin. According to applicant 2, Permethrin is not a skin sensitiser and does not require classification. However, the Buehler method, which was used in Applicant 2 study is not recommended for testing the active substance, the guinea pig maximistation test method is the recommended method for the active substance.
Permethrin is classified as a skin sensitiser, therefore the RMS propose H317: May cause an allergic skin reaction under the CLP Regulation

Environment
Permethrin is classified under CLP as H410 (Acute Cat 1, Chronic Cat 1) very toxic to aquatic life with long-lasting effects. This classification is based on the high toxicity to fish (0.0051 mg a.s./L) and to aquatic invertebrates, with *Daphnia* 0.00127 mg a.s/L, being the most sensitive of the aquatic organisms tested. Chronic toxicity studies resulted in a NOEC of 0.0000047 mg/L for *Daphnia magna*.

2.2. SUMMARY OF THE RISK ASSESSMENT

2.2.1. Human Health Risk Assessment

The technical material supported by the notifiers relates to permethrin as a reaction mass of four stereoisomers (1Rcis, 1Scis, 1Rtrans, and 1Strans), with two pairs of diastereoisomers in a isomeric ratio of 25:75 (cis:trans). Studies were conducted with permethrin 25:75 or with a mixture of isomers where the permethrin samples contain 50-75% of the trans- isomer.

2.2.1.1. Hazard Identification

Toxicokinetics
Following an oral absorption study Permethrin was found to undergo rapid and extensive absorption in the body. According to Gaughan & Casida, 1977, residues levels recorded in the fat, liver and kidney were generally low and there was no evidence for accumulation. However, the cis isomer showed relatively higher residue levels (0.46-0.62 mg/kg tissue) in the fat. Major metabolites identified are Cl2CA in free and glucuronide form, sulfate conjugate of 4'-hydroxy-3-phenoxybenzoic acid, PB acid in free and conjugate form, and hydroxymethyl-Cl2CA as a glucuronide conjugate. Absorption and metabolism of permethrin is rapid and extensive, with only between 3 and 6% of the administered dose being recovered un-metabolised in faeces. Consequently, oral absorption is assumed to be 100%. Absorption via the inhalation route was also set to 100%. Inhalation absorption was assumed to be 100%.

Dermal penetration
Dermal absorption has been set a 3% derived in a human dermal penetration study. The first two volunteers have been excluded from the derivation as they have a very low recovery and were regarded as outlines compared to the other 4 volunteers. In addition, the values have been normalised to 100% to compensate for the low recovery allowing derivation of a dermal absorption value of 3% as a rounded figure.

Acute Toxicity
The acute oral studies submitted had LD_{50} values ranging from 480 - 1623 mg/kg bw/day. Therefore, Permethrin classifies as H302; Harmful if swallowed. Permethrin did not classify as toxic or harmful by the dermal route. Although the inhalation studies submitted by the current applicants indicated the substance did not require classification for inhalation, Permethrin is currently classified under Regulation (EC) No. 1727/2008 as H332: Harmful if inhaled. This classification is based on a study (Brammer A., 1989) referenced in PPP DAR. Combining information in the PPP DAR and biocides CAR the following studies are available; one non-guideline negative study; one guideline positive study; one guideline negative study and an existing classification. The rationale of the RMS was is apply the precautionary principal and retain the classification based on the aforementioned data. No adverse effects or signs of irritation were noted in available human data.

Sensitisation
The study submitted by applicant 1, Parcell (1991) was negative for skin sensitisation. However, two previously evaluated studies (Leah, 1989 & Thakkar, Bharat 1995) both recorded positive results for permenthrin. According to applicant 2, Permethrin is not a skin sensitiser and does not require classification. However, the Buehler method, which was used in Applicant 2 study, is not recommended for testing the active substance. Under Regulation (EC) No. 1727/2008, Permethrin is classified as a skin sensitiser, therefore the RMS proposed to retain the classification H317; May cause an allergic skin sensitisation.

Repeated dose toxicity
Permethrin is of relatively low repeat dose toxicity with effects seen at sub-lethal doses being mainly transient and reversible in nature. The critical effect in rats includes increased absolute and relative liver weight, the target organ. The liver weights were associated with hepatocellular hypertrophy. Via the oral route the 90 day rat studies from both applicants yielded NOAELs of about 175 mg/kg bw/day based on reversible liver effects. The combined overall relevant dermal LOAEL and NOAEL was 2000 and 1000 mg/kg bw/day, respectively, based effects including, tremors, piloerection, statistically significant decrease in bodyweight and food consumption and increased mean relative liver weights in males. Nasal irritation and mild tremor were noted

following inhalation exposure with LOAEL and NOAEL 117.8 and 59.43 mg/kg bw/d, respectively.

The dog was the most sensitive species. A NOAEL of 10 mg/kg bw/day was established in a 6-month dog study based particularly on increased liver weight at 50 and 250 mg/kg/day. An acute NOAEL of 250 mg/kg/day is based on clinical signs, mortality, bodyweight, ophthalmoscopy, electrocardiography. A NOAEL of 5 mg/kg bw/day has been established in a one-year dog study for permethrin (32% *cis*/60% *trans*) on the basis of histopathological changes in the adrenals in males and females, reduced bodyweight gain in females and increased liver weight in both sexes, accompanied by hepatic cellular swelling at 100 mg/kg bw per day. The medium and long-term AELs were derived from this study.

Genotoxicity

Permethrin was tested in a battery of *in vitro* and *in vivo* assays measuring several endpoints of potential genotoxicity such as gene mutation and chromosomal aberration. The *in vitro* tests included four bacterial reverse mutation assays, three mammalian gene mutation tests, a UDS assay and a mammalian chromosome aberration assay. *In vivo* tests included two mammalian bone marrow chromosome aberration tests, a mammalian erythrocyte micro-nucleus test and a Rodent dominant lethal test. Permethrin did not exhibit genotoxic potential in the standard set of tests. However, in one of the chromosome aberration assays (Barrueco et al 1994) as positive result in the absence of S9 was recorded. However this study was not conducted under GLP conditions and the protocol did not conform to the OECD guidance. In addition, two reliable and positive comet assays were submitted by the company. However, lack of guidance on interpretation of comet assays, lack of a OECD guideline, lack a validated protocol and lack of GLP make the import of these tests difficult to quantify. Adopting the weight of evidence approach, factoring in the difficulties associated with comet assays, the conduct and lack of corroborating evidence for the findings of the Barrueco study, the three negative *in vivo* studies and the lack of a genotoxic profile for pyrethroids the RMS has concluded that permethrin is not genotoxic.

Carcinogenicity

Carcinogenicity and long term toxicity of permethrin have been investigated in the rat and the mouse. No treatment related change was seen in the incidence of tumours in either species. In chronic toxicity studies, NOAELs of 50 mg/kg bw/day (McSheehy & Finn, 1980) and 50 mg/kg bw/day (Ishmael & Litchfield, 1988) have been established in the rat for permethrin (25% *cis*/75% *trans*) and permethrin (40% *cis*/60% *trans*) respectively, whilst a NOAEL of 150 mg/kg bw/day has been established for permethrin (40% *cis*/60% *trans*) in the mouse (Ishmael & Litchfield, 1988).

A NOAEL of 75 mg/kg derived in the Baskaran, J. (2007) study with no evidence of carcinogenicity these findings were in line with the other chronic rat and mouse studies.

Reproductive toxicity

Reproductive performance was unaffected in both sets of data submitted. The RMS deemed the 2-generation study submitted by applicant 1 (Bayer) as the most appropriate for determining the overall relevant reproductive NOAEL and LOAEL. James, 1979, observed that following exposure of rats to Permethrin during their reproductive life did not cause significant treatment related maternal or pup effects up to and including 180-mg/kg bw/day. Based on the findings observed under the conditions of this study, the dose of 180mg/kg bw/day was established as the parental and reproductive toxicity NOAEL. Therefore the NOAEL for parental and fertility effects were 180 mg/kg bw/day.

Permethrin exposure to rabbits in utero was not teratogenic. Litters exposed to the high dose of Permethrin (400 mg/kg bw/day) did not exhibit a treatment or dose related

effect on external malformations, visceral or skeletal abnormalities. On the basis of these results, the dose level of 400-mg/kg bw/day was considered to be No Observed Adverse Effect Level (NOAEL) of the study for foetal effects.

Neurotoxicity
Permethrin has no delayed neurotoxic potential such as that associated with certain organophosphates (Bond *et al*, 1980), however, there is evidence that motor activity and acetylcholine receptors in mice can be negatively impacted by repeated inhalation exposure to permethrin (25% *cis*/75% *trans*). Increased rearing activity in male mice and a reduction in muscarinic receptors in the brains of male and female mice was associated with inhalation treatment with permethrin. However, derivation of a NOAEL from the inhalation study appears almost impossible. The study was a whole body exposure study of pups and dams and does not have a pharmacokinetic testing element. Therefore, the amount of exposure via ingestion, inhalation or dermal absorption cannot be quantified. Also, the study was non-guideline, non-GLP for research purposes. In the context of this type of exposure it is very difficult know what the dose actually was and consequently to derive a systemic NOAEL.

It is proposed that a study to investigate the neurotoxic potential of exposure to Permethrin is not required, as there is sufficient data available in the open literature and the mechanism of action is well documented. Rats were administered Permethrin (cis:trans ratio: 36%: 59%, purity 95.3%) at doses of 0, 10, 150 and 300 mg/kg bw. Clinical signs such as tremors, staggered gait and effects on hind limb were noted at 300 mg/kg bw. Neuropathological examination of nervous tissue revealed no treatment-related lesions. The NOAEL was considered to be 150 mg/kg bw (JMPR, 1999). Permethrin (cis:trans ratio: 36%: 59%; purity: 95.3%) was administered in the diet to rats for 28 days, at concentrations of 0, 100, 750, 1500, 3000, 4000 or 5000 ppm. Treatment related clinical signs; similar to those observed in the previous study, were seen at doses ≥ 1500 ppm. The NOAEL was therefore considered to be 750 ppm (38 mg/kg bw/day). Rats were administered Permethrin for 90 days (cis:trans ratio, 36%:59%; purity, 95.3%) at concentrations of 0, 250, 1500 and 2500 ppm in the diet. Clinical signs such as staggered gait, splayed hind limbs and tremors were reported at 1500 ppm. The NOAEL was 250 ppm (15 mg/kg/day).
The aforementioned NOAEL values are all higher than the proposed AEL values for exposure.

Human data
Toxicological evaluations on Permethrin have previously been carried out by the World Health Organisation (1990) and the JMPR (1999). For both evaluations observational data in humans was submitted. In WHO trials in Nigeria, no adverse effects were observed following indoor use of Permethrin at a rate of 0.5 g/m3. In a separate study summarised in the JMPR toxicological evaluation (1999) 23 laboratory workers involved in field trials, formulation or general laboratory work with synthetic pyrethroids (Cypermethrin, Permethrin, Fenvalerate and Fenpropathrin) were examined. No symptoms related to Permethrin were noted. All the workers were examined neurologically and no abnormal findings were recorded.

Toxicological evaluations on Permethrin have previously been carried out by the World Health Organisation (1990) and the JMPR (1999). For both evaluations observational data in humans was submitted. In one report soldiers wore clothing impregnated with 0.2% w/v Permethrin (25:75) after which no adverse effects or signs of irritation were noted. Another, whereby a group of patients was treated for pediculosis capitis with a 1% Permethrin cream rinse. Cutaneous side effects such as pruritus and mild burning/stinging sensations were noted but as the preparation contained isopropanol (20%), a known skin irritant, a direct link to Permethrin was not established. Please refer to IIIA, 6.12.2 for further details. It can be concluded that Permethrin does not cause any adverse effects even when it is directly applied to the skin of humans. This

submission relates to the use of Permethrin as a wood preservative and not for direct application to skin. However, this data is included here as it provides relevant information on the irritating effects of Permethrin, should it come in contact with human skin.

ARfD (acute reference dose) (AEL acute)
The 90-day inhalation rat study submitted by Applicant 2 (Kumar, 2006) was deemed the most appropriate sub-chronic study to provide an NOAEL value that can be used to establish systemic AEL $_{ACUTE-TERM}$ or ARfD reference values. An NOAEL of 0.2201 mg/L was established in the study. This was based on findings of toxicity signs such as nasal irritation and mild tremor at the high dose group (0.4363 mg/L). The overall NOAEL for this study is 0.2201 mg/L, which corresponds to 59.46 mg/kg bw/day.

Dividing the NOAEL value 59.43-mg/kg bw/day by an overall assessment factor of 100 derives a reference value of 0.59-mg/kg bw/day. However, this AEL_{acute} from an inhalation study requires estimate of received dose with all the attendant uncertainties. The oral Ishmael and Litchfield gives a very similar AEL of 0.5 mg/kg bw/day

Therefore, ARfD or AEL_{ACUTE} reference value is set at of 0.5 mg/kg bw/day.

AEL_{ACUTE} reference value of 0.5 mg/kg bw/day

Acceptable operator exposure level (AOEL) AEL_{medium}
The 90-day oral rat study submitted by Applicant 2 (Ramesh, 2002) appeared to be the most appropriate study for AEL $_{MEDIUM-TERM.}$ However, the NOAEL of 7.9, 9.3, and 8.6 mg/kg bw day for males, females and combined sex respectively was established based on liver hypertrophy with no clinical chemistry or hispathological signs and liver weight increases of less than 10%. The effects noted by author my constitute a NOEL but in the opinion of the RMS do not constitute a NOAEL. On this basis the RMS has re-set the NOAEL of this study to the top dose of 172 mg/kg bw/day.

Consequently, AEL must be derived from the dog 12 month study submitted by applicant 1 Bayer Sumatomo.

AEL $_{MEDIUM-TERM}$ reference value of 0.05-mg/kg bw/day.

$AEL_{chronic}$
The lowest NOAEL in key long-term carcinogenicity study was 50 mg/kg bw/day in the rat (McSheehy & Finn 1980). However, in the 12-month dog study (Kalinowski *et al*, 1982 (key)) a more conservative value was derived. In addition, the effects seen in the dog are those normally associated with pyrethroid toxicity. On this basis the $AEL_{LONG-TERM}$ has been set to 0.05 mg/kg bw/day.

$AEL_{LONG-TERM}$ is 0.05 mg/kg bw/day.

Acceptable daily intake (ADI)
In data, unavailable for review, a chronic rat study exists which has a NOAEL of 5 mg/kg bw/day, and this study has been used by the WHO/FAO JMPR to calculate an ADI for technical-grade permethrin with *cis:trans* ratios of 25:75 to 40:60) on the same basis as outlined above, resulting in an ADI of 0.05 mg/kg bw.

Margin of Safety (MOS)
As there is no justification for a margin of safety in excess of 100 the expected MOS will be 100.

Drinking water limit

Exposure to permethrin 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 0.05 mg/kg bw/d) / 10) / 2 litre = 0.15 mg/l can be established.

2.2.1.2. Exposure Assessment and Risk Characterisation

In support of evaluation of Permethrin for possible inclusion on Annex I to the 'Biocides' Directive 98/8/EC, an approach to exposure and risk assessment of Permethrin when used as an active substance in a range of wood preservative products is proposed. The approach proposed focuses on a main purpose of the EU biocidal active substance review process, *i.e.* to review the risks posed by an active substance in the context of its use to ensure no unacceptable risk exists. The proposed approach takes into account worst-case exposure and risk likely to result from use of Permethrin as an active substance in wood preservative products. Consequently, the approach is based on the highest in-product and in-use concentrations of Permethrin known to exist in the context of wood preservative product use.

The highest known in-product concentration of Permethrin in wood preservative products (10.87%) happens to be associated with a water dilutable concentrate type product, whilst the highest known in-use concentration of Permethrin (0.25%) in wood preservative products happens to be associated both with a diluted water dilutable concentrate type product or with a water-based ready to use type product. Application techniques and associated Permethrin exposure scenarios can differ between water dilutable concentrates and water-based ready to use products, and consequently the Permethrin dossier submitted evaluates Permethrin risk in relation to both product types.

It is important to note that the above described in-product and in-use Permethrin concentrations do not represent any specific wood preservative end-use products, rather they can be regarded only as 'representative formulations' in the context of evaluation of end-use products for authorisation; thus, the focus of the proposed risk assessment approach, as with the EU biocidal product active substance review programme, is the active substance, Permethrin.

The approach described has been proposed for a number of reasons. Firstly, it conveniently allows worst-case risk assessment of Permethrin with respect to both in-product and in-use concentrations for the wood preservative product group. Secondly, it allows worst-case risk assessment of Permethrin in the context of application scenarios relevant to both water dilutable concentrates and water-based ready to use products. Thirdly, it addresses some of the difficulties posed to the active substance notifiers who do not themselves market wood preservative end-use products containing the active substance, but who merely market the active substance itself to a wide range of customers for subsequent formulation into a wide range of proprietary products, the precise nature of which is of a confidential nature.

Presented below is a simplified 'representative formulation' of wood preservative type product of the water emulsifiable concentrate (WEC) type. Typical components are suggested which are in no way limiting, and where possible, the properties of the "reference formulation" have been suggested based upon properties of either Permethrin or the typical components, or where possible, all components. The reference formulation contains no substances of concern other than Permethrin, therefore an assessment of the risk of exposure to these components has not been carried forward to the overall exposure and risk assessment. A representative ready to use (RTU) formulation can be assumed to comprise the WEC formulation, diluted in water to a Permethrin concentration of 0.25%.

Trade name:	**Water Emulsifiable Concentrate (WEC)**	
Manufacturer's development code number(s)	Not applicable	
Ingredient of preparation	Function	Content
Permethrin	Active substance	10.87%
Other components	Various	89.13%
Note: Details of typical components are presented in the Confidential Section of the dossier submission		
Physical state of preparation	Liquid	

Permethrin toxicology: Isomer Ratio Comparisons

The following statement has been published by the WHO/FAO, based upon their review of Permethrin toxicity:

"As noted by the 1982 JMPR (Joint Meeting on Pesticide Residues), the acute toxicity of Permethrin (25:75 *cis*-, *trans*-) is less than that of Permethrin (40:60). On short-term administration to rats and mice, Permethrin (25:75) was of similar toxicity to Permethrin (40:60). Permethrin (25:75) is not mutagenic in short term tests or in a dominant lethal assay and this isomeric mixture is not carcinogenic in mice or rats. It is also not teratogenic in, and does not adversely affect the reproduction, of rats. Chronic feeding of Permethrin (25:75) to rats for 2 years increased the liver weights of male rats, as did Permethrin (40:60).

The toxicological profile of Permethrin (25:75) thus resembles that of Permethrin (40:60), although it is less acutely toxic.

Summary of Professional Exposure

Exposure Scenario (indicate duration)		Estimated Internal Exposure				Relevant NOAEL/LOAEL [mg/kg b.w/day] & Reference Value e.g.: AEL (acute or medium or chronic)	AF MOEref	MOE	Exposure /AEL
		estimated inhalation uptake [mg/kg b.w/day]	estimated dermal uptake [mg/kg b.w/day]	estimated oral uptake[mg/kg b.w/day]	estimated total uptake [mg/kg b.w/day]				
Tier 1 (dermal penetration 3.0% / coverall + gloves)	Mixing and Loading - Exposure during dilution of the WEC Duration 10 min, Model 7 TNsG Part 2, (2002)	3.50E-04	5.48E-04	0.00E+00	9.00E-04	5.0	100 0.05	5533	0.018
Tier 1 (dermal penetration 3.0% / coverall + gloves)	Automated Spray Application Duration 60 min, Dipping Model 1 TNsG Part 2, (2002)	0.00E+00	3.26E-03	0.00E+00	3.26E-03	5.0	100 0.05	1533	0.065
Tier 1	Automated Spray – System	1.00E-04	3.05E-03	0.00E+00	3.15E-03	5.0	100	1589	0.063

Exposure Scenario (indicate duration)		Estimated Internal Exposure				Relevant NOAEL/LOAEL [mg/kg b.w/day] & Reference Value e.g.: AEL (acute or medium or chronic)	AF MOEref	MOE	Exposure /AEL
		estimated inhalation uptake [mg/kg b.w/day]	estimated dermal uptake [mg/kg b.w/day]	estimated oral uptake[mg/kg b.w/day]	estimated total uptake [mg/kg b.w/day]				
(dermal penetration 3.0% / coverall + gloves)	maintenance Duration 60 min, Handling Model 1 TNsG Part 2, (2002)						0.05		
Tier 1 (dermal penetration 3.0% / coverall + gloves)	Automated Spray – Application + System maintenance	1.00E-04	6.29E-03	0.00E+00	6.4E-03	5.0	100 0.05	780	0.128
Tier 1 (dermal penet	Manual Dipping/Immersion Application Duration 180 min ,Dipping Model 1	0.00E+00	1.63E-03	0.00E+00	1.63E-03	5.0	100 0.05	3065	0.033

Exposure Scenario (indicate duration)		Estimated Internal Exposure				Relevant NOAEL/LOAEL [mg/kg b.w/day] & Reference Value e.g.: AEL (acute or medium or chronic)	AF MOEref	MOE	Exposure /AEL
		estimated inhalation uptake [mg/kg b.w/day]	estimated dermal uptake [mg/kg b.w/day]	estimated oral uptake[mg/kg b.w/day]	estimated total uptake [mg/kg b.w/day]				
ration 3.0% / cover all + gloves)	TNsG Part 2, (2002)								
Tier 1 (dermal penetration 3.0% / cover all + gloves)	Automated Dipping/Immersion Application Duration 60 min, Handling Model 1 TNsG Part 2, (2002)	3.96E-04	1.22E-02	0.00E+00	1.26E-02	5.0	100 0.05	397	0.252
Tier 2 (dermal penetration 3.0% / cover all + glove	Automated Dipping/Immersion Application Duration 60 min, Handling Model 1 TNsG Part 2, (2002)	1.98E-05	1.22E-02	0.00E+00	1.22E-02	5.0	100 0.05	410	0.244

Exposure Scenario (indicate duration)		Estimated Internal Exposure				Relevant NOAEL/LOAEL [mg/kg b.w/day] & Reference Value e.g.: AEL (acute or medium or chronic)	AF MOEref	MOE	Exposure /AEL
		estimated inhalation uptake [mg/kg b.w/day]	estimated dermal uptake [mg/kg b.w/day]	estimated oral uptake[mg/kg b.w/day]	estimated total uptake [mg/kg b.w/day]				
s + RPE)									
Tier 1 (dermal penetration 3.0% / coverall + gloves)	Automated Dipping/Immersion – System maintenance Duration 60 min , Handling Model 1 TNsG Part 2, (2002)	1.00E-04	3.05E-03	0.00E+00	3.15E-03	5.0	100 0.05	1587	0.063
Tier 1 (dermal penetration 3.0% / coverall + gloves)	Automated Dipping/Immersion – Application + System maintenance	4.96E-04	1.53E-02	0.00E+00	1.58E-02	5.0	100 0.05	316	0.316

Exposure Scenario (indicate duration)		Estimated Internal Exposure				Relevant NOAEL/LOAEL [mg/kg b.w/day] & Reference Value e.g.: AEL (acute or medium or chronic)	AF MOEref	MOE	Exposure /AEL
		estimated inhalation uptake [mg/kg b.w/day]	estimated dermal uptake [mg/kg b.w/day]	estimated oral uptake[mg/kg b.w/day]	estimated total uptake [mg/kg b.w/day]				
Tier 1 (dermal penetration 3.0% / coverall + gloves)	Vacuum Pressure Application Duration 540 min , Handling Model 1 TNsG Part 2, (2002)	7.13E-05	7.32E-04	0.00E+00	8.00E-04	5.0	100 0.05	6229	0.016
Tier 2 (dermal penetration 3.0% / coverall + gloves + PPE)	Vacuum Pressure Application Duration 540 min , Handling Model 1 TNsG Part 2, (2002)	3.50E-06	7.32E-04	0.00E+00	7.30E-04	5.0	100 0.05	6803	0.015
Tier 1 (dermal penetration	Vacuum Pressure Application Duration 9 hours , BEAT model	6.67E-05	1.06E-03	0.00E+00	1.13E-03	5.0	100 0.05	4426	0.023

Exposure Scenario (indicate duration)		Estimated Internal Exposure				Relevant NOAEL/LOAEL [mg/kg b.w/day] & Reference Value e.g.: AEL (acute or medium or chronic)	AF MOEref	MOE	Exposure /AEL
		estimated inhalation uptake [mg/kg b.w/day]	estimated dermal uptake [mg/kg b.w/day]	estimated oral uptake[mg/kg b.w/day]	estimated total uptake [mg/kg b.w/day]				
3.0% / coverall + gloves)									
Tier 1 (dermal penetration 3.0% / coverall + gloves)	Vacuum Pressure – System maintenance Duration 180 min, Handling Model 1 TNsG Part 2, (2002)	2.38E-05	3.43E-04	0.00E+00	3.70E-04	5.0	100 0.05	13596	0.007
Tier 2 (dermal penetration 3.0% / coverall + gloves +	Vacuum Pressure – System maintenance Duration 180 min, Handling Model 1 TNsG Part 2, (2002)	1.17E-06	3.43E-04	0.00E+00	3.50E-04	5.0	100 0.05	14485	0.007

Exposure Scenario (indicate duration)		Estimated Internal Exposure				Relevant NOAEL/LOAEL [mg/kg b.w/day] & Reference Value e.g.: AEL (acute or medium or chronic)	AF MOEref	MOE	Exposure /AEL
		estimated inhalation uptake [mg/kg b.w/day]	estimated dermal uptake [mg/kg b.w/day]	estimated oral uptake[mg/kg b.w/day]	estimated total uptake [mg/kg b.w/day]				
PPE)									
Tier 1 (dermal penetration 3.0% / coverall + gloves)	Vacuum Pressure – Application + System maintenance	9.51E-05	1.08E-03	0.00E+00	1.17E-03	5.0	100 0.05	4272	0.023
Tier 2 (dermal penetration 3.0% / coverall + gloves + RPE)	Vacuum Pressure – Application + System maintenance	4.67E-06	1.08E-03	0.00E+00	1.08E-03	5.0	100 0.05	4629	0.022

