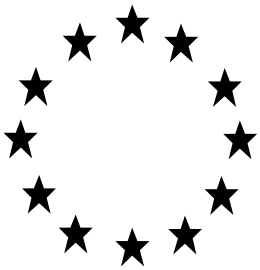
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



NEW SERPOL BASIC

Product type 8

Permethrin as included in the Union list of approved active substances

Case Number in R4BP: BC-SC050005-58

Evaluating Competent Authority: ES-eCA

Date: April 2023 (updated October 2023)

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Overview of applications

Application type	Ref MS	Case nº/Asset nº in the ref MS	Decision date	Assessment carried out (i.e. first authorisation / amendment /MIC)
NA-APP	ES	BC-SC050005-58 ES-0027378-0000	January 2022	First authorisation
NA-AAT	ES	BC-XC073751-35	February 2022	Change in the expiration date of the authorization
NA-AAT	ES	BC-SS083036-12	December 2022	Amendment of the Authorisation after the comments phase with MSCA-France (NA-MRS)
NA-AAT	ES	BC-UG083853-22	January 2023	Amendment of the Authorisation after the comments phase with MSCA-Greece (NA-MRS)
NA-MIC (*)	ES	BC-CJ073464-41	January 2023	Change in the pack size range
NA-AAT	ES	BC-HP085740-24	April 2023	Explanation about previous NA-MIC (BC-CJ073464-41) implemented to all cMS.
NA-AAT	ES	BC-DD088964-35	October 2023	Modification in the SPC - Use # 6 – Curative treatment – Superficial application: Brushing and complementary injection, by non professional users (General public).

(*) The NA-MIC (BC-CJ073464-41) was requested only for Spain, since at the time of the application the product authorization had only been issued in Spain. However, after various clarifications, the applicant confirms his willingness to make it extensible to all the MS concerned. For clarity, the pack sizes that were requested in the MIC are highlighted in blue.

1 CONCLUSION

Physical-chemical properties and Analytical Methods

NEW SERPOL BASIC is a white gel which pH at 1% and density values are 6.6 and 0.7973 g/ml respectively.
The results of the accelerated and long-term stability studies showed that the product is stable when stored at 54 ± 2ºC for 14 days and at room temperature for 2 years. Therefore, a 2 years shelf-life can be granted.
Furthermore, it is not considered to be explosive, flammable, oxidizing, pyrophoric or corrosive.
Regarding analytical methods, HPLC-UV can be considered to be suitable for the identification and quantification of the active substances in the biocidal product.

Efficacy

The efficacy studies submitted have demonstrated that the product is effective as wood preservative against wood boring beetles and termites in Use Class 1 (preventive treatment) and indoor (curative treatment). The product is intended for trained professional, professional and non-professional users, which may use it by different application methods: superficial treatment, brushing and spraying (projection) and treatment by complementary injection.

Sufficient efficacy has been proved for preventive treatment against wood boring beetles and termites at the application dose of 200 g/m^2. In addition, sufficient efficacy has been proved for curative treatment against wood boring beetles and termites at the application dose of 300 ml/m^2. Complementary application by injection has been proved for curative treatment at the application dose of 252 ml/m^2.

Human health

NEW SERPOL BASIC contains the active substance permethrin (0.35%). The substance aliphatic hydrocarbon (hydrocarbons, C12-C16, isoalkanes, cyclics, <2% aromatics) has been identified as substance of concern.

According to the CAR for permethrin there is no indication for endocrine disrupting properties of active substance.

After reviewing the potential ED properties of co-formulants, one substance has been identified as having potential endocrine disrupting properties. If this substance is finally identified as having ED properties in the future, the conditions for granting the biocidal product authorisation will be revised.

After evaluating the exposure and characterizing the risk to human health of the product NEW SERPOL BASIC, the scenarios with an acceptable risk and that meet the conditions to allow their authorization, are the following:

Summary table risk assessment for human health			
Scenario	**Scenario**	**Conclusion**	**Exposed group**
1.	Brush application	A **safe** siutation has been identified for trained professionals and professionals for brushing when gloves and coated coverall are worn.	Trained Professionals, Professionals
2.	High pressure spray application	A **safe** situtation has been identified for trained professionals and professionals for HP spraying when gloves and impermeable coverall are worn. In addition, when trained professionals laundering work clothes, gloves should be worn.	Trained Professionals, Professionals
4.	Pressure injection application	A **safe** situtation has been identified for Trained professionals and professionals for pressure injection when gloves are worn. Borehole injection should always be combined with a curative superficial treatment	Trained Professionals, Professionals
5.	Brushing + pressure injection	A **safe** situtation has been identified for Trained professionals and professionals for brushing and injection when gloves and coated coverall are worn.	Trained Professionals, Professionals
8.	Brushing application	A **safe** situtation has been identified for non-professionals for brushing.	Non-professionals
9.	Spray application	A **safe** situtation has been identified for non-professionals for spraying. Do not clean the sprayer. It should be disposed off after use.	Non-professionals
11.	Brushing + Injection	A **safe** situtation has been identified for non-professionals for brushing and injection.	Non-professionals
12.	Cleaning of brush	A **safe** situtation has been identified.	Trained professionals, Professionals Non-professional
13.	Cleaning of sprayer	A **safe** situtation has been identified.	Trained professionals & Professionals
14.	Laundering contaminated work clothing	A **safe** situation has been identified for trained-professionals when gloves are worn. A **safe** situation has been identified for professionals	Trained-Professionals, Professionals
15.	Sanding treated wood	A **safe** siutation has been identified.	Trained Professionals, Professionals.
16.	Sanding treated wood	A **safe** siutation has been identified.	Non-professional
17.	Toddler chewing treated wood	A **safe** situation has been identified for toddler chewing treated wood chips.	General public (toddler-acute)
18.	Toddler playing on playground weathered structure	A **safe** situation has been identified for toddler playing and mouthing on playground weathered wood structure outdoors	General public (toddler-chronic)

Summary table risk assessment for human health			
Scenario	**Scenario**	**Conclusion**	**Exposed group**
19.	Inhalation volatilased residues indoors	A **safe** situation has been identified for general public inhaling volatilised residues indoors.	General public

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.

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

Environment

The risk characterisation for the environment shows that the intended uses of the biocidal product NEW SERPOL BASIC as a ready-to-use-product used for treatment of wood only indoors where the wood or wood-based product is inside a construction, not exposed to the weather and wetting (UC1), for preventive curative treatment of wood against insects by brushing, spraying or injection do not pose unacceptable risks to the environment.

2 ASSESMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier	**Country (if relevant)**
NEW SERPOL BASIC GEL TRATAMIENTO MADERA, WOOD SERPOL GEL, WOOD TREATMENT GEL	SPAIN

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	MYLVA S.A.
	Address	Via Augusta 48 08006 Barcelona Spain
Authorisation number	ES-0027378-0000	
Date of the authorisation	25/01/2022	
Expiry date of the authorisation	25/01/2032	

2.1.1.3 Manufacturer(s) of the product

Name of manufacturer	MYLVA S.A.
Address of manufacturer	Via Augusta 48 08006 Barcelona Spain
Location of manufacturing sites	Sant Galderic, 23 08395 Sant Pol de Mar, Barcelona Spain

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

Active substance	Permethrin
Name of manufacturer	Caldic Denmark A/S (Denmark) (Acting for Tagros Chemicals India Limited (India)
Address of manufacturer	Jhaver Centre, Rajah Annamalai Building, IV Floor, 72, Marshalls Road, 600 008 Egmore, Chennai, India
Location of manufacturing sites	Tagros Chemicals India Limited, A4/1&2, SIPCOT)Industrial Complex, Kudikadu Cuddalore, Tamil Nadu India

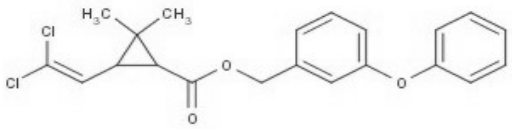
2.1.2 Product composition and formulation

NB: the full composition of the product has been provided in the confidential annex.

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

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	Permehtrin
IUPAC or EC name	3-phenoxybenzyl (1RS,3RS;1RS,3SR)-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	930 g/kg minimum
Structural formula	

2.1.2.2 Candidate(s) for substitution

The biocidal product NEW SERPOL BASIC contains permethrin, which does not meet the criteria for exclusion under article 5 (1) and substitution under Article 10 (1) of the Biocides 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,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate	Active Substance	52645-53-1	258-067-9	0.35
DISOLVENTE ISOPARAFINICO N	Hydrocarbons, C12-C16, isoalkanes, cyclics, <2% aromatics	Non-active substance	Related CAS Nº: 64742-47-8	927-676-8	73.26

2.1.2.4 Information on technical equivalence

The source of active substance Permethrin is the same as was evaluated for inclusion in the Union list of approved active substances. Therefore no check for equivalence is necessary.

2.1.2.5 Information on the substance(s) of concern

According to the definition of a substance of concern laid down in the Guidance on the BPR Volume III Human Health- Assessment & Evaluation– Part B and C Risk Assessment (Version 4.0 December 2017), the following substance of concern was identified: Hydrocarbons, C12-C16, isoalkanes, cyclics, <2% aromatics (CE: 927-676-8).
Please see the confidential annex for further details.

NEW SEPOL BASIC contains Mixture of CMIT/MIT as co-formulant which is currently approved as a biocidal active substance for several product types, but not as PT8. Furthermore, their concentration in the biocidal product is below concentration limits for classification. Therefore, according to the Substances of Concern Guidance, these substances are currently not identified as substances of concern.

Regarding environmental aspects, the biocidal product contains one ingredient different from the active substance (Mixture of CMIT/MIT) classified as dangerous for the environment. This ingredient (Mixture of CMIT/MIT), should not be considered a substance of concern due to the low percentage in which it is present in the biocidal product, not leading to classification. Furthermore, none of the co-formulants meet the PBT/vPvB criteria.

ES CA

The biocidal product NEW SERPOL BASIC contains one active substance, permethrin.

According to the CAR of Permethrin for PT8, this substance (various isomer mixtures) is not a PBT candidate nor are its individual constituent isomers. Permethrin is considered to fulfill the T criteria, but does not fulfill the B criteria. However, permethrin could also be considered as potentially persistent based on a constituent of permethrin (the cis isomer) and therefore fulfill the P criteria.

There is a co-formulant that is being assessed as biocidal active substance under BPR. The concentration of this substance in NEW SEPOL BASIC is below 0.1%. However, is being assess as ED, but a Draft Final Competent Authority Report is not available yet. Consequently, this substance cannot be considered a Substance of Concern at this stage (see the BPR Guidance Vol IV B, C V2.00 October 2017, 8.1.1. ”Other grounds for concern”) but will be considered once the conclusion regarding ED properties of this co-formulant is available.

2.1.2.6 Type of formulation

Gel

2.1.3 Hazard and precautionary statements

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

Classification	
Hazard category	Aquatic Acute 1, Aquatic Chronic 1
Hazard statement	H400: Very toxic to aquatic life H410: Very toxic to aquatic life with long lasting effects
Labelling	
Signal words	Warning
Hazard statements	H410: Very toxic to aquatic life with long lasting effects. EUH066: Repeated exposure may cause skin dryness or cracking" is required. EUH208: Contains "Permethrin, 1,2-benzisothiazol-3(2H)-one and mixture of 5-Chloro-2-methyl-2H-isothiazol-3-one and 2-Methyl-2Hisothiazol-3-one (3:1). May produce an allergic reaction.
Precautionary statements	P273: Avoid release to the environment. P391: Collect spillage. P501(Professionals and non professional): Dispose of content and / or its container as hazardous waste according to the regulations in force. P501(Trained professionals): Dispose of contents and/or their container as hazardous waste to a registered establishment or undertaking, in accordance with current regulation.

2.1.4 Authorised use(s)

2.1.4.1 Use description

Table 1. Use # 1 – **Preventive and Curative treatment – Superficial application: Brushing, by Trained professional and professional users.**

Product Type	PT08- Wood preservatives.
Where relevant, an exact description of the authorised use	NEW SERPOL BASIC is a ready to use wood preservative product to be applied under use class 1 conditions in preventive uses and indoor under curative uses. The product is applied by brushing.
Target organism (including development stage)	Wood boring Beetles *Hylotrupes bajulus L.* (Larvae) *Reticulitermes spp.* (no data)
Field of use	For preventive treatment: Indoor use (UC 1: situation in which the wood or wood based product is inside a construction, not exposed to the weather and wetting). Use Class 1 For curative treatment: Indoor use.
Application method(s)	Brushing
Application rate(s) and frequency	Ready-to-use. Brushing

	Method: Painting with a brush or a roller Treatment: Preventive, Dose: 200 g/m^2 Curative, Dose: 300 ml/m^2 Frequency of use: One application according to dosage is enough to protect timber.
Category(ies) of users	Trained professional, professional.
Pack sizes and packaging material	Plastic (PP) containers, bucket: 5, 7, 7.5, 10, 25, 40, 50, 75, 100, 125, 150, 175, 200, 250, 300, 350, 400, 450, 500, 650, 750, 1000ml; 1, 2, 5, 7, 7.5, 10, 15, 20, 25, 30, 50, 60, 75, 100, 200L* Plastic containers (PP), tube: 5, 7, 7.5, 10, 25, 40, 50, 75, 100, 125, 150, 175, 200, 250, 300, 350, 400, 500, 650, 750, 1000ml.*

*The packaging in ES will be established according to national risk mitigation measures related to maximum size of packaging pending on the category of user.

2.1.4.1.1 Use-specific instructions for use

See section 2.5.1.1.

2.1.4.1.2 Use-specific risk mitigation measures

Wear gloves and coated coveralls.

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 section 2.5.1.3.

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

See section 2.5.1.4.

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 section 2.5.1.5.

2.1.4.2 Use description

Table 2. Use # 2 – **Preventive and Curative treatment – Superficial application: Brushing, by non-professionals users (General public).**

Product Type	PT08 - Wood preservatives
Where relevant, an exact description of the authorised use	NEW SERPOL BASIC is a ready-to-use wood preservative product to be applied under use class 1 conditions in preventive uses and indoor under curative uses. The product is applied by brushing.
Target organism (including development stage)	Wood boring Beetles *Hylotrupes bajulus L.* (Larvae) *Reticulitermes spp.* (no data)
Field of use	For preventive treatment: Indoor use (UC 1: situation in which the wood or wood based product is inside a construction, not exposed to the weather and wetting). Use Class 1. For curative treatment: Indoor.
Application method(s)	Brushing
Application rate(s) and frequency	Ready-to-use. <u>Brushing</u> Method: Painting with a brush or a roller Treatment: Preventive, Dose: 200g/m^2 Curative, Dose: 300 ml/m^2 Frequency of use: One application according to dosage is enough to protect timber.
Category(ies) of users	Non professional (General public).
Pack sizes and packaging material	Plastic container (PP), bucket: 5, 7, 7.5, 10, 25, 40, 50, 75, 100, 125, 150, 175, 200, 250, 300, 350, 400, 450, 500, 650, 750, 1000ml; 1, 2L Plastic container (PP), tube: 5, 7, 7.5, 10, 25, 40, 50, 75, 100, 125, 150, 175, 200, 250, 300, 350, 400, 500, 650, 750, 1000ml

2.1.4.2.1 Use-specific instructions for use

See section 2.1.5.1.

2.1.4.2.2 Use-specific risk mitigation measures

See 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 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 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 section 2.1.5.5.

2.1.4.3 Use description

Table 3. Use # 3 – **Preventive and Curative treatment – Superficial application: High pressure spraying (projection), by Trained professional and professionals users.**

Product Type	PT08- Wood preservatives.
Where relevant, an exact description of the authorised use	NEW SERPOL BASIC is a ready to use wood preservative product to be applied under use class 1 conditions in preventive uses and indoor under curative uses. The product is applied by projection (spraying of a gel product).
Target organism (including development stage)	Wood boring Beetles *Hylotrupes bajulus L.* (Larvae) *Reticulitermes spp.* (no data)
Field of use	For preventive treatment: Indoor use (UC 1: situation in which the wood or wood based product is inside a construction, not exposed to the weather and wetting). Use Class 1 For curative treatment: Indoor use.
Application method(s)	Spraying (projection).
Application rate(s) and frequency	Ready-to-use. Spraying (projection) Method: High-pressure spraying Treatment: Preventive, Dose: 200 g/m^2 Curative, Dose: 300 ml/m^2 Frequency of use: One application according to dosage is enough to protect timber.
Category(ies) of users	Trained professional, professional.
Pack sizes and packaging material	Plastic containers (PP), bucket: 5, 7, 7.5, 10, 25, 40, 50, 75, 100, 125, 150, 175, 200, 250, 300, 350, 400, 450, 500, 650, 750, 1000ml; 1, 2, 5, 7, 7.5, 10, 15, 20, 25, 30, 50, 60, 75, 100, 200L*

	Plastic containers (PP), tube: 5, 7, 7.5, 10, 25, 40, 50, 75, 100, 125, 150, 175, 200, 250, 300, 350, 400, 500, 650, 750, 1000ml.*

*The packaging in ES will be established according to national risk mitigation measures related to maximum size of packaging pending on the category of user.

