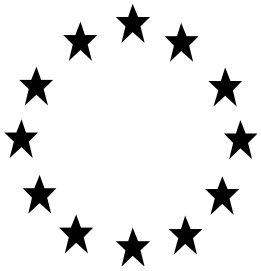
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

Evaluation of active substances

Assessment Report



Permethrin

Product-Type 18

(Insecticides, acaricides and products to control other arthropods)

Rapporteur: Ireland

April 2014

Permethrin PT18

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 18 (insecticide), 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 as an existing active substance, by Tagros Chemicals India Ltd and by TANATEX B.V., hereafter referred to as the applicant, in product-type 18.

It should be noted: The application in support of permethrin by TANATEX B.V. was originally submitted under product-type 9 (fibre, leather, rubber and polymerised materials preservatives). However, following discussions at the Competent Authority meeting in Brussels during July 2011 it was determined and concluded:

"The meeting took note of the document submitted by Tanatex on the subject of the change of PT (from PT 9 to 18) for the dossier submitted for permethrin under the review programme. The meeting however concluded that the protection of wool carpets against larvae of moths and carpets beetles should fall under PT 18, as PT 9 cover substances intended to protect textiles from micro-organisms only. However, it was noted that the ESD for PT9 could be utilised for this assessment."

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 18 was 30 April 2006, in accordance with Annex V of Regulation (EC) No. 1451/2007.

On 28 April 2006, the Irish competent authorities received a dossier from the applicant Tagros. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation on 26 June 2008, following an extension of the completeness check period in order that additional data could be submitted. On 27 January 2009, the Irish competent authorities received a dossier from the applicant TANATEX B.V. (with a letter of Access to data on permethrin held by Bayer Environmental Science). Following an extension of the completeness check period to the 30 June 2009, the Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation on 19 June 2009.

On 21 June 2010, the Rapporteur Member State submittedto 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.

[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

In order to review the competent authority report and the comments received on it, consultations of technical experts from all Member States (peer review) were organised by the Commission. Revisions agreed upon were presented at technical and competent authority meetings and the competent authority report was amended accordingly.

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 18, and, should 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: $C_{21}H_{20}Cl_2O_3$

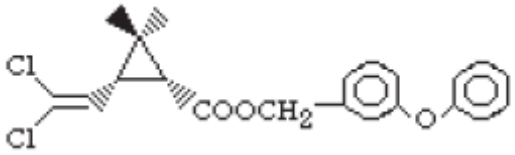
Purity: Permethrin has four stereoisomers:
1Rcis, 1Scis, 1Rtrans, and 1Strans.
Two pairs of diastereomers (each consisting of a non-racemic pair of enantiomers) are present in a ratio of ca. 25:75

Specification ≥93.0% w/w sum of all isomers

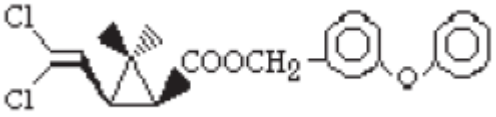
Permethrin is a reaction mass of four stereoisomers
1Rcis permethrin content = 5.0 – 10.0% w/w.
1Scis permethrin content = 15.0 – 20.0% w/w.
1Rtrans permethrin content = 45.0 – 55.0% w/w.
1Strans permethrin content = 17.0 – 27.0% w/w.

Structural formula

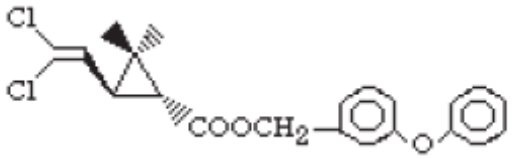
1Rcis isomer –



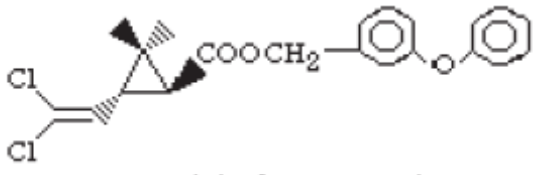
1Scis isomer –



1Rtrans isomer –



1Strans isomer –



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

Application in support of permethrin PT18 was received from two notifiers - TANATEX B.V. (with access to the Bayer Environmental Science/Sumitomo Chemicals (UK) Ltd source of permethrin) and Tagros Chemicals India Ltd.

Permethrin technical (CAS number 52645-53-1) is manufactured in India by Bilag Industries for Bayer Environmental Science/Sumitomo Chemicals (UK) Ltd.

Tagros Chemicals India Ltd manufactures its' own source of Permethrin technical.

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.

Spot treatment product/use (CPMT05EC988)
The representative product CPMT05EC988, is an emulsifiable concentrate formulation containing 5 % (or 0.05% as RTU) Permethrin in the form of liquid. The biocidal product (CPMT05EC988), chosen for the purposes of this submission, is a "dummy product" (or representative formulation). It is a representative formulation manufactured to imitate the typical Permethrin-based products currently available.

CPMT05EC988 is a pale yellow, clear liquid with an aromatic smell. It is not considered to be potentially explosive or contain an oxidising or reducing agent. It has a mean pH of 5.74 and a relative density of 0.9124 g/ml at 20 oC. It has a surface tension of 30.4 mN/m at 20°C, a kinematic viscosity of 14.4 cSt at 20°C and 9.1 cSt at 40°C and a dynamic viscosity of 13.1 cPs at 20°C.

Textile fibre treatment product/use (EULAN SPA 01)
The biocidal product (EULAN SPA 01), chosen for the purposes of this submission, is a representative formulation. It is a representative formulation manufactured to imitate the typical Permethrin-based products currently available. As such, the representative product EULAN SPA 01 contains 10 % w/w Permethrin in the form of liquid.

On the basis of the properties of permethrin (see the active substance dossier, Document IIA) and the other components, the representative formulation, EULAN SPA 01, would be yellow/brown in colour, a liquid, unclassified with respect to explosivity, oxidising properties and flammability, would not be expected to have a pH <5 or >7, and expected to have a relative density of 1.032 (at 20°C). On the basis of storage stability and reactivity data on permethrin and the other components, deterioration or reactivity of the representative formulation towards container material would not be expected to occur under commercial conditions of storage for periods of up to 24 months in closed containers.

Physico-chemical properties for PT18 formulations containing permethrin will be required at member state level when product authorisation is required.

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 prior to 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, 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: 3 – Pest control
Product Type: 18 – Insecticides

Spot treatment product/use (CPMT05EC988)
CPMT05EC988 is a representative product insecticide is an emulsifiable concentrate formulation containing 5 % (or 0.05% as RTU) Permethrin in the form of liquid. The product can be applied for the control of a wide range of flying and crawling insects and is intended for indoor use only.

CPMT05EC988 is proposed for the control of flying insects (e.g. Flies and Mosquitoes) and crawling insects (e.g. Roaches, Mites, Fleas, and Ticks).

The following applications have been investigated:

- Crack and crevice application
- Targeted spot application

Textile fibre treatment product/use (EULAN SPA 01)
The function of permethrin is insecticidal to control keratin feeding textile pests, such as such as *Tineola/tinea* (moths), *Arthrenus* (carpet beetle), *Attagenus* (fur beetle) *Hofmannophilia Ps* (false cloth moth). The efficacy study provided demonstrate that permethrin concentration of 0.0035% (i.e. 0.035 kg of permethrin per tonne of treated material), was effective against cloth moth and fur beetle. The permethrin concentration of 0.0075% (i.e. 0.075 kg of permethrin per tonne of treated material) was effective against all textile pests.

It should be noted that the application rates used in this efficacy test (i.e. 0.035 or 0.075 kg of permethrin per tonne of treated material) are lower than the recommended application rates (up to a maximum of 0.25 kg of permethrin per tonne of material treated). The lower rates were used in order to satisfy the requirements of Woolmark labelling. The rates used are minimum acceptable concentrations (representing permethrin levels in the treated carpet at the end of its service life).

The following application was investigated:

- Wool textile fibres for use in the manufacturer of carpets/rugs

2.1.2.2. Effects on target organism(s)

Permethrin is a contact insecticide which causes convulsions, paralysis and ultimately death in target organisms. It is a type I axonic poison which exerts its effects by means of hyperexcitation of both the peripheral and central nervous systems of target insects. Its effects are characterised by progressive fine whole body tremor, exaggerated start response, uncoordinated muscle twitching and hyperexcitability. Permethrin also induces hepatic microsomal enzymes.

Pyrethroids act on the insect nervous system by slowing action potential decay and thereby initiating repetitive discharges in motor and sensory axons. Electrophysiological studies have suggested that these phenomena result from modification of the gating kinetics of neuronal, voltage-sensitive Na channels. Single channel studies have been conducted which have shown that pyrethroids slow the kinetics of opening and closing of Na channels.

Pyrethroids show high potency and selectivity for insects over mammals. The negative temperature dependence of pyrethroid action is partly responsible for the low mammalian toxicity of these compounds. Type 1 pyrethroids produce a distinct poisoning syndrome characterised by progressive fine whole body tremor, exaggerated start response, uncoordinated muscle twitching and hyperexcitability. The effects are generated largely by effects in the central nervous system. Permethrin also induces hepatic microsomal enzymes.

