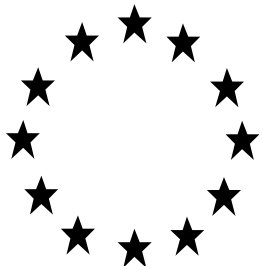
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

DRAFT RISK ASSESSMENT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS



Rodical® InsectProtect

Product type 8

Permethrin as included in the Union list of approved active substances

Asset Number: NL-0016409-0000
Evaluating Competent Authority: NL

Date: 6 December 2020

1 Table of Contents

1 CONCLUSION

The biocidal product Rodical® InsectProtect contains the active substance permethrin. The product is an insecticide for wood preservation for professional use, trained professional use, industrial use and non-professional use.
It is concluded by the eCA that sufficient data have been provided to fulfil the conditions of Article 19 of regulation (EU) 528/2012. When using the product according to the conditions as stated in the SPC, the product will be efficacious and will not present an unacceptable risk to human and animal health nor to the environment.

Rodical® InsectProtect is a stable, transparent, colourless liquid with chemical odour with a permethrin concentration around 0.2% w/w. It has a pH of 4.51. Surface tension of neat test item is 34.1 mN/m. Viscosity is between 1.24-1.29 mm^2/s (20°C) and 0.79-0.82 mm^2/s (40°C). The shelf life is 18 months based on a storage stability test.
No physical hazards are expected for the product.

Rodical® InsectProtect is the 10-fold dilution in water of the F15 concentrate composition. All testing for efficacy was performed on a 10% dilution of F15 concentrate and is therefore applicable for providing efficacy for Rodical InsectProtect.
The comparison of F15 concentrate vs. Rodical® InsectProtect is provided in the confidential annex.

Efficacy of the product for preventive treatment in use class 1 was demonstrated against termites (*Reticulitermes santonensis*) in an EN118 test and against *Hylotrupes bajulus* in two EN46-1 tests at a concentration of 200 g product/m^2 applied on softwood by brushing.

No risks for professionals or industrial users are expected provided that the required PPE are used and use instructions are followed.
The following PPE are required:

- For deluging treatment, spraying and manual dipping: wear protective gloves and coverall.
- For brush treatment no gloves are required.
- For non-professional use, no adverse health effects for unprotected non-professionals are expected for the application by brushing provided that use instructions are followed accordingly. The application via spraying cannot be authorised for non-professional use due to an unacceptable risk for human health.

The environmental compartments which are most sensitive to permethrin are fresh water and sediment. For these compartments, a safe use could be demonstrated for scenario 1, 2 and 3 where no emission to the environment is expected.

For industrial treatment (scenario 4) release to sewers will generally be avoided, based on local legislation. Additionally, the eCA proposed an RMM on the SPC mitigating the emission to the sewer after industrial application for the situations where no local legislation with regards to STP release applies.

The intended uses of the product do not result in risk for the soil compartment including secondary poisoning. Although the tier 1 assessment showed that metabolites reaching groundwater did exceed the trigger value of 0.1 µg/l, taking into account that releases to sewers is not allowed, RMMs will prevent any indirect exposure to soil and groundwater.

The application method dipping by non-professionals was applied for, but was voluntarily withdrawn by the applicant at the end of the evaluation as this method was not deemed realistic for non-professional users.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier	**Country (if relevant)**
RODICAL® InsectProtect	/

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Caldic Denmark A/S
	Address	Mimersvej 1DK-8722 Hedensted, Denmark
Authorisation number	NL-0016409-0000	
Date of the authorisation	5 March 2021	
Expiry date of the authorisation	5 March 2031	

2.1.1.3 Manufacturer of the product

Name of manufacturer	Groupe Titel Holding Labo France
Address of manufacturer	ZI de Ladoux - Rue Bleue BP 70051 • 63118 CEBAZAT France
Location of manufacturing sites	ZI de Ladoux - Rue Bleue BP 70051 • 63118 CEBAZAT France

2.1.1.4 Manufacturer(s) of the active substance(s)

Active substance	Permethrin
Name of manufacturer	Tagros Chemicals India Limited
Address of manufacturer	Jhaver Centre", Rajah Annamalai Building, IV Floor, 72, Marshalls Road Egmore – 600008 Chennai Tamil Nadu India
Location of manufacturing sites	SIPCOT Industrial Complex, A4/1&2, Tamil Nadu, Cuddalore, India

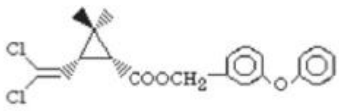
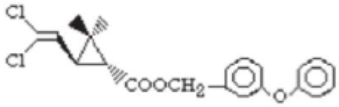
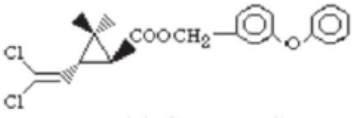
2.1.2 Product composition and formulation

NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	permethrin
IUPAC or EC name	3-phenoxybenzyl (1RS, 3RS; 1RS, 3RS)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate
EC number	258-067-9
CAS number	52645-53-1
Index number in Annex VI of CLP	613-058-00-2
Minimum purity / content	Permethrin has four stereoisomers: 1R-cis, 1S-cis, 1R-trans, 1S-trans. Two pairs of diastereomers (each consisting of a non-racemic pair of enantiomers) are present is a ratio of ca. 25:75. Specification ≥ 93.0% w/w sum of all permethrin isomers. Permethrin content in the product is 0.215%. Permethrin is a reaction mass of four stereoisomers 1R-cis permethrin content = 5.0 - 10.0 %w/w 1S-cis permethrin content = 15.0 - 20.0 %w/w 1R-trans permethrin content = 45.0 - 55.0 %w/w 1S-trans permethrin content = 17.0 - 27.0 %w/w
Structural formula	1Rcis isomer –  1Scis isomer –  1Rtrans isomer –  1Strans isomer – 

2.1.2.2 Candidate(s) for substitution

The product does not contain a candidate for substitution.

Qualitative and quantitative information on the composition of the biocidal product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Permethrin	m-phenoxybenzyl 3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate	Active substance	52645-53-1	258-067-9	0.215*
Propan-2-ol	Propan-2-ol	Non-active substance[1]	67-63-0	200-661-7	0.2
(2-methoxymethylethoxy)propanol	1-(3-methoxypropoxy)propan-1-ol	Non-active substance[2]	34590-94-8	252-104-2	2

** Pure active substance concentration of 0.2±0.03%w/w (TGA 0.215%).*

2.1.2.3 Information on technical equivalence

Not applicable: the active substance contained in the biocidal product is identical to the reference source (supplier is Tagros Chemicals India Ltd.).

2.1.2.4 Information on the substance(s) of concern

Propan-2-ol and (2-methoxypropoxy)propanol are identified as SoCs. For more information please see section 2.1.2.3

1 Non-active substance(s), of which knowledge is essential for proper use of the product. In the SPC in the application the applicant shall indicate also the exact function (e.g. solvent, deterrent, preservative, pigment, etc.). In the SPC which will be disseminated this information will not be provided but limited to the name of non-active substance.

2 Non-active substance(s), of which knowledge is essential for proper use of the product. In the SPC in the application the applicant shall indicate also the exact function (e.g. solvent, deterrent, preservative, pigment, etc.). In the SPC which will be disseminated this information will not be provided but limited to the name of non-active substance.

Furthermore, none of the co-formulants are found to have endocrine disruptor property. Information on the ED screening is included in

- "Others" in section 2.2.6.1 "Assessment of effects" for human health aspect
- "Further Ecotoxicological studies" in section 2.2.8.1 "Effects assessment on the environment" for environment aspect

2.1.2.5 Type of formulation

AL- any other liquid

2.1.3 Hazard and precautionary statements

Classification and labelling of the product according to the Regulation (EC) 1272/2008

Classification	
Hazard category	H400 – H410 – EUH208
Hazard statement	Aquatic Acute 1 - Aquatic Chronic 1 Contains PERMETHRIN. May produce an allergic reaction.
Labelling	
Signal words	Warning
Hazard statements	H410 - Very toxic to aquatic life with long lasting effects EUH 208 - Contains PERMETHRIN. May produce an allergic reaction.
Precautionary statements	P273 - Avoid release to the environment P391 – Collect spillage P501 - Dispose of contents/container to an approved waste disposal plant
Note	/

2.1.4 Authorised use(s)

2.1.4.1 Use description

Table 1. Use # 1 – Preventive Insecticide treatment General public (non-professional) (indoors) Brush/Roller

Product Type	PT8 – Wood preservatives
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	*Reticulitermes* – Termites (genus *Reticulitermes*) – Adults *Hylotrupes bajulus* – House longhorn beetle - Larvae
Field of use	Indoor

	Preventive treatment of softwood and hardwood for use in Use Class 1.
Application method(s)	Brush/Roller
Application rate(s) and frequency	Open system: brush/roller treatment - Can be applied by brush/roller treatment at a rate of 1 L of undiluted product per 5 m2 of wood surface area (200 g/m^2). Apply in 2 layers (2X100g/m^2)
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	Can/container plastic HDPE up to 10L

2.1.4.2 Use-specific instructions for use

See general directions for use, see section 2.1.5.

2.1.4.3 Use-specific risk mitigation measures

During product application (to timbers) and whilst surfaces are drying, do not contaminate the environment. All losses of the product have to be contained by covering the ground (e.g. by tarpaulin) and disposed of in a safe way. Any residues should be collected and disposed as hazardous waste. This product must not be used in areas where bats reside. Treated wood should not come in contact with rain or humidity.

2.1.4.4 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general directions for use, see section 2.1.5.

2.1.4.5 Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use, see section 2.1.5.

2.1.4.6 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use, see section 2.1.5.

Table 2. Use # 2 – Preventive Insecticide treatment professionals (indoors) Spraying/Brush/Roller/Dipping

Product Type	PT8 – Wood preservatives
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	*Reticulitermes* – Termites (genus *Reticulitermes*) – Adults *Hylotrupes bajulus* – House longhorn beetle - Larvae
Field of use	Indoor Preventive treatment of softwood and hardwood for use in Use Class 1.
Application method(s)	Spraying /Brush / Roller / Dipping
Application rate(s) and frequency	Open system: spray treatment - Can be applied by low pressure spray at a rate of 1 L of undiluted product per 5 m^2 of wood surface area (200 g/m^2). Apply in 2 layers (2 X 100g/m^2). Open system: brush/roller treatment - Can be applied by brush/roller treatment at a rate of 1 L of undiluted product per 5 m^2 of wood surface area (200 g/m^2). Apply in 2 layers (2 X 100g/m^2). Open system: dip treatment - Manual dipping Can be applied by dipping at a rate of 1 L of undiluted product per 5 m^2 of wood surface area (200 g/m^2). Apply in 2 layers (2 X 100g/m^2).
Category(ies) of users	Professional
Pack sizes and packaging material	Can/container plastic HDPE up to 10L Container/drum plastic HDPE up to 200 L

2.1.4.7 Use-specific instructions for use

See general directions for use, see section 2.1.5.

2.1.4.8 Use-specific risk mitigation measures

For spraying and manual dipping: wear protective gloves and coverall (material to be specified by the authorisation holder within the product information).

During product application (to timbers) and whilst surfaces are drying, do not contaminate the environment. All losses of the product have to be contained by covering the ground (e.g. by tarpaulin) and disposed of in a safe way. Any residues should be collected and disposed as hazardous waste. This product and the wood treated with this product must not be used in areas where bats reside. Treated wood should not come in contact with rain or humidity.

2.1.4.9 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general directions for use, see section 2.1.5.

2.1.4.10 Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use, see section 2.1.5.

2.1.4.11 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use, see section 2.1.5.

Table 3. Use # 3- Preventive Insecticide treatment Trained professionals (indoors) Spraying/Brush/Roller/Dipping

Product Type	PT8 – Wood preservatives
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	*Reticulitermes* – Termites (genus *Reticulitermes*) – Adults *Hylotrupes bajulus* - House longhorn beetle - Larvae
Field of use	Indoor Preventive treatment of softwood and hardwood for use in Use Class 1.
Application method(s)	Spraying/Brush/Roller/Dipping
Application rate(s) and frequency	Open system: spray treatment -

	Can be applied by low pressure spray at a rate of 1 L of undiluted product per 5 m^2 of wood surface area (200 g/m^2). Apply in 2 layers (2X100g/m^2) <u>Open system: brush/roller treatment -</u> Can be applied by brush/roller treatment at a rate of 1 L of undiluted product per 5 m^2 of wood surface area (200 g/m^2) . Apply in 2 layers (2X100g/m^2) <u>Open system: dip treatment - Manual dipping</u> Can be applied by dipping at a rate of 1 L of undiluted undiluted product per 5 m^2 of wood surface area (200 g/m^2) . Apply in 2 layers (2X100g/m^2)
Category(ies) of users	Trained professional
Pack sizes and packaging material	Can/container plastic HDPE up to 10L Container/drum plastic HDPE up to 200 L

2.1.4.12 Use-specific instructions for use

See general directions for use, see section 2.1.5.

2.1.4.13 Use-specific risk mitigation measures

For spraying and manual dipping: wear protective gloves and coverall (material to be specified by the authorisation holder within the product information). During product application (to timbers) and whilst surfaces are drying, do not contaminate the environment. All losses of the product have to be contained by covering the ground (e.g. by tarpaulin) and disposed of in a safe way. Any residues should be collected and disposed as hazardous waste. This product and the wood treated with this product must not be used in areas where bats reside. Treated wood should not come in contact with rain or humidity.

2.1.4.14 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general directions for use, see section 2.1.5.

2.1.4.15 Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use, see section 2.1.5.

2.1.4.16 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use, see section 2.1.5.

Table 4. Use # 4- Preventive Insecticide Industry (indoors) Spraying/ /Dipping/Flow Coating (deluge)

Product Type	PT8 – Wood preservatives
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	*Reticulitermes* – Termites (genus *Reticulitermes*) – Adults *Hylotrupes bajulus* - House longhorn beetle - Larvae
Field of use	Indoor Preventive treatment of softwood and hardwood for use in Use Class 1.
Application method(s)	Spraying/ /Dipping/Flow Coating (deluge)
Application rate(s) and frequency	<u>Open system: Automated spray treatment -</u> Can be applied by low pressure spray at a rate of 1 L of undiluted product per 5 m^2 of wood surface area (200 g/m^2). Apply in 2 layers (2 X 100g/m^2). <u>Open system: dip treatment - Automated dipping</u> Can be applied by dipping at a rate of 1 L of undiluted product per 5 m^2 of wood surface area (200 g/m^2). Apply in 2 layers (2 X 100g/m^2). <u>Open system: Flow Coating (deluge)</u> Can be applied by Flow Coating (deluge) at a rate of approximately 1 L of undiluted product per 5 m2 of wood surface area (200 g/m2). Apply in 2 layers (2 X 100g/m^2).
Category(ies) of users	Industrial
Pack sizes and packaging material	Can/container plastic HDPE up to 10L Container/drum plastic HDPE up to 200 L

	Container/IBC plastic HDPE up to 1000 L

2.1.4.17 Use-specific instructions for use

See general directions for use, see section 2.1.5.

2.1.4.18 Use-specific risk mitigation measures

For deluging treatment, spraying and manual dipping: wear protective gloves and coverall (material to be specified by the authorisation holder within the product information). Any residues should be collected and disposed as hazardous waste. All industrial application processes must be carried out within a contained area situated on impermeable hard standing with bunding to prevent run-off and a recovery system in place (e.g. sump). Freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water, and that any losses of the product shall be collected for reuse or disposal. Wood treated with this product must not be used in areas where bats reside.

2.1.4.19 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general directions for use, see section 2.1.5.

2.1.4.20 Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use, see section 2.1.5.

2.1.4.21 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use, see section 2.1.5.

2.1.5 General directions for use

2.1.5.1 Instructions for use

Product is ready to use – do not dilute the product

Shake product before use

2.1.5.2 Risk mitigation measures

Do not discharge the biocidal product nor the diluted solution of the biocidal product into the sewage system or the environment.Do not use on wood which may come in direct contact with food, feeding stuff, and livestock animals
Keep children and pets away from treated surfaces until they have dried.
Avoid prolonged contact of pets, particularly cats, to treated surfaces.
Remove or cover terrariums, aquariums, and animal cages before application. Turn off aquarium air-filter while spraying.
Wash hands and exposed skin after use of the product and before meals.
Keep away from food, drink or animal feedstuffs.

2.1.5.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

As a general rule, in case of doubt or if symptoms persist, always call a doctor.

NEVER induce swallowing by an unconscious person.

Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice.

Description of first aid measures

In the event of exposure by inhalation :

In the event of an allergic reaction, seek medical attention.

In the event of splashes or contact with eyes :

Wash thoroughly with soft, clean water for 15 minutes holding the eyelids open.

In the event of splashes or contact with skin :

In the event of an allergic reaction, seek medical attention.

In the event of swallowing :

In the event of swallowing, if the quantity is small (no more than one mouthful), rinse the mouth with water and consult a doctor. Keep the person exposed at rest. Do not force vomiting. Seek medical attention, showing the label. If swallowed accidentally, call a doctor to ascertain whether observation and hospital care will be necessary. Show the label.

Measures to protect environment:

Prevent any material from entering drains or waterways.

Contain and control the leaks or spills with non-combustible absorbent materials such as sand, earth, vermiculite, diatomaceous earth in drums for waste disposal.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Waste:

Waste management is carried out without endangering human health, without harming the environment and, in particular without risk to water, air, soil, plants or animals.

Recycle or dispose of waste in compliance with current legislation, preferably via a certified collector or company.

Do not contaminate the ground or water with waste, do not dispose of waste into the environment.