2.1.4.3.1 Use-specific instructions for use

See section 2.1.5.1.

2.1.4.3.2 Use-specific risk mitigation measures

Wear gloves and impermeable coveralls. Only for trained professional: - Clothes contaminated with the biocidal product must be kept away from general public. - To manipulate the contaminated clothes the user must wear gloves.

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 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 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 section 2.1.5.5.

2.1.4.4 Use description

Table 4. Use # 4 – **Preventive and Curative treatment – Superficial application: spraying (projection), by non professional users (General public).**

Product Type	PT08- Wood preservatives.
Where relevant, an exact description of the authorised use	NEW SERPOL BASIC is a ready to use wood preservative product to be applied under use class 1 conditions in preventive uses and indoor under curative uses. The product is applied by projection (spraying of a gel product).

Target organism (including development stage)	Wood boring Beetles *Hylotrupes bajulus L.* (Larvae) *Reticulitermes spp.* (no data)
Field of use	For preventive treatment: Indoor use (UC 1: situation in which the wood or wood based product is inside a construction, not exposed to the weather and wetting. Use Class 1 For curative treatment: Indoor.
Application method(s)	Spraying (projection).
Application rate(s) and frequency	Ready-to-use. Spraying (projection) Method: Hand-held trigger spray Treatment: Preventive, Dose: 200g/m^2 Curative, Dose: 300 ml/m^2 Frequency of use: One application according to dosage is enough to protect timber.
Category(ies) of users	Non professional (general public).
Pack sizes and packaging material	Plastic container (PP), bucket: 5, 7, 7.5, 10, 25, 40, 50, 75, 100, 125, 150, 175, 200, 250, 300, 350, 400, 450, 500, 650, 750, 1000ml; 1, 2L Plastic container (PP), tube: 5, 7, 7.5, 10, 25, 40, 50, 75, 100, 125, 150, 175, 200, 250, 300, 350, 400, 500, 650, 750, 1000ml

2.1.4.4.1 Use-specific instructions for use

See section 2.1.5.1.

2.1.4.4.2 Use-specific risk mitigation measures

Do not clean the sprayer. It should be disposed off after using.

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 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 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 section 2.1.5.5.

2.1.4.5 Use description

Table 5. Use # 5 – **Curative treatment – superficial application- Brushing and complementary injection by Trained professional and professional users.**

Product Type	PT08- Wood preservatives.
Where relevant, an exact description of the authorised use	NEW SERPOL BASIC is a ready to use wood preservative product to be applied indoor. The product is applied by brushing and complementary injection.
Target organism (including development stage)	Wood boring Beetles *Hylotrupes bajulus L.* (Larvae) *Reticulitermes spp.* (no data)
Field of use	Indoor use
Application method(s)	Brushing and complementary injection (the product is injected into pre-drille holes with a pressure machine).
Application rate(s) and frequency	Ready-to-use. <u>Brushing</u> Method: Painting with a brush or a roller Dose: 300 ml/m^2 Treatment: Curative. Frequency of use: One application according to dosage is enough to cure timber. For intensive treatment: Injection application (252 ml/m^2). To be applied in combination with superficial treatment. 300+252 ml/m^2
Category(ies) of users	Trained professional, professional.
Pack sizes and packaging material	Plastic container(PP), bucket:25, 40, 50, 75, 100, 125, 150, 175, 200, 250, 300, 350, 400, 450, 500, 650, 750, 1000ml; 1, 2, 5, 7, 7.5, 10, 15, 20, 25, 30, 50, 60, 75, 100, 200L* Plastic container (PP), tube: 25, 40, 50, 75, 100, 125, 150, 175, 200, 250, 300, 350, 400, 500, 650, 750, 1000ml.*

*The packaging in ES will be established according to national risk mitigation measures related to maximum size of packaging pending on the category of user.

2.1.4.5.1 Use-specific instructions for use

The product is injected into pre-drilled holes with a pressure machine. For intensive treatment, the application rate of 300 ml/m^2 + fill boring holes with liquid (252 ml/m^2) is appropriate for application method: superficial treatment +injection. Dose: The mean volume of the hole ranges between 10 and 28 ml. The number of holes depends on the volume: for 10 ml/hole, 5 holes/linear m, 25 holes/m^2 or for 28 ml/hole, 3 holes/linear m, 9 holes/m^2. A second injection should be performed if the product does

not penetrate properly on the first injection, but never more than 252 ml/m^2 will be added for a complete treatment.

2.1.4.5.2 Use-specific risk mitigation measures

Wear gloves and coated coveralls.

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 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 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 section 2.1.5.5.

2.1.4.6 Use description

Table 6. Use # 6 – **Curative treatment – superficial application- Brushing and complementary injection by non professional users (General public).**

Product Type	PT08- Wood preservatives.
Where relevant, an exact description of the authorised use	NEW SERPOL BASIC is a ready to use wood preservative product to be applied indoor. The product is applied by brushing and complementary injection.
Target organism (including development stage)	Wood boring Beetles *Hylotrupes bajulus L.* (Larvae) *Reticulitermes spp.* (no data)
Field of use	Indoor use
Application method(s)	Brushing and complementary injection (the product is injected into fly boring holes with a syringe).
Application rate(s) and frequency	Ready-to-use. <u>Brushing</u> Method: Painting with a brush or a roller Dose: 300 ml/m^2 Treatment: Curative. Frequency of use: One application according to dosage is enough to cure timber.

	For intensive treatment: Injection application (252 ml/m^2). To be applied in combination with superficial treatment. 300+252ml/m^2
Category(ies) of users	Non professional (general public).
Pack sizes and packaging material	Plastic container (PP), bucket: 25, 40, 50, 75, 100, 125, 150, 175, 200, 250, 300, 350, 400, 450, 500, 650, 750, 1000ml; 1, 2L Plastic container (PP), tube: 25, 40, 50, 75, 100, 125, 150, 175, 200, 250, 300, 350, 400, 500, 650, 750, 1000ml

2.1.4.6.1 Use-specific instructions for use

The product is injected with a disposable syringe in the fly boring holes made by insects, followed by superficial application. For intensive treatment, the application rate of 300 ml/m^2 + fill fly boring holes with liquid (252 ml/m^2) is appropriate for application method: superficial treatment +injection. A second injection should be performed if the product does not penetrate properly on the first injection, but never more than 252 ml/m^2 will be added for a complete treatment.

2.1.4.6.2 Use-specific risk mitigation measures

See section 2.1.5.2.

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

See section 2.1.5.3.

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

See section 2.1.5.4.

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

See section 2.1.5.5.

2.1.5 General directions for use

2.1.5.1 Instructions for use

Always read the label or leaflet before use and follow all the instructions provided. Comply with the instructions for use. Wash hands thoroughly after handling.

Assure no animals are present during the treatment.

Product can be used to treat softwoods.

The users should inform if the treatment is ineffective and report straightforward to the registration holder.

2.1.5.2 Risk mitigation measures

Do not get in eyes, on skin, or on clothing.

Do not use on wood which may come in direct contact with food, feeding stuff and livestock animals.

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

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.

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

IF INHALED:If symptoms occur call a POISON CENTRE or a doctor.
IF SWALLOWED: If symptons occur call a POISON CENTRE or a doctor.
IF ON SKIN: Take off all contaminated clothing and wash it before a reuse. Wash skin with water. If skin irritation occurs: Get medical advice.
IF IN EYES:If symptons occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.

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

IF MEDICAL ADVICE IS NEEDED, HAVE THE PRODUCT CONTAINER OR LABEL AT HAND

2.1.5.4 Instructions for safe disposal of the product and its packaging

Product disposal:
Respect the rules on clothing and protective measures.
To clean the floor and contaminated objects by this material, use carbonated or soapy water. Do not discharge into drains or the environment. Cover the product with absorbent material such as sand, ground or diatomaceous earth to prevent spreading. Heavily contaminated soil layers must be taken out until a clean layer is found.
Use an apropiate safety container to avoid environmental contamination.
The product should NOT be eliminated in municipal sewers, drains or rivers.

Please, see specific instructions for safe disposal of the product and its packaging provided above.

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

Keep out of reach of children and non-target animals/pets. Store in the original container tightly closed. Store in a dry, cool and well ventilated place. It is recommended to store the product at a temperature between 5ºC and 45ºC. Protect from frost. Store the biocidal product protected from direct sunlight. Shelf life: 2 years.

2.1.6 Other information

Application codes

Definitions:

- 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.

2.1.7 Packaging of the biocidal product*

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
Bucket	5, 7, 7.5, 10, 25, 40, 50, 75, 100, 125, 150, 175, 200, 250, 300, 350, 400, 450, 500, 650, 750, 1000ml; 1, 2L	Plastic PP	Plastic PP	Professional, non-professional.	Yes
Bucket	5, 7, 7.5, 10, 25, 40, 50, 75, 100, 125, 150, 175, 200, 250, 300, 350, 400, 450,	Plastic PP	Plastic PP	Trained professional.	Yes

	500, 650, 750, 1000ml; 1, 2, 5, 7, 7.5, 10, 15, 20, 25, 30, 50, 60, 75, 100, 200L				
Tube	5, 7, 7.5, 10, 25, 40, 50, 75, 100, 125, 150, 175, 200, 250, 300, 350, 400, 500, 650, 750, 1000ml	Plastic PP	Plastic PP	Trained professional, professional, non-professional.	Yes

*The packaging in ES will be established according to national risk mitigation measures related to maximum size of packaging pending on the category of user.

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

No new data in support of the active substance has been submitted.
New data in support of the evaluation of the biocidal product are listed in Annex 3.1.

2.1.8.2 Access to documentation

MYLVA S.A. has submitted a letter of access by owner data of active ingredient Permethrin.

2.2 Assessment of the biocidal product

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

Table 2. Intended use # 1 – Brushing, projection and injection by trained professional, professional and general public.

Product Type(s)	PT08 - Wood preservatives (Preservatives)
Where relevant, an exact description of the authorised use	NEW SERPOL BASIC is a ready-to-use wood preservative product to be applied l under use class 1 conditions. The product is applied by brushing, projection (spraying of a gel product) and injection.
Target organism (including development stage)	*Hylotrupes bajulus L.* (Larvae and Adults) *Reticulitermes sp.* (Larvae and Adults)
Field of use	Use Class 1
Application method(s)	Brushing, projection and injection
Application rate(s) and frequency	250 ml/m^2 One application according to dosage indicated in the label is enough to protect and cure timber
Category(ies) of user(s)	Trained professional, professional and general public.

Pack sizes and packaging material	Packaging of plastic material. Packaging sizes: 5, 7, 7.5, 10, 25, 40, 50, 75, 100, 125, 150, 175, 200, 250, 300, 350, 400, 500, 650, 750, 1000ml; 1, 2, 5, 7, 7.5, 10, 25, 50, 60, 100, 200L

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	OPPTS 830.6302 OPPTS 830.6303 OPPTS 830.6304	Permethrin: 0.35%	Gel	Nichetti, S. 2018
Physical state	ASTM D 4359-90	Permethrin: 0.35%	Liquid	Romero, R. 2021
Colour at 20 °C and 101.3 kPa	OPPTS 830.6302 OPPTS 830.6303 OPPTS 830.6304	Permethrin: 0.35%	White	Nichetti, S. 2018
Odour at 20 °C and 101.3 kPa	OPPTS 830.6302 OPPTS 830.6303 OPPTS 830.6304	Permethrin: 0.35%	Characteristic odour	Nichetti, S. 2018
Acidity / alkalinity	CIPAC MT 75.3	Permethrin: 0.35%	pH (20ºC)= 6.6	Nichetti, S. 2018
Relative density / bulk density	CIPAC MT 3.2 OECD 109	Permethrin: 0.35%	D_4^{20} = 0.7973	Nichetti, S. 2018
Storage stability test – **accelerated storage**	CIPAC MT 46.3 Permethrin active ingredient content with Internal Analytical Method No 1001/2018 adjusted and validated in GLP study CH 1001/2018	Permethrin: 0.35%	Tª: 54°C time: 14 days • Permethrin: $[C]_0$ = 0.36% $[C]_f$ = 0.36% Δ[C] = 0% • cis Permethrin: $[C]_0$ = 0.09% $[C]_f$ = 0.09% Δ[C] = 0% • trans Permethrin: $[C]_0$ = 0.27% $[C]_f$ = 0.28% Δ[C] = +3.70% The appearance of the test item did not change	Nichetti, S. 2018

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Packaging: Opaque packaging. The containers did not present any deformation in either bottom or lateral layers or loss of sample or evident corrosion phenomena. The weight of the test item in its commercial packaging did not change significantly (-0.25%) The percentage of decrease of the active substance is within the established range by Guidance.	
Storage stability test – **long term storage at ambient temperature**	Permethrin active ingredient content with the Internal Analytical Method No. 1001/2018 adjusted and validated in GLP study CH – 1001/2018		Tª: ambient time: 2 years • Permethrin: $[C]_0$ = 0.36% $[C]_{1y}$ = 0.36% $\Delta[C]$ = 0% $[C]_0$ = 0.36% $[C]_{2y}$ = 0.37% $\Delta[C]$ = +2.78% • cis Permethrin: $[C]_0$ = 0.09% $[C]_{1y}$ = 0.089% $\Delta[C]$ = -1.11% $[C]_0$ = 0.09% $[C]_{2y}$ = 0.09% $\Delta[C]$ = 0% • trans Permethrina $[C]_0$ = 0.27% $[C]_{1y}$ = 0.27% $\Delta[C]$ = 0%	Nichetti, S. 2018

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			$[C]_0$ = 0.27% $[C]_{2y}$ = 0.28% Δ[C] = +3.70% Appearance – No significant changes were found Packaging – Opaque packaging. After 2 years the bucket presented a deformation on the bottom while no deformation lateral layers, or loss of sample and evident corrosion. Therefore, it can be stated that the deformation presented did not alter any of the properties of the biocidal product pH_0 = 6.6 pH_{1y} = 6.7 pH_{2y} = 6.7 From the obtained results it can be concluded that the biocidal product is stable after 2 years of storing in its commercial packaging For more information on packaging degradation see the confidential PAR	
Storage stability test – **low temperature stability test for liquids**	The test has not been performed so the sentence "Protect from frost" will be included on the label.			
Effects on content of the active substance	Not relevant since the packaging is opaque.			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
and technical characteristics of the biocidal product - **light**	Nevertheless, due to the active substance is light sensitive, the opacity of the packaging is not suffisant. The sentence "Store the biocidal product protected from direct sunlight" will be included on the label.			
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	See storage stability tests.			
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	See storage stability tests.			
Wettability	Not applicable.			
Suspensibility, spontaneity and dispersion stability	Not applicable.			
Wet sieve analysis and dry sieve test	Not applicable.			
Emulsifiability, re-emulsifiability and emulsion stability	Not applicable.			
Disintegration time	Not applicable.			
Particle size distribution, content of dust/fines, attrition, friability	Not applicable.			
Persistent foaming	Not applicable.			
Flowability/Pourability/ Dustability	Not applicable.			
Burning rate — smoke generators	Not applicable.			
Burning completeness — smoke generators	Not applicable.			
Composition of smoke — smoke generators	Not applicable.			
Spraying pattern — aerosols	Not applicable.			
Physical compatibility	Not applicable. The product is not intended to be used in conjunction with any other products or active substances.			
Chemical compatibility				
Degree of dissolution and dilution stability	No applicable.			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Surface tension	OECD Guideline 115 (Surfase Tension os Aqueous Solution) EU Method A.5	READ ACROSS – Serpol Gel II The measurement has not been performed because the behaviour of the test item was not compatible with the measurement of the surface tension in the experimental conditions used.		
Viscosity	CIPAC MT. 192	• At 20°C from 17262.6 mPa·s to 1463.8 mPa·s • At 40°C from 13359.1 mPa·s to 1341.7 mPa·s Non-newtonian liquid because its dynamic viscosity changes with the shear rate.		