Exposure Scenario (indicate duration)		Estimated Internal Exposure				Relevant NOAEL/LOAEL [mg/kg b.w/day] & Reference Value e.g.: AEL (acute or medium or chronic)	AF MOEref	MOE	Exposure /AEL
		estimated inhalation uptake [mg/kg b.w/day]	estimated dermal uptake [mg/kg b.w/day]	estimated oral uptake[mg/kg b.w/day]	estimated total uptake [mg/kg b.w/day]				
Tier 1	Double Vacuum Low Pressure Application - Duration 360 min , Handling Model 1 TNsG Part 2, (2002)	6.00E-04	0.018	0.00E+00	0.019	5.0	100 0.05	265	0.378
Tier 2 (dermal penetration 3.0% / coverall + gloves + RPE)	Double Vacuum Low Pressure Application - Duration 360 min , Handling Model 1 TNsG Part 2, (2002)	3.00E-05	0.018	0.00E+00	0.018	5.0	100 0.05	273	0.366
Tier 1 (dermal penetration	Double Vacuum Low Pressure – System maintenance Duration 1 hours (Handling Model 1	1.00E-04	2.42E-03	0.00E+00	2.52E-03	5.0	100 0.05	1984	0.05

Exposure Scenario (indicate duration)		Estimated Internal Exposure				Relevant NOAEL/LOAEL [mg/kg b.w/day] & Reference Value e.g.: AEL (acute or medium or chronic)	AF MOEref	MOE	Exposure /AEL
		estimated inhalation uptake [mg/kg b.w/day]	estimated dermal uptake [mg/kg b.w/day]	estimated oral uptake[mg/kg b.w/day]	estimated total uptake [mg/kg b.w/day]				
3.0% / coverall + gloves)	TNsG Part 2, (2002))								
Tier 2 (dermal penetration 3.0% / coverall + gloves + RPE)	Double Vacuum Low Pressure – System maintenance Duration 1 hours (Handling Model 1 TNsG Part 2, (2002))	5.00E-06	2.42E-03	0.00E+00	2.43E-03	5.0	100 0.05	2061	0.049
Tier 1 (dermal penetration 3.0% /	Double Vacuum Low Pressure – Application + System maintenance	6.94E-04	0.0207	0.00E+00	0.021	5.0	100 0.05	234	0.428

Exposure Scenario (indicate duration)		Estimated Internal Exposure				Relevant NOAEL/LOAEL [mg/kg b.w/day] & Reference Value e.g.: AEL (acute or medium or chronic)	AF MOEref	MOE	Exposure /AEL
		estimated inhalation uptake [mg/kg b.w/day]	estimated dermal uptake [mg/kg b.w/day]	estimated oral uptake[mg/kg b.w/day]	estimated total uptake [mg/kg b.w/day]				
coverall + gloves)									
Tier 2 (dermal penetration 3.0% / coverall + gloves + RPE)	Double Vacuum Low Pressure – Application + System maintenance	3.46E-05	0.0207	0.00E+00	0.021	5.0	100 0.05	241	0.415
Tier 1 (dermal penetration 3.0% / coverall + gloves)	Professional Spraying Duration 60 min, Spraying Model 2 TNsG Part 2 (2002)	0.013	0.01		0.023	5.0	100 0.05	217	0.46

Exposure Scenario (indicate duration)		Estimated Internal Exposure				Relevant NOAEL/LOAEL [mg/kg b.w/day] & Reference Value e.g.: AEL (acute or medium or chronic)	AF MOEref	MOE	Exposure /AEL
		estimated inhalation uptake [mg/kg b.w/day]	estimated dermal uptake [mg/kg b.w/day]	estimated oral uptake[mg/kg b.w/day]	estimated total uptake [mg/kg b.w/day]				
Tier 2 Glove with 10% penetration Beat cleaning of spray equipment	1 event per day,4 minutes duration	-	0.89	-	0.015	5.0	100 0.05	333	0.3
Tier 1 (dermal penetration 3.0% / coverall + gloves)	Professional Brushing (outdoors) Duration 240 min, Consumer Painting Model 3 TNsG Part 2 (2002)	0.0017	0.00017		0.002	5.0	100 0.05	2500	0.04
Tier 1 (dermal penetration	Professional Brushing (indoors) Duration 240 min, Consumer Painting	6.50E-04	6.64E-03	0.00E+00	7.29E-03	5.0	100 0.05	686	0.146

Exposure Scenario (indicate duration)		Estimated Internal Exposure				Relevant NOAEL/LOAEL [mg/kg b.w/day] & Reference Value e.g.: AEL (acute or medium or chronic)	AF MOEref	MOE	Exposure /AEL
		estimated inhalation uptake [mg/kg b.w/day]	estimated dermal uptake [mg/kg b.w/day]	estimated oral uptake[mg/kg b.w/day]	estimated total uptake [mg/kg b.w/day]				
3.0% / coverall + gloves)	Model 1 TNsG Part 2 (2002)								
Tier 2 (dermal penetration 3.0% / coverall + gloves + RPE)	Professional Brushing (indoors) Duration 240 min, Consumer Painting Model 1 TNsG Part 2 (2002)	3.17E-05	6.64E-03	0.00+00	6.67E-03	5.0	100 0.05	749	0.133
Tier 1 (dermal penetration 3.0% / coverall + gloves)	Professional Brushing (indoors) Duration 360 min, BEAT model	3.33E-04	1.81E-03	0.00E+00	2.14E-03	5.0	100 0.05	2338	0.043

Exposure Scenario (indicate duration)		Estimated Internal Exposure				Relevant NOAEL/LOAEL [mg/kg b.w/day] & Reference Value e.g.: AEL (acute or medium or chronic)	AF MOEref	MOE	Exposure /AEL
		estimated inhalation uptake [mg/kg b.w/day]	estimated dermal uptake [mg/kg b.w/day]	estimated oral uptake[mg/kg b.w/day]	estimated total uptake [mg/kg b.w/day]				
Tier 1 (dermal penetration 3.0% / no gloves)	Professional Brushing - Cleaning of brushes HEEG model				1.60E-04	5.0	100 0.05	30404	0.003
Tier 2 (dermal penetration 3.0% / gloves)	Professional Brushing - Cleaning of brushes HEEG model				2.00E-05	5.0	100 0.05	304038	0.0003

Summary of Non-professional Exposure

Exposure Scenario (indicate duration)		Estimated Internal Exposure				Relevant NOAEL/LOAEL [mg/kg b.w/day] & Reference Value e.g.: AEL (acute or medium or chronic)	AF MOEref	MOE	Exposure /AEL
		estimated inhalation uptake [mg/kg b.w/day]	estimated dermal uptake [mg/kg b.w/day]	estimated oral uptake [mg/kg b.w/day]	estimated total uptake [mg/kg b.w/day]				
Tier 1 (dermal penetration 3.0% / no PPE)	Brush Application (outdoors) RTU 180 min (Consumer product painting Model 3 TNsG Part 2, (2002))	2.50E-04	5.13E-03	0.00E+00	5.39E-03	50.00	100 0.5	9282	0.011
Tier 1 (dermal penetration 3.0% / no PPE)	Brush Application (indoors) RTU 180 min (Consumer product painting Model 1 TNsG Part 2, (2002))	4.83E-04	4.18E-02	0.00E+00	4.23E-02	50.00	100 0.5	1183	0.085
Tier 1 (dermal penetration 3.0% / no PPE)	Spray Application RTU 180 min (Consumer spraying and dusting Model 3 TNsG Part 2, (2002))	1.80E-02	6.66E-02	0.00E+00	8.46E-02	50.00	100 0.5	591	0.169

Primary exposure to permethrin by professionals and non-professions has been evaluated and summarised in the above tables. Safe uses have been found for all use scenarios as evidenced by MOEs in excess of 100. The MOE (% AEL) for professional use of the simplified 'representative formulation' are acceptable since all MoE are well above 100.

Nonetheless, PPE should be considered for products containing permethrin for professional use and the potential sensitization by permethrin containing products should be assessed prior to authorisation for non-professionals because the active substance is currently classified as a potential sensitiser.

Secondary Acute Exposure

Exposure Scenario (indicate duration)		Estimated Internal Exposure				Relevant NOAEL/LOAEL [mg/kg b.w/day] & Reference Value e.g.: AEL (acute or medium or chronic)	AF MOEref	MOE	Exposure /AEL
		estimated inhalation uptake [mg/kg b.w/day]	estimated dermal uptake [mg/kg b.w/day]	estimated oral uptake [mg/kg b.w/day]	estimated total uptake [mg/kg b.w/day]				
Tier 1 (dermal penetration 3.0% / no PPE)	Adult Handling Treated Timber – Acute Exposure 100 contacts per day	0.00E+00	0.17	0.00E+00	0.17	50	100 0.5	294	0.34
Tier 2 (Dermal penetration 3.0% /	Adult Handling Treated Timber – Acute Exposure 100 contacts per day	0.00E+00	2.10E-01	0.00E+00	2.10E-01	50	100 0.5	238	0.42

gloves)									
Tier 1 (No PPE)	Adult cutting/sanding treated wood posts (Inhalation exposure) - Surface Application 60 min	1.73E-05	3.72E-04	0.00E+00	3.90E-04	50	100 0.5	128319	0.0008
Tier 1 (No PPE)	Infant Chewing treated wood off-cut (Ingestion exposure)	0.00E+00	0.00E+00	1.60E-02	1.60E-02	50	100 0.5	3125	0.032
Tier I	Infant (10 kg) inhalation of volatilised residues	0.0002	-	-	0.0002	50	0.5	250000	0.0004
	Child (34.4 kg) inhalation of volatilised residues	0.0001	-	-	0.0001	50	0.5	500000	0.0002
	Adult (60 kg) inhalation of volatilised residues	0.0001	-	-	0.0001	50	0.5	500000	0.0002

The results above show that exposure through handling timber when wearing protective gloves and *via* inhalation following cutting/sanding treated timber do not present a concern as the MOE is >100. It is considered likely that the adult handling treated timber would wear gloves, as much to protect their hands against splinters as for any potential exposure to Permethrin.

Secondary Chronic Exposure Scenarios

Adult handling treated timber – Chronic Exposure

Secondary Chronic Exposure

Exposure Scenario (indicate duration)		Estimated Internal Exposure				Relevant NOAEL/LOAEL [mg/kg b.w/day] & Reference Value e.g.: AEL (acute or medium or chronic)	AF MOEref	MOE	Exposure /AEL
		estimated inhalation uptake [mg/kg b.w/day]	estimated dermal uptake [mg/kg b.w/day]	estimated oral uptake [mg/kg b.w/day]	estimated total uptake [mg/kg b.w/day]				
Tier 1 (No PPE)	Adult Machine Sanding Treated Timber TNsG Model	1.04E-04	3.72E-04	0.00E+00	4.76E-04	5.00	100 0.05	10499	0.010
Tier 1 (No PPE; Dermal penetration 10%)	Child Playing Playground Structure (Dermal Exposure) TNsG Model	0.00E+00	7.10E-04	0.00E+00	7.10E-04	5.00	100 0.05	7050	0.014
Tier 1 (No PPE; Dermal penetration 10%)	Infant playing on weathered structure (Dermal and ingestion exposure) TNsG Model	0.00E+00	1.06E-03	1.06E-02	1.17E-02	5.00	100 0.05	427	0.234

Overall Assessment of the Risk for the Use of the Active Substance in Biocidal Products

The results above show that exposure to an infant/child from volatilised residues of Permethrin indoors or from playing on a playground structure treated with Permethrin does not present a concern as the MOE is >100. The potential for skin sensitisation from indirect exposure to permethrin treated wood should be considered at product authorisation because the active substance is currently classified as a potential sensitiser.

Combined exposure

The potential for combined exposure is primarily an acute toxicity concern. The rapid metabolism and excretion, combined with the low chronic toxicity of Permethrin suggest that lifetime exposure is not of concern. However, in order to assess combined exposure, both acute and chronic scenarios will be addressed.

Assessing the risk of combined exposure leading to levels which may cause acute effects can best be described by combining the worst case scenarios modelled. Although not a truly appropriate way to address combined exposure, it does present a very worst case exposure, and if this combination suggests low risk, then implicit is the conclusion that more "realistic" risk assessments will also suggest low risk. Similarly, the chronic exposure can be assessed by comparing the daily exposure to the chronic NOAEL.

The following combined exposure scenarios have been assessed. Mixing and loading, application and system maintenance steps were added to calculate the combined exposure.

Combined Exposure following Professional Use of Wood Preservative

Application	Combined Exposure (mg/kg bw/day)	Relevant NOAEL/LOAEL [mg/kg b.w/day] & Reference Value e.g.: AEL (acute or medium or chronic)	AF MOEref	MOE	Exposure /AEL
Automated Spray Application	7.3E-03	0.05	100 0.05	685	0.146
Dipping/Immersion Application	1.58E-02	0.05	100 0.05	3.16E+02	3.16E-01
Vacuum Pressure Application	2.07E-03	0.05	100 0.05	2.42E+03	4.14E-02
Double Vacuum Low Pressure Application	2.1E-02	0.05	100 0.05	235	0.42

From the calculations shown above whereby the combined systemic dose (dermal and inhalation) is compared to the chronic AEL of 0.05 mg/kg bw/day to establish a Margin of Exposure (MOE), it can be determined that there will be no significant exposure from the use of Permethrin during professional timber treatment processes.

Use of permethrin in the aforementioned formulation has been assessed for exposure risk for professional, non-professional primary exposure and adult and child secondary exposure. Acceptable exposure levels have been modelled for all scenarios. Nonetheless, PPE should be considered in combined exposure assessment at the product authorisation level for professional products containing permethrin because the active substance is currently classified as a potential sensitiser.

Aggregated exposure

The need to discuss the aggregated exposure arising when an active substance is approved across multiple product types has been discussed during the substance peer review process. As such, it was proposed that an assessment would be required for permethrin. However, in the absence of robust guidance that would allow a quantitative assessment to be carried out, it was agreed that a qualitative analysis would be conducted.

To summarise there are three possible situations where aggregated exposure relating to human health may be expected:

- Usage of the two PT18 products at work as a professional and at home as a non-professional.
- Usage of the PT8 product at work as a professional and of the PT18 product at home as a non-professional.
- Additional indirect or secondary exposure may also aggregate to the above from the exposure to residues from either treated carpet or treated wood.

2.2.2. Environmental Risk Assessment

2.2.2.1. Fate and Distribution in the Environment

The technical material supported by the notifiers relates to permethrin as a reaction mass of four stereoisomers (1Rcis, 1Scis, 1Rtrans, and 1Strans), with two pairs of diastereoisomers in a isomeric ratio of 25:75 (*cis*:*trans*). Studies were conducted with permethrin 25:75 or with a mixture of isomers where the permethrin samples contain 50-78% of the *trans*- isomer.

2.2.2.1-1. Aquatic compartment including STP and sediment

Permethrin was observed to be hydrolytically stable between pH 3.0/4.0 to 7.6/7 at 25/50°C respectively. Only at pH 9.0/9.6 was permethrin observed to hydrolyse, with DT_{50} values for *cis*- and *trans*-permethrin estimated at 35 days and 42 days, respectively (at pH 9.6 and 25°C).

Permethrin is not readily biodegradable according to OECD 301B (CO2 evolution method)/US EPA OPPTS 835.3110 and OECD 301 F (oxygen consumption). Permethrin (25:75 cis:trans) exhibited inherent primary biodegradability, since its biodegradation was found to be above 20% in a validly conducted test (OECD302 C, BOD test). The results cannot be regarded as evidence of inherent ultimate biodegradability, since biodegradation was not above 70%. An effects study on microorganisms in sewage sludge was provided as a STP simulation test of permethrin degradation (40:60 cis:trans). From the data no clear evidence for degradation is observed. Whilst permethrin as a percentage of radioactivity was observed to decline it is likely that permethrin adsorbed to the sewage sludge (~80% AR) due to the strong adsorption characteristics of the parent compound. The remainder of the parent compound was observed in the supernatant. Permethrin is strongly adsorbed to soil (Mean Kf oc 73,442 L/kg (n= 10)). The two metabolites are more mobile. DCVA exhibited Kfocs ranging from 13.95 L/kg to 356.15 L/kg. Corresponding values for PBA ranged from 70.5 L/kg to 157.3 L/kg.

Permethrin (46:54 and 53:47 *cis:trans*) was observed to degrade in aerobic water/sediments systems, with whole-system DT_{50} values of *cis*- and *trans*-permethrin calculated at 63.7 days and 27.3 days, respectively at 25°C (equivalent to corresponding values at 12 °C of 180.2 days and 77.2 days). Whole-system first order degradation DT_{50} values for permethrin (25:75 *cis*:*trans*) incubated aerobically in water-sediment systems derived from a creek and a pond, in the dark for 120 days at 20 ± 2 °C were much faster and ranged from 14.3 days to 24.6 days (equivalent to a corresponding range at 12 °C of 27.1 days to 46.7 days). The reason for this difference is not clear.

The degradation scheme proposed for the behaviour of permethrin in aerobic water-sediment systems involves as a first step transformation along parallel pathways to 3-phenoxybenzyl alcohol (PB alcohol) and 3-(2,2-dichlorovinyl)-2,2-dimethyl-(1-cyclopropane)carboxylate (DCVA), followed by transformation of 3-phenoxybenzyl alcohol to 3-phenoxybenzoic acid (PBA), with carbon dioxide and bound residues as terminal products.

Maximum observed levels of DCVA, PBA and PB alcohol in the water compartment were 62.6 %AR, 28.8%AR and 38.2 %AR respectively. DCVA and PBA were also major metabolites in the sediment compartment (21.7 % and 16.4 % respectively). The whole-system first order degradation DT_{50} values for PB alcohol was measured at 2.7 days for the pond system (5.1 days at 12°C). No reliable DT_{50} value could be determined for the creek system. Whole-system first order degradation DT_{50} values for PBA were measured at 31.8 days for the creek system (60.3 days at 12°C) and 33.4 days for the pond system (63.3 days at 12°C). A reliable DT_{50} value could not be

evaluated for DCVA in either aquatic system since the maximum observed levels occurred towards the end of the study incubations and only showed small declines thereafter. Whilst no reliable DT_{50} value could be obtained for DCVA in the water/sediment system, the metabolite is common to other pyrethroid chemistry (e.g. cypermethrin) and reliable DT50 values have been reported that provide indicative DT_{50} values in water/sediment (whole system) from 80-145 days for trans-DCVA and 62 to 188 days for cis-DCVA. Further confirmatory data on the degradation of DCVA in water/sediment systems will need to be supplied by the applicants.

Permethrin was observed to degrade more slowly under anaerobic conditions, with whole-system DT_{50} values of *cis*- and *trans*-permethrin calculated at 179.4 days and 114.5 days, respectively (equivalent to corresponding values at 12 °C of 507.6 days and 323.9 days).

A field aquatic dissipation study on a formulated product containing 10.1% w/w permethrin (*cis*:*trans* ratio not specified) indicated rapid dissipation from the water phase to sediment for both *cis*- and *trans*-permethrin, with DT_{50} values for the water phase calculated in the range 1.3 days to 3.1 days. *Cis*- and *trans*-permethrin appeared to be rather immobile in the sediment, remaining in the upper portion (0-5 cm). DT_{50} values determined for the *cis*- and *trans*-permethrin isomers in the sediment phase ranged from 118 to 256 days and 18 to 62 days, respectively. Metabolites were only detected in the water compartment and had disappeared by 90 days after the last application in the North Carolina test site and 120 days after the last application in the California test site. Based on the above results, biodegradation of Permethrin in freshwater occurred under both aerobic and anaerobic conditions.

Direct photolysis of permethrin (49:51 *cis*:*trans*) indicated slow degradation of the test material resulting in a DT_{50} value of 118 days with 12 hr sunlight per day under outdoor conditions at latitude of 50°N and the fall season. Control experiments revealed that permethrin was stable in water for a period of 32 days under exclusion of light. Slow degradation of permethrin under aqueous photolysis was also confirmed using the ABIWAS computer program. Overall, it is concluded that significant photolysis of permethrin will not occur under environmentally relevant pH and temperature conditions (12°C).

2.2.2.1-2. Atmosphere

Volatilization of permethrin is considered to be negligible based on the vapour pressure (2.155×10^{-6} Pa at 20°C, 25:75 *cis:trans*) and Henry constant (4.6×10^{-3} - $> 4.5 \times 10^{-2}$ Pa m^3 mol^{-1}). Permethrin volatilisation loss from a soil surface over 24 hours to the atmosphere was calculated to be 0.73% assuming a temperature of 25 °C. This calculation was performed by the CA using the Dow method (as detailed under Doc III, A7.3.1); the associated volatilisation constant for permethrin was estimated at 7.31×10^{-3} day^{-1}. The software AOPWIN v1.91, which utilises QSAR methods, was used to calculate an atmospheric half-life value of 0.701d for the gas phase reaction of permethrin with photo-chemically produced hydroxyl radicals (24-hour day and a hydroxyl radical concentration of 5×10^5 radicals/cm^3) and 49.27 d for the gas phase reaction of permethrin with ozone (assuming a 24-hour day and an ozone concentration of 7×10^{11} molecules/cm^3). The calculations show that reaction with hydroxyl radicals would be expected to be the major contribution to atmospheric degradation of permethrin via gas phase reaction with photo-chemically generated species. Based on the short half-life for this transformation pathway, it is concluded that permethrin is rapidly degraded and would not be transported over large distances in the atmosphere in gaseous phase.

2.2.2.1-3. Terrestrial compartment

Degradation of permethrin was investigated under aerobic conditions in several soils. The range of reliable SFO DT_{50}s ranged from 77 d to ~141 d at 12°C. The corresponding geomean DT_{50} was 106 d. The *cis* isomer degraded more slowly than the *trans* isomer based on the *cis:trans* ratio at the time of application changing from 40:60 to 50:50 by day 30 and 78:22 by day 365. The geomean DT_{50} is derived from permethrin samples containing 50-78% of the *trans*- isomer. It can be expected that a DT_{50} value of 106 days is conservative enough to represent the degradation in soil at 12°C of permethrin samples containing a *cis:trans* ratio of 25:75.

Results from another submitted set of studies (giving DT_{50} values at 12 °C ranging from 11.0 - 21.2 days) are not considered representative of the behaviour of permethrin in soil since the route of degradation was not identified in these latter studies but was shown not to proceed via formation of DCVA and PBA.

The route of degradation of permethrin in soil appears to be dominated by a two-step process. Permethrin breaks down to form DCVA (max 11.3 %AR, SFO $DT_{50\ 12°C}$ 33.1-~175 d) and PBA (max 15.0 %AR, 1.7-2.5 d at 12°C), and ultimately converts to CO_2. Laboratory test data indicated that NER amounts do not exceed 70% AR after 100 days nor do mineralisation rates fall below 5% AR after 100 days for permethrin.

Permethrin was observed to be relatively stable when exposed to photolysing conditions in soil. A DT_{50} of 200 d (Florida autumn sunlight) was estimated. However, confidence in the accuracy of this value was low since it was beyond the duration of the test (33 d & 3 hr of Florida autumn sunlight). No transformation product greater than 10 %AR was observed.

Permethrin is strongly adsorbed to soil (Mean K_{foc} 73,441 L/kg, K_{oc} 26,930 n = 9). Therefore, leaching is not expected to occur. The two major soil metabolites (DCVA & PBA) are expected to be more mobile. The mean K_{foc} for DCVA was 93.2 L/kg (n = 5). For PBA the K_{foc} was 141.2 L/kg.

2.2.2.2. Effects Assessment

Effects on aquatic organisms

Permethrin is highly toxic to aquatic organisms, especially invertebrates. The highest risk for environmental toxicity is in the water column immediately after the release incident, because permethrin will bind rapidly to sediment and become less bioavailable to organisms. While permethrin does have a tendency to bioconcentrate based upon its lipophilicity, terrestrial and aquatic organisms have demonstrated the ability to depurate permethrin through excretion.

In general, the results of toxicity studies were similar/comparable between Bayer/Sumitomo and Tagros. Both sets of data indicated clearly that acute exposure to permethrin is highly toxic to fish (0.0051 mg a.s./L (Bayer/Sumitomo)) and to aquatic invertebrates, with *Daphnia* 0.00127 mg a.s/L (Bayer/Sumitomo), being the most sensitive of the aquatic organisms tested. A definitive EC_{50} could not be derived from either of the algal studies due to the limited range of concentrations tested (due to solubility issues). Although the EC_{50} values are quite low (> 1.13 mg a.s./L (Bayer/Sumitomo)), they are in excess of the limit of water solubility.

Chronic exposure to permethrin was also highly toxic to the three groups of aquatic organisms, affecting reproduction and survival in fish and *Daphnia* (again, *Daphnia* was the most sensitive species; NOEC 0.0047 µg/L). Permethrin does not appear to have an endocrine affect in fish.

There was a substantial difference (> 2000 fold) in the concentration of test substance used in the Bayer/Sumitomo and Tagros microbial inhibition studies but both studies indicated that permethrin is of low toxicity to these microorganisms and will not inhibit microbial respiration in activated sludge in the field. For substances with a low water solubility and if no effect is seen on the micro-organisms at the highest level, then the NOEC is set at the water solubility concentration (0.00495 mg/l).

For sediment-dwelling organisms, the LC_{50} and NOEC were determined to be 2.110 mg/kg and 0.1 mg/kg, respectively (based upon midge survival and emergence), expressed as concentrations arising in spiked sediment, and were determined to be >0.01 mg/L and 0.001 mg/L, respectively (based upon midge survival and emergence), expressed as concentrations arising in water.

Metabolites
Aquatic metabolites including 3-(2,2-dichlorovinyl)-2,2-dimethyl-(1-cyclopropane)carboxylate (DCVA) and 3-phenoxybenzoic acid (PBA) are far less toxic to aquatic organisms than the parent active ingredient and are not considered to be ecotoxicologically relevant. The metabolites L(E)C_{50}s for fish and aquatic invertebrates are more than three orders of magnitude higher than that observed in tests with permethrin. DCVA *Daphnia magna* 48 hr LC_{50} is ≥ 25 mg a.s./L/.

PNEC Derivation

The following PNECs have been determined for the relevant environmental compartments based on the effects data presented for permethrin and its metabolites DCVA and PBA in Section 4.2 of Document IIA.