Soiled packaging :

Empty container completely. Keep label(s) on container. Give to a certified disposal contractor.

2.1.5.5 Conditions of storage and shelf-life of the product under normal conditions of storage

Storage

Store in original container. Keep the container tightly closed in a dry, well-ventilated place, kept away from direct sunlight. The floor must be impermeable and form a collecting basin so that, in the event of an accidental spillage, the liquid cannot spread beyond this area. Store between 5°C and 30°C.

Shelf Life of the product: 18 months.

2.1.6 Other information

-

2.1.7 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)

Container/Can	up to 10 L	Opaque HDPE	HDPE Plastic closure (screw tamper-evident child-resistant plastic cap; no sealing)	Industrial, (Trained) Professional, non-professional	Yes
Container/Drum	Up to 200L	Opaque HDPE	HDPE Plastic closure	Industrial, (Trained) Professional	Yes
IBC	Up to 1000L	Opaque HDPE	HDPE Plastic closure	Industrial	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

A literature study on Permethrin ecotoxicology data has been done and sufficient quality data are available to apply a Species Sensitive Distribution (SSD) approach resulting in a $PNEC_{freshwater}$ 4.8 ng/l. The study used for setting the $PNEC_{surface\ water}$ at 0.47 ng/l is invalidated. This is described in the document below. This document is also submitted to the rapporteur Ireland and more work is ongoing and will be submitted as soon as available.
The study is included in IUCLID section 13 with the following reference: D. Heijerick & F. Verdonck, 2016, Environmental Risk assessment of Permethrin: PNEC derivation for the freshwater compartment.

2.1.8.2 Access to documentation

A letter of access is available to the original dossier of permethrin is available.

2.2 Assessment of the biocidal product

2.2.1 Intended use(s) as applied for by the applicant

The uses below are the ones applied for by the applicant, without any changes by the e-CA. These uses are assessed in the following chapters.

[See 2.1.4 for the authorised uses, after assessment of the dossier.]

Table 1. Intended use # 1 – Indoor Spray/ Injection/ brushing/ dipping / Flow Coating (deluge) Preventive treatment

Product Type	8
Where relevant, an exact description of the authorised use	Indoor wood preservative.
Target organism (including development stage)	Wood boring beetles House longhorn beetle (*Hylotrupes bajulus*) Termites (genus Reticulitermes)-adults
Field of use	Indoor
Application method(s)	Spray/ Injection/ brushing /dipping/Flow coat (Deluge)
Application rate(s) and frequency	Preventive treatment: Can be applied by brush, dipping/flow coat (deluge) or low pressure spray at a rate of approximately 1 Litre of product per 5 square metres of wood surface area (200 gr/m2) as 2 x 100 g/m2, applyed in 2 layers. Max. surface to be treated for non-professionals: 150m (3L product) for injection and 22m2 (4.4L product for preventive treatment) for spray/brushing Max. frequency for non-professionals: once every 5 years/house. No restriction for industrial, trained professionals, professionals.
Category(ies) of users	Industrial, Trained professional, Professional and non-professional
Pack sizes and packaging material	Please see section 2.1.7.

The application method dipping by non-professionals has been evaluated but was voluntarily withdrawn by the applicant at the end of the evaluation.

Table 2. Intended use # 2 – Indoor Spray/ Injection/ brushing/dipping Curative treatment

Product Type	8
Where relevant, an exact description of the authorised use	Indoor wood preservative.

Target organism (including development stage)	Wood boring beetles Common furniture beetle (*Anobium punctatum)*
Field of use	Indoor
Application method(s)	Spray/ Injection/ brushing /Dipping
Application rate(s) and frequency	Curative treatment: 1) Inject deeply into rafters and elements of high section (framing lumber...) (20 ml of the product ready for use per well, created by drilling). 2) Brushing, dipping or low pressure spraying all sides, ends, cuts, emphasizing the embedded parts and assemblies. Apply in 3 layers at a rate of approximately 1 Litre of product per 3 square metres of wood surface area (300 gr/m2) as 3 x 100 g/m2. Max. surface to be treated for non-professionals: 150m (3L product) for injection and 22m2 (4.4L product for preventive – 6.6L product for curative treatment) for spray/brushing Max. frequency for non-professionals: once every 5 years/house. No restriction for industrial, trained professionals, professionals.
Category(ies) of users	Industrial, Trained professional, Professional and non-professional
Pack sizes and packaging material	Please see the relevant section.

The application method dipping by non-professionals has been evaluated but was voluntarily withdrawn by the applicant at the end of the evaluation.

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Concentration of active substance (% (w/w))	Results	Reference
Physical state at 20 °C and 101.3 kPa	PA-U10-METDESCR	0.2% Batch number: LAD1015079	Homogeneous liquid, free from visible suspended matter and sediment.	23896 Author: Ing. Bernard de RYCKEL Year:2015
Colour at 20 °C and 101.3 kPa		0.2% Batch number: LAD1015079	Colourless	23896 Author: Ing. Bernard de

Property	Guideline and Method	Concentration of active substance (% (w/w))	Results	Reference
				RYCKEL Year:2015
Odour at 20 °C and 101.3 kPa		0.2% Batch number: LAD1015079	Chemical odour	23896 Author: Ing. Bernard de RYCKEL Year:2015
Acidity / alkalinity	CIPAC MT 75.3	0.2% Batch number: LAD1015079	$pH_{100\%}$ = 4.51 (T=16°C)	23896 Author: Ing. Bernard de RYCKEL Year:2015
Relative density / bulk density	EEC A.3	0.2% Batch number: LAD1015079	D^{20}_4 = 1.00	23896 Author: Ing. Bernard de RYCKEL Year:2015
Storage stability test – **accelerated storage**	Test not required as long term storage at ambient temperature report is available. Waived based on label sentence: Store between 5°C and 30°C			
Storage stability test – **long term storage at ambient temperature**	CIPAC 331/TC/M/3 (GC-FID method), as general base CIPAC MT 75.3 PA-U10-METDESCR visual	0.2% Batch number: LAD1015079	Permethrin content initially: 0.2064 ± 0.0009% w/w Cis trans ratio: 24.36±0.04% cis permethrin and 75.64±0.04% trans permethrin After 18 months: 0.1894 ± 0.0018% w/w (-8.2% vs initial) Cis trans ratio: 24.28±0.18% cis permethrin and 75.72±0.18% trans permethrin After 24 months: 0.1828 ± 0.0009% w/w (-11.4% vs initial) Cis trans ratio: 24.36±0.16% cis permethrin and 75.64±0.16% trans permethrin	23896 Author: Ing. Bernard de RYCKEL Year:2015

Property	Guideline and Method	Concentration of active substance (% (w/w))	Results	Reference
	method		pH (100%) initially : 4.51 (at 16°C) After 18 months: 4.14 (at 20°C) After 24 months: 4.06 (at 21-22°C)	
	PA-U10-METDESCR visual method		Appearance test item initlally, after 18 months and after 24 months: homogeneous liquid, free from visible suspended matter and sediment; colourless, chemical odour, Outside aspect packaging material initially, after 18 months and after 24 months: intact opaque white HDPE bottles of 1 litre , of 500 and of 250 mL closing : with a white screw tamper-evident child-resistant plastic cap; no sealing.	
	PA-U10-METDESCR visual method		well closed bottle without deterioration or special anomaly. no leak during shaking or turning. no observable sign of test item contamination on the outer surface. Inside aspect packaging	

Property	Guideline and Method	Concentration of active substance (% (w/w))	Results	Reference
			material initially, after 18 months and 24 months: no visual alteration of package by the test item As the active substance content showed a decrease of more than 10% after 24 months, the product is considered stable until 18 months.	
Storage stability test – **low temperature stability test for liquids**	Waived based on label sentence: Store between 5°C and 30°C			
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Test not required if product is kept away from direct sunlight (to be included on label).			
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Test not required, formulation consists of >90% water. In addition, containers should be stored in a cool, dry place.			
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	-	0.2% Batch number: LAD1015079	No reactivity observed during the long term storage test of 24 months.	23896 Author: Ing. Bernard de RYCKEL Year:2015
Wettability	Not applicable, product is a ready-to-use micro-emulsion (AL). Test for wettability is only applicable for wetting of wettable powder preparations, water soluble powders, water soluble granules and water dispersible granules.			
Suspensibility, spontaneity and dispersion stability	Not applicable, product is a ready-to-use micro-emulsion. Test for suspensibility is only applicable for aqueous suspension concentrates, water dispersible granules, water dispersible powders or suspensibility of formulations forming suspensions on dilutions with water. While test for spontaneity of dispersion and dispersion stability is only applicable for suspension concentrates and water dispersible granules.			
Wet sieve analysis and dry sieve test	Wet sieve: not applicable, product is a ready-to-use micro-emulsion. Test is only applicable to wettable powders, suspension concentrates, water dispersible granules, aqueous			

Property	Guideline and Method	Concentration of active substance (% (w/w))	Results	Reference
	capsule suspensions, dispersible concentrates, suspo-emulsions, water soluble granules and water soluble powders. Dry sieve: not applicable, product is no dustable powder or granular formulation			
Emulsifiability, re-emulsifiability and emulsion stability	Not applicable, product is a ready-to-use micro-emulsion.			
Disintegration time	Not applicable, product is not a tablet			
Particle size distribution, content of dust/fines, attrition, friability	Not applicable, product is a ready-to-use micro-emulsion. Product is no powder or granule.			
Persistent foaming	Not applicable, product is ready-to-use micro-emulsion. No further dilution of the product is necessary.			
Flowability/Pourability/Dustability	Flowability: not applicable, product does not contain granular material Pourability: not applicable, product is no suspension concentrate, capsule suspension or suspoemulsion. Dustability: not applicable, product is no dust			
Burning rate — smoke generators	Not applicable, product is a micro-emulsion, not a smoke generator			
Burning completeness — smoke generators	Not applicable, product is a micro-emulsion, not a smoke generator			
Composition of smoke — smoke generators	Not applicable, product is a micro-emulsion, not a smoke generator			
Spraying pattern — aerosols	Since the product is not sold in a spray packaging, the spraying pattern test is not required.			
Physical compatibility Chemical compatibility	Data are required when label recommendations are made to co-apply the biocidal product with other substances, mixtures or biocidal or non-biocidal products. This is not the case for Rodical® InsectProtect.			
Degree of dissolution and dilution stability	Not applicable, product is a ready-to-use micro-emulsion			
Surface tension	PA-U10-METTENS equivalent to EEC A.5 Plate method: Plate of Wilhelmy	0.2% Batch number: LAD1015079	34.1 mN/m (neat test item)	23896 Author: Ing. Bernard de RYCKEL Year:2015
Viscosity	ASTM D445 Measured in duplo	0.2% Batch number: LAD1015079	1.24 mm^2/s and 1.29 mm^2/s (20°C),	23896 Author: Ing. Bernard de RYCKEL Year:2015

Property	Guideline and Method	Concentration of active substance (% (w/w))	Results	Reference
	Ubbelohde viscosimeter		0.79 mm^2/s and 0.82 mm^2/s (40°C)	

Conclusion on the physical, chemical and technical properties of the product
The Rodical® InsectProtect product is a stable, transparent, colourless liquid with chemical odour with a Permethrin concentration around 0.2% w/w. It has a pH (neat formulation) of 4.51. Surface tension of neat test item is 34.1 mN/m. Viscosity is between 1.24-1.29 mm^2/s (20°C) and 0.79-0.82 mm^2/s (40°C). The shelf-life is 18 months in HDPE at ambient temperature, based on storage stability test.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Concentration of active substance (% (w/w))	Results	Reference
Explosives	Not applicable, formulation does not contain substances with chemical groups associated with explosive properties.			
Flammable gases	Not applicable, product is a micro-emulsion and does not contain gases.			
Flammable aerosols	Not applicable, product is a micro-emulsion.			
Oxidising gases	Not applicable, product is a micro-emulsion. Product does not contain gases, therefore no contribution, greater than that of air, to the combustion of other material can be made.			
Gases under pressure	Product does not contain gases.			
Flammable liquids	EEC A.9	0.2%	Flashpoint is >93°C Not flammable	23896 Author: Ing. Bernard de RYCKEL Year:2015
Flammable solids	Not applicable, product a is micro-emulsion. No solids present.			
Self-reactive substances and mixtures	Not applicable: no substances present in the product which contain chemical groups associated with explosive or self-reactive properties, no substances which detonate or deflagrate rapidly.			
Pyrophoric liquids	Product is not pyrophoric: mixture does not ignite spontaneously in contact with air at normal temperature, all compounds are chemically stable.			
Pyrophoric solids	Not applicable, product is a micro-emulsion and does not contain solids			
Self-heating substances and mixtures	Product is a micro-emulsion. The phenomenon of self-heating applies only to solids.			

Property	Guideline and Method	Concentration of active substance (% (w/w))	Results	Reference
Substances and mixtures which in contact with water emit flammable gases	Product is a ready-to use micro-emulsion. Dilution in water is therefore not applicable.			
Oxidising liquids	Waiver: The only chlorine in the formulation is chemically bonded to carbon. The classification for oxidising substances (Division 5.1) does not need to be applied.			
Oxidising solids	Product is a micro-emulsion and does not contain solids			
Organic peroxides	Product does not contain organic peroxides.			
Corrosive to metals	waiver: the product does not contain ingredients containing corrosive to metal properties (H290). In addition, no alkaline, acid, complexing agents are present, nor are extreme pH values applicable.			
Auto-ignition temperatures of products (liquids and gases)	A. 15	0.2% Batch number: 3932	Auto-ignition temperature: > 600°C	S3016007531R 1/2020 Author: Jordan G. Year: 2020
Relative self-ignition temperature for solids	Product is a micro-emulsion and no solids are present.			
Dust explosion hazard	Product is a micro-emulsion and does not generate dust.			

Conclusion on the physical hazards and respective characteristics of the product
No classification with respect to the physical hazards is required for Rodical® InsectProtect.

2.2.4 Methods for detection and identification

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
*Permethrin** *(purity: 98.3%)*	HPLC-UV	2%w/w permethrin in product (equivalent to 50 mg/L in analytical sample) (n=2)	Concentration 40-45-50-55–60 mg/l: 1 determination at 5 levels. Y= 5.521E04 +3.358 E04 R= 0.9998, R^2 = 0.9996 Concentration 40-45-50-55–60 mg/l: 1 determination at 5 levels. Y= 5.532E04 +1.391 E04 R= 0.9997, R^2 = 0.999	No interference was detected at the retention time	50 mg/L: 99.3, 99.5	99.4	0.5489% (n=12) Horwitz criterion: 3.6%	Not applicable	402/14/1189F/ab-e Author: Jequel Marc Year: 2015
Permethrin	CIPAC 331/TC/M/3 (GC-FID method)	Not applicable	Not applicable	No interference was detected based on a blank formulation and a test item.	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

*This method is not relied on as the analytical methods of the storage stability studies was based on CIPAC 331/TC/M/3 (GC-FID method).

eCA remark: No validation of the analytical methods are deemed necessary for the SoCs Propan-2-ol and (2-methoxypropoxy)propanol, since they are not formed during storage.

Analytical methods for soil									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Residues	HPLC/MS/MS	See AR	See AR	See AR	See AR	See AR	See AR	5.0 µg/kg in soil	Assessment Report permethrin

Analytical methods for air									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Residues	HPLC/MS/MS	See AR	See AR	See AR	See AR	See AR	See AR	5 µg/m^3 air	Assessment Report permethrin
Residues	GC/ECD	See AR	See AR	See AR	See AR	See AR	See AR	0.0001 mg/m^3air	Assessment Report permethrin

Analytical methods for water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Residues	HPLC/MS/MS	See AR	See AR	See AR	See AR	See AR	See AR	0.05 µg/L for drinking and surface water	Assessment Report permethrin

Analytical methods for animal and human body fluids and tisues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
No data required. Permethrin does not classify as toxic or highly toxic.									Assessment Report permethrin

Analytical methods for monitoring of active substances and residues in food and feeding stuff									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Food and feeding stuff will not be exposed to permethrin based on the proposed usage. No data required.									Assessment Report permethrin

eCA remark:
In the coordinaton group meeting (number 22) of 22 March 2017 it was noted that the analytical methods for residues in water as submitted in the Permethrin dossier, is not sensitive enough to enable monitoring at the PNEC. Therefore, new analytical methods for residues in surface water with an adequate limit of quantification should be submitted at the renewal of the active substance dossier.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

Rodical® InsectProtect is a RTU permethrine-based wood preservative for preventive treatment of wood in Use Class 1 by industrial, (trained) professional and general public (non-professional) users.

2.2.5.2 Organisms to be controlled and products, organisms or objects to be protected

The object to be protected is softwood and hardwood for use in use Class 1. The organisms to be controlled are the House Longhorn Beetle (*Hylotrupes bajulus*) and Termites (genus *Reticulitermes*).

The application codes for the authorised uses are given below.