Conclusion on the physical, chemical and technical properties of the product
NEW SERPOL BASIC is a white gel which pH and density values are 6.6 and 0.7973 g/ml respectively. Based on the viscosity results it can be stated that the product shows a non-newtonian behavior. A 2 years shelf life can be granted since the results of the accelerated and long-term stability studies showed that the product is stable when stored at 54 ± 2ºC for 14 days and at room temperature for 2 years.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	Differential Scanning Calorimety (DSC)	Permethrin: 0.35%	The DSC test proves that the product does not have explosive properties. The total heat of decomposition of the test item is <500 J.g-1 and therefore the test item is not a candidate for classification as a UN Class 1 explosive substance.	Nichetti, S. 2022
Flammable gases	Not applicable			
Flammable aerosols	Not applicable			
Oxidising gases	Not applicable			
Gases under pressure	Not applicable			
Flammable liquids	CIPAC MT 12.3	Although the composition of some of the ingredients (Sepigel 305, Uradil AZ515 Z-60, Acticide SPX) is not fully known, it is		Nichetti, S. 2022

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		possible to determine whether they are explosive, oxidizing or flammable based on their safety data Sheet. On the one hand, none of the mixtures is classified as such as explosive, oxidizing or flammable. On the other hand, if any of these mixtures included any compound classified as explosive, oxidizing or flammable that could give rise to the classification of the ingredient itself, it should appear in section 3.2 of your card as a dangerous component. Furthermore, the flash point of the composition is > 130 ºC.		
Flammable solids	Not applicable			
Self-reactive substances and mixtures	See the previous point of explosives properties. The DSC test proves that the product does not have self-reactive properties.			
Pyrophoric liquids	Experience in manufacture or handling shows that the mixture does not heat or spontaneously ignite on coming into contact with air at normal temperatures.			
Pyrophoric solids	Not applicable			
Self-heating substances and mixtures	Not applicable. In general, liquids show no self-heating behaviour unless adsorbed on a large surface, this is not the case of this product.			
Substances and mixtures which in contact with water emit flammable gases	Not applicable			
Oxidising liquids	Although the composition of some of the ingredients (Sepigel 305, Uradil AZ515 Z-60, Acticide SPX) is not fully known, it is possible to determine whether they are explosive, oxidizing or flammable based on their safety data Sheet. On the one hand, none of the mixtures is classified as such as explosive, oxidizing or flammable. On the other hand, if any of these mixtures included any compound classified as explosive, oxidizing or flammable that could give rise to the classification of the ingredient itself, it should appear in section 3.2 of your card as a dangerous component. Regarding the oxidizing properties, for organic substances or mixtures, it is not necessary to apply the classification procedure for this hazard class if the substance or mixture does not contain oxygen, fluorine or chlorine; or if the substance or mixture contains oxygen, fluorine or chlorine and these elements are			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	bound chemically only carbon or hydrogen. Looking at the molecular structure of the known ingredients, the oxygen and chlorine present are chemically bonded to carbon or hydrogen in all cases.			
Oxidising solids	Not applicable			
Organic peroxides	None of the ingredients are organic peroxides.			
Corrosive to metals	READ ACROSS – Serpol Gel II In the Serpol Gel II test (ASTM G-1, equivalent to UN Test C.1) no weight loss or pitting was observed in steel or aluminum, therefore it was concluded that it is not corrosive to metals Furthermore, the pH of the mixture is practically neutral (pH =6.6). Contains no acid, basic or halogen groups in the structure of known ingredients. In addition, we have a metal corrosivity test with the Serpol Gel II product, which has practically the same composition. The only difference is the elimination of the ingredient Wocosen TK45 (Propiconazole, IPBC and naphthalene), which is compensated with organic solvent. The composition agrees at 97.5%.			
Auto-ignition temperatures of products (liquids and gases)	Council Regulation (EC) Nº 440/2008	The autoignition temperature of the product has been determined to be 231 ºC		Nichetti, S. 2022
Relative self-ignition temperature for solids	Not applicable			
Dust explosion hazard	Not applicable			

Conclusion on the physical hazards and respective characteristics of the product
NEW SERPOL BASIC is not considered to be explosive, flammable, oxidizing, pyrophoric or corrosive.

2.2.4 Methods for detection and identification

Analyte (type of analyte e.g. active substance)	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Reference
					Range	Mean	RSD	
Permethrin	HPLC-UV	n= 5 • Permethrin: From 6.06 to 54.57 µg/Ml • cis Permethrin: From 2.44 to 21.93 µg/Ml	• Permethrin: y = 268302x – 160441 R^2=0.99925 • cis Permethrin: y = 264747x – 17027	The Permethrin peaks are well separated and there is no evidence of interferen	97.93% - 100.40 %	98.8 %	1.21	Nichetti, S. 2018

		• trans Permethrin: From 3.63 to 32.64 µg/mL	R^2=0.99929 • trans Permethrin: y = 270691x – 143414 R^2=0.99896.	ces more than 3% at the selected wavelength.				

Conclusion on the methods for detection and identificationof the product
Considering data and results obtained from specificity, linearity, precision and accuracy, the analytical method validation can be considered suitable in compliance with the SANCO/3030/99 rev.4 guideline requirements. The analysis method is HPLC with a UV detector. The quantification of the active ingredient (Permethrin) is carried out comparing the sum of the areas of cis and trans isomers of Permethrin (Permethrin Cis I, Permethrin Cis II, Permethrin Trans I, Permethrin Trans II). For specificity, solvent wash chromatograms (eluent mixture with 20% v/v of 2-propanol), Permethrin reference material (about 30 µg/mL), Technical Permethrin (about 30 µg/mL as Permethrins), placebo and NEW SERPOL BASIC solutions. Permethrin spikes are fine separated and there is no evidence of interference with the placebo. For linearity, 5 samples were used for the Permethrin reference material, another 5 samples for the cis isomer and 5 more for the trans isomer. Recovery was calibrated using Permethrin, cis/trans isomers individually. The entire content is calculated as the sum of the areas. The relative standard deviation RSD% was 1.21% for Permethrin, 1.46% for the cis isomer of Permethrin and 1.24% for the trans isomer of Permethrin. Since the relative standard deviation was lower than the RSDr of Horwitz (3.13 at a Permethrin concentration of 0.36% w/w, 3.85 at a cis isomer concentration of Permethrin of 0.090% w/w and 3.27 at a trans isomer concentration of Permethrin of 0.27% w/w), the test repeatability for the active ingredient was acceptable. In relation to the analytical methods of residues in plant/animal foods, soil, water and air: methods of analysis for the determination of Permethrin residues in air, soil and water have previously been evaluated at EU level and accepted for active substance approval. Methods for detection in body fluids and tissues are not required as the active substance is not considered toxic or highly toxic. Methods for detection in food/feed of plant and animal origin are not required due to lack of exposure via the intended uses.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

NEW SERPOL BASIC is a preventive and curative wood preservative product effective in Use Class 1 applied by brushing, projection (spraying for a gel formulation) and injection.
Efficacy of NEW SERPOL BASIC has been tested against *Hylotrupes bajulus* in TECNALIA Research & Innovation laboratories.
Its formulation containing Permethrin allows NEW SERPOL BASIC to be applied on wood with a maximum protective effect duration. It also allows the user to apply varnish, paint or other coatings after the application, once the product is completely dry.

It is intended to be use by surface applications: brushing and projection (spraying for a gel formulation) for preventive treatment and by surface application brushing, projection (spraying for a gel formulation) and injection application in combination with superficial treatment for curative treatment.

- Superficial preventive application: 200 g of product per m^2 of wood.
- Superficial curative application: 300 ml of product per m^2 of wood.
- Injection curative complementary application: 252 ml of product per m^2 of wood.

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

NEW SERPOL BASIC is a wood protector with curative and protective actions against woodworm and termites (*Reticulotermes spp.).*
The product is intended to be used in order to protect wood for the following field of use:

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

The objects to be protected are articles and structures made of wood, such as parquet, flooring, wood decor (plinths, friezes, baseboards), furniture, carpentry (doors and windows), structural timber like beams, and works of art.

2.2.5.3 Effects on target organisms, including unacceptable suffering

The product NEW SERPOL BASIC is effective against woodworm and termites thanks to its content in the active ingredient permethrin.
Wood boring beetle larvae are killed after contact with treated wood.
The termites eat the treated wood and distribute it around the colony, by trophapaxis, which causes the death, not only of those that have ingested the wood but of part of the colony.
Unacceptable suffering for insects larvae and termites cannot be assessed.

2.2.5.4 Mode of action, including time delay

According to IRAC, Permethrin (CAS N°52645-53-1) is an insecticide in the pyrethroid chemical family, considered type I pyrethroid that acts on the nervous system of insects. It interferes with sodium channels to disrupt the function of neurons, and causes muscles to spasm, culminating in paralysis and death. Permethrin can be effective by contact or ingestion and also acts as a mild repellent

2.2.5.5 Efficacy data

New Serpol Basic is a preventive and curative wood preservative product effective in Use Class 1 applied by brushing, projection (spraying for a gel formulation) and injection. It is effective against woodworm and other insects thanks to its content in the active ingredient permethrin.

The wood preservative product from MYLVA, Serpol Gel II, is a preventive and curative product with insecticide and fungicide action against the target organisms present in wood. The insecticide action from Serpol Gel II is thanks to its content in the active ingredient permethrin. New Serpol Basic and Serpol Gel II have exactly the same content in Permethrin, so in consequence, its efficacy against the target insects attacking wood is the same. Both

formulations have a highly similar matrix so their efficacy could be considered the same in terms of insecticidal action.
Because of that, the studies performed on Serpol Gel II against *Hylotrupes bajulus* (Linnaeus) and *Reticulitermes spp.* can be extrapolated to the product New Serpol Basic. To certify that this extrapolation is correct, one of the efficacy studies has been performed on New Serpol Basic formulation, in order to compare the study performed on Serpol Gel II and certify that results are the same. (Determination of preventive action against Hylotrupes bajulus (Linnaeus) – Part 1: Larvicidal effect according to UNE-EN 46-1:2016).

Experimental data on the efficacy of the biocidal product against target organisms							
Test substance	**Field of use envisaged**	**Organisms to be protected**	**Test organisms**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
SERPOL GEL II	Wood preservative Curative treatment	*Pinus sylvestris*	House longhorn beetle. *Hylotrupes bajulus (L.)*	EN 1390	• Superficial treatment (brushing) • 253,63g/m^2/301,94ml/m^2 •Exposure 12 weeks. Quick action.	Mortality rate: 95 % after 84 days of exposure. 11 larvae of the untreated control specimente were alive. The test is valid.	Report nº: 052526-1-a
SERPOL GEL II	Wood preservative Preventive treatment Curative tretament	*Pinus sylvestris*	Subterranean termite *Reticulitermes grassei*	EN118+ EN73 (Evaporation)	• Superficial treatment (brushing): • 166.01± 1.32 g/m^2 • Exposure: 8 weeks.	The study is validated. Four of the six treated blocks are ranked 1 the other two are ranked 0, at the end of the study.	Report nº: 052526-2-a
SERPOL GEL II	Wood preservative Preventive treatment	*Pinus sylvestris*	House longhorn beetle*: Hylotrupes bajulus (L.)*	EN46-1+ EN73 (evaporation	• Superficial treatment (brushing) •100 % (w/w) • Toxic values: 176 g/ m^2 or 198.82±1.58 ml/m^2	59 larvae (6 specimens*10 larvae) were recovered dead without having made tunnels in the wood. Only one larva were not recovered. At least 80% of the larvae inserted in all untreated control specimens, survive.	Report nº: 052526-3-a
SERPOL GEL II	Determination of toxic values.	*Pinus sylvestris*	Subterranean termite *Reticulitermes grassei*	EN117+ EN73 (evaporation)	• Vacumm impregnation. • Toxic values/b.r.v.: 587.32 ± 47.70 Kg/m^3 • Exposure: 8 weeks.	The study is validated. All treated blocks are ranked 0 at the end of the study.	Report nº: 052526-4-a
SERPOL GEL II	Determination of the toxic values-	*Pinus sylvestris*	House longhorn beetle*: Hylotrupes bajulus (L.)*	EN47+ EN73 (evaporation)	•Vacuum application • Larvae in Category 1 •100% • Toxic values: 564.78±32.48 Kg/m^3 •Exposure: 12 weeks	The protector has not been diluted in several concentrations. Therefore, mic-toxic value could not be calculated. At least 80% of the larvae inserted in all untreated control specimens and specimens treated with the solvent, survive.	Report nº: 052526-5-a
NEW SERPOL Basic	Wood preservative Preventive treatment	*Pinus sylvestris*	House longhorn beetle*: Hylotrupes bajulus (L.)*	EN46-1 (evaporation)	• Superficial treatment (brushing) •100% • Toxic values: 202.22±5.44 ml/m^2 •Exposure: 12 weeks	All larvae recovered are dead not having tunneled. The product is effective against *Hylotrupes bajulus L.* larvae.	Report nº: 076190-a(M1)

Conclusion on the efficacy of the product

According to the applicant NEW SERPOL BASIC is intended to be use class 1 as preventive treatment by superficial application and indoor curative treatment by superficial and injection applications. The efficacy assessment justified that the product meets the requirements for use in preservation of wood for Use Class 1.

The applicant has submitted 6 tests to support these claims.

Preventive treatment. Superficial application (Use class 1), brushing or spraying (projection):

Subterranean termites:

The applicant has submitted a trial to support the claim against termites for superficial treatment (brushing). According to the European Standard EN 599-1, the product have passed ageing procedure before the standards tests (EN 73) for use class 1.

-Preventive dose rate by superficial treatment: 166.01± 1.32 g/m^2 **(200 g/m^2)**

Wood boring beetles**.**

The applicant has submitted two tests against *Hylotrupes bajulus* one with Serpol Gel II and one with New Serpol Basic.

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.

- Preventive dose rate by superficial treatment: 176 g/m^2 or 198.82±1.58 ml/m^2 or 202.22 ml/m^2 (NEW SERPOL BASIC) **(200 g/m^2).**

Curative treatment. Superficial application, brushing or spraying (projection):

Subterranean termites.

According to the TNsG, termite treatments are designed to kill termites already found in the wood and to prevent wood degradation. Therefore, preventive efficacy test can be extrapolated for curative treatment.

Wood boring beetles:

The study against *Hylotrupes bajulus* has shown an efficacy of 95% mortality at a dose of 300ml/m^2 by brushing and with quick acting effect (12 weeks).

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*.

- Curative dose rate by superficial treatment: 253,63 g/m^2 or 301.94 ml/m^2. **(300 ml/m^2).**

Curative treatment.
Complementary Injection application:
According to the specifications of the efficacy guidelines, injection treatment is considered neither a superficial treatment nor a penetrating process. As there is no standardization in this method, we do not consider mandatory to provide tests using this method.

The Applicant recommends the application by injection as a complementary treatment to superficial application.

We consider that the product has already proven to be sufficiently effective only with the brushing application method and therefore, an additional dose is a better case.

For intensive treatments, the application rate of **300 ml/m²** + fill boring holes with liquid (**252 ml/m²**) is appropriate for application method: superficial treatment+injection.

The application rate of superficial application, which has been demonstrated as effective in the former studies, is sufficient to accept the injection treatment as complementary.
Even thought, the applicant has submitted two trials against termites and wood boring beetles with penetrating process as a worst case.
These trials have been performed with no dilution and with vacoumm impregnation.
The toxic values of both tests were around 600kg/m^3. These values are very high even for some type of impregnation treatments (see note in section 5.2.10 of EN 599-1).

According to the applicant, the product is injected into pre-drilles holes with a pressure machine. The use of treated wood will be any structural or decorative use, except for food containers.

The mean volume of the holes would range between 10 and 28 ml. The number of holes depends on the volume: for 10 ml/hole, 5 holes/linear m, 25 holes/m^2 or for 28 ml/hole, 3 holes/linear m, 9 holes/m^2. A second injection should be performed if the product does not penetrate properly on the first injection but never more than 252 ml/m^2 will be added for a complete treatment.

Injection application:
According to the applicant, the application dose for this type of treatment is 30kg/m^3 based on the experience of this product that has been on the market for years.
Dose rate: **30kg/m³** . Even so, we do not have the possibility of being able to calculate either in a theoretical or practical way what the real dose of the the product could be and therefore we consider that without more information, it is not posible to accept this mode of application.

2.2.5.6 Occurrence of resistance and resistance management

Resistance to pyrethroid insecticides such as permethrin has been reported for a number of pests both in agriculture and public health. However, no data has been found in the literature regarding resistance occurrence to permethrin among wood-boring beetle and termites.

To ensure a satisfactory level of efficacy and avoid the development of resistance, the following recommendations have to be implemented:

- Always read the label or leaflet before use and follow all the instructions provided.

- The users should inform if the treatment is ineffective and report straightforward to the registration holder.

