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

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)

MATACARCOMA

Product type 08

Permethrin as included in the Union list of approved active substances

Case Number in R4BP: BC-SG074923-26

Evaluating Competent Authority: Spain

August 2023

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1 CONCLUSION

Physical-chemical properties and Analytical Methods

MATACARCOMA is a AL (Any other liquid) product. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. Its technical characteristics are acceptable for an AL formulation. The stability data indicate a shelf life of more than 2 years at ambient temperature when stored in the commercial packaging material.

The biocidal product is classified as flammable liquid.

The analytical methods provided are fully validated for the determination of the active substance Permethrin. Methods for the determination of the residues are available in the CAR of the active substances.

Efficacy

Based on the efficacy evaluation, the product may be authorised for use class 1 as preventive treatment against wood boring beetles (Dose rate: 100g/m^2), and as curative treatment against wood boring beetles by surface treatment brushing/rolling and spraying for softwood. Dose rate: 200g/m^2.

Human health:

The biocidal product MATACARCOMA contains the active substance permethrin (0.4%).
In addition to the active substance, other substances of concern for human health have been identified.
According to the CAR and BPC Opinion for permethrin, is not considered to have endocrine disrupting properties.
After reviewing the potential ED properties of co-formulants, no substances have been identified as having potential endocrine disrupting properties.

After evaluating the exposure and characterizing the risk to human health of the product MATACARCOMA according to the pattern of use requested by the applicant, the conclusions for each scanario are:

Summary table: scenarios for MATACARCOMA product		
Scenario number	**Scenario and Users (e.g. mixing /loading)**	**Conclusion**
1	Mixing and loading of RTU. Industrial (trained professional and professional)	A **safe** situation has been identified for industrial mixing and loading of product
2	Mixing and loading of RTU Trained professional, professional and non-professional	A **safe** situation has been identified for professional and non-professional mixing and loading of product

Summary table: scenarios for MATACARCOMA product		
Scenario number	**Scenario and Users (e.g. mixing /loading)**	**Conclusion**
3	Brushing and rolling Industrial (trained professional and professional), trained professional, professional and non-professional	A **safe** situation has been identified for industrial and professional brushing application of product when gloves and coverall are worn. Moreover, a **safe** situation has been identified for non-professional brushing application without PPE.
4	Spray application Trained professional Professional	A **unsafe** situation has been identified for professional spraying application of product when using **new** gloves for each work shift and impermeable coverall 5%.
5	Automated spray application Industrial (trained professional and professional)	An **safe** situation has been identified for industrial automated spraying application of product when using gloves and impermeable coverall 5%.
6	Manual dipping Industrial (trained professional and professional), trained professional and professional	A **safe** situation has been identified for industrial and professional manual-dipping application of product when using gloves and impermeable coverall 5%. It is advisice use **new** gloves for each work shift
7	Automated dipping process Industrial (trained professional and professional)	An **safe** situation has been identified for industrial automated spraying application of product when using PPE.
8	Cleaning of brush equipment Industrial (trained professional and professional), trained professional, professional and non-professional	A **safe** situation has been identified for industrial, professional and non-professional cleaning of brush application of product even when no gloves are worn.
9	Cleaning spray-application equipment Industrial (trained professional and professional), trained professional professionals	A **safe** situation has been identified for professional and industrial cleaning spray-application equipment with gloves.
10	Sawing and sanding treated wood Professional	A **safe** situation has been identified for professional cutting and sanding treated wood.
11	Sawing and sanding treated wood Non-professional	A **safe** situation has been identified for non-professional cutting and sanding treated wood.

Summary table: scenarios for MATACARCOMA product		
Scenario number	**Scenario and Users (e.g. mixing /loading)**	**Conclusion**
12	Chewing wood off-cut General public	A **safe** situation has been identified for infant chewing treated wood chips.
13	Playing on playground structure outdoors and mouthing. General public	A **safe** situation has been identified for toddler playing and mouthing on playground weathered wood structure outdoors preventively treated with the product.
14	Inhalation residues indoors General public	A **safe** situation has been identified for general public inhaling volatilised residues indoors.
15	Laundering work-cloths at home General public	A **safe** situation has been identified for general public laundering contaminated work clothing at home derived from dipping application.

Explanatory note (only for Spain authorisation):
According to national legislation, in Spain there are three user categories:
- Trained professional users (TP): pest control operators, having received specific training in biocidal product uses according to the national legislation in force.
- Professional users (P): professionals that use the biocidal products in the context of their profession, that is not pest control operator, and that are unlikely to have received any specific training in biocidal product use according to the national legislation in force. It can be expected that they have some knowledge and skills handling chemicals (if they must use it in their job) and they are able to use correctly some kind of PPE if necessary.
- Non-professional users (NP): users who are not professionals and that apply the biocidal product in the context of their private life.

At the same time, there are also some restrictions of packaging in relation to those user categories and product types. In this case, for professional users the maximum size that can be authorized is 2.5 L.
In that context, the exposure assessment will be the same for professionals and trained professional users and the difference between the two will depend on the expert judgment following "limiting criteria" below:

1. The hazardousness of the product under evaluation.
2. The use being requested.
3. The frequency of use.
4. Complexixy of control measures

The conclusions reached in this PAR, which affect the intermediate category of "Professional", will only be applicable at the Spanish level

Conclusion on environmental risk assessment

For preventive and curative treatment of wood classes 1, emissions are considered negligible. The risks for the application phase and service life are therefore acceptable for treatment of wood in classes 1.

There is a potential risk derived from industrial treatments, however this risk must not be considered relevant based on mandatory risk mitigation measures for wood treatment plants. Storage must only take place on sealed places or under cover to prevent direct release to soil. This will be stated on the label.

- Prevent any release to the environment during the product application phase as well as during the storage and the transport of treated timber;
- During the application phase, prevent any release of cleaning water (after cleaning of floors, tanks, containers) to the environment (sewer, soil, water);
- 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. Before use, store the timber in an area sheltered from the weather;
- Any contaminated water/soil shall be collected, contained and treated as hazardous waste.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier[1]	**Country (if relevant)**
MATACARCOMA IKI-DECOR MATACARCOMAS TRATAMENTO ANTICARUNCHO PECOL WOOD PROTECT	SPAIN

2.1.1.2 Authorisation holer

Name and address of the authorisation holder	**Name**	INDUSTRIAS QUÍMICAS IRURENA, S.A.
	Address	Ctra. de Tolosa s/nº Apartado 30 20730 Azpeitia (Guipúzcoa) Spain
Authorisation number	ES/APP(NA)-2023-08-00XXX	
Date of the authorisation	XX/XX/XXXX	
Expiry date of the authorisation	XX/XX/XXXX	

2.1.1.3 Manufacturer(s) of the product

Name of manufacturer	INDUSTRIAS QUÍMICAS IRURENA, S.A.
Address of manufacturer	Ctra. de Tolosa s/nº Apartado 30 20730 Azpeitia (Guipúzcoa) Spain
Location of manufacturing sites	Ctra. de Tolosa s/nº Apartado 30 20730 Azpeitia (Guipúzcoa) Spain

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

Active substance	Permethrin
Name of manufacturer	LANXESS Deutschland GmbH
Address of manufacturer	Kennedyplatz 1, 50569 Köln - Germany
Location of manufacturing sites	Bayer Vapi Private Limited Plot # 306/3 II Phase, GIDC Vapi – 396 195 Gujarat India

1 Please fill in here the identifying product name from R4BP.

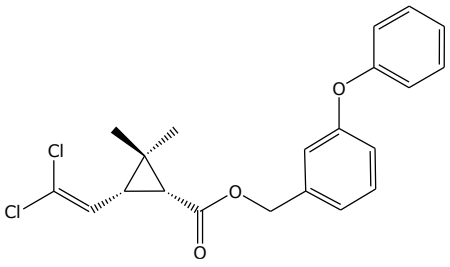
2.1.2 Product composition and formulation

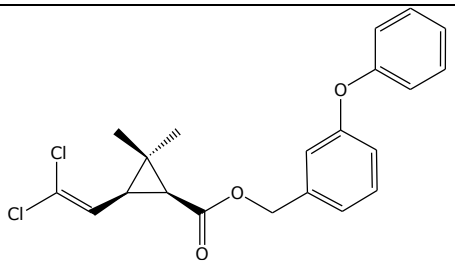
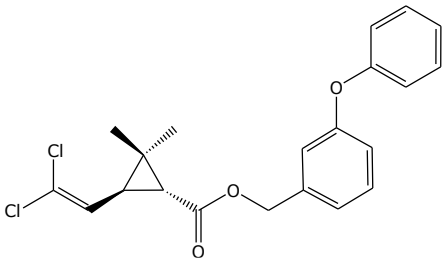
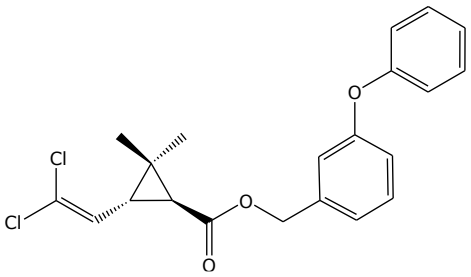
NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

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 constituents	
ISO name	Permethrin
IUPAC or EC name	3-phenoxybenzyl(1RS)-cis,trans-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	930g/kg (93%) Permethrin has four stereoisomers: 1Rcis, 1Scis, 1Rtrans, 1Strans. 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 is a reaction mass of four stereoisomers • 1Rcis permethrin content = 5.0 - 10.0 %w/w • 1Scis permethrin content = 15.0 - 20.0 %w/w • 1Rtrans permethrin content = 45.0 - 55.0 %w/w • 1Strans permethrin content = 17.0 - 27.0 %w/w
Structural formula	1Rcis isomer  1Scis isomer

	 1Rtrans isomer  1Strans isomer 

2.1.2.2 Candidate(s) for substitution

There are no indications that permethrin would fulfil the exclusion criteria specified in article 5(1), nor the substitution criteria specified in Article 10 (1) of Regulation (EU) No 528/2012.

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Permethrin	3-phenoxybenzyl(1RS)-cis,trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate	Active substance	52645-53-1	258-067-9	0.4
Hydrocarbons, c9-c11, n-alkanes, isoalkanes, cyclics, < 2% aromatics	Hydrocarbons, c9-c11, n-alkanes, isoalkanes, cyclics, < 2% aromatics	Solvent	Related CAS No: 64742-48-9	REACH Registration provisional EC Nº: 919-857-5	99.6

2.1.2.4 Information on technical equivalence

The source of the active substance Permethrin is the same as the one 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. Therefore, ther is not a technical equivalence.

2.1.2.5 Information on the substance(s) of concern

According to Annex A of BPR guidance, Volume III Human Health - Assessment & Evaluation (Parts B+C), the product MATACARCOMA contains a substance of concern (SoC) for Human Health, "Hydrocarbons, C9-C11, n-alkanes, isoalkanes, cyclics, < 2% aromatics" triggers the classification of the product with Asp. Tox. 1 (H304).

According to article 3(f) of the BPR "Hydrocarbons, C9-C11, n-alkanes, isoalkanes, cyclics, < 2% aromatics" is also a substance of concern for Enviroment since meets the criteria for classification as hazardous according to Regulation (EC) No 1272/2008, and it is present in the biocidal product at a concentration leading the product to be regarded as hazardous within the meaning of that Regulation, the substance "Hydrocarbons, C9-C11, n-alkanes, isoalkanes, cyclics, < 2% aromatics" triggers the classification of the product with C2.

Please see the confidential annex for further details.

2.1.2.6 Type of formulation

Any other liquid (AL)

2.1.3 Hazard and precautionary statements

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

Classification

Hazard category	Flam. Liq. 3, Asp. Tox. 1, , STOT SE 3, Aquatic Acute 1, Aquatic Chronic 1
Hazard statement	H226, H304, H336, H400, H410
Labelling	
Signal words	Danger
Hazard pictogram	 GHS02 GHS07 GHS08 GHS09
Hazard statements	H226 Flammable liquid and vapour. H304 May be fatal if swallowed and enters airways. H336 May cause drowsiness or dizziness. H410 Very toxic to aquatic life with long lasting effects. EUH066 Repeated exposure may cause skin dryness or cracking. EUH208 Contains Permethrin. May produce an allergic reaction
Precautionary statements	P101 If medical advice is needed, have product container or label at hand. P102 Keep out of reach of children. P103 Read label before use. P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P233 Keep container tightly closed. P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. P370+P378 In case of fire: Use extinguisher powder or CO2 to extinguish. P261 Avoid breathing dust/fume/gas/mist/vapours/spray. P271 Use only outdoors or in a well-ventilated area. P403+P233 Store in a well-ventilated place. Keep container tightly closed. P273 Avoid release to the environment. P391 Collect spillage. P405 Store locked up. Professional: P501: Dispose of contents/ container as hazardous waste to a registered establishment or undertaking, in accordance with current regulations. General public: P501: Dispose of content and/ or its container as hazardous waste according to the regulations in force.
Note	

2.1.4 Authorised use(s)

2.1.4.1 Use #1- Preventive and curative treatments by brushing/roller application indoor - Industrial (trained professional and professional), trained professional and professional

Table 1. Use # 1 – Preventive and curative treatments by brushing/roller application indoor - Industrial (trained professional and professional), trained professional and. professional

Product Type	PT8- Wood preservatives (Preservatives)
Where relevant, an exact description of the authorised use	Insecticide
Target organism (including development stage)	Wood boring beetles *Hylotrupes bajulus*- House longhorn beetle- larvae
Field of use	Indoor Preventive wood preservation in use class 1 against WBB Curative treatment
Application method(s)	Brushing/rolling
Application rate(s) and frequency	Brushing Method: Painting with a brush or a roller Preventive treatment by application rate of 100 g/m^2 Curative treatment by application rate of 200 g/m^2
Category(ies) of users	Industrial (trained professional and professional) Trained professional Professional
Pack sizes and packaging material	Can 1L, 4L, 5L; Bucket 25L; drum 200L; IBC 1000L *

*Note for authorization in Spain: for professional users, the maximum size that can be authorized is 2.5L, except in the industrial field, where there are no container size restrictions for professional users.

2.1.4.1.1 Use-specific instructions for use

Use the solvent-based RTU product undiluted and apply to wood directly out of the original container by using a brush. After the application, clean the equipment with synthetic resin thinners or brush cleaner. The product is for use on timbers not in ground contact, cover and fully protected from the weather but where occasional but not persistent wetting may occur (Use Classes 1 and 2). Treated timber must not be used in external situations where it is in contact with the ground and permanently exposed to wetting, or in permanent contact with fresh or salt water.

See general directions for use (section 2.1.5.1).

2.1.4.1.2 Use-specific risk mitigation measures

Protective gloves and coverall (PF 90%).

See general directions for use (section 2.1.5.2).

2.1.4.1.3 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 (section 2.1.5.3).

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

See general directions for use (section 2.1.5.4).

2.1.4.1.5 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 (section 2.1.5.5).

2.1.4.2 Use #2 –Preventive and curative treatments by brushing/roller application indoor - General public (non-professional)

Table 2. Use # 2 – Preventive and curative treatments by brushing/roller application indoor - General public (non-professional)

Product Type	PT8- Wood preservatives (Preservatives)
Where relevant, an exact description of the authorised use	Insecticide
Target organism (including development stage)	Wood boring beetles *Hylotrupes bajulus*- House longhorn beetle- larvae
Field of use	Indoor Preventive wood preservation in use class 1 against WBB Curative treatment
Application method(s)	Brushing/rolling
Application rate(s) and frequency	Brushing Method: Painting with a brush or a roller Preventive treatment by application rate of 100 g/m^2 Curative treatment by application rate of 200 g/m^2
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	Can 1L

2.1.4.2.1 Use-specific instructions for use

Use the solvent-based RTU product undiluted and apply to wood directly out of the original container by using a brush. After the application, clean the equipment with synthetic resin thinners or brush cleaner. The product is for use on timbers not in

ground contact, cover and fully protected from the weather but where occasional but not persistent wetting may occur (Use Classes 1 and 2). Treated timber must not be used in external situations where it is in contact with the ground and permanently exposed to wetting, or in permanent contact with fresh or salt water. See general directions for use (section 2.1.5.1)

2.1.4.2.2 Use-specific risk mitigation measures

Brushing application without PPE. See general directions for use (section 2.1.5.2).

2.1.4.2.3 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 (section 2.1.5.3).

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

See general directions for use (section 2.1.5.4).

2.1.4.2.5 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 (section 2.1.5.5).

2.1.4.3 Use #3 - Preventive and curative treatments by automated spraying surface application indoor – Industrial (trained professional and professional)

Table 3. Use # 3 – Preventive and curative treatments by automated spraying surface application indoor – Industrial (trained professional and professional)

Product Type	PT8- Wood preservatives (Preservatives)
Where relevant, an exact description of the authorised use	Insecticide
Target organism (including development stage)	Wood boring beetles *Hylotrupes bajulus*- House longhorn beetle- larvae
Field of use	Indoor Industrial Preventive wood preservation in use class 1 against WBB Curative treatment
Application method(s)	Automated spraying.
Application rate(s) and	Preventive treatment by application rate of 100 g/m^2

frequency	Curative treatment by application rate of 200 g/m^2
Category(ies) of users	Industrial (trained professional and professional)
Pack sizes and packaging material	Can 1L, 4L, 5L; Bucket 25L; drum 200L; IBC 1000L

2.1.4.3.1 Use-specific instructions for use

The solvent-based RTU product MATACARCOMA is used undiluted for automated spraying by industrials. Automated spraying is a fully automated process. After the treatment, the wood is lifted out by the fork-lift truck. The wood is then transferred by the fork-lift truck to a storage area where it is placed to dry.

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 must be stored after treatment under shelter and/or on impermeable hard standing to prevent direct losses to soil or water and any losses must be collected for reuse or disposal.

See general directions for use (section 2.1.5.1).

2.1.4.3.2 Use-specific risk mitigation measures

Protective gloves and impermeable coverall (PF 95%).

See general directions for use (section 2.1.5.2).

2.1.4.3.3 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 (section 2.1.5.3).

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

See general directions for use (section 2.1.5.4).

2.1.4.3.5 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 (section 2.1.5.5).

2.1.4.4 Use #4- Preventive treatment by manual dipping application indoor- Industrial (trained professional and professional) and trained professional

Table 4. Use # 4 – Preventive treatment by manual dipping application indoor- Industrial (trained professional and professional) and trained professional

Product Type	PT8- Wood preservatives (Preservatives)
Where relevant, an exact description of the authorised use	Insecticide
Target organism (including development stage)	Wood boring beetles *Hylotrupes bajulus*- House longhorn beetle- larvae
Field of use	Indoor application by industrial and professional users Preventive wood preservation in use class 1 against WBB
Application method(s)	Manual dipping
Application rate(s) and frequency	Preventive treatment by application rate of 100 g/m^2
Category(ies) of users	Industrial (trained professional and professional) Trained professional
Pack sizes and packaging material	Can 1L, 4L, 5L; bucket 25L; drum 200L; IBC 1000L *

2.1.4.4.1 Use-specific instructions for use

The solvent-based MATACARCOMA is used undiluted for manual dipping by industrials and professionals. The transfer of the impregnation solutions to the dipping tank for manual dipping is done automated by connecting lines. During manual dipping, the operator lifts and places – by hand – the wooden article into the dipping tank. The operator then pushes, using a post, the wooden article under the wood preservative in the dipping tank and/or uses a broom to brush the wood preservative onto the wooden article (the article is still in the dipping tank as the preservative is brushed on the wood). The operator then lifts manually the wooden article from the dipping tank and stacks the article to dry.

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 must be stored after treatment under shelter and/or on impermeable hard standing to prevent direct losses to soil or water and any losses must be collected for reuse or disposal.

See general directions for use (section 2.1.5.1).

2.1.4.4.2 Use-specific risk mitigation measures

New gloves per cycle and impermeable coverall (PF 95%).

See general directions for use (section 2.1.5.2).

2.1.4.4.3 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 (section 2.1.5.3).

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

See general directions for use (section 2.1.5.4).

2.1.4.4.5 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 (section 2.1.5.5).

2.1.4.5 Use #5- Preventive treatment by automated dipping application indoor – Industrial (trained professional and professional)

Table 5. Use # 5 – Preventive treatment by automated dipping application indoor - Industrial (trained professional and professional)

Product Type	PT8- Wood preservatives (Preservatives)
Where relevant, an exact description of the authorised use	Insecticide
Target organism (including development stage)	Wood boring beetles *Hylotrupes bajulus*- House longhorn beetle- larvae
Field of use	Indoor application in industrial sites Preventive wood preservation in use class 1 against WBB
Application method(s)	Fully automated dipping
Application rate(s) and frequency	Preventive treatment by application rate of 100 g/m^2
Category(ies) of users	Industrial (trained professional and professional)
Pack sizes and packaging material	Can 1L. 4L, 5L; Bucket 25L; drum 200L; IBC 1000L

2.1.4.5.1 Use-specific instructions for use

The solvent-based RTU product MATACARCOMA is used undiluted for automated dipping by industrials. The transfer of the impregnation solutions to the dipping tank or bathing tray for automated dipping is done automated by connecting lines. For automated dipping, an operator using a fork-lift truck lowers the wood into the dipping tank or transfers the wood to a bathing tray. Automated dipping is a fully automated process. After the treatment, the wood is lifted out by the fork-lift truck. The wood is

then transferred by the fork-lift truck to a storage area where it is placed to dry.

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 must be stored after treatment under shelter and/or on impermeable hard standing to prevent direct losses to soil or water and any losses must be collected for reuse or disposal.

See general directions for use (section 2.1.5.1).

2.1.4.5.2 Use-specific risk mitigation measures

Use protective gloves, coated coverall (PF 95%) and mask P3 during the automated dipping application

See general directions for use (section 2.1.5.2).

2.1.4.5.3 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 (section 2.1.5.3).

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

See general directions for use (section 2.1.5.4).

2.1.4.5.5 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 (section 2.1.5.5).

2.1.5 General directions for use

2.1.5.1 Instructions for use

For industrial users: the user of the product must have received adequate training within the framework of that industry, in a way that allows him to have the knowledge and skills in handling chemical products and in the correct use of the necessary personal protective equipment for the safe performance of his work.

Remove the remains of varnish or old paint from the wood to be treated, in order to facilitate the penetration of MATACARCOMA.

The product is for use on timbers not in ground contact, cover and fully protected from the weather and wetting (Use Class 1). Treated timber must not be used in external situations where it is in contact with the ground and permanently exposed to wetting, or in permanent contact with fresh or salt water. Once the product is dried, a top-coat of varnish is recommended to be applied to treated wood. After varnishing and once dry,

treated wood by MATACARCOMA can be re-paintable.

The labelling of the product shall be including the sentence: Use biocides safely. Always read the label and product information before use.
Aerate adequately the place where the product is applied.

2.1.5.2 Risk mitigation measures

When the product is applied by industrial users the following RMM must be considered to avoid any risk to the environment:
- Prevent any release to the environment during the product application phase as well as during the storage and the transport of treated timber;
- During the application phase, prevent any release of cleaning water (after cleaning of floors, tanks, containers) to the environment (sewer, soil, water);
- 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. Before use, store the timber in an area sheltered from the weather;
- Any contaminated water/soil shall be collected, contained and treated as hazardous waste.

For professionals and no professionals:
When the application take place outside the following RMM should be considered to avoid any risk to the enviroment:

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 tarpoline) and disposed of in a safe way

Do not (use/apply) directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock/pets.

Keep uninvolved persons, children and pets away from treated surfaces/areas until dried.

Contains permethrin, may be dangerous/toxic to pets (e.g. cats, bees, fish and other aquatic organisms).

Keep cats away from treated surfaces. Due to their particular sensitivity to permethrin, the product can cause severe adverse reactions in cats.

Do not use the product for wood, which is foreseen as part of playground structures and other indoor/outdoor structures (e.g. flooring, furniture), to which persons of the general public and pets may have prolonged contact

The product can be harmful to protected species such as bats, hornets or birds. The presence of protected species in the area to be treated must be assessed prior to use of the product. Appropriate protective measures must be taken if necessary.

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

First aid instructions

- IF SWALLOWED: Do NOT induce vomiting.
  If symptoms: Immediately call 112/ambulance for medical assistance.
  If no symptoms: Call a POISON CENTRE or a doctor.

- IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTRE or a doctor.

- IF ON SKIN: Take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation occurs: Get medical advice.

- IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.

IF MEDICAL ADVICE IS NEEDED, HAVE THE PRODUCT CONTAINER OR LABEL AT HAND AND CONTACT THE POISON CONTROL CENTER

Product dangerous for the environment, in case of large spills or if the product contaminates lakes, rivers, or sewers, inform the responsible authorities according to local legislation. Prevent the contamination of drains, surface or subterranean waters, and the ground.

Methods and material for containment and cleaning up: Contain and collect spillage with inert absorbent material (earth, sand, vermiculite, Kieselguhr...) and clean the area immediately with a suitable decontaminant. Deposit waste in closed and suitable containers for disposal, in compliance with local and national regulations.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Industrials and professionals:
Empty containers, unused product, washing water, containers and other waste generated during the treatment application are considered hazardous waste. Deposit packaging waste at the established collection points or deliver it to a registered hazardous waste operator as agreed with the extended producer responsibility system.
Deliver those the other wastes to a registered establishment or undertaking for hazardous waste, in accordance with current.
Code the waste according to Decision 2014/955 / EU.
Do not release to soil, ground, surface water or any kind of sewer.

General public:
Empty containers, unused product and other waste generated during the treatment are considered hazardous waste. Dispose of in accordance with current regulations.
Do not release to soil, ground, surface water or any kind of sewer.

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

Store according to local legislation.
Observe indications on the label.
Store the containers between 5 and 25 º C, in a dry and well-ventilated place, far from sources of heat and direct solar light.
Keep far away from ignition points.

Keep away from oxidising agents and from highly acidic or alkaline materials. Do not smoke. Prevent the entry of non-authorised persons. Once the containers are open, they must be carefully closed and placed vertically to prevent spills. Shelf-life of product > 2 years

2.1.6 Other information

The treated wood must not be used for uses that involve contact with food, feed or livestock. Only in Spain, user categories:

- Industrial users are considered to be the applicator of biocidal products at industrial facilities who have received specific training in the application of wood protectors, according to the current legislation.
- Trained professional users are considered to be the applicator of biocidal products, who have received specific training in the application of wood protectors, according to the current legislation.
- Professional users are considered to be those who in the performance of their professional activity can use biocidal products. This user has some knowledge and skills in the handling of chemicals, and if it necessary he/she is able to use correctly the equipment of personal protection (PPE).
- The general public (non-professional) is considered to be the one who applies the product biocide within the scope of their private life.

At the same time, there are also some restrictions of packaging in relation to those user categories and product types. In this case, for professional and non-professional users the maximum size that can be authorized is 1 L.

In that context, the exposure assessment will be the same for professionals and trained professional users and the difference between the two will depend on the expert judgment following "limiting criteria" below:

1. The hazardousness of the product under evaluation.
2. The use being requested.
3. The frequency of use.
4. Complexity of control measures.

2.1.7 Packaging of the biocidal product

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)**
MATACARCOMA	Can	1L, 4L and 5L	Tinplate with an interior coating	Plastic	Trained professional, Professional and non-professional	Yes

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)
	Bucket	25L	Tinplate with an interior coating	Plastic	Trained professional, Professional	Yes
	Drum	200L	Tinplate	Plastic	Trained professional, Professional, Industrial	Yes
	Intermediate Bulk Container (IBC)	1000L	Plastic	Plastic	Trained professional, Professional, Industrial	Yes

Note for authorization in Spain: for professional users, the maximum size that can be authorized is 2.5L, except in the industrial field, where there are no container size restrictions for professional users.

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

2.1.8.2 The complete list of submitted studies in relation to this application for authorisation can be found in the reference list in Annex 3.1. This list is also included in section 13 of the IUCLID dossier.

2.1.8.3 Access to documentation

The applicant Industrias Químicas Irurena, SA provided a letter of access by LANXESS Deutschland GmbH to the dossier assessed for the approval of all data of active substance permethrin. LANXESS Deutschland GmbH is included in Article 95 list as supplier of active substance Permethrin.

2.2 Assessment of the biocidal product

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

Table 2 Use #1 –Treatment by brushing/roller application indoor – Industrial, professional and general public

Product Type	PT8 – Wood preservatives (Preservatives)
Where relevant, an exact description of the authorised use	Insecticide
Target organism (including development stage)	*Hylotrupes bajulus* – House longhorn beetle - larvae
Field of use	Indoor Preventive and curative wood preservation in use class 1 and 2.
Application method(s)	Brushing /rolling
Application rate(s) and frequency	Preventive treatment at application rate of 100 g/m^2. Curative treatment at application rate of 200 g/m^2
Category(ies) of users	Industrial, Professional (trained and non-trained professionals) and general public (non-professional)

Table 3. Use #2 – Treatment by spraying surface application indoor - Professional

Product Type	PT8 – Wood preservatives (Preservatives)
Where relevant, an exact description of the authorised use	Insecticide
Target organism (including development stage)	*Hylotrupes bajulus* – House longhorn beetle - larvae
Field of use	Indoor Preventive wood preservation in use class 1 and 2
Application method(s)	Spraying
Application rate(s) and frequency	Preventive treatment at application rate of 100 g/m^2. Curative treatment at application rate of 200 g/m^2
Category(ies) of users	Professional (trained and non-trained professionals)
Pack sizes and packaging material	Can 1L, 4L and 5L; bucket 25L; drum 200L and IBC 1000L

Table 4. Use #3 – Treatment by automated spraying surface application indoor - Industrial

Product Type	PT8 – Wood preservatives (Preservatives)
Where relevant, an exact description of the authorised use	Insecticide
Target organism (including development stage)	*Hylotrupes bajulus* – House longhorn beetle - larvae
Field of use	Indoor Industrial Preventive wood preservation in use class 1 and 2.
Application method(s)	Automated spraying in closed system.
Application rate(s) and frequency	Preventive treatment at application rate of 100 g/m^2.
Category(ies) of users	Industrial
Pack sizes and packaging material	Bucket 25L, Drum 200L and IBC 1000L

Table 5. Use #4 –Treatment by Manual dipping -Industrial and Professional

Product Type	PT8 – Wood preservatives (Preservatives)
Where relevant, an exact description of the authorised use	Insecticide
Target organism (including development stage)	*Hylotrupes* bajulus – House longhorn beetle - larvae
Field of use	Indoor application by industrial and by professional users Preventive wood preservation in use class 1 and 2.
Application method(s)	Manual dipping
Application rate(s) and frequency	Preventive treatment at application rate of 100 g/m^2. Curative treatment at application rate of 200 g/m^2
Category(ies) of users	Industrial, Professional
Pack sizes and packaging material	Bucket 25L, Drum 200L and IBC 1000L (industrial and professional). Can 1L, 4L and 5L (professional).