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 provided or available on the efficacy of the different permethrin isomers.

Spot treatment product/use (CPMT05EC988)

Two field studies were carried out on Permethrin-containing insecticidal products. Both studies demonstrated that Permethrin-containing insecticides (containing permethrin at 3.2% w/w) and, therefore, it is highly likely that a product such as the dummy product CPMT05EC988 would be efficacious in the control of insects. Although these trials were both conducted outdoors, they provide relevant information as to the efficacy of Permethrin-based products of a similar concentration to that being supported in this submission.

Textile fibre treatment product/use (EULAN SPA 01)

The target organisms ingest a small amount of the permethrin contained in treated keratin fibres, which once ingested result in death.

2.1.2.3. Humaneness

Not applicable.

2.1.2.4. Resistance

Resistance to Permethrin has been documented in wide varieties of insects. These species include pear psylla (Preem D.J. et al -J.Econ.Entomol.83:2159-2163, 1990), fall army worm (Smith, J.E. Pest Biochem, Physiol. 39:84-91, 1991), German cockroach (Atkinson, T.H.et al - J.Econ.Entomol. 84:1247-1250, 1991), spotted tentiform leafminer (Marshall, D.B. and D.J. Pree. Can.Ent. 118:1123-1130, 1986), diamondback moth (Tabashnik, B.E., N.J. Cushing, and M.W. Johnson. Econ.Entomol. 80:1091-1099), house fly (Shen, J and F.W.Plapp. J.Econ.Entomol.83:1689-1697, 1990), Stable fly (Cilek, J.E and G.I. Greena, J.Econ.entomol. 87:275-279, 1994), headlice (Rupes, V. et al. Cent.Eur.J.Public Health, 3:30-32, 1995) (Mumcuoglu, K.Y.et al, med.Vet.Entomol 9:427-432, 447, 1995), (Burgess, I.F. et al, Brit.Med.J. 311 (7007):752 1995), tobacco budworm (Wolfenbarger, A. and J.vargas-Camplis. Resist.Pest Manage.9:39-42, 1997).

The level of resistance is less than tenfold in some of the species but high levels of resistance have been observed in cockroaches (45-fold) (Atkinson, T.H.et al - J.Econ.Entomol. 84:1247-1250, 1991), lice (up to 385 fold) (Rupes, V. et al. Cent.Eur.J.Public Health, 3:30-32, 1995), and budworm (1400 fold) (Wolfenbarger, A. and J.vargas-Camplis. Resist.Pest Manage.9:39-42, 1997).

Resistance to Permethrin has been documented in a wide variety of organisms. In the Colorado potato beetle, it is suggested that resistance is due to low levels of Permethrin hydrolysis. In the fungus gnat, resistance to Permethrin is attributed to changes in monooxidase activity in the resistant population. In *H. virescens*, altered functioning of the Na+ channels, and a subsequent elevation of the action potential threshold is thought to cause the resistance. Resistance to pyrethroids has developed rapidly (among head lice) since Permethrin was introduced in 1991.

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. Cross-resistance to pyrethroids and the susceptibility to carbaryl suggested that a common site of pyrethroid action exists.

Application of Permethrin synergists such as Piperonyl butoxide (PBO) or Triphenyl phosphate (TPP) to Permethrin resistant head lice suggests that monooxygenases (cytochrome P-450s) and the esterase enzyme systems were responsible for some pyrethroid resistance. A lack of synergism of D-phenothrin resistance by Piperonyl butoxide suggests that a non-oxidative mechanism, such as nerve insensitivity is also present in resistant lice.

It is extremely important to generate a pest management strategy in order to combat the onset of resistance. Assumptions of such a plan include the absence of cross-resistance and lack of similarity in biochemical mechanisms in head lice. The use of synergists for the inhibition of detoxifying enzymes represent not only an alternative to improve control, but a tool for elucidating resistance mechanisms.

The principles of strategies for managing the development of resistance are similar for Permethrin as they are for other synthetic pyrethroids:

- where possible, application treatments should be recommended to be combined with non-chemical measures
- products should always be used in accordance with label recommendations
- complete elimination of insect pests should be attempted in infested areas
- applications should always be made against the most susceptible stages in the pest life cycle

- where an extended period of control is required, treatments should be alternated with products with different modes of action
- levels of effectiveness should be monitored, and instances of reduced effectiveness should be investigated for possible evidence of resistance.

Because of the anticipated low level of selection pressure from the proposed uses, no specific strategy for management of the development of resistance is required.

2.1.3. Classification and Labelling

2.1.3.1. Current classification and labelling of the active substance

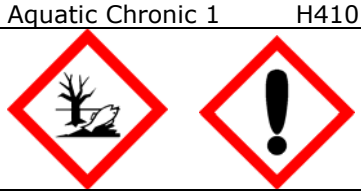
Directive 67/548/EEC

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: (forclassification and 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

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 sensitiser 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 sensitizer 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).

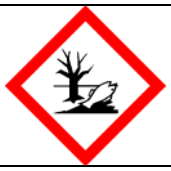
2.1.3.3. Proposal for the classification and labelling of the product(s)

Spot treatment product/use (CPMT05EC988)
The proposed representative classification of products containing permethrin at 5% w/w based on the representative product CPMT05EC988 under Regulation No. (EC) 1272/2008 is outlined below for information purposes:

Directive 99/45/EC

Symbols	 
Classification	Xi: Irritant N: Dangerous for the environmentXi: Irritant
R phrases	R43: May cause sensitization by skin contact R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.R 43: May cause sensitization by skin contact
S phrases	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. S36/37/39: Wear suitable protective clothing, gloves and eye/face protection.

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

Pictogram: (for labelling)	 
Signal word:	Warning
Hazard Statements: (for labelling)	H317: May cause an allergic skin reaction. H410 (Acute Cat 1; Chronic Cat 1): Very toxic to aquatic life with long lasting effects
Precautionary Statements: (for labelling)	P280: Wear eye/face protection and protective gloves P273: Avoid release to the Environment P391: Collect spillage P501: Dispose of contents/container to hazardous waste
	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

Does not classify from a physical-chemical as flammable, explosive or oxidising for classification under Directive 99/45EC or Regulation No. (EC) 1272/2008. No classification required.

Human Health
The classification of R43/H317 "May cause an allergic skin reaction" is transposed from the active substance because the active substance is a skin sensitiser and the concentration limit is exceeded.

Environment
Permethrin is classified as N Dangerous for the Environment and R50/53: Very toxic to aquatic organisms may cause long-term adverse effects in the aquatic environment. Permethrin is assigned R53 as it is not readily biodegradable. Under CLP 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*.

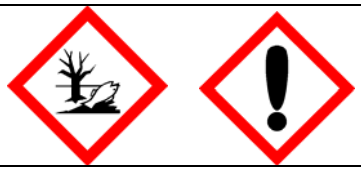
The classification of biocidal products containing permethrin will require to be evaluated at Member State level when product authorisation is required.

Textile fibre treatment product/use (EULAN SPA 01)
The proposed representative classification of products containing permethrin at 10% w/w based on the representative product EULAN SPA 01 under Directive 99/45/EC and Regulation No. (EC) 1272/2008 are outlined below for information purposes:

Directive 99/45/EC

Symbols	
Classification	Xi: Irritant N: Dangerous for the environment
R phrases	R36: Irritating to eyes. R 43: May cause sensitization by skin contact R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
S phrases	S24/25: Avoid contact with skin and eyes. 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.

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. H317:May cause an allergic skin reaction.

	H319: Causes serious eye irritation
Precautionary Statements: (for labelling)	P280: Wear eye/face protection P305+351+313: IF IN EYES: Rinse continuously with water for several minutes. Get medical advice/attention. P273: Avoid release to the Environment P391: Collect spillage P501: Dispose of contents/container to hazardous waste
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 EULAN SPA 01 will not classify as flammable, explosive or oxidising for classification under either Directive 99/45EC or Regulation No. (EC) 1272/2008. No classification required.

Human Health
On the basis of the potential for eye irritation in the rabbit, it is proposed to classify the representative product, EULAN SPA 01, as R36 and H319 under Directive 99/45/EC and the CLP Regulation (EC) No 1272/2008, respectively. The classification of R43/H317 "May cause an allergic skin reaction" is transposed from the active substance because it is classified as a skin sensitizer and the concentration limit is exceeded.

Environment
Permethrin is classified as N Dangerous for the Environment and R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. Permethrin is assigned R53 as it is not readily biodegradable. Under CLP this translates into 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*.

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

2.2. SUMMARY OF THE RISK ASSESSMENT

It should be noted that the application in support of permethrin by TANATEX was originally submitted under product-type 9 (fibre, leather, rubber and polymerised materials preservatives). However, following discussions at the Competent Authority meeting in Brussels during July 2011 it was determined and concluded:

"The meeting took note of the document submitted by Tanatex on the subject of the change of PT (from PT 9 to 18) for the dossier submitted for permethrin under the review programme. The meeting however concluded that the protection of wool carpets against larvae of moths and carpets beetles should fall under PT 18, as PT 9 cover substances intended to protect textiles from micro-organisms only. However, it was noted that the ESD for PT9 could be utilised for this assessment."