Permethrin
PNECsurfacewater = 0.00047µg a.s/l
PNECmicro-organisms (STP) = 0.00495 mg a.s/l
PNEC soil (wet weight) = >0.0876 mg a.s/kg soil wwt
PNECsediment = 0.001mg/kg dwt (2.17×10^{-4} wwt)
PNECoral bird = ≥16.7 mg a.s/kg food
PNECoral small mammal = 120mg a.s/kg food

DCVA
PNECsurfacewater = 0.015 mg/l
PNEC soil (wet weight) = 4.6 mg/kg wwt
PNECsediment = 0.055 mg/kg dwt (0.012 mg/kg wwt)

PBA
PNECsurfacewater = >0.010 mg/l
PNEC soil (wet weight) = 1.44 mg/kg wwt
PNECsediment = 0.042mg/kg dwt (0.009 mg/kg wwt)

Classification

Under CLP, permethrin classifies as H410 (Acute Cat 1, Chronic Cat 1) very toxic to aquatic life with long-lasting effects. This classification is based on the high toxicity to fish (0.0051 mg a.s./L) and to aquatic invertebrates, with *Daphnia* 0.00127 mg a.s/L, being the most sensitive of the aquatic organisms tested. Chronic toxicity studies resulted in a NOEC of 0.0000047 mg/L for *Daphnia magna*. Acute M-Factor: 100, Chronic M-Factor: 10000 (based on 0.00001<L(E)C50≤0.0001) and (0.000001<NOEC≤0.00001, NRD).
Permethrin is not readily biodegradable (LogPow >3, BCF >100).

Effects on terrestrial organisms

Permethrin was found to be toxic to bees (acute contact toxicity; LD_{50}: 0.0235 µg/ bee; acute oral toxicity LD50: 0.163 µg/ bee (Bayer/Sumitomo)). Permethrin may be hazardous to small mammals following acute exposure (rat oral LD_{50}: 480 mg as/kg bw (Bayer/Sumitomo)).

Permethrin is of low toxicity to terrestrial soil-dwelling organisms, including earthworms (EC_{50} = 371 mg a.s./kg), micro-organisms (no observed effect on carbon (40 days) or nitrogen (18 days) metabolism to >31.7 mg/kg dwt) and plants (effects on biomass for all species was < 20% at dose of 6875 g/ha.

Permethrin was found to have low acute avian toxicity LD_{50}: >4640 mg/kg bw (Bayer/Sumitomo) and the long-term dietary study on bobwhite quail showed no effect on reproduction at 500ppm. A known issue from veterinary monitoring, indicates that permethrin toxicity to cats can result from the exposure to concentrated permethrin-containing products.

Results of the seedling emergence study indicated that permethrin technical may affect the emergence of *Helianthus annuus* (sunflower) above nominal concentrations of 0.0128 mg/kg dry soil, though the effects did not follow a continuous dose-response pattern and emergence was not affected in any of the other 5 plant species tested at permethrin concentrations as high as 696 mg/kg dry soil (actual measured value). The study did however show that biomass reduction can occur for non-target plants like *Avena sativa* above 8 mg/kg dry soil. However, both of these endpoints are based on nominal concentrations – the actual concentrations were likely to have been much lower than these values (but could not be determined from the data provided). As such, the results of this test were considered rather tentative (especially the results of the emergence test) and the study was given a reliability score of 2-3.

No phytotoxic effects were observed in any plant species in a 21-day vegetative vigour test (limit test, test concentration 6875 g/ha (9.17 mg/kg)). Significant effects on the inhibition of biomass were observed for *Avena sativa* and *Allium cepa* (most sensitive species) at 6875 g/ha. However, these effects were <20%, suggesting permethrin poses a low risk to terrestrial plants. This is further supported by the justification provided by Bayer/Sumitomo for non-submission of plant toxicity tests. According to Bayer/Sumitomo, "Permethrin has been used in the crop protection field since 1977. During that time it has been cleared for use on several monocotyledonous and dicotyledonous crops, including cotton plants, corn, soybean, coffee, tobacco, oilseed rape, wheat, barley, alfalfa, vegetables, and fruits.

Metabolites

DCVA and FPB-acid (4-fluoro-3-phenoxybenzoic acid) displayed low toxicity to soil-dwelling arthropods (both substances were less toxic to soil macro-organisms than permethrin) and thus are not considered to be ecotoxicologically relevant. The study on FPB-acid was considered relevant to estimate the toxicity of metabolite PBA on soil macro-organisms. In fact, the approach can be regarded as conservative because a QSAR estimation (with the program ECOSAR, vs. 0.99h) gave a 1-day LC_{50} of 3400 mg/kg dry wt soil for 3-phenoxybenzoic acid in earthworms, further supporting the indication that PBA is not toxic to soil organisms.

2.2.2.3. PBT Assessment

Persistence criteria (P, vP)

Active substance

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 permethrin is a mixture of four stereoisomers, consisting of two pairs of diastereomers (1*R*,*cis*, 1*R*,*trans*, 1*S*,*cis*, 1*S*,*trans*). The overall degradation rate of permethrin in any medium varies according to the proportions of the *cis* and *trans* isomers in the mixture. The information presented for permethrin indicates that in general the *trans* isomers tended to degrade more quickly than the *cis* isomers

Permethrin was found to be not readily biodegradable in two tests (25:75 *cis*:*trans* for one test, *cis*:*trans* ratio not specified for the other test). There was evidence of inherent primary biodegradability (but not inherent ultimate biodegradability) in a validly conducted test on 25:75 *cis*:*trans* permethrin.

No half-life data are available for permethrin in either marine water or marine sediment. Degradation-only DT_{50} values for permethrin in freshwater systems are available from laboratory water-sediment studies but pertain to the whole system (water and sediment combined). Whole-system first order DT_{50} values in laboratory aerobic water-sediment tests were 63.7 days for *cis*-permethrin (25 ºC), 27.3 days for *trans*-permethrin (25 ºC) and 14.3 to 24.6 days for 25:75 *cis*:*trans* permethrin (20 ºC). Equivalent values at 12 ºC, extrapolated with the TGD temperature correction equation, are 180.2 days for *cis*-permethrin, 77.2 days for *trans*-permethrin, and 27.1 to 46.7 days for 25:75 *cis*:*trans* permethrin. Under anaerobic laboratory test conditions, whole-system first order DT_{50} values were 179.4 days for *cis*-permethrin (25 ºC) and 114.5 days for *trans*-permethrin (25 ºC). Equivalent values at 12 ºC, extrapolated with the TGD temperature correction equation, are 507.6 days for *cis*-permethrin and 323.9 days for *trans*-permethrin. In order to precisely assess the potential for permethrin to be persistent in water or sediment, specific degradation-only DT_{50} values would be required for these compartments, which may not be feasible to obtain. In the absence of such information it is considered that comparison of whole-system degradation values with the trigger value for sediment is appropriate in this case, since adsorption data indicate that permethrin partitions very strongly to sediment.

Applying this interpretation to the aerobic water-sediment results, extrapolated to 12 ºC, means that the individual *cis*-permethrin isomer (180.2 days) would be adjudged to fulfil the P criterion for freshwater sediment and to slightly exceed the vP criterion. H
In soil permethrin isomeric mixtures, containing 50-78% of the *trans* isomer, exhibited DT_{50} values ranging from 77 days to 141 days at 12°C, when assessed using a conservative DT_{50} estimation method (CO_2 evolution method - please refer to Document IIA for further details). The corresponding geomean DT_{50} is 106 days. Based on these results, the tested permethrin isomeric mixtures do not fulfil the vP criterion for soil but could be adjudged to fulfil the P criterion in two soils at 12 °C. No information was presented on soil degradation rates for the individual *cis* and *trans* isomers. Due to the fact that *cis*-permethrin degrades more slowly than *trans*-permethrin it is possible that the *cis* isomer could fulfil the P criterion in soil more generally.

Metabolites

Primary biodegradation of permethrin in aquatic systems leads to formation of DCVA and PBA as the principal metabolites. These substances were both detected in water and in sediment from two freshwater systems (pond, creek) incubated under aerobic conditions. There appeared to be slow degradation of DCVA in both test systems. DCVA reached high maximum whole-system levels of 84.1% AR for the pond system and 84.3% AR for the creek system, by day 62 in both cases. It had only declined slightly by the end of the incubations (120 days) to levels of 75.3% AR for the pond system and 70.6% AR for the creek system. Due to these small declines a reliable DT_{50} value could not be determined.

Whole-system first order degradation DT_{50} (20 ºC) values for PBA of 31.8 days (60.3 days at 12 ºC) and 33.4 days (63.3 days at 12 ºC) were derived from one of the laboratory aerobic water-sediment studies. If the whole-system DT_{50} (12 ºC) values are compared with the sediment trigger value PBA would be adjudged not to fulfil the P criterion, whereas if these values are compared with the freshwater trigger value PBA would be adjudged to fulfil the P and vP criteria. However it is not clear which comparison is appropriate, or indeed if either comparison is valid, since substantial amounts of PBA were detected in both the water and sediment compartments in the study from which the whole-system DT_{50} values were derived. In this study it was detected in water at maximum levels of 28.5% AR (creek system, day 62) and 28.8% AR (pond system, day 30), and in sediment at maximum levels of 16.4% AR (creek system, day 62) and 12.5% AR (pond system, day 100). In order to reliably assess its potential to be persistent in water or sediment, it would be necessary to have specific degradation-only DT_{50} values for these compartments but it may not be feasible to derive such values.

PB alcohol was observed at >10 % AR in water from the pond system, peaking at a level of 38.2% AR on day 2 and disappearing from the water phase by day 30 in this case. It was not observed at >10% AR in sediment in either of the two systems tested. A whole-system DT_{50} (20 ºC) value of 2.7 days (5.1 days at 12 ºC) was derived for one of the test systems. The whole-system DT_{50} (12 ºC) value does not fulfil the P criteria for either water or sediment.

The principal metabolites of permethrin formed in soil are DCVA and PBA. Soil degradation rate information presented for these metabolites, extrapolated to 12 ºC, gives half-life values for DCVA in two soils of 33.1 and 88.8 days (1*R*,*trans* isomer), 65.4 and ~175 days (1*S*,*trans* isomer), 38.2 and 44.4 days (1*R*,*cis* isomer) and 46.7 and 45.3 days (1*S*,*cis* isomer), and half-life values for PBA in two soils of 1.7 and 2.5 days. Based on these results, DCVA does not fulfil the vP criterion for soil and PBA does not fulfill the P criterion. The 1*S*,*trans* isomer of DCVA fulfils the P criterion in one soil at 12 °C. It should be noted that DCVA and PBA are common metabolites of a number of pyrethroid substances. In order to get a more complete picture of their degradation potential in soil, account could be taken of relevant peer-reviewed values obtained in the EU review programme for pesticides assessed under Directive 91/414/EEC and also of data from other sources.

Conclusion of PBT assessment with respect to persistence
Permethrin as the isomeric mixture 25:75 *cis*:*trans* is not persistent in aquatic systems, on the basis that its whole system DT_{50} (12 ºC) values do not fulfil the P criterion for sediment.

In the case of the terrestrial environment, isomeric mixtures containing 50-78% of the *trans* isomer technically fulfilled the P criterion at 12 ºC in two soils. However, due to deficiencies in the presented data, a conservative DT_{50} estimation method had to be used that is known to underestimate the true degradation rate. In order to accurately assess the potential for persistence in soil, further data would be required that can be reliably fitted with the appropriate degradation kinetics assessment models. If such data

were available it would be expected to show that the isomeric mixtures tested would not in general fulfil the P criterion for soil.

Concerning the individual *cis* and *trans* constituents of permethrin, the *trans* isomer does not fulfil the P criterion for sediment at 12 ºC, whereas the *cis* isomer does and also slightly exceeds the vP criterion.

No information was presented on soil degradation rates for the individual *cis* and *trans* isomers. Although data would be required for a definitive assessment, it is expected that, on the basis of the information presented for isomeric mixtures, there would be potential for *cis*-permethrin to fulfil the soil P criterion and that *trans*-permethrin would not be persistent in soil.

With regard to metabolites, the 1*S*,*trans* isomer of DCVA fulfilled the P criterion in one soil at 12 °C. There might also be potential for DCVA to exhibit persistence in aquatic systems, on the basis of slow degradation in the presented test systems.

PBA is not persistent in soil. The interpretation of its degradation behaviour in aquatic systems is difficult, since the test systems studied showed significant amounts in both the water and sediment compartments. Specific degradation-only DT_{50} values would be required for each compartment in order to reliably assess its potential to be persistent in water or sediment.

PB-alcohol is not persistent in aquatic systems and was not observed in the presented soil data, presumably because it was a transient feature in the soil degradation pathway.

The overall conclusion for persistence is that isomeric mixtures of permethrin are in general unlikely to be persistent in the environment. However permethrin contains a potentially persistent constituent in the *cis* isomer and its degradation pathway includes the metabolite DCVA, which could degrade sufficiently slowly to be persistent in some cases.

Bioaccumulation Aquatic
In principle, the assessment of the (potential for) bioaccumulation in the context of the PBT assessment makes use of measured bioconcentration factors in marine or freshwater organisms. Where these are not available BCF values may be estimated from the octanol/water partition coefficient (Kow) using QSAR models. In addition, Kow values, either experimentally determined or estimated can be used directly to assess the potential for bioaccumulation. Bioaccumulation data from other species may also be used, based on evidence from specific laboratory tests or from field studies.

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

The following relevant information is available for Permethrin:

Parameter	**Value**	**Type of study (measured / estimated value)**	**Source**
Log K_{ow}	4.6	Measured value (pH 4, 7 and 9, 23 °C, 93% technical a.s)	Tagros
	6.1	Measured value (20 °C, 95.5% technical a.s.)	Bayer/ Sumitomo
BCF_{fish}	20,700 l/kg	Estimated value (calculated using USES 4.0)	Tagros

	570 l/kg	Measured value (28 day flow-through test in Bluegill sunfish)	Bayer/ Sumitomo
	2800 l/kg	Fathead minnows: Embryo hatchability, normal larvae at hatch, larval survival, larval growth	Spehar R.L. 1983 Doc IIIA/A7.4.3.2 (1)
$BCF_{chironomid}$	Water: 166 Sediment: 415 Porewater: 296	Measured values (as reported in a published paper (Muir et al., 1985))	Bayer/ Sumitomo
$BCF_{earthworm}$	15108 l/kg wet earthworm	Estimated value (according to the method described by Jager (1998), as detailed in the TGD)	Bayer/ Sumitomo
	23.8 L/kg	Estimated value (calculated using the USES modeling system)	Tagros
BCF_{snails}	800 l/kg	Continuous 30 day flow through exposure	Spehar R.L. 1983 Doc IIIA/A7.4.3.2 (1)

The Log Kow and some of the estimated BCF values would indicate permethrin has a strong potential to bioconcentrate following uptake via water/porewater (e.g. in fish/worms) and subsequently bioaccumulate through the food chain, resulting in toxic concentrations in predatory birds or mammals ingesting biota containing the chemical.

A study Spehar R.L., 1983, was carried out to assess the toxicity of the synthetic pyrethroid, Permethrin, in early life-stages of fathead minnows and snails. This information is presented as a scientific peer-reviewed paper in Aquatic Toxicology Volume 3, Issue 2, February 1983, Pages 171–182. The BCF values reported were 2800 L/Kg for fathead minnows and 800 L/Kg for snails. Data is not lipid normalised and non-GLP. The specification isomeric ratio of permethrin was not given. This study triggered the applicant to include a more recent study, Burgess *et. al.* 1989.

This 28-day bioconcentration study in fish, performed by BAYER/SUMITOMO, measured the BCF at only 570. Both this study and the Chironomid study showed that while Permethrin does appear to accumulate rapidly in the tissues of these aquatic organisms, depuration following exposure cessation was also rapid in both cases. Therefore, *in vivo*, any bioaccumulated permethrin residues will most likely be readily eliminated from organismsHowever, it should be noted that in the Bayer/Sumitomo 28-day flow through test, the lipid content was not normalised in Blugill sunfish. This could have the effect of underestimating the BCF value if the fish had a low lipid content. Likewise the two log Kow values submitted for permethrin, 4.6 Tagros and 6.1 Bayer Sumitomo, gave different BCF values when calculated using the log kow (equation 74 and 75 TGD). These two uncertainties should be recognized when reporting the BCF value of 570 L/Kg.

These findings and conclusions are supported by information gleaned from the literature, by Tagros, who stated that BCFfish values ranging from 290 – 620 have been reported in sheepshead minnows by WHO Permethrin EHC 94, (1990) and Hansen *et al*, (1983). Based on measured BCF_{fish} and $BCF_{chironomid}$ values < 2000 it is concluded that permethrin does not meet the B or vB screening criteria.

Toxicity
From a human health perspective, permethrin is not classified as carcinogenic, mutagenic or toxic for reproduction and there is no other evidence of chronic toxicity, as identified by the classifications: T, R48, or Xn, R48 according to Directive 67/548/EEC.

However, from an environmental perspective, the most critical long-term aquatic endpoint was the reproductive NOEC of 0.0000047 mg a.s./L as determined by TAGROS in a study on Daphnia magna. This low NOEC value indicates a potential for damage to the environment. On this basis, Permethrin does fulfil the screening criteria for "adverse effects to human health or to the environment" in terms of its ecotoxicity, as laid out in Annex D of the Stockholm Convention.
Therefore, with regard to toxicity, it is considered that permethrin does fulfil the T criteria, based on the aquatic ecotoxicology endpoints.

PBT conclusion

Persistence:

Permethrin as the isomeric mixture 25:75 cis:trans is not persistent in aquatic systems, on the basis that its whole system DT50 (12 ºC) values do not fulfil the P criterion for sediment. However, a constituent of permethrin (the cis isomer) may have the potential to be persistent.
Permethrin (25:75) is not considered to fulfil the P or vP criteria.

Bioaccumulation:

The reported Log Pow values for permethrin range from 4.6 to 6.1, indicating it is a fat-soluble molecule with a potential to bioconcentrate. However, experimentally derived BCF values for fish and chironomid ranged from 290 to 620 l/kg. Additionally, these data also indicated that residues were readily eliminated through depuration with approximately 80% of the residues depurated within 14 days.

Permethrin (25:75) is not considered to fulfil the B or vB criteria.

Toxicity:

The most critical long-term aquatic endpoint was the reproductive NOEC of 0.0000047 mg a.s./L on Daphnia magna, which is less than 0.01 mg/l trigger.
Permethrin (25:75) is considered to fulfil the T criteria.

Overall:

Permethrin (various isomer mixtures) is not a PBT candidate nor are its individual constituent isomers.

Permethrin is considered to fulfill the T criteria, but does not fulfill the B criteria. However, permethrin could also be considered as potentially persistent based on a constituent of permethrin (the *cis* isomer) and therefore fulfill the P criteria.

Guidance on PBT assessment (ECHA Guidance: Chapter R.11: PBT Assessment, v.1.1, November 2012) indicates that since the *cis* isomer constituent is present within permethrin at amounts ≥0.1 % w/w then the multi-constituent substance, permethrin, should also be treated as potentially persistent. In this situation permethrin may potentially fulfill the persistency criteria and, hence, fulfill two out of the three PBT criteria. Due to this borderline status and to the difficulties pertaining to the determination of the P classification, it is recommended that permethrin 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 the substance to be considered as a candidate for substitution as identified in the provisions of Article 10 of Regulation (EU) No 528/2012.

2.2.2.4. Exposure Assessment

The biocidal product (Permethrin 10 EC), chosen for the purposes of this submission, is a "dummy product" (or representative formulation), created as part of a theoretical exercise to investigate the potential properties of a Permethrin-containing product used

as a wood preservative. Permethrin 10 EC is a concentrate product contains 10.87% of the active substance Permethrin, combined with a number of inert co-formulants. It is a representative formulation imitating the typical Permethrin-based products currently available. Ready to use products are prepared by diluting the concentrate with water to an in-use concentration of between 0.02% and 0.25%, depending on the application method.

In this assessment, based on the application methods and the life stage of treated wood in-service, emission rates and Predicted Environmental Concentrations (PEC) of Permethrin are calculated for the primary (soil, water) receiving environmental compartments. There is also an assessment of secondary receiving environmental compartments such as sediment. Sediment is assessed in this document because of the expected exposure to this environmental compartment from study data presented in Document III. Groundwater has been assessed using PEARL version 4.4.4 in a separate section at the end of the assessment (Section 8.3.3). In accordance with Directive 98/8/EC, different stages of the life cycle of the product are incorporated into the risk assessment. For wood preservatives PEClocal values are proposed only for the application life stage (i.e. preventive and curative applications) and service life (i.e. storage of industrially treated wood and treated wood in service). Waste disposal has not been specifically dealt with in this CAR due to the absence of quantitative information in the guidance documents.

Therefore this risk assessment is structured into four separate sections following the structure of the ESD. The initial part of the risk assessment of Permethrin deals with exposure to the environment following industrial preventive applications to wood and its subsequent storage at the industrial plant. The second section deals with exposure of Permethrin leaching to the environment from treated wood in service (fence, house and noise barrier). Thirdly, an assessment is made of Permethrin exposure to the environment following in situ curative applications (by brush and spray) to a fence, a cladded house and a bridge by professional and amateur applicators. Finally a niche scenario, injection of a transmission pole, is included as an *in situ* curative treatment applied by professionals. Note that the noise barrier and bridge scenarios were not included in the applicant's submission, however they have been appended by the evaluator for the RMS as they are considered necessary in the ESD. Use classes 1 and 2 (indoor use) have not been included in this document as it is assumed that any emissions from such uses would be lower than those from uses classes 3 or 4. Use class 5 is not covered by the assessments carried out in this document. Therefore any future products coming under this heading would need a separate evaluation.

In summary, potential exposure to surface water and sediment may occur via industrial preventative treatment processes, if not contained, or by leaching from treated wood during storage, if wood is not stored under cover and on an impermeable surfaces. However, both these potential exposure routes can be mitigated against. Exposure to air can only occur during the application stage via the industrial preventative treatment processes. The foreseeable routes of exposure to soil are by leaching from industrially treated wood during storage, if wood is not stored under cover and on an impermeable surface (however this is mitigated against) or via leaching from treated wood in service over the service life of the treated wood. Estimations of the expected concentrations of active substance in the affected compartments are detailed in Document IIB, Section 3

Metabolites
Permethrin has two metabolites greater than 10% in soil - 3-(2,2-dichorovinyl)-2,2-dimethylcyclopropane carboxylic acid (DCVA) and 3-phenoxybenzoic acid (PBA). DCVA has a significantly longer DT50 than the parent compound while that of PBA is significantly shorter. Both have a molar mass approximately half that of the parent compound. Experimental data from the two applicants contributing to the dossier for the active substance have shown that DCVA and PBA can be found in soil, water and

sediment. The risk assessment has been performed on these metabolites using two separate methods – one method gives worst case concentrations in the solid compartments (soil and sediment) while the second results in worst case concentrations in the liquid compartments (micro-organisms STP and surface water). A full explanation and scientific justification for these methods is given in Document IIB, Section 3.

2.2.2.5. Risk Characterisation

Industrial Preventive Uses:

- There are failures for multiple environmental compartments across all the scenarios assessed at both the Application and Storage stages.

- As these scenarios take place in industrial facilities an appropriate risk mitigation measure, specifically, the containment of the emission to the faculty drain and subsequent storage under cover on an impermeable surface, would reduce the risk to zero.

Treated wood in service:

- There are failures for all the scenarios with regard to leaching of the active substance to soil during the initial assessment period (Time 1). However, when the entire service life is assessed (Time 2) the risk ratio is < 1 for several scenarios.

- For the Noise Barrier scenario there is an unacceptably high risk to surface water, sediment and STP organisms following leaching of the active substance to a drain followed by passage through an STP.

Curative treatment:

- There is an unacceptable risk to soil during application of the active substance in both the fence and house scenarios. However this risk can possibly be eliminated by covering the soil during the application stage.

- During the service life there is an unacceptably high risk to soil even when degradation of the active substance is taken into account.

- For the Bridge over pond scenario there is an unacceptably high risk to surface water during both the application and service life stages.

Wood in contact with ground:

- There is a slight risk to soil during the in-service life in this scenario after the initial assessment period of 30-days (Time 1). However when the time-weighted average figure (TWA) is considered (PEC/PNEC ratio = 0.59) a safe use is identified for use-class 4a. It should be noted that for Use Class 4a only the niche scenario "Injection Treatment – Transmission Pole" was assessed; the conclusions of this evaluation do not concern the other uses in use class 4a.

For the metabolites DCVA and PBA there are several failures across the scenarios and use classes evaluated. However the CA notes that (a) metabolite risk ratios are significantly lower than those of the parent compound and (b) there are far fewer metabolite failures than there are for the parent compound. In addition given the highly conservative nature of the exposure assessment carried out for the metabolites (refer to Doc IIB for details), any risk identified is significantly lower than that due to permethrin itself. The CA also notes that emissions in the scenarios examined were calculated assuming that 100% of the active substance leaches out of the article during the assessed time period. This was the only route available as the Applicants elected not to submit a leaching study. Had an acceptable study been carried out it can be expected that many of the scenarios would no longer pose an unacceptable risk to the various

environmental compartments. Therefore using the data available no safe use can be identified for use class 3.

Risk of secondary poisoning
The predicted concentrations of the biocidal product (Permethrin 10 EC) in the environment, suggests a risk of toxicity to birds. Birds and mammals showed a risk ratio of 4.27 and 0.56 respectively from eating fish containing the predicted concentration of permethrin in the biocidal product. Birds and mammals are not at risk from eating permethrin exposed earthworms.

Birds and mammals are not at risk from eating fish or earthworms containing the predicted concentration of the metabolites.

Summary of Secondary Poisoning

Scenario	Concentration	$PEC_{oral\ predator}$	PEC / PNEC birds	PEC / PNEC mammals
Scenario: Application, Aquatic compartment	**$PEC_{surface\ water}$ (mg / l)**	**(mg / kg wet fish)**		
Permethrin	0.25	71.25	4.27	0.56
DCVA	$1.5X10^{-2}$	4.3	0.26	0.036
PBA	$2.05X10^{-2}$	5.8	0.35	0.05
Scenario: Application, Terrestrial compartment	**$PEC_{groundwater}$**	**mg / kg wet earthworm**		
Permethrin	$>1X10^{-6}$	10	0.6	0.08
DCVA	0.0005	8.6	0.51	0.07
PBA	$>1X10^{-6}$	5.4	0.32	0.045

The log Kow of Permethrin was calculated as 4.67: 99% technical a.s. 25:75 indicating it is a fat-soluble molecule with a potential to bioconcentrate following uptake via water/porewater (e.g. in fish/worms) leading to secondary poisoning. The Bioconcentration factors recorded in a 28 day bioconcentration study with permethrin in Bluegill sunfish measured 500-570 L/kg. Data obtained during the subsequent depuration phase indicate removal of residues from whole fish, with time to 50% depuration of 4.7 days.

The rapid rate of depuration demonstrates that, in practice, any Permethrin taken up by aquatic or terrestrial organism will be rapidly eliminated once exposure ceases, thereby mitigating any perceived potential for biomagnification through the food chain that may otherwise lead to secondary poisoning.