Effective Insecticide Resistance Management (IRM) strategies intend to minimise the resistance selective pressure within the populations to any type of insecticide. Alternations or rotations of insecticidal agents with different MoA groups provide a sustainable and effective approach to IRM in this sense.

In this line, IRAC (Insecticidal Resistance Action Committee) encourages producers to clearly indicate the IRAC MoA group number and description on the product label to assist users in the selection of insecticides for use in the rotations or alternations. Therefore, in addition to the detailed product information, a typical label should clearly indicate the IRAC MoA Group number & description, and minimal, brief advice on IRM.

2.2.5.7 Known limitations

No known limitations

2.2.5.8 Evaluation of the label claims

The product has proven effective for the following label claims.

- Preventive treatment against wood boring beetles and termites
- Curative treatment against wood boring beetles and termites

Claim matrix:

User category	Industrial (Trained professional) Professional Non professional/general public	A.30 A.20 A.10
Wood category	Softwood	B.10
Wood product	Solid wood	C.10
Application aim	Preventive Curative	D.40 D.50
Field of use	Use class 1	E.10
Method of application rate	Superficial application. Spraying (projection) Brush/rolling Injection.	 F.11 F.10 F.20
Target organisms	Wood boring beetles Subterranean termites.	G.30 G.51

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

The product is not intended to be used with other products.

2.2.6 Risk assessment for human health

No studies on the effects of NEW SERPOL BASIC on human health have been submitted in the dossier of this biocidal product. However there are valid data available on each of the components in the mixture sufficient to allow the classification according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP Regulation). The effect of active substance and critical concentrations are described in its Assessment Report (PAR). Information on co-

formulants are found on the ECHA dissemination website and the SDSs submitted. Therefore new studies with the biocidal product are scientifically not justified.

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	NEW SERPOL BASIC is neither irritant nor corrosive to the skin.
Justification for the value/conclusion	Based on the classification of the active substance and the coformulants and their respective content in the final formulation. The concentration of components classified for skin irritation or corrosivity is below the limits for classification. Therefore, the product does not meet the criteria for classification for skin corrosion or irritation according to Regulation (EC) Nº 1272/2008. However, taking into account that some of the co-formulants are labelled as EUH066, an appropriate labelling for skin dryness and cracking is indicated.
Classification of the product according to CLP	No classification is required. Supplemental hazard statement EUH066: "Repeated exposure may cause skin dryness or cracking" is required.

Data waiving	
Information requirement	Skin corrosion/irritation study
Justification	The composition of the product is known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the product. In addition, synergistic effects between any of the components are not expected. Consequently, classification of the mixture can be made according to the rules laid down in Regulation (EC) No 1272/2008, therefore this study does not need to be conducted.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Not irritanting to eyes.
Justification for the value/conclusion	Based on the classification of the active substances and the coformulants and their respective content in the final formulation. The concentration of components classified for eye irritation or damage is below the limits for classification. Therefore, the product does not meet the criteria for classification for eye irritatrion or damage according to Regulation (EC) Nº 1272/2008.
Classification of the product according to CLP	No classification is required.

Data waiving

Information requirement	Eye irritation study
Justification	The composition of the product is known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the product. In addition, synergistic effects between any of the components are not expected. Consequently, classification of the mixture can be made according to the rules laid down in Regulation (EC) No 1272/2008, therefore this study does not need to be conducted.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	Based on the classification of the active substance and the coformulants and their respective content in the final formulation. The biocidal product does not meet the criteria for classification for respiratory tract irritation according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP	No classificacion is required.

Data waiving	
Information requirement	Respiratory tract irritation data.
Justification	No experimental data on respiratory tract irritation of the biocidal product are available. However, 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.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	NEW SERPOL BASIC is not a skin sensitizer
Justification for the value/conclusion	Based on the classification of the active substance and the different co-formulants and, their respective content in the final formulation. Permethrin is classified for skin sensitisation according to annex VI of Regulation (EC) No 1272/2008. However, as its concentration is below 1% but above 0.1% (threshold limit for elicitation), EUH208 should be required on the label. In addition, the biocidal product contains BIT and CMIT/MIT(3:1) also classified for skin sensitisation which are above their threshold limit for elicitation, so EUH208 should also be required.
Classification of the product according to CLP	Classification is not required. Labelling with EUH208 (Contains "Permethrin, 1,2-benzisothiazol-3(2H)-one and mixture of 5-Chloro-2-methyl-2H-isothiazol-3-one and 2-Methyl-2Hisothiazol-3-one (3:1)". May produce an allergic reaction) is required.

Data waiving	
Information requirement	Skin sensitization study.
Justification	The composition of the product is known. Sufficient data on the intrinsic properties of the components are available through safety data sheets and other information for each of the individual components in the product. In addition, synergistic effects between any of the components are not expected. Consequently, classification of the mixture can be made according to the rules laid down in Regulation (EC) No 1272/2008, therefore this study does not need to be conducted.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	NEW SERPOL BASIC is not a respiratory sensitizer.
Justification for the value/conclusion	Based on the classification of the active substance and the different co-formulants and, their respective content in the final formulation. None of the components of the product is classified for respiratory sensitization. Therefore, the product does not meet the criteria for classification for respiratory sensitization according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP	No classification is required.

Data waiving	
Information requirement	Respiratory sensitization data.
Justification	The composition of the product is known. Sufficient data on the intrinsic properties of the components are available through 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 the product is not classified.

Acute toxicity

According to Regulation (EC) No 1272/2008, the classification of mixtures based on ingredients of the mixture is determined by calculation from the ATE values (ATEmix):

$$\frac{100}{ATE_{mix}} = \sum_{r} \frac{C_i}{ATE_i}$$

or

$$\frac{100 - (\sum C_{unknown} if > 10\%)}{ATE_{mix}} = \sum_{r} \frac{C_i}{ATE_i}$$

where:

Ci = concentration of ingredient I (% w/w or % w/w)
i = the individual ingredients from 1 to n
n = the number of ingedients
ATEi = Acute Toxicity Estimate of ingredient i

Acute toxicity by oral route

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 of permethrin and the SDSs of the other components. According to Assessment Report of permethrin the LD50 value is 480mg/kg bw. Some coformulants of the product are classified for acute toxicity by oral route but are below their generic cut-off values (table 1.1. of CLP Regulation) so they are not included in the calculation of the acute oral ATE (Acute Toxicity Estimate) of the biocidal product. The calculated oral ATE for NEW SERPOL BASIC 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 is 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.

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	CL_{50}: >5mg/l
Justification for the selected value	The classification of the biocidal product was conducted using endpoints included in Assessment Report of permethrin and the SDSs of the other components. Permethrin is classified as Acute Tox. 4; H332. According to the Assessement Report, the LC_{50} value for permethrin is for dust/mist 4.638mg/l. Another component of the product is classified for acute toxicity by inhalation route but is below its generic cut-off value (table 1.1. of CLP Regulation) so it is not included in the calculation of the acute inhalation ATE (Acute Toxicity Estimate) of the biocidal product. The calculated inhalation ATE for NEW SERPOL BASIC is higher than 5mg/l. Therefore the product does not meet the criteria for

	classification for acute inhalation toxicity according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP	No classification is 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.

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	NEW SERPOL BASIC is not classified for acute dermal toxicity
Justification for the selected value	Based on the classification of the active substances and the coformulants and their respective content in the final formulation. One component of the product is classified for acute toxicity by dermal route but is below its generic cut-off value (table 1.1. of CLP Regulation) so it is not taken into account for the calculation of the acute dermal ATE (Acute Toxicity Estimate) of the biocidal product. 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 is 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.

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Permethrin
Value(s)*	Ready-to-use biocidal product: 70% Dried biocidal product on wood: 70%

Justification for the selected value(s)	As there are no data on the formulation, according to the EFSA guidance on dermal absorption (EFSA Journal, 2017;15(6):4873), a default value of 70% should be used for gel formulation for direct application (GEL/GD).

*

Data waiving	
Information requirement	Dermal absorption study
Justification	There is no experimental data available on the dermal absorption of NEW SERPOL BASIC 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.

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

One substance of concern has been identified for human health:
DISOLVENTE ISOPARAFINICO N (Hydrocarbons, C12-C16, isoalkanes, cyclics, <2% aromatics) which is classified as Asp tox 1; H304 (May be fatal if swallowed and enters airways). EUH066 (Repeated exposure may cause skin dryness or cracking) is proposed, based on local skin effects and reactions that have been described for hydrocarbon solvents. According to the definition of a substance of concern laid down in the Guidance on the BPR Volume III Human Health- Assessment & Evaluation– Part B and C Risk Assessment (Version 4.0 December 2017), the SoC contained in the product is included 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.

Available toxicological data relating to a mixture

Information on the toxicology of the other components of the product was provided based on the corresponding Material Safety Data Sheets. No additionally toxicological concerns are raised by the co-formulants according to the Material Safety Data Sheets for which additionally toxicity testing would be required.
Please, See confidential annex for further details.

Other

NEW SERPOL BASIC contains a hydrocarbon solvent above 10% which classified as Asp tox 1: H304. In accordance with CLP Regulation (point 3.10.3.3.1.2.) *"a mixture is classified as Category 1 when the sum of the concentrations of Category 1 ingredients is ≥ 10 % and the mixture has a kinematic viscosity ≤ 20,5 mm 2 /s, measured at 40 °C".* Hence, taking into account that the dynamic viscosity varied at 40 ºC from 13359.1 mPa·s to 1341.7 mPa·s (Non-newtonian liquid because its dynamic viscosity changes with the shear rate), and the density is 0.7973g/cm^3, the kinematic viscosity measured at 40 °C is far above 20,5mm^2/s based on theoretical calculation. Therefore, NEW SERPOL BASIC should be not classified for aspiration toxicity.

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, none of the co-formulants contained in the product NEW SEPOL BASIC are identified as endocrine disruptors. None of the co-formulants are currently being evaluated in the frame of REACH for its potential ED properties. According to *U.S. EPA Endocrine Disruptor Screening Program (EDSP21)* one substance has been identified as having potential endocrine disrupting properties. If this substance is 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.

2.2.6.2 Exposure assessment

(NA-AAT) December 2022: As a result of the comment phase opened during the MRS procedure with France, this section 2.2.6.2 has been lightly amended (see Scenario 1).

The biocidal product NEW SERPOL BASIC is a ready-to-use (RTU) solvent-based formulation containing permethrin at a concentration of 0.35%. It is used by trained professionals, professionals and non-professionals.

The exposure assessments are based on calculations using models and default values from Biocides Human Health Exposure Methodology, October 2015 (henceforth BHHEM), Recommendations of the BPC Ad hoc WG on Human Exposure and HEEG opinions.

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).

In a second step, the exposure calculated for the individual work tasks are combined for the intended uses and scenarios.

Furthermore, secondary exposure of users and the general public is assessed considering the highest effective retention in wood.

Secondary exposure scenarios could involve skin and oral contact and possible exposure by inhalation. These exposures include 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.

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).

The dermal absorption value of 70% for permethrin is used for the risk assessment. For the justification, please refer to chapter 2.2.6.1 "Information on dermal absorption".

These general considerations apply to all scenarios (work tasks) provided in the "List of scenarios".

The workplace risk for professional operators will be controlled through observance of statutory requirements. They have access to Material Safety Data Sheets (MSDS) and may have some basic knowledge about classification and labelling. The workers are trained and skilled in the main objectives of their occupation and may have some experience and skill in the use of personal protective equipment (PPE) if that is necessary for their normal work.

Non-professional users belong usually to the general public who may or may not read a product label. Although they may not have access to formal PPE, it is expected that the general public will follow some basic recommendation such as do not eat, drink or smoke when working with wood preservatives products in general, avoid contact with eyes and skin and avoid inhaling vapour.

NEW SERPOL BASIC 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.

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	n.a	Yes	Yes	n.a.	Yes	Yes	No
Dermal	n.a.	Yes	Yes	n.a.	Yes	Yes	No
Oral	n.a.	No	No	n.a.	No	Yes	No

"n.a" (not applicable)

General consideration:
Professional and general public may be exposed to volatilised residues from treated wood installed indoors. Based on the document, HEEG opinion 13 on Assessment of Inhalation Exposure of volatilised biocide active substance, to calculate the exposure to volatilised residues from permethrin:

$$\frac{0.328\ .mw\ .vp}{AEL_{long-ter}} = \frac{0.328 * 391.28 * 2.86 * 10^{-6}}{0.5} = 7.34 * 10^{-4} < 1$$

Since the result of this equation is minor than 1, the exposure to volatilised residues indoor can be considered negligible for professional and general public.
Remark: the mw (molecular weight) and vp (vapour pressure) come from the Assessment Report on Permethrin.

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
Primary exposure by professionals			
1.	Brush & roll application	Primary exposure for users when applying by brush (superficial treatment for curative or preventive aim)	Trained professionals, Professionals
2.	Spray HP (high pressure) application	Primary exposure for users when applying by spray (superficial treatment for curative or preventive aim). Spraying done at high pressure (>100 bar)	TP, P
3.	Spray MLP (medium / low pressure) application	Primary exposure for users when applying by spray (superficial treatment for curative or preventive aim). Spraying done at medium (4-7 bar)/low (1-3 bar) pressure.	TP, P
4.	Injection application	Primary exposure for users when applying by injection (pressure impregnation) for curative aim.	TP, P
5.	Brush and injection application	Primary exposure for users during a sequential use (in a single treatment operation) of an injection application followed by a surface (brush) treatment	TP, P
6.	Spray HP and injection application	Primary exposure for users during a sequential use (in a single treatment operation) of an injection application followed by a surface (spray HP) treatment	TP, P
7.	Spray MLP and injection application	Primary exposure for users during a sequential use (in a single treatment operation) of an injection application followed by a surface (spray MLP) treatment	TP, P
12.	Cleaning of brush	Primary exposure during cleaning of a brush after application	TP, P
13.	Cleaning of spray equipment	Primary exposure during cleaning of spray equipment	TP, P
14.	Laundering work clothes	Secondary exposure for an adult laundering work clothing at home (contaminated during use)	TP, P
15.	Sanding of treated wood	Secondary exposure for professionals sanding treated wood after treatment	TP, P
Primary exposure by non-professionals			

8.	Brush & roll application	Primary exposure for users when applying by brush (superficial treatment for curative or preventive aim)	Non-professional
9.	Spray application	Primary exposure for users when applying by spray (superficial treatment for curative or preventive aim). Spraying done at medium (4-7 bar) pressure.	Non-professional
10.	Injection application	Primary exposure for users when applying by injection (pressure impregnation) for curative aim.	Non-professional
11.	Brush and injection application	Primary exposure for users during a sequential use (in a single treatment operation) of an injection application followed by a surface (brush) treatment	Non-professional
12.	Cleaning of brush	Primary exposure during cleaning of a brush after application	Non-professional
Secondary exposure by professionals and general public			
16.	Sanding of treated wood	Secondary exposure for non-professionals sanding treated wood after treatment	General public
17.	Toddler chewing treated wood off-cut	Secondary exposure for toddler ingesting residues when chewing treated wood off-cut	General public
18.	Toddler playing on playgroud structure outdoors	Secondary exposure for toddler playing on a treated wooden playground structure	General public
19.	Inhalation of volatilized residues	Chronic exposure to wood preservatives may arise via residues volatilised from treated wood indoors.	General public

Explanatory note:
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 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.

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

Industrial exposure

Industrial use of the product is not intended.
Permethrin and the biocidal product are produced in the EU. The exposure during the production of the active substance and the formulation of the biocidal product are not assessed under the requirements of the BPR. However, it is assumed that the production is

performed in conformity with national and European occupational safety and health regulations.