As such the risk assessment provided is conducted utilising the PT9 scenarios, since they best fit the actual use of the representative product, EULAN SPA 01. However, the inclusion is proposed for PT18 since the function of the active is insecticidal but the PT9 description only allows for control against organisms causing microbiological deterioration and not insecticidal deterioration.

2.2.1. Human Health Risk Assessment

2.2.1.1. Hazard Identification

The technical material supported by the applicants 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.

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 Cl_2CA in free and glucuronide form, sulfate conjugate of 4'-hydroxy-3-phenoxybenzoic acid, PB acid in free and conjugate form, and hydroxymethyl-Cl_2CA 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 Xn: R22/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 Directive 67/548 as Xn: R20; Harmful by inhalation, and 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.

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 Directives 67/548 and 91/414 and Regulation (EC) No. 1727/2008, Permethrin is classified as a skin sensitiser, therefore the RMS proposed to retain the classification Xn: R43; May cause sensitisation by skin contact and 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.

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 $\geq$ 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 $_{\text{ACUTE-TERM}}$ 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 $_{\text{MEDIUM-TERM.}}$ 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 $_{\text{MEDIUM-TERM}}$ 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 (CPMT05EC988)

Spot treatment product/use (CPMT05EC988)

Product details

Trade name	CPMT05EC988	
Manufacturer's development code number(s)	Not available	
Ingredient of preparation	Function	Content
Permethrin (>93.0% pure)	Insecticide, which has specific action against a wide range of flying and crawling insects.	5% w/w (45.5 g/l)
Physical state of preparation	Viscous liquid	
Nature of preparation	Permethrin 5% EC	

Professional users

Summary of risk assessment calculated for professional users

Exposure scenario	PPE	Systemic dose (mg/kg bw/d)	%AEL long-term (0.05 mg/kg bw/d)	MoS long-trem (5 mg/kg bw/d)
Pest control operator (Tier 1)	Protective gloves	0.088	176	57
Pest control operator (Tier 2a)	Protective gloves, coated coverall	0.046	92	109

*filtering half mask, ** 2 hours duration of task

Acute risks were not considered for professional users, instead the risk assessment was restricted to the more relevant chronic exposure. Professional users are expected to use the biocidal product on a daily basis for 230 working days in the year. However, it is not a realistic worst case to assume 230 days/year working with permethrin based products.

The exposure assessment for professional pest control operators (PCOs) under worst case assumptions yielded a potential inhalation and dermal exposure leading to a systemic dose of 0.088 mg/kg bw/d for an unprotected operator during mixing and loading and spray application (assumed daily working time of 7 hours, gloves by default included in the model).

The comparison to the proposed NOAEL of 5 mg/kg bw/day (based on a 12-month oral toxicity study in dogs) results in a margin of exposure (MoE) of 57 (see **Table 1.2.2.3-1**) which suggests that unprotected operators are at risk.

When protective equipment, such as coated coveralls, is worn the MoE is increased to 109.

As good practise for professional pest control operators (PCO) usually should include the required protective equipment, under worst case assumptions an acceptable risk for professional users is demonstrated.
The use of realistic exposure data demonstrated that the risk to professional users applying Permethrin based spray products is acceptable.

As Permethrin is manufactured outside the EU, exposure during manufacturing of the active substance falls outside the scope of this application and therefore has not been addressed.

Professional pest control operators are exposed to Permethrin during their use in biocidal products such as CPMT05EC988. Any potential risk to workers would only be related to dermal and inhalation routes of exposure.

When either PPE is worn or when typical task durations were considered in the risk assessment it is concluded that CPMT05EC988 is safe for professional users. The MoE calculated were above the assessment factor of 100 indicating an acceptable risk. However, there is a need for managing potential risks to workers with the use of personal protective equipment (PPE). The available monitoring data incorporates the use of gloves and the wearing of coveralls/filtering half mask was included in the risk assessment.

Non- Professional Users

Similar to professional users, chronic risks were considered for non-professional users. However, as non-professional users are expected to use the biocidal product only intermittently for a few events per year, comparison of exposure to limits for acute exposure are considered to be more reasonable.
The exposure assessment for non-professional users under worst case assumptions yielded a potential inhalation and dermal exposure leading to a systemic dose of 0.00080 mg/kg bw/d for an unprotected user during application of a ready-to-use trigger spray.

The comparison to the proposed NOAEL of 5 or 50 mg/kg bw/day for long-term and acute exposure gives rise to a margins of exposure of more than approximately 7000 to 70000 which suggests that unprotected users are at very low risk.

Summary of risk assessment calculated for non-professional users

Exposure scenario	Systemic dose (mg/kg bw/d)	%AEL long-term (0.05 mg/kg bw/d)	MoE long-trem (5 mg/kg bw/d)	%AEL acute (0.5 mg/kg bw/d)	MoE acute (50 mg/kg bw/d)
Amateur	0.00080	1.59	6280	0.16	62798

user trigger spray					

ConsExpo 4.1

The exposure assessment for consumers under worst case assumptions calculated with ConsExpo 4.1 yielded systemic doses ranging from 4.32 x 10^{-4} to 1.07 x 10^{-5} mg/kg bw/day for acute and chronic exposure.

The comparison to the proposed NOAELs of 5 and 50 mg/kg bw/day for long-term and acute exposure gives rise to margins of safety exceeding the propose assessment factor of 100 by several orders of magnitude (indicating an acceptable risk for consumers. The comparison of the estimated exposure to the proposed AELs of 0.05 or 0.5 mg/kg bw/day results in proportions less than 0.1% hence considered to be negligible

Summary of risk assessment calculated for non-professional users by ConsExpo

Exposure scenario	Systemic dose (mg/kg bw/d)	% AEL long-term (0.05 mg/kg bw/d)	MoS long-trem (5 mg/kg bw/d)	% AEL acute (0.5 mg/kg bw/d)	MoS acute (50 mg/kg bw/d)
Acute exposure	0.000432	n.a.	n.a.	0.09	115740
Chronic exposure	1.07 × 10^{-5}	0.02	467290	n.a.	n.a.

n.a. not applicable

Overall assessment of the risk for the use of the active substance in biocidal products

Similar to professional users, non-professional users are exposed to Permethrin during their use in biocidal products such as CPMT05EC988.

Any potential risk to users would be related to dermal and inhalation routes of exposure.

It has been demonstrated by two models that sufficient margins of safety for non-protected amateur users exist, exceeding the relevant assessment factors for chronic and acute effects of 100 by several orders of magnitude.

Comparison to the corresponding Acceptable Exposure Levels demonstrates proportions less than 0.1%, considered to be negligible.

Hence, it is assumed that amateur users are at very low risk when applying CPMT05EC988 as a ready-to-use trigger spray.

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

Indirect exposure as a result of use

Critical end point(s)

The critical endpoints for all exposure scenarios are summarised under point 1.2.2.1.

In the case of indirect exposure as a result of use (secondary exposure) two scenarios are proposed: acute and chronic scenarios.

The secondary exposure for infant and children is mainly occurring via dermal contact. The post application exposure for children estimated using ConsExpo was based on a child crawling over the treated surface for 1 hour during a 7 day period. The model considers that exposure occurs *via* dermal contact through rubbing off.

It is assumed that secondary exposure from general surface spraying will cover secondary exposure from targeted spot or crack & crevice application, where the treated areas are nearly out of reach of children.

Risk characterisation for product type 18

The secondary exposure assessment for the acute scenario under worst case assumptions yielded acute exposures of 0.0267 mg/kg bw.

The comparison to the relevant endpoints gives rise to margins of safety of 1872 which is well above 100 indicating an acceptable risk.

The comparison of the estimated exposure to the proposed AELs results in proportions of 5 to approximately 20%, being well below the limits, indicating an acceptable risk.

Summary of risk assessment for secondary exposure

Exposure scenario	Systemic dose (mg/kg bw/d)	% AEL long-term (0.05 mg/kg bw/d)	MoS long-trem (5 mg/kg bw/d)	% AEL acute (0.5 mg/kg bw/d)	MoS acute (50 mg/kg bw/d)
Acute exposure	0.0267	n.a.	n.a.	5.3	1872

Overall assessment of the risk for the use of the active substance in biocidal products

Secondary exposure of infants who would be in contact or ingest residues is considered to be very low and the margins of safety are very high and therefore, acceptable following exposure due to the use of relevant Permethrin containing products. Therefore, it can be assumed that very little risk to infants exists in this scenario.

Secondary exposure of children crawling on treated surface as a chronic exposure is considered to be acceptable and the margins of safety are well above 100. Therefore, it can be assumed that very little risk to infants exists in this scenario. The comparison of the estimated exposure to the proposed AELs gives rise to a ratio <1, indicating an acceptable risk.

The potential for skin sensitisation from indirect exposure to permethrin treated areas following spot treatments should be considered at product authorisation because the active substance is currently classified as a potential sensitiser.