Conclusion
To conclude, using the data available, no safe use can be identified for class 3. However, a safe use was identified for use-class 4a when the time-weighted average figure (TWA) was considered where wood is in contact with the ground following application to transmission poles by injection treatment. It should be noted that for Use Class 4a only this niche scenario "Injection Treatment – Transmission Pole" was assessed; the conclusions of this evaluation do not concern the other uses in use class 4a.
Environmentally safe uses could also be expected for products for use on wood that will not be exposed to weathering, i.e. use Classes 1 and 2 (situations in which wood is under cover and fully protected from the weather, e.g. framing, roof timbers etc.), since in these cases the potential emissions from treated wood to the outer environment are considered negligible.

2.2.2.6. Aggregated environmental exposure

The need to discuss the aggregated environmental exposure arising when an active substance is approved across multiple product types has been discussed during TMI2012 and TMIII2012. At TMIII 2013 it was proposed that such an assessment would be required for permethrin. However, in the absence of robust guidance that would allow a quantitative assessment to be carried out, it was agreed that a qualitative analysis would suffice. For this, the decision tree finalised by DE at TMIII2012 is used for the discussion.

The current submission includes three product – two under PT18 and one under PT8. In the case of the two PT18 products the only environmental exposure is via emissions to wastewater and subsequent processing at a domestic STP. Clearly in this instance there is potential for usage of the two products to overlap in time and space. At the product authorisation stage the CA should bear in mind that there is a possibility for the a.s to load to the different environmental compartments after discharge from the STP (SW, soil, sludge, sed and GW). The PT8 product also involves discharges to an STP. However in the case of Industrial Preventive Processes the CA has already recommended retention of the wastewaters at the industrial facility and treatment as hazardous waste. Therefore there should be no additional loading of permethrin from this source. The only other possible discharge to STP for PT8 is in the 'Noise Barrier' scenario. This is a niche scenario and thus is unlikely to contribute significant quantities, relative to PT18. Nonetheless CAs should bear this in mind at the product authorisation stage.

The other scenarios in PT8 mostly involve leaching of the a.s. from wood to the soil directly beneath them. Transport through the soil is not expected so it is unlikely that loadings of permethrin from the various scenarios would aggregate to any significant extent. However it is possible to envisage a development containing a high density of houses, fences and other treated wooden products where there may be some possibility for leaching to the one soil body. Again, this should be borne in mind by the CA at product authorisation stage.

To summarise there are two possible situations where aggregated exposure may be expected:

- Overlap in time and space in usage of the two PT18 products (and to a lesser extent the PT8 product) where discharges to a municipal STP result in a loading to the different environmental compartments (SW, soil, sludge, sed and GW).

- Developments containing a high density of treated wooden products where leaching to the same soil body may occur.

2.2.3. List of Endpoints

The most important endpoints, as identified during the evaluation process, are listed in Appendix I.

2.2.4. Conclusions and Decision of the Assessment Report

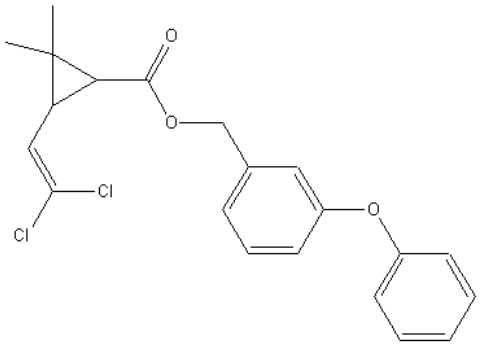
The outcome of the assessment for permethrin in product-type 8 is specified in the BPC opinion following discussions at the fifth meeting of the Biocidal Products Committee (BPC). The BPC opinion is available from the ECHA web-site.

APPENDIX I: LIST OF ENDPOINTS

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

Active substance (ISO Common Name)	Permethrin
Product-type	Product-type 8 (wood preservative)

Identity

Chemical name (IUPAC)	3-phenoxybenzyl(1RS)-cis,trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate or 3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate
Chemical name (CA)	(3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate
CAS No.	52645-53-1
EC No.	258-067-9
Other substance No.	CIPAC 331
Minimum purity of the active substance as manufactured (g/kg or g/l)	≥93% w/w sum of all permethrin isomers Cis:trans permethrin % ratio = 22-28:72-78 cis:trans. 1Rcis permethrin content = 5.0 – 10.0% w/w. 1Scis permethrin content = 15.0 – 20.0% w/w. 1Rtrans permethrin content = 45.0 – 55.0% w/w. 1Strans permethrin content = 17.0 – 27.0% w/w.
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	Refer to Appendix I of Document IIIA, Confidential Information
Molecular formula	$C_{21}H_{20}Cl_2O_3$
Molecular mass	391.29 g/mol
Structural formula	

Physical and Chemical Properties

Melting point (state purity)	33°C – 35°C (99.3%, 25:75 cis:trans) (Tagros)
Boiling point (state purity)	305°C (99.3%, 25:75 cis:trans) (Tagros)
Temperature of decomposition	>100°C (Bayer/Sumitomo)
Appearance (state purity)	Viscous, yellow to pale-brown liquid free from extraneous impurities. Mild characteristic odour (94.” % w/w, 25:75 cis:trans) (Tagros)
Relative density (state purity)	1.2250 (99.3%, 25:75 cis:trans) (Tagros)
Surface tension	Not relevant - The water solubility of permethrin is reported as being <4.95µg/l and therefore fulfils the criteria for exclusion (Bayer/Sumitomo) 0.06314 N/m at 20 - 22ºC (93.01%, 25:75 cis:trans) (Tagros)
Vapour pressure (in Pa, state temperature)	2.155 x 10^{-6} Pa at 20°C (99.30%, 25:75 cis:trans) (Tagros)
Henry’s law constant (Pa m^3 mol^{-1})	K > 4.5 x10^{-2} Pa m^3 mol^{-1} (Bayer/Sumitomo) K = 4.6 x 10^{-3} Pa m^3 mol^{-1} (Tagros)
Solubility in water (g/l or mg/l, state temperature)	<0.00495 mg/l at 20°C (99.0%, 25:75 cis:trans) (Bayer/Sumitomo) 0.18 mg/l at 20°C (99.30%, 25:75 cis:trans) (Tagros)
Solubility in organic solvents (in g/l or mg/l, state temperature)	The solubility of the test item is > 250 g/L in all solvents tested at both 20°C and 30°C: hexane, toluene, dichloromethane, methanol, acetone and ethyl acetate(97.3%, 25:75 cis:trans) (Bayer/Sumitomo)
Stability in organic solvents used in biocidal products including relevant breakdown products	A methanolic solution of permethrin exposed to light for 4 weeks showed no evidence of decomposition (Technical material, 25:75 cis:trans) (Bayer/Sumitomo) The information is not required, as Permethrin is not supplied in an organic solvent. Residual traces of toluene are present in technical Permethrin, but at very low levels (Tagros)
Partition coefficient (log P_{OW}) (state temperature)	log P_{OW} = 4.67 +/- 0.01 at 25°C (99.3%, 25:75 cis:trans)

	Effect of pH: (93.01%, 25:75) Water = 4.62 ± 0.05 pH 4.0 buffer = 4.63 ± 0.06 pH 7.0 buffer = 4.58 ± 0.04 pH 9.0 buffer = 4.60 ± 0.04 (Tagros)
Hydrolytic stability (DT_{50}) (state pH and temperature)	
Dissociation constant	Molecule is not expected to dissociate
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	λmax 214 nm (99.0%, 25:75 cis:trans) (Bayer/Sumitomo) λmax 218 nm structure (99.3%, 25:75 cis:trans) (Tagros)
IR Spectral data	The spectra confirm the molecular structure (99.3%, 25:75 cis:trans) (Tagros).
NMR Spectral data	The spectra confirm the molecular structure (99.3%, 25:75 cis:trans) (Tagros).
MS Spectral data	The spectra confirm the molecular structure (96.5%, 25:75 cis:trans) (Tagros).
Photostability (DT_{50}) (aqueous, sunlight, state pH)	
Quantum yield of direct phototransformation in water at Σ > 290 nm	
Flammability	Not flammable Determined not to have an auto-ignition temperature below 400°C (Technical material, 25:75 cis:trans) (Bayer/Sumitomo) Flash point = 219 +/- 2°C (Technical material, 25:75 cis:trans) (Bayer/Sumitomo) Flash point > 100°C (94.1%, 25:75 cis:trans) (Tagros).
Explosive properties	Not explosive based on experimental results (Tagros) and theoretical considerations
Oxidising properties	Non-oxidising based on theoretical considerations

Classification and Proposed Labelling

With regard to physical/chemical data	Does not classify from a phys/chem. point of view

With regard to toxicological data	Warning H302+H332: Harmful if inhaled and swallowed H317: May cause an allergic skin reaction
With regard to fate and behaviour data	Not applicable
With regard to ecotoxicological data	Hazard Statements: H410 (Acute Cat 1; Chronic Cat 1): Very toxic to aquatic life with long lasting effects. M-factor Acute M-Factor: 100, Chronic M-Factor: 10000 (based on 0.001<L(E)C50≤0.01) and (0.000001<NOEC≤0.00001, NRD)

CHAPTER 2: METHODS OF ANALYSIS

Analytical Methods for the Active Substance

Technical active substance (principle of method)	CIPAC method 331/TC/M/3: GLC with FID detection to determine permethrin content. (Bayer/Sumitomo) CIPAC method 331/TC/M/3: GLC with FID detection to determine permethrin content. (Tagros)
Impurities in technical active substance (principle of method)	GLC with FID detection GC/MS (Bayer/Sumitomo) GLC with FID detection HPLC-UV GC/MS (Tagros)

Analytical Methods for Residues

Soil (principle of method and LOQ)	Brumhard, B. 2008 Soil samples of were extracted in a microwave extractor with a mixture of acetonitrile/water and ammonium formate. The sample was cleaned up by centrifugation. Identification and quantitation of the test item was done using HPLC MS/MS detection in the Multiple Reaction Monitoring mode. The method was validated using a silt loam soil (Höfchen) and a sandy loam soil (Laacher Hof). LOQ = 5.0 µg/kg in soil (permethrin) (Bayer/Sumitomo)
Air (principle of method and LOQ)	Air is sucked through XAD adsorption tubes at about 1.5 L/min for 6 hours (total air sampling volume about 0.5 m^3). Subsequently, the adsorption material is extracted with acetone. The extract is diluted with methanol/water (1/2 v/v) and analysed by HPLC/MS/MS, monitoring two parent-daughter ion transitions. LOQ = 5 µg/m^3 air (Bayer/Sumitomo) Air is sucked through adsorption tubes at about 1.8 L/min for 6 hours at 35°C. Subsequently, the adsorption material is extracted with acetone. The extract was analysed for permethrin using GC/ECD. GC-MS/MS was used as a confirmatory method (three ions with an m/z > 100).

	LOQ = 0.0001 mg/m^3air (Tagros)
Water (principle of method and LOQ)	Acidified water samples are diluted with acetonitrile and analysed by HPLC-MS/MS using positive ionisation mode without further cleanup. Concentrations were quantified using external matrix-matched standard solutions LOQ = 0.05 µg/L for drinking and surface water, Permethrin only. (Bayer/Sumitomo)
Body fluids and tissues (principle of method and LOQ)	No data required. Molecule does not classify as toxic or highly toxic.
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	No data required. Proposed use is for wood preservation.
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	No data required. Proposed use is for wood preservation.

CHAPTER 3: IMPACT ON HUMAN HEALTH

Absorption, Distribution, Metabolism and Excretion in Mammals

Rate and extent of oral absorption:	Extensive and rapid. BAYER/SUMITOMO and TAGROS
Rate and extent of dermal absorption:	3% within 120 h BAYER/SUMITOMO
Distribution:	In general, tissue (fat, liver and kidney) residues were very low. The *cis* isomer showed relatively higher residue levels (0.46-0.62 mg/kg tissue) in the fat BAYER/SUMITOMO
Potential for accumulation:	No evidence of accumulation. BAYER/SUMITOMO
Rate and extent of excretion:	Rapidly and extensively excreted in urine and faeces almost completely eliminated within a few days (>95% excreted within 12 days) BAYER/SUMITOMO
Toxicologically significant metabolite(s)	Cl_2CA (free and glucuronide form), 4'-hydroxy-3-phenoxybenzoic acid (sulphate conjugate), PBacid (free and conjugated form) and hydroxymethyl-Cl2CA (glucuronide and lactone conjugate) BAYER/SUMITOMO

Acute Toxicity

Rat LD_{50} oral	480 - 554 mg/kg bw BAYER/SUMITOMO and TAGROS
Rat LD_{50} dermal	> 2000 mg/kg bw BAYER/SUMITOMO and TAGROS
Rat LC_{50} inhalation	> 4.638 (MAC) - 23.5 mg/L* BAYER/SUMITOMO and TAGROS *According to Directives 67/548 and 91/414 Permetrhin will classify
Skin irritation	Non irritating BAYER/SUMITOMO and TAGROS
Eye irritation	Non irritating BAYER/SUMITOMO and TAGROS
Skin sensitization (test method used and result)	Sensitising (M&K). BAYER/SUMITOMO Directive 67/548, 91/414)

Repeated Dose Toxicity

Species/ target / critical effect	Rat Increased absolute and relative liver weights which were associated with hepatocellular hypertrophy

Lowest relevant oral NOAEL / LOAEL	NOAEL = 5 mg/kg bw day based on adaptive hepatic changes in the 1 year dog study. BAYER/SUMITOMO
Lowest relevant dermal NOAEL / LOAEL	NOAEL = 1000 mg/kg bw/day in a 90 day dermal study in rats TAGROS LOAEL = 2000 mg/kg bw/day in a 90day dermal study in rats TAGROS
Lowest relevant inhalation NOAEL / LOAEL	NOAEL = 0.2201 mg/L (equivalent to 59.43 mg/kg bw/day) in a 90 day inhalation study in rats TAGROS LOAEL = 0.4363 mg/L (equivalent to 117.8 mg/kg bw/day) in a 90 day inhalation study in rats TAGROS

Genotoxicity	Negative in bacterial and mammalian cell gene mutation tests. Suggested clastogenicity *in vitro* in non-glp Mammalian chromosome aberrations studies Tested in vivo, permethrin (25% cis/75% trans) did not demonstrate genotoxic potential in mouse micronucleus, chromosomal aberrations or dominant lethal assays BAYER/SUMITOMO and TAGROS No genotoxic potential

Carcinogenicity

Species/type of tumour	Rat No carcinogenic potential No test substance related tumors. BAYER/SUMITOMO, TAGROS
Lowest dose with tumours	Not relevant

Reproductive Toxicity

Species/ Reproduction target / critical effect	Rat 180 mg/kg bw/day BAYER/SUMITOMO 500mg/kg bw/day TAGROS
Lowest relevant reproductive NOAEL / LOAEL	NOAEL = 180 mg/kg bw/day (High dose) LOAEL = >180 mg/kg bw/day (High dose) BAYER/SUMITOMO NOAEL = 500 mg/kg bw/day (High dose) LOAEL = >500 mg/kg bw/day (High dose) TAGROS
Species/Developmental target / critical effect	Rat/Rabbit No treatment related teratogenic effects BAYER/SUMITOMO, TAGROS

Lowest relevant developmental NOAEL / LOAEL	NOAEL = 400 mg/kg bw/day (High dose) LOAEL = >400 mg/kg bw/day (High dose) BAYER/SUMITOMO NOAEL = 500 mg/kg bw/day (High dose) LOAEL = >500 mg/kg bw/day (High dose) TAGROS

Neurotoxicity / Delayed Neurotoxicity

Species/ target/critical effect	Motor activity and acetylcholine receptors in mice can be negatively impacted by repeated inhalation exposure to permethrin, at high concentration. Increased vertical activity of male mice is likely to have been induced by treatment with 250 mg/m3 permethrin at the age of 10 to 16 days, whilst the NOEL at age 4 months for a reduction in acetylcholine receptors is 250 mg/m3 in male mice and 2.7 mg/m3 in females. BAYER/SUMITOMO
Lowest relevant developmental NOAEL / LOAEL	The NOAEL at age 4 months for receptor changes is 250 mg/m^3 in male mice and 2.5 mg/m^3 in females.

Other Toxicological Studies

Not applicable

Medical Data

Following various uses of products containing Permethrin at different concentrations, symptoms of poisoning were not reported in any case following dermal exposure. Further to direct application to the skin, Permethrin may induce some cutaneous side effects such as skin sensations, paresthesia and erythema. However Permethrin is not deemed to be used directly on the skin. No methods for the determination of Permethrin in body fluids are required as it is not toxic. However, urinary levels of 3-phenoxybenzyl degradation products may be a useful index of exposure to Permethrin. TAGROS

Summary

	Value	Study	Safety factor
AOEL (short-term) AEL_{ACUTE} (Operator Exposure)	0.5 mg/kg bw/day	Rat 2 year oral study (acute effect) BAYER/SUMITOMO	100
AOEL /AEL_{MEDIUM}	0.05 mg/kg	12-month dog	100

	bw/day	study. BAYER/SUMITOMO	
$AEL_{Long-term}$	0.05 mg/kg bw/day	12-month dog study. BAYER/SUMITOMO	100

Acceptable Exposure Scenarios (including method of calculation)

Industrial users	Not applicable (please see professional users below)
Professional users	**Wood Preservative Treatment.** Mixing and Loading - Model 7 TNsG Part 2, (2002). Automated Spray Application; Dipping Model 1 TNsG Part 2, (2002). Dipping/Immersion Application; Dipping Model 1 TNsG Part 2, (2002). Vacuum Pressure Application; Handling Model 1 TNsG Part 2, (2002). Double Vacuum Low Pressure; Application Handling Model 1 TNsG Part 2, (2002). Professional Spraying Spraying; Model 2 TNsG Part 2 (2002). Professional Brushing (outdoors); Consumer Painting Model 3 TNsG Part 2 (2002). Professional Brushing (indoors); Consumer Painting Model 1 TNsG Part 2 (2002). Professional Brushing - Cleaning of brushes; HEEG model.
Non-professional users	**Wood Preservative Treatment.** Brush Application (outdoors) Ready to use product; Consumer product painting Model 3 TNsG Part 2, (2002) Brush Application (indoors) Ready to use product; Consumer product painting Model 1 TNsG Part 2, (2002)
Indirect exposure as a result of use	**Wood Preservative Treatment.** Adult Handling Treated Timber – Acute Exposure. TNsG Part 3, (2002) p. 50 Adult cutting/sanding treated wood posts. TNsG Part 3, (2002) p. 50 Infant Chewing treated wood off-cut. TNsG Part 3, (2002) p. 50 Adult Machine Sanding Treated Timber. TNsG Part 3, (2002) p. 50 Child Playing Playground Structure; TNsG Model. Part 3, (2002) p. 50 Infant playing on weathered structure; TNsG Model. Part 3, (2002) p. 50

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)	BAYER/SUMITOMO (Study 1 – 40:60 *cis*:*trans* permethrin) pH 3, 6, 9 (all at 25 ºC): hydrolytically stable (Study 2 – 40:60 *cis*:*trans* permethrin) pH 5.7 (25 ºC): DT_{50} >200 days pH 7.6 (25 ºC): DT_{50} >200 days pH 9.6 (25 ºC): DT_{50} = 35 days (*cis*-permethrin), DT_{50} = 42 days (*trans*-permethrin) Metabolites: major metabolites not relevant for normal environmental conditions TAGROS (Study 1 – 25:75 *cis*:*trans* permethrin) pH 4 (50 ºC): <10% hydrolysis after 5 days (implies DT_{50} at 25 ºC >1 year) pH 7 (50 ºC): ~10% hydrolysis after 5 days (implies DT_{50} at 25 ºC >1 year) pH 9 (50 ºC): DT_{50} = 54.0 hours pH 9 (60 ºC): DT_{50} = 20.4 and 23.2 hours (n = 2) pH 9 (70 ºC): DT_{50} = 9.06 hours pH 9 (25 ºC): DT_{50} = 29.5 days (estimated with Arrhenius equation) (Study 2 – 25:75 *cis*:*trans* permethrin) pH 4, 7, 9 (all at 50 ºC): hydrolytically stable (<10% hydrolysis in each case) Metabolites: major metabolites not relevant for normal environmental conditions
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	BAYER/SUMITOMO (49:51 *cis*:*trans* permethrin) DT_{50} (extrapolated) = 118 days (latitude 50ºN, autumn, 12 hours sunlight per day) Metabolites: up to 19 transformation products detected, the most prominent of which accounted for 5.6% of applied radioactivity TAGROS (Calculation with ABIWAS programme, assuming quantum yield equals one, and using molar absorption coefficients obtained from a UV/Vis study on 25:75 *cis*:*trans* permethrin) Estimated theoretical half-lives (for latitude 55ºN) range from 6.42 x 10^5 days (July) to 3.35 x 10^{14} days (December). Metabolites: no data presented
Readily biodegradable (yes/no)	BAYER/SUMITOMO (permethrin *cis*:*trans* ratio not specified) No (OECD 301F) TAGROS (25:75 *cis*:*trans* permethrin) No (OECD 301B)
Biodegradation in seawater	Not applicable
Non-extractable residues	BAYER/SUMITOMO

	(aerobic water-sediment study – 46:54 and 53:47 *cis*:*trans* permethrin) 18% AR, alcohol-labelled ^{14}C-permethrin (at 30 days, study end, n = 1); 17% AR, acid-labelled ^{14}C-permethrin (at 30 days, study end, n = 1) (anaerobic water-sediment study – 46:54 and 53:47 *cis*:*trans* permethrin) 31% AR, alcohol-labelled ^{14}C-permethrin (at 367 days, study end, n = 1); 34% AR, acid-labelled ^{14}C-permethrin (at 367 days, study end, n = 1) <u>TAGROS</u> (aerobic water-sediment study – 25:75 *cis*:*trans* permethrin) Creek-derived system: maximum of 47.3% AR after 120 days for phenoxyphenyl-labelled permethrin; maximum of 14.1% AR after 120 days for vinyl-labelled permethrin Pond-derived system: maximum of 55.0% AR after 86 days for phenoxyphenyl-labelled permethrin; maximum of 19.1% AR after 86 days for vinyl-labelled permethrin
Distribution in water / sediment systems (active substance)	<u>BAYER/SUMITOMO</u> (aerobic water-sediment study – 46:54 and 53:47 *cis*:*trans* permethrin) Distribution of total radioactivity reported for water and sediment, since levels of permethrin were not presented for water and sediment individually but for the whole system. Water: For treatment with acid-labelled ^{14}C-permethrin, radioactivity level rose to a maximum of 14.9% after 14 days and declined to 8.9% by the end of the study (30 days). For treatment with alcohol-labelled ^{14}C-permethrin, radioactivity level reached a maximum of 4.18% after 21 days, declining to 1.31% by day 30. DT_{50} in water not reported for permethrin. Sediment: For treatment with acid-labelled ^{14}C-permethrin, radioactivity level was 98.5% immediately after dosing and had declined to 91.3% by day 30. For treatment with alcohol-labelled ^{14}C-permethrin, radioactivity level was 98.6% immediately after dosing and had declined to 84.0% by day 30. DT_{50} in sediment not reported for permethrin. Whole system: For treatment with acid-labelled ^{14}C-permethrin, total permethrin declined from 99.81% AR on day 0 to 56.25% AR by day 30, *cis*-permethrin declined from 46.01% AR on day 0 to 33.68% AR by day 30 and *trans*-permethrin declined from 53.81% AR on day 0 to 22.57% AR by day 30. For treatment with alcohol-labelled ^{14}C-permethrin, total permethrin declined from 99.91% AR on day 0 to 59.48% AR by day 30, *cis*-permethrin declined from 54.07% AR on day 0 to 38.67% AR by day 30 and *trans*-permethrin declined from 45.84% AR on day 0 to 20.81% AR by day 30. Whole system DT_{50}: 40.4 days for total permethrin (1st order, r^2 = 0.981, n = 1); 63.7 days for *cis*-permethrin (1st order, r^2 = 0.991, n = 1); 27.3 days for *trans*-permethrin (1st order,

r^2 = 0.975, n = 1) (Equivalent DT_{50} values at 12 ºC, extrapolated from 25 ºC, are 114.3 days for total permethrin, 180.2 days for *cis*-permethrin and 77.2 days for *trans*-permethrin.)

Mineralisation: 8.91% AR, alcohol-labelled ^{14}C-permethrin (at 30 days, study end, n = 1); 2.80% AR, acid-labelled ^{14}C-permethrin (at 30 days, study end, n = 1)

(anaerobic water-sediment study – 46:54 and 53:47 *cis*:*trans* permethrin)
Distribution of total radioactivity reported for water and sediment, since levels of permethrin were not presented for water and sediment individually but for the whole system.

Water: For treatment with acid-labelled ^{14}C-permethrin, radioactivity level rose to a maximum of 22% after 90 days and declined to 5% by the end of the study (367 days). For treatment with alcohol-labelled ^{14}C-permethrin, radioactivity level reached a maximum of 2.7% after 59 days, declining to 0.08% by day 367. DT_{50} in water not reported for permethrin.

Sediment: For treatment with acid-labelled ^{14}C-permethrin, radioactivity level was 97.4% immediately after dosing and had declined to 64.6% by day 367. For treatment with alcohol-labelled ^{14}C-permethrin, radioactivity level was 100.9% of nominal applied immediately after dosing and had declined to 48.0% by day 367. DT_{50} in sediment not reported for permethrin.

Whole system: For treatment with acid-labelled ^{14}C-permethrin, total permethrin declined from 97.07% AR on day 0 to 24.04% AR by day 367, *cis*-permethrin declined from 44.80% AR on day 0 to 15.01% AR by day 367 and *trans*-permethrin declined from 52.27% AR on day 0 to 9.04% AR by day 367. For treatment with alcohol-labelled ^{14}C-permethrin, total permethrin declined from 100.35% of nominal AR on day 0 to 14.53% AR by day 367, *cis*-permethrin declined from 53.26% AR on day 0 to 10.85% AR by day 367 and *trans*-permethrin declined from 47.09% AR on day 0 to 3.69% AR by day 367. Whole system DT_{50}: 144.7 days for total permethrin (1^{st} order, r^2 = 0.952, n = 1); 179.4 days for *cis*-permethrin (1^{st} order, r^2 = 0.938, n = 1); 114.5 days for *trans*-permethrin (1^{st} order, r^2 = 0.962, n = 1) (Equivalent DT_{50} values at 12 ºC, extrapolated from 25 ºC, are 409.4 days for total permethrin, 507.6 days for *cis*-permethrin and 323.9 days for *trans*-permethrin.)