Use # 1 :

Categories	**Matrix wording**	**Code for product**
User category	Non-professional / general public	A.10
Wood category	Softwood and Hardwood	B.10 / B.20
Wood product	Solid wood / Reconstituted solid wood	C.10 / C.11
Application aim - Field of use	Preventive treatment – Use class 1	D.40 E.10
Method of application and rate	Superficial application / brush/roller 1 L of undiluted product per 5 m^2 of wood surface area (200 g/m^2) Superficial application / spraying 1 L of undiluted product per 5 m^2 of wood surface area (200 g/m^2) Superficial application / dipping 1 L of undiluted product per 5 m^2 of wood surface area (200 g/m^2)	F.10 F.11 F.14
Target organisms	House longhorn beetle (*Hylotrupes bajulus*) Termites (genus *Reticulitermes*)	G.31 G.50

Use # 2 and 3 :

Categories	**Matrix wording**	**Code for product**
User category	Professional	A.30
Wood category	Softwood and Hardwood	B.10 / B.20
Wood product	Solid wood / Reconstituted solid wood	C.10 / C.11
Application aim - Field of use	Preventive treatment – Use class 1	D.40 E.10
Method of application and rate	Superficial application / brush/roller 1 L of undiluted product per 5 m^2 of wood surface area (200 g/m^2) Superficial application / spraying 1 L of undiluted product per 5 m^2 of wood surface area (200 g/m^2) Superficial application / dipping	F.10 F.11 F.14

	1 L of undiluted product per 5 m^2 of wood surface area (200 g/m^2)	
Target organisms	House longhorn beetle (*Hylotrupes bajulus*) Termites (genus *Reticulitermes*)	G.31 G.50

Use # 4 :

Categories	**Matrix wording**	**Code for product**
User category	Industrial	A.20
Wood category	Softwood and Hardwood	B.10 / B.20
Wood product	Solid wood / Reconstituted solid wood	C.10 / C.11
Application aim - Field of use	Preventive treatment – Use class 1	D.40 E.10
Method of application and rate	Superficial application / spraying 1 L of undiluted product per 5 m^2 of wood surface area (200 g/m^2) Superficial application / dipping 1 L of undiluted product per 5 m^2 of wood surface area (200 g/m^2) Flow coating 1 L of undiluted product per 5 m^2 of wood surface area (200 g/m^2)	F.11 F.14 F.12
Target organisms	House longhorn beetle (*Hylotrupes bajulus*) Termites (genus *Reticulitermes*)	G.31 G.50

2.2.5.3 Effects on target organisms, including unacceptable suffering

The target organisms ingest a small amount of the treated wood which, once ingested, results in death of the target pests. Lethality (knockdown) is the only recognised effect.

As the target organisms are invertebrates, animal welfare was not assessed.

2.2.5.4 Mode of action, including time delay

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

It should also be noted that permethrin may 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.

2.2.5.5 Efficacy data

The product to be registered, Rodical® InsectProtect, is the 10-fold dilution in water of the F15 concentrate composition. All testing for efficacy was performed on a 10% dilution of F15 concentrate and is therefore applicable for providing efficacy for Rodical® InsectProtect.
The comparison of F15 concentrate vs. Rodical® InsectProtect is provided in the confidential annex.

Experimental data on the efficacy of the biocidal product against target organism(s) Preventive use							
Wood preservative	Preventive wood preservation (Use Class 1)	F15 concentrate batch no. LAD 1014276	*Reticulitermes santonensis*(of European origin)	Brushing DIN EN 118:2013 and DIN EN 73:2014	10% dilution 200 g/m^2 Applied by brushing Tested on *Pinus sylvestris* 8 weeks	200g/m^2 did effectively protect wood against the attack by termites (5 replicates showed an attack rating of 1, one replicate showed an attack rating of 2).	*2014-4.1-8664-2 Te, PD Dr. H. J. Kunte and PD. Dr. R. Plarre, 2015*
Wood preservative	Preventive wood preservation (Use Class 1)	F15 concentrate batch no. LAD 1014276	*Hylotrupes bajulus*	EN 46-1 and EN 73:2014 Tested on *Pinus sylvestris*	10% dilution 166 g/m^2 applied by brushing 4 weeks	100% mortality effective against *Hylotrupes bajulus* after 4 weeks 89% survival of control organisms	*401/14/209F/a, Brunet and Paulmier, 2015*
Wood preservative	Preventive wood preservatio	F15 concentrate batch	*Hylotrupes bajulus*	EN 46-1 and EN 73:2014	10% dilution 200 g/m^2	100% mortality of *Hylotrupe*	*401/14/209F/b, Brunet and Paulmier, 2015*

	n (Use Class 1)	no. LAD 1014276		Tested on *Pinus sylvestris*	applied by brushing 4 weeks	*s bajulus* after 4 weeks 96% survival of control organisms	

Conclusion on the efficacy of the product
The product to be registered, Rodical® InsectProtect, is the 10-fold dilution in water of the F15 concentrate composition. All testing for efficacy was performed on a 10% dilution of F15 concentrate and is therefore applicable for providing efficacy for Rodical® InsectProtect. The comparison of F15 concentrate vs. Rodical® InsectProtect is provided in the confidential annex. Efficacy of the product for preventive treatment in use class 1 was demonstrated against termites (*Reticulitermes santonensis*) in an EN118 test and against *Hylotrupes bajulus* in two EN46-1 tests at a concentration of 200 g product/m^2 applied on softwood by brushing. See section 2.2.5.8 for a full evaluation of the label claims.

2.2.5.6 Occurrence of resistance and resistance management

There are no reported cases of development of resistance involving the use of permethrin in wood preservation.

2.2.5.7 Known limitations

No known limitations.

2.2.5.8 Evaluation of the label claims

Efficacy of the product in preventive treatment against *Hylotrupes bajulus* larvae was demonstrated in two tests according to EN46-1+EN73. According to the EN599-1 standard, the preventive effectiveness of the test substance is proven if 100% mortality is achieved at the end of the test for the treated samples. For each treated sample, 100% mortality was achieved after 4 weeks exposure. The product was tested at two application rates: 166 g/m^2 and 200 g/m^2 . Both were considereds effective against *Hylotrupes bajulus* larvae.

Efficacy of the product in preventive treatment against *Reticulitermes santonensis* (of European origin) was demonstrated in a test according to EN118+EN73. According to the EN599-1 standard, the preventive effectiveness of the test substance is proven if at most 1 of the replicates show a damage of rating >2 at the end of the test for the treated samples. 5 replicates showed an attack of damage rating of 1, the 6^{th} replicate showed a

damage rating of 2. The product tested at an application rate of 200 g/m^2 is considered as effective against *Reticulitermes santonensis* (of European origin).

Based on the results of the efficacy tests the minimum application rate for preventive efficacy is 200 g/m^2 of the RTU product (which is a 10% dilution of the F15 concentrate product used in the efficacy tests).

Preventive treatment by injection and curative treatment were also applied for in the original submission of the dossier. However, these uses were withdrawn at the request of the applicant.

2.2.5.9 Relevant information if the product is intended to be authorised for use with other biocidal product(s)

The product is not intended to be used with other biocidal product(s).

2.2.6 **Risk assessment for human health**

No toxicological test data are available on the product. Effects on human health are derived from information on the components. Active substance effects and critical concentrations are described in the permethrin assessment report (April 2014). Information on co-formulants are found on the ECHA dissemination website. Exposure modellings have been performed for worst case scenarios.

The concentration of the active substance permethrin in the product is 0.215% with a purity of minimum 93%. As the maximum purity is not specified, calculations for risk assessment purposes are made with the assumption of a 100% purity, so with a concentration of 0.215%.

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	The product is not classified for skin corrosion or irritation.
Justification for the value/conclusion	Classification is based upon CLP mixture rules. Two ingredients are classified as H315 but is present under limit of 10%. The pH of the formulation is not lower than 2.0 or higher than 13.5 and is therefore not considered to be corrosive to skin.
Classification of the product according to CLP	No classification for this endpoint.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	The product is not classified for eye irritation.
Justification for the value/conclusion	Classification is based upon CLP mixture rules. Three ingredients are classified as H319 but sum of the concentrations is present under limit of 10%. The pH of the formulation is not lower than 2.0 or higher than 13.5 and is therefore not considered to be corrosive to skin.
Classification of the product according to CLP	No classification for this endpoint.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	The product is not classified for respiratory tract irritation.
Justification for the conclusion	Classification is based upon CLP mixture rules. No ingredients are classified for this endpoint.
Classification of the product according to CLP	No classification for this endpoint.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	The product carries the phrase EUH208.
Justification for the value/conclusion	Classification is based upon CLP mixture rules. One ingredient (permethrin) is classified as H317. The concentration of this ingredient is under the limit for H317 (1%) but above the limit for EUH208 (0.1%).
Classification of the product according to CLP	The product carries the phrase EUH208: Contains permethrin. May produce an allergic reaction.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	The product is not classified for respiratory sensitization.
Justification for the value/conclusion	Classification is based upon CLP mixture rules. No ingredients are classified for this endpoint.
Classification of the product according to CLP	No classification for this endpoint.

Acute toxicity

Acute toxicity by oral/inhalation/dermal route

Value used in the Risk Assessment – Acute oral/inhalation/dermal toxicity	
Value	The product is not classified for acute oral/inhalation/dermal toxicity.

Justification for the selected value	Classification is based upon CLP mixture rules. Oral: one ingredients is classified for oral route as H302 (Cat.2), however its concentration is below the general cut-off value. Therefore, a calculation does not have to be made. Inhalation: two ingredients are classified for inhalation route as H332 (Cat. 3), however their concentrations are below the general cut-off value. Therefore, a calculation does not have to be made. Dermal: no ingredients are classified for dermal route
Classification of the product according to CLP	No classification for these endpoints.

STOT SE

Conclusion used in Risk Assessment – STOT SE	
Value/conclusion	The product is not classified for H336.
Justification for the value/conclusion	Classification is based upon CLP mixture rules. One ingredient is classified as H336. The concentration of this ingredients is under the limit of 20%
Classification of the product according to CLP	No classification for this endpoint.

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption	
Value(s)	Dermal absorption of permethrin is 3% according to the CAR of permethrin (2014). Information on dermal absorption from the mixture in the product is not available.
Justification for the selected value(s)	There are currently no testing requirements on mixtures regarding this endpoint. For the AR, an additional document on evaluation of dermal absorption and skin effects of permethrin is provided to the eCA. In this document, it is shown that the variation of the dermal absorption of permethrin is small, regardless of the type of formulation. An overview of studies is provided in the report. Several type of formulations and solutions of permethrin in solvents were used and all conclude the dermal absorption for humans is never higher than a few %. Although the product formulation of Rodical® InsectProtect is a water-based formulation that contains additional co-formulants, the concentration of each co-formulant is relatively low. The product is a ready-for-use formulation which mainly consists of water (see full composition in conf. annex.) In the AR a dermal absorption value of 3% was derived based on a human volunteer study in which a solvent based formulation was used. In general, solvent-based formulantions have a higher dermal absorption value compared to water-based formulations. The formulation and the co-formulants present in the formulation are not classified as skin irritants. Therefore, conclusions made from the results presented in

	the report on dermal absorption and skin effects of permethrin provided to the eCA can be used to derive a worst case dermal absorption for permethrin for the product Rodical® InsectProtect. The rate of absorption is generally inversely related to the concentration of the active substance. However, based on the available data provided to the eCA there was no relationship between the rate of absorption and the dose applied for permethrin. A pro-rata correction is therefore not considered necessary for the current application. The rate of absorption was found to be different among the test species used. Several studies performed in rat indicated that up to 46% of the dose applied is dermally absorbed. Moreover, when dermal absorption was compared between rat skin and human skin in an in vitro assay it appeared that the rate of absorption in human skin is about 10-fold less than in rat skin. This difference between man and rat was confirmed in several clinical studies. By appling triple pack approach, the dermal absorption of up to 46% in rat is corrected to 4.6% for human.All in all, a worst case value was determined based on the available data on substance level. Based on the combined information available from CAR, EFSA guidance and additional data presented in the report it can be concluded that the worst case value for dermal absorption of permethrin is 5%. This value is used for risk assessment in this PAR. For the substances of concern, a default value of 50% absorption is considered for water based formulations (containing < 5% of the substance) according to the EFSA guidance on dermal absorption (2017).

eCA note: The read-across was not accepted during the commenting phase. Therefore the calculations are adjusted to the default value of 50% absorption for water based formulations (containing < 5% of the substance) according to the EFSA guidance on dermal absorption (2017).

Available toxicological data relating to non active substance(s) (i.e. substance(s) of concern)

In order to identify the relevant substances of concern (SoC), the European Commision's Note on 'Substances of Concern – proposed human health (toxicology) assessment scheme for authorisation of biocidal products (CA-Nov14-Doc.5.11)' is followed.

A substance is identified as a SoC when it is taken into consideration for certain classification fo the product according to CLP, Article 11(2) (criterion 1).
Substances for which Community workplace exposure limits are available, are also identified as SoC (criterion 5). Also ingredients that are active substances for Product Types other than the one under consideration (criterion 2), synergists and substances that have been included on the candidate list (REACH regulation) are regarded as SoC .

Based on criterion 1, no ingredients are identified as SoC as the product has no human health hazard classification except for EUH208. Based on criterion 5, the co-formulants Propan-2-ol and (2-methoxymethylethoxy)propanol are identified as a SoC. In addition, propan-2-ol can be categorised as SoC-criterion 2. The substance is present at >0.1% concentration in this formulation and is an approved active substance under BPR.

According to the EU SoC guidance (CA-Nov14-Doc.5.11) SoCs are categorised in different Bands. Band C includes SoCs which trigger products to be classified for repeated dose toxicity, lactation effects and/or carcinogenicity, mutagenicity or reprotoxicity in the lowest category. Also SoC with Workplace Exposure Limits or active substances under BPR are included in this band. For SoCs included in band C, a fully quantitative risk assessment is needed. The co-formulants Propan-2-ol (IPA) and (2-methoxymethylethoxy)propanol (DMP) are identified as a SoC in band C as they have a workplace exposure limit for inhalation exposure, and propan-2-ol is also an approved active substance under BPR. The inhalation exposure towards these substances during the use of the product will be estimated for each use and compared with the existing workplace limit.

An overview on the SoCs is given in the table below.

	Identification substances of concern	CAS	Concentration (%)	Classification 1272/2008 (CLP)	Band	WPL	AEL short/med./long term (mg/kg bw)
1	propan-2-ol	67-63-0	0.2	H225, flamm. liquid 2 H319, eye irrit. 2 H336, STOT 3, narcosis	C	TWA: 200 ppm STEL: 400 ppm	10.7 (general population) 17.9 (professional user)
2	(2-methoxymethylethoxy)propanol	34590-94-8	2	none	C	TWA8h: 308 mg/m^3 With "skin" notation	51.3* (long term)

*A systemic AEL can be derived from the SCOEL value of 2-methoxymethylethoxy)propanol. For (2-methoxymethylethoxy)propanol a worker exposure limit of 308 mg/m^3 (50 ppm) 8h-TWA value based on systemic effects (neurotoxicity) and a skin notation were set by the Scientific Committee for Occupational Exposure Limits (SCOEL/SUM/45; 1993). The SCOEL value can be converted to the systemic AEL as following:

308 mg/m^3 × 1.25 m^3/hour ×8 hours/day × 100% absorption
= 3080 mg/person/day
= 51.3 mg/kg bw/day for a person of 60 kg

The systemic AEL of 51.3 mg/kgbw /day will be used in the risk assessment for (2-methoxymethylethoxy)propanol in this PAR.

Available toxicological data relating to a mixture

There are no toxicological test data available on the mixtures.

Other

Assessment for endocrine disrupting properties for non-active substances

According to the ED (endocrine disruptor) criteria with respect to humans established in the Comission Delgated Regulation (EU) 2017/2100, a substance shall be considered as having endocrine disrupting properties if it meets all of the following criteria:

a) it shows an adverse effect in [an intact organism or its progeny]/[non-target organisms], which is a change in the morphology, physiology, growth, development, reproduction or life span of an organism, system or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress or an increase in susceptibility to other influences;
b) it has an endocrine mode of action, i.e. it alters the function(s) of the endocrine system;
c) the adverse effect is a consequence of the endocrine mode of action.

To examine if any of the co-formulants contained in the product may possess ED properties, a screening was performed by examining whether the co-formulants are

- Classified as CMR or PBT;
- Identified as ED in the DG Santé's Impact Assessment study on Screening of available evidence on chemical substances for the identification of endocrine disruptors;
- Identified as ED in the EU list of potential endocrine disruptors; or
- Listed in CoRAP linked to ED concerns.

Subsequently, it was examined if there are any concerns for adverse effects to meet the critaria a.

From this criteria ED screening was performed by NL CA for co-formulants contained in Rodical® InsectProtect. For none co-formulant (see confidential Annex), an ED concern has been raised. Therefore ED potency of co-formulants was not examined further.

2.2.6.2 Exposure assessment

The product is intended for **industrial, professional and non-professional** use. It can be used in different wood treatment applications:

- low pressure spraying
- brushing
- injection
- manual dipping
- flow coating (only industrial/professional users)

Professional and non-professional users can get exposed during loading and during application of the product. The most relevant primary exposure routes are inhalation and dermal exposure. Primary oral exposure is not considered to be relevant for adult users.

As exposure during low pressure spraying and brushing application is assumed to be a worse case than during injection, application during injection is not considered in this risk assessment.

Post-application exposure of (non-)professional users can occur during cleaning of equipment such as sprayers and brushes. Also the sanding of treated wooden structures can lead to post-application exposure, for professionals as well as non-professionals.

Several post-application scenarios are relevant for the general public. Inhalation, dermal and oral exposure are possible.

Identification of main paths of human exposure towards active substance(s) and substances of concern from its use in biocidal product

Summary table: relevant paths of human exposure							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Industrial use	**Professional use**	**Non-professional use**	**Industrial use**	**Professional use**	**General public**	**Via food**
Inhalation	yes	yes	yes	n.a.	yes	yes	n.a.
Dermal	yes	yes	yes	n.a.	yes	yes	n.a.
Oral	no	no	no	n.a.	no	Yes (children)	n.a.