2.2.1.3. Exposure Assessment and Risk Characterisation (EULAN SPA 01)

Textile fibre treatment product/use (EULAN SPA 01)

Professional Users – Primary Exposure – Textile preservation

Exposure Scenario (indicate duration)		Estimated Internal Exposure				Relevant NO(A)EL / [mg/kg b.w/day] & A(0)EL	AF [1]	MOE [2]	Exposure /AOEL [3]
		estimated oral uptake [mg/kg b.w/day]	estimated inhalation uptake [mg/kg b.w/day]	estimated dermal uptake [mg/kg b.w/day]	estimated total uptake [mg/kg b.w/day]				
Tier 1 (no PPE)	Scenario 1, Model 7 Mixing and Loading[4]; Loading of biocide into a closed system Daily activity taking 10 mins	N/A	N/A	3.00E-04	3.00E-04	5.00 5.00E-02	100	1.67E+04	6.00E-03
Tier 2 (PPE; chemical resistant gloves)	Scenario 1, Model 7 Mixing and Loading[4]; Loading of biocide into a closed system Daily activity taking 10 mins	N/A	N/A	3.00E-05	3.00E-05	5.00 5.00E-02	100	1.67E+05	6.00E-04
Tier 1 (no PPE)	Scenario 2, Rinsing/cleaning Foulard Chassis and pipelines; TNsG / ConsExpo background documents Daily activity taking 20 mins	N/A	N/A	2.38E-02	2.38E-02	5.00 5.00E-02	100	210	0.48
Tier 2 (PPE; chemical resistant gloves)	Scenario 2, Rinsing/cleaning Foulard Chassis and pipelines; TNsG / ConsExpo background documents Daily activity taking 20 mins	N/A	N/A	2.38E-03	2.38E-03	5.00 5.00E-02	100	2100	0.048

[1] Assessment factor
[2]Margin of exposure (MOE) = NO(A)EL (mg/kg bw/day) / Exposure (mg/kg bw/day); Value >AF is considered acceptable
[3]Estimated total uptake / A(O)EL; value <1 is considered acceptable
[4]TNsG Human Exposure Model 7 (75% tile)
N/A = not applicable

From the calculations shown above whereby the systemic dose (dermal) is compared to the $AEL_{CHRONIC}$ of 5.00E-02 mg/kg bw/day to establish a Margin of Exposure (MOE), it can be determined that the MOE is significantly greater than 100 and therefore exposure to professional users will not constitute a risk to human health. Nonetheless, PPE should be considered for professional products containing permethrin because the active substance is currently classified as a potential sensitiser.

NON-PROFESSIONAL USERS

Application Product Type 18

EULAN SPA 01 is applied by professional users only. The only non-professional exposure will be indirect exposure.

INDIRECT EXPOSURE AS A RESULT OF USE

Application Product Type 18

Secondary (indirect) exposure will result from adults and children coming into contact with carpets which have been made from wool treated with EULAN SPA 01. Exposure to children may occur *via* contact with the carpet by crawling on carpeted floors. Infants are considered to be at greatest risk due to their hand-to-mouth activity and their play activity and therefore, this scenario will be used to characterise the risk to both infants/children and adults. In addition to the model used in Scenario 3, estimation of secondary exposure using real data has been presented in Scenario 4. The potential for inhalation exposure to permethrin in carpet fibres generated during carpet fitting has also been investigated for carpet fitters and this is presented in Scenario 5.

Relevant exposure paths

Scenario 3 - Child crawling on EULAN SPA 01 treated carpet

No model is available (in Europe or elsewhere) to specifically estimate exposure to a child crawling on a carpet treated with a preservative. ConsExpo however contains a model to calculate post application exposure to a child following the application of carpet powder which can be adapted to permethrin use. This model calculated exposure from the dermal and oral route.

Scenario 4 – Child crawling on permethrin-treated carpets

No model is available (in Europe or elsewhere) to specifically estimate exposure to a child crawling on a carpet treated with a preservative. However, Berger-Preiss E *et al.* 2002, included this investigation in their study 'Indoor pyrethroid exposure in homes with woollen textile floor coverings' summarised in TNG summary. In this study of exposure to permethrin *via* treated carpets in homes in Hanover, Germany they estimated the daily oral, inhalation and dermal intake from a small child playing on a wool carpet using actual data collected in the study.

Scenario 5 – Inhalation exposure to carpet fitters

No exposure model is available (in Europe or elsewhere) to specifically estimate inhalation exposure to an adult fitting carpets as a daily activity and therefore the model presented in TNsG Part 3, 2002, page 38, 'inhalation of spray from once-through system, adult' was used to calculate the potential exposure to an adult fitting carpets. Data on total suspended particulate matter (TSP) and concentration of Permethrin in the TSP is available from the study report entitled (Pauluhn, J. 1994) Permethrin incorporated in carpets, study on the assessment of respiratory and behavioural effects on rats.

Secondary (indirect) exposure as a result of use – Secondary Exposure

Exposure Scenario (indicate duration)		Estimated Internal Exposure				Relevant NO(A)EL / [mg/kg b.w/day] & A(O)EL	AF[1]	MOE[2]	Exposure /AOEL[3]
		estimated oral uptake [mg/kg b.w/day]	estimated inhalation uptake [mg/kg b.w/day]	estimated dermal uptake [mg/kg b.w/day]	estimated total uptake [mg/kg b.w/day]				
Tier 1 No PPE	Scenario 3 Child crawling on EULAN SPA 01 treated carpet	3.69E-02	-	1.16E-02	4.85E-02	5.00 5.00E-02	100	1.03E+02	9.70E-01
Tier 1 No PPE	Scenario 4 Child crawling on permethrin treated carpet	8.6E-04	2.3E-06	8.7E-04	1.70E-03	5.00 5.00E-02	100	2.94E+03	3.40E-02
Tier 1 No PPE	Scenario 5 Inhalation/dermal exposure to carpet fitters	-	5.00E-04	0.00249	3.00E-03	5.00 5.00E-02	100	1.600E+03	6.00E-02

[1] Assessment factor
[2]Margin of exposure (MOE) = NO(A)EL (mg/kg bw/day) / Exposure (mg/kg bw/day); Value >AF is considered acceptable
[3]Estimated total uptake / A(O)EL; value <1 is considered acceptable

From the calculations shown above whereby the systemic dose (total of oral, dermal and inhalation exposure where appropriate) is compared to the AEL_{MEDIUM} of 5.00E-02 mg/kg bw/day to establish a Margin of Exposure (MOE), it can be determined that the MOE is greater than 100 and therefore secondary exposure will not constitute a risk to human health.

Overall Assessment Of The Risk For The Use Of The Active Substance In Biocidal Products

MOE and Exposure/AOEL values for the critical effects concerning the workplace and indirect exposure towards permethrin

Workplace operation	PPE	Exposure path	Body dose (mg/kg bw/d)	Repeated dose toxicity (NOAEL = 5 mg/kg bw/day)	Repeated dose toxicity (AOEL = 5.0E-02 mg/kg bw/day)
				MOE	Exposure / AOEL
Professional Exposure					
Loading of biocide into a closed system – Scenario 1	No PPE	Dermal	3.00E-04	1.67E+04	6.00E-03
Rinsing/cleaning of Foulard chassis and pipelines – Scenario 2	No PPE	Dermal	2.38E-04	2.10E+04	4.76E-03
Indirect or Secondary Exposure					
Child crawling on EULAN SPA 01 treated carpets – Scenario 3	No PPE	Oral / dermal	4.85E-02	1.03E+02	9.70E-01
Secondary exposure, child crawling on permethrin treated carpet – Scenario 4	No PPE	Inhalation / oral / dermal	1.70E-03	2.94E+03	3.40E-02
Secondary exposure, inhalation and dermal exposure to carpet fitters – Scenario 5	No PPE	Inhalation/ dermal	3.00E-03	1.600E+03	6.00E-02

From the calculations shown above whereby the systemic dose is compared to the AEL_{MEDIUM} of 5.00E-02 mg/kg bw/day to establish a Margin of Exposure (MOE), it can be determined that the MOE is greater than 100 and therefore primary or secondary exposure will not constitute a risk to human health. Note that PPE (chemical resistant gloves) would normally be worn by professional workers.

The potential for skin sensitisation from indirect exposure to permethrin treated areas following fibre treatments should be considered at product authorisation because the active substance is currently classified as a potential sensitiser.

Combined exposure

Spot treatment product/use (CPMT05EC988)

Professional exposure has been modelled using spraying model 1 from the TNsG 2002. This model combines operator exposure during mix and load steps with exposure during application. As professional exposure has been estimated using a model that considers combined exposure (mix, load and application) combined exposure for professionals is deemed to have been assessed. Non-professional application involves a premixed trigger spray so combined exposure is not relevant.

Textile fibre treatment product/use (EULAN SPA 01)

For textile preservation, combined exposure has been considered for a worker who may perform both mixing/loading and rinsing/cleaning/repair tasks in the same working day. The combined systemic exposure data are presented below:

The following combined exposure scenarios have been assessed:

MOE and Exposure/AOEL values for the Combined Exposure to Professional Workers

Workplace operation	PPE	Exposure path	Body dose (mg/kg bw/d)	Repeated dose toxicity (NOAEL = 5 mg/kg bw/day)	Repeated dose toxicity (AOEL = 5.0E-02 mg/kg bw/day)
				MOE	Exposure / AOEL
Professional Exposure					
Loading of biocide into a closed system – Scenario 1 and Rinsing/cleaning – Scenario 2	No PPE Scenarios 1 and 2	Dermal	2.38E-02	9.29E+03	0.482

From the calculations shown above whereby the systemic dose (dermal) is compared to the AEL_{MEDIUM} of 5.00E-02 mg/kg bw/day to establish a Margin of Exposure (MOE), it can be determined that combined exposure will not add a significant additional exposure to the professional exposure encountered.