Mineralisation: 43% AR, alcohol-labelled ^{14}C-permethrin (at 367 days, study end, n = 1); 24% AR, acid-labelled ^{14}C-permethrin (at 367 days, study end, n = 1)
(field aquatic study – permethrin *cis*:*trans* ratio not specified)
Cis- and *trans*-permethrin dissipated rapidly from water and remained primarily in the upper 0-5 cm sediment fraction. Estimated half-life values for water and sediment represent total transfers from these compartments rather than specific

	degradation-only values. Water: DT_{50} = 1.8, 3.1 days for *cis*-permethrin (n = 2); DT_{50} = 1.3, 1.4 days for *trans*-permethrin (n = 2) Sediment: DT_{50} = 118, 256 days for *cis*-permethrin (n = 2); DT_{50} = 18, 62 days for *trans*-permethrin (n = 2) <u>TAGROS</u> (2 aerobic water-sediment systems – 25:75 *cis*:*trans* permethrin) Water: For the phenoxphenyl-label treatment, permethrin decreased from initial levels of 89.8-96.8% AR to 4.7-18.7% AR by day 30 and to 0% AR by day 62 in both cases. For the vinyl-label treatment, permethrin decreased in one system from an initial level of 95.8% AR to 12.8% AR by day 30 and to 0% AR by day 62, and in the other system from an initial level of 94.4% AR to 3.0% AR by day 14 and to 0% AR by day 30. DT_{50} (dissipation values) = 2.2, 2.3 days for phenoxyphenyl-label treatment; 1.4, 2.2 days for vinyl-label treatment (1^{st} order, r^2 >0.85 in all cases) (Equivalent DT_{50} values at 12 ºC, extrapolated from 20 ºC, are 4.2 and 4.4 days for phenoxyphenyl-label treatment, and 2.7 and 4.2 days for vinyl-label treatment.) Sediment: For the phenoxyphenyl-label treatment, permethrin increased from initial levels of 2.6-3.8% AR to reach a maximum level of 57.1% AR (day 14) in one system and 67.0% AR (day 7) in the other system, and had declined to 0% AR by 100 days in both cases. For the vinyl-label treatment, permethrin increased from initial levels of 2.6-3.6% AR to reach a maximum level of 60.3% AR (day 14) in one system and 62.5% AR (day 7) in the other system, and had declined to 0% AR by 86-100 days. DT_{50} in sediment not reported. Whole system: For the phenoxyphenol-label treatment, permethrin decreased from initial levels of 93.6-99.4% AR to 0% AR by day 100 in both cases. For the vinyl-label treatment, permethrin decreased from initial levels of 98.0-98.4% AR to 0% AR by 86-100 days. Whole system DT_{50}: 24.6, 24.6 days for phenoxyphenyl-label treatment; 14.3, 24.3 days for vinyl-label treatment (SFO in all cases, geometric mean = 21.4 days) (Equivalent DT_{50} values at 12 ºC, extrapolated from 20 ºC, are 46.7 and 46.7 days for phenoxyphenyl-label treatment, and 27.1 and 46.1 days for vinyl-label treatment, geometric mean = 40.6 days.) Mineralisation: 30.1-45.4% AR by study end (day 120) for phenoxyphenyl-label treatment; 8.4-14.1% AR by study end (day 120) for vinyl-label treatment
Distribution in water / sediment systems (metabolites)	<u>BAYER/SUMITOMO</u> (aerobic water-sediment study – 46:54 and 53:47 *cis*:*trans* permethrin) *Cis*- and *trans*-DCVA and 3-phenoxybenzoic acid

(PBA) were the main metabolites found.

Total DCVA (*cis*- plus *trans*-DCVA) n = 2 replicates
Water: maximum of 14.03-14.05% AR after 14 days, declined to 5.63-7.73% after 30 days
Sediment: maximum of 15.06-15.73% AR after 30 days
Whole system: maximum of 21.00-24.80% AR after 21 days, declined to 20.69-23.46 after 30 days
DT_{50} value not calculated for any compartment.

PBA
Whole system: maximum of 5.74% AR (averaged) after 21 days and had declined to 4.78% AR (averaged) by day 30
DT_{50} value not calculated.

(anaerobic water-sediment study – 46:54 and 53:47 *cis*:*trans* permethrin)
Cis- and *trans*-DCVA and 3-phenoxybenzoic acid (PBA) were the main metabolites found.

Total DCVA (*cis*- plus *trans*-DCVA): n = 2 replicates
Water: maximum of 14.34-26.28% AR after 90 days, declined to 0.03-4.31% AR after 367 days
Sediment: maximum of 8.50-8.57%% AR after 269 days, declined to 0.47-7.77% AR after 367 days
Whole system: maximum of 21.64-33.02% AR after 90 days, declined to 0.50-12.08% AR after 367 days
DT_{50} value not calculated for any compartment.

PBA
Whole system: maximum of 3.19% AR (averaged) after 30 days, 0.69% AR (averaged) on day 120 and had disappeared by day 181
DT_{50} value not calculated

(field aquatic study – permethrin *cis*:*trans* ratio not specified)
Cis- and *trans*-DCVA and 3-phenoxybenzoic acid (PBA) were the main metabolites found.

Water: *trans*-DCVA and PBA detected immediately after the second application at both study sites; *cis*-DCVA detected immediately after the fifth application at one site and immediately after the sixth application at the other site. Metabolites had disappeared by 90 days after the last application at one site and by 120 days after the last application at the other site.
DT_{50} (dissipation values) = 28, 33 days for *cis*-DCVA (1^{st} order, n = 2); 22, 23 days for *trans*-DCVA (1^{st} order, n = 2); 7.5, 14 days for PBA (1^{st} order, n = 2)

Sediment: no detections of *cis*/*trans*-DCVA or PBA
DT_{50} in sediment not reported.

<u>TAGROS</u>
(2 aerobic water-sediment systems, pond and creek – 25:75 *cis*:*trans* permethrin)
3-Phenoxybenzyl alcohol, 3-phenoxybenzoic acid (PBA) and DCVA were the main metabolites

found.

3-Phenoxybenzyl alcohol
Water: for creek-derived system detected at a maximum level of 5.5% AR on day 1 and had disappeared by day 62, for pond-derived system detected at a maximum level of 38.2% AR on day 2 and had disappeared by day 30
DT_{50} in water not reported.
Sediment: for creek-derived system detected at a maximum level of 3.3% AR on day 7 and had disappeared by day 100, for pond-derived system detected at a maximum level of 2.6% AR on day 30 and had disappeared by day 62
DT_{50} in sediment not reported.
Whole system: for creek-derived system detected at a maximum level of 5.6% AR on day 1 and had disappeared by day 100, for pond-derived system detected at a maximum level of 38.5% AR on day 2 and had disappeared by day 62.
Whole system DT_{50}: 2.7 days for pond system (SFO, equivalent DT_{50} values at 12 ºC, extrapolated from 20 ºC, is 5.1 days), could not be determined for creek system.

PBA
Water: for creek-derived system detected at a maximum level of 28.5% AR on day 62 and had declined to 1.0% AR by day 120, for pond-derived system detected at a maximum level of 28.8% AR on day 30 and had declined to 10.3% AR by day 120
DT_{50} in water not reported.
Sediment: for creek-derived system detected at a maximum level of 16.4% AR on day 62 and had declined to 5.0% AR by day 120, for pond-derived system detected at a maximum level of 12.5% AR on day 100 and had decreased to 9.0% AR by day 120
DT_{50} in sediment not reported.
Whole system: for creek-derived system detected at a maximum level of 44.9% AR on day 62 and had declined to 6.0% AR by day 120, for pond-derived system detected at a maximum level of 33.8% AR on day 30 and had declined to 19.3% AR by day 120
Whole system DT_{50}: 31.8 and 33.4 days for creek and pond systems respectively (both SFO, equivalent DT_{50} values at 12 ºC, extrapolated from 20 ºC, are 60.3 and 63.3 days, geometric mean = 61.8 days).

DCVA
Water: for creek-derived system detected at a maximum level of 62.6% AR on day 100 and had declined to 58.5% AR by day 120, for pond-derived system detected at a maximum level of 62.5% AR on day 100 and had declined to 61.5% AR by day 120
Sediment: for creek-derived system detected at a maximum level of 21.7% AR on day 62 and had declined to 13.0% AR by day 120, for pond-

	derived system detected at a maximum level of 17.0% AR on day 86 and had declined to 14.4% AR by day 120 Whole system: for creek-derived system detected at a maximum level of 78.9% AR on day 100 and had declined to 71.5% AR by day 120, for pond-derived system detected at a maximum level of 78.8% AR on day 100 and had declined to 75.9% AR by day 120 DT_{50} values not calculated as levels had not declined sufficiently by study end.

Route and Rate of Degradation in Soil

Mineralisation (aerobic)	<u>BAYER/SUMITOMO</u> (Study 1 – 40:60 and 50:50 *cis*:*trans* permethrin) CO_2: 48.6-50.3% AR after 365 days, ^{14}C-cyclopropyl permethrin, n = 1 soil; 42.5-46.5% AR after 365 days, ^{14}C-phenyl permethrin, n = 1 soil Degradation declined markedly after 90 days, possibly due to a decline in microbial biomass. Therefore, CO_2 levels are also presented for day 30, day 90 and day 120. CO_2 (day 30): 7.8-10.2% AR, ^{14}C-cyclopropyl permethrin, n = 1 soil; 9.7-11.6% AR, ^{14}C-phenyl permethrin, n = 1 soil CO_2 (day 90): 25.1-25.8% AR, ^{14}C-cyclopropyl permethrin, n = 1 soil; 22.2-27.9% AR, ^{14}C-phenyl permethrin, n = 1 soil CO_2 (day 120): 30.8-31.8% AR, ^{14}C-cyclopropyl permethrin, n = 1 soil; 27.7-33.2% AR, ^{14}C-phenyl permethrin, n = 1 soil (Study 2 (literature data) – 22:78 and 46:54 *cis*:*trans* permethrin) CO_2 (day 28): 30, 31, 43 and 49% AR, n = 4 soils (Study 3 (literature data) – individual isomers of permethrin) 1R-*cis*: CO_2 at 9.4-15.2% AR after 2 weeks, n = 2 soils 1R-*trans*: CO_2 at 36.3-50.3% AR after 2 weeks, n = 2 soils 1S-*cis*: CO_2 at 9.3-21.3% AR after 2 weeks, n = 2 soils 1S-*trans*: CO_2 at 42.7-58.4% AR after 2 weeks, n = 2 soils <u>TAGROS</u> (1 study, 1 soil and 2 radiolabels – 25:75 *cis*:*trans* permethrin) CO_2: max 38% AR (day 93), 36% AR at study end (day 122) and max 52% AR at study end (day 122)
Laboratory studies (range or median, with number of measurements, with regression	DT_{50lab} (25 °C, aerobic) <u>BAYER/SUMITOMO</u>

coefficient)	(Study 1 – 40:60 and 50:50 *cis*:*trans* permethrin) DT_{50lab} (25 °C, aerobic): 37 days, n = 1 soil (1st order, using data for 0-90 days, r^2 = 0.989 (Study 2 (literature data) – 22:78 and 46:54 *cis*:*trans* permethrin) Two different methods were used. Method 1 is a conservative estimation based on CO_2 evolution rates (representing ultimate degradation). Method 2 is based on the measured level of permethrin remaining after 28 days (representing primary degradation). Method 1 DT_{50lab} (25 °C, aerobic): 27.3, 31.4, 47.6 and 49.8 days, n = 4 soils (1st order, r^2 = 0.958-0.992) Method 2 DT_{50lab} (25 °C, aerobic): 7.3, 10.3, 10.4 and 15.1 days, n = 4 soils (1st order, r^2 not relevant since estimation based on reported level at one timepoint only) (Study 3 (literature data) – individual isomers of permethrin) 1R-*cis*: DT_{50lab} (25 °C, aerobic) = 6.4-8.1 days, n = 2 soils (1st order) 1R-*trans*: DT_{50lab} (25 °C, aerobic) = 3.9-4.1 days, n = 2 soils (1st order) 1S-*cis*: DT_{50lab} (25 °C, aerobic) = 5.8-9.8 days, n = 2 soils (1st order) 1S-*trans*: DT_{50lab} (25 °C, aerobic) = 2.5-3.1 days, n = 2 soils (1st order) DT_{90lab} (25 °C, aerobic) <u>BAYER/SUMITOMO</u> (Study 1 – 40:60 and 50:50 *cis*:*trans* permethrin) DT_{90lab} (25 °C, aerobic): 123 days, n = 1 soil (1st order, using data for 0-90 days, r^2 = 0.989 (Study 2 (literature data) – 22:78 and 46:54 *cis*:*trans* permethrin) Method 1 (ultimate degradation – based on CO_2 evolution) DT_{90lab} (25 °C, aerobic): 90.8, 104.4, 158.2 and 165.4 days, n = 4 soils (1st order, r^2 = 0.958-0.992) Method 2 (primary degradation – based on level of permethrin at day 28) DT_{90lab} (25 °C, aerobic): 24.1, 34.1, 34.6 and 50.2 days, n = 4 soils (1st order, r^2 not relevant since estimation based on reported level at one timepoint only) (Study 3 (literature data) – individual isomers of permethrin) 1R-*cis*: DT_{90lab} (25 °C, aerobic) = 21.3-26.9 days, n = 2 soils (1st order) 1R-*trans*: DT_{90lab} (25 °C, aerobic) = 13.0-13.6 days, n = 2 soils (1st order)

	1S-*cis*: DT_{90lab} (25 °C, aerobic) = 19.3-32.6 days, n = 2 soils (1st order) 1S-*trans*: DT_{90lab} (25 °C, aerobic) = 8.3-10.3 days, n = 2 soils (1st order) DT_{50} (12 °C, aerobic) BAYER/SUMITOMO Extrapolation from aerobic lab data at 25 °C (Study 1 and Study 2 (literature data) used). The two sets of half-lives obtained for Study 2 were each combined separately with the half-life from Study 1, giving two datasets at 25 °C of 27.3, 31.4, 37.0, 47.6 and 49.8 days (dataset 1), and 7.3, 10.3, 10.4, 15.1 and 37.0 days (dataset 2). Both datasets were individually extrapolated to 12 °C. Extrapolated half-lives at 12 °C (dataset 1) 77.2, 88.8, 105, 135 and 141 days (n = 5 soils) Extrapolated half-lives at 12 °C (dataset 2) 20, 29, 29, 43 and 105 days (n = 5 soils) Note: The datasets were extrapolated with the TGD equation, $DT_{50}(12\ °C) = DT_{50}(25) \cdot e^{(0.08\ (25-12))}$ DT_{50lab} (20°C, anaerobic): Not determined. Degradation in the saturated zone: No data presented. TAGROS (3 studies covering 4 soils and 2 radiolabels – 25:75 *cis*:*trans* permethrin) 3 studies were carried out using 4 soils and 2 different radiolabels giving 8 sets of results. The studies followed OECD guidance however different metabolites were reported to those known in the literature. Therefore the values reported below refer to a degradation via a different pathway. DT_{50lab} (20 °C, aerobic) 11.2 (SFO), 10.2 (SFO), 10.4 (FOMC), 9.6 (FOMC), 7.1 (SFO), 6.6 (SFO), 5.8 (FOMC), 6.7 (SFO) days DT_{90lab} (20 °C, aerobic) 37.1, 33.8, 55.0, 46.8, 23.7, 21.8, 24.4, 22.4 days DT_{50} (12 °C, aerobic) extrapolated from data at 20°C, 21.2, 19.3, 19.7, 18.2, 13.5, 12.5, 11, 12.7 days
Field studies (state location, range or median with number of measurements)	DT_{50f}: Not determined. DT_{90f}: Not determined.

Anaerobic degradation	Not applicable.
Soil photolysis	BAYER/SUMITOMO (49:51 *cis*:*trans* permethrin) Losses of 7.9% and 21.1% AR observed for ^{14}C-acid-and ^{14}C-alcohol-labelled permethrin respectively. DT_{50} in the region of 200 days (Florida autumn sunlight equivalents) – extrapolated beyond study duration, which was equivalent to 33 days and 3 hours of Florida autumn sunlight. Up to 9 transformation products detected, with the most prominent accounting for 4.9% AR.
Non-extractable residues	BAYER/SUMITOMO (Study 1 – 40:60 and 50:50 *cis*:*trans* permethrin) Maximum levels of 20.2-42.6% AR after 365 days, ^{14}C-cyclopropyl permethrin, n = 1 soil; 28.8-34.6% AR after 275 days, ^{14}C-phenyl permethrin, n = 1 soil (Study 2 (literature data) – 22:78 and 46:54 *cis*:*trans* permethrin) 26.0, 28.5, 38.7 and 45.0% AR after 28 days, n = 4 soils (Study 3 (literature data) – individual isomers of permethrin) 1R-*cis*: 27.3-36.4% AR after 2 weeks, n = 2 soils 1R-*trans*: 28.6-39.8% AR after 2 weeks, n = 2 soils 1S-*cis*: 31.6-32.3% AR after 2 weeks, n = 2 soils 1S-*trans*: 25.9-37.3% AR after 2 weeks, n = 2 soils TAGROS (1 study, 1 soil and 2 radiolabels – 25:75 *cis*:*trans* permethrin) max 60% AR (day 93), 51% AR at study end (day 122) and max 39% AR (day 30), 29% AR at study end (day 122)
Relevant metabolites - name and/or code, % of applied a.i. (range and maximum)	BAYER/SUMITOMO (Study 1 – 40:60 and 50:50 *cis*:*trans* permethrin) DCVA and 3-phenoxybenzoic acid (PBA) were the main metabolites found. DCVA: maximum of 11.3% AR on day 14 and had declined to ~3% AR by day 365, n = 1 soil PBA: maximum of 15% AR on day 30 and had declined to ~3% AR by day 365, n = 1 soil 3-(2,2-dichlorovinyl)-2-methylcyclopropane-1,2-dicarboxylic acid detected at a maximum of 7% AR after 14-30 days, n = 1 soil. (Study 2 (literature data) – 22:78 and 46:54 *cis*:*trans* permethrin) DCVA, PBA and 3-phenoxybenzoic alcohol identified and reported to collectively represent 2-20% AR but individual levels not specified.

	(Study 3 (literature data) – individual isomers of permethrin) Three metabolites identified. Metabolite A: 3-hydroxybenzyl (1R)-*cis*,*trans*-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate Metabolite B: 3-(4-hydroxyphenoxy)benzyl (1R)-*cis*,*trans*-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate Metabolite C: 3-phenoxybenzoic acid For treatment with 1R-*cis*-permethrin, metabolite A detected at 10.7-11.4% AR after 2 weeks, n = 2 soils. For treatment with 1S-*cis*-permethrin, metabolite A detected at 8.7-12.4% AR after 2 weeks, n = 2 soils. Metabolites B and C <10% AR for all treatments. <u>Metabolite rate of degradation (aerobic, 12 ºC)</u> DCVA (literature data) – individual isomers (extrapolated from lab data at 25 ºC) 1R-*cis*-DCVA: DT_{50} = 38.2-44.4 days, n = 2 soils (1^{st} order) 1R-*trans*-DCVA: DT_{50} = 33.1-88.8 days, n = 2 soils (1^{st} order) 1S-*cis*-DCVA: DT_{50} = 46.7-45.3 days, n = 2 soils (1^{st} order) 1S-*trans*-DCVA: DT_{50} = 65.4-174.8 days, n = 2 soils (1^{st} order) PBA (extrapolated from lab data at 25 ºC) DT_{50} = 1.7-2.5 days, n = 2 soils (1^{st} order) <u>TAGROS</u> (3 studies covering 4 soils and 2 radiolabels – 25:75 *cis*:*trans* permethrin) 6 metabolites were detected but none of the established literature metabolites (DCVA, PBA and 3-phenoxybenzoic alcohol) were found using TLC analysis. 1 of the 6 metabolites (M1) reached max of 36% AR, DT_{50} 5.1-16.3 days at T=20°C (SFO, 9.7-30.9 at T=12°C) All other detected metabolites < 10% AR
Soil accumulation and plateau concentration	Not applicable

Adsorption / Desorption

Ka , Kd	<u>BAYER/SUMITOMO</u> K_F (Freundlich adsorption coefficient) Permethrin (*cis*:*trans* ratio not specified): 344, 355, 378, 446, 1517 (arithmetic mean = 608, 1/n = 1.09-1.32, n = 5: 4 soils and 1 sediment) DCVA (53.7:46.3 *cis*:*trans*): 0.184, 0.224, 2.893 (arithmetic mean = 1.10, 1/n = 0.871-0.957, n = 3 soils) PBA: 0.67, 1.34, 1.54, 2.68 (arithmetic mean = 1.56, 1/n = 0.92-1.0, n = 4 soils)
Ka_{oc} , Kd_{oc}	
pH dependence (yes / no) (if yes type of dependence)	$K_{F(des)}$ (Freundlich desorption coefficient) Permethrin (*cis*:*trans* ratio not specified): 265, 287, 330, 600, 6349 (arithmetic mean = 1566,

1/n = 1.01-1.42, n = 5: 4 soils and 1 sediment)
DCVA (53.7:46.3 *cis*:*trans*): 0.498, 0.676, 5.678 (arithmetic mean = 2.284, n = 3 soils)
PBA: 0.87, 1.85, 3.00, 4.21 (arithmetic mean = 2.48, n = 4 soils)

$K_{F,oc(ads)}$ (Freundlich adsorption coefficient based on organic carbon content)
Permethrin (*cis*:*trans* ratio not specified): 28200, 31500, 34100, 96600, 194000 (arithmetic mean = 76900, 1/n = 1.09-1.32, n = 5: 4 soils and 1 sediment)
DCVA (53.7:46.3 cis:trans): 13.95, 31.05, 356.15 (arithmetic mean = 133.71, 1/n = 0.871-0.957, n = 3 soils)
PBA: 50.65, 105.03, 189.90, 287.76 (arithmetic mean = 158.33, 1/n = 0.92-1.0, n = 4 soils)

$K_{F,oc(des)}$ (Freundlich desorption coefficient based on organic carbon content)
Permethrin (*cis*:*trans* ratio not specified): 25500, 27000, 50000, 125000, 404400 (arithmetic mean = 126000, 1/n = 1.01-1.42, n = 5: 4 soils and 1 sediment)
DCVA (53.7:46.3 *cis*:*trans*): 31.11, 114.19, 699.17 (arithmetic mean = 281.49, n = 3 soils)
PBA: 70.08, 165.10, 368.90, 374.73 (arithmetic mean = 244.7, n = 4 soils)

pH dependence
No for permethrin and PBA.
Yes for DCVA. Lowest $K_{F,oc}$ value was obtained with the most alkaline soil tested and highest value was obtained with the most acidic soil tested.

<u>TAGROS</u>

Tier 1, 2 and 3 studies were carried out for Permethrin, PBA and DCVA in 5 soils.

$K_{d(ads)}$ (distribution coefficient for adsorption)

Permethrin (25:75 *cis*:*trans*): 56.4, 75.9, 64.7, 55.7, 59.7 L/kg (arithmetic mean = 62.5 L/kg, n = 5 soils)

PBA: 0.72, 3.27, 6.04 L/kg (arithmetic mean = 3.34 L/kg, n= 3 soils)

DCVA (25:75 *cis*:*trans*): 0.76, 0.64 L/kg (arithmetic mean = 0.70, n = 2 soils)

$K_{d(des)}$ (distribution coefficient for desorption)

Permethrin (25:75 *cis*:*trans*): 118.5, 891.7, 161.5, 116.9, 97.7 L/kg (arithmetic mean = 277.26 L/kg, n=5 soils)

PBA: 6.96, 4.44 L/kg (arithmetic mean = 5.70 L/kg, n = 2 soils)

DCVA (25:75 *cis*:*trans*): 2.51 L/kg (n = 1 soil)

$K_{d,oc(ads)}$ (distribution coefficient for adsorption based on organic carbon content)

Permethrin (25:75 *cis*:*trans*): 6556.16, 4415.38, 5988.79, 2691.22, 3408.52 L/kg (arithmetic mean = 4612.01 L/kg, n=5 soils)

	PBA: 83.7, 190.1, 291.8 L/kg (arithmetic mean = 188.53 L/kg, n=3 soils) DCVA (25:75 *cis*:*trans*): 44.2, 30.9 L/kg (mean = 37.6, n = 2 soils) $K_{d,oc(des)}$ (distribution coefficient for desorption based on organic carbon content) Permethrin (25:75 *cis*:*trans*): 13782.84, 51961.17, 14957.3, 5622.7, 5585.2 L/kg (arithmetic mean = 18381.84 L/kg, n=5 soils) PBA: 808.7, 258.1 L/kg (arithmetic mean = 533.42 L/kg, n = 2 soils) DCVA (25:75 *cis*:*trans*): 145.9 L/kg (n = 1 soil) $K_{F,oc(ads)}$ (Freundlich coefficient for adsorption based on organic carbon content) Permethrin (25:75 *cis*:*trans*): 139092, 87432, 92019, 13165, 18309 L/kg (arithmetic mean = 70003 L/kg, n = 5 soils, 1/n = 1.01-1.16) PBA: 70.5, 127.1, 157.3 L/kg (arithmetic mean = 118.3 L/kg, n = 3 soils, 1/n = 0.64-0.95) DCVA (25:75 *cis*:*trans*): 44.96, 19.64 L/kg (mean = 32.3, n = 2 soils, 1/n = 0.42-0.87) $K_{F,oc(des)}$ (Freundlich coefficient for desorption based on organic carbon content) Permethrin (25:75 *cis*:*trans*): 182684, 20243, 197504, 31735, 55458 L/kg (arithmetic mean = 97525 L/kg, n = 5 soils, 1/n = 0.87-1.11)PBA: 83.5, 83.1 L/kg (arithmetic mean = 83.3 L/kg, n=2 soils, 1/n = 0.58-0.64) DCVA (25:75 *cis*:*trans*): 46.33 L/kg (n = 1 soil, 1/n = 0.84) H dependence No obvious relationship for distribution values normalised to organic carbon content.

Fate and Behaviour in Air

Direct photolysis in air	Not applicable
Quantum yield of direct photolysis	Not applicable
Photo-oxidative degradation in air	Calculation with AOPWIN (v 1.91). Gas-phase reaction with photochemically produced hydroxyl radicals would be major contribution to atmospheric degradation. Half-life = 0.47 days (based on a 12-hour day and hydroxyl radical concentration of 1.5×10^6 radicals/cm^3) or 0.701 days (based on a 24-hour day and hydroxyl radical concentration of 5×10^5 radicals/cm^3)
Volatilisation	Expected to be minimal due to low vapour pressure, low Henry's Law constant and high adsorption potential.