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
1.	Flow coating (deluge)	Primary exposure, Flow coating (deluge)	Industrial users
2.	Loading	Primary exposure. The user loads the product in a container or a spraying device.	Industrial, professionals, non-professionals (inhalation, dermal)
3.	Application: spraying	Primary exposure. The user applies the product on the to be treated wooden surface by low pressure spraying	Industrial, professionals, non-professionals (inhalation, dermal)
4	Application: brushing	Primary exposure. The user applies the product on the to be treated wooden surface by brushing	Industrial, professionals, non-professionals (inhalation, dermal)
	Application: injection	Primary exposure. A professional user applies the product on the to be treated wood by injection. *Assumed to be not worst case, so not assessed.*	Industrial, professionals, non-professionals (inhalation, dermal)
5	Application: manual dipping	Primary exposure. A professional user applies the product on the to be treated wood by manual dipping of objects in the product.	Industrial, professionals , non-professionals (inhalation, dermal)
6	Post-application: cleaning of equipment	Primary exposure. The user cleans the spraying or brushing equipment used.	Professionals, (dermal)
7	Post-application: handling of treated wood	Primary exposure. A professional handles treated wood.	Professionals, non-professionals (dermal)
8	Post-application: sanding of treated wood	Secondary exposure. A professional or non-professional sands treated wood.	Professionals, non-professional (dermal, inhalation)
9	Post-application: inhalation of volatilized residues	A person is exposed to the product by inhalation of volatilized residues in the air.	General public, chronic inhalation exposure

10	Post-application: chewing wood off-cut	An infant chews on a wood off-cut that had been treated with the product.	General public (infant), acute oral exposure
11	Post-application: playing on playground structure outdoors and mouthing	A child is dermally and orally exposed while playing on a treated playground structure	General public (infant and child), chronic exposure

Industrial exposure

Description of Scenario 1		
During automated flow coating (deluge), wood is passed through an enclosed tunnel where a wood preservative is sprayed on the timber. Due to its contained nature, operator exposure is expected to be low, and mainly constitutes handling freshly sprayed wood. Although there is no generic model available for automated flow coating, the professional dipping model is considered as a good approximation in assessing exposure from the deluge process (User Guidance, version 1, 2002, p. 47). Deluge processes are operated on a batch basis, assuming as a worst case one batch per day, with a duration of 60 minutes per event. The Dipping Model 1 is used to assess exposure of industrial users and includes dipping wooden articles, mixing/loading, handling wet articles and loading/unloading (based on values as reported in Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure. Dermal exposure to the SoC propan-2-ol was considered to be negligible compared to exposure via inhalation due to a very volatile nature of the substance. Therefore dermal exposure is not calculated. Inhalation exposure to propan-2-ol is calculated using ConsExpo.		
Tier 1	Parameters	Value
	Body weight user	60 kg (HEEG opinion 17 on default human factors)
	Weight fraction compound: -permethrin -propan-2-ol -(2-methoxymethylethoxy)propanol	 -0.2% -0.2% -2%
	Inhalation uptake fraction	1
	Dermal uptake	50% permethrin 50% (SoC)
	Inhalation rate	0.021 m^3/min (default for an adult 1.25 m^3/h; conversion from /h to /min: 60)
	Indicative inhalation exposure	< 1 mg/m^3 (HEadhoc recommendation 6)
	Indicative dermal exposure	Body: 178 mg/min (75th percentile dermal exposure, TNsG 2002, Dipping Model 1) For tier 1 calculations (without PPE), the actual exposure inside gloves will be converted to potential exposure (25.7 mg/min) using a multification factor of 100, following HEEG opinion 2 on Potential & Actual hand exposure

	Exposure duration	60 min (HEEG opinion 8)
Tier 2	PPE	Protection factor 90% for coverall. 25.7 mg product (actual hand exposure inside gloves)

Calculations for Scenario 1

Tier 1

Exposure – Inhalation = inhalation rate * indicative exposure value * exposure duration = 1.25 mg product

Exposure – Dermal = indicative exposure value * exposure duration = 164880 mg product (potential dermal exposure)

Uptake on the day of event – Inhalation = exposure * weight fraction compound / weight adult user

- Permethrin:
  0.00004 mg/kg bw/day

Uptake on the day of event – Dermal = (body exposure + hand exposure) * weight fraction compound * dermal uptake fraction / weight adult user

- Permethrin:
  2.748 mg/kg bw/day
- (2-methoxymethylethoxy)propanol:
  27.48 mg/kg bw/day

Tier 2

Exposure – Dermal = indicative exposure value * exposure duration = 2610 mg product (actualdermal exposure)

Uptake on the day of event – Dermal = (body exposure + hand exposure) * weight fraction compound * dermal uptake fraction / weight adult user

- Permethrin:
  0.04350 mg/kg bw/day
- (2-methoxymethylethoxy)propanol:
  2.037 mg/kg bw/day

Inhalation exposure to propan-2-ol and (2-methoxymethylethoxy)propanol

Due to the volatile nature of the 2 SoC, the inhalation exposure needs to be calculated by an alternative model, as the current Model (Dipping Model 1) is not appropriate to describe the exposure to such volatile compounds. The Consexpo models are deemed more relevant for volatiles substances. For all applications, it is considered that the model

'exposure to vapour: evaporation' is most suitable as this describes the release of substance from the surface of a product by the evaporation process and will lead to the highest amount of volatile substance available for inhalation exposure. In addition, the task and exposure duration for spraying is longer than for dipping. Therefore, the values obtained from scenario 3 are adopted (see full details under scenario 3).

Summary table: estimated systemic exposure from industrial uses						
Exposure scenario 1: Application by automated flow coating (deluge),	**Tier**	**Estimated external exposure (mg/m³)**	**Estimated inhalation uptake** (mg/kg/d)	**Estimated dermal uptake** (mg/kg/d)	**Estimated oral uptake**	**Estimated total uptake** (mg/kg/d)
Permethrin	1/no PPE	n.a.	0.00004	2.748	n.a.	2.748
	2/gloves and coverall	n.a.	0.00004	0.04350	n.a.	0.044
propan-2-ol	1/no PPE	43	0.91	n.a.	n.a.	0.91
	2/gloves	43	0.91	n.a.	n.a.	0.91
(2-methoxymethylethoxy)propanol	1/no PPE	3.7	0.077	27.48	n.a.	27.557
	2/gloves	3.7	0.077	2.037	n.a.	2.114

Professional exposure

Scenario 2: loading

The models used for the exposure estimations during the application of the product include a mixing and loading step. Therefore, a separate mixing and loading scenario is not worked out.

Scenario 3: application - spraying

Two models were taken into consideration for the exposure estimation for the professional spraying application:

- Spraying model 2, TNsG 2002 (p. 143)

Both models include mixing and loading liquid (and powder) insecticides in compression sprayers or dusting applicators, and applying by low pressure spraying, indoors and outdoors, overhead and downwards.

The models cover scenario 2 and 3.

To take into account the worst case situation, calculations were made with the highest indicative exposure values, from the TNsG Spraying model 2.

Description of Scenario 3		
A professional user applies the product on the to be treated wooden surface by medium pressure spraying (4-7 bar). The professional user spends maximum 40 minutes per application on the spraying of wood preservative and usually performs 2 applications per day, resulting in a total exposure duration of 80 minutes per day. The dermal and inhalation exposures are estimated. Oral exposure is not relevant for professional users. Dermal exposure to a SoC propan-2-ol was considered to be negligible compared to exposure via inhalation due to a very volatile nature of the substance. Therefore dermal exposure is not calculated. Inhalation exposure to propan-2-ol is calculated using ConsExpo.		
	Parameters	Value
Tier 1	Body weight	60 kg (HEEG opinion 17 on default human factors)
	Weight fraction compound: -permethrin -propan-2-ol -(2-methoxymethylethoxy)propanol	 -0.2% -0.2% -2%
	Dermal uptake	50% permethrin 50% (SoC)
	Inhalation uptake fraction	1
	Inhalation rate	0.021 m^3/min (default for an adult 1.25 m^3/h; conversion from /h to /min: 60)
	Indicative inhalation exposure	76 mg/m^3 (75^{th} percentile, TNsG 2002, Spraying model 2)
	Indicative dermal exposure	222 mg/min (body, 75th percentile dermal exposure, TNsG 2002, Spraying model 2) 273 mg/min (hand exposure no gloves, TNsG 2002, Spraying model 2)
	Exposure/spray duration	2x 40 = 80 min (HEAdhoc Recommendation no 6)
Tier 2	PPE	Protection factor 90% for coverall. 7.8 mg/min (hand exposure inside gloves, TNsG 2002, Spraying model 2)

Calculations for Scenario 3

Tier1

Exposure – Inhalation = inhalation rate * indicative exposure value * exposure duration = 127 mg product

Exposure – Dermal = indicative exposure value * exposure duration = 39600 mg product (potential dermal exposure)

Uptake on the day of event – Inhalation = exposure * weight fraction compound / weight adult user

- Permethrin:
  0.0042 mg/kg

Uptake on the day of event – Dermal = (body exposure * + potential hand exposure) * weight fraction compound * dermal uptake fraction / weight adult user

- Permethrin:
  0.660 mg/kg bw/day
- (2-methoxymethylethoxy)propanol:
  6.60 mg/kg bw/day

Tier2

Exposure – Dermal = indicative exposure value * exposure duration = 2400 mg product (actualdermal exposure)

Uptake on the day of event – Dermal = (body exposure * + actual hand exposure inside gloves) * weight fraction compound * dermal uptake fraction / weight adult user

- Permethrin:
  0.040 mg/kg bw/day
- (2-methoxymethylethoxy)propanol:
  3.064 mg/kg bw/day

Inhalation exposure to propan-2-ol and (2-methoxymethylethoxy)propanol

Due to the volatile nature of the 2 SoC, the inhalation exposure needs to be calculated by an alternative model, as the current Model (Spraying Model 2) is not appropriate to describe the exposure to such volatile compounds. The Consexpo models are deemed more relevant for volatiles substances. For all applications, it is considered that the model 'exposure to vapour: evaporation' is most suitable as this describes the release of substance from the surface of a product by the evaporation process and will lead to the highest amount of volatile substance available for inhalation exposure.

For PT8 indoor spray application, there are no values presented in the harmonized scenarios for room surface or volume to be treated. The ESD for PT8 also does not refer to indoor spraying treatment as scenario. The ESD for PT18 is consulted, where indoor surface spray application is described:

According to Consexpo software, default volume for a living room is 58 m^3. Although a unique default value might not be relevant for all types of applications, in this scenario this volume has been chosen as a default value (58 m^3). This value is quite consistent with the value in Expofacts (http://cem.jrc.it/expofacts/) where the mean volume of a room in EU countries is around 60 m^3.

For the typical surface of a room, different values have been found. From the extraction of the Consexpo database (Bremmer et al. 2006) and according to the technical note for guidance on human exposure: surface for a room = 22 m^2. This value will be used in the present document for general spray applications. This value is quite consistent with database of Expofacts, where the mean room area is around 24 m^2.

These values for room size & area are taken into account. Given that the maximum application rate is 300 g/m^2 of diluted product, the total amount of product used would be 6600 g when the entire room surface area would be treated at this rate. The release area will be set equal to the treated surface area.

All settings for inhalation exposure during spray application are indicated below:

Inhalation

Label	Value
Exposure model	Exposure to vapour - Evaporation
Exposure duration	80 minute
Product is substance in pure form	No
Molecular weight matrix	18 g/mol
The product is used in dilution	No
Amount of solution used	6600 g
Weight fraction substance (DPM)	2%
Weight fraction substance (IPA)	0.2%
Room volume	58 m³
Ventilation rate	0.6 per hour
Inhalation rate	1.25m³/hr
Application temperature	22°C
Vapour pressure (DPM)	60 Pa
Vapour pressure (IPA)	5780 Pa
Molecular weight (DPM)	148 g/mol
Molecular weight (IPA)	60.09 g/mol

Mass transfer coefficient	10m/hr
Release area mode	Constant
Release area	22 m²
Emission duration	80 minute
Absorption model	Fixed fraction
Absorption fraction	1

* DPM: (2-methoxymethylethoxy)propanol ; IPA: propan-2-ol

Summary table: estimated systemic exposure from professional uses						
Exposure scenario 3: application by spraying	**Tier/PPE**	**External inhalation uptake (mg/m³)**	**Estimated inhalation uptake** (mg/kg/d)	**Estimated dermal uptake** (mg/kg/d)	**Estimated oral uptake**	**Estimated total uptake** (mg/kg/d)
Permethrin	1/no PPE	n.a.	0.0042	0.660	n.a.	0.664
	2/gloves and coverall	n.a.	0.0042	0.040	n.a.	0.044
propan-2-ol	1/no PPE	45	1.2	n.a.	n.a.	1.2
	2/gloves	45	1.2	n.a.	n.a.	1.2
(2-methoxymethylethoxy)propanol	1/no PPE	4.0	0.11	6.60	n.a.	6.71
	2/gloves	4.0	0.11	3.064	n.a.	3.174

Scenario 4: application - brushing

For the exposure estimation in this application scenario BfR study (Summary Report - Human Exposure to Wood Preservatives, Lingk, W.; Reifenstein, H.; Westphal, D.; Plattner, E., BfR Wissenschaft, 2006was used.

Description of Scenario 4		
A professional user applies the product on the to be treated wooden surface by brushing. A maximum exposure duration of 240 minutes was taken into account. The dermal and inhalation exposures are estimated. Oral exposure is not relevant for professional users. Expoure is based on Summary Report - Human Exposure to Wood Preservatives, Lingk, W.; Reifenstein, H.; Westphal, D.; Plattner, E., BfR Wissenschaft, 2006 Dermal exposure to a SoC propan-2-ol was considered negligible compared to exposure via inhalation due to a very volatile nature of the substance. Therefore dermal exposure is not calculated. Inhalation exposure to propan-2-ol is calculated using ConsExpo.		
Tier 1	Parameters	Value
	Body weight	60 kg (HEEG opinion 17 on default human factors)
	Weight fraction compound: -permethrin -propan-2-ol -(2-methoxymethylethoxy)propanol	 -0.2% -0.2% -2%
	Dermal absorption	50% (permethrin) 50% (SoC)
	Inhalation rate	0.021 m^3/min (default for an adult 1.25 m^3/h; conversion from /h to /min: 60)
	Indicative inhalation exposure	Inhalation exposure: Inhalation (non-volatile compounds): 0.0016 mg/m2
	Indicative dermal exposure	Indicative values normalized to 1 % active substance: Dermal exposure: Hands: 0.5417 mg/m2 Body: 0.2382 mg/m2 Exposure duration: 240 min Application area : 31.6 m2
	Exposure/spray duration	240 min

Calculations for Scenario 4

<u>See Annex 3.2 for calculations for permethrin</u>

- (2-methoxymethylethoxy)propanol:

0.912 mg/kg bw/day

Inhalation exposure to propan-2-ol (IPA) and (2-methoxymethylethoxy)propanol

Due to the volatile nature of the 2 SoC, the inhalation exposure needs to be calculated by an alternative model, as the current Model (Consumer Painting Model 3) is not appropriate to describe the exposure to such volatile compounds. The Consexpo models are deemed more relevant for volatiles substances. For all applications, it is considered that the model 'exposure to vapour: evaporation' is most suitable as this describes the release of substance from the surface of a product by the evaporation process and will lead to the highest amount of volatile substance available for inhalation exposure.

For PT8 indoor brush application, there are no values presented in the harmonized scenarios for room surface or volume to be treated. The ESD for PT8 also does not refer to indoor brushing treatment as scenario. The ESD for PT18 is consulted, where indoor surface spray application is described:

> According to Consexpo software, default volume for a living room is 58m3. Although a unique default value might not be relevant for all types of applications, in this scenario this volume has been chosen as a default value (58 m3). This value is quite consistent with the value in Expofacts (http://cem.jrc.it/expofacts/) where the mean volume of a room in EU countries is around 60m3.
>
> For the typical surface of a room, different values have been found. From the extraction of the Consexpo database (Bremmer et al. 2006) and according to the technical note for guidance on human exposure: surface for a room = 22 m2. This value will be used in the present document for general spray applications. This value is quite consistent with database of Expofacts, where the mean room area is around 24 m2.

Although brushing treatment may differ from spray treatment, the same settings for type of room can be taken over. The values for room size & area from the PT18 spray treatment scenario are taken into account. Given that the maximum application rate is 300 g/m2 of diluted product, the total amount of product used would be 6600 g when the entire room surface area would be treated at this rate.
The main difference will be the required time to perform the treatment), as treatment by brushing is slower than spraying (i.e. 240 min for brushing treatment vs. 80 min for spraying.

All settings for inhalation exposure during brush application are indicated below:

Inhalation

Label	Value
Exposure model	Exposure to vapour - Evaporation
Exposure duration	240minute
Product is substance in pure form	No
Molecular weight matrix	18 g/mol

The product is used in dilution	No
Amount of solution used	6600 g
Weight fraction substance (DPM)	2%
Weight fraction substance (IPA)	0.2%
Room volume	58 m³
Ventilation rate	0.6 per hour
Inhalation rate	1.25 m³/hr
Application temperature	22°C
Vapour pressure (DPM)	60 Pa
Vapour pressure (IPA)	5780 Pa
Molecular weight (DPM)	148 g/mol
Molecular weight (IPA)	60.1 g/mol
Mass transfer coefficient	10 m/hr
Release area mode	Constant
Release area	22 m²
Emission duration	240minute
Absorption model	Fixed fraction
Absorption fraction	1

* DPM: (2-methoxymethylethoxy)propanol ; IPA: propan-2-ol

Summary table: estimated systemic long-term exposure from professional uses						
Exposure scenario 4: **Application by brushing**	**Tier**	**External inhalation exposure (mg/m3)**	**Estimated inhalation uptake** (mg/kg/d)	**Estimated dermal uptake** (mg/kg/d)	**Estimated oral uptake**	**Estimated total uptake** (mg/kg/d)
Permethrin	1/no PPE	n.a.	0.0002	0.0041	n.a.	0.0412
propan-2-ol	1/no PPE	41	3.4	n.a.	n.a.	3.4
(2-methoxymethylethoxy)propanol	1/no PPE	4.5	0.37	0.912	n.a.	1.282

Scenario 5: application – manual dipping

The exposure during this application scenario was estimated by using the indicative values of TNsG Dipping Model 1 (following HEadhoc recommendation 6).