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 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.

Conclusion on 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 applicants 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 photoylsing 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 LD50: >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 organisms. However, 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 DT_{50} (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 P_{ow} 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

Spot treatment product/use (CPMT05EC988)

The environmental exposure assessment has been performed in accordance with the emission scenario document for insecticides, acaricides and products to control arthropods (PT 18) for household and professional use (OECD, 2008) and was based on information relating to the use patterns of the dummy product, CPMT05EC988. In addition, recent modifications agreed upon by member states at the Biocides Technical Meetings and published in the most recent version of the MOTA (Manual of Technical

Agreements, Vs. 4, 2011) were also included to derive the PEC values in the present risk assessment. CPMT05EC988 is an emulsion concentrate formulation which contains 5 % w/w or 0.05 %w/w permethrin, with a *cis:trans* isomeric ratio of 25:75 for indoor professional/non-professional use, respectively, in targeted spot applications against crawling and flying insects resting on surfaces. The professional product is applied using a lever operated knapsack sprayer. The product for non-professional users is applied using a manual sprayer. The main emission route of the product is via wastewater from sewage treatment plants after the cleaning of the treated area or the applicators clothing. There are no direct emissions to surface water or sediment. Consequently, aquatic or sediment organisms are not directly exposed to the active substance. Direct exposure of the air compartment is considered negligible. The half-life of permethrin in the trophosphere was calculated to be 0.701 d assuming a hydroxyl radical concentrations of 5 x 10^5 radicals/cm^3 (24 hr day). Therefore, permethrin is rapidly degraded by photochemical processes. Soil and groundwater maybe indirectly contaminated via the land application of sewage sludge. The concentration in porewater of agricultural soil has been calculated to provide an indication for potential groundwater contamination risk. All groundwater concentrations are less than the EU trigger value of 0.1 □g/L.

Three major metabolites (>10%AR) were observed in water-sediments systems: 2,-dimethyl-3-(2,2-dichorovinyl)-2,2-dimethylcyclopropane carboxylic acid (DCVA), 3-phenoxybenzoic acid (PBA) and PB alcohol. In order to estimate potential environmental exposure to the major metabolites associated with losses to the wastewater compartment during the service life of CPMT05EC988, it has been assumed that metabolites are formed at the point of emission (from Clocaleff and diluted by the default factor of 10) at a quantity equivalent to 100 % of the parent adjusted to take into account differences in the molar masses of the compounds. These PECs represents an extreme worst-case estimate of surface water exposure as experimental data have shown that the metabolites are formed at only a fraction of the quantity of parent under a range of environmental conditions. PECs for the major sediment metabolites (> 10%AR) have been calculated from the surface water PECs using the equilibrium partitioning method.

DCVA and PB acid were observed at 11.3 % AR and 15.0 %AR in soil. It is difficult to predict the actual quantity of metabolites present in soil after sludge application, since the parent will potentially have been subject to transformation either in soil or in the sludge itself under very different environmental conditions. Initial concentrations of the metabolites in soil following application of sewage sludge to land were estimated on the worst-case assumption that the metabolite is formed in the sludge at a quantity equivalent to 100% of the parent (adjusted to take into account differences in the molar masses of the compounds). The concentrations arising in soil after 10 successive yearly applications of sludge was then calculated. Finally, the time weighted average concentration arising in soil was calculated in accordance with the TGD. The concentration in porewater of agricultural soil was calculated to provide an indication of potential groundwater contamination. All groundwater concentrations were less than the EU trigger value of 0.1 □g/L.

Textile fibre treatment product/use (EULAN SPA 01)

The biocidal product (EULAN SPA 01), chosen for the purposes of this submission, is a "dummy product" (or representative formulation), created to investigate the potential properties of a Permethrin-containing product used as a textile preservative. The representative formulation, consisting of Permethrin, co-formulants and a dilution agent allows a worst-case risk assessment for 10% Permethrin when used as a preservative for textiles (PT09) A maximum fixation rate of 0.25 kg Permethrin per tonne of treated material is envisaged.

Air emissions are considered to be a negligible pathway due to the high attachment characteristics of the biocidal compounds. However, emissions to waste water are significant, the majority of which are generated during the wet processing stage (see Document IIB for a more detailed description of the application stages). Therefore exposure to microorganisms in the STP can be expected. This is followed by indirect exposure to surface water, soil, sediment and ground water. However it must be noted that generally the working solution containing permethrin is recycled and is not discarded. Therefore exposure to the listed compartments will be significantly lowered.

Releases may also occur during the service life of textile articles. For indoor articles subject to cleaning, a total release to waste water can be assumed over the service life. This would also apply to imported fibres already containing biocides applied for preservation during storage and transport. As with the application stage, indirect exposure to surface water, soil, sediment and ground water can also be expected.

The "*INERIS Emission scenario document for biocides used as preservatives in the textile processing industry (Products Type 09 and 18)*" has been used to assess the loading of Permethrin to the relevant compartments for the scenarios described above.

In addition Permethrin has two environmentally relevant metabolites - 3-(2,2-dichorovinyl)-2,2-dimethylcyclopropane carboxylic acid (DCVA) and 3-phenoxybenzoic acid (PBA). These have been assessed in a similar fashion.

2.2.2.5. Risk Characterisation (CPMT05EC988)

Spot treatment product/use (CPMT05EC988)

Overall summary of the environmental risk characterisation

	Compartment:	STP	Surface water	Sediment	Local soil	Agricultural soil	Grassland soil
Permethrin	professional	0.002	**1.75** [a]	**2.22** [b]	$9.5X10^{-4}$	$6X10^{-4}$	$2X10^{-4}$
	non-professional	0.001	**1.29** [a]	**1.64** [b]	$7X10^{-4}$	$5X10^{-4}$	$2X10^{-4}$
DCVA	professional	-	$1X10^{-4}$	0.02	$2X10^{-5}$	$9X10^{-6}$	$3.6X10^{-6}$
	non-professional	-	$7.9X10^{-5}$	0.016	$8.8X10^{-6}$	$6.67X10^{-6}$	$2.7X10^{-6}$
PBA	professional	-	$1.6X10^{-4}$	0.03	$3.8X10^{-6}$	$6.35X10^{-7}$	$2.5X10^{-7}$
	non-professional	-	$1.2X10^{-4}$	0.02	$2.8X10^{-6}$	$4.71X10^{-7}$	$1.88X10^{-7}$

[a] If the product were applied in dry cleaned areas only the ratios for professional and non-professional use become 0.142 and 0.099 respectively.
[b] If the product were applied in dry cleaned areas only the ratios for professional and non-professional use become 0.18 and 0.13 respectively.

The risk ratios for STP, surface water, sediment and soil organisms were calculated using the most conservative PECs and PNECs. Results showed that there is no risk from permethrin to STP microorganisms from the indoor spot treatment in houses (professional & non-professional use) and larger buildings (professional use only).

The risk ratio for surface water from indirect exposure is slightly above 1 for professional and non-professional uses indicating a risk to aquatic organisms. This risk is partly due to the very low EC_{50} NOEC for surface water, 0.0000047 mg/L recorded in the *Daphnia magna* study. If the product is restricted to use in dry cleaned areas (Scenario 2), emissions to wastewater from the wet cleaning of treated surfaces would be eliminated. Consequently, the surface water PEC would be reduced, as it would now solely depend on the emissions from the applicator (e.g. washing of applicators clothes). This restriction results in a limited safe use for both categories of users. The CA notes if there was no release of wastewater (i.e. 100 % of the applicators coveralls are disposable & 100% of surfaces are cleaned by vacuum/broom) there would only be

emissions to municipal wastes and none to the soil, water. However, this risk mitigation measure may not be practical. Permethrin metabolites DCVA and PBA were not observed to pose a risk to aquatic organisms.

Permethrin poses a slight risk to sediment organisms with a risk ratio > 1 for both professional and non-professional uses of the product. The metabolites DCVA and PBA were not observed to pose a risk to the sediment compartment.

Exposure of permethrin to soil will occur via application of STP sludge after use indoors. PECs for three different soils were generated: a PEC in local soil for comparison against terrestrial ecosystem endpoints, a PEC in agricultural soil for comparison against crop endpoints for human consumption and a PEC in grassland soil for comparison against endpoints in grass for cattle. No risks to soil from permethrin and metabolites DCVA and PBA were identified.

In conclusion, due to the intended indoor use of the product CPMT05EC988 and the risk ratios calculated for STPs, surface water, sediment and grassland organisms for the scenarios given, there is no risk to wildlife when professional/non-professional use is restricted to targeted spot applications in dry cleaned areas or the dry cleaning of areas subject to wetting. There is no risk of secondary poisoning via the food chain.