Monitoring Data, if available

Soil (indicate location and type of study)	No data presented.

Surface Water (indicate location and type of study)	No data presented.
Groundwater (indicate location and type of study)	No data presented.
Air (indicate location and type of study)	No data presented.

CHAPTER 5: EFFECTS ON NON-TARGET SPECIES

Toxicity data for aquatic species (most sensitive species of each group)

(Annex IIA, point 8.2, Annex IIIA, point 10.2)

Permethrin

Species	Time-scale	Endpoint	Toxicity
Fish			
Oncorhynchus mykiss	96 h	Mortality, LC_{50}	0.0051 mg a.s./L (Bayer/Sumitomo)
Zebrafish (*Danio rerio*)	35 days	NOEC (reduced survival) LC_{10}	0.00041 mg a.s./L (Tagros) 0.00059 mg a.s./L (Tagros)
Invertebrates			
Daphnia magna	48 h	immobility and mortality, LC_{50}	0.00127 mg a.s./L (Bayer/Sumitomo)
Daphnia magna	21 d	Reproduction, NOEC EC_{50}	0.0000047 mg a.s./L(Tagros) 0.0001874 mg/L (Tagros)
Algae			
Pseudokirchneriella subcapitata	72 h	Cell density, E_rC_{50}	> 1.13 mg a.s./L (Bayer/Sumitomo)
Pseudokirchneriella subcapitata	72 h	Cell density, NOEC Cell density, E_rC_{10}	<0.0131 mg a.s./L (Bayer/Sumitomo) 0.0023 mg a.s./L (Bayer/Sumitomo)
Microorganisms			
Activated sewage sludge	3 hours	EC_{50} NOEC	> 1000 mg/l (Tagros) 0.00495 mg/l[2] (Tagros)
Activated sewage sludge	3 hours	EC_{50} NOEC	> 0.42 mg/l (Bayer/Sumitomo) 0.00495 mg/l[2] (Bayer/Sumitomo)
[2] According to TM II 06 and TM II 08, for substances with low water solubility and if no effects on microorganisms are observed at the highest tested concentration, then water solubility is set as the NOEC			
Sediment dwelling organisms			

Chironomus riparius	10-d (spiked sediment) 96hr (spiked water)	adult emergence, LC_{50} survival, LC_{50}	2.110 mg/kg (Bayer/Sumitomo) 0.00289 mg/L (Bayer/Sumitomo)
Chironomus riparius	5-d after last emergence (spiked sediment)	adult emergence, NOEC	0.1 mg/kg (Bayer/Sumitomo)

Metabolites (DCVA, PBA)

Species	Time-scale	Endpoint	Toxicity
Fish			
DCVA : Rainbow trout	96 h	Mortality, LC_{50}	≥14.7 mg a.s./L (Bayer/Sumitomo)
Invertebrates			
DCVA *:Daphnia magna*	48 h	mortality, LC_{50}	25 mg a.s./L (Bayer/Sumitomo)
Algae			
PBA : *C..pyrenoidosa/ S.quadricauda*	14d	EC_{50} / growth yield	>10 mg a.s./L (Bayer/Sumitomo)

Effects on Earthworms or other Soil Non-target Organisms

Acute toxicity to earthworms	EC_{50} = 371 mg a.s./kg (126 mg/kg dwt converted to artificial soil 3,4% O.M) (Bayer/Sumitomo)
Reproductive toxicity to earthworms	Not required
Reproductive toxicity to *Hypoaspis aculeifer* Canestrini	**DCVA**: 14 day NOEC (Mortality) = 100 $mg.kg^{-1}$soil converted to artificial soil 167 mg/kg dwt 14 day LC_{50} (Mortality) = 400.9 $mg.kg^{-1}$soil converted to artificial soil = 668 mg/kg dwt 34 day NOEC (Reproduction) >316 $mg.kg^{-1}$soil converted to artificial soil >526 mg/kg dwt **FPBA**: 14 day NOEC (Mortality) = 940 $mg.kg^{-1}$soil converted to artificial soil 1567 mg/kg dwt 14 day LC_{50} (Mortality) > 940 $mg.kg^{-1}$soil converted to artificial soil > 1567 mg/kg dwt 34 day NOEC (Reproduction) = 297 $mg.kg^{-1}$soil converted to artificial soil 495 mg/kg dwt (Bayer/Sumitomo)

Effects on Soil Micro-organisms

Nitrogen mineralisation	No observed effect on carbon (40 days) or

	nitrogen (18 days) metabolism to >31.7 mg/kg dwt (Converted to artificial soil 3.4% O.M) (Bayer/Sumitomo). No effects on carbon (28 days) or nitrogen (42 days) metabolism in a field soil tested up to 6.875 kg of Permethrin Technical/ha, 42 days after application (= 9.17 mg/kg dwt) (Tagros)
Carbon mineralisation	No observed effect on carbon (40 days) or nitrogen (18 days) metabolism to >31.7 mg/kg dwt (Converted to artificial soil 3.4% O.M) (Bayer/Sumitomo). No effects on carbon (28 days) or nitrogen (42 days) metabolism in a field soil tested up to 6.875 kg of Permethrin Technical/ha, 42 days after application (= 9.17 mg/kg dwt) (Tagros)

Effects on Terrestrial Vertebrates

Acute toxicity to mammals	LD50: 480 mg as/kg bw (Bayer/Sumitomo)
Acute toxicity to birds	LD50: >4640 mg/kg bw (Bayer/Sumitomo)
Dietary toxicity to birds	LC50: >10000 ppm (Bayer/Sumitomo)
Reproductive toxicity to birds	NOEC: 500 ppm (Bayer/Sumitomo)

Effects on Honeybees

Acute oral toxicity	LD50: 0.163 µg/ bee (Bayer/Sumitomo)
Acute contact toxicity	LD50: 0.0235 µg/ bee (Bayer/Sumitomo)

Effects on other Beneficial Arthropods

Acute oral toxicity	Not Required
Acute contact toxicity	Not Required
Acute toxicity to…	Not Required

Bioconcentration

Bioconcentration factor (BCF)	500 – 570[m] L/kg (fish) (Bayer/Sumitomo) 166[m] L/kg (chironomid in water) (published study) 415[m] L/kg (chironomid in sediment) (published study) 166[m] L/kg (chironomid in porewater) (published study) 15108[e] L/kg (earthworm) (Bayer/Sumitomo)
Depuration time (DT50) (DT90)	DT_{50} = 4.7 ± 0.34 days (Bayer/Sumitomo)
Level of metabolites (%) in organisms accounting for > 10 % of residues	Not Applicable

[m] Measured; [e] Estimated

CHAPTER 6: OTHER ENDPOINTS

Acute toxicity to plants:

Seedling Emergence:	$NOER_{emergence}$ < 0.0128 mg/kg dry soil. (Tagros) $NOER_{biomass}$ = 1.6 mg/kg dry soil. (Tagros)
Vegetative vigour:	Effects on biomass for all species was < 20% at dose of 6875 g/ha (Tagros)

APPENDIX II: LIST OF INTENDED USES

Product-type:
PT 8 - Wood Preservative

Claim of the participant:
An insecticide for use as a wood preservative through the control of wood-destroying organisms (preventative and curative).

Target organisms:
Wood destroying insects, including for example: Deathwatch beetle (*Xestobium rufovillosum*); Furniture beetle (*Anobium punctatum*); Old House Borer (*Hylotrupes bajulus*); Termite (*Reticulitermes santonensis*); Japanese termite (*Reticulitermes speriaus*); Formosan subterranean termite (*Coptotermes formosanus*); Powderpost beetle (*Lyctus brunneus*) and other wood boring species.

Concentration:
Bayer/Sumitomo
No actual biocidal product was supported as part of this evaluation. Reference or "dummy" formulations representative of the highest concentration of a typical wood preservative product were supplied, which included:

Ready-to-use solvent-based formulation: 0.25% w/w

Water emulsifiable concentrate formulation: 2.5% w/w

Tagros
No actual biocidal product was supported as part of this evaluation. The reference or "dummy" formulation representative of the highest concentration of a typical wood preservative product was supplied, which included:

Permethrin 10 EC is a 10.87% water emulsifiable concentrate (EC). Ready to use products are prepared by diluting this guide recipe concentrate (EC) with water to an in-use concentration of between 0.02% and 0.25%, depending on the application method. Only the diluted WEC (RTU 0.25% Permethrin) is available for non-professional use. In-use concentrations, used in the risk assessment, are detailed below.

Categories of users:
Industrial, professional and non-professional uses are proposed.

Type of application:
Industrial preventive wood preservative applied in automated spraying, vacuum pressure, double vacuum pressure, flow coating or dipping treatment plants. Timber treated with this active substance may be placed in Biological Hazard Classes (also referred to as Use Classes) 1, 2, 3 and 4a
Permethrin containing products in Professional and Amateur use may be applied by brushing and spraying, and in professional use by remedial brushing and spraying and remedial injection.

Bayer/Sumitomo
No actual biocidal product was supported as part of this evaluation. Reference or "dummy" formulations with representative applications included:

Industrial application by professionals: Spraying, vacuum pressure, double vacuum pressure, flow coating or dipping treatment.

Remedial and *in-situ* application by professionals: Brushing, spraying, injection

Application by amateurs: Brushing

Tagros
No actual biocidal product was supported as part of this evaluation. Reference or "dummy" formulations with representative applications included:

Industrial application by professionals: Spraying, pressure impregnation (e.g. vacuum pressure, double vacuum pressure).

Professional application: spraying, brushing

Amateur application: spraying, brushing

Summary of intended uses for the product

A summary of the intended application types, in-use concentrations and effective retentions in wood for Permethrin EC is given below;

Application type	**Permethrin conc. in preservative % (w/w)**	**Maximum effective retention in wood (a.s./m² or a.s./m³)**
Spraying (automated: spray tunnel) (Industrial)	0.25	0.5 g/m^2
Flow-coating (Industrial)	0.25	0.5 g/m^2
Dipping of wooden articles (Industrial and Professional)	0.25	0.5 g/m^2
Vacuum pressure treatment (Industrial)	0.02	0.1 kg/m^3
Double vacuum low pressure treatment inc. vacumat (Industrial)	0.25	0.1 kg/m^3
Painting by brushing (Professional and Non-professional)	0.25	0.5 g/m^2
Remedial treatment spraying indoors (Professional and Non-professional)	0.25	0.7 g/m^2
Remedial treatment injection in holes (Professional)	0.25	0.7 g/m^2

Summary of intended uses for Reference Formulations, Water Emulsifiable Concentrate & Ready To Use Solvent Based Product

Object and/or situation (a)	Member State or Country	Product name	Organisms controlled (c)	Formulation		Application			Remarks: (m)
				Type (d-f)	Conc. of as (i)	type	Dose rate	method kind (f-h)	
Insecticide	None (reference purpose)	**Product 1**	Wood destroying insects	EC (1)	2.5% ww	Preventive Curative	Diluted at 0.25%in solution Diluted at 0.25%in solution	P1 Vacuum Pressure application P2 Double Vacuum Pressure application P3 Dipping application P4 Spray application C1 Spray treatment C2 Brushing	(1) : Water Emulsifiable Concentrate
Insecticide	None (reference purpose)	**Product 2**	Wood destroying insects	RTU-SB (2)	0.25% ww	Preventive Curative	N.A.(3) N.A.(3)	P1 Vacuum Pressure application P2 Double Vacuum Pressure application P3 Dipping application P4 Spray application C1 Spray treatment C2 Brushing	(2) : Ready to use – solvent based (3) Not applicable

(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. For studies marked Yes(i) data protection is claimed under Article 12.1(c) (i), for studies marked Yes(ii) data protection is claimed under Article 12.1(c) (ii). These claims are based on information from the applicant. It is assumed that the relevant studies are not already protected in any other Member State of the European Union under existing national rules relating to biocidal products. It was however not possible to confirm the accuracy of this information.

Active Substance - Reference list by author (Tagros)

Author(s)	Section No.	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data Protection Claimed (Yes/No)	Owner
Patil, S.K.	IIA, 1.3/1 (IIIA, 3.3)	2002	Physico-chemical Studies on Permethrin for a. Boiling point, b. Relative density, c. Vapour pressure, d. Solubility in water, e. Partition coefficient n-octanol/water. Rallis Research Centre, Rallis India Limited, Report no. 3348/02, GLP, (unpublished).	Yes	Tagros Chemicals India Ltd
Pushpamalini, T.	IIA, 1.3/2 (IIIA, 3.1.1)	2005	Studies on the Physico-chemical Properties of Permethrin Technical. International Institute of Biotechnology and Toxicology (IIBAT), Report no. 15306, GLP (unpublished).	Yes	Tagros Chemicals India Ltd
Patil, S.K.	IIA, 1.3/3 & 1.3/4 (IIIA, 3.1.2, 3.1.3)	2002	Physico-chemical Studies on Permethrin for a. Boiling point, b. Relative density, c. Vapour pressure, d. Solubility in water, e. Partition coefficient n-octanol/water. Rallis Research Centre, Rallis India Limited, Report no. 3348/02, GLP, (unpublished).	Yes	Tagros Chemicals India Ltd
Pushpamalini, T.	IIA, 1.3/5 (IIIA, 3.7)	2004a	Studies on the Solubility of Permethrin Technical in Xylene, Hexane and Methanol. International Institute of Biotechnology and Toxicology (IIBAT), Report no. 14237, GLP (unpublished).	Yes	Tagros Chemicals India Ltd
Pushpamalini, T.	IIA, 1.3/6 (IIIA, 3.7)	2005	Studies on the Physico-chemical Properties of Permethrin Technical. International Institute of Biotechnology and Toxicology (IIBAT), Report no. 15306, GLP (unpublished).	Yes	Tagros Chemicals India Ltd

Author(s)	Section No.	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data Protection Claimed (Yes/No)	Owner
Sathiyanarayanan, S.	IIA, 1.3/7 (IIIA, 3.5)	2006a	Permethrin Technical: Laboratory Study of Water Solubility. International Institute of Biotechnology and Toxicology (IIBAT), Report no. 06020, GLP (unpublished).	Yes	Tagros Chemicals India Ltd.
Loganayagi, C.	IIA, 1.3/8 (IIIA, 3.13)	2006	Permethrin Technical: Laboratory Study of Surface Tension. International Institute of Biotechnology and Toxicology (IIBAT), Report no. 06023, GLP (unpublished)	Yes	Tagros Chemicals India Ltd.
Sathiyanarayanan, S.	IIA, 1.3/8 (IIIA, 3.13)	2006b	Permethrin Technical: Laboratory Study of Partition Coefficient. International Institute of Biotechnology and Toxicology (IIBAT), Report no. 06022, GLP (unpublished)	Yes	Tagros Chemicals India Ltd.
Pushpamalini, T.	IIA, 1.3/8 (IIIA, 3.10)	2005	Studies on the Physico-chemical Properties of Permethrin Technical. International Institute of Biotechnology and Toxicology (IIBAT), Report no. 15306, GLP (unpublished).	Yes	Tagros Chemicals India Ltd
Pushpamalini, T.	IIA, 1.3/9 (IIIA, 3.12)	2004b	Studies on the Flash Point/Flammability of Permethrin Technical. International Institute of Biotechnology and Toxicology (IIBAT), Report no. 14232, GLP (unpublished).	Yes	Tagros Chemicals India Ltd
Joseph, R.	IIA, 1.4.1 (IIIA, 4.1/1, 4.1/2, 4.1/3, 4.1/4, 4.1/5, 4.1/6 and 4.1/7)	2005	Studies on the Purity Profile of Five Batches of Permethrin Technical. International Institute of Biotechnology and Toxicology (IIBAT), Report no.: 15368, GLP (unpublished).	Yes	Tagros Chemicals India Ltd
Pushpamalini, T.	IIA,1.4.2/1 (IIIB, 4.1/1)	2004	Analytical Test Report of Permethrin 10% w/w EC. International Institute of Biotechnology and Toxicology (IIBAT), Report no. 14280, GLP (unpublished).	Yes	Tagros Chemicals India Ltd

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Joseph, R.	IIA,1.4.3/1 (IIIA, 4.2.a/1	2004a	Studies on the Persistence of Permethrin Technical in Loamy Sand Soil. International Institute of Biotechnology and Toxicology (IIBAT), Report no. 14358, GLP (unpublished).	Yes	Tagros Chemicals India Ltd
Joseph, R.	IIA, 1.4.3/2 (IIIA, 4.2.a/2)	2004b	Studies on the Adsoption Desorption of Permethrin Technical. International Institute of Biotechnology and Toxicology (IIBAT), Report no. 14291, GLP (unpublished).	Yes	Tagros Chemicals India Ltd
Sathiyanarayanan, S.	IIA, 1.4.3/3 (IIIA, 4.2.b)	2006	Analytical Method for the Determination of Residues of Permethrin in Air. International Institute of Biotechnology and Toxicology (IIBAT), Report no. 06021, GLP (unpublished).	Yes	Tagros Chemicals India Ltd
Joseph, R.	IIA, 1.4.3/3 (IIIA, 4.2.c)	2004c	Studies on the Hydrolisis (Abiotic) of Permethrin Technical. International Institute of Biotechnology and Toxicology (IIBAT), Report no. 14375, GLP (unpublished).	Yes	Tagros Chemicals India Ltd
Berry, R.W.	IIA, 2.3/1 (IIIB 5.10/1)	1977	The Evaluation of Permethrin for Wood Preservation. Pestic. Sci., No. 8, pp. 284-290	No	Public literature
De Groot, P. and Helson, B.V.	IIA, 2.3/2 (IIIB 5.10/2)	1993	Efficacy and Timing of Insecticides Sprays for Control of White Pine Weevil (Coleoptera: Curculionidae) in High-Value Pine Plantations. Journal of Economic Entomology, Vol. 86, No. 4, pp. 1171-1177	No	Public literature
Ocloo, J.K.	IIA, 2.3/3 (IIIB 5.10/3)	1983	A Comparative Study of teh Protection offered to Wood Samples by Permethrin, Dieldrin and Lindane against damage by Subterranean Termites and Fungi. The International Journal of Wood Preservation, Vol. 3, No. 1, pp. 31-38	No	Public literature

Author(s)	Section No.	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data Protection Claimed (Yes/No)	Owner
Werner, R.A. et al.	IIA, 2.3/4 (IIIB 5.10/4)	1984	Field Evaluation of Fenitrothion, Permethrin and Chlorpyrifos for Protecting White Spruce trees from Spruce Beetle (Coleoptera: Scolytidae) Attack in Alaska. Journal of Economic Entomology, Vol. 77, No. 4, pp. 995-998	No	Public literature
[redacted]	IIA, 3.1 (IIIA, 6.2/1)	2005	Literature Review of Permethrin Toxikokinetic Studies Absorption, Distribution, Excretion and Metabolism in Mammals. [redacted] Report no. Not documented, non-GLP (unpublished)	Yes	Tagros Chemicals India Ltd
[redacted]	IIA, 3.2/1 (IIIA, 6.1.1)	1998a	Acute Oral Toxicity Study of Permethrin Technical in Rats. [redacted] GLP (unpublished).	Yes	Tagros Chemicals India Ltd
[redacted]	IIA, 3.2/2 (IIIA, 6.1.2/1)	1998b	Acute Dermal Toxicity Study of Permethrin Technical in Rats. [redacted] GLP (unpublished).	Yes	Tagros Chemicals India Ltd
[redacted]	IIA, 3.2/2 (IIIA, 6.1.2/2)	2006	Acute Dermal Toxicity Study with Permethrin Technical in Wistar Rats. [redacted] GLP (unpublished).	Yes	Tagros Chemicals India Ltd
[redacted]	IIA, 3.2/3 (IIIA, 6.1.3)	1998	Acute Inhalation Toxicity Study of Permethrin Technical in Rats. [redacted] GLP (unpublished).	Yes	Tagros Chemicals India Ltd

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[redacted]	IIA, 3.3/1 (IIIA, 6.1.4/1)	1998c	Acute Dermal Irritation Study of Permethrin Technical in Rabbits. [redacted] GLP (unpublished).	Yes	Tagros Chemicals India Ltd
[redacted]	IIA, 3.3/2 (IIIA, 6.1.4/2)	1998d	Acute Eye Irritation Study of Permethrin Technical in Rabbits. [redacted] GLP (unpublished).	Yes	Tagros Chemicals India Ltd
[redacted]	IIA, 3.4 (IIIA, 6.1.5)	1998e	Skin Sensitisation Study of Permethrin Technical in Guinea Pigs [Buehler Test]. [redacted] GLP (unpublished).	Yes	Tagros Chemicals India Ltd
[redacted]	IIA, 3.5/1 (IIIA, 6.3.1)	2002	Permethrin: 28-Day Dietary Range Finding Study in Wistar Rats. [redacted] GLP (unpublished)	Yes	Tagros Chemicals India Ltd
[redacted]	IIA, 3.5/2 (IIIA, 6.4.1/1)	2003	Repeated Dose (90-Day) Oral Toxicity Study with Permethrin in Wistar Rats. [redacted] GLP (unpublished)	Yes	Tagros Chemicals India Ltd
[redacted]	IIA, 3.5/3 (IIIA, 6.4.1/2)	2006	Subacute Oral Toxicity Study with Permethrin Technical in Swiss Albino Mice. [redacted] GLP (unpublished).	Yes	Tagros Chemicals India Ltd
[redacted]	IIA, 3.5/4 (IIIA, 6.4.2)	2006	Subacute Dermal Toxicity Study with Permethrin Technical in Wistar Rats. [redacted] GLP (unpublished)	Yes	Tagros Chemicals India Ltd

Author(s)	Section No.	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data Protection Claimed (Yes/No)	Owner
[redacted]	IIA, 3.5/5 (IIIA, 6.4.3)	2006	Subchronic Inhalation Toxicity Study of Permethrin Technical in Wistar Rats. [redacted], GLP (unpublished)	Yes	Tagros Chemicals India Ltd
[redacted]	IIA, 3.6.1/1 (IIIA, 6.6.1)	1999	*Salmonella Typhimurium* Reverse Mutation Assay of Permethrin Technical. Microbiology Section, [redacted], GLP (unpublished).	Yes	Tagros Chemicals India Ltd
[redacted]	IIA, 3.6.1/2 (IIIA, 6.6.2)	2003	*In Vitro* Mammalian Chromosome Aberration Test with Permethrin. [redacted], GLP (unpublished).	Yes	Tagros Chemicals India Ltd
[redacted]	IIA, 3.6.1/3 (IIIA, 6.6.3)	2002	*In vitro* Mammalian Cell Gene Mutation Test with Permethrin. [redacted], GLP (unpublished).	Yes	Tagros Chemicals India Ltd
[redacted]	IIA, 3.6.2 (IIIA, 6.6.4)	1998	Chromosomal Aberration Study of Permethrin Technical in Mice. [redacted] GLP (unpublished)	Yes	Tagros Chemicals India Ltd
[redacted]	IIA, 3.7 (IIIA, 6.7)	2007	Combined Chronic Toxicity / Carcinogenicity Study of Permethrin Technical in Wistar Rats. [redacted] GLP (unpublished)	Yes	Tagros Chemicals India Ltd
[redacted]	IIA, 3.8.1 (IIIA, 6.8.1)	2006a	Teratogenic Evaluation of Permethrin Technical in New Zealand White Rabbits. [redacted] GLP (unpublished)	Yes	Tagros Chemicals India Ltd

Author(s)	Section No.	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data Protection Claimed (Yes/No)	Owner
[redacted]	IIA, 3.8.2 (IIIA, 6.8.2)	2006b	Oral Two Generation Reproduction Toxicity Study with Permethrin Technical in Wistar Rats. [redacted] GLP (unpublished)	Yes	Tagros Chemicals India Ltd
JMPR	IIA, 3.9, IIA, 3.10.1/2, IIA, 3.10.2/2 (IIIA, 6.9, IIIA, 6.12.1/2, and IIIA, 6.12.2/2)	1999	(JMPR) Pesticide Residues in Food – Permethrin – 1999. Joint meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group , non GLP (published)	No	Public literature
JMPR	IIA, 3.10.1/1 and IIA, 3.10.2/1 (IIIA, 6.12.1/1 and IIIA, 6.12.2/1)	1990	Environmental Health Criteria (EHC) 94 – Permethrin (1990). International Programme on Chemical Safety (IPAS), World Health Organisation, non GLP (published)	No	Public literature
Premnadh, N.	IIA, 3.10.3 (IIIA, 6.12.3)	2006	To Whom So Ever It May Concern Tagros Chemicals India Ltd, Report no. Not applicable, non GLP (unpublished)	Yes	Tagros Chemicals India Ltd
WHO	IIA, 3.10.5 (IIIA, 6.12.5)	1984	Data Sheet on Pesticides No. 51 Permethrin, (WHO)	N	Public literature
[redacted]	IIA, 3.10.5 (IIIA, 6.12.5/2)	2005	Literature Review of Permethrin Toxikokinetic Studies Absorption, Distribution, Excretion and Metabolism in Mammals. [redacted] Not documented, non-GLP (unpublished)	Yes	Tagros Chemicals India Ltd
WHO	IIA, 3.10.7 (IIIA, 6.12.7)	1984	Data Sheet on Pesticides No. 51 Permethrin, (WHO)	N	Public literature
Clarke, N.	IIIA, 4.1.1.1-1 (7.1.1.2.1)	2003	Permethrin: Assessment of Ready Biodegradability; CO2 Evolution Test. Safepharm Laboratories Limited, Report No.: 1667/003, GLP	Yes	Copyr s.p.a

Author(s)	Section No.	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data Protection Claimed (Yes/No)	Owner
			(unpublished).		
Sathiyanarayanan S.	IIA, 4.1.1.1-2 (IIIA 7.1.1.2.2)	2006	Assessment of Inherent Biodegradability of Permethrin Technical by modified MITI Test (II). International Institute of Biotechnology and Toxicology (IIBAT), Report no. 06012 (unpublished)	Yes	Tagros Chemicals India Ltd
Morlock, G.	IIA, 4.1.1.1-3/1 (IIIA 7.1.2.2.2-1)	2006a	Degradation and metabolism of Permethrin (^{14}C-Vinyl label and ^{14}C-Phenoxyphenyl label) in one water/sediment system (creek) under aerobic conditions - laboratory test. GAB Biotechnologie GmbH & GAB Analytik GmbH, Report no. 20051415/02-CUWS (unpublished)	Yes	Tagros Chemicals India Ltd
Morlock, G.	IIA, 4.1.1.1-3/2 (IIIA 7.1.2.2.2-2)	2006b	Degradation and metabolism of Permethrin (^{14}C-Vinyl label and ^{14}C-Phenoxyphenyl label) in one water/sediment system (pond) under aerobic conditions - laboratory test. GAB Biotechnologie GmbH & GAB Analytik GmbH, Report no. 20051415/01-CUWS (unpublished)	Yes	Tagros Chemicals India Ltd
White, D.F., Mullee, D.M.	IIA, 4.1.1.2-1/1 (7.1.1.1.1)	2003	Permethrin: Determination of Abiotic Degradation, Hydrolysis as a Function of pH and Adsorption Coefficient. Safepharm Laboratories Limited, Report No.: 1667/004, GLP (unpublished).	Yes	Copyr s.p.a
Joseph, R.	IIA, 4.1.1.2-1/2 (7.1.1.1.1)	2004a	Studies on the Hydrolysis (Abiotic) of Permethrin technical. International Institute of Biotechnology and Toxicology (IIBAT), Report no.: 14375, GLP (unpublished).	Yes	Tagros Chemicals India Ltd.
Klöppel, H.	IIA, 4.1.1.2-2 (IIIA 7.1.1.1.2)	2006	Aquatic photodegradation and quantum yield of Permethrin, Fraunhofer Institute for Molecular Biology and Applied Ecology,	Yes	Tagros Chemicals India Ltd

Author(s)	Section No.	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data Protection Claimed (Yes/No)	Owner
			Report no. GAB-012/7-05 (unpublished)		
McManus, K.	IIA, 4.1.1.3-1 (IIIA, 7.3.2)	2006b	Environmental distribution of Permethrin (Mackay Level I fugacity model). Rivendell Consulting Limited, Report no. RI2006/03/30, Non-GLP (unpublished).	Yes	Tagros Chemicals India Ltd.
Joseph, R.	IIA, 4.1.1.3-2 (IIIA, 7.2.3.1)	2004b	Studies on the Adsoption Desorption of Permethrin technical. International Institute of Biotechnology and Toxicology (IIBAT), Report no. 14291, GLP (unpublished)	Yes	Tagros Chemicals India Ltd
[redacted]	IIA, 4.2.1.1-1 (IIIA, 7.4.1.1-1)	2004	Acute Toxicity Study of Permethrin technical in Freshwater Fish, *Poecilia reticulata.* [redacted] GLP (unpublished)	Y	Tagros Chemicals India Ltd.
[redacted]	IIA, 4.2.1.1-2 (IIIA, 7.4.1.1-2)	1998a	Acute Toxicity Study of Permethrin Technical in Common Carp, *Cyprinus carpio*. [redacted] GLP (unpublished)	Y	Tagros Chemicals India Ltd
[redacted]	IIA, 4.2.1.2 (IIIA, 7.4.3.2)	2006a	Zebrafish (*Danio rerio*), Early Life Stage Toxicity Test (OECD 210) with Permethrin technical. [redacted] GLP (unpublished)	Y	Tagros Chemicals India Ltd.
Sharma, V.G.S	IIA, 4.2.1.3 (IIIA, 7.4.1.1-2)	1998b	24 h EC_{50} Acute Immobilisation Study of Permethrin Technical in *Daphnia magna*. Department of Ecotoxicology, JAI Research Foundation (JRF). Report no. 1597, GLP (unpublished)	Y	Tagros Chemicals India Ltd.