Table 6. Use #5 –Treatment by Automated dipping – Industrial use

Product Type	PT8 – Wood preservatives (Preservatives)
Where relevant, an exact description of the authorised use	Insecticide

Target organism (including development stage)	*Hylotrupes* bajulus – House longhorn beetle - larvae
Field of use	Indoor application in industrial sites Preventive wood preservation in use class 1 and 2.
Application method(s)	Fully automated dipping
Application rate(s) and frequency	Preventive treatment at application rate of 100 g/m^2.
Category(ies) of users	Industrial use
Pack sizes and packaging material	Bucket 25L, Drum 200L and IBC 1000L.

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual method	IKI-DEKOR MATACARCOMAS (Permethrin 0.4%)	Very fluid liquid	Report nº: 095128-2-a (2021)
Colour at 20 °C and 101.3 kPa	Visual method	IKI-DEKOR MATACARCOMAS (Permethrin 0.4%)	Transparent and colourless	Report nº: 095128-2-a (2021)
Odour at 20 °C and 101.3 kPa	Visual method	IKI-DEKOR MATACARCOMAS (Permethrin 0.4%)	Solvent naphtha odour	Report nº: 095128-2-a (2021)
pH	Internal method	IKI-DEKOR MATACARCOMAS (Permethrin 0.4%)	pH = 5.7	Report nº: 102786-a (2022)
Relative density	UNE-EN ISO 2811-1:2016	IKI-DEKOR MATACARCOMAS (Permethrin 0.4%)	The density of the product is 0.76 g/cm3.	Report nº: 095128-3-a (2021)
Storage stability test – **accelerated storage stability test 6 weeks at 45ºC**	CIPAC MT46.3	IKI-DEKOR MATACARCOMAS (Permethrin 0.4%)	Temperature 45ºC (6 weeks) The appearance of the packaging and the weight of the test item did not change significantly..	Report nº: 095128-2-a (2021)

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			The chemical stability after CIPAC test of the permethrin active ingredient in the product is acceptable, with a decrease below 10%, meeting the established FAO/WHO criteria for biocidal products.	
Storage stability test – **long term storage at ambient temperature**	CIPAC MT 46.3	IKI-DEKOR MATACARCOMAS (Permethrin 0.4%)	The chemical stability of the permethrin active ingredient in the product IKI-Dekor Matacarcomas complies with a decrease below 10%, meeting the established FAO/WHO criteria for biocidal products. The initial value complies with the nominal value of 0.4% Permethrin. There is no change in the appearance of the product. The 1000 ml metal container is in good condition.	Report nº: 095128-1-a (2021)
Storage stability test – **low temperature stability test 7 days at 0ºC**	This study does not need to be conducted as the product must not be stored under conditions of ≤ 0°C.			
Effects on content of the active substance and technical	Please refer to the results of long term storage stability test.			Reportnº: 095128-1-a (2021)

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
characteristics of the biocidal product - **light**				
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Please refer to the results of long term storage stability test.			Reportnº: 095128-1-a (2021)
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	Please refer to the results of long term storage stability test.			Reportnº: 095128-1-a (2021)
Wettability	Not applicable for this type of formulation.			
Suspensibility, spontaneity and dispersion stability	Not applicable for this type of formulation.			
Wet sieve analysis and dry sieve test	Not applicable for this type of formulation.			
Emulsifiability, re-emulsifiability and emulsion stability	Not applicable for this type of formulation.			
Desintegration time	Not applicable for this type of formulation.			
Particle size distribution, content of dust/fines, attrition, friability	Not applicable for this type of formulation.			
Persistent	Not applicable for this type of formulation.			

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
foaming				
Pourability	Not applicable for this type of formulation.			
Burning rate — smoke generators	Not applicable for this type of formulation.			
Burning completeness — smoke generators	Not applicable for this type of formulation.			
Composition of smoke — smoke generators	Not applicable for this type of formulation.			
Spraying pattern — aerosols	Not applicable for this type of formulation.			
Physical compatibility	The product is not intended to be used in combination with other products.			
Chemical compatibility	The product is not intended to be used in combination with other products.			
Degree of dissolution and dilution stability	The study does not need to be conducted as both products are not diluted before application.			
Surface tension	DIN EN 14370 ASTM D 971	IKI-DEKOR MATACARCOMAS (Permethrin 0.4%)	23.6 mN/m.	Figueras J. 2021, BYK Aditives & Instruments
Viscosity at 20ºC and 40ºC	ASTM D1200 - 94	IKI-DEKOR MATACARCOMAS (Permethrin 0.4%)	Viscosity at 20ºC = 9.9 s Viscosity at 40ºC = 9.8 s	Report nº: 102786-a (2022)

Conclusion on the physical, chemical and technical properties of the product

The product "MATACARCOMA" is a AL (Any other liquid) product. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is a transparent very fluid liquid. There is no effect of high temperature on the stability of the formulation, since after 6 weeks at 45 ºC, neither the active ingredient content nor the technical properties were changed.

The stability data indicate a shelf life of at least more than 2 years at ambient temperature when stored in commercial packaging material. Its technical characteristics are acceptable for an AL formulation.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	The study does not need to be conducted because there are no chemical groups present in the molecule which are associated with explosive properties.			
Flammable gases	Not applicable to AL formulations.			
Flammable aerosols	Not applicable to AL formulations.			
Oxidising gases	Not applicable to AL formulations.			
Gases under pressure	Not applicable to AL formulations.			
Flammable liquids	Calculation from SDS - EQGEST	IKI-DEKOR MATACARCOMAS (Permethrin 0.4%)	Flash point = 39ºC The product is classified as flammable liquid Category 3 (H226)	SDS IKI-DEKOR MATACARCOMAS
Flammable solids	Not applicable to AL formulations.			
Self-reactive substances and mixtures	There are no chemical groups present in the molecule which are associated with explosive or self-reactive properties and hence, the classification procedure does not need to be applied. Therefore, this study is not necessary.			
Pyrophoric liquids	The experience in manufacture or handling shows that the product does not ignite spontaneously on coming into contact with air at normal temperatures. Therefore, this study is not need to be performed.			
Pyrophoric solids	Not applicable to AL formulations.			
Self-heating substances and mixtures	The product MATACARCOMA does not ignite itself at temperature < 255ºC, so it shall not be classified as a self-heating substance or mixture. Therefore, this study is not necessary.			
Substances and mixtures which in contact with water emit flammable gases	The product is intended to be used diluted in water. So, in contact with water it do not emit flammable gases.			
Oxidising liquids	The study does not need to be conducted because there are no chemical groups present in the molecule which are associated with oxidising properties and hence, the classification procedure does not need to be applied.			
Oxidising solids	Not applicable to AL formulations.			
Organic peroxides	The study does not need to be conducted because the substance does not fall under the definition of organic peroxides according to GHS and the relevant UN Manual of test and criteria.			
Corrosive to metals	UN Test C1	IKI-DEKOR MATACARCOMAS (Permethrin 0.4%)	No degradation of any of the samples was observed in the visual inspection carried out at the end of the test. The loss of material recorded in all cases is below what is established in the specification (13.5% for 7 days of exposure). Therefore, product is not corrosive.	Report nº a370.2- (2022)
Auto-ignition temperatures of products (liquids and gases)	Calculation from SDS - EQGEST	IKI-DEKOR MATACARCOMAS (Permethrin 0.4%)	255-270 ºC	SDS IKI-DEKOR MATACARCOMAS

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Relative self-ignition temperature for solids	Not applicable to AL formulations.			
Dust explosion hazard	Not applicable to AL formulations.			

Conclusion on the physical hazards and respective characteristics of the product
MATACARCOMA (AL) has no oxidizing, no organic peroxides and explosive properties. The flash point of the product was 39 ºC, therefore the product need to be classified as 'flammable liquid' cat 3. Hence, the product require classification under Regulation (EC) nº 1272/2008 for physical hazards.

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	GC-FID	0.100 mg/ml 5 samples	Linear in the concentration range 0.02-05 mg/ml (Corr. =0.99972	Yes	[93.78-96.63]	95.3	1.18	0.02 mg/ml	Report nº. 102786-1-a (2022)

Analytical methods for monitoring									
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		
Please refer to the active substances' AR for further methods and information.									

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		
Please refer to the active substances' AR for further information.									

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		
Please refer to the active substances' AR for further information.									

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		
Please refer to the active substances' AR for further information.									

Analytical methods for animal and human body fluids and tissues									
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		
Please refer to the active substances' AR for further information.									

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		

Please refer to the active substances' AR for further information.

Conclusion on the methods for detection and identificationof the product
The analytical methods provided are fully validated for the determination of the active substance permethrin. The results were satisfactory according to point 3.8.1 of the Guidance on the PPR: Volume I Parts A+B+C.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

MATACARCOMA is a ready to use solvent-based wood preservation product based on the active substance permethrin.

It is used for preventive and curative treatment of wood against Wood Boring Beetles by superficial application on wood for use in use class 1. The application rate for a preventive treatment is 100 g/m^2 whilst curative treatment is at 200 g/m^2.

The product should to be applied with a top varnish-coat on wood that is exposed to weathering.

The product is applied by industrial users, trained professional, professional users and general public.

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

The organisms to be controlled for preventive and curative treatments against Wood Boring Beetles.

The object to be protected is wood (more specifically wood in use class 1 for preventive treatment and curative treatment).

2.2.5.3 Effects on target organisms, including unacceptable suffering

MATACARCOMA product causes mortality on larvae of house longhorn beetle (*Hylotrupes bajulus*) and in general in WBB.

2.2.5.4 Mode of action, including time delay

The mode of action of the insecticidal active substance permethrin is a neurotoxic effect mediated through preventing the closure of the voltage-gated sodium channels in the axonal membranes.

2.2.5.5 Efficacy data

Function and field of use envisaged	Test substance	Test organism and organism to be protected	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
Wood preservative: preventive treatment PT-08	**IKI-DEKOR MATACARCOMAS** (Permethrin 0.4%)	House longhorn beetle*: Hylotrupes bajulus* (larvae) *Pinus sylvestris*	EN 46-1:2016) +EN84 (leaching) Application by surface treatment	Superficial treatment (brushing) Target retention: 99.81 ±3.34 ml/m^2. (~100g/m^2) Exposure time: 4 weeks Tested concentration: 100%	Considering that the all larvae recovered are dead not having tunneled and according with UNE-EN 599-1:2010+A1:2014 standard, the product is effective against recently hatched *Hylotrupes bajulus* larvae at application dose of 99.81 ±3.34 ml/m^2	[redacted] 2021. TECNALIA. Report No 092354-3-a (M1) Key study. [redacted] 2021. TECNALIA. Report No 092354-3-a (M1)
Wood preservative: preventive treatment PT-08	**MATACARCOMAS EX-77** (0.1-1% Permethrin)	House longhorn beetle*: Hylotrupes bajulus* (larvae) *Pinus sylvestris*	EN 46-1:2008) +EN73 (leaching) Application by surface treatment	Dipping application method Target retention: 98,75±4,57 g/m^2. Exposure time: 4 semanas Tested concentration: 100%	100% larvae were recovered dead without having made tunnels in the wood. 100% of the larvae inserted in all untreated control specimens survive.	[redacted] 2010. TECNALIA. Report No 23984-2 Test not valid.
Wood preservative: curative treatment PT-08	**IKI-DEKOR MATACARCOMAS** (Permethrin 0.4%)	House longhorn beetle*: Hylotrupes bajulus* (larvae) *Pinus sylvestris*	EN 1390: 2021	Superficial treatment (brushing) Application rate: 249.99±2.28 ml/m^2. (~200g/m^2) Exposure time: 12 weeks Tested concentration: 100%	≥90% larvae were recovered dead. Considering that the mortality percentage is 93,32% and according with EN 14128:2004 standard, the product is effective against *Hylotrupes bajulus* larvae at application dose of 249.99 ±2.28 ml/m^2	[redacted] 2021. TECNALIA. Report No 092354-6-a (M1) Key study [redacted] 2021. TECNALIA. Report No 092354-6-a

Function and field of use envisaged	Test substance	Test organism and organism to be protected	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
Wood preservative: curative treatment PT-08	**MATACARCOMAS EX-77** (0.1-1% Permethrin)	House longhorn beetle*: Hylotrupes bajulus* (larvae) *Pinus sylvestris*	EN 1390: 2007	Superficial treatment (brushing two coats) Application rate: 198.01±1.20 g/m^2) Exposure time: 12 weeks Tested concentration: 100%	87% larvae were recovered dead without having made tunnels in the wood. 100% of the larvae inserted in all untreated control specimens survive.	[redacted] 2010. TECNALIA. Report No 23984-1(M1) Test not valid.
Insecticidal (Preventive and Curative)	**IKI-DEKOR MATACARCOMAS** (Permethrin 0.4%)	*Pinus sylvestris* *Abies alba*	UNE EN 46-1:2016)	Immersion treatment (dipping) Wood types: Spruce and pine wood Procedure: The immersion process is carried out in both supports (spruce and pine wood). All the test pieces used have all faces sealed with epoxy varnish, except for the face to be treated, and have the measurements established by standard EN 46-1:2016 (50*25*15mm). Concentration tested: 100% Exposure time: 2 successive immersions of 5 min are made with an intermediate time of 30 min.	The objective of the test is to demonstrate the feasibility of achieving retention of 200 g/m^2 by immersion with IKIDECOR MATACARCOMAS on a Pine and Spruce support. Results: In both woods and with a 5 min immersion, the 100 g/m^2 required for preventive efficacy is reached. With 2 successive immersions of 5 min and an interval of 30 min between them, the 200 gr/m^2 required for curative efficacy is reached.	[redacted] 2022. TECNALIA. Report No 102786-2

Conclusion on the efficacy of the product

PREVENTIVE TREATMENT:

Surface treatment:

Wood boring beetles

The applicant has submitted two test against *Hylotrupes bajulus* to support a preventive treatment against Wood Boring Beetles one of them was withdrawn. This test is included in the efficacy table as not valid due to the ambiguous concentration of active substance.

Thanks to *Test report: 092354-3*-a (M1) according to EN46-1: 2016+EN84 (leaching), the product has demonstrated preventive efficacy against *Hylotrupes bajulus.*

According to the TNsG on product evaluation (2008) for general claims against "wood boring beetles*", it is acknowledged that the majority of applications for authorization are likely to be for treatment against H. bajulus. Therefore, data against this beetle species should be available and will be considered adequate to cover this claim*. Therefore, we accept that the applicant has only provided tests on this insect.

'Wood boring beetles' claim is accepted for preventive treatment.

This claim is required for the Use class 1, this class is authorized.

The study has been carried out in softwood and for surface application.

Dose rate: 99,81ml/m^2 or ~100 g/m^2.

Use class 1: situation in which the wood or wood based product is inside a construction, not expose to the weather and wetting.

The application methods indicated in the EN 46-1 standard for the treatment of the samples are by brushing as well as by dipping. The test has been done by brushing, therefore we consider that the application by brushing or spraying is covered in this test.

The application method by immersion has been requested, the applicant has provided a justification to cover this method and has indicated the necessary immersion time and the amount of product used that is needed to achieve a retention of 100g/m^2. Therefore, the immersion method has been accepted.

CURATIVE TREATMENT:

Surface treatment:

Wood Boring Beetles

The applicant has submitted two test according EN 1390 against *Hylotrupes bajulus* to support a curative treatment against Wood Boring Beetles, one of them was withdrawn. This test is included in the efficacy table as not valid due to the ambiguous concentration of active substance.

Curative dose rate by superficial treatment: 249,99 mL/m^2 or ~200 g/m^2.

The basic curative norm (EN14128) indicates that insecticidal activity tests should be carried out against *Hylotrupes bajulus* and *Anobium punctatum* or only against the most resistant insect. (section 5.2.3 a and b).

The laboratory has justified that *Hylotrupes bajulus* is more ressistant than *Anobium puctatum.* It is based on the smaller size of *Anobium puctatum*, the laying of eggs in the most superficial layers of the wood and the faster biological cycle with respect to *Hylotrupes bajulus*. This causes the *Annobium* larvae to die earlier, since they need less wood and less exposure time. They also report that they have verified over the years that *Hylotrupes bajulus* is more resistant than *Anobium*. We accept justification of the applicant about that *Hylotrupes bajulus* is the less sensitive target for MATACARCOMA. The applicant has only provided tests on this insect and 'Wood boring beetles' claim was accepted for superficial curative treatment.

A general Wood Boring Beetle claim for curative treatment is covered at 200g /m^2,

corresponding to 249.99 ml/m^2.

In conclusion, MATACARCOMA has demonstrated its efficacy:
For preventive treatment of soft wood by superficial application (brushing, spraying, dipping) at the application of 100 g/m^2 against WBB. Therefore the efficacy assessment justified that the product meet the requirements for use in preservation of Use Class 1 wood.

For curative treatment of soft wood by superficial application (brushing, spraying) at the application of 200 g/m^2 against WBB.

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.
No resistance against permethrin has been reported for woodboring beetles.

2.2.5.7 Known limitations

MATACARCOMA is intended to be used indoors protected from weather, however in order to prevent any emission from the treated wood to the environment, after product's application and once the product is dried, a top-coat of varnish is recommended to be applied to treated wood. After varnishing and once dry, treated wood by MATACARCOMA can be re-paintable.

2.2.5.8 Evaluation of the label claims

Claim matrix:

	MATACARCOMA	
User category	General public Industrial Trained Professional and Professional	A.10; A.20; A.30
Wood category	Softwood	B.10
Wood product	Solid wood	C.10
Application aim	Preventive treatment Curative	D.40 D.50
Field of use	User class 1	E.10
Method of application rate	Superficial application / brush treatment Superficial application / spray treatment Superficial application / dipping treatment	F.10 F.11 F.14
Target organisms	House longhorn beetle.	G.31

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

2.2.6 Risk assessment for human health

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	Not corrosive or irritating to skin.
Justification for the value/conclusion	Based on intrinsic properties of individual components of the biocidal product MATACARCOMA.
Classification of the product according to CLP	No classification for skin corrosion/irritation required. EUH066 is required based on SoC.

Data waiving	
Information requirement	Skin corrosion and irritation
Justification	Studies on potential skin corrosive or skin irritating properties of the product MATACARCOMA are not required. In order to avoid further testing on vertebrates no studies on skin corrotion and irrritation of the product were conducted as there are valid data available on each component of the mixture sufficient to allow classification of the mixture according to the rules laid down in the Regulation (EC) 1072/2008 (CLP) and no synergistic effects between any of the components are expected. None of the components in the product are classified with respect to skin corrosion/irritation. Therefore, according to the CLP principles, **MATACARCOMA does not need to be classified with respect to skin corrosion/irritation**. However, MATACARCOMA contains the SoC "hydrocarbons, C9-C11, n-alkanes, isoalkanes, cyclics, < 2% aromatics" in a substantial amount which may cause skin dryness or cracking. According to Annex II, chapter 1.2.4 of the Regulation (EC) No 1272/2008 (CLP), for substances and mixtures which may cause concern as a result of skin dryness, flaking or cracking but which do not meet the criteria for skin irritancy, additional labelling with EUH066 is required. Thus, the label of MATACARCOMA shall bear the statement **EUH066**: **"Repeated exposure may cause skin dryness or cracking".**

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Not irritating to eye

Justification for the value/conclusion	Based on intrinsic properties of individual components of the biocidal product MATACARCOMA.
Classification of the product according to CLP	No classification is required.

Data waiving	
Information requirement	Eye irritation
Justification	In order to avoid further testing on vertebrates no studies on eye irritation of the product were conducted as there are valid data available on each component of the mixtures sufficient to allow classification of the mixtures according to the rules laid down in the Regulation (EC) 1072/2008 (CLP) and no synergistic effects between any of the components are expected. MATACARCOMA has not ingredients classified as eye irritant. Therefore, the **product MATACARCOMA is not classified as eye irritant.**

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	Not irritating to the respiratory tract.
Justification for the value/conclusion	Based on intrinsic properties of individual components of the biocidal product MATACARCOMA.
Classification of the product according to CLP	No classification required.

Data waiving	
Information requirement	Respiratory tract irritation
Justification	In order to avoid further testing on vertebrates no studies on respiratory tract irritation of the products were conducted as there are valid data available on each component of the mixtures sufficient to allow classification of the mixtures according to the rules laid down in the Regulation (EC) 1072/2008 (CLP) and no synergistic effects between any of the components are expected. So, the **product MATACARCOMA is not classified as respiratory tract irritant**.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	No sensitising to skin.
Justification for the value/conclusion	Based on intrinsic properties of individual components of the biocidal product MATACARCOMA.
Classification of the product according to CLP	No classification required.

Data waiving	
Information requirement	Skin sensitization
Justification	In order to avoid further testing on vertebrates no studies on the skin sensitization of the products were conducted as there are valid data available on each component of the mixtures sufficient to allow classification of the mixtures according to the rules laid down in the Regulation (EC) 1072/2008 (CLP) and no synergistic effects between any of the components are expected. Permethrin has a harmonized classification of Skin Sens. 1 (H317). According to Table 3.4.5 of the CLP Regulation (EC) No 1272/2008, the generic concentration limit of a component of a mixture classified

	as skin sensitizer that triggers the classification of the mixture is ≥ 1%. As the concentration of permethin in the product is below the concentration limit of ≥ 1% for skin sensitization, **MATACARCOMA is not classified as skin sensitizer**. According to Annex II, chapter 2.8 of the Regulation (EC) No 1272/2008 (CLP), for substances and mixtures which may cause concern as a result of containing at least one substance classified as sensitising and present in a concentration equal to or greater than 0,1 % or in a concentration equal to or greater than that specified under a specific note for the substance in part 3 of Annex VI shall bear the statement. Thus, the label of MATACARCOMA shall bear the statement **EUH208**: **"Contains permethrin. May produce an allergic reaction".**

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not sensitizing to respiratory tract.
Justification for the value/conclusion	Based on intrinsic properties of individual components of the biocidal product MATACARCOMA.
Classification of the product according to CLP	No classification required.

Data waiving	
Information requirement	Respiratory sensitization
Justification	For the biocidal product the composition is known. Sufficient data on the intrinsic properties of the components are available from safety data sheets and other information for each of the individual components in the product. Consequently, classification of the mixture can be made according to the rules laid down in Regulation (EC) No 1272/2008. None of the ingredients are classified as respiratory sensitizers, so **MATACARCOMA is not classified as respiratoy sensitizer.**

Acute toxicity

Value used in the Risk Assessment – Acute oral toxicity	
Value	DL_{50}: >2000mg/kg bw.
Justification for the selected value	The classification of the biocidal product was conducted using endpoints included in Assessment Report (PT8) of permethrin and the SDSs of the other components. According to Assessment Report, the worst case acute oral LD_{50} for Permethrin is 480mg/kg bw. The calculated oral ATE for MATACARCOMA is higher than 2000mg/kg bw. Therefore the product does not meet the criteria for classification for acute oral toxicity according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP	No classification required.

Data waiving	
Information requirement	Acute oral toxicity study
Justification	No studies have been performed with the biocidal product in order to avoid unnecessary testing with vertebrates. The composition of the product is known and there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP Regulation), and synergistic effects between any of the components are not expected Therefore, this study does not need to be conducted. According to chapter 3.1.3.6 "Classification of mixtures based on ingredients of the mixture (Additivity formula)" of the CLP Regulation, the ATE of the mixture (ATE_{mix}) is determined by calculation from the ATE values for all relevant ingredients according to the following formula and using the LD50/LC50-values as provided for in section 11 ("Toxicological Information") of the SDS of the respective components for Oral, Dermal or Inhalation Toxicity: $\frac{100}{ATE_{mix}} = \sum_{n} \frac{C_i}{ATE_i}$ where: C_i = concentration of ingredient i (% w/w or % v/v) i = the individual ingredient from 1 to n n = the number of ingredients ATE_i = Acute Toxicity Estimate of ingredient i. Permethrin is classified with Acute Tox. 4; H302 with a LD50 value of 480 mg/kg bw. The concentration of and permethrin in MATACAROMA is 0.4%. According to CLP Regulation, section 3.1.3.3., page 124, "(d) when only range data (or acute toxicity hazard category information) are available for components in a mixture, they may be converted to point estimates in accordance with Table 3.1.2 when calculating the

	classification of the new mixture using the formulas in sections 3.1.3.6.1 and 3.1.3.6.2.3". In table 3.1.2, the converted acute toxicity point estimated is 500 for the experimentally obtained acute toxicity range values of 300 < LD50 ≤ 2000 mg/kg bw. The potential acute oral toxicity of the product is calculated as follows: ATEmix = 100/[(0.4/480)] = 120000 mg/kg bw. According to Tab.3.1.2 of the CLP Regulation (EC) No 1272/2008, the calculated ATE of the mixture for acute oral toxicity is > 2000 mg/kg bw. Thus, **MATACARCOMA does not need to be classified with respect to acute oral toxicity**.

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	CL50: >5mg/l
Justification for the selected value	Based on intrinsic properties of individual components of the biocidal product MATACARCOMA.
Classification of the product according to CLP	No classification required.

Data waiving	
Information requirement	Acute inhalation toxicity study
Justification	No studies have been performed with the biocidal product in order to avoid unnecessary testing with vertebrates. The composition of the product is known and there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP Regulation), and synergistic effects between any of the components are not expected Therefore, this study does not need to be conducted. According to chapter 3.1.3.6 "Classification of mixtures based on ingredients of the mixture (Additivity formula)" of the CLP Regulation, the ATE of the mixture (ATE_{mix}) is determined by calculation from the ATE values for all relevant ingredients according to the following formula and using the LD50/LC50-values as provided for in section 11 ("Toxicological Information") of the SDS of the respective components for Oral, Dermal or Inhalation Toxicity: $\frac{100}{ATE_{mix}} = \sum_{n} \frac{C_i}{ATE_i}$ where: C_i = concentration of ingredient i (% w/w or % v/v) i = the individual ingredient from 1 to n n = the number of ingredients ATE_i = Acute Toxicity Estimate of ingredient i. permethrin is classified with Acute Tox. 4; H332. The LC50 value for permethrin is for dust/mist 4.638 mg/L, according to the CAR. The concentration of permethrin in MATACARCOMA is 0.4%. The potential acute inhalation toxicity of the product is calculated as follows: ATE_{mix} = 100/[(0.4/4.638)] = 1159.5 mg/L According to Tab.3.1.2 of the CLP Regulation (EC) No 1272/2008, the calculated ATE of the mixture for acute inhalation toxicity is > 5 mg/L

	for dust/mist mg/kg bw. Thus, MATACARCOMA **does not need to be classified with respect to acute inhalation toxicity**.

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not acutely toxic via the dermal route.
Justification for the selected value	Based on the classification of permethrin and the different co-formulants and, their respective content in the final formulation. None of the components of the product is classified for acute dermal toxicity. Therefore, the product does not meet the criteria for classification according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP	No classification required.

Data waiving	
Information requirement	Acute dermal toxicity study
Justification	No studies have been performed with the biocidal product in order to avoid unnecessary testing with vertebrates. The composition of the product is known and there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP Regulation), and synergistic effects between any of the components are not expected. Therefore, this study does not need to be conducted. **MATACARCOMA is not classified as Acute toxicity by dermal route**.

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Permethrin
Value(s)	70%
Justification for the selected value(s)	Default value from EFSA guidance on dermal absorption for organic solvent-based dilution.(EFSA Journal 2017; 15(6):4873)

Data waiving	
Information requirement	Dermal absorption study
Justification	There is no experimental data available on the dermal absorption of MATACARCOMA since no study has been conducted thus far. As a result, risk assessment calculations for human exposure have been

	made according to the EFSA guidance on dermal absorption (EFSA Journal, 2017;15(6):4873) using a default value of 70% dermal absorption for this product.

Endocrine disrupting properties

Since 7 June 2018, date when the Regulation (EU) 2017/2100 came into force, endocrine disrupting properties assessment of active substance and co-formulants is mandatory according to the article 19 of BPR.
According to the CAR and BPC Opinion (April 2014), permethrin is not considered to have endocrine disrupting properties. However, a comprehensive ED-assessment for the active substance and its metabolites according to Regulation (EU) 2017/2100 and the "Revised Guidance Document 150 on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption" will need to be performed at the renewal stage.
After examining the possible ED properties of co-formulants, several substances have been identified as having potential endocrine disrupting properties. If these substances are identified as having ED properties in the future, the conditions for granting the biocidal product authorisation will be revised.
Please, refer to the confidential annex for more information.