Description of Scenario 5		
A professional user applies the diluted product on the to be treated wooden surface by manual dipping of the objects into the product. Following the HEEG opinion 8, an exposure duration of 30 minutes per day is reasonable. The dermal and inhalation exposures are estimated. Oral exposure is not relevant for professional users. Dermal exposure to the SoC propan-2-ol was considered negligible compared to exposure via inhalation due to a very volatile nature of the substance. Therefore dermal exposure is not calculated. Inhalation exposure to propan-2-ol is calculated using ConsExpo.		
Tier 1	Parameters	Value
	Body weight user	60 kg (HEEG opinion 17 on default human factors)
	Weight fraction compound: -permethrin -propan-2-ol -(2-methoxymethylethoxy)propanol	(diluted concentration) -0.2% -0.2% -2%
	Inhalation uptake fraction	1
	Dermal uptake	50% (permethrin) 50% (SoC)
	Inhalation rate	0.021 m^3/min (default for an adult 1.25 m^3/h; conversion from /h to /min: 60)
	Indicative inhalation exposure	< 1 mg/m^3 (HEAdhoc recommendation 6)
	Indicative dermal exposure	Body: 178 mg/min (75th percentile dermal exposure, TNsG 2002, Dipping Model 1) 25.7 mg/min (max.actual hand exposure inside gloves, TNsG 2002, Dipping model 4) Hand: 2570 mg/min For tier 1 calculations (without PPE), the actual exposure inside gloves will be converted to potential exposure using a multification factor of 100, following HEEG opinion 2 on Potential & Actual hand exposure
	Exposure duration	30 min (HEEG opinion 8)

Tier 2	PPE	Protection factor 90% for coverall. 25.7 mg/min (actual hand exposure inside gloves)

Calculations for Scenario 5

Tier 1

Exposure – Inhalation = inhalation rate * indicative exposure value * exposure duration = 0.63 mg product

Exposure – Dermal = indicative exposure value * exposure duration = 82440 mg product (potential dermal exposure)

Uptake on the day of event – Inhalation = exposure * weight fraction compound / weight adult user

- Permethrin:
  0.00001 mg/kg bw/day

Uptake on the day of event – Dermal = (body exposure + hand exposure) * weight fraction compound * dermal uptake fraction / weight adult user

- Permethrin:
  1.374 mg/kg bw/day
- (2-methoxymethylethoxy)propanol:
  13.74 mg/kg bw/day

Tier 2

Exposure – Dermal = indicative exposure value * exposure duration = 1305 mg product (actualdermal exposure)

Uptake on the day of event – Dermal = (body exposure + hand exposure) * weight fraction compound * dermal uptake fraction / weight adult user

- Permethrin:
  0.02175 mg/kg
- (2-methoxymethylethoxy)propanol:
  1.019 mg/kg bw/day

Inhalation exposure to propan-2-ol and (2-methoxymethylethoxy)propanol

Due to the volatile nature of the 2 SoC, the inhalation exposure needs to be calculated by an alternative model, as the current Model (Dipping Model 1) is not appropriate to describe the exposure to such volatile compounds. The Consexpo models are deemed more relevant for volatiles substances. For all applications, it is considered that the model 'exposure to vapour: evaporation' is most suitable as this describes the release of substance from the surface of a product by the evaporation process and will lead to the highest amount of volatile substance available for inhalation exposure. In addition, the task and exposure duration for spraying is longer than for dipping. Therefore, the values obtained from scenario 3 are adopted (see full details under scenario 3).

Summary table : estimated systemic exposure from professional uses						
Exposure scenario 5: **Application by manual dipping**	**Tier**	**External inhalation exposure (mg/m³)**	**Estimated inhalation uptake** (mg/kg/d)	**Estimated dermal uptake** (mg/kg/d)	**Estimated oral uptake**	**Estimated total uptake** (mg/kg/d)
Permethrin	1/no PPE	n.a.	0.00001	1.374	n.a.	1.374
	2/gloves and coverall	n.a.	0.00001	0.0212	n.a.	0.022
propan-2-ol	1/no PPE	36	0.38	n.a.	n.a.	0.38
	2/gloves	36	0.38	n.a.	n.a.	0.38
(2-methoxymethylethoxy)propanol	1/no PPE	2.8	0.03	13.74	n.a.	13.77
	2/gloves	2.8	0.03	1.0185	n.a.	1.0485

Scenario 6: post-application – cleaning of equipment

Description of Scenario 6
The professional user is exposed to the product during cleaning of used equipment (sprayer or brushes). The equipment will be washed out under running water. According to HEEG Opinion 11 (2010), brushes used to apply water-based solutions are often cleaned under a running tap; the running water washing both the paint from the brush and any contamination from the hands. It is therefore concluded that exposure during the cleaning of brushes after applying Rodical Insect Protect is negligible. A similar cleaning procedure is likely to be used for spraying equipment, also resulting in a negligible level of exposure. .

Scenario 7: post-application – handling of treated wood

Description of Scenario 7		
An adult user handles treated wooden objects and is dermally exposed to the product. Exposure to propan-2-ol or (2-methoxymethylethoxy)propanol is not considered due to the high volatility of the substance, i.e. no significant amount of the substance will be present anymore post-treatment. Highly volatile substances will have evaporated during the treatment or shortly after the treatment of the wood. Any exposure after the treatment has been performed (and the wood has been left to dry) is considered negligible for such substances.		
Tier 1	Parameters	Value
	Body weight user	60 kg (adult, HEEG opinion 17 on default human factors)
	Weight fraction compound: -permethrin	 -0.200%
	Application rate product	300 g/m^2 (equal to 30 mg/cm^2)
	Surface area hands	820 cm^2 (adult, HEEG opinion 17 on default human factors)
	Surface of hands contaminated	20% (User guidance v1, p 56)
	Transfer efficacy from wood	2% (TNsG 2002, page 206)
	Dermal absorption	50% (permethrin)

Calculations for Scenario 7

see Annex 3.2 for calculation

Summary table: estimated systemic exposure from professional uses					
Exposure scenario 7: handling of treated wood	**Tier**	**Estimated inhalation uptake**	**Estimated dermal uptake** (mg/kg)	**Estimated oral uptake**	**Estimated total uptake** (mg/kg)
Permethrin	1/no PPE	n.a.	0.164	n.a.	0.164

Scenario 8: post-application – sanding of treated wood

The exposure in this post-application scenario is estimated by using the example scenario for the sanding of treated wood posts, described in the TNsG 2002, part 3 (p. 50).

Description of Scenario 8		
A professional worker is exposed to the product via dermal and inhalative route during sanding of treated wood. In a first tier scenario a professional adult is sanding for 6 hours per working day. The active substances are fixed in the outer 1 cm layer of treated wooden posts (4 x 4 x 250 cm) to be used for an outdoor play area (scenario from TNsG 2002, Part 3, p. 50). The active substances are in the outer 1 cm of the wood and as a worst-case, retention in the wood is assumed to be 100%. Exposure to propan-2-ol (IPA) or (2-methoxymethylethoxy)propanol (DMP) is not considered due to the volatility of the substance, i.e. no significant amount of the substance will be present anymore post-treatment. Highly volatile substances will have evaporated during the treatment or shortly after the treatment of the wood. Any exposure after the treatment has been performed (and the wood has been left to dry) is considered negligible for such substances. Nevertheless, exposure values are given as a theoretical worst case.		
Tier 1	Parameters[1]	Value
	Body weight user	60 kg (HEEG opinion 17 on default human factors)
	Weight fraction compound: -permethrin	-0.2%
	Dermal uptake	50% (permethrin)
	Application rate product	300 g/m^2 (highest treatment quantity) (equal to 0.0864 mg permethrin/cm3)
	Retention in wood	100 % (worst case)
	Layer thickness	1 cm (TNsG 2002, Part 3, p. 50)
	Volume wooden post	4000 cm^3 (TNsG 2002, Part 3, p. 50)
	Treated volume wooden post	3008 cm^3 (calculation)
	Dermal exposed area	410 cm^2 (= 2 hands, one side, HEEG opinion 17, 2013)
	Fraction of skin contaminated	20% (User Guidance version 1, p. 56)
	Transfer efficiency	2% for rough-sawn wood (TNsG 2002, part2, p. 204)
	Indicative value wood dust in air	5 mg/m^3 (Operator Exposure Limit (OEL) of the EU for respirable hardwood dust as worst-case)
	Task duration	6 hours

	Inhalation rate	1.25 m^3/h (HEEG opinion 17, 2013)
	Density of wood dust	400 mg/cm^3 (TAB-2017)

Calculations for Scenario 8

Application rate permethrin in the 1 cm outerlayer of a wood post is calculated as following:

The outersurface are of the post is 4x4 x2 +4x250 x 4 = 32 + 4000 = 4032 cm2.
300 g product/m2 x 0.4032 m2 x 0.215% permethrin= 260 mg permethrin is applied on the wood post.

Assuming this amount stays only on the outer 1 cm layer the application rate of the a.s. is 260 mg /3008 cm3 = 0.0864 mg/cm3

Dermal internal exposure on the day of event = concentration in 1 cm wood * dermal exposed area * fraction of skin contaminated* transfer efficiency * dermal uptake/body weight user

- Permethrin:
  $1.21x10^{-3}$ mg/kg bw/day

Inhalation exposure on the day of event = concentration in 1 cm wood * indicative value wood dust in air * task duration * inhalation rate / density of wood dust/body weight user

- Permethrin:
  $1.35x10^{-4}$ mg/kg bw/day

Exposure scenario 8	**Tier**	**Estimated inhalation uptake** (mg/kg/d)	**Estimated dermal uptake** (mg/kg/d)	**Estimated oral uptake** (mg/kg/d)	**Estimated total uptake** (mg/kg/d)
Permethrin	1	$1.35x10^{-4}$	$1.21x10^{-3}$	n.a.	0.0013

Combined scenarios

The same professional user can perform an application scenario and the cleaning of the equipment in sequence. However, as it is a water-based product exposure during cleaning is expected to result in a neglible level of exposure (see scenario 6).

Non-professional exposure

Exposure during the non-professional scenarios to permethrin is estimated by using the indicative values in the TNsG. For two SoCs ConsExpo was used to estimate inhalation exposure due to their high volatile nature.

Scenario 2: loading

As the product will be applied from can (packaging for no-prof up to 10L), no exposure is expected.

Scenario 3: application - spraying

For this application scenario, calculations were made with the Consumer Spraying and Dusting Model 3, TNsG 2002, in accordance with the CAR.

Description of Scenario 3		
A non-professional user applies the product on the to be treated wooden surface by low pressure spraying. The dermal and inhalation exposures are estimated. Oral exposure is not relevant in this scenario. Dermal exposure to a SoC propan-2-ol was considered to be negligible compared to exposure via inhalation due to a very volatile nature of the substance. Therefore dermal exposure is not calculated. Inhalation exposure to propan-2-ol is calculated using ConsExpo.		
	Parameters	Value
Tier 1	Body weight	60 kg (HEEG opinion 17 on default human factors)
	Weight fraction compound: -permethrin -propan-2-ol -(2-methoxymethylethoxy)propanol	 -0.2% -0.2% -2%
	Inhalation uptake fraction	1
	Dermal uptake	50% (permethrin) 50% (SoC)
	Inhalation rate	1.25 m^3/h (HEEG opinion 17, 2013)
	Indicative inhalation exposure	115 mg/ m^3
	Indicative dermal exposure	120 mg/min (75th percentile dermal exposure, TNsG 2002, Consumer Spraying and Dusting model 3) 176 mg/min (75th percentile hand exposure without gloves, TNsG 2002, Consumer Spraying and Dusting model 3)
	Exposure duration	180 min

Calculations for Scenario 3

Tier 1

Exposure – Inhalation = inhalation rate * indicative exposure value * exposure duration = 431 mg product

Exposure – Dermal = indicative exposure value * exposure duration =
21600 mg product (potential body exposure)
31680 mg product (potential hand exposure)

Uptake on the day of event – Inhalation = exposure * weight fraction compound / weight adult user

- Permethrin:
  0.0144 mg/kg bw/day

Uptake on the day of event – Dermal = (body exposure + hand exposure) * weight fraction compound * dermal uptake fraction / weight adult user

- Permethrin:
  0.888 mg/kg bw/day
- (2-methoxymethylethoxy)propanol:
  8.88 mg/kg bw/day

Inhalation exposure to propan-2-ol and (2-methoxymethylethoxy)propanol

Due to the volatile nature of the 2 SoC, the inhalation exposure needs to be calculated by an alternative model, as the current Model (Consumer Spraying and Dusting Model 3) is not appropriate to describe the exposure to such volatile compounds. The Consexpo models are deemed more relevant for volatiles substances. For all applications, it is considered that the model 'exposure to vapour: evaporation' is most suitable as this describes the release of substance from the surface of a product by the evaporation process and will lead to the highest amount of volatile substance available for inhalation exposure.

For PT8 indoor spray application, there are no values presented in the harmonized scenarios for room surface or volume to be treated. The ESD for PT8 also does not refer to indoor spraying treatment as scenario. The ESD for PT18 is consulted, where indoor surface spray application is described:

> According to Consexpo, default volume for a living room is 58 m^3. Although a unique default value might not be relevant for all types of applications, in this scenario this volume has been chosen as a default value (58 m^3). This value is quite consistent with the value in Expofacts (http://cem.jrc.it/expofacts/) where the mean volume of a room in EU countries is around 60 m^3.
>
> For the typical surface of a room, different values have been found. From the extraction of the Consexpo database (Bremmer et al. 2006) and according to the technical note for guidance on human exposure: surface for a room = 22 m^2. This value will be used in the present document for general spray applications. This value is quite consistent with database of Expofacts, where the mean room area is around 24 m^2.

These values for room size & area are taken into account. Given that the maximum application rate is 300 g/m2 of diluted product, the total amount of product used would be

6600 g when the entire room surface area would be treated at this rate. The release area will be set equal to the treated surface area.

All settings for inhalation exposure during spray application are indicated below:

Inhalation

Label	Value
Exposure model	Exposure to vapour - Evaporation
Exposure duration	180 minute
Product is substance in pure form	No
Molecular weight matrix	18 g/mol
The product is used in dilution	No
Amount of solution used	6600 g
Weight fraction substance (DPM)	2%
Weight fraction substance (IPA)	0.2%
Room volume	58 m³
Ventilation rate	0.6 per hour
Inhalation rate	1.25 m³/hr
Application temperature	22°C
Vapour pressure (DPM)	60 Pa
Vapour pressure (IPA)	5780 Pa
Molecular weight (DPM)	148 g/mol
Molecular weight (IPA)	60.1 g/mol
Mass transfer coefficient	10 m/hr
Release area mode	Constant
Release area	22 m²
Emission duration	180 minute
Absorption model	Fixed fraction
Absorption fraction	1

* DPM: (2-methoxymethylethoxy)propanol ; IPA: propan-2-ol

Summary table: estimated systemic exposure from non-professional uses						
Exposure scenario 3: application by spraying	**Tier/PPE**	**Estimated external exposure (mg/m³)**	**Estimated inhalation uptake** (mg/kg/d)	**Estimated dermal uptake** (mg/kg/d)	**Estimated oral uptake**	**Estimated total uptake** (mg/kg/d)
Permethrin	1/no PPE	n.a.	0.0144	0.888	n.a.	0.9
propan-2-ol	1/no PPE	43	2.7	n.a.	n.a.	2.7
(2-methoxymethylethoxy) propanol	1/no PPE	4.4	0.28	8.88	n.a.	9.16

Scenario 4: application - brushing

For this application scenario, calculations were made with the Consumer Painting Model 3, TNsG 2002

Description of Scenario 4		
A non-professional user applies the product on the to be treated wooden surface by brushing. The dermal and inhalation exposures are estimated. Oral exposure is not relevant. The exposure duration is 150 min (acc. to TNsG 2002 User Guidance – Version 1, p. 51 for non-professionals. Dermal exposure to a SoC propan-2-ol was considered negligible compared to exposure via inhalation due to a very volatile nature of the substance. Therefore dermal exposure is not calculated. Inhalation exposure to propan-2-ol is calculated using ConsExpo.		
Tier 1	Parameters	Value
	Body weight	60 kg (HEEG opinion 17 on default human factors)
	Weight fraction compound: -permethrin -propan-2-ol -(2-methoxymethylethoxy)propanol	 -0.20% -0.2% -2%
	Inhalation uptake fraction	1
	Dermal uptake	50% (permethrin) 50% (SoC)
	Inhalation rate	0.021 m^3/min (default for an adult 1.25 m^3/h; conversion from /h to /min: 60)
	Indicative inhalation exposure	4.16 mg/m^3 (75th percentile, TNsG 2002, Consumer product painting Model 3)
	Indicative dermal exposure	Body: 16.9 mg/min (75th percentile dermal exposure, TNsG 2002, Consumer product painting Model 3) Hand: 5.91 mg/min (75th percentile hand exposure without gloves, TNsG 2002, Consumer product painting Model 3)
	Exposure duration	150 min

Calculations for Scenario 4

Tier 1

Exposure – Inhalation = inhalation rate * indicative exposure value * exposure duration = 13 mg product

Exposure – Dermal = indicative exposure value * exposure duration =
3421 mg/product

Uptake on the day of event – Inhalation = exposure * weight fraction compound / weight adult user

- Permethrin:
  0.0004 mg/kg bw/day

Uptake on the day of event – Dermal = (body exposure * + hand exposure) * weight fraction compound * dermal uptake fraction / weight adult user

- Permethrin:
  0.057 mg/kg bw/day
- (2-methoxymethylethoxy)propanol:
  0.57mg/kg bw/day

Inhalation exposure to propan-2-ol and (2-methoxymethylethoxy)propanol

Due to the volatile nature of the 2 SoC, the inhalation exposure needs to be calculated by an alternative model, as the current Model (Consumer product Painting Model 3) is not appropriate to describe the exposure to such volatile compounds. The Consexpo models are deemed more relevant for volatiles substances. For all applications, it is considered that the model 'exposure to vapour: evaporation' is most suitable as this describes the release of substance from the surface of a product by the evaporation process and will lead to the highest amount of volatile substance available for inhalation exposure. The scenario is already performed in scenario 3, therefore, the values obtained from scenario 3 are adopted (see full details under scenario 3).