Risk of Primary Poisoning

Data on the toxicity of Permethrin to birds and mammals are available and are summarised (Doc IIA, Section 4.2). In the terrestrial compartment, permethrin was found to have low avian toxicity but was toxic to bees and may be hazardous to small mammals following acute exposure. It is of low toxicity to terrestrial soil-dwelling organisms, including earthworms, micro-organisms and plants. The soil metabolites DCVA and FPB-acid (analogue for PBA) displayed lower toxicity to soil macro-organisms than the parent active ingredient and thus are not considered to be ecotoxicologically relevant.

Data on the toxicity of Permethrin to aquatic organisms are available and are summarised (Doc IIA, Section 4.2). Permethrin is potentially 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. Aquatic metabolites including DCVA and 3-phenoxy benzoic acid (PBA) are far less toxic to aquatic organisms than the parent active ingredient and are not considered to be ecotoxicologically relevant.

Risk of Secondary Poisoning

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.

$PEC_{oral,predator}/PNEC_{oral}$ ratios determined for fish-eating mammals and birds ($2X10^{-6}$ and $1.4X10^{-5}$ respectively) and for earthworm eating mammals and birds ($8.3X10^{-6}$ and $6 X 10^{-5}$ respectively) indicate that there is no risk of secondary poisoning following the appropriate use of Permethrin. The calculated $PEC_{oral,predator}/PNEC_{oral}$ ratios showed no risk of metabolite poisoning for aquatic or terrestrial organisms.

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.

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	$8.22X10^{-7}$	0.000235	$1.4X10^{-5}$	$2X10^{-6}$
DCVA	$4.57X10^{-7}$	0.00015	$9X10^{-6}$	$1.25X10^{-6}$
PBA	$4.68X10^{-7}$	0.00015	$9X10^{-6}$	$1.25X10^{-6}$
Scenario: Application, Terrestrial compartment	**$PEC_{groundwater}$**	**mg/kg wet earthworm**		
Permethrin	$1.13X10^{-7}$	0.001	$6X10^{-5}$	$8.33X10^{-6}$
DCVA	$1.21X10^{-5}$	0.08	0.005	$6.6X10^{-4}$
PBA	$1.17X10^{-6}$	0.01	$6X10^{-4}$	$8.3X10^{-5}$

The predicted concentrations of the dummy product CPMT05EC988 in the environment from use as a PT18 suggests no risk of toxicity to birds and mammals from permethrin or its metabolites, DCVA and PBA, from secondary poisoning via the food chain.

Conclusion
In conclusion, due to the intended indoor use of the product CPMT05EC988 and the risk ratios calculated for STPs, surface water, sediment and grassland organisms for the scenarios given, there is no risk to wildlife when use is restricted to targeted spot applications in dry cleaned areas. There is no risk of secondary poisoning via the food chain.

2.2.2.6. Risk Characterisation (EULAN SPA 01)

Textile fibre treatment product/use (EULAN SPA 01)

The following scenarios were assessed:

Scenario 1; Environmental emission scenario - Application
Scenario 2; Environmental emission scenario – Service Life

Overall summary of the environmental risk characterisation

Default production volumes:

Compartment:		STP	Surface water	Sediment	Local soil	Agricultural soil
Permethrin	Application	**1.979**	**2003.106**	**2544**	**1.088**	0.700
	Service life	0.012	**12.327**	**15.640**	0.007	0.004
DCVA	Application	**3.729**	0.123	**24.58**	0.014	0.010
	Service life	0.023	0.0008	0.15	$8.397X10^{-5}$	$6.359X10^{-5}$
PBA	Application	**3.901**	0.193	**33.55**	0.004	0.001
	Service life	0.024	0.001	0.21	$2.692X10^{-5}$	$4.487X10^{-6}$

Realistic production volumes:

Compartment:		STP	Surface water	Sediment	Local soil	Agricultural soil
Permethrin	Application	0.139	**141.064**	**179.263**	0.077	0.049
	Service life	$8.6X10^{-4}$	0.868	**1.101**	$4.715X10^{-4}$	$3.037X10^{-4}$
DCVA	Application	0.263	0.009	**1.73**	$9.6X10^{-4}$	$7.3X10^{-4}$
	Service life	0.002	$5.34X10^{-5}$	0.011	$5.913X10^{-6}$	$4.478X10^{-6}$
PBA	Application	0.275	0.014	**2.36**	$3.076X10^{-4}$	$5.132X10^{-5}$
	Service life	0.002	$8.38X10^{-5}$	0.015	$1.896X10^{-6}$	$3.160X10^{-7}$

The 'Default production volume' ratios are based on figures from the ESD for PT9/18 while the 'Realistic production volume' ratios are based on data supplied by the applicant concerning production volumes in their plant (refer to Doc IIB for further details). In this instance the latter figures are considered more relevant for evaluating the environmental risk.

On analysis of the risk ratios calculated for STPs, surface water, sediment and grassland organisms for the two scenarios given the following can be concluded:

- For Permethrin there is a risk to aquatic organisms from the application scenario. This risk can be mitigated against by containment of the emissions to the facility drains. There is no risk to aquatic organisms from the service life scenario.

- For Permethrin there is a significant risk to sediment organisms from application and a slight risk from service life. This risk can be mitigated also by containment to facility drain in the case of the application stage. However it may not be possible to mitigate against the risk for the release during service life. In this instance the RMS feels that given the conservative nature of the calculation carried out during the exposure assessment – 100% loss of Permethrin during service life, no provision made for degradation of the active substance during the various stages of the lifetime of the carpet – the risk is not considered significant .

- No risk was shown to soil organisms.

For the two metabolites DCVA and PBA there is a slight risk to sediment organisms for the application scenario. However, as in the case for the parent compound, this risk can be mitigated against by containment of the emissions to the facility drains.

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	$6.63X10^{-5}$	0.038	0.002	$3.2X10^{-4}$
DCVA	$1.3X10^{-4}$	0.074	0.004	$6.1X10^{-4}$
PBA	$1.36X10^{-4}$	0.0775	0.0046	$6.46X10^{-4}$
Scenario: Application, Terrestrial compartment	**$PEC_{groundwater}$**	**mg/kg wet earthworm**		
Permethrin	$9.09X10^{-6}$	1.12	0.007	0.001
DCVA	$2.63X10^{-5}$	0.357	0.021	0.003
PBA	$1.03X10^{-6}$	0.014	$8.4X10^{-4}$	$1.6X10^{-4}$

The $PEC_{oral,predator}/PNEC_{oral}$ ratios determined for fish-eating mammals and birds ($3.2X10^{-4}$ and 0.002 respectively) and for earthworm eating mammals and birds (0.001 and 0.007 respectively) indicate that there is no risk of secondary poisoning following the

appropriate use of EULAN SPA 01. The risk ratio to metabolites DCVA and PBA were also acceptable.

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.

Therefore, the predicted concentrations of EULAN SPA 01 in the environment from use in PT 18 suggests no risk of toxicity to birds and mammals from Permethrin or its metabolites DCVA and PBA from secondary poisoning via the food chain.

2.2.2.7. 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

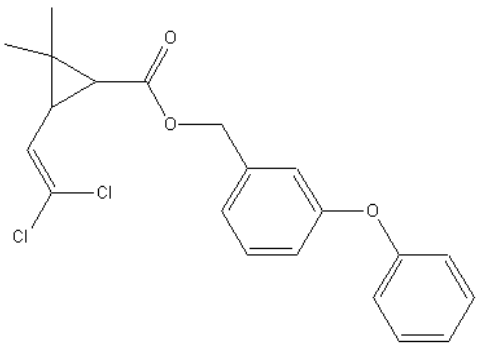
The outcome of the assessment for permethrin in product-type 18 is specified in the BPC opinion following discussions at the fifth meeting of the Biocidal Products Committee (BPC).

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 18 (insecticide)

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 Xn, R22, R20, R43 S2, S13, S24, S36/37/39
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 /	NOAEL = 400 mg/kg bw/day (High dose)

LOAEL	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
Non-professional user			
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 bw/day	12-month dog study.	100

		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	**Textile preservation.** Scenario 1,TNsG Human Exposure to Biocidal Products, Part 2, June 2002 Model 7 Mixing and Loading; Loading of biocide into a closed system. Scenario 2, Rinsing/cleaning Foulard Chassis and pipelines; TNsG / ConsExpo background documents. **low-pressure insecticide application.** Model 1 for professional spraying TNsG Human Exposure to Biocidal Products, Part 2, June 2002, p. 143.
Non-professional users	**Textile preservation.** Professional only application. **low-pressure insecticide application.** Consumer spraying and dusting model 1 TNsG Human Exposure to Biocidal Products, Part 2, June 2002 p.194 and ConsExpo 4.1: Human exposure to consumer products. General surface (trigger spray)
Indirect exposure as a result of use	**Textile preservation.** Child crawling on treated carpet ConsExpo and Berger-Preiss E *et al.* 2002, 'Indoor pyrethroid exposure in homes with woollen textile floor coverings'. Inhalation exposure to carpet fitters TNsG Part 3, 2002, page 38, 'inhalation of spray from once-through system, adult' and data on total suspended particulate matter (TSP) and concentration of Permethrin in the TSP is available from the study report entitled (Pauluhn, J. 1994) **Low-pressure insecticide application.** ConsExpo 4.1 Post-application: children crawling on a treated surface.