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

According to the note for discussion on substances of concern (SoC), CA-Nov14-Doc.5.11, MATACARCOMA contains the substance of concern (SoC) "Hydrocarbons, C9-C11, n-alkanes, isoalkanes, cyclics, < 2% aromatics" triggers the classification of the product with Asp. Tox. 1 (H304). Furthemore, EUH066 (Repeated exposure may cause skin dryness or cracking) and EUH208 (Contains permethrin. May produce an allergic reaction) are proposed.

According to the Guidance on the Biocidal Products Regulation, Vol III, Part B+C (2017), the SoC contained in the product ends up in Band A.
Associated evaluation and risk management requirements according to the SoC banding approach for Band A are limited to the application of P-statements normally associated with concerned H statements.
For more information see confidential annex.

Available toxicological data relating to a mixture

No toxicological studies have been performed with the formulated product. Instead of that, the classification of the product relies on the available toxicity studies for the active substance Permethrin.

No further studies on the toxicity of the product are considered necessary as there are valid data available on the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) 1072/2008 (CLP) and synergistic effects between any of the components are not expected and the rest of the coformulants.

Other

2.2.6.1.1 Aspiration Hazard

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	May pose an aspiration toxicity hazard
Justification for the value/conclusion	Based on intrinsic properties of individual components of the biocidal product MATACARCOMA.
Classification of the product according to CLP	H304: May be fatal if swallowed and enters airways

Data waiving	
Information requirement	Up to April 2016, there are no testing requirements for aspiration toxicity hazard under the BPR.
Justification	Studies on potential aspiration toxicity hazard of the product MATACARCOMA are not required. According to Table 3.10.1 "Hazard category for aspiration toxicity" of the CLP Regulation (EC) No 1272/2008, "a substance is classified in Aspiration toxicity Category 1: (a) based on reliable and good quality human evidence or (b) if it is a hydrocarbon and has a kinematic viscosity of 20,5 mm^2/s or less, measured at 40°C." For MATACARCOMA, the exact composition is known. For each of the individual components in the product, valid data on the intrinsic properties are available through state-of-the-art safety data sheets. Consequently, classification of the mixture can be made according to the rules laid down in Regulation (EC) No 1272/2008 (CLP) and testing of the components and/or of the biocidal product itself is not required. The SoC "Hydrocarbons, C9-C11, n-alkanes, isoalkanes, cyclics, < 2% aromatics" is a hydrocarbon and has a kinematic viscosity as provided in the SDS of 0.9 mm^2/s at 40°C. The concentration of the SoC in MATACARCOMA is above the concentration limit of ≥ 10% for classification with Aspiration toxicity Category 1. Thus, MATACARCOMA needs to be classified with respect to aspiration toxicity hazard.

2.2.6.1.2 Specific target organ toxicity

Conclusion used in the Risk Assessment – Specific target organ toxicity — Single exposure, Hazard Category 3, Narcosis	
Value/conclusion	STOT SE; H336
Justification	Based on intrinsic properties of individual components of the biocidal product MATACARCOMA.
Classification of the product according to CLP	MATACARCOMA is classified as STOT SE 3; H336: May cause drowsiness or dizziness.

Data waiving	
Information requirement	Specific target organ toxicity — Single exposure
Justification	No studies have been performed with the biocidal product in order to avoid unnecessary testing with vertebrates. The composition of the product is known and there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP Regulation), and synergistic effects between any of the components are not expected. Therefore, this study does not need to be conducted. Taking into account that one of the components of the product (Hydrocarbons, C9-C11, n-alkanes, isoalkanes, cyclics, < 2% aromatics) is classified as STOT SE 3, H336, **the product MATACARCOMA is classified as STOT SE 3, H336**.

2.2.6.2 Exposure assessment

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	no	Yes	Yes	n.a.
Dermal	Yes*	Yes	Yes	no	Yes	Yes	n.a.
Oral	no	no	no	no	no	Yes	n.a.

n.a. not applicable

Explanatory note:

The exposure assessments are based on model calculations using models and default values from Biocides Human Health Exposure Methodology (October 2015) and HEEG opinions. Justifications for deviations from Biocides Human Health Exposure Methodology are provided in the respective description of the scenarios.

As a first step, primary exposure assessments are performed for all individual scenarios (work tasks) which are relevant for wood preservatives – PT8 (see table "list of scenarios" below) considering the concentration of 0.4% permethrin.

In a second step, the exposure calculated for the individual work tasks are combined (added up) for the following intended uses:

- Use #1 – Treatment by brushing/roller application indoor – Industrial (trained professional and professional), trained professional and professional and general public.
- Use #2 – Treatment by spraying surface application indoor –Trained professional and professional.
- Use #3 – Treatment by automated spraying surface application indoor Industrial (trained professional).
- Use #4 – Treatment by Manual dipping indoor -Industrial (trained professional), trained professional and professional.
- Use #5 – Treatment by Automated dipping indoor – Industrial (trained professional).

In order to assess the worst case, the exposure assessment for all scenarios have been developed by considering the highest application rate (200 g/m^2) from curative treatment.

Additionally, qualitative assessments are performed to adress corrosion and irritating local effects of the product according to the "Guidance on the BPR: Volume III, Part B, Risk Assessment (Version 2.0 of October 2015)".

Secondary (indirect) exposure is defined as the exposure via the environment, which the exposed person may not be aware of (for example handling treated material, consumption of residues in food or drinking water), and which may even be long-term (TNsG on Annex I inclusion p. 20 (EC, 2002b)).

Secondary exposure scenarios involve skin contact and possible exposure by inhalation. Treated wood is not placed on the market until the product is dry. In practice, persons handling large amounts of treated timber (e.g. professional users of treated timber) would be expected to wear gloves to protect their hands from splinters or abrasions.

Secondary exposure of the general public includes dermal contact with contaminated surfaces or handling contaminated objects. Skin contact and oral contact with treated wood objects or hand-to-mouth contact is related to infants, toddlers and children playing on weathered structure. Children and infants are assumed to be a group at risk due to their low body weight and some secondary exposure scenarios are related to them. The exposure of toddler is considered to be covered by those of infants due to the lower body weight of infants.

Secondary exposure can occur soon after the application of the product or as a single event (acute phase), or thereafter during the long term and may be continuous (chronic phase).

Dermal exposure may occur during the mix and loading step through the hands, during spraying application where the hands and the body are exposed, in the cleaning of the

application equipment and during disposal of product's aerosol can and cleaning of the treated areas through hands and forearms.

MATACARCOMA is labelled with EUH066 which is triggered by "Aliphatic hydrocarbon" (CAS 64742-47-8). According to the guidance on BPR (Volume III, Part B +C, February 2017), this substance of concern and its related hazard falls under band A, meaning the classification, hazard phrases and related risk mitigation measures should be applied to the product authorization. EUH066 warns for skin cracking after repeated use, and is only applicable for the professional worker who will be exposed repeatedly. Therefore, this warning sentence and the related precaution is only reguired for the professional user, who may be protected by use of gloves. As a non-professional user is not expected to use the product repeatedly, the warning and risk-mitigation is not needed/applicable.

According to the different types of formulation and the application methods, the following scenarios are considered relevant for the assessment of human risk exposure:

List of scenarios

Summary table: scenarios for MATACARCOMA			
Scenario number	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
Primary exposure			
1	Mixing and loading of RTU	Primary exposure by users during preparation of the product before application by loading formulation in the container to be used for application. The solvent-based RTU product is delivered in Intermediate Bulk Container (IBC) or by tanker. Dilution is not required for the RTU product. This task is done by professional where they are exposed during the mixing and loading operations during automated addition by connecting lines.	Industrial (Trained professiona and professionall)
2	Mixing and loading of RTU	Primary exposure by users during preparation of the product before application. The fluid is delivered in a container and is decanted from containers that are manually handled. This task is done by users where they are exposed during the mixing and loading operations during manual addition.	Trained professional, Professional, Non-professional
3	Application: brushing and rolling	Primary exposure during product application. The activities of the users are stirring the RTU product and applying it to wood using a brush indoors.	Industrial (Trained professional and professional), Trained professional, Professional, Non-professional
4	Application: spraying	Primary exposure during product application. Spraying application is performed by the operator on the wood surfaces by a handheld or knapsack sprayer, in absence of general public. Indoor application at premises like parquet, flooring, wood decor (plinths, friezes, baseboards) or carpentry (doors and windows) is considered a worse case for human exposure.	Trained professional,
5	Application: Automated spray	Primary exposure during product application. The spraying process is done by automated machines in hermetic closed tanks at indoor industrial premises without operator presence during the application.	Industrial (Trained professional and professional)
6	Application: manual dipping	Primary exposure during product application. During manual dipping, the operator lifts and places – by hand – the wooden article into the dipping tank. The operator then pushes, using a post, the wooden article under the wood preservative in the dipping tank and/or uses a broom to brush the wood preservative onto the wooden article (the article is still in the dipping tank as the preservative is brushed on	Industrial (Trained professional), Trained professional,

Summary table: scenarios for MATACARCOMA			
Scenario number	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
		the wood). The operator then lifts manually the wooden article from the dipping tank and stacks the article to dry. Manual dipping is undertaken during a very short time during the day.	
7	Application: automated dipping	After loading the product into vessels systems, the product may be applied to the freshly cut wood by two different methods. (1) Automated dipping process. (2) Fully automated dipping process. For automated dipping, an operator using a fork-lift truck lowers the wood into the dipping tank or transfers the wood to a bathing tray. Automated dipping is a fully automated process. After the treatment, the wood is lifted out by the fork-lift truck. The wood is then transferred by the fork-lift truck to a storage area where it is placed to dry. Due to the fully automation exposure from 1 cycle per day is considered. The operator exposure arises from handling the treated wood.	Industrial (Trained professional and professional)
8	Post-application: Cleaning application equipment - brushing	Primary exposure by cleaning of brush by washing out after product application	Industrial (Trained professional and professional), Trained professional, Professional, Non-professional
9	Post-application: Cleaning application equipment - spraying/dipping	Primary exposure by cleaning of spraying /dipping equipment after product application. The post-application phase includes disposal. For maintenance of treatment vessels and dipping tanks, test and clean greasing door seals, collecting fallen timber as well as clearing sludge is considered. For maintenance of flow coating systems, the cleaning of spray nozzles is considered.	Industrial (Trained professional and professional), Trained Professional, Professional
Secondary exposure by professionals and general public			
10	Sawing and sanding treated wood	Secondary exposure from cutting and sanding treated wood by professional worker (chronic exposure).	Professional
11	Sawing and sanding treated wood	Secondary exposure from cutting and sanding treated wood by general public (acute exposure).	General public (adult)
12	Chewing wood off-cut	Secondary exposure by infant picks up and chews wood off-cut, which has been treated with wood preservative (acute exposure).	General public (infant)
13	Playing on playground	Secondary exposure by infant playing on and mouthing weathered structure (chronic	General public (infant)

Summary table: scenarios for MATACARCOMA			
Scenario number	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
	structure outdoors and mouthing	exposure).	
14	Inhalation of volatilized residues	Secondary exposure to wood preservatives may arise via residues volatilised from treated wood indoors (chronic exposure).	General public (infant and child, adult)
15	Laundering work-cloths	Secondary exposure: laundering is undertaken in a domestic, automatic washing machine	General public (adult)

2.2.6.2.1 Industrial exposure

Scenario [1] – Mixing and loading of RTU

Description of Scenario [1] Mixing/loading of RTU
The solvent-based RTU product is delivered in IBC or by tanker. Dilution is not required for the RTU product. The transfer of the RTU product is done automated by connecting lines. According to HEEG Opinion 17, endorsed at TM III 2013, "where the wood preservative fluid is delivered by tanker and is transferred from the tanker into the dip tank using connecting hosing then, it could be assumed, providing the operator wears suitable PPE, exposure of the operator's skin is minimal and does not need to be quantified." The inhalation exposure is considered to be less than during the individual applications phases and, thus, to be covered by the application scenarios.

Calculations for Scenario [1]

Not required since the exposure can be regarded to be negligible

Further information and considerations on scenario [1]

Qualitative local risk assessments are provided in chapter 2.2.6.3 "Risk characterisation for human health".

Scenario [3] – Application by brushing/rolling

Description of Scenario [3]. Application by brushing/rolling
At industrial brushing scenario the user applies the product over the wood by using a brush in absence of general public. This task is developed for preventive treatments.

According to Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure, following values are used in exposure assessment (Consumer painting model 3):		
	Parameters	Value
Tier 1	Hand exposure[1]	0.5417 mg/m^2
	Body exposure[1]	0.2382 mg/m^2
	Inahalation[1]	0.0016 mg/m^2
	Exposure duration[1]	240 min
	Application area[1]	31.6 m^2
	Dermal absorption (default value)	70%
	Body weight[2]	60 kg
	Inhalation rate[2]	1.25 m^3/h
Tier 2	Coverall permeation[3]	10%
	Gloves Permeation[3]	10%

[1] Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure and Biocides Human Health Exposure Methodology

[2] HEAdhoc Recommendation no. 14 Default human factor values for use in exposure assessment for biocidal products

[3] HEEG Opinion 9 Default protection factors for protective clothing and gloves.

Calculations for Scenario [3]

Summary table: estimated exposure from users					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		[mg/kg bw/d]	**[mg/kg bw/d]**	**[mg/kg bw/d]**	**[mg/kg bw/d]**
Scenario [3] - Brushing /rolling	TIER 1 (without PPE)	3.37E-06	1.15E-03	-	1.15E-03
	TIER 2 (with gloves and coated coverall)	3.37E-06	1.15E-04	-	1.18E-04

Further information and considerations on scenario [3]

Qualitative local risk assessments are provided in chapter 2.2.6.3 "Risk characterisation for human health".

The calculation sheets are provided in Annex 3.2

Scenario [5] – Application by automated spraying

Description of Scenario [5]. Application by automated spraying		
Industrial automated spraying scenario, as requested for the applicant, includes the following operations: an operator using a fork-lift truck (or similar) equipment lowers the wood into the spraying tank. Spraying process is carried out by automated machines in hermetic closed tanks without operator presence during the application. Wood is lifted out of the tank by the fork-lift truck (or similar). The wood is then transferred by the forklift truck (or similar) to a storage area where it is placed to dry. Reading across from HEEG opinion 8 – (Defaults and appropriate models to assess human exposure for dipping processes), dermal exposure pattern of automated spraying is comparable to that of automated dipping process. Based on this assumption the appropriate model to assess the automated spraying process is Handling model 1. This model is used to assess the professional intermittently handling water-wet or solvent-damp wood and associated equipment after vacuum pressure processes (p. 26 of User Guidance, 2002). For application a default value of 30 minutes was used, by 3 cycles per day.		
	Parameters	Value
Tier 1	Hand exposure[1]	260 mg/cycle (inside used gloves).
	Body exposure[1]	158 mg/cycle
	Inahalation[1]	0.6 mg/m^3
	Exposure duration[2]	3 cycles
	Dermal absorption	70%
	Body weight[3]	60 kg
	Inhalation rate[3]	1.25 m^3/h
Tier 2	Coverall permeation[4]	5%
Tier 3	Hand exposure new gloves for each work shift[4] (reduces hand-in glove exposure to approximately half)	130 mg/cycle (inside new gloves).

[1] Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure.

[2] HEEG opinion 8 - Defaults and appropriate models to assess human exposure for dipping processes (PT 8)

[3] HEAdhoc Recommendation no. 14 Default human factor values for use in exposure assessment for biocidal Products

[4] HEEG Opinion 9 Default protection factors for protective clothing and gloves.

Calculations for Scenario [5]

Summary table: estimated exposure from users					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		[mg/kg bw/d]	**[mg/kg bw/d]**	**[mg/kg bw/d]**	**[mg/kg bw/d]**

Scenario [5] Automated spraying	TIER 1 with gloves (including in model)	2.50E-05	5.85E-02	-	5.85E-02
	TIER 2 with gloves (including in model)+ impermeable coverall 5%	2.50E-05	3.75E-02	-	3.75E-02
	TIER 3 with gloves (new gloves each cycle)+ impermeable coverall 5%	2.50E-05	1.93E-02	-	1.93E-02

Further information and considerations on scenario [5]

Qualitative risk assessments are provided in chapter 2.2.6.3 "Risk characterisation for human health".

The calculation sheets are provided in Annex 3.2.

Scenario [6] – Application by manual dipping

Description of Scenario [6]. Application by manual dipping
During manual dipping, the operator lifts and places – by hand – the wooden article into the dipping tank. The operator then pushes, using a post, the wooden article under the wood preservative in the dipping tank and/or uses a broom to brush the wood preservative onto the wooden article (the article is still in the dipping tank as the preservative is brushed on the wood). The operator then lifts manually the wooden article from the dipping tank and stacks the article to dry. Manual dipping is undertaken during a very short time during the day. A duration time of 30 min is considered according to Biocides Human Health Exposure Methodology (October 2015) – PT8 "Professional manual dipping of wood articles". The model used is Dipping model 1 (TNsG 2002 User Guidance – Version 1 and HEEG opinions 8 - 2009) for dermal and inhalation exposure estimation. This model includes the mixing/loading. However, according to BPC Recommendation no.6 (version 4) "*A realistic scenario should include the mixing and loading, application and the post-application phase. In addition, maintenance which is conducted infrequently may also occur on a day of application.*" In view of that, the following options from the model has been used for each sub-task of the main task: • Pre-application: Option 3: Automated mixing and loading • Application: Dipping Model 1, TNsG 2002 • Post application: Option 3: Automated draining and reloading

	Parameters		Value
Tier 1	Pre-application	Hand exposure[1]	0.92 mg/min (without gloves)
		Exposure duration[1]	10 min
		Frequency	daily
	Application	Hand exposure[1]	25.70 mg/min (inside gloves)
		Body exposure[1]	178 mg/min
		Inahalation[1]	1 mg/m^3
		Exposure duration[1]	30 min
		Frequency	daily
	Post-application	Hand exposure[1]	0.92 mg/min (without gloves)
		Exposure duration[1]	10 min
		Frequency	monthly
	Dermal absorption (default value)		70%
	Body weight[2]		60 kg
	Inhalation rate[2]		1.25 m^3/h
	Protective gloves (Pre & Post-application) [3]		10%
Tier 2	Coated coverall[3]		5%
	Protective gloves (Pre & Post-application) [3]		10%
Tier 3	Protective gloves – new gloves for each work shift[3]		5%
	Impermeable coverall[3]		5%

[1] Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure. Protective gloves (including in model) [3]10%

[2] HEAdhoc Recommendation no. 14 Default human factor values for use in exposure assessment for biocidal Products.

[3] HEEG Opinion 9 Default protection factors for protective clothing and gloves.

Calculations for Scenario [6]

Summary table: estimated exposure from users					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		[mg/kg bw/d]	**[mg/kg bw/d]**	**[mg/kg bw/d]**	**[mg/kg bw/d]**
Scenario [6] (Manual dipping)	TIER 1 with gloves (including in model)	4.17E-05	2.85E-01	-	2.85E-01

	TIER 2 with gloves + coated coverall 5%	4.17E-05	4.85E-02	-	4.85E-02
	TIER 3 with new gloves for each work shift + impermeable coverall 5%	4.17E-05	3.12E-02	-	3.13E-02

Further information and considerations on scenario [6]

Qualitative risk assessments are provided in chapter 2.2.6.3 "Risk characterisation for human health".

The calculation sheets are provided in Annex 3.2.

Scenario [7] – Application by fully automated dipping

Description of Scenario [7]. Application by fully automated dipping		
For fully automated dipping, an operator using a fork-lift truck lowers the wood into the dipping tank or transfers the wood to a bathing tray. Automated dipping is an automated process. After the treatment, the wood is lifted out by the fork-lift truck. The wood is then transferred by the fork-lift truck to a storage area where it is placed to dry. The operator exposure arises from handling the treated wood. Four cycles (60 min per cycle) per day are considered according to Biocides Human Health Exposure Methodology (October 2015) – PT8 "Professional automated dipping/immersion of wood articles". Use in fully automated dipping processes where all steps in the treatment and drying process are mechanised and no manual handling takes place, including when the treated articles are transported through the dip tank to the draining/drying and storage (if not already surface dry before moving to storage). Where appropriate, the wooden articles to be treated must be fully secured (e.g. via tension belts or clamping devices) prior to treatment and during the dipping process, and must not be manually handled until the treated articles are surface dry. The untreated wood may only be lowered by a separate lifting unit into the dipping tank. According to the HEEG opinion 18 - For exposure assessment for professional operators undertaking industrial treatment of wood by fully automated dipping where all steps in the treatment and drying process are mechanised and no manual handling takes place the dermal exposure is assumed to decrease by a factor of 4 i.e. 1 cycle per day. The model used is Handling model 1 solvent-based (TNsG 2002 User Guidance – Version 1 and HEEG opinions 8 and 18 - 2009/2013) for dermal and inhalation exposure estimation.		
	Parameters	Value
Tier 1	Hand exposure[1]	130 mg/cycle (inside new gloves per shift work)

	Body exposure[1]	158 mg/cycle
	Inahalation[1]	negligible
	Dermal absorption (default value)	70%
	Body weight[2]	60 kg
	Exposure duration	4 cycle (fully automated)
Tier 2	Coverall[3]	95% protection
Tier 3	Fully automated dipping process factor for drying processes	4

[1] Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure.

[2] HEAdhoc Recommendation no. 14 Default human factor values for use in exposure assessment for biocidal Products.

[3] HEEG Opinion 9 Default protection factors for protective clothing and gloves. Impermeable coveralls.

Calculations for Scenario [7]

Summary table: estimated exposure from users					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		[mg/kg bw/d]	**[mg/kg bw/d]**	**[mg/kg bw/d]**	**[mg/kg bw/d]**
Scenario [7] Fully automated dipping	TIER 1 with new gloves (including in model)	-	5.38E-02	-	5.38E-02
	TIER 2 with new gloves (including in model)+ coverall 5%	-	2.57E-03	-	2.57E-03
	TIER 3 FULLY AUTOMATED 1/4 (with new gloves (including in model)+ coverall 5%)	-	6.44E-04	-	6.44E-04

Further information and considerations on scenario [7]

Qualitative risk assessments are provided in chapter 2.2.6.3 "Risk characterisation for human health".

The calculation sheets are provided in Annex 3.2.

Scenario [8] – Cleaning brushing

Description of Scenario [8]. Cleaning brushing equipment		
A post-application task which may lead to some degree of exposure is cleaning the brush used to apply the product. Brush cleaning by professionals can be expected to last for no more than 15 minutes and might result in some exposure to hands. To calculate the exposure due to washing out brushes, the HEEG opinion 11 and its computerised calculator have been used. Cleaning the brush used for applying paint may be done by repeated dipping and swilling it in a vessel containing an appropriate solvent. A large brush might have a size of 10 x 10 x 2 cm, corresponding to a volume of 200 ml. It is assumed that after painting one eighth (1/8) of the brush volume is paint. Cleaning is assumed to be done in three steps, each time using fresh solvent. The volume at each step should be large enough to allow a sufficient dilution of the residues in the brush. For a brush having a volume of 200 ml the volume of the cleaning solvent-based would be at least 400 ml per step. Each washing step is assumed to result in an approximately 10-fold dilution of the residues in the brush (i.e. 10 % of the paint originally on the brush remains after one washing). After each step the brush is assumed to be squeezed by the hand to get rid of as much solvent as possible. It is assumed that with this step 50% of the solution in the washed brush is released and may potentially contaminate the hand. However, it is further assumed that the squeezing is not done by the bare hand but rather by wrapping it first with a cleaning rag, which absorbs 90% of the released liquid. It is assumed the brush is washed and squeezed for a maximum of 3 times. During brush cleaning, professionals may retain gloves worn during brush application of the product (Tier 2 assessment). No exposure of areas of the body other than the hands is assumed to occur; and exposure via inhalation is considered negligible.		
	Parameters	Value
Tier 1	Volume of each washing solution[1]	400 mL
	Remaining residues in brush after each washing step[1]	10%
	Remaining residues in brush after each washing squeezing[1]	50%
	Penetration through cleaning cloth during squeezing[1]	10%
	Dermal absorption (default value)	70%
	Body weight[2]	60 kg
Tier 2	Gloves	90% protection

[1] Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure.

[2] HEAdhoc Recommendation no. 14 Default human factor values for use in exposure assessment for biocidal Products.

[3] HEEG Opinion 9 Default protection factors for protective clothing and gloves. Impermeable coveralls.

Calculations for Scenario [8]

Summary table: estimated exposure from users					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		[mg/kg bw/d]	**[mg/kg bw/d]**	**[mg/kg bw/d]**	**[mg/kg bw/d]**
Scenario [8] - Cleaning brush	Tier 1/ no gloves	-	4.67E-03	-	4.67E-03
	Tier 2/ with gloves	-	4.67E-04	-	4.67E-04

Further information and considerations on scenario [8]

Qualitative risk assessments are provided in chapter 2.2.6.3 "Risk characterisation for human health".

The calculation sheets are provided in Annex 3.2.

Scenario [9] – Cleaning dipping/spraying equipment

Description of Scenario [9]. Cleaning spray equipment		
This scenario is developed by using Recommendation no. 4 of the BPC Ad hoc Working Group on Human Exposure - Cleaning of spray equipment in antifouling use (PT21), BEAT. This exposure model considers inhalation exposure as not relevant. For sovent-solution as MATACARCOMA, 20 minutes is deemed sufficient for this task.		
	Parameters	Value
Tier 1	Hand exposure[1]	35.87 mg/min
	Body exposure[1]	19.28 mg/min
	Inahalation[1]	negligible
	Dermal absorption (default value)	70%
	Body weight[2]	60 kg
	Exposure duration[1]	20 min
Tier 2	Hand protection with gloves[3]	10%

[1] Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure.

[2] HEAdhoc Recommendation no. 14 Default human factor values for use in exposure assessment for biocidal Products.

[3] HEEG Opinion 9 Default protection factors for protective clothing and gloves. Impermeable coveralls.

Calculations for Scenario [9]

Summary table: estimated exposure from users					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		[mg/kg bw/d]	**[mg/kg bw/d]**	**[mg/kg bw/d]**	**[mg/kg bw/d]**
Scenario [9] Cleaning spray equipment	TIER 1 without PPE	negligible	3.91E-02	-	3.91E-02
	TIER 2 with gloves	negligible	1.62E-02	-	1.62E-02

Further information and considerations on scenario [9]

Qualitative risk assessments are provided in chapter 2.2.6.3 "Risk characterisation for human health".

The calculation sheets are provided in Annex 3.2.

Combined scenarios

Combined exposures by same active substance by different tasks may occur. For this assessment, mixing and loading, application and cleaning process for industrials were combined for the active substance.

Combined scenarios for dipping treatment are not necessary as exposure model has already takes into account pre- and post-application tasks.

Summary table: estimated combined exposure from industrial users					
Combined scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		[mg/kg bw/d]	**[mg/kg bw/d]**	**[mg/kg bw/d]**	**[mg/kg bw/d]**
Brushing treatment [3] + [8]	[3] Tier 2 +[8] Tier 2/	3.37E-06	5.82E-04	-	5.85E-04
Automated spraying treatment [5] + [9]	[3] Tier 1 (gloves) + [9] Tier 2 (gloves)	2.50E-05	7.47E-02	-	7.48E-02
	[3] Tier 2 (gloves and impermeable coverall 5%) + [9] Tier 2 (gloves and coverall)	2.50E-05	4.14E-02	-	4.14E-02
	[3] Tier 3 (new gloves each cycle	2.50E-05	2.32E-02	-	2.32E-02

	(including in model) + impermeable coverall 5%) +[9] Tier 2 (gloves and coverall)				

2.2.6.2.2 *Professional exposure*

Only for Spain:
According to national legislation, in Spain there are until three user categories:

- Trained professional users (TP): pest control operators, having received specific training in biocidal product uses according to the national legislation in force.
- Professional users (NTP): professionals that use the biocidal products in the context of his profession, that is not pest control operator, and that are unlikely to have received any specific training in biocidal product use according to the national legislation in force. It can be expected that they have some knowledge and skills handling chemicals (if they must use it in their job) and they are able to use correctly some kind of PPE if necessary.
- Non-professional users (NP): users who are not professionals and that apply the biocidal product is in his private life.

At the same time, there are also some restrictions of packaging in relation to those user categories and product types. In this case, for professional users the maximum size that can be authorized is 2.5L.
In that context, the exposure assessment will be the same for professionals and trained professional users and the difference between the two will depend on the expert judgment following "limiting criteria" below:

5. The hazardousness of the product under evaluation.
6. The use being requested.
7. The frequency of use.
8. Complexixy of control measures.

The conclusions reached in this PAR, which affect the intermediate category of "Professional", will only be applicable at the Spanish level

Scenario [2] – Mixing and loading of RTU

Description of Scenario [2] Mixing/loading of RTU
The solvent-based RTU product is delivered in IBC/drum (200 – 1000 L) or in a can/bucket/jerry can (up to 20 L). Dilution is not required for the RTU product. For IBC/drum, the transfer of the RTU product is done automated by connecting lines. According to HEEG opinion 18 (2013), "where the wood preservative fluid is delivered by tanker and is transferred from the tanker into the dip tank using connecting hosing then, it could be assumed, providing the operator wears suitable PPE, exposure of the operator's skin is minimal and does not need to be quantified." For the automated mixing and loading, the inhalation exposure is considered to be less than during the individual applications phases and, thus, to be covered by them. Alternatively, the RTU product is delivered in containers (up to 4 L) and decanted before

Description of Scenario [2] Mixing/loading of RTU		
application into smaller containers which can be handled manually. For the manual mixing and loading task the "Mixing and loading Model 7 – pouring liquids" is used for dermal and inhalation exposure according to HEEG opinion 1 (2008).		
	Parameters	Value
Tier 1	Body weight	60 kg
	Exposure duration	10 min
	Hand exposure	101 mg/min
	Inhalation exposure	0.94 mg/m^3
	Dermal absorption (default value)	70%
Tier 2	Gloves	Dermal: 1.01 mg/min (under gloves)

Calculations for Scenario [2] Mixing/loading of RTU

Summary table: estimated exposure from users					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		[mg/kg bw/d]	**[mg/kg bw/d]**	**[mg/kg bw/d]**	**[mg/kg bw/d]**
Scenario [2] - Mixing & loading	TIER 1 (without PPE)	1.31E-05	4.71E-02	-	4.71E-02
	TIER 2 (with gloves)	1.31E-05	4.71E-04	-	4.84E-04

Further information and considerations on scenario [2] Mixing/loading of RTU

Qualitative local risk assessments are provided in chapter 2.2.6.3 "Risk characterisation for human health".