Summary table: estimated systemic long-term exposure from non-professional uses						
Exposure scenario 4: **Application by brushing**	**Tier**	**Estimated external exposure (mg/m³)**	**Estimated inhalation uptake** (mg/kg/d)	**Estimated dermal uptake** (mg/kg/d)	**Estimated oral uptake**	**Estimated total uptake** (mg/kg/d)
Permethrin	1/no PPE	n.a.	0.0004	0.057	n.a.	0.057
propan-2-ol	1/no PPE	43	2.7	n.a.	n.a.	2.7
(2-methoxymethylethoxy)propanol	1/no PPE	4.4	0.28	0.57	n.a.	0.85

Scenario 5: application – manual dipping

The exposure during this application scenario was estimated by using the indicative values of TNsG Dipping Model 1 (following HEadhoc recommendation 6).

Description of Scenario 5
A non-professional user can apply the diluted product on the wooden surface to be treated by manual dipping of the objects into the product. This will mainly concern small objects, such as small decorative timber pieces (which could be attacked by wood destroying insects). Following the HEEG opinion 8, an exposure duration of 30 minutes per day is assumed for manual dipping of fences, sheds or window frames. The objects for non-professionals will be smaller that the objects described in the professional manual dipping scenario, it is assumed the treatment by non-professional will not take longer than the duration for professionals. The dermal and inhalation exposures are estimated. Oral exposure is not relevant. Dermal exposure to a SoC propan-2-ol was considered negligible compared to exposure via inhalation due to a very volatile nature of the substance. Also by the time of cleaning propan-2-ol has already been evaporated from spraying equipment. Therefore no exposure to propan-2-ol is expected and thus not considered. The model and parameters used are identical to the Tier 1 calclaution of scenario 5 "application-manual dipping" for professionals. Therefore these are not repeated, and only the output is summarised in the table below.

Summary table: estimated systemic exposure from non-professional uses						
Exposure scenario 5	**Tier**	**External estimated exposure (mg/m³)**	**Estimated inhalation uptake** (mg/kg/d)	**Estimated dermal uptake** (mg/kg/d)	**Estimated oral uptake**	**Estimated total uptake** (mg/kg/d)
Permethrin	1/no PPE	n.a.	0.00001	1.374	n.a.	1.374
propan-2-ol	1/no PPE	36	0.38	n.a.	n.a.	0.38
(2-methoxymethylethoxy)propanol	1/no PPE	2.8	0.03	13.74	n.a.	13.77

Scenario 6: post-application – cleaning of equipment

Description of Scenario 6
For this non-professional post-application scenario, please refer to the professional users have been performed (scenario 6). : According to HEEG Opinion 11 (2010), brushes used to apply water-based solutions are often cleaned under a running tap; the running water washing both the paint from the brush and any contamination from the hands. It is therefore concluded that exposure during the cleaning of brushes after applying Rodical Insect Protect is negligible. A similar cleaning procedure is likely to be used for spraying equipment, also resulting in a negligible level of exposure.

Scenario 7: post-application – handling of treated wood

Description of Scenario 7		
A non-professional user handles treated wooden objects and is dermally exposed to the product. Exposure to propan-2-ol or (2-methoxymethylethoxy)propanolis not considered due to the volatility of the substance, i.e. no significant amount of the substance will be present anymore post-treatment. Highly volatile substances will have evaporated during the treatment or shortly after the treatment of the wood. Any exposure after the treatment has been performed (and the wood has been left to dry) is considered negligible for such substances.		
Tier 1	Parameters	Value
	Body weight user	60 kg (adult, HEEG opinion 17 on default human factors)
	Dermal uptake	50% (permethrin)
	Weight fraction compound: -permethrin	 -0.2%
	Application rate product	300 g/m^2 (equal to 30 mg/cm^2)
	Surface area hands	820 cm^2 (adult, HEEG opinion 17 on default human factors)
	Surface of hands contaminated	20% (User guidance v1, p 56)
	Transfer efficacy from wood	2% (TNsG 2002, page 206)

Calculations for Scenario 7

Summary table: estimated systemic exposure from non-professional uses					
Exposure scenario 7	**Tier**	**Estimated inhalation uptake**	**Estimated dermal uptake** (mg/kg)	**Estimated oral uptake**	**Estimated total uptake** (mg/kg)
Permethrin	1/no PPE	n.a.	0.164	n.a.	0.164

Scenario 8: post-application – sanding of treated wood

Calculations for this scenario are similar to the calculations in scenario 5 for professionals, only the task duration and use frequency are different. The exposure is based on the example scenario for the sanding of treated wood posts, described in the TNsG 2002, part 3 (p. 50).

Description of Scenario 8		
A non-professional worker is exposed to the product via dermal and inhalative route during sanding of treated wood. The adult is sanding for 1 hour per day. The active substances are fixed in the outer 1cm layer of treated wooden posts (4 x 4 x 250 cm) to be used for an outdoor play area (scenario from TNsG 2002, Part 3, p. 50). The active substances are in the outer 1 cm of the wood and as a worst-case, retention in the wood is assumed to be 100%. Exposure to propan-2-ol or (2-methoxymethylethoxy)propanol is not considered due to the volatility of the substance, i.e. no significant amount of the substance will be present anymore post-treatment. Highly volatile substances will have evaporated during the treatment or shortly after the treatment of the wood. Any exposure after the treatment has been performed (and the wood has been left to dry) is considered negligible for such substances.		
Tier 1	Parameters	Value
	Body weight user	60 kg (adult, HEEG opinion 17 on default human factors)
	Weight fraction compound: -permethrin	 -0.20%
	Inhalation uptake fraction	1
	Dermal uptake	50% (permethrin)
	Application rate product	300 g/m^2 (equal to 0.0864 mg permethrin/cm3, see scenario 8 professionals for the calculation)
	Retention in wood	100 % (worst case)
	Layer thickness	1 cm (TNsG 2002, Part 3, p. 50)
	Volume wooden post	4000 cm^3 (TNsG 2002, Part 3, p. 50)
	Treated volume wooden post	3008 cm^3 (calculation)
	Dermal exposed area	410 cm^2 (= 2 hands, one side, HEEG opinion 17, 2013)
	Fraction of skin contaminated	20% (User Guidance version 1, p. 56)
	Transfer efficiency	2% for rough-sawn wood (TNsG 2002, part2, p. 204)
	Indicative value wood dust in air	5 mg/m^3 (Operator Exposure Limit (OEL) of the EU for respirable hardwood dust as worst-case)
	Task duration	1 hour

	Inhalation rate	1.25 m^3/h (HEEG opinion 17, 2013)
	Density of wood dust	0.4 g/cm^3 (TAB)

Calculations for Scenario 8

Dermal internal exposure on the day of event = concentration in 1 cm wood * dermal exposed area * fraction of skin contaminated* transfer efficiency * dermal uptake/body weight user

- Permethrin:

  $1.2x10^{-3}$ mg/kg bw/day

Inhalation exposure on the day of event = concentration in 1 cm wood * indicative value wood dust in air * task duration * inhalation rate / density of wood dust/body weight user

- Permethrin:

  $2.25x10^{-5}$ mg/kg bw/day

Summary table: estimated systemic exposure from non-professional uses					
Exposure scenario 8	**Tier**	**Estimated inhalation uptake** (mg/kg/d)	**Estimated dermal uptake** (mg/kg/d)	**Estimated oral uptake**	**Estimated total uptake** (mg/kg/d)
Permethrin	1	2.25E-05	1.2E-03	n.a.	0.0012

Exposure of the general public

Scenario 9: post-application – inhalation of volatilized residues

The potential risk from inhalation exposure to volatilized residues of the product is estimated by following HEEG opinion 13 on volatilized inhalation exposure. Exposure to propan-2-ol or (2-methoxymethylethoxy)propanol is not considered due to the volatility of the substances, i.e. no significant amount of the substance will be present anymore post-treatment. Highly volatile substances will have evaporated during the treatment or shortly after the treatment of the wood. Any exposure after the treatment has been performed (and the wood has been left to dry) is considered negligible for such substances.

The first tier screening

Permethrin:

W = (P*V*M) / (R*T)
W is the amount of substance in 1m3 air (g)
P is the vapour pressure (Pa)

V is the volume of air (1m3)
M is the molecular weight (g/mol)
R is the gas constant (8.314 J/mol/K)
T is the temperature (K)
→ (2.2E-6 x 1 x 391.3) / 8.314 x (278 + 200) x 1000 = 3.47E-4 mg/m3

Systemic exposure:

	Daily inhalation rate (m3/day)	Body weight (kg)	Systemic exposure (mg/kg bw/day)
Infant	20.16	8	8.756E-04
Child	31.68	23.9	4.606E-04
Adult	30	60	1.737E-04

Scenario 10: post-application – chewing wood off-cut

The exposure estimation is based on the example scenario for chewing wood off-cut, described in the TNsG 2002, part 3 (p. 50).

Description of Scenario 10		
An infant chews on a wood off-cut that had been treated with the product. The child is orally exposed to the product. Exposure to propan-2-ol or (2-methoxymethylethoxy)propanol is not considered due to the volatility of the substance, i.e. no significant amount of the substance will be present anymore post-treatment. Highly volatile substances will have evaporated during the treatment or shortly after the treatment of the wood. Any exposure after the treatment has been performed (and the wood has been left to dry) is considered negligible for such substances		
Tier 1	Parameters	Value
	Body weight user	8 kg (HEEG opinion 17 on default human factors)
	Weight fraction compound: -permethrin	 -0.2%
	Application rate product	300 g/m^2 (equal to 0.0864 mg permethrin/ cm3)
	Retention in wood	100 % (worst case)
	Layer thickness	1 cm (TNsG 2002, Part 3, p. 50)
	Volume wooden post	4000 cm^3 (TNsG 2002, Part 3, p. 50)
	Treated volume wooden post	3008 cm^3 (calculation)
	Size wood chip	16 cm^3 (TNsG 2002, Part 3, p. 50)
	Extraction from wood	10%
	Oral absorption	100%

Calculations for Scenario 10

Oral internal exposure = amount in one wood chip * extraction from wood * oral absorption / body weight

- Permethrin:

  0.0864 mg/cm3 x 16 cm3 x 10% x 100%/ 8 kg = 0.017 mg/kg

Summary table: estimated short-term systemic exposure from the general public					
Exposure scenario 10	**Tier**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake** (mg/kg)	**Estimated total uptake** (mg/kg)
Permethrin	1	n.a.	n.a.	0.017	0.017

Scenario 11: post-application – playing on playground structure outdoors and mouthing

The exposure estimation is based on the example scenario for playing on playground structure outdoors (and mouthing), described in the TNsG 2002, part 3 (p. 50-51).

Description of Scenario 11		
A child plays on playground structures that are treated with the product. The child is dermally and orally (through mouthing) exposed. Exposure to propan-2-ol or (2-methoxymethylethoxy)propanol is not considered due to the volatility of the substance, i.e. no significant amount of the substance will be present anymore post-treatment. Highly volatile substances will have evaporated during the treatment or shortly after the treatment of the wood. Any exposure after the treatment has been performed (and the wood has been left to dry) is considered negligible for such substances		
Tier 1	Parameters	Value
	Body weight user	8 kg (infant, HEEG opinion 17 on default human factors)
	Weight fraction compound: -permethrin	 -0.2%
	Application rate product	300 g/m^2
	Surface area hands	196.8 cm^2 (HEEG opinion 17)
	Surface of hands contaminated	20% (User guidance v1, p 56)
	Transfer efficacy from rough-sawn wood	2% (TNsG 2002, part 2, p 204)
	Dermal uptake	50% (permethrin)
	Oral external exposure	= dermal external exposure (assuming 100% hand-to-mouth transfer)
	Oral absorption	100%

Calculations for Scenario 11

Dermal external exposure = application rate product * weight fraction compound * surface area hands * fraction of hands surface contaminated * transfer efficacy from rough-sawn wood = 0.0254 mg

Dermal internal exposure on the day of event = dermal external exposure * dermal absorption
/ body weight = 0.0015mg/kg

Oral internal exposure on the day of event = dermal external exposure * oral absorption

/ body weight = 0.0032 mg/kg

Summary table: estimated systemic exposure from the general public					
Exposure scenario 12	**Tier**	**Estimated inhalation uptake**	**Estimated dermal uptake** (mg/kg)	**Estimated oral uptake** (mg/kg)	**Estimated total uptake** (mg/kg)
Permethrin	1	n.a.	0.0015	0.0032	0.0047

Monitoring data

There are no monitoring data available for the product.

Dietary exposure
Food and feeding stuff will not be exposed to permethrin based on the proposed usage. The label will contain: 'Wash hands and exposed skin after use of the product and before meals. Keep away from food, drink or animal feedstuffs.'
Timber being treated is also not in direct contact with food/feed or drink as the following RMM is included "Do not use on surfaces or utensils likely to be in direct contact with food, feed, drinks and animals.'.
Therefore, no dietary exposure is foreseen for the product.

2.2.6.3 Risk characterisation for human health

The estimated exposure levels are compared with exposure limits for each relevant co-formulant in the product. Exposure levels for the active substance permethrin are compared to the AEL values described in the CAR. The exposure values of the SoC are also compared with the AEL values as described in the section on substances of concern (2.2.6.1).

Reference values to be used in Risk Characterisation

Reference	**Study**	**NOAEL (LOAEL)**	**AF[1]**	**Correction for oral absorption**	**Value**
Permethrin (adopted from CAR PT8 permethrin)					
AELshort-term	90 day inhalation rat study	59.46 mg/kg bw/day	100	-	0.5 mg/kg bw
AELmedium-term	one-year dog study	5 mg/kg bw	100	-	0.05 mg/kg bw
AELlong-term	one-year dog study	5 mg/kg bw	100	-	0.05 mg/kg bw
ARfD	0.5 mg/kg bw				
ADI	0.05 mg/kg bw				
(2-methoxymethylethoxy)propanol (recalculated from SCOEL,)					
AEL	recalculated from	308 mg/m3	-	-	51.3 mg/kg bw

	SCOEL value				
ARfD	Not applicable				
ADI	Not applicable				
2-propanol (adopted from CAR PT2 propan-2-ol (IPA))					
AELshort-term, professionals	Inhalation, Human volunteer study	68.2 mg/kg bw	3.8	-	17.9 mg/kg bw/d
AELmedium-term, professionals	Inhalation, Human volunteer study	68.2 mg/kg bw	3.8	-	17.9 mg/kg bw/d
AELlong-term, professionals	Inhalation, Human volunteer study	68.2 mg/kg bw	3.8	-	17.9 mg/kg bw/d
AELshort-term, non-professionals	Inhalation, Human volunteer study	68.2 mg/kg bw	6.4	-	10.7 mg/kg bw/d
AELmedium-term, non-professionals	Inhalation, Human volunteer study	68.2 mg/kg bw	6.4	-	10.7 mg/kg bw/d
AELlong-term, non-professionals	Inhalation, Human volunteer study	68.2 mg/kg bw	6.4	-	10.7 mg/kg bw/d
ARfD	Not applicable				
ADI	Not applicable				

* The SCOEL value of 2-methoxymethylethoxy)propanol can be converted to the systemic AEL as following:

308 mg/m^3 × 1.25 m^3/hour ×8 hours/day × 100% absorption
= 3080 mg/person/day
= 51.3 mg/kg bw/day for a person of 60 kg

Risk for industrial users

Systemic effects

Task/ Scenario	**Tier**	**Exposure limit**	**Exposure limit value** (mg/kg/d)	**Estimated uptake** (mg/kg/d)	**%AEL**	**Acceptable (yes/no)**

Scenario 1: application – flow coating						
Permethrin	1/none	$AEL_{long-term}$	0.05	2.748	5496	no
	2/gloves and coverall	$AEL_{long-term}$	0.05	0.044	87	yes
propan-2-ol	1/none	$AEL_{long-term}$	17.9	0.91	5	yes
	2/gloves	$AEL_{long-term}$	17.9	0.91	5	yes
(2-methoxymethylethoxy)propanol	1/none	$AEL_{long-term}$	51.3	27.557	54	yes
	2/gloves	$AEL_{long-term}$	51.3	2.114	4	yes

Risk for professional users

Systemic effects

Task/ Scenario	**Tier**	**Exposure limit**	**Exposure limit value** (mg/kg/d)	**Estimated uptake** (mg/kg/d)	**%AEL**	**Acceptable (yes/no)**
Scenario 3: application – spraying						
Permethrin	1/none	$AEL_{long-term}$	0.05	0.664	1328	no
	2/gloves and coverall	$AEL_{long-term}$	0.05	0.044	88	yes
propan-2-ol	1/none	$AEL_{long-term}$	17.9	1.2	7	yes
	2/gloves	$AEL_{long-term}$	17.9	1.2	7	yes
(2-methoxymethylethoxy)propanol	1/none	$AEL_{long-term}$	51.3	6.71	13	yes
	2/gloves	$AEL_{long-term}$	51.3	3.174	6	yes
Scenario 4: application – brushing						
Permethrin	1/none	$AEL_{long-term}$	0.05	0.041	82	yes

propan-2-ol	1/none	$AEL_{long-term}$	17.9	3.4	19	yes
(2-methoxymethylethoxy)propanol	1/none	$AEL_{long-term}$	51.3	1.282	2	yes
Scenario 5: application – manual dipping						
Permethrin	1/none	$AEL_{long-term}$	0.05	1.374	2748	no
	2/gloves and coverall	$AEL_{long-term}$	0.05	0.022	44	yes
propan-2-ol	1/none	$AEL_{long-term}$	17.9	0.38	2	yes
	2/gloves	$AEL_{long-term}$	17.9	0.38	2	yes
(2-methoxymethylethoxy)propanol	1/none	$AEL_{long-term}$	51.3	13.77	27	yes
	2/gloves	$AEL_{long-term}$	51.3	1.0485	2	yes
Scenario 6: post-application – cleaning of equipment						
Permethrin	1/none	$AEL_{long-term}$	0.05			negligible
propan-2-ol	1/none	$AEL_{long-term}$	17.9			negligible
(2-methoxymethylethoxy)propanol	1/none	$AEL_{long-term}$	51.3			negligible
Scenario 7: post-application – handling treated wood						
Permethrin	1/none	AEL_{acute}	0. 5	0.164	33	yes
Scenario 8: post-application – sanding of treated wood						
Permethrin	1/none	$AEL_{long-term}$	0.05	0.0013	2.7	yes

For (2-methoxymethylethoxy)propanol
a Community workplace exposure limits (IOELVs – Indicative Occupational Exposure Limit Values) is present, therefore, a quantitative risk assessment is conducted for inhalation. The highest mean event concentration was derived for scenario 3 ”application by spraying” and scenario 4 “application by brushing” for propan-2-ol and 2-methoxymethylethoxy)propanol, respectively. The results are presented in the table below.