Professional exposure

Scenario [1]. Application – Brushing and rolling by trained professionals and professionals

Description of Scenario [1]		
The scenario describes the primary exposure for a professional (TP&P) user stirring and pouring the RTU product and applying it by brushing and rolling. New Serpol Basic is applied indoors by a professional with a brush/roll at a maximum of 239.1 g/m^2 (equivalent to 300 mL/m^2) with curative aim or 200 g/m^2 with preventive aim. The activity can be divided into two different phases: 1A) A loading step is considered assuming an user manually load the product into a tray prior to brush and roller application. The model "Mixing and Loading Model 7" has been used. 1B) Application phase. In this phase, the exposure assessment is carried out following the Recommendation 6, v4 (proposed model No 23, Professional brush treatment) based on "Consumer painting model 3" Dermal and inhalatory exposure are relevant for both models.		
	Parameters	Value
Tier 1 & 2	Content of permethrin (%w/w)	0.35%
	Body weight (adult)[1]	60 kg
	Dermal absorption	70%
	Inhalatory absorption	100%
	Inhalation rate (adult)[1]	1.25 m^3/h <> 0.0208 m^3/min
Scenario 1A – Loading step[2]		
Tier 1 (No PPEs)	Exposure duration	10 min
	Indicative dermal exposure	101 mg/min
	Indicative inhalation exposure	0.94 mg/m^3
Tier 2 (gloves & clothes)	Indicative dermal exposure (inside gloves & clothes)	1.01 mg/min
	Indicative inhalation exposure	0.94 mg/m^3
Scenario 1B – Application step		
Tier 1 (No PPEs)	Exposure duration	240 min
	Application area per minute	7.6 min/m^2
	Total application area	31.6 m^2
	Indicative dermal exposure (values normalized to 1% active substance)	Hands: 0.5417 mg/m^2 Body: 0.2382 mg/m^2
	Indicative inhalation exposure	0.0016 mg/m^2
Tier 2 (gloves & coated coverall)	Gloves penetration[4]	10%
	Coated coverall penetration[4]	10%

[1] *BHHEM, p15 & 16*

[2] *Mixing and loading model 7 for pouring and pumping liquids. (see Recommendation No. 6, v4, p 11)*

[3] *Professional brush treatment (see Recommendation No. 6, v4, p 24)*

[4] *HEEG opinion 9 (Default protection factors for protective clothing and gloves).*

Calculations for Scenario [1]

The calculation sheets are provided in Annex 3.2

Summary table: estimated exposure from brushing & rolling professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [1A]	1/No PPE	1.14E-05	4.124E-02	-	0.0413
	2/Gloves	1.14E-05	4.124E-04	-	0.0004
Scenario [1B]	1/No PPE	0.0003	0.10063	-	0.1009
	2/Gloves & coated coverall	0.0003	0.01006	-	0.0104
Scenario 1 = [1A+1B]	1/No PPE	3.114E-04	1.141	-	0.142
	1A(2)gloves& 1B(1)no PPE	3.114E-04	0.101	-	0.101
	2/Gloves & coated coverall	3.114E-04	0.0104	-	0.011

Further information and considerations on scenario [1]

As we will see, the risk of this scenario is acceptable when the operator wears gloves and coated coveralls. Therefore, these will be the conditions of use for the scenario 1 when evaluated it in combination with other scenarios, such as e.g. brush cleaning.

Combined scenarios

The Scenario 1 (Brushing and rolling by trained professionals and professionals) can combine with the following scenarios:

- Scenario 12. Cleaning of a brush.
- Scenario 14. Laudering working clothes
- Scenario 15. Professional sanding treated wood.

Summary table: combined systemic exposure from professional uses				
Scenarios combined	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated Dermal Uptake (mg/kg bw/d)**	**Estimated Oral Uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 1 (Tier 2)	3.114E-04	0.0104	-	0.011
Scenario 12 (Tier 1/ No PPE)	-	0.0043	-	0.0043
Scenario 12 (Tier 2 / Gloves)	-	0.0004	-	0.0004
Scenario 14 from scen 1 (Tier 1 / No PPE)	-	0.0029	-	0.0029
Scenario 15 (Tier 1 / No PPE)	0.00024	0.00295	-	0.00319
Scenario 15 (Tier 2 / Gloves)	0.00024	0.000295	-	0.00054

Scenario [2]. High pressure spraying by professional operators

Description of Scenario [2]		
The scenario describes the primary exposure for a professional (TP&P) user applying the RTU product by manual high-pressure spraying. New Serpol Basic is applied indoors by a professional with a spraying device at a maximum of 239.1 g/m^2 (equivalent to 300 mL/m^2) with curative aim or 200 g/m^2 with preventive aim. According to the BHHEM[1], the "Spraying Model 3" is used for dermal and inhalation exposure; in accordance with HEAdhoc Recommendation No 6, the default settings of this model have been updated into HEAdhoc Recommendation No 17. The model is based on measurement data collected during high pressure (>100 bar) airless spraying of antifouling paints, but the data are equally applicable to many high-pressure paint spraying operations. It provides data of dermal exposure [potential body and actual hand exposure (measurements of hand exposure inside gloves)] and exposure to aerosols by inhalation. The studies carried out on the application of antifoulants, which have led to this model, are based on a duration of the work ranged from 40 to 360 minutes (median about 180 minutes, default value proposed in the model). Therefore, we consider that the model covers the use in wood treatment, where the duration of the task is estimated at 40 min, with two applications per day, that is, 80 min per day. The model covers spray application overhead and forwards. It already contains the loading phase. Therefore, a separate calculation for this phase has not been performed.		
	Parameters	Value
Tier 1 (No PPEs)	Content of permethrin (%w/w)	0.35%
	Body weight (adult)[1]	60 kg
	Dermal absorption	70%
	Inhalatory absorption	100%
	Inhalation rate (adult)[1]	1.25 m^3/h <> 0.0208 m^3/min
	Task duration[2]	40 min/task
	Frequency of use[2]	2 task/day
	Exposure duration[2]	80 min
	Indicative value for dermal (hands) exposure (75th percentile)[3]	80.17 mg/min
	Indicative value for dermal (body) exposure (75th percentile)[3]	195.04 mg/min
	Indicative value for dermal inhalation exposure (75th percentile)[3]	11.3 mg/m^3
	Penetration	100%
Tier 2 (gloves)	Indicative value for dermal (hands) exposure inside gloves (75th percentile)[3]	1.14 mg/min

Tier 3 (gloves & coated coverall)	Coated coverall penetration[4]	10%
Tier 4 (gloves & impermeable coverall)	Impermeable coverall penetration[4]	5%
Tier 5 (gloves & double coverall)	Double coverall penetration[4]	1%
Tier 6 & 7 (new gloves per shift)	Reduces hand-in-glove exposure to approximately half	0.52

[1] *BHHEM, p15 & 16*
[2] *BHHEM, p52*
[3] *BHHEM, October 2015, p 287,288 & 289. According to Recommendation No 6, v4, p45, updated into HEAdhoc Recommendation No 17.*
[4] *HEEG opinion 9 (Default protection factors for protective clothing and gloves).*

Calculations for Scenario [2]

The calculation sheets are provided in Annex 3.2

Summary table: estimated exposure from high pressure spraying professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [2]	1/ No PPEs	0.0011	0.8990	-	0.9001
	2/ Gloves	0.0011	0.6409	-	0.6420
	3/ Gloves & coated coverall	0.0011	0.0674	-	0.0685
	4/ Gloves & impermeable coverall	0.0011	0.0356	-	0.0367
	5/ Gloves & double coverall	0.0011	0.0101	-	0.0112
	6/ New gloves per shift & impermeable coverall	0.0011	0.0338	-	0.0349
	7/ New gloves per shift & double coverall	0.0011	0.0083	-	0.0094

Further information and considerations on scenario [2]

As we will see, the risk of this scenario is acceptable when the operator wears gloves and impermeable coveralls (tier 4). Therefore, these will be the first conditions of use for the scenario 2 when evaluated it in combination with other scenarios, such as e.g. cleaning of spraying equipment.

Combined scenarios

The Scenario 2 (high pressure spraying by trained professionals and professionals) can combine with the following scenarios:

- Scenario 13. Cleaning of spraying equipment
- Scenario 14. Laudering working clothes
- Scenario 15. Professional sanding treated wood.

Summary table: combined systemic exposure from professional uses				
Scenarios combined	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 2 (Tier 4)	0.0011	0.0356	-	0.0367
Scenario 2 (Tier 5)	0.0011	0.0101	-	0.0112
Scenario 2 (Tier 6)	0.0011	0.0338	-	0.0349
Scenario 2 (Tier 7)	0.0011	0.0083	-	0.0094
Scenario 13 Tier 1 / No PPE	-	0.0359	-	0.0359
Scenario 13 Tier 2 / Gloves	-	0.0149	-	0.0149
Scenario 13 Tier 3 (gloves & coated coverall)	-	0.0036	-	0.0036
Scenario 13 Tier 4 (gloves & impermeable coverall)	-	0.0030	-	0.0030
Scenario 13 Tier 5 (gloves & double coverall)	-	0.0025	-	0.0025
Scenario 14 from scen 2 (Tier 2 / gloves)	-	0.0066	-	0.0066
Scenario 15 (Tier 1 / No PPE)	0.00024	0.00295	-	0.00319
Scenario 15 (Tier 2 / Gloves 90%)	0.00024	0.000295	-	0.00054

Scenario [3] Medium/low pressure spraying by professional operators

Description of Scenario [3]		
The scenario describes the primary exposure for a professional (TP&P) user applying the RTU product by manual medium/low-pressure (4 to 7 bar) spraying. New Serpol Basic is applied indoors by a professional with a spraying device at a maximum of 239.1 g/m^2 (equivalent to 300 mL/m^2) with curative aim or 200 g/m^2 with preventive aim. In accordance with HEAdHoc Recommendation 6, v4 (p. 24),"Spraying model 2" (BHHEM, October 2015, p286)) is considered appropriate for this scenario. This model, which is based on professional spray applications (medium pressure) indoors and outdoors in an overhead and downward direction, includes an exposure component for mixing and loading activities. It provides data of dermal exposure [potential body and actual hand exposure (measurements of hand exposure potential and inside gloves)] and exposure to aerosols by inhalation. The exposure duration is 80 min (by two events of 40 min).		
	Parameters	Value
Tier 1 (No PPEs)	Content of permethrin (%w/w)	0.35%
	Body weight (adult)[1]	60 kg
	Dermal absorption	70%
	Inhalatory absorption	100%
	Inhalation rate (adult)[1]	1.25 m^3/h <> 0.0208 m^3/min
	Task duration[2]	40 min/task
	Frequency of use[2]	2 task/day
	Exposure duration[2]	80 min
	Indicative value for dermal (hands) exposure (75th percentile)[2]	273 mg/min
	Indicative value for dermal (body) exposure (75th percentile)[2]	222 mg/min
	Indicative value for dermal inhalation exposure (75th percentile)[2]	76 mg/m^3
	Penetration	100%
Tier 2 (gloves)	Indicative value for dermal (hands) exposure inside gloves (75th percentile)[2]	7.8 mg/min
Tier 3 (gloves & impermeable coverall)	Impermeable coverall penetration[3]	5%
Tier 5 (gloves & double coverall)	Double coverall penetration[3]	1%
Tier 4 & 6 & 7 (new gloves per shift)	Reduces hand-in-glove exposure to approximately half	0.52

Tier 7 (RPE)	Relative penetration of respiratory protection – filtering half masks / FFP1	25%

[1] *BHHEM, p15 & 16*
[2] *Recommendation No 6, v4, No 24 (p24)*
[3] *HEEG opinion 9 (Default protection factors for protective clothing and gloves).*

Calculations for Scenario [3]

The calculation sheets are provided in Annex 3.2

Summary table: estimated exposure from medium/low pressure professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [3]	1 (No PPEs)	0.0074	1.6170	-	1.6244
	2 (gloves)	0.0074	0.7507	-	0.7581
	3 (gloves & impermeable coverall)	0.0074	0.0617	-	0.0691
	4 (new gloves per shift & impermeable coverall)	0.0074	0.0495	-	0.0569
	5 (gloves & double coverall)	0.0074	0.0327	-	0.0401
	6 (new gloves per shift & double coverall)	0.0074	0.0205	-	0.0279
	7 (new gloves per shift & double coverall & RPE-FFP1)	0.0018	0.0205	-	0.0223

Further information and considerations on scenario [3]

As we will see, the risk of this scenario is acceptable when the operator wears gloves and double coveralls (tier 5). Therefore, these will be the initial conditions of use for the scenario 3 when evaluated it in combination with other scenarios, such as e.g. cleaning of spraying equipment.

Combined scenarios

The Scenario 3 (medium/low pressure spraying by trained professionals and professionals) can combine with the following scenarios:

- Scenario 13. Cleaning of spraying equipment
- Scenario 14. Laudering working clothes.
- Scenario 15. Professional snading treated wood.

Summary table: combined systemic exposure from professional uses				
Scenarios combined	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 3 [5]	0.0074	0.0327	-	0.0401
Scenario 3 [6]	0.0074	0.0205	-	0.0279
Scenario 3 [7]	0.0018	0.0205	-	0.0223
Scenario 13 Tier 1 / No PPE	-	0.0359	-	0.0359
Scenario 13 Tier 2 / Gloves	-	0.0149	-	0.0149
Scenario 13 Tier 3 (gloves & coated coverall)	-	0.0036	-	0.0036
Scenario 13 Tier 4 (gloves & impermeable coverall)	-	0.0030	-	0.0030
Scenario 13 Tier 5 (gloves & double coverall)	-	0.0025	-	0.0025
Scenario 14 from scen 3 (Tier 2 / gloves)	-	0.0078	-	0.0078
Scenario 15 (Tier 1 / No PPE)	0.00024	0.00295	-	0.00319
Scenario 15 (Tier 2 / Gloves)	0.00024	0.000295	-	0.00054

Scenario [4]. Borehole pressure injection by professional operators.

Description of Scenario [4]		
The scenario describes the primary exposure for a professional (TP&P) user applying the RTU product to the drills using a wood injector (pressure impregnation). According to HEAdHoc Recommendation 6, v4, p25, proposed model to assess primary exposure to PT8 for professional borehole pressure impregnation application, Subsoil treatment model 2′ has been used. Mixing and loading are including in the application, therefore, likely to provide an overestimate of exposure for the ready-to-use formulations not requiring mixing, as this case. It provides data of dermal exposure (measurements of hand exposure inside gloves) and exposure by inhalation. Likewise, inhalation exposure is practically negligible compared to dermal, so the hypothetical use of respiratory protection is indifferent. It is assumed that protective gloves are worn by professional users (only in-glove exposure values are reported for the model relating to injection under pressure). The exposure duration is 80 min.		
	Parameters	Value

Tier 1 (gloves)	Content of permethrin (%w/w)	0.35%
	Body weight (adult)[1]	60 kg
	Dermal absorption	70%
	Inhalatory absorption	100%
	Inhalation rate (adult)[1]	1.25 m^3/h <> 0.0208 m^3/min
	Indicative value for dermal (hands) exposure inside gloves (75th percentile)[2]	8 mg/min
	Indicative value for dermal inhalation exposure (75th percentile)[2]	0.57 mg/m^3
	Exposure duration	80 min
	Penetration	100%

[1] *BHHEM, p15 & 16*
[2] *Recommendation No 6, v4, No 26 (p25)*

Calculations for Scenario [4]

The calculation sheets are provided in Annex 3.2

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/ PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [4]	1 / Gloves	0.00006	0.02613	-	0.02619
	2 / New gloves per shift	0.00006	0.01359	-	0.01365

Further information and considerations on scenario [4]

As we will see, the risk of this scenario is acceptable when the operator wears gloves (tier 1). Therefore, these will be the conditions of use for the scenario 4 when evaluated it in combination with other scenarios.
Borehole injection should always be combined with a curative superficial treatment.

Combined scenarios

The Subsoil treatment model 2 does not provide exposure parameters for the body, from which it follows that the exposure occurs essentially on the hands. Therefore, the contamination of the clothes here is negligible.
We do not have models for cleaning injection equipment, but we assume as a worst case an exposure similar to cleaning spraying equipment (evaluated in scenario 13).
Therefore, the Scenario 4 (borehole pressure injection by trained professionals and professionals) can combine with the following scenarios:

- Scenario 13. Cleaning of spray equipment
- Scenario 15. Professional sanding treated wood.

Summary table: combined systemic exposure from professional uses				
Scenarios combined	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 4 Tier 1 / Gloves	0.00006	0.02613	-	0.02619
Scenario 4 Tier 2 / New gloves per shift	0.00006	0.01359	-	0.01365
Scenario 13 Tier 1 / No PPE	-	0.0359	-	0.0359
Scenario 13 Tier 2 / Gloves	-	0.0149	-	0.0149
Scenario 13 Tier 3 (gloves & coated coverall)	-	0.0036	-	0.0036
Scenario 13 Tier 4 (gloves & impermeable coverall)	-	0.0030	-	0.0030
Scenario 13 Tier 5 (gloves & double coverall)	-	0.0025	-	0.0025
Scenario 15 (Tier 1 / No PPE)	0.00024	0.00295	-	0.00319
Scenario 15 (Tier 2 / Gloves)	0.00024	0.000295	-	0.00054

Scenario [5] Brushing and borehole pressure injection by professional operators.

Description of Scenario [5]
The scenario describes the primary exposure for a professional (TP&P) applying a more intensive treatment when curative treatment by borehole injection is joined to curative or preventive superficial treatment by brushing/rolling. Both treatments are described in the scenarios 1 and 4, which provide the following exposure values for this scenario 5.