The calculation sheets are provided in Annex 3.2.

Scenario [3] - Application by brushing/rolling

This scenario has already been assessed for industrial exposure. No differences are considered between industrial and professional users at application process so same outputs from industrial exposure assessment are deemed for professional users.

Calculations for Scenario [3]

Summary table: estimated exposure from users

Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
		[mg/kg bw/d]	[mg/kg bw/d]	[mg/kg bw/d]	[mg/kg bw/d]
Scenario [3] - Brushing /rolling	TIER 1 (without PPE)	3.37E-06	1.15E-03	-	1.15E-03
	TIER 2 (with protective gloves and coated coverall)	3.37E-06	1.15E-04	-	1.18E-04

Further information and considerations on scenario [3]

Qualitative local risk assessments are provided in chapter 2.2.6.3 "Risk characterisation for human health".

The calculation sheets are provided in Annex 3.2.

Scenario [4] - Application by spraying

Description of Scenario [4]. Application by spraying		
Spraying application is performed by the operator on the wood surfaces by a handheld or knapsack sprayer in absence of general public. Indoor application at premises like parquet, flooring, wood decor (plinths, friezes, baseboards) or carpentry (doors and windows) is considered a worse case for human exposure. This task is developed for preventive and curative treatments. Following the Biocides Human Health Exposure Methodology, to evaluate the operator exposure for the application method for professionals, spraying model 2 of TNsG 2002, Part 2, has been chosen as the most similar scenario. This model is evaluated for indoor treatments which is considered worst-case scenario for human risk compared to outdoor use. The model includes the tasks for "mixing and loading" and "spray application" at a pressure from 4 to 7 bar.		
	Parameters	Value
Tier 1	Hand exposure[1]	273 mg/min
	Body exposure[1]	222 mg/min
	Inahalation[1]	76 mg/m^3
	Exposure duration[1]	80 minutes (by two events of 40 minutes) without distinction between the M&L and application phases.
	Dermal absorption (default value)	70%
	Body weight[2]	60 kg
	Inhalation rate[2]	1.25 m^3/h

Tier 2	Protective gloves[3]	10%
Tier 3	Coverall permeation[3]	5%
Tier 4	Coverall permeation[3]	5%
	Protective gloves – new gloves for each work shift[3]	5%

[1] Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure

[2] HEAdhoc Recommendation no. 14 Default human factor values for use in exposure assessment for biocidal Products.

[3] HEEG Opinion 9 Default protection factors for protective clothing and gloves.

Calculations for Scenario [4]

Summary table: estimated exposure from users					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		[mg/kg bw/d]	**[mg/kg bw/d]**	**[mg/kg bw/d]**	**[mg/kg bw/d]**
Scenario 4 (spraying)	TIER 1 without gloves	8.44E-03	1.85E+00	-	1.86E+00
	TIER 2 with gloves (including in model)	8.44E-03	8.58E-01	-	8.66E-01
	TIER 3 with gloves (including in model)+ coverall 5%	8.44E-03	7.06E-02	-	7.908E-02
	TIER 4 with new gloves for each work shift (including in model)+ impermeable coverall 5%	8.44E-03	5.66E-02	-	6.50E-02

Further information and considerations on scenario [4]

Qualitative local risk assessments are provided in chapter 2.2.6.3 "Risk characterisation for human health".

The calculation sheets are provided in Annex 3.2.

Scenario [6] - Application by manual dipping

This scenario has already been assessed for industrial exposure. No differences are considered between industrial and trained professional users at application process so same outputs from industrial exposure assessment are deemed for professional users.

Calculations for Scenario [6]

Summary table: estimated exposure from users					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		[mg/kg bw/d]	**[mg/kg bw/d]**	**[mg/kg bw/d]**	**[mg/kg bw/d]**
Scenario [6] (Manual dipping)	TIER 1 with gloves (including in model)	4.17E-05	2.85E-01	-	2.85E-01
	TIER 2 with gloves (including in model)+ coverall 5%	4.17E-05	4.85E-02	-	4.85E-02
	TIER 3 with new gloves for each work shift (including in model)+ coverall 5%	4.17E-05	3.12E-02	-	3.13E-02

Further information and considerations on scenario [6]

Qualitative local risk assessments are provided in chapter 2.2.6.3 "Risk characterisation for human health".

The calculation sheets are provided in Annex 3.2.

Scenario [8] – Cleaning brushing equipment

As in the case of scenario [3] brushing application, this scenario has already been assessed for industrial exposure and no differences are considered between industrial and professional users at application process. Hence, same outputs from industrial exposure assessment are deemed for professional users.

Calculations for Scenario [8]

Summary table: estimated exposure from users					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		[mg/kg bw/d]	**[mg/kg bw/d]**	**[mg/kg bw/d]**	**[mg/kg bw/d]**
Scenario [3] - Cleaning brush	Tier 1/ no gloves	-	4.67E-03	-	4.67E-03
	Tier 2/ with gloves	-	4.67E-04	-	4.67E-04

Further information and considerations on scenario [8]

Qualitative risk assessments are provided in chapter 2.2.6.3 "Risk characterisation for human health".

The calculation sheets are provided in Annex 3.2.

Scenario [9] – Cleaning spraying equipment

The same exposure assessment carried out for industrial users is deemed for professional users. Hence, same outputs from industrial exposure assessment are deemed for professional users.

Calculations for Scenario [9]

Summary table: estimated exposure from users					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		[mg/kg bw/d]	**[mg/kg bw/d]**	**[mg/kg bw/d]**	**[mg/kg bw/d]**
Scenario [9] Cleaning spray equipment	TIER 1 without PPE	negligible	3.91E-02	-	3.91E-02
	TIER 2 with gloves	negligible	1.62E-02	-	1.62E-02

Due that professional users are trained to use PPE in their work-tasks, Tier 2 is deemed as the most adequate.

Further information and considerations on scenario [9]

Qualitative risk assessments are provided in chapter 2.2.6.3 "Risk characterisation for human health".
The calculation sheets are provided in Annex 3.2.

Combined scenarios

Combined exposures by same active substance by different tasks may occur. For this assessment, mixing and loading, application and cleaning process for professionals were combined for the active substance.

Combined scenarios for dipping treatment are not necessary as exposure model has already takes into account pre- and post-application tasks.

Summary table: estimated combined exposure from professional users					
Combined scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**

		[mg/kg bw/d]	[mg/kg bw/d]	[mg/kg bw/d]	[mg/kg bw/d]
Combined brushing treatment [2]+[3]+[8]	[2] Tier 2 (gloves) + [3] Tier 2 (gloves) + [8] Tier 2 (gloves)	1.64E-05	1.06E-03	-	1.08E-03
Combined spraying treatment [4] + [9]	[4] Tier 2 (gloves) + [9] Tier 2 (gloves)	8.44E-03	8.74E-02	-	8.83E-01
	[4] Tier 3 (gloves and coverall) +[9] Tier 2 (gloves and coverall)	8.44E-03	8.68E-02	-	9.52E-02
	[4] Tier 4 (new gloves for each work shift + impermeable coverall 5% + [9] Tier 2 (gloves and coverall)	8.44E-03	7,28E-02		8,12E-02

2.2.6.2.3 Non-professional exposure

Scenario [2b] – Mixing and loading of RTU

Description of Scenario [2b] Mixing/loading of RTU		
According to HEEG opinion 1, for smaller quantities (<1L), Mixing&Loading model 2 (HSL 2001) in TNsG version 1 part 2 p.134 is used as worst case to assess the risk for general public at single event.		
	Parameters	Value
Tier 1	Body weight	60 kg
	Dermal absorption (default value)	70%
	Exposure duration	1 single event
	Hand exposure (bare hands)	12.8 mg/event

Calculations for Scenario [2b] Mixing/loading of RTU

Summary table: estimated exposure from users					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		[mg/kg bw/d]	**[mg/kg bw/d]**	**[mg/kg bw/d]**	**[mg/kg bw/d]**
Scenario [2] - Mixing & loading	TIER 1 (without PPE)	-	5.97E-04	-	5.97E-04

Further information and considerations on scenario [2b] Mixing/loading of RTU

Qualitative local risk assessments are provided in chapter 2.2.6.3 "Risk characterisation for human health".

The calculation sheets are provided in Annex 3.2.

Scenario [3] - Application by brushing/rolling

Description of Scenario [3]. Application by brushing/rolling		
This task is developed for preventive treatments where general public applies the product over the wood by using a brush. As worst case, this scenario has been assessed for general public by taking into account the same indicative values as considered for professional users but without PPE.		
	Parameters	Value
Tier 1	Hand exposure[1]	0.5417 mg/m^2
	Body exposure[1]	0.2382 mg/m^2
	Inahalation[1]	0.0016 mg/m^2
	Exposure duration[1]	240 min
	Application area[1]	31.6 m^2
	Dermal absorption (default value)	70%
	Body weight[2]	60 kg
	Inhalation rate[2]	1.25 m^3/h

[1] Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure and Biocides Human Health Exposure Methodology

[2] HEAdhoc Recommendation no. 14 Default human factor values for use in exposure assessment for biocidal products

Calculations for Scenario [3]

Summary table: estimated exposure from users					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		[mg/kg bw/d]	**[mg/kg bw/d]**	**[mg/kg bw/d]**	**[mg/kg bw/d]**
Scenario [3] - Brushing /rolling	TIER 1 (without PPE)	3.37E-06	1.15E-03	-	1.15E-03

Further information and considerations on scenario [3]

Qualitative local risk assessments are provided in chapter 2.2.6.3 "Risk characterisation for human health".

The calculation sheets are provided in Annex 3.2.

Scenario [8] – Cleaning brushing equipment

As in the scenario before [3], the same scenario used for professional users is considered for general public without considering the use of gloves as PPE (Tier 1).

Description of Scenario [8]. Cleaning brushing equipment
A post-application task which may lead to some degree of exposure is cleaning the brush used to apply the product. Brush cleaning by professionals can be expected to last for no more than 15 minutes and might result in some exposure to hands. To calculate the exposure due to washing out brushes, the HEEG opinion 11 and its computerised calculator have been used. Cleaning the brush used for applying paint may be done by repeated dipping and swilling it in a vessel containing an appropriate solvent. A large brush might have a size of 10 x 10 x 2 cm, corresponding to a volume of 200 ml. It is assumed that after painting one eighth (1/8) of the brush volume is paint. Cleaning is assumed to be done in three steps, each time using fresh solvent. The volume at each step should be large enough to allow a sufficient dilution of the residues in the brush. For a brush having a volume of 200 ml the volume of the cleaning solvent-based would be at least 400 ml per step. Each washing step is assumed to result in an approximately 10-fold dilution of the residues in the brush (i.e. 10 % of the paint originally on the brush remains after one washing). After each step the brush is assumed to be squeezed by the hand to get rid of as much solvent as possible. It is assumed that with this step 50% of the solution in the washed brush is released and may potentially contaminate the hand. However, it is further assumed that the squeezing is not done by the bare hand but rather by wrapping it first with a cleaning rag, which absorbs 90% of the released liquid. It is assumed the brush is washed and squeezed for a maximum of 3 times. No exposure of areas of the body other than the hands is assumed to occur; and exposure via inhalation is considered negligible.

	Parameters	Value
Tier 1	Volume of each washing solution[1]	400 mL
	Remaining residues in brush after each washing step[1]	10%
	Remaining residues in brush after each washing squeezing[1]	50%
	Penetration through cleaning cloth during squeezing[1]	10%
	Dermal absorption (EFSA default value)	70%
	Body weight[2]	60 kg

[1] HEEG opinion 11 - Exposure model Primary exposure scenario – washing out of a brush which has been used to apply a paint (TM III 2010).

[2] HEAdhoc Recommendation no. 14 Default human factor values for use in exposure assessment for biocidal Products.

Calculations for Scenario [8]

Summary table: estimated exposure from users					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		[mg/kg bw/d]	**[mg/kg bw/d]**	**[mg/kg bw/d]**	**[mg/kg bw/d]**
Scenario [8] - Cleaning brush	Tier 1/ no gloves	-	4.67E-03	-	4.67E-03

Further information and considerations on scenario [8]

Qualitative risk assessments are provided in chapter 2.2.6.3 "Risk characterisation for human health".

The calculation sheets are provided in Annex 3.2.

Combined scenarios

Combined exposures by same active substance by different tasks may occur. For this assessment, mixing and loading, application and cleaning processes concerned to brushing treatment by non-professionals were combined for the active substance.

Summary table: estimated combined exposure from non-professional users					
Combined scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		[mg/kg bw/d]	**[mg/kg bw/d]**	**[mg/kg bw/d]**	**[mg/kg bw/d]**
Brushing treatment NP [2]+[3]+[8]	[2] Tier 1 + [3] Tier 1 + [8] Tier 1 / no PPE	3.37E-06	6.35E-03	-	6.35E-03

2.2.6.2.4 *Secondary exposure*

Secondary exposure may occur in the residential environment following pest-control measures. These exposures include inhalation of volatilized residues and dermal contact of contaminated surfaces. Hand-to-mouth contact might apply to infants and toddlers playing on the floor. Adults may be subject to inhalation exposure only, whereas children may be exposed by inhalation and dermal contact (playing on the floor). Toddlers and infants may be additionally exposed via oral ingestion (hand-to-mouth contact).

In addition, in those cases where work-cloths are washed at home, indirect exposure can occur also.

Reference Scenarios for preventive and curative Products:	Acute phase reference scenarios: - Adult - cutting and sanding treated wood (non-professional) - Infant - chewing wood off-cut Chronic phase reference scenarios: - Adult - cutting and sanding treated wood (professional) - Adult - inhalation of volatilised residues indoors - Adult - laundering work clothes at home - Child - playing on playground structure outdoors - Infant - playing on weathered structure and mouthing

Scenario [10] – Sawing and sanding treated wood

Description of Scenario [10] - Sawing and sanding treated wood		
Cutting and sanding treated wood by professional worker is considered a chronic exposure scenario. The curative application rate of 200 $g_{product}/m^2$ of the solvent-based product (taking into account the concentration of 0.4% permethrin) is considered the highest-end-retention. According to TNsG 2002 User Guidance- Version 1, the model exposure data used in these calculations are derived from exposure studies on amateurs where no gloves were worn. Considering professionals would usually wear gloves, the exposure level would be lower in practice. Furthermore, the acute sanding scenario is extrapolated to the chronic situation by assuming that the exposure time is 6 hours per day. For dermal exposure (hands - no gloves worn), the concentration on the surface of timber is taken into account, with the conservative assumption that the entire retained a.s. is present on the surface. The surface area of both palms of hands is 420 cm² and during prolonged and repeated contact 20% of the hand is contaminated (TNsG 2002, Part 3, p.51 and User Guidance, p.52). The transfer efficiency is 2% for rough-sawn wood (TNsG 2002, Part 2, p.206) and dermal uptake is 10% (TNsG 2002, Part 3, p.50). During sawing/sanding of treated wood, dermal and inhalation exposure of workers is considered. This secondary exposure scenario is based on TNsG 2002 User guidance - Version 1 and TNsG 2002, part III.		
	Parameters	Value
Tier 1	Application rate	200 g/m²
	Density of the product	0.76 g/ml
	Dermal absorption (EFSA default value)	70%
	Body weight[1]	60 kg
	Inhalation rate[2] (short- and long-term)	1.25 m³/h (0.021 m³/min)
	Hand area (palms of both hands) (adult)[2]	410 cm²
	Assuming that 20% of hand area will be contaminated (adult).	82 cm²
	Transfer coefficient[3]	2%
	Exposure duration	6 h
	Generated dust / m³ of sanded treated wood. U.K. WEL of 5 mg/m³ wood dust (8-hour time-weighted average)	5 mg/m³
	Density of wood[4]	0.4 g/cm³
	Volume of wooden post to be sanded	4000 cm³

[1] HEAdhoc Recommendation no. 14 Default human factor values for use in exposure assessment for biocidal products.

[2] HEEG opinion 17. Default human factor values for use in exposure assessments for biocidal products (2013).

[3] TNsG 2007. Human exposure to Biocidal Products (for dried fluids on rough sawn wood).

[4] Manual of Technical Agreements of the Biocides Technical Meeting (MOTA) V.6 (2013), 4.2.5 for PT8 (p 30.).

Calculations for Scenario [10] – Sawing and sanding treated wood

Summary table: estimated exposure from users					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		[mg/kg bw/d]	**[mg/kg bw/d]**	**[mg/kg bw/d]**	**[mg/kg bw/d]**
Scenario [10] - Sawing and Sanding treated wood	Tier 1/ no gloves	1.26E-04	1.57E-04	-	2.85E-04

Further information and considerations on scenario [10]

Local exposure and risk assessment is not relevant for sawing and sanding treated dried wood, since the concentrations of the active substance and SoC to which dermal contact occurs is reduced by the transfer coefficient of 2 % for dried fluids on rough sawn wood.

For the SoC "hydrocarbons, C9-C11, n-alkanes, isoalkanes, cyclics, < 2% aromatics", it can be assumed that it is completely evaporated when the wood is dried.

Consequently, performance of a local exposure and risk assessment is not required.

The calculation sheets are provided in Annex 3.2.

Scenario [11] – Sawing and sanding treated wood

Description of Scenario [11] - Sawing and sanding treated wood
Cutting and sanding treated wood by general public (adults) is considered an acute exposure scenario. The application rate of 200 g product/m² (curative treatment, worst-case) of the solvent-based product (taking into account the concentration of 0.4% permethrin) is considered the highest-end-retention. For the acute situation, exposure duration of 1 h is assumed. The model exposure data used in these calculations are derived from exposure studies on amateurs where no gloves were worn. During sawing/sanding of treated wood, dermal and inhalation exposure of adults is considered. This secondary exposure scenario is based on TNsG 2002 User guidance - Version 1 and TNsG 2002, part III.

	Parameters	Value
Tier 1	Application rate	200 g/m²
	Density of the product	0.76 g/ml
	Dermal absorption (default value)	70%
	Body weight[1]	60 kg
	Inhalation rate[2] (short- and long-term)	1.25 m³/h (0.021 m³/min)
	Hand area (palms of both hands) (adult)[2]	410 cm²
	Assuming that 20% of hand area will be contaminated (adult).	82 cm²
	Transfer coefficient[3]	2%
	Exposure duration	1 h
	Generated dust / m³ of sanded treated wood. U.K. WEL of 5 mg/m³ wood dust (8-hour time-weighted average)	5 mg/m³
	Density of wood[4]	0.4 g/cm³
	Volume of wooden post to be sanded	4000 cm³

[1] HEAdhoc Recommendation no. 14 Default human factor values for use in exposure assessment for biocidal products.

[2] HEEG opinion 17. Default human factor values for use in exposure assessments for biocidal products (2013).

[3] TNsG 2007. Human exposure to Biocidal Products (for dried fluids on rough sawn wood).

[4] Manual of Technical Agreements of the Biocides Technical Meeting (MOTA) V.6 (2013), 4.2.5 for PT8 (p 30.).

Calculations for Scenario [11] – Sawing and sanding treated wood

Summary table: estimated exposure from users					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		[mg/kg bw/d]	**[mg/kg bw/d]**	**[mg/kg bw/d]**	**[mg/kg bw/d]**
Scenario [11] - Sawing and Sanding treated wood	Tier 1/ no gloves	2.10E-05	1.53E-03	-	1.55E-03

Further information and considerations on scenario [11]

Local exposure and risk assessment is not relevant for sawing and sanding treated dried wood, since the concentrations of the active substance and SoC to which dermal contact occurs is reduced by the transfer coefficient of 2 % for dried fluids on rough sawn wood.

For the SoC "hydrocarbons, C9-C11, n-alkanes, isoalkanes, cyclics, < 2% aromatics", it can be assumed that it is completely evaporated when the wood is dried.

Consequently, performance of a local exposure and risk assessment is not required.

The calculation sheets are provided in Annex 3.2.

Scenario [12] – Chewing wood off-cut

Description of Scenario [12] - Chewing wood off-cut		
Infant picks up and chews wood off-cut, which has been treated with wood preservative. This scenario is considered an acute exposure scenario. The application rate of 200 mL product/m² (curative treatment, worst case) of the solvent-based product (taking into account the 0.4% permethrin) is considered the highest-end-retention. For infants who are chewing wood it is assumed that the active substances in the treated timber is located in the outer 1 cm layer. It is assumed that the infant is chewing a 4 cm × 4 cm × 1 cm = 16 cm³ chip and in doing so extracts 10% of the active substance. For children this scenario is not relevant according to TNsG 2002. This scenario is regarded as unrealistic for children, as opposed to infants, because children are highly unlikely to chew treated wood in any significant amounts. This secondary exposure scenario is based on TNsG on Human Exposure to Biocidal Products Part 3, p42 as revised by User Guidance version 1 p50-54 (EC, 2002a). During sawing/sanding of treated wood, dermal and inhalation exposure of adults is considered.		
	Parameters	Value
Tier 1	Application rate	200 g/m²
	Extraction by chewing[1]	10%
	Size of wood composites chip[1]	16 cm³
	Surface of wood composite chip treated[1]	16 cm²
	Oral absorption	100%
	Dermal absorption (default value)	70%
	Body weight[2]	8 kg

[1] TNsG on Human Exposure to Biocidal Products Part 3, p42 as revised by User Guidance version 1 p50-54 (EC, 2002a).

[2] HEAdhoc Recommendation no. 14 Default human factor values for use in exposure assessment for biocidal products.

Calculations for Scenario [12] – Chewing wood off-cut

Summary table: estimated exposure from infant by chewing wood off-cut					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		[mg/kg bw/d]	**[mg/kg bw/d]**	**[mg/kg bw/d]**	**[mg/kg bw/d]**
Scenario [12] - Chewing wood off-cut	Tier 1/ no gloves	-	-	1.60E-02	1.60E-02

Further information and considerations on scenario [12]

For the SoC "hydrocarbons, C9-C11, n-alkanes, isoalkanes, cyclics, < 2% aromatics", it can be assumed that it is completely evaporated when the wood is dried.

Consequently, performance of a local exposure and risk assessment is not required.

The calculation sheets are provided in Annex 3.2.

Scenario [13] – Playing on playground structure outdoors and mouthing

Description of Scenario [13] - Playing on playground structure outdoors and mouthing		
Toddler playing on and mouthing weathered structure. These scenarios are considered chronic exposure scenarios. The application rate of 200 mL product/m² of the solvent-based product (taking into account the concentration of 0.4% permethrin) is considered the highest-end-retention. In this scenario, during playing on timber structure, dermal as well as oral (through hand-to-mouth transfer) exposure is considered. This secondary exposure scenario is based on TNsG 2002 User guidance - Version 1 and TNsG 2002, part III, and on the HEAdhoc Recommendation no. 5 (2015).		
	Parameters	Value
Tier 1	Application rate	200 g/m²
	Density of the product	0.76 g/ml
	Dermal absorption (default value)	70%
	Body weight[1]	10 kg
	Contact surface (hands)[1]	231 cm²
	Hands contaminated area (%)[2]	20%
	Dislodgeable fraction for dried objects on wood (%)[2]	2%
	Wood surface area mouthing [2]	50 cm²
	Oral absorption	100%

[1] HEAdhoc Recommendation no. 14 Default human factor values for use in exposure assessment for biocidal products.

[2] TNsG on Human Exposure to Biocidal Products Part 3, p51.

Calculations for Scenario [13] – Playing on playground structure outdoors and mouthing

Summary table: estimated exposure from toddler playing on playground structure outdoors and mouthing					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		[mg/kg bw/d]	**[mg/kg bw/d]**	**[mg/kg bw/d]**	**[mg/kg bw/d]**
Scenario [13] - Playing on playground structure outdoors and mouthing	Tier 1/ no PPE	-	5.16E-03	1.11E-03	6.27E-03

Further information and considerations on scenario [13]

Local exposure and risk assessment is not relevant for playing on playground structure outdoors and mouthing, since the concentration of the active substance and the SoC to which dermal contact occurs are reduced by the transfer coefficient of 2 % for dried fluids on rough sawn wood.

For the SoC "hydrocarbons, C9-C11, n-alkanes, isoalkanes, cyclics, < 2% aromatics", it can be assumed that it is completely evaporated when the wood is dried.

Consequently, performance of a local exposure and risk assessment is not required..

The calculation sheets are provided in Annex 3.2.

Scenario [14] – Inhalation of volatilized residues

Description of Scenario [14] - Inhalation of volatilized residues
Chronic exposure to wood preservatives may arise via residues volatilised from treated wood indoors. Permethrin has a very low vapour pressures of 2.155E-06 Pa (at 20°C). Although, inhalation from treated dried wood is considered to be very low, exposure by volatilised residues indoors was calculated using the SVC (saturated vapour concentration) approach (according to HEEG opinion 13 on Assessment of Inhalation Exposure of Volatilised Biocide Active Substance, 2011). As a Tier-1 screening tool whether inhalation exposure can be neglected or should be included into the risk assessment, the following screening test which is based on the toddler representing the worst case is proposed for the active substance: $0.328 \times \frac{mw \times vp}{AEL_{long-term}} \leq 1$ Let mw and vp denote the molecular weight (in g/mol) and the vapour pressure (in Pa).For toddler (based on an inhalation rate of 8 m^3/24 hr and bw of 10 kg) and using an AEL in mg a.s./kg bw/d, if then risk from inhalation exposure for the toddler is negligible,

otherwise inhalation exposure should be included in the risk assessment. If the inhalation risk for the toddler is negligible then the inhalation risk for the infant, child and for the adult can also be considered to be negligible.

For the product, there are three active substances:

Active substance	Vapour pressure a.s. (Pa)	Molecular weight a.s.	AEL longterm (mg a.s./kgbw/d)	Cte	Result	Negligible / included
Permethrin	2.16E-06	391.29	0.05	0.328	5.53E-03	negligible

Based on the results table above, the inhalation exposure of permethrin can be deemed negligible and the risk assessment for this scenario is not considered necessary.

[1] HEEG opinion 13 on Assessment of Inhalation Exposure of Volatilised Biocide Active Substance).

Calculations for Scenario [14] – Inhalation of volatilized residues

Not necessary.

Further information and considerations on scenario [14]

Local exposure and risk assessment is not relevant for inhalation of volatilized residues. When the wood is dried, it can be assumed that the SoC "hydrocarbons, C9-C11 n-alkanes, isoalkanes, cyclics, < 2% aromatics" it is completely evaporated

Consequently, performance of a local exposure and risk assessment is not required.

Scenario [15] – Laundering work clothes

Description of Scenario [15] - Laundering work clothes

Exposure to MATACARCOMA can occur when washing contaminated work clothes. Persons at risk are adults. The exposure is considered acute intermediary, as it does not occur on a daily basis but may be longer-term.

In general, this approach assumes that the washing is carried out in a domestic automatic washing machine, therefore, the exposure will be dermally through the hands, from handling the contaminated clothes before and during the introduction of the clothes in the washing machine. Laundering is considered to be after a five day work week as the worst case, hence the total amount of product on work clothes is assumed to be five times the daily contamination associated with the application method used and it is assumed that the clothing to be washed is a coverall worn by a professional. The contamination of the coveralls is based on the worst professional scenario, manual spraying (Scenario [2.b]) as Tier 1 and on manual dipping [2.d] from which the tier that shows safe use as Tier 2.

The sum transfer area is determined by estimating how many times the coverall is touched by the hands while preparing it for laundering. As a first tier, it is assumed that this happens three times, twice with the palms of both hands and once with the total hands surface, the sum transfer area is 1640 cm^2. As a worst-case assumption, 50% of the residues in the touched area is transferred to the skin (transfer

coefficient). The scenario is modelled after the CAR for Propiconazole in PT8 (FI CA, 2007).		
	Parameters	Value
Tier 1	Clothing contamination from spraying scenario [2.b]	32566 mg/day
	Days before washing	5 days
	Percentage dislodgeable (transfer coefficient)[2]	30%
	Surface of medium coated coverall[2]	22700 cm^2
	Sum transfer area[3]	1640 cm^2
	Dermal absorption	70%
	Body weight	60 kg
Tier 2	Clothing contamination from brushing scenario [3]	6.77 mg/day

[1] Clothing contamination equals the highest potential body exposure minus the amount that penetrates through the clothing (10 %), and is expressed as mg a.s./day.

[2] TNsG 2002, part 2, p 204 Cotton, knitwear, plastic, wood Dried fluid 30 % - wet hand.

[3] See the CAR for Propiconazole (FI CA, 2007).

Calculations for Scenario [15] – Laundering work clothes

Summary table: estimated exposure from people laundering work clothes					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		[mg/kg bw/d]	**[mg/kg bw/d]**	**[mg/kg bw/d]**	**[mg/kg bw/d]**
Scenario [15] Laundering work clothes	TIER 1 From spray application	-	8.53E-02	-	8.53E-02
	TIER 2 From manual dipping	-	2.57E-02	-	2.57E-02

Further information and considerations on scenario [15]

No further information is considered relevant for this scenario.