Task/ Scenario	OEL (mg/m3)	Estimated inhalation exposure (mg/m3)	exposure/OEL %	aceptable (yes/no)
(2-methoxymethylethoxy)propanol	308	4.5	1%	yes

Local effects
Product is not classified, nor contains substances for which an AEC is derived, therefore no additional risk assessment for local effects is needed.

Conclusion
Therefore, no risks for professionals or industrial users are expected providing that the required PPE are used and use instructions are followed.

The following PPE are required:
- For deluging treatment, spraying and manual dipping: wear protective gloves and coverall.
- For brush treatment no gloves are required.

Risk for non-professional users

Systemic effects

Task/ Scenario	Tier	Exposure limit	Exposure limit value (mg/kg/day)	Estimated uptake (mg/kg/day)	%AEL	Acceptable (yes/no)
Scenario 2: loading : no exposure is expected as it concerns RTU product directly applied from can						
Scenario 3: application - spraying						
Permethrin	1/none	$AEL_{short-term}$	0.5	0.9	180	no
propan-2-ol	1/none	$AEL_{short-term}$	10.7	2.7	25	yes
(2-methoxymethylethoxy)propanol	1/none	$AEL_{short-term}$	51.3	9.16	18	yes
Scenario 4: application - brushing						
Permethrin	1/none	$AEL_{short-term}$	0.5	0.057	11	yes
propan-2-ol	1/none	$AEL_{short-term}$	10.7	2.7	25	yes

(2-methoxymethylethoxy)propanol	1/none	$AEL_{short-term}$	51.3	0.85	1.7	yes
Scenario 5: application – manual dipping						
Permethrin	1/none	$AEL_{short-term}$ $AEL_{short-term}$	0.5	1.374	275	no
propan-2-ol	1/none	$AEL_{short-term}$	10.7	0.38	4	yes
(2-methoxymethylethoxy)propanol	1/none	$AEL_{short-term}$	51.3	13.77	27	yes
Scenario 6: post-application – cleaning of equipment						
Permethrin	1/none	$AEL_{short-term}$	0.5			negligible
propan-2-ol	1/none	$AEL_{short-term}$	10.7			negligible
(2-methoxymethylethoxy)propanol	1/none	$AEL_{short-term}$	28.5			negligible
Scenario 7: post-application – handling of treated wood						
Permethrin	1/none	$AEL_{short-term}$	0.5	0.164	33	yes
Scenario 8: post-application – sanding of treated wood						
Permethrin	1/none	$AEL_{short-term}$	0.5	0.0012	0.06	yes

For (2-methoxymethylethoxy)propanol a Community workplace exposure limits (IOELVs – Indicative Occupational Exposure Limit Values) is present, therefore, a quantitative risk assessment is conducted for inhalation. The air concentrations are the highest for scenario 4 "application-brushing" among all sceanrios evaluated for non-professionals. The results of scenario 4 are presented in the table below.

Task/ Scenario	**OEL (mg/m3)**	**Estimated inhalation exposure (mg/m3)**	**exposure/OEL %**	**aceptable (yes/no)**
(2-methoxymethylethoxy)propanol	308	4.4	1%	yes

It should be noted that the OEL values represent worker exposure limits and are thus not necessarily representative for non-professional use. An additional safety factor may be

applied to protect the broader variation present in the genral public. However, there is no default value that can be applied to convert OEL to limit value applicable to the general public. Considering the low %OEL of up to 1% for the current application, the exposure of the non-professionals are concluded to be acceptable.

Local effects
Product is not classified, nor contains substances for which an AEC is derived, therefore no additional risk assessment for local effects is needed.

Conclusion
Based on the risk assessment, non-professional use of Rodical Insect protect is not considered acceptable for the use via spraying and manual dipping. Please note that the application method dipping by non-professionals was applied for, but was voluntarily withdrawn by the applicant at the end of the evaluation as this method was not deemed realistic for non-professional users.

The application via brushing resulted in an acceptable risk level when a total combined risk level is considered (summation of %AEL of AS + summation of SoCs) without the assumption of PPE.
.

Risk for the general public

Systemic effects

Task/ Scenario	**Tier**	**Exposure limit**	**Exposure limit value** (mg/kg/day)	**Estimated uptake** (mg/kg/day)	**Hazard quotient**	**Acceptable (yes/no)**
Scenario 9: post-application – inhalation of volatilized residues (infant)						
Permethrin	1/none	$AEL_{short-term}$	0.5	8.756E-04	0.18	yes
Scenario 10: post-application – chewing wood off-cut (acute)						
Permethrin	1/none	$AEL_{short-term}$	0.5	0.017	3	yes
Scenario 11: post-application – playing on playground structure outdoors and mouthing						
Permethrin	1/none	$AEL_{short-term}$	0.5	0.0047	1	yes

Combined scenarios
No combined exposure is foreseen.

Conclusion
All scenario's resulted in acceptable risk.

It should be noted that the exposure and risk assessment of the general public in the PAR applies only to dried residues. Potential contact to wet surfaces was not assessed. For adults it can be assumed that they generally avoid contact to wet treated surfaces. However, for younger children and for pets this cannot be assumed. To avoid contact to wet surfaces by

children and pets, the following RMM was therefore assigned: "Keep children and pets away from treated surfaces until dried".

In conclusion, no adverse health effects for the general public are expected when using the product according to instructions.

2.2.7 Risk assessment for animal health

Not relevant for the use of this product. To prevent the exposure of animals the following RMMs are included:
- Keep away from food, drink or animal feedstuffs.
- Do not use on wood which may come in direct contact with food, feeding stuff, and livestock animals
- Keep children and pets away from treated surfaces until they have dried.
- Avoid prolonged contact of pets, particularly cats, to treated surfaces.
- Remove or cover terrariums, aquariums, and animal cages before application. Turn off aquarium air-filter while spraying.

2.2.8 Risk assessment for the environment

Notes to the reader:
The risk assessment is based on the pure active content in the product, although a technical grade was included in the product. This, however, does not change the conclusions of underlying evaluation.
The application rate used in the environmental risk assessment is higher than the authorized dosage. This does not influence the risk assessment nor the RMMs to set in place.
An ED screening for this product can be found in the confidential annex. The available information suggest that none of the non-active substances or co-formulants have endocrine disruptive properties.

2.2.8.1 Effects assessment on the environment

Active substance effects and PNEC values are described in the competent authorities' assessment report on permethrin (April 2014).
The risk characterisation ratios have been calculated using the PNEC values published in the CAR for Permethrin PT 8 (2014). An overview of the PNEC values used is given in the table below. Additional refinements are ongoing for the PNEC sediment and removal in STP, but these are not yet finalised at this stage.

PNEC values for the a.s. permethrin and the major metabolites PBA and DCVA (according to assessment report PT8, 2014)			
Substance	**Compartment**	**Value**	**Unit**
Permethrin	Fresh water	4.7×10^{-4}	µg/L
	Sediment	2.17×10^{-4}	mg/kg_{wwt}
	STP	4.95	µg/L
	Soil	0.175	mg/kg_{wwt}*
	Birds	16.7	mg/kg_{food}
	Mammals	120	mg/kg_{food}
3-Phenoxybenzoic acid (PBA)	Fresh water	0.01	mg/L
	Sediment	0.009	mg/kg_{wwt}
	Soil	1.44	mg/kg_{wwt}
DCVA	Fresh water	0.015	mg/L
	Sediment	0.012	mg/kg_{wwt}
	Soil	4.6	mg/kg_{wwt}

* The evaluation of the permethrin confirmatory data was discussed at the BPC Meeting in early March 2017. RMS for permethrin (Ireland) can inform the CG members that an Env WG e-consultation was requested by BPC Members during the last BPC meeting in March, regarding the PNECsoil. The e-consultation concluded on the 13th March.
It was agreed that the conclusions of this e-consultation could be announced at CG-22 in the event of a clear majority opinion. The opinions received from MSs in the e-consultation provided a clear majority opinion in relation to the proposed PNECsoil.
The MSs were in favour of using an AF of 50 and deriving the PNECsoil for permethrin on the soil micro-organism study. The new PNECsoil is 0.198 mg/kg dwt, corresponding to 0.175 mg/kg wwt.

According to the AR for the a.s. permethrin (2014), the metabolites are far less toxic to aquatic organisms than the parent a.s. and are, according to the AR (2014), not ecotoxicologically relevant. The same applies for the soil compartment. Quantitative risk assessments for the major water and soil metabolites will therefore not be calculated and presented in the PAR.
However, the two major metabolites (DCVA and PBA) are expected to be more mobile in soil with mean K_{oc} for DCVA of 93.2 L/kg (n = 5) and for PBA of 141.2 L/kg, which may result in leaching to the groundwater. Therefore, the risk for the groundwater is quantitatively assessed for the major metabolite DCVA (worst case DT_{50} soil [12°C]: 175 d) covering the significantly more rapidly degrading PBA (DT_{50} soil [12°C]: 2.5 d).

Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required

No information is available on the ecotoxicity of the biocidal product. As regards the classification of the products, CLP mixture rules were used.
The product is classified as H400 – H410 acute Cat. 1 and Chronic Cat. 1.

Further Ecotoxicological studies

No new data available

Data waiving	
Information requirement	-
Justification	data on the active substance gives sufficient information

Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)

No new data available

Data waiving	
Information requirement	-
Justification	No additional need for testing based on intented use

Supervised trials to assess risks to non-target organisms under field conditions

No new data available

Data waiving	
Information requirement	-
Justification	No additional need for testing, product is not a bait or granule

Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk

No new data available

Data waiving	
Information requirement	-
Justification	No additional need for testing, product is not a bait or granule

Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)

Not relevant

Foreseeable routes of entry into the environment on the basis of the use envisaged

The biocidal product is intended for the treatment of wood indoor and outdoor under cover, fully protected from the weather and not exposed to wetting (Use class 1). The product can be used by industrial users, where application of the product takes place inside a facility. The product can also be used by professionals (RTU) and non-professionals (RTU) on site (in-situ). Direct exposure to the air during application is considered to be negligible, due to dilution and rapid degradation of permethrin in the troposphere by photochemical processes. Emission to the indoor air during application of the product is considered to be completely released to outdoor air by venting the room.

Based on the applicant's description of the intended indoor uses and suggested assessment methods, an e-consultation was initiated by the eCA (03-07-2018) to discuss possible scenario's with other member states. After member state discussion it was concluded that it is **not** appropriate to include new scenario's for PT8 during this ongoing risk assessment (quote: "Changing the rules during the game is inappropriate"). The concerned member states were France, Germany and Sweden. For future situations, an addition of PT18 elements is welcomed to the PT8 ESD. For these elements, agreements are yet to be finalised.
Therefore, for the current product assessment, no new scenarios are included and the ESD for PT8 is used, along with updates from the TAB when applicable.

In line with item 177 from the ESD PT8 *"For indoor treatments by spraying, brushing and injection, no scenarios are proposed in this document because related emissions to the environment are considered to be negligible."*, the emission is considered negligible when the product is applied by professionals and amateurs *in situ*.

The industrial application can result in emission, based on the ESD defaults. See section Exposure assessment.
For the storage phase after industrial application the standard risk mitigation "freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water, and that any losses of the product shall be collected for reuse or disposal" is applied (see ENV 96, TAB 2018). A quantitative risk assessment for the storage phase is therefore not provided.

The indirect environmental exposure via waste disposal to landfill, has not been considered in this exposure assessment. This is because the effect of the substances' dilution with other wastes and the significant containment measures at landfill sites according to European Union (EU) waste regulations (EU Directive 99/31/EC) eliminates any concerns.

Further studies on fate and behaviour in the environment (ADS)

No new data available

Data waiving	
Information requirement	-
Justification	data on the active substance gives sufficient information, fate of active substance is not influenced by other components in the product

Leaching behaviour (ADS)

No data generated, products are UC1 only.

Testing for distribution and dissipation in soil (ADS)

No new data available

Data waiving	
Information requirement	-
Justification	data on the active substance gives sufficient information, distribution and dissipation of active substance is not influenced by other components in the product

Testing for distribution and dissipation in water and sediment (ADS)

No new data available

Data waiving	
Information requirement	-
Justification	data on the active substance gives sufficient information, distribution and dissipation of active substance is not influenced by other components in the product

Testing for distribution and dissipation in air (ADS)

No new data available

Data waiving	
Information requirement	-
Justification	data on the active substance gives sufficient information, distribution and dissipation of active substance is not influenced by other components in the product

If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)

Not relevant for intended use of the product.

If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions (ADS)

Not relevant for intended use of the product.

2.2.8.2 Exposure assessment

The product is categorised as Use Class 1 (UC1), meaning that it is intended for the treatment of wood indoor and outdoor under cover, fully protected from the weather and not exposed to wetting. See **Foreseeable routes of entry into the environment on the basis of the use envisaged** for details.

General information

Assessed PT	PT 8
Assessed scenarios	Scenario 1: treatment by injection, RTU, non-professionals Scenario 2: treatment by brushing or spraying, RTU, non-professionals Scenario 3: treatment by professionals, RTU Scenario 4: Flow coating deluge (Industrial)
ESD(s) used	Emission Scenario Document for Product Type 8: Revised emission scenario document for wood preservatives, September 2013
Approach	Scenario 1-4: Consumption based
Distribution in the environment	Guidance on the Biocidal Product Regulation. Volume IV: Environment - Part B+C: Assessment and Evaluation. European Chemicals Agency, Report no. ECHA-17-G-23-EN, Helsinki, Finland, 2017.
Groundwater simulation	No higher tier simulation for emission to groundwater.
Confidential Annexes	NO
Life cycle steps assessed	Scenarios 1-4: Production: No Formulation No Use: Yes (application only) Service life: No
Remarks	-

Emission estimation

Scenario [1] treatment by injection, RTU, non-professionals

No emission expected according to item 177 in the PT8 ESD.

Scenario [2] treatment by spraying or brushing, RTU, non-professionals

No emission expected according to item 177 in the PT8 ESD.

Scenario [3] treatment by professionals, RTU

No emission expected according to item 177 in the PT8 ESD.

Scenario [4] Flow coating deluge (industrial)

Flow coating deluge is an industral proces for the treatment of wood, performed by trained professionals in dedicated installations. In the ESD for PT8, an emission scenario is described for automated spraying. The scenario considers both the treatment and subsequent outside drying of treated wood. As the product is only to be used for the treatment of wood indoor, emission to soil through leaching during drying is not taken into account here. Although run-offs are generally collected via drip pads and recycled, a default fraction of product that is lost during floor and equipment cleaning is considered to reach the facility drain. The product is water-based, and thus, in contrast to solvent-based products, emission to air will be negligible. Therefore, direct emission will mainly occur via the STP.
For the total area of wood that is treated per day, the scenario distinguishes between small and large plants. The $AREA_{wood\text{-}treated}$ for large plants is used, as this approach is worst-case.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: **Flow coating deluge (industrial)**			
Quantity of substance applied per m^2 of wood (Q_{ai})	0.3 kg/m^2 x 0.2% = $6x10^{-4}$	kg/m^2	According to user instructions for a 0.2% RTU solution
Area of wood treated ($AREA_{wood\text{-}treated}$)	20000	m^2/day	ESD PT8, large plant
Fraction released to facility drain ($F_{facilitydrain}$)	0.0001	-	Default value for compounds with a solubility in water of < 0.25 mg/L (ESD PT8)
Fraction released to air (F_{air})	0.001	-	No default value for products compounds with a vapour pressure < 0.005 exists (ESD PT8

			table 4.2), but set equal to the F_{air} for the range 0.005 - <0.05

Calculations for Scenario [*4*]
Emission to the STP is calculated according to the formula described in the ESD for PT8: $Elocal_{facilitydrain} = Q_{ai} \times AREA_{wood\text{-}treated} \times F_{facilitydrain}$. PEC values and PEC/PNEC ratios are calculated with SimpleTreat 4.0 using default parameters except for Css which is manually changed to 30 mg/L (ENV 9, TAB 2018).