Calculations for Scenario [5]

Starting from scenarios 1 and 4, which have presented an acceptable exposure, we have:
Scenario 5 (Tier 1) = Scen 1 (Tier 2) + Scen 4 (Tier 1) = 0.011+0.02619 = 0.037

Summary table: estimated exposure from brushing and borehole pressure injection professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 1	2/Gloves & coated coverall	3.114E-04	0.0104	-	0.011
Scenario 4	1/ Gloves	0.00006	0.02613	-	0.02619
Scenario 4	2/ New gloves per shift	0.00006	0.01359	-	0.01365
Scenario 5	1/ Gloves & coated coverall	3.71E-04	0.03653	-	0.037

Further information and considerations on scenario [5]

As we will see, the risk of this scenario is acceptable when the operator wears gloves and coated coveralls. Therefore, these will be the initial conditions of use for the scenario 5 when evaluated it in combination with other scenarios, such as e.g. brush cleaning.

Combined scenarios

We do not have models for cleaning injection equipment, but we assume as a worst case an exposure similar to cleaning spraying equipment (evaluated in scenario 13).

The Scenario 5 (Brushing and borehole pressure injection by professionals operators) can combine with the following scenarios:

- Scenario 12. Cleaning of a brush.
- Scenario 13. Cleaning spray equipment.
- Scenario 14. Laudering of working clothes.
- Scenario 15. Professional sanding treated wood.

Summary table: combined systemic exposure from professional uses				
Scenarios combined	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 5 (Tier1 / Gloves & coated coverall)	3.71E-04	0.03653	-	0.037
Scenario 12 (Tier 1/ No PPE)	-	0.0043	-	0.0043
Scenario 12 (Tier 2 / Gloves)	-	0.0004	-	0.0004
Scenario 13 (Tier 2 / Gloves)	-	0.0149	-	0.0149
Scenario 13 Tier 3 (gloves & coated coverall)	-	0.0036	-	0.0036
Scenario 14 from scenario 1 (Tier 1 / No PPE)	-	0.0029	-	0.0029
Scenario 15 (Tier 1 / No PPE)	0.00024	0.00295	-	0.00319
Scenario 15 (Tier 2 / Gloves)	0.00024	0.000295	-	0.00054

Scenario [6]] High pressure spraying and borehole pressure injection by professional operators.

Description of Scenario [6]
The scenario describes the primary exposure for a professional (TP&P) applying a more intensive treatment when curative treatment by borehole injection is joined to curative or preventive superficial treatment by high pressure spraying. Both treatments are described in the scenarios 2 and 4, which provide the following exposure values for this scenario 6.

Calculations for Scenario [6]

Starting from scenarios 2 and 4, which have presented an acceptable exposure, we have:
Scenario 6 (Tier 1) = Scen 2 (Tier 4) + Scen 4 (Tier 1) = 0.0367 + 0.02619 = 0.06289
Scenario 6 (Tier 2) = Scen 2 (Tier 6) + Scen 4 (Tier 2) = 0.0349 + 0.01365 = 0.04855
Scenario 6 (Tier 3) = Scen 2 (Tier 5) + Scen 4 (Tier 1) = 0.0112 + 0.02619 = 0.03739

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 2	4/ gloves & impermeable coverall	0.0011	0.0356	-	0.0367
	5/ (gloves & double coverall)	0.0011	0.0101	-	0.0112
	6/ new gloves per shift & impermeable coverall	0.0011	0.0338	-	0.0349
	7/ new gloves per shift & double coverall	0.0011	0.0083	-	0.0094
Scenario 4	1 (gloves)	0.00006	0.02613	-	0.02619
	2 (New gloves per shift)	0.00006	0.01359	-	0.01365
Scenario 6	1 (Gloves & impermeable coverall)	0.00116	0.0617	-	0.06289
	2 (New gloves per shift & impermeable coverall	0.00116	0.04739	-	0.04855
	3 (gloves & double coverall)	0.00116	0.03623	-	0.03739

Further information and considerations on scenario [6]

As we will see, the risk of this scenario is acceptable when the operator wears new gloves per shift and impermeable coveralls (tier 2). Therefore, these will be the starting conditions of use for the scenario 6 when evaluated it in combination with other scenarios, such as e.g. cleaning of spraying equipment.

Combined scenarios

The model used in injection (Subsoil treatment model 2) does not provide exposure parameters for the body, from which it follows that the exposure occurs essentially on the hands. Therefore, the contamination of the clothes from injection is negligible.

We do not have models for cleaning injection equipment, but we assume as a worst case an exposure similar to cleaning spraying equipment (evaluated in scenario 13).

Therefore, the Scenario 6 (HP spraying and borehole pressure injection by trained professionals and professionals) can combine with the following scenarios:

- Scenario 13. Cleaning of spray equipment (x 2)
- Scenario 14. Laudering of working clothes (from scenario 2)
- Scenario 15. Professional sanding treated wood.

Summary table: combined systemic exposure from professional uses				
Scenarios combined	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 6 (Tier 2 / New gloves per shift & impermeab coverall)	0.00116	0.04739	-	0.04855
Scenarios 6 (Tier 3 / Gloves & double coverall)	1.16E-03	0.03623	-	0.03739
Scenario 13 Tier 1 / No PPE	-	0.0359	-	0.0359
Scenario 13 Tier 2 / Gloves	-	0.0149	-	0.0149
Scenario 13 Tier 3 (gloves & coated coverall)	-	0.0036	-	0.0036
Scenario 13 Tier 4 (gloves & impermeable coverall)	-	0.0030	-	0.0030
Scenario 13 Tier 5 (gloves & double coverall)	-	0.0025	-	0.0025
Scenario 14 from scen 2 (Tier 2 / gloves)	-	0.0066	-	0.0066
Scenario 15 (Tier 1 / No PPE)	0.00024	0.00295	-	0.00319
Scenario 15 (Tier 2 / Gloves)	0.00024	0.000295	-	0.00054

Scenario [7]. Medium/low pressure spraying and borehole pressure injection by professional operators.

Description of Scenario [7]
The scenario describes the primary exposure for a professional (TP&P) applying a more intensive treatment when curative treatment by borehole injection is joined to curative or preventive superficial treatment by medium/low pressure spraying. Both treatments are described in the scenarios 3 (MLP spraying) and 4 (pressure injection), which provide the following exposure values for this scenario 7.

Calculations for Scenario [7]

Starting from scenarios 3 and 4, which have presented an acceptable exposure, we have:
Scenario 7 (Tier 1) = Scen 3 (Tier 5) + Scen 4 (Tier 1) = 0.0401+0.02619 = 0.06629
Scenario 7 (Tier 2) = Scen 3 (Tier 6) + Scen 4 (Tier 2) = 0.0279+0.01365 = 0.04155
Scenario 7 (Tier 3) = Scen 3 (Tier 7) + Scen 4 (Tier 2) = 0.0223+0.01365 = 0.03595

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 3	5 (gloves & double coverall)	0.0074	0.0327	-	0.0401
	6 (new gloves per shift & double coverall)	0.0074	0.0205	-	0.0279
	7 (new gloves per shift & double coverall & RPE-FFP1)	0.0018	0.0205	-	0.0223
Scenario 4	1 (gloves)	0.00006	0.02613	-	0.02619
	2 (New gloves per shift)	0.00006	0.01359	-	0.01365
Scenario 7	1 (gloves & double coverall)	0.00746	0.05883	-	0.0663
	2 (new gloves per shift & double coverall)	0.00746	0.03409	-	0.04155
	3 (new gloves per shift & double coverall & RPE-FFP1)	0.00186	0.03409	-	0.03595

Further information and considerations on scenario [7]

As we will see, the risk of this scenario is acceptable when the operator wears new gloves per shift and double coveralls (tier 2). Therefore, these will be the starting conditions of use for the scenario 7 when evaluated it in combination with other scenarios, such as e.g. cleaning of spraying equipment.

Combined scenarios

The model used in injection (Subsoil treatment model 2) does not provide exposure parameters for the body, from which it follows that the exposure occurs essentially on the hands. Therefore, the contamination of the clothes from injection is negligible.
We do not have models for cleaning injection equipment, but we assume as a worst case an exposure similar to cleaning spraying equipment (evaluated in scenario 13).
Therefore, the Scenario 7 (MLP spraying and borehole pressure injection by trained professionals and professionals) can combine with the following scenarios:

- Scenario 13. Cleaning of spray equipment (x 2)
- Scenario 14. Laudering of working clothes (from scenario 2)

- Scenario 15. Professional sanding treated wood.

Summary table: combined systemic exposure from professional uses				
Scenarios combined	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 7 (Tier 2 / New gloves per shift & double coverall)	0.00746	0.03409	-	0.0415
Scenario 7 (Tier 3 / New gloves per shift & double coverall 6 RPE-FFP1)	0.00186	0.03409	-	0.03595
Scenario 13 Tier 1 / No PPE	-	0.0359	-	0.0359
Scenario 13 Tier 2 / Gloves	-	0.0149	-	0.0149
Scenario 13 Tier 3 (gloves & coated coverall)	-	0.0036	-	0.0036
Scenario 13 Tier 4 (gloves & impermeable coverall)	-	0.0030	-	0.0030
Scenario 13 Tier 5 (gloves & double coverall)	-	0.0025	-	0.0025
Scenario 13 Tier 6 (new gloves per shift & impermea coverall)	-	0.0018	-	0.0018
Scenario 13 Tier 7 (new gloves per shift & double coverall)	-	0.0013	-	0.0013
Scenario 14 from scen 3 (Tier 2 / gloves)	-	0.0078	-	0.0078
Scenario 15 (Tier 1 / No PPE)	0.00024	0.00295	-	0.00319
Scenario 15 (Tier 2 / Gloves)	0.00024	0.000295	-	0.00054

Scenario [12]. Cleaning of a brush by adult

Description of Scenario [12]		
Primary exposure. The scenario describes an adult cleaning the brush after application of the product. The cleaning of a brush is assessed using "Exposure model: Washing out of a brush which has been used to apply a paint" (HEEG opinion 11). The model describes the cleaning as first dipping and swilling of the brush using fresh solvent, then squeezing by wrapping with a cleaning rag. Cleaning is assumed to be done in three steps. It reflects a worst-case situation which assumes all contamination remains on the hands at the end of the activity and is available for dermal absorption. The user is indifferent: it is valid for all three (TP, P & NP). According to the model, inhalation exposure is considered to be negligible. Only dermal exposure is relevant.		
	Parameters	Value
Tier 1 (no PPE)	Content of permetrhrin (%w/w)	0.35%
	Body weight (adult)[1]	60 kg
	Dermal absorption	70%
	Product density	0.7973 g/mL
	Volume of brush (corresponding to a brush size of 10x10x2 cm)[2]	200 ml
	Volume of product remaining on brush after application[2]	25 ml
	Volume of each washing solution[2]	400 ml
	Percentage of residues remaining in brush after each washing step[2]	10%
	Percentage of residues remaining in brush after squeezing (following each washing step)[2]	50%
	Percentage of residues absorbed by cloth[2]	90%
	Percentage of residues available to contaminate the hand[2]	10%
Tier 2 (gloves)	Gloves penetration[3]	10%

[1] *BHHEM, p 15*
[2] *HEEG opinion 11 (Primary exposurescenario –washing out of a brush which has been used to apply a paint).*
[3] *HEEG opinion 9 (Default protection factors for protective clothing and gloves).*

Calculations for Scenario [12]

The calculation tool provided in the HEEG opinion 11 is used. The calculation sheets are provided in Annex 3.2

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral Uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [12]	1 /No PPE	-	0.0043	-	0.0043
	2 /Gloves	-	0.0004	-	0.0004

Further information and considerations on scenario [12]

As we will see, the risk of this scenario is acceptable without wearing gloves.

Combined scenarios

The possible combinations of this scenario have already been considered (see scenarios 1 and 5).

Scenario [13]. Cleaning of spray equipment by professional operators.

Description of Scenario [13]		
Primary exposure. The scenario describes an operator cleaning the spray equipment after the application of the product. The model used is "Cleaning of spray equipment" from BEAT for dermal exposure estimation. The input-parameters are according to HEAdhoc Recommendation no. 4, 2014. This model does not provide an indicative value for inhalation exposure. However, inhalation exposure is considered to be negligible during cleaning of spray equipment. Exposure duration provided by the model is 20 min.		
	Parameters	Value
Tier 1 (No PPEs)	Content of permetrhrin (%w/w)	0.35%
	Dermal absorption	70%
	Body weight (adult)[1]	60 kg
	Exposure duration[2]	20 min
	Indicative value (hands)[2]	35.87 µL/min
	Indicative value (body)[2]	19.28 µL/min
	Product density	0.7973 g/mL <> mg/µL
	Penetration	100%
Tier 2 (gloves)	Penetration gloves[3]	10%
Tier 3 (gloves & coated coverall)	Penetration coated coverall[3]	10%
Tier 4 (gloves & impermeable coverall)	Penetration impermeable coverall[3]	5%
Tier 5 (gloves & double coverall)	Penetration double coverall[3]	1%
Tier 6 & 7 (new gloves per shift)	Penetration gloves[3]	5%

[1] *BHHEM, p 15*
[2] *Recommendation No 4. Cleaning of spray equipment in antifouling use (PT21)*
[3] *HEEG opinion 9 (Default protection factors for protective clothing and gloves).*

Calculations for Scenario [13]

The calculation sheets are provided in Annex 3.2

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 13	Tier 1 / No PPE	-	0.0359	-	0.0359
	Tier 2 / Gloves	-	0.0149	-	0.0149
	Tier 3 / gloves & coated coverall	-	0.0036	-	0.0036
	Tier 4 / gloves & impermeable coverall	-	0.0030	-	0.0030
	Tier 5 / gloves & double coverall	-	0.0025	-	0.0025
	Tier 6 / new gloves per shift & impermeable coverall	-	0.0018	-	0.0018
	Tier 7 / new gloves per shift & double coverall	-	0.0013	-	0.0013

Further information and considerations on scenario [13]

As we will see, the risk of this scenario is acceptable without wearing PPEs.

Combined scenarios

The possible combinations of this scenario have already been considered (see scenarios 2, 3, 6 and 7).

Scenario [14] Secondary exposure for a professional laundering contaminated work clothing

At TM III08 it was decided that this scenario should be considered where there was a possibility of workers taking soiled workwear home to launder, but that the exposure scenario was not required when wood preservatives were applied under industrial conditions. For industrial treatments, it was assumed the employer would employ professional means to launder contaminated workwear where contact with dirty clothes would be insignificant. This scenario has therefore only been considered for application methods which can be undertaken on a small scale by professionals (i.e. when application is through spraying, brush/roller application or injection). This is the case.

Description of Scenario [14]
An activity with potential for some contamination is the laundering of contaminated work clothing (e.g. a coverall). Persons at risk are adults. The relevant exposure route is

dermal. The exposure is considered acute intermediary, as it does not occur on a daily basis but may be longer-term.
This approach assumes that laundering occurs mechanically (in a domestic automatic washing machine) without any exposure risk to humans. Contact with effluent is unlikely to occur. The only likely exposure can occur during handling of the dirty clothing while preparing it for laundry. The exposure route is dermal (mainly to hands) and is dependent on the area concentration of dislodgeable residues on the surface of the clothing and the transfer coefficient to the human skin.
For the following it is assumed, that the clothing to be washed is a coverall used by a professional worker (considered to represent the worst case).
It is assumed that the coverall is washed after one working week, corresponding to 5 working days, and the total residues accumulate during this time and account for 5 times the daily deposits associated with the application method used. The highest exposure for the body (and therefore for work clothes that can be washed), occurs in tier 4 of the scenario 3 (medium / low pressure spraying).
The clothing contamination equals the highest potential body exposure (scenario 3, tier 4) minus the amount that penetrates through the clothing:
17760 – 177.6 = 17582.4 mg product/d.
The sum transfer area is determined by estimating how many times the coverall is touched by the hands while preparing it for laundering. 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 cm2. As a worst-case assumption, 30% of the residues in the touched area is transferred to the skin (transfer coefficient).
Note: As we have seen, the worst possible case for this scenario is to consider the work clothes from tier 4 of scenario 3, but the exposure generated by the work clothes from scenarios 2 (tier 4) and 1 will also be calculated.