Combined scenarios

No combined scenarios are considered of concern for general public.

Monitoring data

No monitoring studies have been developed by the applicant as they are not considered necessary.

Dietary exposure

Not required since exposure to food, drinking water or livestock can be excluded when the product is applied according to the recommended uses. Additionally, the RMM "Do not apply the product to wood or place treated wood in areas where food/feed, food utensils or food processing surfaces may come into contact with, or be contaminated by the product or treated wood" is applied to exclude contact with food and feedstuff.

Exposure associated with production, formulation and disposal of the biocidal product

Production/formulation of the biocidal product

Exposure resulting from the production and formulation of the active substance and of the biocidal product is not considered. The production/formulation of the biocidal product is done in accordance with local and national occupational health and safety regulations.

During the production and formulation of the biocidal product, human are not exposed to the product residues as the process is automated in a closed system and the operator is segregated from the product source.

Therefore, no risk assessment is needed at this regard. Moreover, all the steps of the manufacturing process at IRURENA manufacturing plants are performed according to the instructions given in the Directive 98/24/EC - risks related to chemical agents at work.

Environmental exposure

In case of spillages, the biocidal product is taken up with inert material (sand, earth, chemical absorbent, etc.) and collected in dedicated properly labelled drums. It is disposed of as chemical waste in accordance with local and national laws and regulations. Consequently, there is no release into the environment and, thus, no environmental exposure assessment is applicable.

Disposal of the biocidal product

The waste disposal has to be done in accordance with Directive 2008/98/EC, covering waste and dangerous waste. For the disposal of the product and packaging, the allocation of waste identity numbers/waste descriptions must be carried out according to the EEC, specific to the industry and process.

Aggregated exposure

Not applicable as this product is not intended to be used under a different biocidal product type.

Summary of exposure

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group**	**Tier/PPE**	**Estimated total uptake (mg/kg bw/d)**
1	Industrial (trained professional and professional)	-	negligible
2	Trained professional Professional	Tier 2 / gloves	4.84E-04
2b	Non-professional	Tier 1 / none	5.97E-04
3	Industrial (trained professional and professional), Trained professional, Professional. Non-professional	Tier 1/ none	1.15E-03
		Tier 2/ Gloves and coverall	1.18E-04
4	Trained professional Professional	Tier 1/ None	1.86E+00
		Tier 2/ Gloves	8.66E-01
		Tier 3/ Gloves and coverall 5%	7.90E-02
		Tier 4/ new gloves for each work shift (including in model)+ impermeableble coverall 5%	6.50E-02
5	Industrial (trained professional and professional)	Tier 1/ gloves (including in model)	5.85E-02
		Tier 2/ gloves (including in model)+ impermeable coverall 5%	3.75E-02
		Tier 3/ new gloves each cycle (including in model) + impermeable coverall 5%	1.93E-02
6	Industrials (trained professional), Trained professional, Professional	Tier 1/ gloves (including in model)	2.85E-01
		Tier 2/ gloves (including in model)+ coverall 5%	4.85E-02
		Tier 3/ new gloves for each work shift (including in model)+ impermeable coverall 5%	3.13E-02
7	Industrials (trained professional and professional)	Tier 1/ new gloves (including in model)	5.38E-02
		Tier 2/ new gloves (including in model)+ coverall 5%	2.57E-03
		Tier 3 (fully automated) 1/4/ new gloves (including in model) and impermeable coverall 5%	6.44E-03
8	Industrial (trained professional and professional), Trained professional, Professionals, Non-professional	Tier 1/ none	4.67-03
		Tier 2/ Gloves	4.67-04

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group**	**Tier/PPE**	**Estimated total uptake (mg/kg bw/d)**
9	Industrials(trained professional and professional), Trained professional, Professional	Tier 1/ none	3.91E-02
		Tier 2/ Gloves	1.62E-02
Combined [3] + [8]	Industrial (trained professional and professional), Trained professional, Professional	[3] Tier 2/ (gloves and coverall+[8] Tier 2 (gloves)	5.85E-04
Combined [5] + [9]	Industrials (trained professional and professional)	[5] Tier 1 (gloves) + [9] Tier 2 (gloves)	7.48E-02
		[5] Tier 2 (gloves and impermeable coverall) + [9] Tier 2 (gloves and coverall)	4.14E-02
		[5] Tier 3 (new gloves, impermeable coverall) +[9] Tier 2 (gloves)	2.32E-02
Combined [2] + [3] + [8]	Trained professional, Trained professional, Professional	[2] Tier 2 (gloves) + [3] Tier 2 (gloves) + [8] Tier 2 (gloves)	1.08E-03
Combined [4] + [9]	Trained professional Professional	[4] Tier 2 (gloves) + [9] Tier 2 (gloves)	8.83E-01
		[4] Tier 3 (gloves and coverall 5%) +[9] Tier 2 (gloves)	9.52E-02
		[4] Tier 4 (new gloves for each work shift (including in model)+ impermeable coverall 5%) +[9] Tier 2 (gloves)	8.12E-02
Combined [2] + [3] + [8]	Non-professionals (general public)	[2] Tier 1 + [3] Tier 1 + [8] Tier 1/ no PPE	6.35E-03
10 – secondary chronic exposure	Trained professional, Professional	Tier1/ None	2.85E-04
11 – secondary acute exposure	general public –adult	Tier1/ None	1.55E-03
12 – secondary acute exposure	general public - infant	Tier1/ None	1.60E-02
13 – secondary chronic exposure	general public - infant	Tier1/ None	6.27E-03
14 – secondary chronic exposure	general public	Tier1/ None	n.r.
15 – secondary exposure chronic exposure	general public - adult	Tier1 from spraying application/ None	8.53E-02
		Tier2 from dipping scenario/ None	2.57E-02

Risk characterisation for human health

2.2.6.3 Risk characterisation for human health

The risk characterisation is conducted by comparison of human exposure and the toxicity using the Acceptable Exposure Limit (AEL) approach in which the exposure estimates are compared with the systemic reference values that were determined by dividing the relevant N(L)OAEL (mg/kg/day) by an overall Assessment Factor (AF). Risks are considered acceptable if the systemic exposure/AEL ratio is < 1.

Reference values to be used in Risk Characterisation for <u>Permethrin</u>

The data provided in the following table are according to the AR on permethrin (PT8 – 2014).

Reference	Study	NOAEL (LOAEL)	AF[1]	Correction for oral absorption	Value
AELshort-term	2 year oral study in rats (acute effects)	59.43 mg/kg bw/d[2]	100	-	0.5 mg/kg bw/d[2]
AELmedium-term	1 year study in dog	5 mg/kg bw/d	100	-	0.05 mg/kg bw/d
AELlong-term	1 year study in dog	5 mg/kg bw/d	100	-	0.05 mg/kg bw/d
ARfD	-	-	-	-	n.r.
ADI	-	-	-	-	n.r.

[1] The default assessment factor of 100 is obtained from [10 (interspecies variation) x 10 (intraspecies variation)] which is considered appropriate by the active substance's AR.

[2]According to AR (PT8 – 2014), "*dividing the NOAEL value 59.43-mg/kg bw/day by an overall assessment factor of 100 derives a reference value of 0.59-mg/kg bw/day. However, this AEL$_{acute}$ from an inhalation study enquires estimate of received dose with all the attendant uncertainties. The oral Ishmael and Litchfield gives a very similar AEL of 0.5 mg/kg bw/day Therefore, ARfD or AEL$_{acute}$ reference value is set at of 0.5 mg/kg bw/day*."

n.r.: not relevant

Maximum residue limits or equivalent

Not relevant

Risk for industrial users

General remark:

The results reflect industrial applications using the product MATACARCOMA containing 0.4% permethrin.

Systemic effects

Scenario / task	Tier/ PPE	Systemic NOAEL (mg/ kg bw /d)	AEL (mg/kg bw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ AEL (%)	Acceptable (Yes/No)

Scenario / task	Tier/ PPE	Systemic NOAEL (mg/ kg bw /d)	AEL (mg/kg bw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ AEL (%)	Acceptable (Yes/No)
Scenario [1] / Mixing and loading of RTU (automated)	-	5	0.05	negligible	negligible	yes
Scenario [3] - Brushing /Rolling application	TIER 1 (without PPE)	5	0.05	1.15E-03	2.30%	yes
	TIER 2 (with gloves and coverall)	5	0.05	1.18E-04	0.24%	yes
Scenario [5] Automated spraying	TIER 1 with gloves (including in model)	5	0.05	5.85E-02	**117.00%**	**no**
	TIER 2 with gloves (including in model)+ coverall 5%	5	0.05	3.75E-02	72.00%	yes
	TIER 3 with new gloves each cycle (including in model) + impermeable coverall 5%	5	0.05	1.93E-02	38.60%	yes
Scenario [6] Manual dipping	TIER 1 with gloves (including in model)	5	0.05	2.85E-01	**570.00%**	**no**
	TIER 2 with gloves (including in model)+ coverall 5%	5	0.05	4.85E-02	97.00%	yes
	TIER 3 new gloves for each work shift (including in model)+ impermeable coverall 5%	5	0.05	3.13E-02	62.60%	yes
Scenario [7] Fully automated dipping	TIER 1 with gloves (including in model)	5	0.05	5.38E-02	**107.60%**	**no**
	TIER 2 with gloves (including in model)+ coverall 5%	5	0.05	2.57E-03	5.14%	yes
	TIER 3 FULLY AUTOMATED 1/4 (with new gloves (including in model)+ coverall 5%)	5	0.05	6.44E-04	1.29%	yes
Scenario [8] - Cleaning brush	Tier 2/ with gloves	5	0.05	4.67E-04	0.93%	yes
Scenario [9] Cleaning spray equipment	TIER 1 without PPE	5	0.05	3.91E-02	78.20%	yes
	TIER 2 with gloves (including in model)	5	0.05	1.62E-03	32.40%	yes

Combined scenarios

Scenario / task	Tier/ PPE	Systemic NOAEL (mg/ kg bw /d)	AEL (mg/kg bw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ AEL (%)	Acceptable (Yes/No)
Brushing treatment [3] + [8]	[3] Tier 2 +[8] Tier 2/ with PPE	5	0.05	5.85E-04	1.17%	yes
Automated spraying treatment [5] + [9]	[5] Tier 1 + [9] Tier 2	5	0.05	7.48E-02	**149.60%**	**no**
	[5] Tier 2 + [9] Tier 2	5	0.05	4.14E-02	82.80%	yes
	[5] Tier 3 + [9] Tier 2	5	0.05	2.32E-02	46.40%	yes

Combined exposure to several active substances within the biocidal product

Not required.

Local effects

With respect to local effects, the RTU product MATACARCOMA has a classification of STOT SE 3 (H336), Asp. Tox. 1 (H304) and EUH066.

The qualitative exposure and risk assessment for local effects is performed based on the Guidance on the Biocidal Products Regulation, Vol III, Part B (2015) and is addressed in the following table (on next page).

Hazard			Exposure							Risk
Hazard category	**Effects in terms of C&L**	**Additional relevant hazard information**	**PT**	**Who is exposed?**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant RMM* & PPE****	**Conclusion on risk**
Low	Asp. Tox. 1; H304	-	8	Industrials (trained professional)	The RTU product MATACARCOMA containing permethrin is used undiluted by industrials for wood preservation by brushing/roller (use #1), automated spraying (use #3), manual dipping (use #4) and automated dipping (use # 5)	Skin Inhalation	Daily; More than few hours per day	Use # 3&5: High level of containment, Use # 1, 3-5: Controlled exposure with technical RMM, PPE and good ventilation Use # 3&5: practically negligible exposure due to automated tasks (e.g. automated mixing and loading or automated application) Potential exposure to undiluted product is only during brief contact during connecting lines, with technical RMM and PPE.	Technical and organisational RMM adequate for the low category are achievable: + adverse effect expected only after repeated, prolonged exposure (STOT-SE and EUH066). + high degree of operational RMMs (high level containment (only for use #3 and #5), easy maintenance, minimization of manual phases, regular cleaning of equipment and work area, good standard of general ventilation). + high degree of organisational RMMs (permit to work procedures, trained orkers, intensive supervision of workers for proper use of RMM, good standard of personal hygiene). + Avoid breathing dust/fume/gas/mist/vapours/spray (P261). + professionals using appropriate PPE (gloves, protective clothing, eye /face protection) (P280)	Acceptable: + installed RMM at place + trained workers + use of appropriate PPE
Low	EUH 066	-								
Low	STOT SE 3; H336	-								

* RMM: risk mitigation measures

** PPE: personal protective equipment

Conclusion

The solvent-based RTU product MATACARCOMA containing permethrin is used undiluted by industrials for wood preservation by brushing (use #1), automated spraying (use #3), manual dipping (use #4) and automated dipping (use #5).

Workers in industrial premises are trained professionals. Appropriate PPE (gloves, impermeable coverall (95% protection), eye/face protection) should be used for exposure control.

Using the RTU product containing 0.4% permethrin and "hydrocarbons, C9-C10, n-alkanes, isoalkanes, cyclics, < 2% aromatics", the following risk characterisation is given:

Brushing/ rolling treatment: the risk during the individual intended use #1 is acceptable for the RTU product, by considering default protective personal equipment (gloves, coverall) for industrial users.

Automated spraying: the risk exposure during the individual intended use #2 is considered acceptable for MATACARCOMA product when gloves (90% protection) and impermeable coverall (95% protection) are considered (Tier 2) for industrial users. There is not necessary to use new gloves per cycle. There is not necessary to use of fully automated.

Manual dipping: the risk during the individual intended use #4 is considered acceptable for the RTU MATACARCOMA product when gloves (90% protection) and impermeable coverall (95% protection) are considered (Tier 2) for industrial users. Even if there is no risk, it is recommendable to new gloves per cycle.

Automated dipping: the risk during the individual intended use #5 is considered acceptable for the RTU MATACARCOMA product, when considering default protective personal equipment (Tier 2: gloves (90% protection)) and impermeable coverall (95% protection)) for industrial users. There is not necessary to use new gloves per cycle. There is not necessary to use of fully automated.

Risk for professional users

The exposure assessment for trained professional and non-trained operators is evaluated. Both trained professional and non-trained professional users should wear gloves and coverall as PPE for their protection. The main difference between them is the frequency of applications over a year. Whilst the product application is considered daily for trained professional users, only few treatments are deemed for non-trained professional users who uses the product occasionally or when the infestation appears. In order to difference both users $AEL_{long\text{-}term}$ is considered to establish the risk of trained professional users and $AEL_{med\text{-}term}$ is used for non-trained professional users.

The exposure assessment for trained and non-trained professional operators is evaluated under the comparison with the proposed $AEL_{long\text{-}term}$ and $AEL_{med\text{-}term}$ respectively for permethrin as a Risk Characterization Ratio (RCR). If this quotient is above to the trigger value of 100% it will mean an unacceptable risk exposure for human. Due that $AEL_{long\text{-}term}$ and $AEL_{med\text{-}term}$ values are the same for Permethrin, similar outputs are expected to be obtained for both professional users so the current assessment is focused on trained professional as the worst representative case.

Systemic effects

Scenario / task	Tier/ PPE	Systemic NOAEL (mg/ kg bw /d)	AEL (mg/ kg bw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ AEL (%)	Acceptable (Yes/No)
Scenario [2] / Mixing and loading of RTU	TIER 2 (with gloves)	5	0.05	4.84E-04	0.97%	yes
Scenario [3] - Brushing /Rolling application	TIER 1 (without PPE)	5	0.05	1.15E-03	2.30%	yes
	TIER 2 (with gloves and coverall)	5	0.05	1.18E-04	0.24%	yes
Scenario [4] spraying	TIER 1 without gloves	5	0.05	1.86E+00	3720%	**no**
	TIER 2 with gloves (including in model)	5	0.05	8.66E-01	1732%	**no**
	TIER 3 with gloves (including in model)+ coverall 5%	5	0.05	7.90E-02	158%	**no**
	TIER 4 with new gloves for each work shift(including in model)+ impermeable coverall 5%	5	0.05	6.50E-02	130%	**no**
Scenario [6] Manual dipping	TIER 1 with gloves (including in model)	5	0.05	2.85E-01	570%	**no**
	TIER 2 with gloves (including in model)+ coverall 5%	5	0.05	4.85E-02	97%	yes
	TIER 3 with new gloves for each work shift (including in model)+ impermeable coverall 5%	5	0.05	3.13E-02	62.6%	yes
Scenario [8] - Cleaning brush	Tier 2/ with gloves	5	0.05	4.67E-04	0.93%	yes
Scenario [9] Cleaning spray equipment	TIER 2 with gloves	5	0.05	1.62E-02	32.4%	yes
Scenario [10] - Sawing and sanding treated Wood. (Secondary exposure)	Tier 1/ no gloves	5	0.05	2.85E-04	0.57%	yes

Combined scenarios

Scenario / task	Tier/ PPE	Systemic NOAEL (mg/ kg bw /d)	AEL (mg/kg bw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ AEL (%)	Acceptable (Yes/No)
Brushing treatment [2]+[3] + [8]	[2] Tier 2 + [3] Tier 2 + [8] Tier 2	5	0.05	1.08E-03	2.16%	Yes
Spraying treatment [4] + [9]	[4] Tier 2 + [9] Tier 2	5	0.05	8.83E-01	**1496%**	**No**

Scenario / task	Tier/ PPE	Systemic NOAEL (mg/ kg bw /d)	AEL (mg/kg bw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ AEL (%)	Acceptable (Yes/No)
	[4] Tier 3 +[9] Tier 2	5	0.05	9.52E-02	**190%**	**No**
	[4] Tier 5 +[9] Tier 2	5	0.05	8.12E-02	**162%**	**No**

Combined exposure to several active substances within the biocidal product

Not required.

Local effects

With respect to local effects, the RTU product MATACARCOMA has a classification of STOT SE 3 (H336), Asp. Tox. 1 (H304) and EUH066.

The qualitative exposure and risk assessment for local effects is performed based on the Guidance on the Biocidal Products Regulation, Vol III, Part B (2015) and is addressed in the following table (on next page).

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Hazard			Exposure							Risk
Hazard category	**Effects in terms of C&L**	**Additional relevant hazard information**	**PT**	**Who is exposed?**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant RMM* & PPE****	**Conclusion on risk**
Low	Asp. Tox. 1; H304	-	8	Professional	The RTU product MATACARCOMA containing permethrin is used undiluted by professional users for wood preservation by brushing/roller (use #1), spraying (use #2) and manual dipping (use #4)	Skin Inhalation	Daily by trained professional (more than few hours per day) and few times per year by non-trained professional users;	Use # 1, #2 and #: Controlled exposure with technical RMM, PPE and good ventilation Potential exposure only, with technical RMM and PPE.	Technical and organisational RMM adequate for the low category are achievable: • High degree of operational RMMs (easy maintenance, minimization of manual phases, regular cleaning of equipment and work area, good standard of general ventilation). • High degree of organisational RMMs (permit to work procedures, trained workers, intensive supervision of workers for proper use of RMM, good standard of personal hygiene). • Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray. (P261). • professionals using appropriate PPE (protective gloves, protective clothing, eye/face protection) (P280). • proper instructions for use.	Acceptable: + installed RMM at place + trained workers + use of appropriate PPE
Low	EUH 066	-								
Low	STOT SE 3; H336	-								

* RMM: risk mitigation measures

** PPE: personal protective equipment

Conclusion

The solvent-based RTU MATACARCOMA product containing permethrin is used undiluted by professionals for wood preservation by brushing (use #1), spraying (use #2) and manual dipping (use #4).

Appropriate PPE (protective gloves or new gloves for each work shift, impermeable coverall or protective coverall should be used for exposure control is considered for professional users.

Using the RTU product containing 0.4% permethrin and "hydrocarbons, C9-C10, n-alkanes, isoalkanes, cyclics, < 2% aromatics", the following risk characterisation is given:

Brushing/ rolling treatment: the risk during the individual intended use #1 is acceptable for the MATACARCOMA product, by considering default protective personal equipment (gloves, coverall) for professional users (trained and non-trained).

Spraying: the risk during the individual intended use #2 is considered unacceptable for the MATACARCOMA product, considering default protective personal equipment (new gloves for each work shift + impermeable coverall) for professional users (trained and non-trained).

Manual dipping: the risk during the individual intended use #4 is considered acceptable for the RTU MATACARCOMA product, considering default protective personal (gloves + impermeable coverall) for professional users (trained and non-trained). It is recommendable to use new gloves for each work shift.

Risk for non-professional users

Non-professional users use the product occasionally over the year so $AEL_{short\text{-}term}$ is deemed to establish the risk for this users. According to Guidance on the BPR: Volume III Parts B+C Version 4.0 (2017) no PPE are considered in the risk assessment of non-professional users.

Systemic effects

Scenario / task	Tier/ PPE	Systemic NOAEL (mg/ kg bw /d)	AEL (mg/kg bw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ AEL (%)	Acceptable (Yes/No)
Scenario [2b] / Mixing and loading of RTU	Tier 1/ no PPE	5	0.5	5.97E-04	1.19%	yes
Scenario [3] - Brushing /Rolling application	Tier 1/ no PPE	5	0.5	1.15E-03	2.31%	yes
Scenario [8] - Cleaning brush	Tier 1/ no PPE	5	0.5	4.67E-03	9.34%	yes
Scenario [11] - Sawing and sanding treated Wood (Secondary exposure)	Tier 1/ no PPE	5	0.5	1.55E-03	3.10%	yes

Combined scenarios

Scenario / task	Tier/ PPE	Systemic NOAEL (mg/ kg bw /d)	AEL (mg/kg bw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ AEL (%)	Acceptable (Yes/No)
Brushing treatment [2]+[3]+[8]	[2] Tier 1 + [3] Tier 1 + [8] Tier 1	5	0.5	6.35E-03	12.7%	Yes

Combined exposure to several active substances within the biocidal product

Not required.

Local effects

With respect to local effects, the RTU product MATACARCOMA has a classification of STOT SE 3 (H336), Asp. Tox. 1 (H304) and EUH066.

The qualitative exposure and risk assessment for local effects is performed based on the Guidance on the Biocidal Products Regulation, Vol III, Part B (2015) and is addressed in the following table (on next page).

Hazard			Exposure							Risk
Hazard category	**Effects in terms of C&L**	**Additional relevant hazard information**	**PT**	**Who is exposed?**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant RMM***	**Conclusion on risk**
Low	Asp. Tox. 1; H304	-	8	Non-professional (general public)	The RTU product MATACARCOMA containing permethrin is used undiluted by non-professional users for wood preservation by brushing/roller (use #1)	Skin Inhalation	Few times a year (few hours per event)	Use # 1: low. Controlled exposure with technical RMM, and good ventilation Potential exposure only, with technical RMM.	Technical and organisational RMM adequate for the low category are achievable: • Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray. (P261). • proper instructions for use.	Acceptable: The frequency of application can be demmed casual and the potential grade of exposure very low when the label instructions are followed.
Low	EUH 066	-								
Low	STOT SE 3; H336	-								

* RMM: risk mitigation measures

Conclusion

The solvent-based RTU MATACARCOMA containing permethrin shows acceptable risk exposure when they are used undiluted by non-professionals for wood preservation by brushing (use #1).

Risk for the general public

The risk assessment of general public is done considering the $AEL_{short-term}$ of the active substance. The table below shows the risk obtained for each human group.

Systemic effects

Scenario / task	**Tier/ PPE**	**Systemic NOAEL (mg/ kg bw /d)**	**AEL (mg/kg bw/d)**	**Estimated uptake (mg/kg bw/d)**	**Estimated uptake/ AEL (%)**	**Acceptable (Yes/No)**
Sawing and sanding treated Wood / [11] - (acute scenario)	Tier 1/ no PPE	5	0.5	1.55E-03	3.10%	yes
Chewing wood off-cut / [12] – acute scenario	Tier 1/ no PPE	5	0.5	1.60E-02	32.0%	yes
Playing on playground structure outdoors and mouthing / [13] – chronic scenario	Tier 1/ no PPE	5	0.05	6.27E-03	12.54%	yes
Inhalation of volatilized residues / [14] – chronic scenario	Tier 1 / no PPE	5	0.05	n.r.	n.r.	yes
Laundering work clothes / [15] – chronic scenario	TIER 1 From spraying application	5	0.05	8.53E-02	**170.6%**	no
	TIER 2 From manual dipping	5	0.05	2.57E-02	51.4%	yes

Combined exposure to several active substances within the biocidal product

Not required.

Local effects

With respect to local effects, the RTU product MATACARCOMA has a classification of STOT SE 3 (H336), Asp. Tox. 1 (H304) and EUH066.

From secondary exposure EUH066 and Asp.Tox.1 (H304) are not expected as both effects are attributed to the SoC "hydrocarbons, C9-C11, n-alkanes, isoalkanes, cyclics, < 2% aromatics", which is assumed to be completely evaporated when the wood is dried. The effects of STOT SE 3 (H336) can also be excluded as inhalation exposure is expected to be negligible after treated wood are dried.

Conclusion

An acceptable risk exposure is expected for general public by secondary exposure when they entry in contact with wood treated from MATACARCOMA product.

Only scenario of laundering work clothes providing from spraying application shows unacceptable risk when $AEL_{long\text{-}term}$ values are considered. It is important to bear in mind that when dermal absorption value used in active substance's CAR is considered in the assessment exposure, an acceptable risk is obtained. On the other hand, if $AEL_{short\text{-}term}$ is considered instead of $AEL_{long\text{-}term}$ in the risk exposure, acceptable risk is expected regardless the value of dermal absorption used.

When the second worst scenario that involves high level of coverall contamination is considered (scen [6] - manual dipping), an acceptable risk is obtained which means that the laundering work-cloth scenarios from the rest of uses (#1, #3 and #5) can be deemed acceptable as they are covered by this second worse case.

Risk for consumers via residues in food

Not relevant.

MATACARCOMA is not intended to be used in places where food is kept or entrance in contact with food during its application. Therefore, no risk is derived for consumers via residues in food. In addition, in order to avoid any potential risk by its use, the following RMM is set on product's label:

- Do not (use/apply) directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock.

According to Guidance on the BPR: Volume III Parts B+C Version 4.0 December 2017; Annex A: Substances of Concern – Proposed Human Health (Toxicology) Assessment Scheme for Authorisation of Biocidal Products, "hydrocarbons, C9-C11, n-alkanes, isoalkanes, cyclics, < 2% aromatics" has been identified as SoC in the formulation from MATACARCOMA product so the risk assessment developed above and derived from combined exposure to the active substance and the SoC is considered sufficient to set the risk of the product.

2.2.7 Risk assessment for animal health

Not relevant.

2.2.8 Risk assessment for the environment

ESCA: Please notice that the risk assessment for the environment is reported as provided by the applicant. The ES CA position is presented in grey boxes.

The environmental exposure assessment of MATACARCOMA product, containing Permethrin and formulated as a wood preservative, was assessed in accordance with the Guidance on the Biocidal Products Regulation (Volume IV Environment, version 2.0, October 2017) and the technical agreements for biocides (TAB, February 2021). This assessment was likewise performed following the recommendations of the Revised Emission Scenario Document for Wood Preservatives (OECD, 2013).
MATACARCOMA is intended to be used for the curative and preventive treatment of wood by industrial, professional or amateur users.
According to OECD (2013), industrial emissions are considered to occur during the treatment process including post-treatment conditioning as well as during storage of treated wood prior to shipment. Furthermore, industrial processes are considered to be continuous, while *in-situ* emissions are considered discontinuous.
Industrial local floors are cemented, so run-off is generally collected and recycled via drip pads. However, unintentional spills, floor cleaning, equipment cleaning and washing waters, drag-out on tyres may reach the facility drain. Even though release of the collected waste water to a sewage treatment plant (STP) is nowadays not permitted anymore in EU member state countries, the corresponding emission pathway (facility drain to surface water via STP) is considered the worst case which can occur.
The table below shows a summary of the application patterns used in the environmental risk assessment:

Use		**Application method**	**Dose**
Preventive and curative	Industrial (Use classes 1 and 2)	Brushing	Preventive*: 100 g/m^2
		Automated spraying	
		Dipping	
		Fully automated dipping	
	Professional (Use classes 1 and 2)	Brushing	Curative: 200 g/m^2 Preventive: 100 g/m^2
		Spraying	
		Manual dipping	
	Industrial (Use classes 1 and 2)	Brushing	Curative: 200 g/m^2 Preventive: 100 g/m^2

*According to

According to the OECD Series on Emission Scenario Documents, Nº 2, Part 1 (Emission Scenario Document for Wood Preservatives), industrial treatments are only considered as preventive treatments so no curative application in deemed in the current RA. Following the same OECD series, potential emissions from treated wood as "Use Class 1" and "Use Class 2" to the outer environment are considered negligible and therefore, none exposure scenarios are proposed for industrial operators, professional and amateurs for *in situ* indoor treatments. However, indoor air emissions are relevant for human exposure assessment, and it has been considered in the corresponding assessment.