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
Air	1.2E-02	
STP	1.2E-03	

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway								
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water
Scenario 1	No	No	Not relevant	Not relevant	No	No	No	No
Scenario 2	No	No	Not relevant	Not relevant	No	No	No	No
Scenario 3	No	No	Not relevant	Not relevant	No	No	No	No
Scenario 4	(yes)	(yes)	Not relevant	Not relevant	yes	yes	(yes)	(yes)

(yes) means an indirect exposure. Yes is a direct exposure.

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	Value	Unit	Remarks
Molecular weight	391.29	g/mol	<100%, 25:75 cis:trans
Melting point	35	°C	<100%, 25:75 cis:trans
Boiling point	305	°C	<100%, 25:75 cis:trans

Vapour pressure (at 20°C)	2.155E-06	Pa	<100%, 25:75 cis:trans
Water solubility (at 20°C)	0.00495	mg/l	<100%, 25:75 cis:trans
Log Octanol/water partition coefficient	4.67	Log 10	<100%
Organic carbon/water partition coefficient (Koc)	26930	l/kg	(Arithmetic mean, n= 10)
Henry's Law Constant (at 25°C)	4.5E-02	$Pa/m^3/mol$	<100%, 25:75 cis:trans
Biodegradability	No		
DT_{50} for degradation in soil	106	d (at 12ºC)	(geometric mean, n=5)

Calculated fate and distribution in the STP		
Compartment	Percentage [%] All scenarios	Remarks
Air	9.18E-3	Calculated with SimpleTreat 4.0
Water	27.6	
Sludge	72.4	
Degraded in STP	0	

Calculated PEC values

Summary table on calculated PEC values					
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{GW}**
	[mg/l]	[mg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/l]
Scenario 1	n.a.	n.a.	n.a.	n.a.	n.a.
Scenario 2	n.a.	n.a.	n.a.	n.a.	n.a.
Scenario 3	n.a.	n.a.	n.a.	n.a.	n.a.
Scenario 4	1.66E-04	1.59E-05	9.33E-03	1.61E-02	<0.001

The main metabolites of permethrin in water and soil are 3-(2,2-dichlorovinyl2,2-dimethyl-(1-cyclopropane)carboxylate (DCVA), 3-phenoxybenzoic acid (PBA) and 4-fluoro-3-phenoxybenzoic acid (FPB-acid). According to the CAR for Permethrin (2014), these metabolites are however far less toxic compared to permethrin, and are not considered ecotoxicologically relevant. Therefore, no PECstp, PECsw, PECsed and PECsoil values will be calculated for these metabolites.
Tier 1 calculations for groundwater concentrations are calculated and are presented below, taking into account the transformation of permethrin to the 2 relevant metabolites. The mean Kfoc from the CAR for Permethrin (2014) was used. The exposure for the groundwater

is quantitatively assessed for the major metabolite DCVA (worst case DT_{50} soil [12°C]: 175 d) covering the significantly more rapidly degrading PBA (DT_{50} soil [12°C]: 2.5 d).

Summary table on calculated PEC values metabolite DCVA		
	PEC_{soil}	**PEC_{GW}**
	[mg/kg_{wwt}]	[µg/l]
Scenario 1	n.a.	n.a.
Scenario 2	n.a.	n.a.
Scenario 3	n.a.	n.a.
Scenario 4	1.82E-03	1.0

Primary and secondary poisoning

Primary poisoning
The product is used for the treatment of wood indoors, which is covered from rain and is not exposed to humidity. Direct poisoning of non-target organisms is therefore not expected.

Secondary poisoning
Secondary poisoning is calculated only for scenario 4.
The $PEC_{oral,\ predator}$ was taken from the PT8 CAR for Permethrin (2014), both for worm eating and fish eating predators.

$PNEC_{birds}$=16.7 mg a.s./kg food (CAR for Permethrin, 2014)

$PNEC_{mammals}$= 120 mg a.s./kg food (CAR for Permethrin, 2014)

2.2.8.3 Risk characterisation

Atmosphere

Permethrin has a very low volatilization, due to the low vapor pressure of permethrin, low Henry's Law constant and high adsorption potential. Therefore, exposure of the atmosphere is considered negligible for the proposed scenarios. Furthermore, in the atmosphere, permethrin is expected to degrade rapidly, mainly via gas phase reaction with photo-chemically generated hydroxyl radicals, with a half-life degradation value of 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).

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values	
	$PEC/PNEC_{STP}$
Scenario 4: Flow coating deluge (Industrial)	0.03

Conclusion:

Only scenario 4 is expected to result in emission to the environment. There is no risk for the micro-organisms in the STP for the described scenarios.

Aquatic compartment

Summary table on calculated PEC/PNEC values		
	PEC/PNEC$_{water}$	**PEC/PNEC$_{sed}$**
Scenario 4: Flow coating deluge (Industrial)	**33.9**	**43.0**

Conclusion: Only scenario 4 is expected to result in emission to the environment. The exposure calculated results in unacceptable risk for water and sediment compartment. Release during industrial application can be avoided, when release of wood preservatives from the treating installation to the sewage is mitigated. The following RMM is prescribed: *Do not discharge the biocidal product nor the diluted solution of the biocidal product into the sewage system or the environment.*
This phrase is included on the SPC, general directions for use.

Terrestrial compartment

Calculated PEC/PNEC values	
	PEC/PNEC$_{soil}$
Scenario 4: Flow coating deluge (Industrial)	0.09

Conclusion: Only scenario 4 is expected to result in emission to the environment. No unacceptable risk to the terrestrial compartment was found for all scenarios.

Groundwater

Based on the uses of the product, no risk for the contamination of groundwater during application or service life of treated wood is to be expected.
As the predicted concentration of permethrin in pore water under agricultural soil after sludge application remains below the generic cut-off value for individual pesticides of 0.1 µg/l, no groundwater contamination is expected.
For the metabolite DCVA (also covering metabolite PBA), an exact threshold concentration of 1.0 µg/l occurs for scenario 4 when a tier 1 assessment (EPM) is done. The leaching to groundwater will be avoided when appropriate risk mitigation measures are taken and release to sewers/STP is avoided by collecting residues (see RMM **Aquatic compartment**).

Primary and secondary poisoning

Primary poisoning

Not applicable

Secondary poisoning

Summary table on secondary poisoning of fish-eating predators				
Scenario	**PEC_{water} (mg/L)**	**$PEC_{oral\ predator}$ (mg/kgwwt)**	**$PEC/PNEC_{birds}$**	**$PEC/PNEC_{mammals}$**
Scenario 4: Flow coating deluge (Industrial)	1.59E-05	4.54E-03	2.71E-04	3.77E-05

Summary table on secondary poisoning of worm-eating predators					
Scenario	**PEC_{soil} (mg/kg wwt)**	**$PEC_{porewater}$ (mg/L)**	**$PEC_{oral\ predator}$**	**$PEC/PNEC_{birds}$**	**$PEC/PNEC_{mammals}$**
Scenario 4: Flow coating deluge (Industrial)	1.61E-02	<0.001	1.74E-02	1.04E-03	1.45E-04

Conclusion: The scenarios described do not result in risk for secondary poisoning via the consumption of contaminated earthworms or fish by birds or mammals.

Mixture toxicity

Not applicable. In the product, permethrin is the only evaluated substance for the environment.

Additionally, an SoC is present in this product: propan-2-ol is present as a co-formulant in a concentration of 0.2%. Because propan-2-ol is a biocidal active substance, it triggers the SoC criteria.
The risk assessment for propan-2-ol is discussed qualitatively:

The active substance propan-2-ol is expected to mostly evaporate and the main emission into the environment will be to air. Additionally, the substance is expected to degrade quickly once deposited into the sewer and consecutive STP. The degradation products of this substance are water and carbon dioxide. These are not considered relevant for the environmental risk assessment as these are natural occurring compounds.

Criteria for the examination of environmental risks to air are not specified in the form of a numerical standard. The assessment of potential impacts on air quality is aimed to minimize the risk for stratospheric ozone depletion. There are no indications that propan-2-ol contributes to depletion of the ozone layer as the compound is not listed as 'controlled substance' in Annex I of Regulation (EC) No 1005/2009 of the European Parliament. Moreover, AOPwin calculates for the active substances propan-1-ol and propan-2-ol, a half-life of 3.2 and 3.1 days in air (OH timeframe 24 hrs/day, 0.5×10^6 OH radicals/cm^3), respectively. Although the calculated half live is above the trigger of 2 days,

which is used as cut off value to identify chemicals that could be of potential concern for long range transport through the atmosphere, the active substance is known to be readily biodegradable once deposited and unacceptable risks to terrestrial and aquatic environments are therefore not expected.

Consequently, the potential environmental risks related to emission to air and sewer are therefore considered acceptable.

PBT assessment
The product does not contain any coformulants that fulfil the PBT criteria

Aggregated exposure (combined for relevant emission sources)

An aggregated exposure assessment is required based on the different uses for the same product. Since the emission for this product is only evaluated for a single intended use, no aggregated exposure assessment is required.

Overall conclusion on the risk assessment for the environment of the product
The environmental compartments which are most sensitive to permethrin are fresh water and sediment. For these compartments, a safe use could be demonstrated for scenario 1, 2 and 3 where no emission to the environment is expected. For industrial treatment (scenario 4) release to sewers will generally be avoided, based on local legislation. Additionally, the eCA proposed an RMM on the SPC mitigating the emission to the sewer after industrial application for the situations where no local legislation with regards to STP release applies. The intended uses of the product do not result in risk for the soil compartment including secondary poisoning. Although the tier 1 assessment for the metabolites reaching groundwater did exceed the trigger value of 0.1 µg/l, taking into account that releases to sewers is not allowed due to RMMs will exclude any indirect exposure to soil (and groundwater).

2.2.9 Measures to protect man, animals and the environment

For the measures to protect animals and the environment we refer to sections 2.2.6, 2.2.7 and 2.2.8 and the SPC.

2.2.10 Assessment of a combination of biocidal products

Biocidal product is not intended to be authorised for the use with other biocidal products.

2.2.11 Comparative assessment

Not relevant

3 ANNEXES

3.1 List of studies for the biocidal product

Reference	Author	Year	Title	Testing laboratory	Report no.	Report date
study report	Ing. Bernard de RYCKEL	2015	Physical and chemical properties and storage stability tests for F 15 Ready to use (permethrin 0.20 % w/w).	Centre wallon de Recherches agronomiques Département Agriculture et Milieu naturel Unité Physico-chimie et Résidus des Produits Phytopharmaceutiques et des Biocides	23896	2015-11-27
study report	Berit Lindegaard and Elisabeth Morsing	2014	Storage Stability of Rodical®Impregnation	Eurofins IProduct Safety Laboratories	609191	
study report	labofrance	2014	compte rendu d'analyses	LABOFRANCE	-	2014-07-07
CAR permethrin	Rapporteur : Ireland	2014	Assessment Report - Permethrin (product-type 8)	-	-	2014-04
Study report	Jequel Marc	2015	Physico-chemical tests on a Wood Preservative F15 CONCENTRATE Validation of analytical method and chemical analysis of the active ingredient declared in the test item	Laboratoire de Chimie-Ecotoxicologie FCBA	402/14/1189F/ab-e	2015-05-13
study report	Dr. E.-M. Fennert, Dipl. Ing (FH) T. Kolling	2015	Determination of the eradicant action against larvae of Hylotrupes	MPA Eberswalde Materialprüfanstalt Brandenburg GmbH	32/14/9821/01	

			bajulus (L.) according to EN 1390 (2006)			
study report	Brunet and Paulmier	2015	preventive effectiveness against Hylotrupes bajulus according to EN 46-1 and EN 73	FCBA	401/14/209F/a	2015-07-23
study report	Brunet and Paulmier	2015	preventive effectiveness against Hylotrupes bajulus according to EN 46-1 and EN 73	FCBA	401/14/209F/b	2015-07-23
study report	PD.Dr. H. J. Kunte and PD. Dr. R. Plarre	2015	test report: Wood preservatives - Determination of preventive action against European Reticulitermes species	BAM Federal Institute for Materials Research and Testing	2014-4.1-8664-2 Te	2015-05-11
Study report	Dr George Jordan	2020	Vapour Flammability Testing	DEKRA Process Safety Facility	S3016007531R1/2020	2020-05-06

3.2 Output tables from exposure assessment tools

Most Output Tables from human risk assessment are included in section 2.2.6, except for scenario 4 and 7, which are included below.
Output Tables from environmental risk assessment are included in confidential Annex.

Human health, scenario 4, application brushing (professionals)

DERMAL			
hands exposure value	0,5417	mg b.p/m2	Hexp
hands exposure value (with gloves)	0,05417	mg b.p/m2	Hexp(PPE)
body exposure value	0,2382	mg b.p/m2	Bexp
body exposure value (with coverall)	0,02382	mg b.p/m2	Bexp(PPE)
duration	240	min	
application area	31,6	m2	A
dermal exposure value to product	24,64484	mg b.p	exp * A / (1/C) = D
dermal exposure value to product with PPE	2,464484	mg b.p	D/10
concentration active	0,200	%	C
dermal absorption	50,000	%	DA
systemic dermal systemic dose	2,46E+00	mg a.s.	D*DA = sysD
systemic dermal systemic dose with PPE	2,46E-01		
body weight	60	kg	bw
systemic dermal dose per kg bw	0,0411	mg a.s./kg bw	sysD/bw
systemic dermal dose per kg bw with PPE	0,0041	mg a.s./kg bw	sysD/bw
INHALATION			
inhalation exposure value	0,0016	mg b.p/m2	exp
application area	31,6	m2	
inhalation exposure to product	0,05056	mg b.p	exp * A / (1/C) = I
concentration active	0,200	%	C
inhalation absorption	100	%	IA
systemic inhalation dose	0,010112	mg a.s.	I*C*IA=sysI
systemic inhalation dose per kg bw	0,0002	mg a.s./kg bw	sysI/bw
systemic inhalation dose per kg bw with RPE	0,0000	mg a.s./kg bw	sysI/bw/10

RISK

	total exposure	AEL	%AEL
Systemic dose (no PPE)	0,0412	0,05	82,49
Systemic dose (with PPE)	0,0043	0,05	8,55

Scenario 7, handling treated wood (professionals and non-professionals)

DERMAL			
hands surface area	820	cm2	HA
hands exposure value	164	cm2	expHA
number of contacts	100	per day	n
concentration active	0,200	%	c
dermal absorption	50,000	%	DA
applciation rate	30,000	mg/cm2	rate
transfer efficiency	2,000	%	TE
systemic dermal systemic dose	9,84	mg a.s.	expHA*n*c*DA*rate*TE =sysD
systemic dermal systemic dose with PPE	NVT		
body weight	60	kg	bw
systemic dermal dose per kg bw	0,164	mg a.s./kg bw	sysD/bw
TOTAL			
Systemic dose (no PPE)	0,164	mg a.s./kg bw	D25

RISK

	total exposure	AEL	%AEL
Systemic dose (no PPE)	0,164	0,50	32,80

3.3 New information on the active substance

A literature study has been done and sufficient quality data are available to apply a Species Sensitive Distribution (SSD) approach resulting in a $PNEC_{freshwater}$ 4.8 ng/l. The study used for setting the $PNEC_{surface\ water}$ at 0.47 ng/l is invalidated. This is described in the document below. This document is also submitted to the rapporteur Ireland and more work is ongoing and will be submitted as soon as available.
The study is included in IUCLID section 13 with the following reference: D. Heijerick & F. Verdonck, 2016, Environmental Risk assessment of Permethrin: PNEC derivation for the freshwater compartment.

3.4 Residue behaviour

Information on residue behaviour can be found in the CAR of permethrin. Several analytical methods have been developed to detect residue levels in air, soil and water. Methods to detect residues in body fluids and food and feeding stuffs have not been developed since permethrin is not classified as toxic or highly toxic.
Here a general description of residues in soil, water and body is given based on the data available in the permethrin CAR.

Bound residues in soil were formed up to a maximum level of 39.8% of applied radioactivity after two weeks incubation at a temperature of 25 ± 2 °C under dark conditions. Further analysis of the bound soil residue showed that the distribution of the residues was principally in the humic acid fraction (up to 24.6% applied radioactivity), with maximum levels of radioactivity in the fulvic acid and humic fraction accounting for 11.3% and 8.4%, respectively. Maximum bound residue levels for each isomer were all obtained with the Kodaira soil (light clay), which had higher organic matter (15.3%) and clay content (29%) than the Azuchi soil (sandy clay loam, organic matter 2.5%, clay 17%).

Another study demonstrated that in fresh water, the half-life for depuration of tissue residues in fish was approximately 4/5 days with approximately 80% of the accumulated residues depurated within 14 days. This data would indicate that bioconcentration in fish tissues would not significantly occur and any residues accumulated are readily eliminated. ^{14}C-permethrin appears to rapidly bioaccumulate in chironomids in water and sediment systems (Log BCF 1 to 2) but depuration is also rapid following cessation of exposure.

Following an oral absorption study Permethrin was found to undergo rapid and extensive absorption in the body. 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.

3.5 Summaries of the efficacy studies

See section 2.2.5.5 and IUCLID.

3.6 Confidential annex

See separate document.

3.7 Other

-