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 (1^{st} order, r^2 = 0.981, n = 1); 63.7 days for *cis*-permethrin (1^{st} order, r^2 = 0.991, n = 1); 27.3 days for *trans*-permethrin (1^{st} 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) TAGROS (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)	BAYER/SUMITOMO (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 coefficient)	DT_{50lab} (25 °C, aerobic) <u>BAYER/SUMITOMO</u> (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)

BAYER/SUMITOMO
(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	<u>BAYER/SUMITOMO</u> (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	<u>BAYER/SUMITOMO</u> (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 <u>TAGROS</u> (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)	<u>BAYER/SUMITOMO</u> (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=20ºC (SFO, 9.7-30.9 at T=12ºC) 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) $K_{F(des)}$ (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)
Ka_{oc} , Kd_{oc}	
pH dependence (yes / no) (if yes type of dependence)	

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.

TAGROS
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:
Main Group 3: (Pest Control)
Product type 18 (Insecticides, acaricides and products to control other arthropods).

Claim of the participant:

Spot treatments - **CPMT05EC988**
For indoor use by professional and non-professional users against flying and crawling insects.

Treatment of textile fibres - **EULAN SPA 01**
Moth and beetle proofing agent for the treatment of wool, wool blends, feathers and animal hairs.

Target organisms:

Spot treatments - **CPMT05EC988**
Flying insects (e.g. flies and mosquitoes) and crawling insects (e.g. roaches, mites, fleas and ticks).

Treatment of textile fibres - **EULAN SPA 01**
Textile pests including:
- *Tineola/tinea* (moths);
- *Arthrenus* (carpet beetle);
- *Attagenus* (fur beetle);
- *Hofmannophila pseudospretella* (brown house/false clothes moth).

Concentration:

Spot treatments - **CPMT05EC988**
5% w/w Permethrin
0.05% w/w Permethrin (RTU – non-professional)

Treatment of textile fibres - **EULAN SPA 01**
EULAN SPA 01 contains 10% permethrin. The maximum recommended application rate is: 2.5 kg EULAN SPA 01 per tonne of wool treated corresponding to 0.25 kg permethrin per tonne of wool treated. To ensure uniform application it is recommended that EULAN SPA 01 is automatically added in the water circuit by means of a dosing pump.

Categories of users:

Spot treatments - **CPMT05EC988**
Professional and non-professional users.

Treatment of textile fibres - **EULAN SPA 01**
industrial/professional users

Type of application:

Spot treatments - **CPMT05EC988**

Professional users - Lever-operated knapsack sprayer.
Non- professional users - Manual RTU sprayer.

Treatment of textile fibres - **EULAN SPA 01**

Incorporated into textiles during wet processing (dying stage) by dipping/imersion.

Spot treatments - **CPMT05EC988**

Summary of intended uses

Product name Organism controlled Object and/or situation	Formulation		Application				Applied amount per treatment
	Type	Conc. of a.s.	Method kind	Organisms controlled	Number max	Interval between applications	g a.s./m² (max)
CPMT05EC988 Flying & crawling insects Indoor use by professional users in households* and commercial areas**	EC	5% w/w Permethrin (45.5 g/L)	Lever-operated knapsack sprayer	Flying and crawling insects	1 to maximum 2 per year	min 14 days First application at beginning of infestation, repeat as necessary	0.011 g as/m² (0.24% water solution, 1 litre solution / 10 m²)
CPMT05EC988 Flying & crawling insects Indoor use by non-professional users in households* and commercial areas**	EC	0.05% w/w Permethrin (0.455 g/L)	Manual sprayer	Flying and crawling insects	1 to maximum 2 per year	min 14 days First application at beginning of infestation, repeat as necessary	0.011 g as/m² (24.2 mL product/m²)

a.s. active substance, refers to content of Permethrin
*Non-food/feed areas inside residential homes
**Non-food/feed areas of commercial establishments, including garbage rooms, lavatories, offices, machine rooms, garages, packaged goods storage areas and other non-food/feed areas
***Applications should not be varied in different parts of the Community depending on the geographical or climatic conditions

Treatment of textile fibres - **EULAN SPA 01**

Product name Organism controlled Object and/or situation	Formulation		Application				Applied amount per treatment
	Type	Conc. of a.s.	Method kind	Organisms controlled	Number max	Interval between applications	g a.s./m² (max)
EULAN SPA 01 Textile pests Industrial application professionals	EC	10% w/w Permethrin	Immersion	Keratin feeding textile pests. *Tineola*/*tinea* (moths), *Arthrenus* (carpet beetle), *Attagenus* (fur beetle)	1	N/A	Applied at a maximum rate of 0.25% w/w (weight of product for weight of goods treated). This is equivalent to a maximum application rate of 0.25 kg permethrin per tonne of material treated.

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

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
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] 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

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, 3.3/1 (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] 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.
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).	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
			Report No.: GAB-012/4-21, GLP (unpublished)		
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
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

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, 5.0/3 (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 Products – 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
Garofani, S.	IIB 1.3/1 (IIIB, 3.1.1, 3.1.2, 3.1.3)	2006a	Pertrin E: Determination of the Colour, Odour and Physical State. ChemService S.r.l. Testing Laboratory, Report no. CH-368/2005, GLP (unpublished).	Yes	Copyr S.p.a.
Garofani, S.	IIB 1.3/2 (IIIB, 3.5)	2006b	Pertrin E: Determination of the pH Value. ChemService S.r.l. Testing Laboratory, Report no. CH-369/2005, GLP (unpublished).	Yes	Copyr S.p.a.
Garofani, S.	IIB 1.3/3 (IIIB, 3.6)	2006c	Pertrin E: Determination of the Relative Density. ChemService S.r.l. Testing Laboratory, Report no. CH-370/2005, GLP (unpublished).	Yes	Copyr S.p.a.
Garofani, S.	IIB 1.3/4 (IIIB, 3.10)	2006d	Pertrin E: Determination of the Surface Tension. ChemService S.r.l. Testing Laboratory, Report no. CH-371/2005, GLP (unpublished).	Yes	Copyr S.p.a.
Garofani, S.	IIB 1.3/5 (IIIB, 3.11)	2006e	Pertrin E: Determination of the Viscosity. ChemService S.r.l. Testing Laboratory, Report no. CH-372/2005, GLP (unpublished).	Yes	Copyr S.p.a.
Nowak, J.T. *et al*	IIB, 2.6/1 (IIIB, 5.10/2)	2000	Efficacy tests and determination of optimal spray timing values to control Nantucket pine tip moth (Lepidoptera: Tortricidae) infestations. *J. Econ. Entomol. 93(6): 1708-1713*	No	Public literature
Shea, P.J. *et al*	IIB, 2.6/2 (IIIB, 5.10/3)	1984	Effects of five insecticides on two primary parasites of the western spruce budworm, *Choristoneura occidentalis* (Freeman) (Tortricidae). *Protection Ecology, 7 (1984) 259-268*	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
Llewellyn, D.M. *et al*.	IIB, 3.2.2.1 (IIIB, 5.10/1)	1996	Occupational exposure to Permethrin during its use as a public hygiene insecticide. Ann. Occup. Hyg., Vol 40, No. 5, pp. 499-509	N	Public literature
[redacted]	IIB, 4.1 (IIIB, 6.4)	2005	Literature Review of Permethrin Toxikokinetic Studies Absorption, Distribution, Excretion and Metabolism in Mammals. [redacted] non-GLP (unpublished)	Yes	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-	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
			77-12; Not GLP; Unpublished		
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-Permethrin in Volunteers. Final [redacted]	Yes	Sumitomo
[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	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
			Inc. Report No. HEFG 79-C106; Not GLP; Unpublished		
[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; Unpublished	Yes	Sumitomo
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
Bond A.L. et al	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]	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)		
[redacted]	6,1,4	1979	Rabbit Eye Irritation, FMC 30062 [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] (Unpublished)	Yes	Sumitomo
[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 30061 [redacted] (Unpublished)	Yes	Sumitomo
[redacted]	6,1,4	1975	Rabbit Primary Dermal IrritationCompound FMC 30953 [redacted]	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] (Unpublished)		
[redacted]	6,1,4	1975	Rabbit Eye Irritation Compound No. FMC 3095 [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
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.	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] (Unpublished)		
[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] (Unpublished)	Yes	Sumitomo
[redacted]	6,3,1	1975	21z73 – Preliminary Investigation into the Cumulative Oral Toxicity in Dogs. [redacted]	Yes	Sumitomo
[redacted]	6,6,4	1975	21z73 Dominant Lethal Study in Male Mice. [redacted] (Unpublished)	Yes	Sumitomo
[redacted]	6,6,4	1976	27z75, Dominant Lethal Study in Male Mice. [redacted]	Yes	Sumitomo
[redacted]	2,7	2000	Quantification of Active Ingredient and impurities of Permethrin technical (5-batch analysis) by GC-MS. [redacted] GLP; Unpublished.	Yes	Bayer
[redacted]	2,8	2000	Quantification of Active Ingredient and impurities of Permethrin technical (5-batch analysis) by GC-MS. [redacted] GLP; Unpublished.	Yes	Bayer
[redacted]	4,2	2000	Quantification of Active Ingredient and impurities of Permethrin technical (5-batch analysis) by GC-MS. [redacted] 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] Not GLP; Unpublished	Yes	Sumitomo
[redacted]	6,3,3	1980	Permethrin Technical. Inhalation Study in Rats – 16 x	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
			6 Hour Exposures Over a 3 Week Period. [redacted]		
[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
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.	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
			WLC 92(a)/881444; GLP; Unpublished		
[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
[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