2.2.8.1 Effects assessment on the environment

The PNEC values for Permethrin the PNEC values have been taken from the Assessment Report for PT8 (April 2014).
The PNEC values used in the risk assessment are the following:

Summary table on PNEC values for active substances and their relevant metabolites						
Substance (- metabolite)	***$PNEC_{STP}$ (mg/L)***	***$PNEC_{water}$ (mg/L)***	***$PNEC_{sediment}$ (mg/kg_{wwt})***	***$PNEC_{soil}$ (mg/kg_{wwt})***	***$PNEC_{bird}$ (mg a.s./kg food***	***$PNEC_{mammal}$ (mg a.s./kg food)***
Permethrin[1]	*0.00495*	*4.7E-07*	*2.17E-04*	*0.175*	*16.7*	*120*
- DCVA[2]	*n.r.*	*0.015*	*0.012*	*4.6*	*-*	*-*
- PBA[3]	*n.r.*	*0.010*	*0.009*	*1.44*	*-*	*-*

n.r. not relevant

[1] Permethrin:

PNECwater: lowest NOEC value from the aquatic invertebrate endpoints of 0.0047 µg/l (AF = 10)

PNECsed: NOEC value from the 5-d Chironomus riparius study of 0.01 mg/kg dwt (AF = 100).

PNECsoil: The IE (RMS for permethrin) evaluation of the permethrin confirmatory data was discussed at the BPC Meeting in early March 2017. IE can inform the CG members that an ENV WG e-consultation was requested by BPC Members during the 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 $PNEC_{soil}$ for permethrin on the soil micro-organism study. The new PNECsoil is 0.198 mg/kg dwt, corresponding to 0.175 mg/kg wwt.

[2] DCVA:

PNECwater: EC_{50} value from the fish study of $\geq$ 14.7 mg/l (AF = 1000).

PNECsed: the PNEC values were calculated using the equilibrium partitioning method

PNECsoil: NOEC value from the Hypoaspis aculeifer study of 526 mg/kg/dwt (AF = 100)

[3] PBA:

PNECwater: EC50 value from the algae study of > 19 mg/l (AF = 1000)

PNECsed: the PNEC values were calculated using the equilibrium partitioning method.

PNECsoil: FPBA NOEC value from the Hypoaspis aculeifer study of 495 mg/kg/dwt (AF = 300)

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

The biocidal product MATACARCOMA is a ready-to-use (RTU) solvent-based formulation containing permethrin. The product has not been tested for toxicity on aquatic and terrestrial organisms.
According to the "Guidance on information requirements (Version 1.1 November 2014), testing on the product/mixture does not need to be performed if there are valid data available on each of the components in the mixture sufficient to allow classification according to the rules laid down in Directive 1999/45/EC (DPD) and Regulation (EC) No

1272/2008 (CLP), and if synergistic effects between any of the components are not expected.
For all components of the biocidal product valid data are available through state-of-the art safety data sheets. The relevant component of the product which is classified with respect to the environment is the active substance permethrin. The other ingredient is not classified as being hazardous to the environment. (The exact composition of the product is confidential and is provided in the IUCLID file as well as in the confidential Annex of the PAR.)
Permethrin is classified with Aquatic Acute 1; H400 and Aquatic Chronic 1; H410 with the following M-Factors: Chronic = 10000; Acute = 100.

Harmonised environmental classification of the active substance

The environmental classification of the active substance is the following:

Harmonised environmental classification for the substance			
substance	**Env. Classification**	**M-Factor**	**Concentration of substance in the product (%)**
Permethrin	H400, H410	M=100 M(chronic)=10000	0.4

ES CA: ESCA agrees with the classification given by the applicant.

Environmental classification of the biocidal product

Taking into account the highest concentration of 0.4% permethrin and its corresponding M-Factors, permethrin is considered the decisive substance for the classification of environmental hazards. Synergistic effects between the components are not expected. Consequently, classification of the mixtures can be made according to the rules laid down in Regulation (EC) No 1272/2008 (CLP) and testing of the components and/or of the biocidal product itself is not necessary.
Applying the provisions of the CLP Regulation and considering the concentration of 0.4% of permethrin with an M-Factor of 10000 for chronic hazard and an M-Factor of 100 for acute hazard, the biocidal product MATACARCOMA needs to be classified with Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410).
Regarding the ecotoxicological properties, the formulation is very toxic to aquatic organisms.
According to Regulation (EC) No 1272/2008 the product is classified as Aquatic Acute 1 (H400: Very toxic to aquatic life)/Aquatic Chronic 1 (H410: Very toxic to aquatic life with long lasting effects) with the signal word "Danger".

Conclusion on the environmental classification and labelling of the product

Classification:
Aquatic Acute cat. 1 (H400)
Aquatic Chronic cat. 1 (H410)

Labelling:
Warning H410

Precautionary statements
P273 – Avoid release to the environment

P391 – Collect spillage
P501 - Dispose of contents/container as hazardous waste to a registered establishment or undertaking, in accordance with current regulations

ES CA: ES CA agrees with the classification of the biocidal product.

PBT-assessment:
According to the PT8-AR of Permethrin (2014), Permethrin does not fulfil the PBT nor the vPvB criteria. However, permethrin could also be considered as potentially persistent based on a constituent of permethrin (the *cis* isomer) and therefore fulfill the P criteria.

Endocrine disruption activity of non-active substances

The Commission Delegated Regulation (EU) 2017/2100 specifying the scientific criteria for the determination of endocrine-disrupting properties (ED criteria) under Regulation (EU) No 528/2012 (BPR) establishes that the ED criteria become applicable by 7 June 2018 for biocides (https://www.ctgb.nl/onderwerpen/hormoon-verstoorders).

No further ecotoxicological studies are available for MATACARCOMA. The product was not tested for potential endocrine disruption properties. MATACARCOMA contains the active substance Permethrin and one co-formulants (see confidential PAR).

For the active substance, no ED assessment is required because for active substances which have been approved, the EU assessment should be followed. As discussed in the Assessment Report for Permethrin (April 2014), acute and chronic exposure to Permethrin was highly toxic to the three groups of aquatic organisms, affecting reproduction and survival in fish and D*aphnia* (Daphnia was the most sensitive species in the acute and chronic tests). Permethrin does not have an endocrine effect on fish.

For the co-formulants a screening was performed by consulting:

- ECHA data for identification of ED and PBT, under REACH or BPR or CLP
- Identified as ED by United States EPA (https://comptox.epa.gov/dashboard/)
- Identified as ED by the United Nations Environment (July 2017) Programme(http://wedocs.unep.org/bitstream/handle/20.500.11822/25634/edc_report2.pdf?sequence=1&isAllowed=y and https://wedocs.unep.org/bitstream/handle/20.500.11822/25635/edc_report2_factsheet.pdf?sequence=1&isAllowed=y)

During screening performance none co-formulant triggered an alert for ED property.

Further Ecotoxicological studies

No data is available on the product. Please refer to active substance data on AR.

ES CA: not relevant.

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

No studies were performed or available on the ecotoxicology of the biocidal product MATACARCOMA.
For all components of MATACARCOMA product, valid data are available through state-of-the art safety data sheets. The decisive component of the product for the classification of environmental hazards is the active substance permethrin.
For the performance of the environmental exposure and risk assessment only data on the active substance permethrin are required. The available data are sufficient to perform the exposure and risk assessment.

Further studies are therefore not required.

ES CA: not relevant.

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

According to the "Guidance on information requirements (Version 1.1 November 2014)", higher tier field studies may be required if a habitat such as a water body, wetland, forest or field is treated. This is not the intended use for PT8 products.

ES CA: not relevant.

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

No data is available on MATACARCOMA product. Please refer to active substance's CAR.

ES CA: not relevant.

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

Not relevant for PT8 products

ES CA: not relevant.

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

According to intended uses (Use classes 1 and 2), emissions to the environment can only occur during industrial application of the wood preservative and subsequent storage of the treated structures. In general, emissions to sewage water during applications in joineries and carpentry shops are not likely to occur, because treatment containers are stand-alone devices without direct connection to the sewage. Residues and waste solutions from application containers will be treated as special waste and will not be discharged into the public sewage system. The revised ESD for PT 8 confirms that the release of wood preservatives from treatment installations to the drain connected to an STP is not permitted in EU countries. Nevertheless, this scenario is going to be considered in this risk assessment. The same applies to the storage of treated commodities. According to the

revised ESD for PT 8 it can be assumed, that most storage places are sealed and run-off from storage places will be collected and disposed of safely.

ESCA:

Emission to the environment can occur from industrial application and storage. According to the ESD for PT8 it can be assumed that most storage places for treated wood are sealed to prevent any release to the soil. Furthermore, release of wood preservatives from the treatment plants to the STP is not permitted anymore however, these exposure scenarios are listed in the ESD and have been assessed by the applicant.

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

According to the "Guidance on the Biocidal Products Regulation, Volume IV: Environment, Part A (2014)" further studies may be required for "products that are used outside, with direct emission to soil, water or surfaces, the components in the product may influence the fate and behaviour (and ecotoxicity) of the active substance." This is not the case of MATACARCOMA product which is intended to be used indoor as Uses classes 1 and 2.

ES CA: not relevant.

Leaching behaviour (ADS)

No new data is deemed necessary. The biocidal product MATACARCOMA is intended to be used indoors as UC1 and UC2 where no exposure to the environment occur. Only at preventive or curative industrial processes during the product application and storage treatment of treated wood there is a possibility of emission to the environment. However, in order to avoid any emission to the environment, storage area of industrial facilities must be covered and paved.
According to Summary of conclusions of the 2nd EU Leaching Workshop, "*No leaching test is required if no risk is identified for the active substance (AS) and substances of concerns (SoC) for Time 1 and Time 2 by assuming:*

- *50% leaching during Time 1 and*
- *100% leaching during Time 2*."

In view of that, the environmental risk assessment of the product is focused in the worst case assumption, 50% of the active substance is assumed to leach after an initial time period of 30 days and 100% of the active substance is assumed to leach after a given longer time period. Hence, the average daily flux is estimated as Qa.i.*50% /30days for Time 1.

ES CA: not relevant.

Testing for distribution and dissipation in soil (ADS)

No further data is deemed necessary. According to the "Guidance on the Biocidal Products Regulation, Volume IV: Environment, Part A (2014)" further studies may be required "if

there are indications that other components in the product influence distribution and degradation characteristics".
The composition of the product and the application techniques for this product is not suspected to influence the properties of the active substancesin such a way that may alter the conclusions of the environmental risk characterisation. Hence, the environmental exposure and risk assessments, which are based on the data set of the active substance, do not require the performance of further studies.

ES CA: not relevant.

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

No further data is deemed necessary. The environmental exposure and risk assessments, which are based on the data set of the active substance, do not require the performance of further studies.

ES CA: not relevant.

Testing for distribution and dissipation in air (ADS)

Not required as active substance is not volatile. Due to the low vapour pressures ofPermethrin (2.155 x 10^{-6} Pa at 20°C) the emission to air is negligible and consequently not relevant.

ES CA: not relevant.

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)

MATACARCOMA product is not intended to be sprayed near to surface waters.

ES CA: not relevant.

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)

The product is not intended to be sprayed outdoors.

ES CA: not relevant.

2.2.8.2 Exposure assessment

MATACARCOMA is a PT-8 formulation intended to be used indoors in sawmills. The biocidal product is used for preventive and curative protection of wood and constructional timbers. The product is intended to be applied by industrial, professional and non-professional users. Following OECD series on ESD Nº2 for wood preservatives, two potential scenarios

from industrial users can be considered of concern to the environment: automated spraying and automated dipping treatments. Under these conditions, the wood dries off naturally by losing its humidity and no leaching of any substance of concern occurs to the environment. The aim of this wood protection treatment is to prevent mould and blue mould's attack. As MATACARCOMA is intended to be used as UC1 and UC2, only application and storage treated-wood at industrial facilities have been considered of concern stages of emission in the environmental risk assessment. Hence, the environmental risk assessment of MATACARCOMA product is focused in industrial treatment.

The solvent-based formulation may be applied at industrial preventive process and storage of treated wood by:

- Automated dipping treatment (included green chain) is a surface treatment process which is developed in rafts where the wood is dipped for a short time.
- Automated spraying treatment is a surface treatment a process which is developed in closed spray tunnels/deluging.

After the treatment, a short time of post-treatment conditioning takes place. This step allows the treated wood to become surface dry to prevent dripping or for the preservative to be bound to the wood. Due that the product is intended for UC1 and UC2, this process takes place over the raft where the wood is drained until drain has finished and then the wood is stored under cover. In other cases as automated spraying, post-treatment conditioning period may be shortened by the use of accelerated fixation techniques, elevated temperatures, or increased ventilation.

The product is intended to be marketed and applied on European level, where the industrial application of wood preservatives is regulated by local authorities and in sawmills where storage places are paved and sealed to prevent any direct release to aquatic or soil compartments. At these sealed places and where run-off from storage is collected and disposed of by save means, the storage place scenario does not need to be considered (ENV/JM/MONO(2013)21).

Use Classes (UC) 1 and 2 are the main UCs intended to be covered by MATACARCOMA product. This involves the use of the product on wood to be used indoors out of weather conditions. Therefore, following OECD series on ESD Nº2 no emission to environment is expected for treated wood in service life or other *in-situ* applications. On the other hand, the product can also be applied as long as a cover resin is used after product's application. The layer of resin will help to remain the product in the treated wood and avoid its release to the environment by leaching process at adverse weather conditions.

The environmental exposure assessment of MATACARCOMA has been developed in accordance with the recommendations of the OECD Emission Scenario Document for wood preservatives (PT8) and the Technical Guidance Document (TGD) on risk assessment (ECB Part II, 2003).

General information

Assessed PT	PT8
Assessed	Stage - Product application and storage before shipping (Industrial)

scenarios	Scenario [1]: Automated dipping (preventive treatment) Sub-scenario [1.1]: Application Sub-scenario [1.2]: Storage before shipping Scenario [2]: Automated spraying Sub-scenario [2.1]: Application Sub-scenario [2.2]: Storage before shipping
ESD(s) used	Emission Scenario Document for Product Type 8: OECD SERIES ON EMISSION SCENARIO DOCUMENTS Number 2; Revised Emission Scenario Document for Wood Preservatives (27 September 2013); ENV/JM/MONO(2013)21 EUSES 2.2.0.
Approach	**Scenario 1.1:** Automated dipping treatment. (this scenario also involves "green chain" application which is regarded as a type of dipping application (ENV/JM/MONO(2013)21)). **Scenario 1.2:** Storage treated wood after Automated dipping treatment. **Scenario 2.1:** Automated spraying. **Scenario 2.2:** Storage treated wood after Automated dipping treatment.
Distribution in the environment	Calculations based on ECHA-Guidance (2015) BPR, Vol. IV, ENV – Part B., considering ECHA's excel sheets to estimate the environmental emissions. Outputs from ECHA'S excel sheets and EUSES 2.2.0 of these estimations can be found in section 13 of IUCLID dossier and in Annex 3.2 of the current dossier.
Groundwater simulation	Initially it was assessed following ESD guidance. No refinement of the results was necessary
Confidential Annexes	Yes
Life cycle steps assessed	Scenarios [1] and [2]: Production: No Formulation No Use: Yes Service life: No
Remarks	All emission scenarios have been developed by following the ESD – PT8. The calculation sheets for the emission estimation are attached in Annex 3.2

ESCA:
According to the applicant the product is intended for wood UC1 and UC2. However, according to the efficacy studies only, wood for use class 1 has been supported. As described in the ESD for PT8, the emission to the environment from wood UC1 is considered negligible. Emission to the environment can occur from industrial application and storage. According to the ESD for PT8 it can be assumed that most storage places for

treated wood are sealed to prevent any release to the soil. Furthermore, release of wood preservatives from the treatment plants to the STP is not permitted anymore. These exposure scenarios are however listed in the ESD and have been assessed by the applicant.

Emission estimation

In accordance with the approach taken in the AR, the Predicted Environmental Concentration (PEC) in surface water, groundwater and sediment were calculated for the industrial intended uses. The following PEC values were calculated by the published recently ESD's excel sheets (15/11/2017) and the Technical Guidance Document on Risk Assessment part II (TGD II).

The PEC in groundwater is calculated as a direct function of the PEC in soil, and therefore full calculations for both soil and groundwater are presented in the current dossier.

Scenario [1] – Automated dipping treatment

Dipping and immersion are superficial application processes and are typically used in sawmills and carpentry / joinery industries.

The immersion period lasts anything from a very short period of a few minutes to over one hour depending on the end use application of the treated commodity and the application rate of the wood preservative. After the required immersion period the packs or pieces of wood, which are slightly raised at one end to aid liquid run off, are hoisted out of the liquid and usually held above the open tank for excess liquid to fall back into the dipping tank and be re-used. When the excess liquid has been drained, the pieces or packs of wood are moved to a post treatment conditioning location which is usually bounded and the timber is allowed to dry before being moved off-site or used on site. Any further drips are contained and recycled.

As it was mentioned before, no leaching data is regarded because the product is intended to be applied in wood to be used as Use Classes 1 and 2. In addition, a coat of resin product can be applied after the product application in order to increase the retention of the product in the wood during the service life.

Alternatively, it is important to point out that the use of this product (without any coat of resin product) at industrial premises where the storage place is sealed and run-off from storage places will be collected and disposed of by safe means. In that case, the storage place scenario does not need to be considered. In any other case where the sealing of the storage place is not given or unsure, the storage scenario will need to be assessed.

The following table shows the used parameters in the environmental emission assessment for the automated dipping scenario.

Application phase [1.1]

Input parameters for calculating the local emission from automated dipping process

Input	Value	Unit	Remarks
Scenario: **1.1 – Automated dipping (application)**			
Application rate of biocidal product	4	kg/m^3	S (estimated following TAB ENV 114 (2019)[1]
Quantity of a substance applied per m^3 of wood *(Q_{ai})*	0.016	Kg/m^3	S
Volume of wood treated per day (*VOLUMEwood-treated)*	100	m^3/d	D
Fraction released to facility drain *($F_{facilitydrain}$)*	0.0001	[-]	D (water solubility < 0.25 mg/l)
Fraction released to air *(F_{air})*	0.001	[-]	D (vapour pressure at 20ºC < 0.005Pa)

D=default, S=based on information of applicant

[1] To convert the quantity of a substance applied from kg.m^{-2} to kg.m^{-3} the application rate (0.2 kg.m^{-2}) should be multiplied by a factor of 40 (worst case).

ES CA: according to the applicant the application rate for this use is 0.2 kg.m^{-2}, the worst case, so the application rate should be 8 kg.m^{-3} instead of 4 kg.m^{-3} but, since this change do not modified the conclusions of the assessment, values have not been recalculated. ES CA agrees with the rest of the values indicated by default.

As it was mentioned before the product is intended to be used in wood which are intended to be used as use classes 1 or 2 where the treated wood will be always covered and fully protected from the weather. This entails that storage step (minimum 24 hrs) must be done in sealed places where residues from drain must be collected and disposal by safe means under regional normative in order to avoid any release to the environment. Therefore, storage of treated wood prior to shipping (including removal processes in the receiving environmental compartment, soil) should not release any residue to the environment so it should not has to be assessed in the current dossier. At anyway in order to cover all worse cases, storage treatment under dipping application process has been also assessed as scenario [1.2.]

- **Calculations**

The local emissions to air and facility drain during the day of application are calculated according to the equations 4.2 and 4.3 from the revised ESD PT8 as following:

$Elocal,air = Q_{ai} \cdot AREA_{wood\text{-}treated} \cdot (F_{air} + F_{drift})$

$Elocal,facilitydrain = Q_{ai} \cdot AREA_{wood\text{-}treated} \cdot F_{facilitydrain}$

The results are presented in the following table.

Resulting local emissions		
Active substance	**Local emission ($Elocal_{air}$) [kg·d^{-1}]**	**Local emission ($Elocal_{facilitydrain}$)* [kg·d^{-1}]**
Permethrin	1.6E-03	1.6E-04

*Elocal, facilitydrain = Elocal, wastewater

Storage phase [1.2]

During storage, soil can be exposed – if the label instruction is not followed and storage place is not covered – due to leaching from treated wood via rainfall. In addition, surface water can be exposed via rain run-off from the storage place.

The input parameters for calculating the local emissions and concentrations following leaching are presented in the following table.

Input parameters for calculating the local emission from automated dipping process			
Input	**Value**	**Unit**	**Remarks**
Scenario:**1.2 – Automated dipping (storage)**			
Effective surface area of treated wood, considered to be exposed to rain, per 1 m^2 storage area (i.e. soil) *($AREA_{wood-expo}$)*	11	$m^2.m^{-2}$	D
Surface area of the storage place (*$AREA_{storage}$)*	700	m^2	D
Duration of the initial assessment period (*TIME1)*	30	D	D
Duration of a longer assessment period *(TIME2)*	7300	D	D (Value agreed at the WG IV 2015 (Tolyfluanid discussion) (20 years))
Average daily flux i.e. the average quantity of a substance that is daily leached out of 1 m^2 of treated wood during 14 day storage period. *($FLUX_{storage,dipp}$)*	9.3E-05	$kg.m^{-2}.d^{-1}$	S*
Bulk density of wet soil (*RHO_{soil}*)	1700	Kg/m^3	D
Soil depth (*$DEPTH_{soil}$)*	0.5	M	D
Fraction of rainwater running off the storage site *(F_{runoff})*	0.5	[-]	D
Flow rate of surface water (creek/river) *($FLOW_{surfacewater}$)*	25920	$m^3.d^{-1}$	D**
First order rate constant for removal from soil *(K)*	6.67E-03	d^{-1}	S (Estimated by EUSES 2.2.0)
Soil-water partitioning coefficient (*$K_{soil-water}$*)	84.43	$m^3.m^{-3}$	S (Estimated by EUSES 2.2.0)

D=default, S=based on information of applicant.

* Tier 1: worst-case assumption where 50% of the active substance is assumed to leach after an initial time period of 30 days and 100% of the active substance is assumed to leach after a given longer time period = (Qa.i.*50% /30days)*14.

** This value corresponds to 0.3 $m^3.s^{-1}$ which is the default value for a small creek.

ESCA: ESCA has recalculated the First order rate constant for removal from soil (K) and the Soil-water partitioning coefficient ($K_{soil-water}$) obtained the following values, 6.54E-03 and 808,1 respectivaly and the average daily flux calculated has been calcultated with an application rate of 0.1 $kg.m^{-2}$ instead of 0.2 $kg.m^{-2}$, but since the conclussions of the assessment do not change, the results has not been recalculated.

The cumulative quantities of substance leached over 30 days and 7300 days (Qleach,storage,time) are calculated according to the equations 4.5 and 4.6 from the revised ESD PT8 as following:

Qleach,storage,time1 = FLUXstorage,spray . AREAwood-expo . AREAstorage . TIME 1

Qleach,storage,time2 = FLUXstorage,spray . AREAwood-expo . AREAstorage . TIME 2

The local emissions to surface water during the storage phase are calculated according to the equation 4.9 and 4.10 from the revised ESD PT8 as following:

Elocal,surfacewater,time1 = Qleach,storage time1 . Frunoff / TIME 1

Elocal,surfacewater,time2 = Qleach,storage time2 . Frunoff / TIME 2

The local concentrations into the soil and the surface water are calculated according to the equations 4.7/4.8/4.11/4.12 from the revised ESD PT8 as following:

Clocal,surfacewater,time 1 = Elocal,surfacewater,time1 / FLOWsurfacewater

Clocal,surfacewater,time 2 = Elocal,surfacewater,time2 / FLOWsurfacewater

Clocal,soil,time 1 = Qleach,storage,time1 . (1 – Frunoff) / Vsoil . RHOsoil

Clocal,soil,time 2 = Qleach,storage,time2 . (1 – Frunoff) / Vsoil . RHOsoil

The results are presented in the following table (without considering removal processes).

Resulting cumulative quantity of substance leached		
Active substance	**Cumulative quantity of substance leached over 30 days TIME 1 [kg]**	**Cumulative quantity of substance leached over 20 years TIME 2 [kg]**
Permethrin	21.48	5.23E+03

Resulting local emissions to surface water compartment		
Active substance	**Local emission due to leaching after 30 days TIME 1 [kg·d^{-1}]**	**Local emission due to leaching after 20 years TIME 2 [kg·d^{-1}]**
Permethrin	0.358	0.358

Resulting local concentrations to surface water compartment		
Active substance	**Local concentration into surface water after 30 days TIME 1 [mg·L^{-1}]**	**Local concentration into surface water after 20 years TIME 2 [mg·L^{-1}]**
Permethrin	0.014	0.014

Resulting local concentrations to soil compartment		
Active substance	**Local concentration in soil after 30 days TIME 1 [mg·kg$_{wwt}^{-1}$]**	**Local concentration in soil after 20 years TIME 2 [mg·kg$_{wwt}^{-1}$]**
Permethrin	18.052	4.39E+03

ESCA: this scenario has been calculated with the lower application rate (0.1 kg.m-2) instead of the worst case (0.2 kg.m-2). But, since this change do not modified the environmental risk assessment, values have not been recalculated.

Scenario [2] – Automated spraying

This type of superficial application process is typically used in sawmills and carpentry / joinery industries. Concentrates of the wood preservative are diluted with water, to prepare a ready for use treatment solution. The wood, whether in debarked logs or fully or partly machined timber are moved through one or more longitudinal or transversal boxes on a continuously moving conveyor system.

The product is applied as a spray which is usually as a coarse spray using a particle spray size to ensure the wetting of the timber with the correct amount of wood preservative.
The spray boxes are relatively contained and splashguards surround the spraying boxes to eliminate any droplets of spray from entering the rest of the mill area and may have local exhaust ventilation.

After the timber has been treated it is stacked or sorted, mechanically either dries on the conveyor belt or in the post treatment drip dry conditioning area before being moved off-site to manufacturers or used on site.

The treatment apparatus is typically established in a contained or bounded area manufactured from materials resistant to the wood preservative product. Provision is made for the collection, recycling and reuse of wood preservative collected from the conveyor or drip dry area. The release of product's residues from the treating installation or where the treated timber is stored into a surface water drain or drain connected to a Sewage Treatment Plant (STP) is not permitted and so any installation where this occurs is in contravention of environmental protection legislation and the licence to operate the treatment process.

Following the ESD excel-sheets for automated spraying application, two sub-scenarios have been developed in function of the size of sawmill which has effect in the area of wood treated per day.

The following table shows the used parameters in the environmental emission assessment for the automated dipping scenario.

Application phase [2.1]

Input parameters for calculating the local emission from automated spraying process			
Input	**Value**	**Unit**	**Remarks**
Scenario:**2.1 – Automated spraying (application)**			
Area of wood treated per day (large plant) *($AREA_{wood\text{-}treated}$)*	20000*	m^2/d	D
Application rate of the product	0.1**	kg/m^2	S
Quantity of a substance applied per m^2 of wood *(Q_{ai})*	4E-04	Kg/m^2	S
Fraction released to facility drain *($F_{facilitydrain}$)*	0.0001	[-]	D (water solubility < 0.25 mg/l)
Fraction released to air *(F_{air})*	0.001	[-]	D (vapour pressure at 20ºC < 0.005Pa)

Input parameters for calculating the local emission from automated spraying process			
Input	**Value**	**Unit**	**Remarks**
Scenario:**2.1 – Automated spraying (application)**			
Fraction of spray drift deposition *(F_{drift})*	0.001	[-]	D

D=default, S=based on information of applicant
*The $AREA_{wood\text{-}treated}$ of 20000 m^2.d-1 (large plant) represents a worst case situation and is therefore used in this risk assessment.
** Based on preventive application rate.
As in the scenario before, the environmental risk derived from the storage of treatment wood during the application and before shipping has been taken in account as a worse case for the automated spraying application.

- **Calculations**

The local emissions to air and facility drain during the day of application are calculated according to the equations 4.2 and 4.3 from the revised ESD PT8 as following:

$Elocal,air = Q_{ai} \cdot AREA_{wood\text{-}treated} \cdot (F_{air} + F_{drift})$
$Elocal,facilitydrain = Q_{ai} \cdot AREA_{wood\text{-}treated} \cdot F_{facilitydrain}$

The results are presented in the following table.

Resulting local emissions		
Active substance	**Local emission ($Elocal_{air}$) [kg·d^{-1}]**	**Local emission ($Elocal_{facilitydrain}$)* [kg·d^{-1}]**
Permethrin	1.6E-02	8E-04

*Elocal, facilitydrain = Elocal, wastewater

Storage phase [2.1]

During storage, soil can be exposed – if the label instruction is not followed and storage place is not covered – due to leaching from treated wood via rainfall. In addition, surface water can be exposed via rain run-off from the storage place.

The $AREA_{storage}$ of 790 m^2 (large plant) represents a worst case situation and is therefore used in this risk assessment.

The input parameters for calculating the local emissions and concentrations following leaching are presented in the following table.

Input parameters for calculating the local emission from automated spraying process			
Input	**Value**	**Unit**	**Remarks**
Scenario:**2.2 – Automated spraying (storage)**			
Effective surface area of treated wood, considered to be exposed to rain, per 1 m^2 storage area (i.e. soil) *($AREA_{wood\text{-}expo}$)*	11	$m^2.m^{-2}$	D
Surface area of the storage place in a large plant *($AREA_{storage}$)*	790	m^2	D (worst case)

Input parameters for calculating the local emission from automated spraying process			
Input	**Value**	**Unit**	**Remarks**
Scenario:**2.2 – Automated spraying (storage)**			
Duration of the initial assessment period *(TIME 1)*	30	d	D
Duration of a longer assessment period *(TIME 2)*	7300	d	D (Value agreed at the WG IV 2015 (Tolyfluanid discussion) (20 years))
Average daily flux i.e. the average quantity of a substance that is daily leached out of 1 m^2 of treated wood during 3 day storage period. *($FLUX_{storage,spray}$)*	2.00E-05	$kg.m^{-2}.d^{-1}$	S*
Volume of treated wood stacked per m^2 of storage area (i.e. soil) *($VOLUME_{wood-stacked}$)*	2	$m^3.m^{-2}$	D
Bulk density of wet soil *(RHO_{soil})*	1700	Kg/m^3	D
Soil depth *($DEPTH_{soil}$)*	0.5	m	D
Fraction of rainwater running off the storage site *(F_{runoff})*	0.5	[-]	D
Flow rate of surface water (creek/river) *($FLOW_{surfacewater}$)*	25920	$m^3.d^{-1}$	D**
First order rate constant for removal from soil *(K)*	6.67E-03	d^{-1}	S (Estimated by EUSES 2.2.0)
Soil-water partitioning coefficient ($K_{soil-water}$)	84.43	$m^3.m^{-3}$	S (Estimated by EUSES 2.2.0)

D=default, S=based on information of applicant

* Tier 1: worse-case assumption where 50% of the active substance is assumed to leach after an initial time period of 30 days and 100% of the active substance is assumed to leach after a given longer time period = (Qa.i.*50% /30days)*3.