Author(s)	Section No.	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data Protection Claimed (Yes/No)	Owner
Schäfers, C.	IIA, 4.2.1.4 (IIIA, 7.4.3.4)	2006b	*Daphnia magna*, Reproduction test (OECD 211) Semi-static exposure, Permethrin technical. Fraunhofer Institute for Molecular Biology and Applied Ecology (IME). Report No.: GAB-012/4-21, GLP (unpublished)	Y	Tagros Chemicals India Ltd.
Mead, C.	IIA, 4.2.1.5 (IIIA, 7.4.1.3)	2003	Permethrin: Algae Inhibition Test. SafePharm Laboratories Limited. Report no. 1667/001, GLP (unpublished)	Y	Copyr s.p.a.
Clarke, N.	IIA, 4.2.1.6 (IIIA, 7.4.1.4)	2003b	Permethrin: Assessment of the Inhibitory Effect on the Respiration of Activated Sewage Sludge. Safepharm Laboratories Limited. Report no. 1667/002, GLP (unpublished)	Y	Copyr s.p.a.
Sunil Dutt, M.	IIA, 4.2.3-1 (IIIA, 7.5.1.2)	2006	Toxicity of Permethrin technical to Earthworm, *Lampito mauritii*. International Institute of Biotechnology and Toxicology (IIBAT). Report no. 06039, GLP (unpublished)	Y	Tagros Chemicals India Ltd
Kölzer, U.	IIA, 4.2.3-2 (IIIA, 7.5.1.1)	2006	Assessment of the side effects of Permethrin Technical on the activity of the soil microflora. GAB Biotechnologie GmbH & GAB Analytik GmbH, Report No.: 20051446/01-ABMF, GLP (unpublished)	Y	Tagros Chemicals India Ltd.
Balluff, M.	IIA, 4.2.3-3 (IIIA, 7.5.1.3/1)	2006a	Seedling emergence dose-response test for non-target plants following multiple rate applications of Permethrin Technical 25/75. eurofins-GAB GmbH Report No.: 20064034/S1-FGSE, GLP (unpublished).	Y	Tagros Chemicals India Ltd
Balluff, M.	IIA, 4.2.3-4 (IIIA, 7.5.1.3/2)	2006b	A greenhouse limit test to determine the effects of Permethrin Technical 25/75 on the vegetative vigour of six species of plants. eurofins-GAB GmbH Report No.: 20064034/S1-FGVV, GLP (unpublished).	Y	Tagros Chemicals India Ltd
Tomlin, C.D.S.	IIA, 5.0/1 (IIIA, 3.10)	2000	The Pesticide Manual.	No	Public Domain

Author(s)	Section No.	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data Protection Claimed (Yes/No)	Owner
Pushpamalini, T.	IIA, 5.0/2 (IIIA, 3.10)	2005	Studies on the Physico-chemical Properties of Permethrin Technical. International Institute of Biotechnology and Toxicology (IIBAT), Report no. 15306, GLP (unpublished).	Yes	Tagros Chemicals India Ltd
Pushpamalini, T.	IIA, 5.0/3 (IIIA, 3.12)	2004b	Studies on the Flash Point/Flammability of Permethrin Technical. International Institute of Biotechnology and Toxicology (IIBAT), Report no. 14232, GLP (unpublished).	Yes	Tagros Chemicals India Ltd

Biocidal Product - Reference list by author (Tagros)

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Pushpamalini, T.	IIB 1.3/01 (IIIB, 3.3)	2004a	Studies on the Oxidising Properties of Permethrin 10% w/w EC. International Institute of Biotechnology and Toxicology (IIBAT). Report no. 14275, GLP (unpublished).	Yes	Tagros Chemicals India Ltd
Pushpamalini, T.	IIB 1.3/02 (IIIB, 3.4)	2004b	Studies on the Flash Point of Permethrin 10% w/w EC. International Institute of Biotechnology and Toxicology (IIBAT). Report no. 14276, GLP (unpublished).	Yes	Tagros Chemicals India Ltd
Pushpamalini, T.	IIB 1.3/03 (IIIB, 3.5)	2004c	Studies on the Acidity/Alkalinity of Permethrin 10% w/w EC. International Institute of Biotechnology and Toxicology (IIBAT), Report no. 14277, GLP (unpublished).	Yes	Tagros Chemicals India Ltd
Pushpamalini, T.	IIB 1.3/04 (IIIB, 3.6)	2004d	Studies on the Relative Density of Permethrin 10% w/w EC. International Institute of Biotechnology and Toxicology (IIBAT), Report no. 14278, GLP (unpublished).	Yes	Tagros Chemicals India Ltd
Loganayagi, C	IIB 1.3/05 (IIIB, 3.10)	2006	Permethrin 10% EC w/w: Laboratory Study of Surface Tension. International Institute of Biotechnology and Toxicology (IIBAT). Report no. 06319, GLP (unpublished).	Yes	Tagros Chemicals India Ltd

Radhakrishnan, D.	IIB 1.3/06 (IIIB, 3.11)	2006	Permethrin 10% EC w/w: Laboratory Study of Viscosity. International Institute of Biotechnology and Toxicology (IIBAT). Report no. 06300, GLP (unpublished).	Yes	Tagros Chemicals India Ltd
Pushpamalini, T.	IIB 1.3/07 (IIIB, 3.7)	2004e	Studies on the Accelerated Storage Stability of Permethrin 10% w/w EC. International Institute of Biotechnology and Toxicology (IIBAT). Report no. 14279, GLP (unpublished).	Yes	Tagros Chemicals India Ltd
Berry, R.W.	IIB, 2.3/1 (IIIB 5.10/1)	1977	The Evaluation of Permethrin for Wood Preservation. Pestic. Sci., No. 8, pp. 284-290	No	Public literature
De Groot, P. and Helson, B.V.	IIB, 2.3/2 (IIIB 5.10/2)	1993	Efficacy and Timing of Insecticides Sprays for Control of White Pine Weevil (Coleoptera: Curculionidae) in High-Value Pine Plantations. Journal of Economic Entomology, Vol. 86, No. 4, pp. 1171-1177	No	Public literature
Ocloo, J.K.	IIB, 2.3/3 (IIIB 5.10/3)	1983	A Comparative Study of teh Protection offered to Wood Samples by Permethrin, Dieldrin and Lindane against damage by Subterranean Termites and Fungi. The International Journal of Wood Preservation, Vol. 3, No. 1, pp. 31-38	No	Public literature
Werner, R.A. et al.	IIB, 2.3/4 (IIIB 5.10/4)	1984	Field Evaluation of Fenitrothion, Permethrin and Chlorpyrifos for Protecting White Spruce trees from Spruce Beetle (Coleoptera: Scolytidae) Attack in Alaska. Journal of Economic Entomology, Vol. 77, No. 4, pp. 995-998	No	Public literature
McManus, K	IIB 3.3.2 (IIIB, 7.3.1)	2006a	Atmospheric oxidation of Permethrin – Atkinson calculation. Rivendell Consulting Limited, Report no.: RI/2006/04/07 (unpublished).	Yes	Tagros Chemicals India Ltd

[redacted]	IIB 5.4 /1 (IIIB 6.1.3)	2003b	Acute Inhalation Toxicity Study of Permethrin 10% EC to Rat. [redacted] (unpublished).	Y	Tagros Chemicals India Ltd.
[redacted]	IIB 5.4 /2 (IIIB 6.1.1)	2003a	Acute Oral Toxicity Study of Permethrin 10% EC in Rat. [redacted] (unpublished).	Y	Tagros Chemicals India Ltd.
[redacted]	IIB 5.4 /3 (IIIB 6.1.2)	2002a	Acute Dermal Toxicity of Permethrin 10% EC to Rat. [redacted] (unpublished).	Y	Tagros Chemicals India Ltd.
[redacted]	IIB 5.5/1 (IVB 6.1.4 /1)	2002b	Acute Eye Irritation /Corrosion Study of Permethrin 10% EC in Rabbit. [redacted] (unpublished).	Y	Tagros Chemicals India Ltd.
[redacted]	IIB 5.5/2 (IIIB 6.1.4/2)	2002c	Acute Dermal Irritation/Corrosion Study of Permethrin 10% EC in Rabbit. [redacted] (unpublished).	Y	Tagros Chemicals India Ltd.
Sunil Dutt, M.	IIB 5.2.2 (IIIA, 7.5.1.2)	2006	Toxicity of Permethrin technical to Earthworm, *Lampito mauritii*. International Institute of Biotechnology and Toxicology (IIBAT). Report no. 06039, GLP (unpublished).	Y	Tagros Chemicals India Ltd

Active substance - Reference list by author (Bayer/Sumitomo)

Author(s)	Section Number	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data protection claimed	Owner
[redacted]	7,1,1,2,1	1980	Permethrin for the Control of Animals in Water Mains. [redacted]; Not GLP; Unpublished	Yes	Sumitomo
[redacted]	7,4,1,1	1980	Permethrin for the Control of Animals in Water Mains. [redacted] Not GLP; Unpublished	Yes	Sumitomo
[redacted]	7,4,1,2	1980	Permethrin for the Control of Animals in Water Mains [redacted] Not GLP; Unpublished	Yes	Sumitomo
Agnihotri, N.P, Jain, H.K, Gajbhiye, V.T.	7,1,2,2,2	1986	Persistence of some synthetic pyrethroids in soil, water and sediment - Part 1. J. Ent. Res., 10 (2), 147-151; Not GLP; Published	No	N/A
Allsup, T.L. & Russell, K. H.	7,1,1,1,1	1976	Hydrolysis of FMC 33297 Insecticide. FMC Corporation. Report No. W-0103; Not GLP; Unpublished	Yes	Sumitomo
Alsager, D.E.	7,4,1,2	1975	Acute Toxicity of Insecticide FMC 33297 to the Freshwater Invertebrate Gammarus lacustris lacustris. Bio-Scientific Report No. TR-108-75; Not GLP; Unpublished	Yes	Sumitomo
[redacted]	7,5,3,1,1	1975b	Acute oral toxicity studies with FMC33297 insecticide in sparrows (Passer domesticus). [redacted] Not GLP; Unpublished	Yes	Sumitomo
Alvarez, M. & Dziedzic, J.E.	7,1,1,1,1	1977	Hydrolysis of FMC 33297. FMC Corporation. Report No. CGP-77-12; Not GLP; Unpublished	Yes	Sumitomo
Amos, R. and Donelan, R. B.	7,1,1,1,2	1987	Permethrin: Photolysis in sterile water at pH5. Report No. RJ0577B, 15 June 1987; Not GLP; Unpublished	Yes	Sumitomo
[redacted]	6,1,1	1975	Acute Oral Toxicity in Rats. [redacted]	Yes	Sumitomo
[redacted]	6,6,3	1994	Induction of structural chromosomal aberrations in human lymphocyte cultures and CHO cells by permethrin. Teratogenesis, Carcinogenesis, and Mutagenesis 14:31-38.	No	N/A
[redacted]	6,2	1987	Percutaneous Absorption of Topically Applied 14C-	Yes	Sumitomo

Author(s)	Section Number	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data protection claimed	Owner
			Permethrin in Volunteers. [redacted]		
[redacted]	7,4,1,1	1974a	Acute Toxicity of FMC 33297 Technical To Bluegill (lepomis macrochirus) and Rainbow Trout (Salmo gairdneri). [redacted] Not GLP; Unpublished	Yes	Sumitomo
[redacted]	7,4,1,1	1974b	Acute Toxicity of FMC 37400 Technical To Bluegill (lepomis macrochirus) and Rainbow Trout (Salmo gairdneri). [redacted] Not GLP; Unpublished	Yes	Sumitomo
[redacted]	7,4,1,1	1975a	Acute Toxicity of Two FMC Compounds (33297 technical and 3.2 e.c.) to Bluegill Sunfish (lepomis macrochirus), Rainbow Trout (Salmo gairdneri) and Water Flea (Daphnia magna). [redacted] Not GLP; Unpublished	Yes	Sumitomo
[redacted]	7,4,1,2	1975a	Acute Toxicity of Two FMC Compounds (33297 technical and 3.2 e.c.) to Bluegill Sunfish (lepomis macrochirus), Rainbow Trout (Salmo gairdneri) and Water Flea (Daphnia magna [redacted] Not GLP; Unpublished	Yes	Sumitomo
Bentley, R.E. & Sleight, B.H.	7,4,1,2	1975b	Acute Toxicity of FMC 33297 Technical to Water Flea (Daphnia magna). Bionomics Inc. Report No. HEFG 79-C106; Not GLP; Unpublished	Yes	Sumitomo
[redacted]	7,4,1,1	1975c	Acute Toxicity of FMC 33297 to Bluegill (Lepomis macrochirus), Channel Fish, (Ictalurus punctatus) and Crayfish (Procambarus clarkii) [redacted] Not GLP; Unpublished	Yes	Sumitomo
[redacted]	7,4,1,2	1975c	Acute Toxicity of FMC 33297 to Bluegill (Lepomis macrochirus), Channel Fish, (Ictalurus punctatus) and Crayfish (Procambarus clarkii) [redacted] Not GLP;	Yes	Sumitomo

Author(s)	Section Number	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data protection claimed	Owner
			Unpublished		
Berry, R.W	5,3,1	1977	The evaluation of permethrin for wood preservation. Pestic. Sci, 8, 284-290; Not GLP; Published	No	N/A
Berry, R.W	5,3,1	1980	Determination of Eradicant Action against Anobium punctatum larvae. EN 48& BS5436:1977 BRE Report PRL B 8002(2); PR 168/014; Not GLP; Unpublished	Yes	Sumitomo
Berry, R.W	5,3,1	1982	Determination of Toxic values against Anobium punctatum by egg-laying and larval survival. EN 49 & BS5434:1977 BRE Report PJ 07 31; PR 168/014; Not GLP; Unpublished	Yes	Sumitomo
Bogue, L.G.	3,4	1988	Evidence of Structure for 3-Phenoxybenzyl Alcohol. The Wellcome Foundation, Ltd. Report No. DAPC 88-4	Yes	Sumitomo
[redacted]	6,9	1980	Neurotoxicity of permethrin after oral administration in the hen	Yes	Sumitomo
[redacted]	6,1,4	1975	Rabbit Primary Dermal Irritation. Compound No. FMC 33297. [redacted] (Unpublished)	Yes	Sumitomo
[redacted]	6,1,4	1975	Rabbit Eye Irritation. Compound No. FMC 33297. [redacted] (Unpublished)	Yes	Sumitomo
[redacted]	6,1,3	1976	Acute Inhalation. Compound No. FMC 33297 [redacted] (Unpublished)	Yes	Sumitomo
[redacted]	6,1,4	1979	Rabbit Eye Irritation, FMC 3006 [redacted] Unpublished)	Yes	Sumitomo
[redacted]	6,1,2	1975	Acute Dermal Toxicity in Rabbits. FMC 30953 [redacted] (Unpublished)	Yes	Sumitomo
[redacted]	6,1,4	1979	Rabbit Primary Dermal Irritation. [redacted] (Unpublished)	Yes	Sumitomo
[redacted]	6,1,1	1975	Acute Oral Toxicity in Rats with Compound FMC 33297. [redacted]	Yes	Sumitomo

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			[redacted] (Unpublished)		
[redacted]	6,1,1	1975	Acute Oral Toxicity in Rats with Compound FMC 33297. [redacted] (Unpublished)	Yes	Sumitomo
[redacted]	6,1,1	1975	Acute Oral Toxicity in Rats. [redacted] (Unpublished)	Yes	Sumitomo
[redacted]	6,1,2	1975	Acute Dermal Toxicity in Rabbits. Compound FMC 33297 3.2 EC [redacted] (Unpublished)	Yes	Sumitomo
[redacted]	6,1,2	1975	Acute Dermal Toxicity in Rabbits. Compound FMC 33297. [redacted] (Unpublished)	Yes	Sumitomo
[redacted]	6,1,2	1975	Acute Dermal Toxicity in Rabbits. Compound No. FMC 30061 [redacted] (Unpublished)	Yes	Sumitomo
[redacted]	6,1,2	1975	Acute Dermal Toxicity in RabbitsCompound No. FMC 30062 [redacted] (Unpublished)	Yes	Sumitomo
[redacted]	6,1,4	1975	Rabbit Primary Dermal Irritation, FMC 3006 [redacted] Unpublished)	Yes	Sumitomo
[redacted]	6,1,4	1975	Rabbit Primary Dermal IrritationCompound FMC 3095 [redacted] Unpublished)	Yes	Sumitomo
[redacted]	6,1,4	1975	Rabbit Eye Irritation Compound No. FMC 30953 [redacted] (Unpublished)	Yes	Sumitomo
[redacted]	6,1,4	1975	Rabbit Eye Irritation. FMC 30061 [redacted] Unpublished)	Yes	Sumitomo
Brogdon, W.G, McAllister, J.C	5,7	1998	Insecticide Resistance and Vector Control. Emerging Infectious Diseases, US CDC Publication, Vol.4 No.4; Not GLP; Unpublished	No	N/A
Brown, P.M and Leahey, J.P.	7,2,2,4	1987	Permethrin: Photolysis on a soil surface. Report No. RJ0581B, 29 April 1987; Not GLP; Unpublished	Yes	Bayer

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Buguhn, M.A.	3,5	1989	Personal Communication from ICI Agricultural Products, Wilimington, DE to United States Department of Agriculture; Not GLP; Unpublished	Yes	Sumitomo
Canadian Environmental Modelling Centre.	7,1,3	1999	Level I Model, Version 2.11. (Unpublished)	Yes	Sumitomo
Caplan, J.A., Isbister, J.	7,4,1,4	1979	14C-Permethrin (acid and alcohol label) Activated Sludge Metabolism. Biosperics Inc. Report 9PL-7-SL; Not GLP; Unpublished	Yes	Sumitomo
Carey, J.K., Lea, R.G., Reeves, N.	5,3,1	1999a	Determination of Toxic Values against larvae of Hylotrupes bajulus. (Laboratory method) EN 47:1988 BRE Report No. TCR 32/99; Not GLP; Unpublished	Yes	Sumitomo
Carey, J.K., Lea, R.G., Reeves, N.	5,3,1	1999b	Determination of Toxic Values against larvae of Hylotrupes bajulus. (Laboratory method) EN 47:1988 BRE Report No. TCR 33/99; Not GLP; Unpublished	Yes	Sumitomo
Chapman, R.A., Tu, C.M., Harris, C.R., Cole, C.	7,2,1	1981	Persistence of five pyrethroid insecticides in sterile and natural, mineral and organic soil. Bull. Env. Contam. Toxicol. 26, 513-519; Not GLP; Published	No	N/A
[redacted]	6,1,5	1973	Guinea Pig Sensitisation Study with 21z73 using the 'Maximisation' Test Method. [redacted] (Unpublished)	Yes	Sumitomo
[redacted]	6,3,1	1974	10-Day Cumulative Oral Toxicity Study with 21z73 in Rabbits. [redacted]	Yes	Sumitomo
[redacted]	6,1,4	1974	Ocular Irritancy of 21z73 in Rabbits. [redacted] npublished)	Yes	Sumitomo
[redacted]	6,3,1	1975	21z73 – Preliminary Investigation into the Cumulative Oral Toxicity in Dogs. [redacted]	Yes	Sumitomo

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[redacted]	6,6,4	1975	21z73 Dominant Lethal Study in Male Mice. [redacted] npublished)	Yes	Sumitomo
[redacted]	6,6,4	1976	27z75, Dominant Lethal Study in Male Mice. [redacted]	Yes	Sumitomo
Chhatre, A.S.	2,7	2000	Quantification of Active Ingredient and impurities of Permethrin technical (5-batch analysis) by GC-MS. Bilag Industries internal report no. C008551; GLP; Unpublished.	Yes	Bayer
Chhatre, A.S.	2,8	2000	Quantification of Active Ingredient and impurities of Permethrin technical (5-batch analysis) by GC-MS. Bilag Industries internal report no. C008551; GLP; Unpublished.	Yes	Bayer
Chhatre, A.S.	4,2	2000	Quantification of Active Ingredient and impurities of Permethrin technical (5-batch analysis) by GC-MS. Bilag Industries internal report no. C008551; GLP; Unpublished.	Yes	Bayer
[redacted]	4,2	1986	An Analytical Method or the Estimation of Absorbed Permethrin in Man by Measurement of its Metabolites 88H73 and 34W86 in Urine. [redacted] Unpublished	Yes	Sumitomo
[redacted]	6,3,3	1980	Permethrin Technical. Inhalation Study in Rats – 16 x 6 Hour Exposures Over a 3 Week Period [redacted]	Yes	Sumitomo
[redacted]	6,6,3	1977	Mutagenicity of BW 21z73 in L5178Y/TK+/- Mouse Lymphoma Cells With and Without Exogenous Metabolic Activation [redacted]	Yes	Sumitomo
[redacted]	6,6,1	1979	Salmonella/Mammalian-Microsome Plate Incorporation and Pre-Incubation Mutagenesis Assays [redacted]	Yes	Sumitomo

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			8I8012		
Conrad, A.U., Fleming, R.J., Crane, M.	7,4,3,5,1	1999	Laboratory and field response of chironomus riparius to a pyrethroid insecticide. Water Research, 33, 7, 1603-1610; Not GLP; Published	No	N/A
[redacted]	6,2	1977	Urinary Excretion in Man of (3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylic acid (CVA) after Oral Ingestion of Permethrin (NRDC 134) – A First Report [redacted]	Yes	Sumitomo
Davis, M. L.	7,2,3,1	1991	Sorption/Desorption of 14C-Permethrin on Soils by the Batch Equilibrium Method. Battelle Memorial Institute. Report No. Sc900199; GLP; Unpublished	Yes	Sumitomo
[redacted]	6,9	1980	21-day neuropathological study in the Sprague-Dawley rat of Permethrin (21z73ZJ) administered in the diet. [redacted]	Yes	Sumitomo
Dengler, D.	7,4,1,4	1999	Testing of Toxic Effects of Permethrin Technical Insecticide on Activated Sludge with the Respiration Inhibition Test. GAB Biotechnologie GmbH & IFU Umweltanalytik GmbH. Report No. 99385/01-AAHT; GLP; Unpublished	Yes	Sumitomo
Douglas, M.T., Sewell, I.G., Standing, M.B.	7,4,1,2	1988	The Acute Toxicity of 21z to Daphnia magna. Huntingdon Research Centre. Report No. WLC 92(a)/881444; GLP; Unpublished	Yes	Sumitomo
[redacted]	6,2	1977	NRDC 143Whole Body Autoradiography Study in Rats (Male and Pregnant Female). [redacted]	Yes	Sumitomo
[redacted]	6,2	1977	NRDC 143 Whole Body Autoradiography Study in Male Rats. [redacted]	Yes	Sumitomo
[redacted]	7,5,3,1,1	1975a	Acute oral LD50 in Mallard Duck with FMC33297. [redacted] Not GLP; Unpublished	Yes	Sumitomo