Author(s)	Section Number	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data protection claimed	Owner
			[redacted]		
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
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
Glass, M.A.	6,12	1991	Permethrin 25/75 Technical. The Wellcome Foundation Ltd. Report No. MAG/214/hsc	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

Author(s)	Section Number	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data protection claimed	Owner
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]	Yes	Sumitomo
[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] 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,	7,1,1,1,2	1978	Pyrethroid Photodecomposition:	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
L.O.,Fullmer, D.G.			Permethrin. Journal of Agricultural Food Chemistry. Vol. 26, No. 3, 590-595.; Not GLP; Published		
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. pp308-322	No	N/A
[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] (Unpublished)	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-	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
			884; Not GLP; Published		
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
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
[redacted]	3,4	1981	Evidence for the structure of Permethrin (25/75) from ^{1}H NMR Spectroscopy. [redacted] 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).	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
			29, 81-90.; Not GLP; Published		
[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] Not GLP; Unpublished	Yes	Sumitomo
[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] (Unpublished)	Yes	Sumitomo
[redacted]	6,1,1	1979	Acute Oral Toxicity I Rats with FMC 33297 [redacted]	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
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] (Unpublished)	Yes	Sumitomo
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.	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
			J.P.Leahey. Published by Taylor & Francis; Not GLP; Published		
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 Princes Risborough Laboratory Report; Not GLP; Unpublished	Yes	Sumitomo
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;	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		
[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
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
[redacted]	7,1,1	1981	Degradation of Permethrin in chlorinated water. [redacted] Not GLP; Unpublished	Yes	Sumitomo
Rickett, F.E. & Knight,	7,1,1,1,2	1976	Photostability of Permethrin Isomers. The Wellcome	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
P.J.			Foundation Ltd. Report No. HCDF 76-1; Not GLP; Unpublished		
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
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

Author(s)	Section Number	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data protection claimed	Owner
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. 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	7,4,1,1	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
[redacted]	6,2	1982	Dermal Penetration and Distribution of 14C-Labelled Permethrin Isomers [redacted]	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	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
			and Chemistry, 20, 3, 652-659; Not GLP; Published		
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. Jai Research Foundation. Report No. 260/JRF/PC/97; GLP; Unpublished	Yes	Bayer
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	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
			vector management; Not GLP; Published		
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] (Unpublished)	Yes	Sumitomo
[redacted]	6,3,1	1974	10-Day Cumulative Oral Toxicity Study with 21z73 in Mice [redacted]	Yes	Sumitomo
[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] (Unpublished)	Yes	Sumitomo
[redacted]	6,4,1	1976	27z75Rat Oral 90 Day Toxicity Study. [redacted]	Yes	Sumitomo

Biocidal Products – Reference list by author (TANATEX)

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Comment	Data Protection Claimed (Yes/No)	Owner
B6.4	[redacted]	1987	Percutaneous Absorption of Topically Applied ^{14}C-Permethrin in Volunteers, Final	Refer to Section IIIA of PT08	Yes	TANATEX Chemicals B.V. holds a LOA

			[redacted]	dossier		
-	[redacted]	1992	Permethrin: A one-generation study with the Northern Bobwhite (Colinus virginianus); [redacted] GLP; Unpublished	Refer to Section IIIA of PT08 dossier	Yes	TANATEX Chemicals B.V. holds a LOA
B6.6(2)	Berger-Preiss E. *et al*	2002	Indoor pyrethroid exposure in homes with woollen textile floor coverings. Int. J. Environ. Health 205, 459-472 (2002), Non GLP, Published.	-	Yes	TANATEX Chemicals B.V.
B6.1.2	[redacted]	1990	Investigations on acute dermal toxicity in male and female Wistar rats, [redacted] GLP, Unpublished.	-	Yes	TANATEX Chemicals B.V.
B7.7.1.1(1)	[redacted]	1990a	Acute toxicity of EULAN SPA to fish (test organism: zebra fish = *Brachydanio rerio*). [redacted] Non GLP, Unpublished.	-	Yes	TANATEX Chemicals B.V.
B7.7.1.1(2)	[redacted]	1990b	The Acute Toxicity of EULAN SPA to Daphnia magna STRAUS (Crustacea). [redacted] Non GLP. Unpublished.	-	Yes	TANATEX Chemicals B.V.
B6.1.1	[redacted]	1990	Investigations on acute oral toxicity in male and female Wistar rats, [redacted] GLP, Unpublished.	-	Yes	TANATEX Chemicals B.V.
B7.4	Kanne R	1990a	Biological Degradation of Eulan SPA – Closed bottle test (OECD Guideline 301D). Bayer AG, WV-LE Umweltschutz/AWALU Mikrobiologie, Leverkusen, Germany. Non GLP. Unpublished.	-	Yes	TANATEX Chemicals B.V.

B7.8.5	Kanne R.	1990b	Test for inhibition of oxygen comsumption by activated sludge (ISO 8192-1986). Bayer AG, WV-LE Umweltschutz/AWALU Mikrobiologie, Leverkusen, Germany. Non GLP. Unpublished.	-	Yes	TANATEX Chemicals B.V.
B5.3	Kloesgen M.	2003	Affinity of permethrin (EULAN SPA 01) according to the exhaust process - Laboratory tests. Lanxess Deutschland GmbH, Leverkusen, Germany, Non GLP, Unpublished.	-	Yes	TANATEX Chemicals B.V.
-	Kloesgen M	2008	EULAN SPA 01 – Elimination in the sewage treatment plant, Tanatex Deutschland GmbH R&D - ATD 51368 Leverkusen, Germany Non GLP, Unpublished.	-	Yes	TANATEX Chemicals B.V.
B4.1	Kuck	1997	Analytical Method 2011-0537101-97E Eulan SPA/Eulan ETS (10% formulation), Bayer, ZF-Zentrale Analytik Leverkusen, Building O13, D-51368 Leverkusen, Report No. not given, 29 January 1997	-	Yes	TANATEX Chemicals B.V.
B6.2(1)	[redacted]	1998a	Acute skin irritation test (patch test) of EULAN SPA 01 in rabbits. [redacted] GLP. Unpublished.	-	Yes	TANATEX Chemicals B.V.
B6.2(2)	[redacted]	1998b	Acute eye irritation study of EULAN SPA 01 by installation into the conjunctival sac of rabbits, [redacted] GLP, Unpublished.	-	Yes	TANATEX Chemicals B.V.
B5.10.2	Nentwig	2003	Task 11/03: Efficacy of textile samples treated with Eulan SPA 01 (10 % Permethrin) with Foulard-application against textile pests, Bayer Environmental	-	Yes	TANATEX Chemicals B.V.

			Science, Non GLP, Unpublished.			
B6.3	[redacted]	1991	Skin Sensitisation in the Guinea Pig of a Permethrin 25/75 cis/trans Isomer Ratio, [redacted]	Refer to Section IIIA of PT08 dossier	Yes	TANATEX Chemicals B.V. holds a LOA
B6.6(3)	[redacted]	1994	Permethrin incorporated in carpets, Study on the assessment of respiratory and behavioural effects on rats, [redacted] GLP, Unpublished.	-	Yes	TANATEX Chemicals B.V.
B6.6(1)	Schödel	1990	Permethrin in the air around the workplace. Bayer AG Leverkusen, Analytical Centre, Non GLP, Unpublished.	-	Yes	TANATEX Chemicals B.V.
B3.1	TANATEX Chemicals B.V.	2008	SDS, Product Safety Information, Tanatex chemicals, 25.09.2008, Not GLP, Unpublished	-	Yes	TANATEX Chemicals B.V.
B3.4	TANATEX Chemicals B.V.	2008	SDS, Product Safety Information, Tanatex chemicals, 25.09.2008, Not GLP, Unpublished	-	Yes	TANATEX Chemicals B.V.
B3.5	TANATEX Chemicals B.V.	2008	SDS, Product Safety Information, Tanatex chemicals, 25.09.2008, Not GLP, Unpublished	-	Yes	TANATEX Chemicals B.V.
B3.6	TANATEX Chemicals B.V.	2008	SDS, Product Safety Information, Tanatex chemicals, 25.09.2008, Not GLP, Unpublished	-	Yes	TANATEX Chemicals B.V.
B3.7	TANATEX Chemicals B.V.	2008	SDS, Product Safety Information, Tanatex chemicals, 25.09.2008, Not GLP, Unpublished	-	Yes	TANATEX Chemicals B.V.
B3.10.2	TANATEX Chemicals B.V.	2008	SDS, Product Safety Information, Tanatex chemicals, 25.09.2008, Not GLP, Unpublished	-	Yes	TANATEX Chemicals B.V.