** This value corresponds to 0.3 $m^3.s^{-1}$ which is the default value for a small creek.

ESCA: ESCA has recalculated the First order rate constant for removal from soil (K) and the Soil-water partitioning coefficient ($K_{soil-water}$) obtained the following values, 6.54E-03 and 808,1 respectivaly, but since the conclussions of the assessment do not change, the results has not been recalculated.

- **Calculations**

The cumulative quantities of substance leached over 30 days and 7300 days (Qleach,storage,time) are calculated according to the equations 4.5 and 4.6 from the revised ESD PT8 as following:

Qleach,storage,time1 = FLUXstorage,spray . AREAwood-expo . AREAstorage . TIME 1

Qleach,storage,time2 = FLUXstorage,spray . AREAwood-expo . AREAstorage . TIME 2

The local emissions to surface water during the storage phase are calculated according to the equation 4.9 and 4.10 from the revised ESD PT8 as following:

Elocal,surfacewater,time1 = Qleach,storage time1 . Frunoff / TIME 1

Elocal,surfacewater,time2 = Qleach,storage time2 . Frunoff / TIME 2

The local concentrations into the soil and the surface water are calculated according to the equations 4.7/4.8/4.11/4.12 from the revised ESD PT8 as following:

Clocal,surfacewater,time 1 = Elocal,surfacewater,time1 / FLOWsurfacewater

Clocal,surfacewater,time 2 = Elocal,surfacewater,time2 / FLOWsurfacewater

Clocal,soil,time 1 = Qleach,storage,time1 . (1 – Frunoff) / Vsoil . RHOsoil

Clocal,soil,time 2 = Qleach,storage,time2 . (1 – Frunoff) / Vsoil . RHOsoil

The results are presented in the following table (without considering removal processes).

Resulting cumulative quantity of substance leached		
Active substance	**Cumulative quantity of substance leached over 30 days TIME 1 [kg]**	**Cumulative quantity of substance leached over 20 years TIME 2 [kg]**
Permethrin	5.214	1.27E+03

Resulting local emissions to surface water compartment		
Active substance	**Local emission due to leaching after 30 days TIME 1 [kg·d^{-1}]**	**Local emission due to leaching after 20 years TIME 2 [kg·d^{-1}]**
Permethrin	0.087	0.087

Resulting local concentrations to surface water compartment		
Active substance	**Local concentration into surface water after 30 days TIME 1 [mg·L^{-1}]**	**Local concentration into surface water after 20 years TIME 2 [mg·L^{-1}]**
Permethrin	3.35E-03	3.35E-03

Resulting local concentrations to soil compartment		
Active substance	**Local concentration in soil after 30 days TIME 1 [mg·kg$_{wwt}^{-1}$]**	**Local concentration in soil after 20 years TIME 2 [mg·kg$_{wwt}^{-1}$]**
Permethrin	3.882	944.7

Fate and distribution in exposed environmental compartments

The fate and distribution in exposed environmental compartments are covered by the active substance data on permethrin.

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
Scenario 1	yes	yes	n.r.[1]	n.r.	yes	no	yes	yes	n.r.
Scenario 2	yes	yes	n.r.[1]	n.r.	yes	no	yes	yes	n.r.

[1] Risk for seawater is covered by those for fresh water as no additional data on marine organisms is available and therefore PEC/PNEC rations are identical.
n.r. not relevant

Calculations

Predicted environmental concentrations (PECs) are calculated according to the Exposure Scenario Document (ESD) for wood preservatives (version 2013). Removal of the active substances from exposed environmental compartments by leaching to groundwater and/or biodegradation is considered, but evaporation from soils was excluded as none of the active substances are volatile.

The exposure assessment of each of the previous presented emission routes is explained in more detail in the following sections. The PECs are calculated by using the default values listed in the ESD unless otherwise noted. The physical-chemical parameters applied in the assessment for the different compartments (STP, water, sediment, and soils) are given elsewhere.

Emission during industrial treatment and storage

Emission to the sewer during industrial treatment, and soil and surface water during storage was calculated according to the corresponding scenarios as specified in the ESD without modifications. Emission was calculated for automated dipping and automated spraying. It is important to take into account that storage exposure must not be to occur according label instructions as the product is intended to be used for Use Classes (UC) 1 and 2 where treated wood must be protected to the environment. In view of that the current environmental assessment should be considered as the worst-case.

Calculations for metabolites

DCVA and PBA are the metabolites identified for permethrin. They have been deemed in all compartments.

The concentrations of metabolites in the environmental compartments are calculated by multiplying active substance concentrations and amounts leached over the assessment period with the differences in molar weight. This approach considers 100% transformation of the parent into the metabolite or metabolites:

- DCVA: 0.534
- PBA: 0.547

However, metabolites were not considered in case of release to the sewer as the active substance is not readily biodegradable and information on the appearance of metabolites during sewage treatment is lacking (e.g. STP simulation studies is not available). Metabolites are therefore assumed to be formed after being released to the aquatic (in effluent) or terrestrial (in sewage sludge) environment. Because the guidance does not consider degradation in the receiving freshwater body including sediment, it is not possible to calculate PECs in the receiving aquatic compartments. Metabolites in soils via distribution of sewage sludge were not considered as well. Possible risks of metabolites in soils are sufficiently covered by the risk assessment for direct emission as the latter results in a higher daily emission.

Subsequent distribution of the metabolites in the environment was based on the metabolite's physical-chemical properties as presented elsewhere.

The physical-chemical properties of the active substances and their metabolites considered in the environmental exposure assessment are summarised below.

Input parameters (only set values)* for calculating the fate and distribution in the environment for Permethrin			
Input	Value	Unit	Remarks
Molecular weight	391.29	g/mol	
Melting point	33	°C	
Vapour pressure (at 20°C)	2.155 x 10^{-6}	Pa	
Water solubility (at 20°C)	< 0.00495	mg/l	
Log Octanol/water partition coefficient	4.67	Log 10	
Henry's law constant (25ºC)	4.6E-03	Pa m^3 mol^{-1}	
Organic carbon/water partition coefficient (Koc)	26930	l/kg	
Biodegradability	No		
DT_{50} for degradation in soil	106	d (at 12ºC)	
DT_{50} for biodegradation in water/sediment	46.7	d (at 12ºC)	

*Values are deduced from the Permethrin PT8 AR (April 2014) and CAR.

Input parameters (only set values)* for calculating the fate and distribution in the environment for DCVA			
Input	Value	Unit	Remarks
Molecular weight	209.07	g/mol	
Melting point	>12°C	°C	No data is available, it is assumed that the metabolite is a fluid in the environment
Vapour pressure (at 25°C)	0.26	Pa	
Water solubility (at 25°C)	127.6	mg/l	
Organic carbon/water partition coefficient (Koc)	188.53	L/kg	

Biodegradability	No		
DT_{50} for degradation in water/sediment	188	d	Worst-case value as published in the assessment report is applied.
DT_{50} for degradation in soil	175	d (12°C)	
The ratio between the molar masses of DCVA and permethrin is 0.534.			

*Values are deduced from the Permethrin PT8 AR (April 2014) and CAR.

Input parameters (only set values)* for calculating the fate and distribution in the environment for PBA			
Input	Value	Unit	Remarks
Molecular weight	214.22	g/mol	
Melting point	>12	°C	No data is available, it is assumed that the metabolite is a fluid in the environment
Vapour pressure (at 25°C)	4.21×10^{-4}	Pa	
Water solubility (at 25°C)	16.91	mg/l	
Organic carbon/water partition coefficient (Koc)	37.55	l/kg	
DT_{50} for degradation in water/sediment	63.3	d	Worst-case value as published in the assessment report is applied.
DT_{50} for degradation in soil	2.5	d (at 12ºC)	
The ratio between the molar masses of PBA and Permethrin is 0.547			

*Values are deduced from the Permethrin PT8 AR (April 2014) and CAR.

The distribution in the STP was calculated for each substance with SimpleTreat 4.0 based on the physical-chemical properties as listed above. As explained previously, the metabolites DCVA and PBA (from permethrin) are formed after the STP. For these metabolites no distribution was calculated.

Calculated fate and distribution in the STP				
	Compartment			
	Air	Water	Sludge	Degrated in STP
Percentage [%]	0.0023	21.67	78.33	0

Calculated PEC values

Permethrin		**PEC_{STP} (mg/L)**	**$PEC_{surface\ water}$ (mg/L)**	**$PEC_{sediment}$ (mg/kg_{wwt})**	**PEC_{soil} (mg/kg_{wwt})**	**$PEC_{groundwater}$ (mg/L)**
Application phase	Automated dipping [1.1]	5.90E-05	5.87E-06	3.63E-04	8.15E-05	1.10E-06
	Automated spraying [2.1]	2.94E-04	2.94E-05	1.82E-03	4.36E-04	6.09E-06
Storage	Automated	-	1.38E-02	0.854	18.05294	0.363

phase	dipping [1.2] (Time 1)					
	Automated dipping [1.2] (Time 2)	-	1.38E-02	0.854	4.39E+03	88.5
	Automated spraying [2.2] (Time 1)	-	3.35E-03	0.207256	3.882353	7.81E-02
	Automated spraying [2.2] (Time 2	-	3.35E-03	0.207256	944.7059	19

DCVA		**PEC_{STP} (mg/L)**	**$PEC_{surface\ water}$ (mg/L)**	**$PEC_{sediment}$ (mg/kg_{wwt})**	**PEC_{soil} (mg/kg_{wwt})**	**$PEC_{groundwater}$ (mg/L)**
Application phase	Automated dipping [1.1]	3.15E-05	3.13E-06	1.94E-04	4.35E-05	5.87E-07
	Automated spraying [2.1]	1.57E-04	1.57E-05	9.72E-04	2.33E-04	3.25E-06
Storage phase	Automated dipping [1.2] (Time 1)	-	7.37E-03	4.56E-01	9.64E+00	1.94E-01
	Automated dipping [1.2] (Time 2)	-	7.37E-03	4.56E-01	2.34E+03	4.73E+01
	Automated spraying [2.2] (Time 1)	-	1.79E-03	1.11E-01	2.07E+00	4.17E-02
	Automated spraying [2.2] (Time 2	-	1.79E-03	1.11E-01	5.04E+02	1.01E+01

PBA		**PEC_{STP} (mg/L)**	**$PEC_{surface\ water}$ (mg/L)**	**$PEC_{sediment}$ (mg/kg_{wwt})**	**PEC_{soil} (mg/kg_{wwt})**	**$PEC_{groundwater}$ (mg/L)**
Application phase	Automated dipping [1.1]	3.23E-05	3.21E-06	1.99E-04	4.46E-05	6.02E-07
	Automated spraying [2.1]	1.61E-04	1.61E-05	9.96E-04	2.38E-04	3.33E-06
Storage phase	Automated dipping [1.2] (Time 1)	-	7.55E-03	4.67E-01	9.87E+00	1.99E-01
	Automated dipping [1.2] (Time 2)	-	7.55E-03	4.67E-01	2.40E+03	4.84E+01

	Automated spraying [2.2] (Time 1)	-	1.83E-03	1.13E-01	2.12E+00	4.27E-02
	Automated spraying [2.2] (Time 2	-	1.83E-03	1.13E-01	5.17E+02	1.04E+01

Primary and secondary poisoning

Primary poisoning

A direct uptake of the product is unlikely; therefore primary poisoning is not deemed relevant.

Secondary poisoning

According to Vol IV, Part B the calculation of a possible risk to man via the food chain ($PEC_{oral,predator}$) should be conducted if the active substance shows a potential for bioaccumulation, indicated by a log K_{ow} value >3.

In view of that permethrin is the active substance considered of concern for secondary poisoning and the current assessment is focused in it.

For the risk characterisation the following PNEC-values were used:

- $PNEC_{bird}$ = 16.7 mg a.s./kg food
- $PNEC_{small\ mammal}$ = 120 mg a.s./kg food

The $PEC_{oral,predator}$ was calculated for the aquatic and for the terrestrial food chain according to the equation no. 76 and 82c of the BPR Guidance Volume IV Environment – Part B (2015). The highest $PEC_{surfacewater}$, the highest PEC_{soil} and porewater concentration were used as input parameter in the calculations. The PEC-values without degradation were taken into account as a worst case:

For aquatic food chain:

Scenario	**$PEC_{local,water}$** [$mg.l^{-1}$]	**BCF_{fish}** [$l.kg^{-1}$wet fish]	**BMF** [-]	**$PEC_{oral,predator}$** [$mg.kg^{-1}_{wet\ fish}$]
Automated dipping [1.1]	7.34E-06	570	2	6.69E-03
Automated spraying [2.1]	3.67E-05	570	2	3.35E-02
Automated dipping [1.2] (Time 1)	1.73E-02	570	2	1.57E+01
Automated dipping [1.2] (Time 2)	1.73E-02	570	2	1.57E+01
Automated spraying [2.2] (Time 1)	4.19E-03	570	2	3.82E+00
Automated spraying	4.19E-03	570	2	3.82E+00

[2.2] (Time 2				

For terrestrial food chain:

Scenario	**$PEC_{local,soil}$** [$mg.kg_{wwt}^{-1}$]	**PEC_{gw}** [mg/L]	**$BCF_{earthworm}$** [$l.kg^{-1}$]	**CONVsoil** [kgwwt.kg-1dwt]	**Fgut** [kgdwt.kg-1wwt]	**$PEC_{oral,predator}$** [$mg.kg^{-1}_{wet\ earthworm}$]
Automated dipping [1.1]	8.15E-05	1.10E-06	15108	1.13	0.1	1.49E-02
Automated spraying [2.1]	4.36E-04	6.09E-06	15108	1.13	0.1	8.27E-02
Automated dipping [1.2] (Time 1)	1.81E+01	3.63E-01	15108	1.13	0.1	4.93E+03
Automated dipping [1.2] (Time 2)	4.39E+03	8.85E+01	15108	1.13	0.1	1.20E+06
Automated spraying [2.2] (Time 1)	3.88E+00	7.81E-02	15108	1.13	0.1	1.06E+03
Automated spraying [2.2] (Time 2	9.45E+02	1.90E+01	15108	1.13	0.1	2.58E+05

2.2.8.3 Risk characterisation

The environmental risk characterization for biocidal active substances in the context of Article 5 and Annex VI of BPR, Regulation (EU) 528/2012 involves the comparison of PEC and PNEC values for each relevant environmental compartment as well as for non-target organisms. Risk Characterisation Ratios (PEC/PNEC) are derived for the use of the wood preservative. The calculated PEC/PNEC ratios are provided for the STP, the aquatic and terrestrial compartment in the following tables.

If the PEC/PNEC ratio is below 1, this is interpreted as an acceptable risk to the environment. Calculated PEC/PNEC values are summarized below, values above 1 are marked with red colour.

Permethrin		**PEC/ $PNEC_{STP}$**	**PEC/ $PNEC_{surface\ water}$**	**PEC/ $PNEC_{sediment}$**	**PEC/ $PNEC_{soil}$**	**$PEC_{groundwater}$ (mg/L)**
Application phase	Automated dipping [1.1]	0.01	**12.49**	**1.67**	4.66E-04	1.10E-06
	Automated spraying [2.1]	0.06	**62.55**	**8.39**	2.49E-03	6.09E-06
Storage phase	Automated dipping [1.2] (Time 1)	**-**	**>100**	**>100**	**>100**	**0.36**
	Automated dipping [1.2] (Time 2)	**-**	**>100**	**>100**	**>100**	**88.50**

	Automated spraying [2.2] (Time 1)	-	**>100**	**>100**	**22.18**	**0.08**
	Automated spraying [2.2] (Time 2	-	**>100**	**>100**	**>100**	**19.00**

DCVA		**PEC/ $PNEC_{STP}$**	**PEC/ $PNEC_{surface\ water}$**	**PEC/ $PNEC_{sediment}$**	**PEC/ $PNEC_{soil}$**	**$PEC_{groundwater}$ (mg/L)**
Application phase	Automated dipping [1.1]	-	2.09E-04	1.62E-02	9.46E-06	5.87E-07
	Automated spraying [2.1]	-	1.05E-03	8.10E-02	5.06E-05	3.25E-06
Storage phase	Automated dipping [1.2] (Time 1)	-	0.49	**38.00**	**2.10**	**0.19**
	Automated dipping [1.2] (Time 2)	-	0.49	**38.00**	**509.62**	**47.26**
	Automated spraying [2.2] (Time 1)	-	0.12	**9.22**	0.45	**0.04**
	Automated spraying [2.2] (Time 2	-	0.12	**9.22**	**109.67**	**10.15**

PBA		**PEC/ $PNEC_{STP}$**	**PEC/ $PNEC_{surface\ water}$**	**PEC/ $PNEC_{sediment}$**	**PEC/ $PNEC_{soil}$**	**$PEC_{groundwater}$ (mg/L)**
Application phase	Automated dipping [1.1]	-	3.21E-04	2.21E-02	3.10E-05	6.02E-07
	Automated spraying [2.1]	-	1.61E-03	1.11E-01	1.66E-04	3.33E-06
Storage phase	Automated dipping [1.2] (Time 1)	-	0.75	**51.90**	**6.86**	**0.20**
	Automated dipping [1.2] (Time 2)	-	0.75	**51.90**	**1667.59**	**48.41**

	Automated spraying [2.2] (Time 1)	-	0.18	**12.60**	**1.47**	**0.04**
	Automated spraying [2.2] (Time 2	-	0.18	**12.60**	**358.86**	**10.39**

Atmosphere

Due to the low vapour pressures of Permethrin (2.155 x 10^{-6} Pa at 20°C) the emission to air seems to be negligible and consequently not relevant. Therefore, the air compartment is not considered for the active substance in the environmental risk assessment.

Sewage treatment plant (STP)

For Sewage Treatment Plant (STP), all PEC/PNEC ratios are lower than 1 for all the evaluated scenarios. So, we can conclude that the use of MATACARCOMA product represents acceptable risks for STP.

Aquatic compartment

For the aquatic compartment (surface-water and sediment), risks were identified during the application phase and during the storage phase for the active substance and at storage phase for the main metabolites too. However, those risks should be considered not relevant based on mandatory risk mitigation measures for wood treatments plants. Therefore, the aquatic risk from industrial treatments (application and storage phases) should be deemed acceptable under RMM.

Terrestrial compartment

For the soil compartment, emissions from industrial application phases show acceptable risk regardless the type of application. On the other hand, the industrial storage scenario provided elevated PEC/PNEC ratios for TIME 1 and 2. According to the revised ESD for PT 8 it can be assumed, that most storage places are sealed and run-off from storage places will be collected and disposed of safely – this is not taken into account in the calculations and must be taken into account as RMM in order to reach a safe use for the environment.

Groundwater

The estimations of releases of active substances and their relevant degradation products for the groundwater compartment disclose acceptable risk derived from application phases for the active substance and its metabolites. However, an unacceptable risk for the active substance and its metabolites for storage phases is obtained regardeless the type of previous application and the time of store for this compartment. Groundwater exposure is derived from soil compartment by leaching. Taking into account the mentioned RMM before, where industrial treatments must be developed on sealed facilities that avoid any release to the environment, the potential risk of groundwater can be considered safe.

Primary and secondary poisoning

Secondary poisoning is relevant only for the active substance permethrin. Therefore, the secondary poisoning was assessed for the service life for wood treated by surface treatment, considered as a worst case. PEC and risk ratios for the risk of secondary poisoning for birds and mammals are summarised in the following table.

Scenario	*Via fish*		*Via earthworm*	
	PEC/ PNECbirds	**PEC/ PNECmammals**	**PEC/ PNECbirds**	**PEC/ PNECmammals**
Automated dipping [1.1]	3.99E-05	5.58E-05	8.91E-05	1.24E-04
Automated spraying [2.1]	2.00E-04	2.79E-04	4.93E-04	6.89E-04
Automated dipping [1.2] (Time 1)	9.38E-02	1.31E-01	**29.39**	**41.08**
Automated dipping [1.2] (Time 2)	9.38E-02	1.31E-01	**7166.10**	**10014.63**
Automated spraying [2.2] (Time 1)	2.28E-02	3.18E-02	**6.32**	**8.84**
Automated spraying [2.2] (Time 2	2.28E-02	3.18E-02	**1538.49**	**2150.04**

ES CA: the risk assessment for the environment should be included for both, permethrin and the substance of concern however, only the active substance has been included. However, since the conclusion of the assessment do not change, the assessment of the SoC is not needed.

- ***Mixture toxicity***

Not required, the environmental risk assessment of the biocidal product is focused in permethrin as the only substance of concern for the environment.

ES CA: A substance of concern has been identified for the environment, Hidrocarburos, C9-C11, n-alcanos, isoalcanos, cíclicos, <2% aromáticos, which is classified as C2, according to the FDS of MATACARCOMA. It is present in the product in 99,6% and classifies the product as C2 so, it is considered a substance of concern for the environment thus, it should be included in the risk assessment for the environment. However doe to the risk found for the permethrin and the RMM indicated, no emissions to the environment are expected so the evaluation of this substance is not needed and the mixture toxicity is not included.

- ***Aggregated exposure (combined for relevant emission sources)***

Not relevant

Overall conclusion on the risk assessment for the environment of the product
There is a potential risk derived from industrial treatments, however this risk must not be considered relevant based on mandatory risk mitigation measures for wood treatment plants. Storage must only take place on sealed places or under cover to prevent direct release to soil. This will be stated on the label. - Prevent any release to the environment during the product application phase as well as during the storage and the transport of treated timber; - During the application phase, prevent any release of cleaning water (after cleaning of floors, tanks, containers) to the environment (sewer, soil, water); - 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. Before use, store the timber in an area sheltered from the weather; - Any contaminated water/soil shall be collected, contained and treated as hazardous waste. Taking into account the RMMs above, the uses of the biocidal product MATACARCOMA by the industrial processes - automated spraying and automated dipping – and by *in situ* processes -brush, spray and dipping for the uses of treated wood in UC 1 and UC 2 should not represent unacceptable risks to the environment if appropriate risk mitigation measures are considered. On the other hand, where the product is applied by professional users and general public as UC 1 and 2, no environmental risk is expected.

ESCA:
ESCA agrees with the conclussions given by the applicant, although, doe to the efficacy studies, the biocidal product MATACARCOMAS wil be only authorized for UC 1.

2.2.9 Measures to protect man, animals and the environment

See risk mitigation measures for authorized uses

2.2.10 Assessment of a combination of biocidal products

No applicable

2.2.11 Comparative assessment

No applicable

3 ANNEXES[2]

3.1 List of studies for the biocidal product

LIST OF STUDIES FOR THE BIOCIDAL PRODUCT

Section No	Reference No	Author	Year	Title	Owner of data	Letter of access		Data protection claimed		Essential studies for evaluation	
						Yes	No	Yes	No	Yes	No
2.2.5	092354-3-a(M1)	[redacted]	[redacted]	Wood preservatives-determination of the preventive action against recently hatched larvae of *Hylotrupes bajulus (Linnaeus)* Part 1: Applcation by surface treatment (laboratory method). EN 46-1:2016	INDUSTRIAS QUÍMICAS IRURENA, S.A.		x	x		x	
2.2.5	092354-3-a	[redacted]	[redacted]	Wood preservatives-determination of the preventive action against recently hatched larvae of *Hylotrupes bajulus (Linnaeus)* Part 1: Applcation by surface treatment (laboratory method). EN 46-1:2016	INDUSTRIAS QUÍMICAS IRURENA, S.A.		x	x			x
2.2.5	23984-2	[redacted]	[redacted]	Determinación de la eficacia preventiva contra *Hylotrupes bajulus (Linnaeus)*- Parte 1: Efecto larvicida según la norma UNE-EN 46-1:2008	INDUSTRIAS QUÍMICAS IRURENA, S.A.		x	x			x
2.2.5	092354-6-a(M1)	[redacted]	[redacted]	Determination of the eradicant action against *Hylotrupes bajulus (Linnaeus)* - larvae according to UNE-EN 1390:2021	INDUSTRIAS QUÍMICAS IRURENA, S.A.		x	x		x	
2.2.5	092354-6-a	[redacted]	[redacted]	Determination of the eradicant action against *Hylotrupes bajulus (Linnaeus)* - larvae according to UNE-EN 1390:2021	INDUSTRIAS QUÍMICAS IRURENA, S.A.		x	x			x
2.2.5	23984-1 (M1)	[redacted]	[redacted]	Determinación de la eficacia curativa contra *Hylotrupes bajulus (Linnaeus)*- UNE-EN 1390:2007	INDUSTRIAS QUÍMICAS IRURENA, S.A.		x	x			x
2.2.5	102786-2	[redacted]	[redacted]	Test de immersion de IKIDECOR MATACARCOMAS sobre maderas de abeto y pino.	INDUSTRIAS QUÍMICAS IRURENA, S.A.		x	x		x	

2 When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included.

3.2 Output tables from exposure assessment tools

Human Risk Assessment

Scenario [2] - Mixing & loading (Trained professional,

Task / Scenario :	model mixing and loading 7 for pouring and pumping liquids		
Model used :			
dilución producto (ready-to-use)	100%		
Active substance (% w/w) - permethrin	0,40%		
Body weight (kg)	60	Tier 2 / Under clothes and gloves (HEEG	
	units		Tier 1/ No PPEs
Dermal exposure			
Body			
clothing type			
Indicative value from model	mg/min		
duration	min	10	10
potential dermal deposit	mg	0,00	0,00
clothing penetration from model	%	100%	100%
actual dermal deposit (product)	**mg**	**0,00**	**0,00**
Hands and body exposure			
indicative value from model (under clothes & gloves)	mg/min	1,01	101
duration	min	10	10
potential dermal deposit	g	10,10	1010,00
gloves penetration from model	%	100%	100%
actual hand deposit (product)	**mg**	**10,1**	**1010,0**
Total Actual dermal exposure			
product	**mg**	**10,1**	**1010,0**
active substance permethrin	**mg**	**0,040**	**4,040**
Skin penetration permethrin	%	70%	70%
Estimated dermal uptake permethrin	**mg**	**2,83E-02**	**2,83E+00**
systemic dose via skin permethrin	**mg/kg bw**	**4,713E-04**	**4,713E-02**
Exposure by inhalation			
indicative value from model	mg/m3	0,94	0,94
duration	min	10	10
inhalation rate	m3/min	2,08E-02	2,08E-02
inhaled volume	m3	0,2	0,2
potential inhaled product	mg	0,2	0,2
mitigation factor by RPE	value	1	1
inhaled product through RPE	**mg**	0,1958	0,1958
Estimated inhalation uptake permetrina	**mg**	7,83E-04	7,83E-04
systemic inhaled dose (ai) permethrin	**mg/kg bw**	**1,31E-05**	**1,31E-05**
Total Dose			
total product	**mg**	**0,224**	**3,024**
Estimated total systemic uptake permethrin	**mg/kg bw**	**4,84E-04**	**4,71E-02**
Estimated total systemic uptake/AEL (%) permethrin	**%**	0,97%	94,29%

Professional

Scenario [2b] - Mixing & loading (non-Professional)

Task / Scenario :	mixing and loading	Se ha utilizad
Model used :	loading 2 NP	
dilución producto (ready-to-use)	100%	
Active substance (% w/w) - permethrin	0,40%	
Body weight (kg)	60	
	units	Tier 1/ No PPEs
Dermal exposure		
Body		
clothing type		
Indicative value from model	mg/min	
duration	min	10
potential dermal deposit	mg	0,00
clothing penetration from model	%	100%
actual dermal deposit (product)	**mg**	**0,00**
Hands and body exposure		
indicative value from model (under clothes & gloves)	mg/event	12,8
duration	min	1
potential dermal deposit	g	12,80
gloves penetration from model	%	100%
actual hand deposit (product)	**mg**	**12,8**
Total Actual dermal exposure		
product	**mg**	**12,8**
active substance permethrin	**mg**	**0,051**
Skin penetration permethrin	%	70%
Estimated dermal uptake permethrin	**mg**	**3,58E-02**
systemic dose via skin permethrin	**mg/kg bw**	**5,973E-04**
Exposure by inhalation		
indicative value from model	mg/m3	
duration	min	0
inhalation rate	m3/min	0,00E+00
inhaled volume	m3	0,0
potential inhaled product	mg	0,0
mitigation factor by RPE	value	0
inhaled product through RPE	**mg**	0,0000
Estimated inhalation uptake permetrina	**mg**	
systemic inhaled dose (ai) permethrin	**mg/kg bw**	**0,00E+00**
Total Dose		
total product	**mg**	**0,036**
Estimated total systemic uptake permethrin	**mg/kg bw**	**5,97E-04**
Estimated total systemic uptake/AEL (%) permethrin	**%**	1,19%