Author(s)	Section Number	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data protection claimed	Owner
[redacted]	7,5,3,1,2	1975b	Eight-day dietary LC50 in Bobwhite Quail and Mallard Duck with FMC33297. [redacted] Not GLP; Unpublished	Yes	Sumitomo
Fleming, R.J., Holmes, D., Nixon S.J.	7,4,3,5,1	1998	Toxicity of permethrin to Chironommus reparius in artificial and natural sediments. Environmental Toxicology and Chemistry, 17, 7, 1332 - 1337; Not GLP; Published	No	N/A
[redacted]	6,9	1978	Effects of intravenous permethrin on the cardiovascular and autonomic nervous systems of anaesthetised dogs and rats.	Yes	Sumitomo
Fujie, G.H.	3,5	1975	Solubility of FMC 33297 in Water. The Wellcome Foundation, Ltd. Report No. HEFG 82-C2; Not GLP; Unpublished	Yes	Sumitomo
Gangolli, S. (Ed)	2	1999	The Dictionary of Substances and their Effects, Volume 6. (2nd Edition). Publ. The Royal Society of Chemistry.	No	N/A
Garrod, A.N.I., Guiver, R., Rimmer, D.A	5,6	2000	Potential exposure of Amateurs (Consumers) through painting Wood Preservative and Antifoulant preparations. Ann. Occup. Hyg., 44, 6, 421-426; Not GLP; Published	No	N/A
[redacted]	6,2	1979	Determination of Urine Metabolite Levels Following Inhalation of the Insecticide Permethrin in Rats. [redacted]	Yes	Sumitomo
Giddings, J.M., Solomon, K.R., Maund, S.J.	7,4(2)	2001	Probabilistic Risk Assessment of Cotton Pyrethroids: II. Aquatic mesocosm and Field Studies. Environmental Toxicology and Chemistry, 20, 3, 660-668; Not GLP; Published	No	N/A
Gize, A.P. & Rich, P.G.	3,10	1991	Thermal Decomposition of Permethrin in Varied Partial Pressures of Oxygen at 500°C and 800°CThe Wellcome Foundation Ltd. Report No. HTQC/91/C006; Not GLP; Unpublished	Yes	Sumitomo

Author(s)	Section Number	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data protection claimed	Owner
Gize, A.P. & Rich, P.G.	3,11	1991	Thermal Decomposition of Permethrin in Varied Partial Pressures of Oxygen at 500°C and 800°CThe Wellcome Foundation Ltd. Report No. HTQC/91/C006; Not GLP; Unpublished	Yes	Sumitomo
[redacted]	6,12	1991	Permethrin 25/75 Technical. [redacted]	Yes	Sumitomo
Griffiths, G. R.	3,4	1981	Evidence of Structure of Permethrin. The Wellcome Foundation Ltd. Report No. DACR 81-133	Yes	Sumitomo
Gruning, R., Pospischil, R., Cymorek, S., Metzner, W.	5,3,2	1986	Pyrethroids: Isomerism and efficacy. IRG/WP/1284; Not GLP; Published	Yes	Sumitomo
[redacted]	6,1,2	1976	21z73 - Dermal Toxicity in the Female Rat. [redacted] Unpublished)	Yes	Sumitomo
[redacted]	6,1,2	1976	21z73 - Dermal Toxicity in the male Rat. [redacted]	Yes	Sumitomo
Hatfield, M.W.	7,2,2,2	1996a	Aquatic dissipation of permethrin in California and North Carolina. American Agricultural Services Report on Study No. AA940907; GLP; Unpublished	Yes	Bayer
Hatfield, M.W.	7,2,2,2	1996b	Addendum to "Aquatic dissipation of permethrin in Califirnia and North Carolina. American Agricultural Services Inc., Study No. AA940907."; GLP; Unpublished	Yes	Bayer
Hawkins, D.R.	7,2,2,1	1992	The aerobic soil metabolism of 14C -Permethrin. Report number HRC/ISN 251/911499; GLP; Unpublished	Yes	Bayer
Hawkins, D.R.	4,2	1992	The aerobic soil metabolism of 14C -Permethrin. Report number HRC/ISN 251/911499; GLP; Unpublished	Yes	Bayer
[redacted]	7,4,1,2	1975a	Acute Toxicity of FMC 33297 3.2 e.c. to Eastern Oysters (Crassostrea virginica), Pink Shrimp (Penaeus duorarum), and Fiddler Crabs (Uca pugilator). [redacted] Not	Yes	Sumitomo

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			GLP; Unpublished		
[redacted]	7,4,1,2	1975b	Acute Toxicity of FMC 33297 technical (95.7%) to Eastern Oysters (Crassostrea virginica), Pink Shrimp (Penaeus duorarum), and Fiddler Crabs (Uca pugilator). [redacted] Not GLP; Unpublished	Yes	Sumitomo
[redacted]	7,4,1,1	1975c	Acute Toxicity of Nine Compounds (FMC 30061, 30063, 30075, 30077, 300078, 30080, 33297 technical, 30953, 30062) to Sheepshead Minnow (Cyprinodon variegates). [redacted] Not GLP; Unpublished	Yes	Sumitomo
Hendley, P., Holmes, C., Maund, S.J., Travis, K.Z., Zhang, M.	7,4(3)	2001	Probabilistic Risk Assessment of Cotton Pyrethroids: III. A spatial analysis of the mississippi, USA, cotton landscape. Environmental Toxicology and Chemistry, 20, 3, 669-678; Not GLP; Published	No	N/A
Heubach, G.	2,4	1982	Plant Protection/Designs of a Substance. Hoechst. Report No. HEU-366; Not GLP; Unpublished	Yes	Sumitomo
Heubach, G.	2,5	1982	Plant Protection/Designs of a Substance. Hoechst. Report No. HEU-366; Not GLP; Unpublished	Yes	Sumitomo
Hollinshead, D.T.	3,10	1981	Storage Data Sheet Wellcome Research Laboratories.	Yes	Sumitomo
Holmstead, R.L., Casida, J.E., Ruzo, L.O.,Fullmer, D.G.	7,1,1,1,2	1978	Pyrethroid Photodecomposition: Permethrin. Journal of Agricultural Food Chemistry. Vol. 26, No. 3, 590-595.; Not GLP; Published	No	N/A
Ishmael, J. & Litchfield, M.H.	6,5	1988	Chronic Toxicity and Carcinogenic Evaluation of Permethrin in Rats and Mice. Fundamental and Applied Toxicology. Vol. 11. pp308-322	No	N/A
Ishmael, J. & Litchfield, M.H.	6,7	1988	Chronic Toxicity and Carcinogenic Evaluation of Permethrin in Rats and Mice. Fundamental and Applied Toxicology. Vol. 11. pp308-	No	N/A

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			322		
[redacted]	6,9	1997	Motor activity measurements in male and female mice postnatally exposed to Permethrin by inhalation; [redacted]	Yes	Sumitomo
Jadhav, G. D. & Pawar, V.M.	7,1,2,2,2	1984	Persistence of Permethrin and Cypermenthrin in Water and Sediment. Pestology Vol. 3 No. 9 37-40; Not GLP; Published	No	N/A
[redacted]	6,8,1	1976	Foetal toxicity study of 21z73 (NRDC 143) in the rabbit	Yes	Sumitomo
[redacted]	6,8,1	1974	Foetal Toxicity of 21z73 (NRDC 143) in the Rat. [redacted]	Yes	Sumitomo
[redacted]	6,8	1979	A Multigeneration Reproduction Study of 21z73 (Permethrin) in the Rat. [redacted]	Yes	Sumitomo
[redacted]	6,7	1980	Carcinogenicity Study in Mice with Permethrin [redacted]	Yes	Sumitomo
Johnen, B.G, Slinger, J.M, Bridgman, P.A.	7,5,1,1	1977	P557: Effect on carbon and nitrogen turnover by soil microorganisms. ICI internal report AR2659/B; Not GLP; Unpublished	Yes	Sumitomo
Jordan, E.G. & Kaufman, D.D.	7,1,2,2,2	1986	Degradation of cis- and trans - Permethrin in Flooded Soil. J. Agric. Food. Chem. 34, 880-884; Not GLP; Published	No	N/A
Joyce, J.R.	3,4	1988	Evidence of Structure for Cis-Permethrin. The Wellcome Foundation, Ltd. Report No. DAPC 88-2	Yes	Sumitomo
Joyce, J.R.	3,4	1988	Evidence of Structure for Trans-Permethrin. The Wellcome Foundation, Ltd. Report No. DAPC 88-3	Yes	Sumitomo
Kaneko, H, Ohkawa, H, Miyamoto, J.	7,2,1	1978	Degradation and Movement of Permethrin Isomers in Soil. J. Pesticide Sci. 3, 43-51; Not GLP; Published	No	N/A

Author(s)	Section Number	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data protection claimed	Owner
Kaufman, D.D., Clark Haynes; S., Jordan, E.G, Kayser, A.J.	7,2,1	1978	Permethrin Degradation in Soil and Microbial Cultures. In Synthetic Pyrethroids; Not GLP; Published	No	N/A
[redacted]	6,4,1	1979	A Three-Month Oral Toxicity Study of FMC 33297 in Rats. [redacted]	Yes	FMC?
[redacted]	6,4,1	1979	A Three-Month Oral Toxicity Study of FMC 33297 in Beagle Dogs. [redacted]	Yes	Sumitomo
Kumar, A.	7,5,1,2	1997	Permethrin Technical Acute toxicity in Earthworm. Jai Research Foundation Report 1054/JRF/ECO/97; GLP; Unpublished	Yes	Sumitomo
[redacted]	7,4,3	1976	Pilot study exposure of crayfish (Procambarus clarki); channel catfish (Ictalurus punctatus) and bluegill sunfish (Lepomis macrochirus) to aged FMC33297 in a model aquatic ecosystem. [redacted] Not GLP; Unpublished	Yes	Sumitomo
Lindon, J.C.	3,4	1981	Evidence for the structure of Permethrin (25/75) from ^{1}H NMR Spectroscopy. The Wellcome Foundation. Report No.BMNA/81/29; Not GLP; Unpublished	Yes	Sumitomo
Lines, C.B. & Balderson, K. E.	3,10	1986	Results of a Three-Year Storage Test on Permethrin. The Wellcome Foundation, Ltd. Report No. DASD 86-6	Yes	Sumitomo
Lord, K., McKinley, M., Walker, N.	7,2,1	1982	Degradation of Permethrin in Soils. Environ. Poll. (Series A). 29, 81-90.; Not GLP; Published	No	N/A
[redacted]	7,4,1,2	1979	Determination of the Acute Toxicity of WRL Compound 21z to the Fresh Water Shrimp (Gammarus pulex) Using Acetone as the Solvent. [redacted] Not GLP; Unpublished	Yes	Sumitomo
[redacted]	7,4,1,1	1978a	Determination of the Acute Toxicity of 21z (WRL) to Bluegill Sunfish (Lepomis macrochirus) Using Acetone as the Solvent. [redacted]	Yes	Sumitomo

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			[redacted] Not GLP; Unpublished		
[redacted]	7,4,1,1	1978b	Determination of the Acute Toxicity of Compound 21z (WRL) to Rainbow Trout (Salmo gairdneri) Using Acetone as a Solvent. [redacted] Not GLP; Unpublished	Yes	Sumitomo
[redacted]	7,4,1,1	1978c	Determination of the Acute Toxicity of Compound 21z (WRL) to Rainbow Trout (Salmo gairdneri) Using Dimethyl Sulphoxide as the Solvent. [redacted] Not GLP; Unpublished	Yes	Sumitomo
[redacted]	7,4,1,1	1978d	Determination of the Acute Toxicity of 21z (WRL) to Bluegill Sunfish (Lepomis macrochirus) Using Dimethyl Sulphoxide as the Solvent. [redacted] Not GLP; Unpublished	Yes	Sumitomo
[redacted]	6,1,1	1974	Comparative Acute Oral Toxicity in Mice with FMC 33297, FMC 37400, FMC 35171 and FMC 30960. [redacted]	Yes	Sumitomo
[redacted]	6,1,1	1979	Acute Oral Toxicity I Rats with FMC 33297 [redacted]	Yes	Sumitomo
Maund, S.J., Travis, K.Z., Hendley, P., Giddings, J.M., Solomon, K.R.	7,4(5)	2001	Probabilistic Risk Assessment of Cotton Pyrethroids: V. Combining landscape-level exposures and ecotoxicological effects data to characterise risks. Environmental Toxicology and Chemistry, 20, 3, 687-692; Not GLP; Published	No	N/A
[redacted]	6,5	1980	21z: Potential Toxicity and Oncogenicity in Dietary Administration to Rats for a Period of 104 weeks. [redacted] (Unpublished)	Yes	Sumitomo
[redacted]	6,7	1980	21z: Potential Toxicity and Oncogenicity in Dietary Administration to Rats for a Period of 104 weeks. [redacted]	Yes	Sumitomo

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			[redacted] (Unpublished)		
Meister et al (1983), Worthing & Walker (1987), FAO/WHO (1980), Wells et al (1986)	2	1990	Environmental Health Criteria 94: Permethrin. IPCS. World Health Organisation. Not GLP; Published	No	N/A
Meister et al (1983), Worthing & Walker (1987), FAO/WHO (1980), Wells et al (1986)	3,1,1	1990	Environmental Health Criteria 94: Permethrin. IPCS. World Health Organisation. Not GLP; Published	No	N/A
Meister et al (1983), Worthing & Walker (1987), FAO/WHO (1980), Wells et al (1986)	3,1,2	1990	Environmental Health Criteria 94: Permethrin. IPCS. World Health Organisation. Not GLP; Published	No	N/A
[redacted]	6,1,1	1978	Report on the Acute Oral and Percutanous Toxicity of the Raw Materials and Intermediates used in the Production of the Insecticide Permethrin [redacted]	Yes	Sumitomo
[redacted]	6,1,2	1978	Report on the Acute Oral and Percutanous Toxicity of the Raw Materials and Intermediates used in the Production of the Insecticide Permethrin [redacted]	Yes	Sumitomo
Miller, T. A., Salgado, V.L.	5,4	1985	Chapter 2. The mode of action of pyrethroids on insects. In: The Pyrethroid Insecticides. Ed. J.P.Leahey. Published by Taylor & Francis; Not GLP; Published	No	N/A
Muir, D.C.G., Rawn, G.P, Townsend, B.E., Lockhart, W.L., and Greenhalgh, R.	7,4,2	1985	Bioconcentration of cypermethrin, deltamethrin, fenvalerate, and permethrin by Chironomus tentans larvae in sediment and water. Environmental Toxicology and Chemistry. 4:51-61; Not GLP; Published	No	N/A
No Author	3,10	1976	Storage Data for Batch C-6 38 5-131 of NRDC 143 (25 cis: 75 Trans).	Yes	Sumitomo
No Author	5,3,1	1980	No Author; 1980; Determination of Toxic Values against Anobium punctatum larvae. EN 21& BS5215:1975	Yes	Sumitomo

Author(s)	Section Number	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data protection claimed	Owner
			Princes Risborough Laboratory Report; Not GLP; Unpublished		
No Author	5,3,1	1981	Determination of Toxic Values against Hylotrupes bajulus larvae. EN 47 & BS 5435:1977 Princes Risborough Laboratory Report No. 80/11; Not GLP; Unpublished	Yes	Sumitomo
No Author	2,7	2000	Evaluation of the purities of working reference standard materials. Bilag Industries internal report no. RD180701. Unpublished.	Yes	Bayer
No Author	2,8	2000	Evaluation of the purities of working reference standard materials. Bilag Industries internal report no. RD180701. Unpublished.	Yes	Bayer
No Author	4,2	1980a	Determination of Permethrin in Liquid and Powder Formulations Report No. E1/390/80; Not GLP; Unpublished	Yes	Sumitomo
No Author	3,7	No date	UK Drug Master File: No date; Veterinary Medicines Directorate. FMS 25/75 cis-/trans- technical Permethrin. Applicants Part; not GLP; Unpublished	Yes	Sumitomo
No Author	4,2	No date	Method of Analysis – Determination of Permethrin and Cypermethrin Residues in Water; Not GLP; Unpublished	Yes	Sumitomo
Orsler, R.J., Stone, M.W.S.	5,3,2	1984	The permanence of permethrin in wood preservation. IRG/WP/1284; Not GLP; Unpublished	Yes	Sumitomo
[redacted]	6,1,5	1991	Skin Sensitisation in the Guinea Pig of a Permethrin 25/75 cis/trans Isomer Ratio [redacted]	Yes	Sumitomo
[redacted]	6,3,1	1979	Cumulative Oral Toxicity of Permethrin in Dogs (Staircase Dosing [redacted]	Yes	Sumitomo
[redacted]	6,1,1	1976	Acute Toxicity of Oral Dosing of Permethrin (21z73) in the Cat. [redacted]	Yes	Sumitomo

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Powell, P.K., Robinson, W.H	5,3,2	1992	Penetration and permanence of permethrin in four softwoods. J. Economic Entomology, 85, 5, 1818 - 1821; Not GLP; Published	No	N/A
[redacted]	6,6,3	1997	Chromosomal Aberration Study of Permethrin Technical in Mice	Yes	Bayer
[redacted]	6,6,4	1997	Micronucleus Test of Permethrin Technical in Mice. [redacted] (Unpublished)	Yes	Bayer
Racey, P.A & Swift, S.M	5,2	1986	The residual effects of remedial timber treatments on bats. Biological conservation, 35, 215-214; Not GLP; Published	No	N/A
[redacted]	6,6,1	1997	Permethrin Technical Salmonella Typhimurium Reverse Mutation Assay	Yes	Bayer
[redacted]	6,4,1	1978	Permethrin Oral Administration to Dogs for 6 Months. [redacted]	Yes	Sumitomo
Rich, P.G	2,7	1995	Agrevo Environmental Health. Raw material specification: Permethrin 25:75	Yes	Sumitomo
Rich, P.G	4,2	1995	Agrevo Environmental Health. Method of Analysis Permethrin 25/75; Not GLP; Unpublished	Yes	Sumitomo
Rickett, F.E.	7,1,1	1981	Degradation of Permethrin in chlorinated water. Wellcome Research Report No. HEFH 81-5; Not GLP; Unpublished	Yes	Sumitomo
Rickett, F.E. & Knight, P.J.	7,1,1,1,2	1976	Photostability of Permethrin Isomers. The Wellcome Foundation Ltd. Report No. HCDF 76-1; Not GLP; Unpublished	Yes	Sumitomo
Robinson, R.A & Ryan, J.E.	7,1,2,2,2	1996a	Aerobic aquatic metabolism of [14C]Permethrin. XenoBiotic Laboratories, Inc., Plainsboro, NJ. report Ref. Study No. XBL94092, Report Ref. RPT00220.;GLP; Unpublished	Yes	Bayer
Robinson, R.A & Ryan, J.E.	7,1,2,2,2	1996b	Anaerobic aquatic metabolism of [14C]Permethrin. XenoBiotic Laboratories, Inc., Plainsboro, NJ. report Ref. Study No. XBL94091, Report Ref. RPT00252; GLP; Unpublished	Yes	Bayer

Author(s)	Section Number	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data protection claimed	Owner
Robinson, R.A & Ryan, J.E.	4,2	1996c	Aerobic aquatic metabolism of [14C]Permethrin. XenoBiotic Laboratories, Inc., Plainsboro, NJ. report Ref. Study No. XBL94092, Report Ref. RPT00220.;GLP; Unpublished	Yes	Bayer
Rodes, C.E et al	5,6	2001	Experimental methodologies and preliminary transfer factor data for estimation of dermal exposure to particles. J. Exposure Analysis and Environmental Epidemiology, 11, 123-139; Not GLP; Published	No	N/A
Rutherford, D., Reay, R.C, Ford, M.G.	5,3,2	1983	Loss of pyrethroids from treated wood. Biodeterioration 5, 144 - 153; Not GLP; Published	No	N/A
Sakata, S., Mikami, N., Yamada, H.	7,2,1	1992	Degradation of Pyrethroid Optical Isomers in Soil. J. Pesticide. Sci. 17, 169-180; Not GLP; Published	No	N/A
Satheesh, V.K.	7,4,1,3	1997	Alga (Selenastrum capricornutum), Growth Inhibition Test for Permethrin Technical. Jai Research Foundation. Report No. 1015/JRF/BTC/97; GLP; Unpublished	Yes	Sumitomo
Schimmel, S. C., Garnas, R.L., Patrick, J.M, Moore, J.C	7,1,1,1,2	1983	Acute Toxicity, Bioconcentration and Persistence of AC222,705, Benthiocarb, Chlorpyrifos, Fenvalerate, Methyl Parathion and Permethrin in the Estuarine Environment. J. Agric. Food Chem. Vol. 31, 104-113; Not GLP; Published	No	N/A
Schimmel, S. C., Garnas, R.L., Patrick, J.M, Moore, J.C	7,1,1,2,3	1983	Acute Toxicity, Bioconcentration and Persistence of AC222,705, Benthiocarb, Chlorpyrifos, Fenvalerate, Methyl Parathion and Permethrin in the Estuarine Environment. J. Agric. Food Chem. Vol. 31, 104-113; Not GLP; Published	No	N/A
Schimmel, S. C., Garnas, R.L., Patrick, J.M, Moore, J.C	7,4,2	1983	Acute Toxicity, Bioconcentration and Persistence of AC222,705, Benthiocarb, Chlorpyrifos, Fenvalerate, Methyl Parathion and Permethrin in the Estuarine Environment. J.	No	N/A

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			Agric. Food Chem. Vol. 31, 104-113; Not GLP; Published		
Schimmel, S. C., Garnas, R.L., Patrick, J.M, Moore, J.C	7,4,1,1	1983	Acute Toxicity, Bioconcentration and Persistence of AC222,705, Benthiocarb, Chlorpyrifos, Fenvalerate, Methyl Parathion and Permethrin in the Estuarine Environment. J. Agric. Food Chem. Vol. 31, 104-113; Not GLP; Published	No	N/A
Sharom M. & Soloman, K. R.	7,1,2,2,2	1981	Adsorption-Desorption, Degradation and Distribution of Permethrin in Aqueous Systems. J. Agric. Food. Chem. 29, 1122-1125; Not GLP; Published	No	N/A
[redacted]	6,6,1	1976	In vitro Microbiological Mutagenicity Study of an FMC Compound 33297[redacted]	Yes	Sumitomo
Smith, S. & Willis, G.H.	7,2,3,2	1985	Movements of pesticides in soil columns as affected by anhydrous ammonia. Env. Tox. Chem, 4, 425-434; Not GLP; Published	No	N/A
Snodgrass, H. & Nelson, D.C.	6,2	1982	Dermal Penetration and Distribution of 14C-Labelled Permethrin IsomersUnited States Army Environmental Hygiene AgencyReport No. 75-51-0351-83	No	N/A
Solomon, K.R., Giddings, J.M., Maund, S.J.	7,4(1)	2001	Probabilistic Risk Assessment of Cotton Pyrethroids: I. Distributional analysis of Laboratory Aquatic Toxicity Data. Environmental Toxicology and Chemistry, 20, 3, 652-659; Not GLP; Published	No	N/A
Tamilselvan, C.	3,4	1996a	GC/MS analysis of Permethrin technical. Report No. 1573/JRF/PC/96 (Unpublished)	Yes	Bayer
Tamilselvan, C.	3,4	1996b	UV-vis absorption spectra of Permethrin technical. Report No. 05/UV/JRF/PC/96 (Unpublished)	Yes	Bayer
Tamilselvan, C.	3,1,3	1997a	Density of Permethrin Technical. Jai Research Foundation. Report No. DEN/PMT/28; GLP; Published	Yes	Bayer
Tamilselvan, C.	3,6	1997b	Dissociation constants of Permethrin Technical in water.	Yes	Bayer

Author(s)	Section Number	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data protection claimed	Owner
			Jai Research Foundation. Report No. 260/JRF/PC/97; GLP; Unpublished		
Tamilselvan, C.	3,9	1997c	Partition Coefficient (n-octanol/water) of Permethrin Technical. Jai Research Foundation. Report No. 264/JRF/PC/97; GLP; Unpublished	Yes	Bayer
[redacted]	6,8,1	1979	21z: Effects of Oral Administration upon Pregnancy in the Rabbit. [redacted]	Yes	Sumitomo
Thom, E	2,7	No date	Aventis Environmental Science: Active Substance Specification	Yes	Sumitomo
Thompson, R.S. & Williams, T.D.	7,4,1,2	1978	Determination of the Acute Toxicity of Compound 21z (WRL) to Daphnia magna Using Acetone as the Solvent. The Wellcome Foundation, Ltd. Report No. HEFG 78-10; Not GLP; Unpublished	Yes	Sumitomo
Travis, K.Z., Hendley, P.	7,4(4)	2001	Probabilistic Risk Assessment of Cotton Pyrethroids: IV. Landscape-level exposure characterisation. Environmental Toxicology and Chemistry, 20, 3, 679-686; Not GLP; Published	No	N/A
UNEP, FAO, WHO	5,7	2002	Reducing and Eliminating the Use of Persistent Organic Pesticides - Guidance on Alternative Strategies for Sustainable Pest and Vector Management, Chapter 3. Specific aspects of pest and vector management; Not GLP; Published	No	N/A
US EPA	7,1,3	2000	EPI-Suite, US EPA	No	N/A
US EPA	7,1,1,2,1	2000	EPI-Suite, US EPA	No	N/A
[redacted]	6,3,1	1974	10-Day Cumulative Oral Toxicity with 21z73 in Rats. [redacted]	Yes	Sumitomo
[redacted]	6,1,1	1975	21z73 (25/75) Effect of Different Solvents on the Rat Oral Toxicity [redacted]	Yes	Sumitomo
[redacted]	6,3,1	1974	10-Day Cumulative Oral Toxicity Study with 21z73 in	Yes	Sumitomo

Author(s)	Section Number	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data protection claimed	Owner
			Mice [redacted]		
[redacted]	6,1,1	1975	Effects on the Rat Oral Toxicity of Changes in the cis/trans Ratio with 21z73 (NRDC 143) Series. [redacted]	Yes	Sumitomo
Wells, D. et al.	3,2	1986	Vapour Pressure of Permethrin. Pesticide Science. Vol. 17, 473-476; Not GLP; Published	No	N/A
Williams, I. H. & Brown, M.J.	7,2,1	1979	Persistence of Permethrin and WL 43775 in Soil. J. Agric. Food Chem. 27, No. 1, 130-132; Not GLP; Published	No	N/A
[redacted]	6,4,1	1975	21z73, Rat Oral 90 Day Study. [redacted]	Yes	Sumitomo
[redacted]	6,4,1	1976	27z75Rat Oral 90 Day Toxicity Study. [redacted]	Yes	Sumitomo