	Parameters	Value
Tier 1 (No PPE)	Permethrin content (%w/w)	0.35%
	Potential daily clothing contamination (from scenario 3)	17582.40 mg product/d
	Potential weekly (5 days) clothing contamination (from scenario 3)	87912 mg product
	Potential daily clothing contamination (from scenario 2)	14823.04 mg product/d
	Potential weekly (5 days) clothing contamination (from scenario 2)	74115.2 mg product
	Potential daily clothing contamination (from scenario 1)	2.33 mg permethrin/d
	Potential weekly (5 days) clothing contamination (from scenario 1)	11.64 mg permethrin
	Surface medium-sized coverall[2]	22700 cm^2
	Skin surface area in contact[3]	1640 cm^2
	Percentage dislodgeable (Transfer coefficient)[1]	30%

	Penetration[4]	100%
	Dermal absorption	70%
Tier 2 (gloves)	Penetration[4]	10%

[1] *BHHEM, v1, p 171. Cotton, knitwear, plastic, wood Dried fluid 30 % - wet hand*

[2] *Commonly accepted estimated value*

[3] *Based on a surface area of both palms of 410 cm2 and total surface of both hands of 820 cm2; see HEAdhoc Recommendation no. 14.*

[4] *HEEG opinion 9*

Calculations for Scenario [14]

The calculation sheets are provided in Annex 3.2

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 14 (from scen 3)	1 No PPE	-	0.0778	-	0.0778
Scenario 14 (from scen 3)	2 (gloves)	-	0.0078	-	0.0078
Scenario 14 (from scen 2)	1 No PPE	-	0.0656	-	0.0656
Scenario 14 (from scen 2)	2 (gloves)	-	0.0066	-	0.0066
Scenario 14 (from scen 1)	1 No PPE	-	0.0029	-	0.0029

Further information and considerations on scenario [14]

As we will see, the risk of this scenario 14 is acceptable wearing gloves (tier 2) for work clothes used in scenarios 2 and 3. For work clothes used in scenario 1 (brushing), it is acceptable without using gloves.

Combined scenarios

As a worst case, the exposure obtained in this scenario is considered, combining it with the rest of the scenarios (see scenarios 1,2,3,5,6 and 7).

Scenario [15]. Secondary exposure for professional users sanding treated wood

Professional (secondary) exposure to 'New Serpol Basic' for an adult professional sanding treated timber using a hand-held power sander has been estimated based on the following

assumptions/parameters described in the TNsG on Human Exposure to Biocidal Products Part 3, p50-51 as revised by User Guidance version 1 p55-56 (EC, 2002).

Description of Scenario [15]

Cutting and sanding treated wood by professional worker is considered a chronic exposure scenario. The professional user may be instructed to wear protection equipments (PPEs), including RPE if necessary.
A worse scenario for this product is for superficial treatment curative aim, considered the highest-end-retention with an application rate of 552 mL/m^2 (curative superficial treatment 300 mL/m^2 + curative injection treatment 252 mL/m^2 ; that is, at a relative b.p. density of 0.7973 g/ml, the application rate is 440.1 g/m^2).
The duration of a sanding task for professionals is estimated to 6 hours.
As a worst case it is also assumed that wood sanded has a density of 0.4 g/cm^3.

Inhalation route:
A person (professional) is sanding the surface of treated wood (4 cm x 4 cm x 2.5 m, surface area of 4032 cm^2) (TNsG 2002, Part 3, p.50). The active substance is in the outer 1 cm layer, where 100% retention by the wood is assumed.
The Operator Exposure Limit (OEL) of the EU for respirable hardwood dust is 5 mg/m^3.

Dermal route (hands):
The surface area of both palms of hands is 410 cm^2 and during prolonged and repeated contact 20% of the hand is contaminated and this is the assumed transfer coefficient per day. The transfer efficiency is 2% for rough sawn wood.

	Parameters	Value
Tier 1	Volume of wood to be sanded in 1h[1]	4000 cm^3
	Product application rate (dose)	552 ml/m^2 <>44.01 mg/cm^2
	Product density	0.7973 g/ml
	Wood density[2]	0.4 g/ml
	Dust concentration in air (occupational exposure limit for wood dust)[5]	5 mg/m^3
	Inhalation rate[3]	1.25 m^3/h
	Inhalation absorption	100%
	Dermal absortion	70%
	Exposure duration[1]	6 h
	Body weight[3]	60 kg
	Transfer efficiency coefficient-dislodgeable residue wood to hands[4]	2%
	Hand surface[3]	410 cm^2
	Proportion of hand surface area contaminated[1]	20%
Tier 2 / Gloves	Penetration	10%

[1] TNsG on Human Exposure to Biocidal Products Part 3, p50-51 as revised by User Guidance version 1 p55-56 (EC, 2002)

[2] Manual of Technichal Agreements (MOTA, v6, p 30, question 4.2.5)

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

[4] *Biocides Human Health Exposure Methodology* (BHHEM 2015, p. 171).Rough sawn wood / dried fluid

[5] Directive 2004/37/EC

Calculations for Scenario [15]

Relevant calculations are included in Annex 3.2

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 15	1 / No PPEs	0.00024	0.00295	-	0.00319
Scenario 15	2 / Gloves	0.00024	0.000295	-	0.00054

Further information and considerations on scenario [15]

As we will see, the risk of this scenario 15 is acceptable without wearing PPEs.

Combined scenarios

The possible combinations of this scenario have already been considered (see scenarios 1, 2, 3, 4, 5 and 6).

Non-professional exposure

Scenario [8]. Application – Brushing and rolling by non-professionals

Description of Scenario [8]		
Primary exposure. The activities of the non-professional users are stirring the RTU product containing 0.35% permethrin and applying it to wood using a brush/roll indoors. New Serpol Basic is applied indoors by non-professionals with a brush/roll at a maximum of 239.1 g/m^2 (equivalent to 300 mL/m^2) with curative aim or 200 g/m^2 with preventive aim. The TNsG 2002 "Consumer painting model 1" according to Biocides Human Health Exposure Methodology, chapter 6.2, p. 216 (version 1, October 2015) is used for dermal and inhalation exposure estimation. The model is based on consumer exposure during brush painting 16 m^2 of rough wooden joists (overhead) and the undersides of floorboards, and includes decanting. According to Recommendation no. 10, painting of rougher wood surface would tend to favour generation of aerosols and splashes. This model can be assumed to represent the very worst case while painting. The exposure duration is 26.5 min (according to Recommendation no. 10).		
	Parameters	Value
Tier 1 (No PPEs)	Content of permethrin (%w/w)	0.35%
	Body weight (adult)[1]	60 kg
	Dermal absorption	70%
	Inhalatory absorption	100%
	Inhalation rate (adult)[1]	1.25 m^3/h <> 0.0208 m^3/min
	Indicative (75th % value) hands & forearms exposure[2]	150 mg/min
	Indicative (75th % value) leg, feet & face exposure[2]	35.7 mg/min
	Indicative (75th % value) inhalation exposure[2]	3.1 mg/m^3
	Exposure duration[3]	26.5 min

[1] *BHHEM, p15 & 16*

[2] *BHHEM, p 216*

[3] *Recommendation No. 10, p 10 (HSL 2001- Consumer Product Painting Model 1)*

Calculations for Scenario [8]

The calculation sheets are provided in Annex 3.2

Summary table: estimated exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 8	1/ No PPE	0.0001	0.2009	-	0.201
	2/ (Refined approach) No PPE	0.0005	0.0802	-	0.081

Further information and considerations on scenario [8]

As we will see, the risk of this scenario is acceptable in tier 1 (no PPE is needed).
If necessary, in a second step (tier 2) we would take a more refined approach using the harmonized parameters in Recommendation 10 (see calculations in scenario 11).

Combined scenarios

It is assumed that, in the same day, a non-professional user will only perform the task of applying the product and cleaning the brush.
The Scenario 8 (Brushing and rolling by non-professionals) can combine with the following scenario:

- Scenario 12 (Cleaning of a brush)

Summary table: combined systemic exposure from non-professional uses				
Scenarios combined	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 8 (No PPE)	0.0001	0.2009	-	0.201
Scenario 12 (No PPE)	-	0.0043	-	0.0043

Scenario [9]. Spraying by non-professionals

Description of Scenario [9]
Primary exposure. New Serpol Basic can be applied by non-professional users as a spray treatment. It is applied at a maximum of 239.1 g/m^2 (equivalent to 300 mL/m^2) with curative aim or 200 g/m^2 with preventive aim. The use of 'Consumer product spraying and dusting model 3' (BHHEM, v1, p. 218 & 346) is considered appropriate in this scenario. This model relates to surface spraying of rough wooden joists and the undersides of floorboards, overhead indoors, using a hand-held medium pressure sprayer (medium/coarse spray). It provides data of dermal and inhalation exposure. Loading is included. For non-professional use, a spray duration of 40 minutes/day (1-2 times per year) is assumed (User Guidance 2002 p. 42). The Tier 1 assessment assumes that no clothing or gloves are worn.

	Parameters	Value
Tier 1	Content of permethrin (%w/w)	0.35%
	Body weight (adult)[1]	60 kg
	Dermal absorption	70%
	Inhalatory absorption	100%
	Inhalation rate (adult)[1]	1.25 m^3/h <> 0.0208 m^3/min
	Indicative (75th % value) hands & forearms exposure[2]	176 mg/min
	Indicative (75th % value) leg, feet & face exposure[2]	120 mg/min
	Indicative (75th % value) inhalation exposure[2]	115 mg/m^3
	Exposure duration[3]	40 min

[1] *BHHEM, p15 & 16*

[2] *BHHEM, p 218*

[3] *Human Exposure to Biocidal Products (TNsG 2002) User Guidance version 1, p. 42*

Calculations for Scenario [9]

The calculation sheets are provided in Annex 3.2

Summary table: estimated exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 9	1 (No PPEs)	0.0056	0.4835	-	0.489

Further information and considerations on scenario [9]

As we will see, the risk of this scenario is acceptable in tier 1 (no PPE is worn).

Combined scenarios

It is assumed that, in the same day, a non-professional user will only perform the task of applying the product and, if necessary cleaning the sprayer.

The exposure estimated value for this scenario is very high, therefore, to represent an acceptable risk, the non-professional user should not contemplate combined scenarios.
In this sense, it is advised that no cleaning will take place. The product is only used incidentally and the sprayer will be disposed off after use. This will also prevent possible residual contamination following re-use for other purposes. So, the following sentence is included in the use-specific risk mitigation measures for non-professional uses:
"After use, dispose of the sprayer".

Scenario [10]. Injection by non-professional users

Primary exposure. A non-professional user applies the product on the to be treated wood by injection.
For non-professional users there is no any exposure specific model, but the exposure during the spraying or the brushing application is assumed to be a worse case than during injection. Therefore, for the non-professional user, it is assumed that exposure by injection is covered by the other two application methods.
The product is only used incidentally and the injector will be disposed off after use.
Borehole injection should always be combined with a curative superficial treatment

Scenario [11] Brushing combined with injection by non-prfessional users.

Description of Scenario [11]		
Primary exposure. No specific model for injection is available to assess exposure. Considering that the injection will not lead to higher exposure than brushing application, for this scenario, in a conservative approach, the exposure values of the exposure model taken for the brushing application have been multiplied by two in order to simulate an application by brushing followed by an application by injection. Following a conservative approach, scenario 8 has been evaluated with model "Consumer product painting model 1", which according to Recommendation No. 10 supposes an overestimation of exposure. Therefore, here we will address a more refined approach to calculate exposure by brushing, using the harmonized values proposed in Recommendation no. 10. Likewise, and being conservative in this regard, an exposure time of 240 min is considered, typical of professional users.		
	Parameters	Value
Tier 1 (No PPE) /Consumer product painting model 1	Parameters from scenario 8	Values x 2
Tier 2 (No PPE)/ Harmonisation in Recomm. 10	Content of permethrin (%w/w)	0.35%
	Body weight (adult)[1]	60 kg
	Product density	0.7973 g/mL (or mg/µL)
	Dermal absorption	70%
	Inhalatory absorption	100%
	Inhalation rate (adult)[1]	1.25 m^3/h <> 0.0208 m^3/min
	Indicative (75th % value) hands exposure[2]	2 x 9.14 µL/min
	Indicative (75th % value) body exposure[2]	2 x 1.12 µL/min
	Indicative (50th % value) inhalation exposure[2]	2 x 1.63 mg/m^3
	Exposure duration[3]	240 min

[1] *BHHEM, p15 & 16*

[2] *Recommendation No. 10, p 6, Table 1*

[3] *Recommendation No. 6, v4, p 24*

Calculations for Scenario [11]

The calculation sheets are provided in Annex 3.2

Summary table: estimated exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 11	1 / No PPE	0.0004	0.8038	-	0.804
Scenario 11	2 / No PPE (Refined approach)	0.0009	0.1603	-	0.161

Further information and considerations on scenario [11]

As we will see, the risk of this scenario is acceptable in tier 2 (refined approach, but no PPE is worn).

Combined scenarios

It is assumed that, in the same day, a non-professional user will only perform the task of applying the product and cleaning the brush. The product is only used incidentally and the injector will be disposed off after use

Summary table: combined systemic exposure from non-professional uses				
Scenarios combined	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 11 / tier 2 (No PPE)	0.0009	0.1603	-	0.161
Scenario 12 / tier 1 (No PPE)	-	0.0043	-	0.0043

Scenario [12]. Cleaning of a brush by adult

Description of Scenario [12]
Primary exposure. The scenario describes an adult cleaning the brush after application of the product. The cleaning of a brush is assessed using "Exposure model: Washing out of a brush which has been used to apply a paint" (HEEG opinion 11). The model describes the cleaning as first dipping and swilling of the brush using fresh solvent, then squeezing by wrapping

with a cleaning rag. Cleaning is assumed to be done in three steps. It reflects a worst-case situation which assumes all contamination remains on the hands at the end of the activity and is available for dermal absorption. The user is indifferent: it is valid for all three (TP, P & NP). According to the model, inhalation exposure is considered to be negligible. Only dermal exposure is relevant.		
	Parameters	Value
Tier 1 (no PPE)	Content of permetrhrin (%w/w)	0.35%
	Body weight (adult)[1]	60 kg
	Dermal absorption	70%
	Product density	0.7973 g/mL
	Volume of brush (corresponding to a brush size of 10x10x2 cm)[2]	200 ml
	Volume of product remaining on brush after application[2]	25 ml
	Volume of each washing solution[2]	400 ml
	Percentage of residues remaining in brush after each washing step[2]	10%
	Percentage of residues remaining in brush after squeezing (following each washing step)[2]	50%
	Percentage of residues absorbed by cloth[2]	90%
	Percentage of residues available to contaminate the hand[2]	10%

[1] *BHHEM, p 15*
[2] *HEEG opinion 11 (Primary exposurescenario –washing out of a brush which has been used to apply a paint).*

Calculations for Scenario [12]

The calculation tool provided in the HEEG opinion 11 is used. The calculation sheets are provided in Annex 3.2

Summary table: estimated exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral Uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [12]	1 /No PPE	-	0.0043	-	0.0043

Further information and considerations on scenario [12]

As we will see, the risk of this scenario is acceptable without wearing gloves.

Combined scenarios

The possible combinations of this scenario have already been considered (see scenarios 8 and 11).

Exposure of the general public

Scenario [16]. Secondary exposure for non-professionals during sanding and cutting treated wood

Secondary exposure to 'New Serpol Basic' for an non-professional adult sanding treated timber using a hand-held power sander has been estimated based on the following assumptions/parameters described in the TNsG on Human Exposure to Biocidal Products Part 3, p50-51 as revised by User Guidance version 1 p55-56 (EC, 2002). The activity would be carried out on an occasional basis and therefore would involve an acute, not chronic, exposure.

Description of Scenario [16]		
Secondary acute exposure. A worse scenario for this product is for superficial treatment curative aim, considered the highest-end-retention with an application rate of 552 mL/m^2 (curative superficial treatment 300 mL/m^2 + curative injection treatment 252 mL/m^2 ; that is, at a relative b.p. density of 0.7973 g/ml, the application rate is 440.1 g/m^2). The duration of a sanding task for professionals is estimated to 1 hour. As a worst case it is also assumed that wood sanded has a density of 0.4 g/cm^3. During sawing/sanding of treated wood, dermal and inhalation exposure of adults is considered. Exposure towards dust containing permethrin is considered to be associated with systemic exposure: *Inhalation route:* An adult is sanding the surface of treated wood (4 cm x 4 cm x 2.5 m, surface area of 4032 cm^2) (TNsG 2002, Part 3, p.50). The active substance is in the outer 1 cm layer, where 100% retention by the wood is assumed. The Operator Exposure Limit (OEL) of the EU for respirable hardwood dust is 5 mg/m^3. *Dermal route (hands):* The surface area of both palms of hands is 410 cm^2 and during prolonged and repeated contact 20% of the hand is contaminated and this is the assumed transfer coefficient per day. The transfer efficiency is 2% for rough sawn wood.		
	Parameters	Value
Tier 1	Volume of wood to be sanded in 1h[1]	4000 cm^3
	Product application rate (dose)	552 ml/m^2 <>44.01 mg/cm^2
	Product density	0.7973 g/ml
	Wood density[2]	0.4 g/ml
	Dust concentration in air (occupational exposure limit for wood dust)[5]	5 mg/m^3
	Inhalation rate[3]	1.25 m^3/h
	Inhalation absorption	100%
	Dermal absorption	70%

	Exposure duration[1]	1 hour
	Body weight[3]	60 kg
	Transfer efficiency coefficient-dislodgeable residue wood to hands[4]	2%
	Hand surface[3]	410 cm^2
	Proportion of hand surface area contaminated[1]	20%

[1] TNsG on Human Exposure to Biocidal Products Part 3, p50-51 as revised by User Guidance version 1 p55-56 (EC, 2002)

[2] Manual of Technichal Agreements (MOTA, v6, p 30, question 4.2.5)

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

[4] Biocides Human Health Exposure Methodology (BHHEM 2015, p. 171).Rough sawn wood / dried fluid

[5] Directive 2004/37/EC

Calculations for Scenario [16]

Relevant calculations are included in Annex 3.2

Summary table: estimated exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 16	1 / No PPE	4.04E-05	2.95E-03	-	0.00299

Further information and considerations on scenario [16]

As we will see, the risk of this scenario 16 is acceptable without wearing PPEs.