Scenario [3] –

Brushing/rolling

Task / Scenario :	Brush application		
Model used :	Recom 6,v4-pto23, p24 : Professional brush treatment (PT8) based on "Consumer painting model 3"		
dilución producto (ready-to-use)	100,00%		
		TIER 1	TIER 2
Active substance (% w/w) - permethrin	0,40%		
Body weight (kg)	60		
	units	without EPI	with gloves and coated coverall
Potential dermal exposure			
Body			
clothing type			
Indicative value from model (normalized to 1% as)	mg/m^2	0,2382	0,2382
Applicatio area *	m^2	31,6	31,6
potential dermal deposit	mg	7,53	7,53
clothing penetration from model	%	100%	10%
actual dermal deposit (product)	**mg**	**7,53**	**0,75**
Hands exposure			
indicative value from model (normalized to 1% as)	mg/m^2	0,5417	0,5417
Application area *	m^2	31,6	31,6
potential dermal deposit	mg	17,12	17,12
gloves penetration from model	%	100%	10%
actual hand deposit (product)	**mg**	**17,12**	**1,71**
Total Actual dermal exposure			
Total product	**mg**	**24,64**	**2,46**
Total active substance permethrin	**mg**	**0,10**	**0,01**
Skin penetration permethrin	%	70%	70%
Estimated dermal uptake permethrin	**mg**	**6,90E-02**	**6,90E-03**
Systemic dose via skin permethrin	**mg/kg bw**	**1,15E-03**	**1,15E-04**
Exposure by inhalation			
indicative value from model	mg/m^2	0,0016	0,0016
Application area *	m^2	31,6	31,6
inhalation rate	m3/min	2,08E-02	2,08E-02
inhaled volume	m3		
potential inhaled product (normalized to 1% as)	mg	0,0506	0,0506
mitigation factor by RPE	value	1	1
inhaled product through RPE	**mg**	0,05056	0,05056
Estimated inhalation uptake permethrin	**mg**	2,02E-04	2,02E-04
systemic inhaled dose (ai) - permethrin	**mg/kg bw**	**3,37E-06**	**3,37E-06**
Total Dose (Dermal + inhalation)			
total product	**mg**	**24,695**	**2,515**
Estimated total systemic uptake permethrin	**mg/kg bw**	**1,15E-03**	**1,18E-04**
* Application area (1m^2/7,6min)*240min			
Estimated total systemic uptake/AEL (%) - permethrin	**%**	2,31%	0,24%

Scenario [4] –
Spraying

Task / Scenario :	Spraying model 2							
Model used :	Recommendation 8 of BPC Ad hoc (24 professional spray treatment including M&L) (4-7 bar pressure) PT08							
Product dilution	100%							
		TIER 1	TIER 2	TIER 3	TIER 3a	TIER 4	TIER 5	TIER 6
Active substance (% w/w) permethrin	0,40%							
Body weight (kg)	60							
	units	without PPE	with gloves (including in model)	with gloves (including in model) + impermeable coverall 95%	with gloves (including in model) + double coverall 99%	with new gloves + impermeable coverall 95%	with new gloves + double coverall 99%	with new gloves + impermeable coverall 95+FPP
Potential dermal exposure								
Body								
clothing type								
indicative value from model	mg/min	222	222	222	222	222	222	222
duration	min	80	80	80	80	80	80	80
potential dermal depost	mg	17760,00	17760,00	17760,00	17760,00	17760,00	17760,00	17760,00
clothing penetration from model	%	100%	100%	5%	1%	5%	1%	5%
actual dermal deposit (product)	mg	17760,00	17760,00	888,00	177,60	888,00	177,60	888,00
Hands exposure								
indicative value from model	mg/min	273	7,80	7,80	7,80	4,06	4,06	4,06
duration	min	80	80	80	80	80	80	80
potential dermal depost	mg	21840,00	624,00	624,00	624,00	324,48	324,48	324,48
gloves penetration from model	%	100%	100%	100%	100%	100%	100%	100%
actual hand deposit (product)	mg	21840,00	624,00	624,00	624,00	324,48	324,48	324,48
Actual dermal exposure								
product	mg	39600,00	18384,00	1512,00	801,60	1212,48	602,08	1212,48
active substance permetrina	mg	158,40	73,54	6,05	3,21	4,85	2,01	4,85
Skin penetration permetrina	%	70%	70%	70%	70%	70%	70%	70%
Estimated dermal uptake permethrin	mg	1,11E+02	5,15E+01	4,23E+00	2,24E+00	3,39E+00	1,41E+00	3,39E+00
systemic dose via skin permetrina	mg/kg bw	1,8480	0,8579	0,0706	0,0374	0,0566	0,0234	0,0566
Exposure by inhalation								
indicative value from model	mg/m3	76	76	76	76	76	76	76
duration	min	80	80	80	80	80	80	80
inhalation rate	m3/min	2,08E-02	2,08E-02	2,08E-02	2,08E-02	2,08E-02	2,08E-02	2,08E-02
inhaled volume	m3	1,7	1,7	1,7	1,7	1,7	1,7	1,7
potential inhaled product	mg	126,7	126,7	126,7	126,7	126,7	126,7	126,7
mitigation factor by RPE	value	1	1	1	1	1	1	0,25
inhaled product through RPE	mg	126,7	126,7	126,67	126,7	126,7	126,7	31,7
Estimated inhalation uptake permethrin	mg	5,07E-01	5,07E-01	5,07E-01	5,07E-01	5,07E-01	5,07E-01	1,27E-01
systemic inhaled dose (a) permetrina	mg/kg bw	8,44E-03	8,44E-03	8,44E-03	8,44E-03	8,44E-03	8,44E-03	2,11E-03
TOTAL								
Estimated total uptake permethrin	mg/d	111,387	51,982	4,740	2,751	3,902	1,912	3,822
Estimated systemic total uptake permethrin	mg/kg bw/d	1,8564	0,8664	0,0790	0,0459	0,0650	0,0319	0,0637
Estimated uptake/AEL (%) Permethrine	%	3713%	1733%	158%	92%	130%	64%	117%

Scenario [5] – Automated spray

Task / Scenario :		Spray Industrial				
Model used :		Recommendation 6 of BPC Ad hoc (model 21) 2 cycles/day			Handling model 1 solvent based	Handling model 1 solvent based
dilución producto (worst case)	100,0%					
		TIER 1	TIER 2	TIER 3	TIER 4	TIER 4
Active substance (% w/w) Permetrina	0,400%					
Body weight (kg)	60					
	units	with gloves (including in model)	with gloves (including in model)+ coverall 5%	with gloves (including in model)+coverall 5%+mask P3	hand exposure new gloves for each work shift	hand exposure new gloves for each work shift+mask P3
Potential dermal exposure						
Body						
clothing type						
Indicative value from model	mg/ciclo	158	158	158	158	158
duration	ciclos	3	3	3	3	3
potential dermal deposit	mg	474,00	474,00	474,00	474,00	474,00
clothing penetration from model	%	100%	5%	5%	5%	5%
actual dermal deposit (product)	**mg**	**474,00**	**23,70**	**23,70**	**23,70**	**23,70**
Hands exposure						
Indicative value from model	mg/ciclo	260,00	260,00	260,00	130,00	130,00
duration	ciclos	3	3	3	3	3
potential dermal deposit	mg	780,00	780,00	780,00	390,00	390,00
gloves penetration from model	%	100%	100%	100%	100%	100%
actual hand deposit (product)	**mg**	**780,00**	**780,00**	**780,00**	**390,00**	**390,00**
Actual dermal exposure						
product	**mg**	**1254,00**	**803,70**	**803,70**	**413,70**	**413,70**
active substance permetrina	**mg**	**5,02**	**3,21**	**3,21**	**1,65**	**1,65**
Skin penetration permetrina	%	70%	70%	70%	70%	70%
active substance via the skin permetrina	**mg**	**3,51E+00**	**2,25E+00**	**2,25E+00**	**1,16E+00**	**1,16E+00**
systemic dose via skin permetrina	**mg/kg bw**	**5,85E-02**	**3,75E-02**	**3,75E-02**	**1,93E-02**	**1,93E-02**
Exposure by inhalation						
Indicative value from model	mg/m3	0,6	0,6	0,6	0,6	0,6
duration	min	30	30	30	30	30
inhalation rate	m3/min	2,08E-02	2,08E-02	2,08E-02	2,08E-02	2,08E-02
inhaled volume	m3	0,6	0,6	0,6	0,6	0,6
potential inhaled product	mg	0,4	0,4	0,4	0,4	0,4
mitigation factor by RPE	value	1	1	2,50%	1	2,50%
inhaled product through RPE	mg	0,3750	0,3750	0,0094	0,3750	0,0094
active substance through RPE permetrina	mg	1,50E-03	1,50E-03	3,75E-05	1,50E-03	3,75E-05
systemic inhaled dose (all) permetrina	**mg/kg bw**	**2,50E-05**	**2,50E-05**	**6,25E-07**	**2,50E-05**	**6,25E-07**
Dose						
total	mg	3,513	2,252	2,250	1,160	1,158
systemic dose permetrina	**mg/kg bw**	**5,85E-02**	**3,75E-02**	**3,75E-02**	**1,93E-02**	**1,93E-02**
Estimated uptake/AEL (%) permetrina	%	117,09%	75,06%	75,01%	38,66%	38,61%

Scenario [6] – Manual dipping (industrial)

Task / Scenario :	Manual dipping model					
Model used :	Recommendation 8 of BPC Ad hoc (model 22)					
dilución producto (worst case)	100,0%					
		TIER 1	TIER 2	TIER 3	TIER 4	TIER 4	TIER 4
Active substance (% w/w) Permetrina	0,400%						NO VALE
Body weight (kg)	60		with gloves (including in model)+ coverall 5%	with gloves (including in model)+ coverall 5%+mask P3	with new gloves (including in model)+ coverall 5%	with new gloves (including in model)+ coverall 5%+mask P3	(including in model)+ coverall 5%+mask P3+Dermal
	units	with gloves (including in model)					
Potential dermal exposure							
Body							
clothing type							
indicative value from model from application	mg/min	178	178	178	178	178	178
duration	min	30	30	30	30	30	30
potential dermal deposit	mg	5340,00	5340,00	5340,00	5340,00	5340,00	5340,00
clothing penetration from model	%	100%	5%	5%	5%	5%	5%
actual dermal deposit (product)	mg	5340,00	267,00	267,00	267,00	267,00	267,00
Hands exposure							
indicative value from pre-application model	mg/min	0,92	0,92	0,92	0,92	0,92	0,92
duration	min	10	10	10	10	10	10
potential dermal deposit	mg	9,20	9,20	9,20	9,20	9,20	9,20
gloves penetration from model	%	10%	10%	10%	5%	10%	10%
actual hand deposit (product)	mg	0,92	0,92	0,92	0,46	0,92	0,92
indicative value from application model	mg/min	25,70	25,70	25,70	13,36	13,36	25,70
duration	min	30	30	30	30	30	30
potential dermal deposit	mg	771,00	771,00	771,00	400,92	400,92	771,00
gloves penetration from model	%	100%	100%	100%	100%	100%	100%
actual hand deposit (product)	mg	771,00	771,00	771,00	400,92	400,92	771,00
indicative value from pre-application model	mg/min	0,92	0,92	0,92	0,92	0,92	0,92
duration	min/day	10	10	10	10	10	10
potential dermal deposit	mg	9,20	9,20	9,20	9,20	9,20	9,20
gloves penetration from model	%	10%	10%	10%	5%	10%	10%
actual hand deposit (product)	mg	0,92	0,92	0,92	0,46	0,92	0,92
TOTAL HAND deposit (product)		772,84	772,84	772,84	401,84	402,78	772,84
Actual dermal exposure							
product	mg	6112,84	1038,84	1038,84	668,84	668,78	1038,84
active substance permetrina	mg	24,45	4,16	4,16	2,68	2,68	4,16
Skin penetration permetrina	%	70%	70%	70%	70%	70%	3%
active substance via the skin permetrina	mg	1,71E+01	2,91E+00	2,91E+00	1,87E+00	1,88E+00	1,25E-01
systemic dose via skin permetrina	mg/kg bw	2,86E-01	4,86E-02	4,86E-02	3,12E-02	3,13E-02	2,08E-03
Exposure by inhalation							
indicative value from model	mg/m3	1	1	1	1	1	1
duration	min	30	30	30	30	30	30
inhalation rate	m3/min	2,08E-02	2,08E-02	2,08E-02	2,08E-02	2,08E-02	2,08E-02
inhaled volume	m3	0,6	0,6	0,6	0,6	0,6	0,6
potential inhaled product	mg	0,6	0,6	0,6	0,6	0,6	0,6
mitigation factor by RPE	value	1	1	2,50%	1	2,50%	2,50%
inhaled product through RPE	mg	0,625	0,625	0,015625	0,625	0,015625	0,015625
active substance through RPE permetrina	mg	2,50E-03	2,50E-03	6,25E-05	2,50E-03	6,25E-05	6,25E-05
systemic inhaled dose (al) permetrina	mg/kg bw	4,17E-06	4,17E-06	1,04E-08	4,17E-06	1,04E-08	1,04E-08
Dose							
total	mg	17,118	2,914	2,912	1,876	1,876	0,126
systemic dose permetrina	mg/kg bw	2,86E-01	4,86E-02	4,86E-02	3,13E-02	3,13E-02	2,08E-03
Estimated uptake/AEL (% permetrina	%	570,62%	97,14%	97,05%	62,51%	62,51%	4,16%

Scenario [7] – Automated dipping (industrial)

Task / Scenario :	Automated dipping				
Model used :	Recommendation 8 of BPC Ad hoc (model 19/20 (Fully automated dipping)				Handling model 1 water based
dilución producto (worst case)	100,0%				
		TIER 1	TIER 2	TIER 2	TIER 3
Active substance (% w/w) Permetrina	0,400%				Fully automated
Body weight (kg)	60				
	units	with gloves (including in model)	with gloves (including in model)+ coverall 5%	with gloves (including in model)+ coverall 5%+new gloves	1/4 (with gloves (including in model)+ coverall 5%)
Potential dermal exposure					
Body					
clothing type					
indicative value from model	mg/ciclo	158	158	158	158
duration	ciclos	4	4	4	4
potential dermal deposit	mg	632,00	632,00	632,00	632,00
clothing penetration from model	%	100%	5%	5%	5%
actual dermal deposit (product)	mg	632,00	31,60	31,60	31,60
Hands exposure					
indicative value from model	mg/ciclo	130,00	130,00	67,60	130,00
duration	ciclos	4	4	4	4
potential dermal deposit	mg	520,00	520,00	270,40	520,00
gloves penetration from model	%	100%	100%	100%	100%
actual hand deposit (product)	mg	520,00	520,00	270,40	520,00
Actual dermal exposure					
product	mg	1152,00	551,60	302,00	551,60
active substance Permetrina	mg	4,61	2,21	1,21	2,21
Skin penetration Permetrina	%	70%	70%	70%	70%
active substance via the skin Permetrina	mg	3,23E+00	1,54E+00	8,46E-01	3,86E-01
systemic dose via skin Permetrina	mg/kg bw	5,38E-02	2,57E-02	1,41E-02	6,44E-03
Exposure by inhalation					
indicative value from model	mg/m3	1,9	1,9	1,9	
duration	min	240	240	240	
inhalation rate	m3/min	2,08E-02	2,08E-02	2,08E-02	
inhaled volume	m3	5,0	5,0	5,0	
potential inhaled product	mg	9,5	9,5	9,5	
mitigation factor by RPE	value	1	1	1	
inhaled product through RPE	mg	9,5	9,5	9,5	
active substance through RPE Permetrina	mg	3,80E-02	3,80E-02	3,80E-02	9,50E-03
systemic inhaled dose (al) Permetrina	mg/kg bw	6,33E-04	6,33E-04	6,33E-04	1,58E-04
Dose					
total	mg	3,264	1,582	0,884	
systemic dose Permetrina	mg/kg bw	5,38E-02	2,57E-02	1,41E-02	6,44E-03
					Aceptable tier 1
Estimated uptake/AEL (%) Permetrina	%	107,52%	51,48%	28,19%	12,87%

Scenario [8] – Cleaning brush

General Exposure Calculator For Washing Out Of Brushes The systemic dermal exposure is calculated as follows:			
Activity and Parameters	**Tier 1 No gloves**	**Tier 2 Gloves**	**Units**
Volume of brush	**200**	**200**	**ml**
Volume of paint remaining on brush after painting ($^1/_8$ of 200 ml = 25 ml)	25	25	ml
Density of paint	**0,770**	**0,770**	**g/ml**
Weight of paint on brush after painting = volume of paint remaining on brush after painting (ml) x density of paint (g/ml)	19,25	19,25	g
Concentration of a.s. in paint	**0,400%**	**0,400%**	**% w/w**
A. Weight of a.s. on brush after painting	77,0000	77,0000	mg
B. Residues of a.s. on brush after 1st washing (10% of A)	7,7000	7,7000	mg
Amount of a.s. removed from the brush into the cleaning fluid (A-B)	69,3000	69,3000	mg
C. Weight of a.s. squeezed out from brush onto cloth (50% of B)	3,8500	3,8500	mg
Cloth absorbs 90% of a.s. squeezed out of brush therefore, weight of a.s. available to contaminate the hand (10% of C)	0,3850	0,3850	mg
Penetration of a.s. through gloves	**100**	**10**	**%**
Weight of a.s. on hand	0,38500	0,03850	mg
Dermal absorption of a.s.	**70,00**	**70,00**	**%**
Weight of a.s. entering the body	0,26950	0,02695	mg
D. Weight of a.s. left on the brush after 1st wash and squeezing (B – C)	3,8500	3,8500	mg
E. Residues of a.s. on brush after 2nd washing (10% of D)	0,3850	0,3850	mg
Amount of a.s. removed from the brush into the cleaning fluid (D-E)	3,4650	3,4650	mg
F. Weight of a.s. squeezed out from brush onto cloth (50% of E)	0,1925	0,1925	mg
Cloth absorbs 90% of a.s. squeezed out of brush therefore, weight of a.s. available to contaminate the hand (10% of F)	0,0193	0,0193	mg
Penetration of a.s. through gloves	100	10	%
Weight of a.s. on hand	0,01925	0,00193	mg
Dermal absorption of a.s.	70,00	70,00	%
Weight of a.s. entering the body	0,01348	0,00135	mg
G. Weight of a.s. left on the brush after 2nd wash and squeezing (**E** – **F**)	0,1925	0,1925	mg
H. Residues of a.s. on brush after 3rd washing (10% of G)	0,0193	0,0193	mg
Amount of a.s. removed from the brush into the cleaning fluid (G – H)	0,1733	0,1733	mg
I. Weight of a.s. squeezed out from a brush onto a cloth (50% of H)	0,0096	0,0096	mg
Cloth absorbs 90% of a.s. squeezed out of brush therefore, weight of a.s. available to contaminate the hand (10% of I)	0,0010	0,0010	mg
Penetration of **a.s.** through gloves	100	10	%
Weight of a.s. on hand	0,00096	0,00010	mg
Dermal absorption of a.s.	70,00	70,00	%
Weight of a.s. entering the body	0,00067	0,00007	mg
Total weight of a.s. entering the body *(to 4 decimal places)*	**2,84E-01**	**2,84E-02**	**mg**
Body weight	**60**	**60**	**kg**
TOTAL SYSTEMIC DERMAL DOSE OF ACTIVE SUBSTANCE *(to 4 decimal places)*	**4,73E-03**	**4,73E-04**	**mg a.s./kg bw**

Scenario [9] – Cleaning spray-equipment

Performed according to Recommendation nº 4								
	Units	Tier 1 (No PPE)	Tier 2 (gloves)	Tier 3 (gloves& coated coverall)	Tier 4 (gloves& impermeable coverall)	Tier 5 (gloves& double coverall)	Tier 6 (new gloves per shift & impermeable coverall)	Tier 7 (new gloves per shift & double coverall)
Content of active substance	%	0,40%	0,40%	0,40%	0,40%	0,40%	0,40%	0,40%
Product density	g/mL <> mg/µL	0,76	0,76	0,76	0,76	0,76	0,76	0,76
Body weight	Kg	60	60	60	60	60	60	60
Dermal absorption	%	70%	70%	70%	70%	70%	70%	70%
Time exposure	min	20	20	20	20	20	20	20
Indicative value (hands)	µL/min	35,87	35,87	35,87	35,87	35,87	35,87	35,87
Indicative value (body)	µL/min	19,28	19,28	19,28	19,28	19,28	19,28	19,28
Penetration (PPE for hands)	%	100%	10%	10%	10%	10%	5%	5%
Penetration (PPE for body)	%	100%	100%	10%	5%	1%	5%	1%
DERMAL EXPOSURE								
Hands exposure	mg a.s.	1,5266	0,1527	0,1527	0,1527	0,1527	0,0763	0,0763
Body exposure	mg a.s.	0,8206	0,8206	0,0821	0,0410	0,0082	0,0410	0,0082
Total dermal exposure	mg a.s.	2,3472	0,9732	0,2347	0,1937	0,1609	0,1174	0,0845
Systemic estimated total uptake	mg/kg bw/d	0,0391	0,0162	0,0039	0,0032	0,0027	0,0020	0,0014
Estimated uptake/AEL (%) Permethrine	%	78%	32%	8%	6%	5%	4%	3%
RISK (Yes or No acceptable)		**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**

Scenario [10] – Sawing and Sanding treated wood by professional users

Professional sanding treated wood	Permethrin	Units
AS concentration	0,400%	
Volume of wood to be sanded in 1h	4,00E+03	cm^3
Area of wood to be sanded in 1h surface area	4,03E+03	cm^2
Rate of product absorbed in wood (Application dose)	2,00E-02	kg/m^2
Amount of product absorbed in wood	8,06E-03	kg
Product density	1,02E+00	g/mL
Amount of product absorbed in wood sanded in 1h	2,02E-06	kg/cm^3
Amount of substance absorbed in wood sanded in 1h	8,06E-09	kg/cm^3 wood
Wood density	4,00E+02	mg/cm^3
Inhalation		
Dust concentration in air (occupational exposure limit for wood dust)	5	mg/m^3
Inhalation rate	1,25	m^3/h
Exposure duration	6	h
Dust inhaled	37,5	mg/day
Amount of active substance inhaled rate	7,56E-04	mg/day
Body weight	60	kg
Inhalation exposure	**1,26E-05**	**mg/kg/day**
Dermal		
Application rate	2,00E+00	mg/cm^2
Percentage dislodgeable (%)	2%	
Hand surface	410	cm^2
Transfer to hands (%)	20%	
A.S. Contamination of hand surface	0,0131	mg a.s.
Dermal absorption (%)	70,00%	
Dermal exposure	**1,53E-04**	mg a.s/kg bw/d
Total Exposure	1,66E-04	mg a.s/kg bw/d

Scenario [11] – Sawing and Sanding treated wood by non-professional users

Non-Professional sanding treated wood	Permethrin	Units
AS concentration	0,400%	
Volume of wood to be sanded in 1h	4,00E+03	cm^3
Area of wood to be sanded in 1h surface area	4,03E+03	cm^2
Rate of product absorbed in wood (Application dose)	2,00E-02	kg/m^2
Amount of product absorbed in wood	8,06E-03	kg
Product density	1,02E+00	g/mL
Amount of product absorbed in wood sanded in 1h	2,02E-06	kg/cm^3
Amount of substance absorbed in wood sanded in 1h	8,06E-09	kg/cm^3 wood
Wood density	4,00E+02	mg/cm^3
Inhalation		
Dust concentration in air (occupational exposure limit for wood dust)	5	mg/m^3
Inhalation rate	1,25	m^3/h
Exposure duration	1	h
Dust inhaled	6,25	mg/day
Amount of active substance inhaled rate	1,26E-04	mg/day
Body weight	60	kg
Inhalation exposure	**2,10E-06**	**mg/kg/day**
Dermal		
Application rate	2,00E+00	mg/cm^2
Percentage dislodgeable (%)	2%	
Hand surface	410	cm^2
Transfer to hands (%)	20%	
A.S. Contamination of hand surface	0,0131	mg a.s.
Dermal absorption (%)	70,00%	
Dermal exposure	**1,53E-04**	mg a.s/kg bw/d
Total Exposure	1,55E-04	mg a.s/kg bw/d

Scenario [12] – Chewing wood off-cut

Toddler chewing wood composites chips (acute)	**Permethrin**	**Unidades**
AS concentration	0,400%	
Oral		
Application rate	20,00	mg/cm^2
A.S.Concentration in treated wood	8,00E-02	$a.s.mg/cm^2$
Extraction by chewing	10%	
Size of wood composites chip	16	cm^2
Oral absorption	100%	
Estimated oral (total) uptake	1,28E-01	mg a.s
Body weight (infant)	8	kg
Estimated Systemic total uptake	1,60E-02	mg/kg bw/day

Scenario [13] – Chewing wood off-cut

Toddler playing on playground structure and mouthing.	Permethrin	Units
AS concentration	0,40%	%
Body weight (toddler)	10	kg
Dermal exposure to dried product		
Application rate for RTU product	20	mg/cm2
Amount of a.s. per unit treated surface area for dried product	0,0800	mg/cm2
Transfer coefficient of dried product from treated surface to hand	2%	%
Amount of a.s. that is transferable from treated surface to hand	0,00160	mg/cm2
Total area of toddler hands in contact with the removed dried product	46,08	cm2
Amount of a.s. on palms of both hands from contact with removed dried product	0,07373	mg a.s
Dermal absorption	70,00%	%
Estimated dermal uptake	0,05161	mg a.s.
Systemic dermal exposure to dried product	0,00516	mg/kg bw/day

Oral exposure to dried product from hand to mouth transfer

Transfer coefficient of dried product from hand to mouth	50%	%
Amount of a.s. transferrable to the mouth	0,01106	mg a.s.
Oral absorption	100%	%
Estimated oral uptake	0,01106	mg a.s.
Systemic oral exposure to dried product	0,00111	mg/kg bw/day
Estimated Total uptake	0,06267	mg a.s.
Estimated systemic total uptake	0,00627	mg/kg bw/day

Screening test according HEEG OPINION 13:

	Permethrin
AS vapour pressure Pa	2.16E-06
AS MW	391.29
Gases cte	8.31451
Temperature (K)	298
AEC $_{long\ term}$ (mg as/m3)	0.05
Cte	0.328
Result	5.53E-03
Negligible	**yes**

Scenario [14] – Inhalation exposure

Exposición inhalatoria permethrin	Adultos	Niños	Toodler	Bebés	Unidades
Presión de vapor s.a.	2,86E-06	2,86E-06	2,86E-06	2,86E-06	Pa
Pm de s.a.	391,28	391,28	391,28	391,28	g/mol
Constante de gases	8,31451	8,31451	8,31451	8,31451	J/mol K
Temperatura (ºK)	298	298	298	298	K
Tasa de inhalación	16	12	8	5,4	m^3/día
Pc	60	23,9	10	8	Kg
Concentración del vapor saturado	4,52E-09	4,52E-09	4,52E-09	4,52E-09	g/m^3
Exposición inhalatoria	7,23E-05	5,42E-05	3,61E-05	2,44E-05	mg/día
Exposición sistémica inhalatoria	**1,20E-06**	**2,27E-06**	**3,61E-06**	**3,05E-06**	**mg/kg pc/día**
AEL chronic	0,05	0,05	0,05	0,05	mg/kg pc/día
%AEL	2,41E-03	4,54E-03	7,23E-03	6,10E-03	
ACEPTABLE	SI	SI	SI	SI	

Scenario [15] – Laundering work clothes

Potential daily clothing contamination (from brushing scenario)	mg as/día	2,4021
Potential weekly clothing contamination	mg (as)	12,0105
Surface medium-sized coverall	cm^2	22700
Total deposit mg (as)/cm^2	mg (as)/cm^2	0,0005291
Skin surface area in contact	cm^2	1640
Transfer coefficient	%	30%
Potential dermal contamination	mg (as)	0,2603
Dermal absorption		70%
Body weight	kg	60
Estimated dermal uptake permethrin	**mg (as)**	0,1822
Estimated systemic total uptake permethrin	**mg/kg bw**	0,00304

Task / Scenario :	Laundering work clothes		
Model used :	From spray application	From manual dipping	From brushing scenario
Product's dilution	100%		
Body weight (kg)	60 units	TIER 1 From spraying application	TIER 2 From manual dipping
Potential dermal exposure Hands exposure		without PPE	without PPE
indicative value from model	mg/day	16872	5073
potential dermal deposit during 5 days work	mg	84360,00	25365,00
surface medium-sized coverall	cm^2	22700	22700
actual hand deposit (product)	mg/cm2	3,72	1,12
Actual dermal exposure			
active substance a.s. (Permethrin)	mg/cm2	1,49E-02	4,47E-03
Skin penetration a.s. (Permethrin)	%	70%	70%
active substance via the skin a.s (Permethrin)	mg/cm2	1,04E-02	3,13E-03
active substance via the skin a.s (IPBC)	mg/cm2	0,00E+00	1,68E-01
active substance via the skin a.s (Propiconazole)	mg/cm2	0,00E+00	3,35E-02
Skin surface area in contact	cm2	1,64E+03	1,64E+03
Transfer coefficient	%	30%	30%
systemic dose via skin a.s. (Permethrin)	**mg/kg bw**	**8,53E-02**	**2,57E-02**

Dose				
total	mg	1279,894	384,833	0,514
systemic dose a.s. (Permethrin)	**mg/kg bw**	**8,53E-02**	**2,57E-02**	**3,43E-05**

3.3 New information on the active substance

No new data has been submitted.

3.4 Residue behaviour

No new data has been submitted.

3.5 Summaries of the efficacy studies (B.5.10.1-xx)[3]

All efficacy test information is summarized in the efficacy table, section 2.2.5.5.

3.6 Other

[3] If an IUCLID file is not available, please indicate here the summaries of the efficacy studies.