Combined scenarios

It is not foreseeable that, in the case of a non-professional user, the sanding / sawing of the treated wood will be carried out the same day of treatment. Therefore, possible combined scenarios are not considered.

Scenario [17]. Secondary exposure (acute) for a toddler chewing treated wood off-cut

It is assumed that infants and toddlers may play nearby persons who are handling and sawing New Serpol Basic pre-treated wood. The infant chews on one of the pieces of wood. Exposure of infants resulting from chewing of treated wood was estimated using the example calculation provided in the TNsG, 2002, part 3 (worked examples, page 50) as revised by User Guidance version 1, p56 (june 2002).

Description of Scenario [17]		
Secondary acute exposure. A worse scenario for this product is for curative treatment, considered the highest-end-retention with an application rate of 552 mL/m^2 (curative superficial treatment 300 mL/m^2 + curative injection treatment 252 mL/m^2 ; that is, at a relative b.p. density of 0.7973 g/ml, the application rate is 440.1 g/m^2). This scenario is considered to represent the worst case for secondary oral exposure. This is an incidental event and exposure duration is therefore best described as acute. For simplification, 100% retention of all active substances in the wood is assumed. It is also assumed that all a.s. is bound in the outermost 1 cm of the timber volume and that this part is accessible to infants for chewing. It is further assumed that only a small fraction of the total preservative become released by chewing, as most of it is bound inside of the piece of wood. A reasonable assumption is that 10% may become released. It is considered that an infant (from 1 to 12 months of age and 8 kg of weight) is always supervised by an adult and therefore, the exposure of a toddler (of 1 to 2 years of age and 10 kg of weight) is assumed as the worst possible case.		
	Parameters	Value
Tier 1	Wood chip size[1]	16cm^3
	Surface of wood composite chip treated[1]	16 cm^2
	Extraction percentage by chewing[1]	10%
	Body weight[2]	10 kg
	Product application rate (dose)	552 ml/m^2 <>44.01 mg/cm^2
	Oral absoption[3]	100%
	Content of permethrin in the product	0.35%

[1] *TNsG on Human Exposure to Biocidal Products, 2002, Part 3, p50*

[2] *HEAdhoc Recommendation no. 14*

[3] *Permethrin PT8 Assessment Report (2014)*

Calculations for Scenario [17]

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 17	1 / No PPE	-	-	0.0246	0.0246

Further information and considerations on scenario [17]

As we will see, the risk of this scenario 17 is acceptable.

Scenario [18]. Secondary exposure (chronic) for a toddler playing on playground wethered structures and mouthing.

Toddlers who play on treated wooden playground wethered structures may be dermal and oral exposure to the product. According to the application rate of the product, the worst case corresponds to wood subjected to a curative treatment, considered the highest-end-retention with an application rate of 552 mL/m^2 (curative superficial treatment 300 mL/m^2 + curative injection treatment 252 mL/m^2 ; that is, at a relative b.p. density of 0.7973 g/ml, the application rate is 440.1 g/m^2).
Following the indications of TNsG, it is considered a secondary exposure from a chronic point of view.

Description of Scenario [18]		
Secondary chronic exposure. 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, v1 and on the HEAdhoc Recommendation no. 5 (2015).		
	Parameters	Value
Tier 1	Toddler body weight[1]	10 kg
	Product application rate (curative)	552 ml/m^2<>44.01 mg/cm^2
	Contact surface (hands)[1]	230.4 cm^2
	Contaminated area[2]	20%
	Dislogeable fraction[3]	2%
	Transferable coefficient of dried paint from hand to mouth[4]	50%
	Dermal absorption	70%
	Oral absorption	100%

[1] HEAdhoc Recommendation no. 14
[2] TNsG, 2002, v1, part 3, p 51
[3] TNsG, 2002, v1, part 2, p 204 (rough sawn wood-dried fluid)
[4] Recommendation no 5 (Consexpo. Pest Control Fact Sheet, 2006; section 2.2.7 "Parameters for hand-mouth contact")

Calculations for Scenario [18]

Summary table: estimated exposure from toddler playing on playground wethered structures and mouthing after curative treatment.					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 18	1 / No PPE	-	0.00994	0.00213	0.01207

Further information and considerations on scenario [18]

As we will see, the risk of this scenario 18 is acceptable.

Scenario [19]. Secondary exposure general public – Inhalation volatilased residues indoors

This scenario is considered for the General public that stays in a premise where the wood has been treated with the biocide product.

Description of Scenario [19]

The exposure assessment due to this scenario has been carried out according to HEEG Opinion 13.
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 each active substance:

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:

$$0.328 \frac{mw\ vp}{AEL_{long\text{-}term}} \leq 1$$

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 beconsidered to be negligible.

The product has one active substance, and based on the results table below, the inhalation exposure of permethrin should not be included in the risk assessment.

Active substance	Vapour pressure a.s.	Molecular weight a.s.	AEL long term (mg a.s./kg/bw/d)	Constant	Result	**Negligible / Included**
Permethrin	2.86E-06	391.28	0.05	0.328	7.34E-03	negligible

Monitoring data

No further information on surveys or studies with the actual biocidal product or with a surrogate were submitted.

Dietary exposure

The biocidal product is only intended to be used for the preservation of wood that does not come into direct contact with food, feedstuff or livestock animals and therefore dietary exposure assessment is not necessary. Furthermore, the following risk mitigation measure is proposed to avoid direct or accidental contamination of food/feedstuff:

- Do not use on wood which may come into direct contact with food, feeding stuffs and livestock animals.

Estimating Livestock Exposure to Active Substances used in Biocidal Products

Food, drinking water or livestock exposure by permethrin can be excluded when applied the product according to the recommended uses.

Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)

Food, drinking water or livestock exposure by permethrin can be excluded when applied the product according to the recommended uses.

Estimating transfer of biocidal active substances into foods as a result of non-professional use

Food, drinking water or livestock exposure by permethrin can be excluded when applied the product according to the recommended uses.

Information of non-biocidal use of the active substance

Permethrin:

Summary table of other (non-biocidal) uses			
	Sector of use	**Intended use**	**Reference value(s)**
1.	Plant protection products	COMMISSION DECISION of 27 December 2000 concerning the non-inclusion of permethrin in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance	(1)
2.	Veterinary use	Antiparasitic agents/Agents againstectoparasites	(2)

(1) COMMISSION REGULATION (EU) 2017/623 of 30 March 2017 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acequinocyl, amitraz, coumaphos, diflufenican, flumequine, metribuzin, permethrin, pyraclostrobin and streptomycin in or on certain products.

(2) COMMISSION REGULATION (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin.

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

Mylva, S.A. has been granted with letter of access to the active substances data Permethrin. Permethrin and the biocidal product are produced in the EU. The exposure during the production of the acive substances and the formulation of the biocidal product are not assessed under the requirements of the BPR. However it is assumed that the production, formulation and disposal of the product, are performed in conformity with national and European occupational safety and health regulations.

Aggregated exposure

Aggregated exposure is not relevant.

Summary of exposure assessment

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group**	**Tier/PPE**	**Estimated total uptake (mg/kg bw/d)**
1. Brushing	Trained professional & professional	T1/ No PPE	0.142
		T2/ Gloves & coated coverall	**0.011**
2. High pressure spraying	Trained professional & professional	T1/ No PPE	0.9001
		T2/ Gloves	0.6420
		T3/ Gloves & coated coverall	0.0685
		T4/ Gloves & impermeable coverall	**0.0367**
		T5/ Gloves & double coverall	**0.0112**
		T6/ New gloves per shift & impermeable coverall	**0.0349**
		T7/ New gloves per shift & double coverall	**0.0094**
3. Medium/ low pressure spraying	Trained professional & professional	T1/ No PPE	1.6244
		T2/ Gloves	0.7581
		T3/ Gloves & impermeable coverall	0.0691
		T4/ New gloves per shift & impermeable coverall	0.0569
		T5/ Gloves & double coverall	**0.0401**
		T6/ New gloves per shift & double coverall	**0.0279**
		T7/ New gloves per shift & double coverall & RPE-FFP1	**0.0223**
4. Pressure injection	Trained professional & professional	T1/ Gloves	**0.02619**
		T2/ New gloves per shift	**0.01365**
5. brushing & pressure injection	Trained professional & professional	T1/ Gloves & coated coverall	**0.037**
6. HP spraying & pressure injection	Trained professional & professional	T1/ Gloves & impermeable coverall	0.06289
		T2/ New gloves per shift & impermeable coverall	**0.04855**
		T3/ Gloves & double coverall	**0.03739**
		T1/ Gloves & double coverall	0.0663

7. MLP spraying & pressure injection	Trained professional & professional	T2/ New gloves per shift & double coverall	**0.04155**
		T3/ New gloves per shift & double coverall & RPE-FFP1	**0.03595**
8. Brushing	Non-prfessional	T1/ No PPE	**0.201**
		T2 (refined approach)/ No PPE	**0.081**
9. Spraying	Non-prfessional	T1/ No PPE	**0.489**
10. Injection	Non-prfessional	T1/ No PPE	Covered
11. Brushing & injection	Non-prfessional	T1/ No PPE	0.804
		T2/ No PPE (Refined approach)	**0.161**
12. Cleaning of a brush	Trained professional & Professional & Non-professional	T1/ No PPE	**0.0043**
		T2/ Gloves	**0.0004**
13. Cleaning of sprayer	Trained professional & Professional	Tier 1 / No PPE	**0.0359**
		Tier 2 / Gloves	**0.0149**
		Tier 3 / gloves & coated coverall	**0.0036**
		Tier 4 / gloves & impermeable coverall	**0.0030**
		Tier 5 / gloves & double coverall	**0.0025**
		Tier 6 / new gloves per shift & impermeable coverall	**0.0018**
		Tier 7 / new gloves per shift & double coverall	**0.0013**
14. Work clothes launder	Trained professional & Professional	T1/ No PPE (clothes from scen 3)	0.0778
		T2/ Gloves (clothes from scen 3)	**0.0078**
		T1/ No PPE (clothes from scen 2)	0.0656
		T2/ Gloves (clothes from scen 2)	**0.0066**
		T1/ No PPE (clothes from scen 1)	**0.0029**
15. Sanding treated wood	Trained professional & Professional	T1/ No PPE	**0.00319**
		T2/ Gloves	**0.00054**
16. Sanding treated wood	Non-professional	T1/ No PPE	**0.00299**

17. Toddler chewing treated wood	Bystanders	T1/No PPE	**0.0246**
18. Toddler playing on playground wethered structures	Bystanders	T1/No PPE	**0.01207**
19. Inhalation volatilased residues indoor	Bystanders	T1/No PPE	Negligible

2.2.6.3 Risk characterisation for human health

(NA-AAT) January 2023: As a result of the comment phase opened during the MRS procedure with Greece, this section 2.2.6.3 has been amended, in order to include certain harmonized and commonly accepted RMMs for products containing pyrethrins / pyrethroids.

Reference values to be used in Risk Characterisation

Reference	Study	NOAEL (LOAEL)	AF[1]	Correction for oral absorption	Value
AELshort-term	Acute effect study in rats	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 AF of 100 is applied on the basis of a 10-fold factor for inter-species variation and a 10 factor for intra-species variation.

[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

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

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 direct application.gel (EFSA Journal 2017; 15(6):4873)

General remark: : the defaults given by the EFSA guidance are unrealistically high when compared to dermal absorption data available on permethrin. Therefore, the exposure values obtained here are most likely overestimated.

Value(s) used in the Risk Assessment – Oral & Inhalation absorption

Substance	Permethrin
Values	100%
Justification for the selected value(s)	According to Assessment Report of permethrin PT8 (Ireland. April 2014)

Maximum residue limits or equivalent

MRLs or other relevant reference values	Reference	Relevant commodities	Value
MRL	Reg. (EU) 396/2005 Reg. (EC) 839/2008 Reg. (UE) 2017/623 (PPP)	All	0.05* or 0.1* mg/kg
	Reg. (EC) 37/2010 (VMP)	Bovine edible tissues	Fat: 0.5 mg/kg Muscle, liver, kidney and milk: 0.05 mg/kg

*MRL set at LOQ
PPP: plant protection product
VMP: veterinary medicinal product

As the product is to be used for preventive and curative treatment of interior woods that do not come in direct contact with food and feedstuff, the existing MRLs are not expected to be exceeded.

Risk for industrial users

No industrial use is foreseen.

Risk for trained professional users

Trained professional users are expected to use the biocidal product on a daily basis. Hence exposure levels are compared to $AEL_{long\text{-}term}$ for risk assessment purposes.

Systemic effects
In the following table, the results are provided for permethrin.

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	$AEL_{long\text{-}term}$ mg/kgbw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Brush & roll application / **Scenario 1**	1/No PPE	5	0.05	0.142	284	No
	2/Gloves & coated coverall	5	0.05	0.011	**22**	**Yes**
Spray HP (high pressure) application / **Scenario 2**	1/ No PPE	5	0.05	0.9001	1800	No
	2/ gloves	5	0.05	0.6420	1284	No
	3/ gloves & coated coverall	5	0.05	0.0685	137	No
	4/ gloves & impermeable coverall	5	0.05	0.0367	**73**	**Yes**

	5/ gloves & double coverall	5	0.05	0.0112	**22**	**Yes**
	6/ New gloves per shift & impermeable coverall	5	0.05	0.0349	**70**	**Yes**
	7/ New gloves per shift & double coverall	5	0.05	0.0094	**19**	**Yes**
Spray MLP (medium / low pressure) application / **Scenario 3**	1/ No PPE	5	0.05	1.6244	3249	No
	2/ gloves	5	0.05	0.7581	1516	No
	3/ gloves & impermeable coverall	5	0.05	0.0691	138	No
	4/ new gloves per shift & imperm coverall	5	0.05	0.0569	114	No
	5/ gloves & double coverall	5	0.05	0.0401	**80**	**Yes**
	6/ new gloves per shift & double coverall	5	0.05	0.0279	**56**	**Yes**
	7/ new gloves per shift & double coverall & RPE-FFP1	5	0.05	0.0223	**45**	**Yes**
Pressure injection application / **Scenario 4**	1/ gloves	5	0.05	0.02619	**52**	**Yes**
	2/ new gloves per shift	5	0.05	0.01365	**27**	**Yes**
Brush and pressure injection application / **Scenario 5**	1/ gloves & coated coverall	5	0.05	0.037	**74**	**Yes**
Spray HP and pressure injection application / **Scenario 6**	1/ gloves & impermeable coverall	5	0.05	0.06289	125	No
	2/ new gloves per shift & impermea coverall	5	0.05	0.04855	**97**	**Yes**
	3/ gloves & double coverall	5	0.05	0.03739	**74**	**Yes**
Spray MLP and pressure injection application / **Scenario 7**	1/ gloves & double coverall	5	0.05	0.0663	133	No
	2/ new gloves per shift & double coverall	5	0.05	0.04155	**83**	**Yes**

	3/ new gloves per shift & double coverall & RPE-FFP1	5	0.05	0.03595	**72**	**Yes**
Cleaning of brush / **Scenario 12**	1/ No PPE	5	0.05	0.0043	**9**	**Yes**
	2/ Gloves	5	0.05	0.0004	**1**	**Yes**
Cleaning of spray equipment / **Scenario 13**	1/ No PPE	5	0.05	0.0359	**72**	**Yes**
	2/ gloves	5	0.05	0.0149	**30**	**Yes**
	3/ gloves & coated coverall	5	0.05	0.0036	**7**	**Yes**
	4/ gloves & impermeable coverall	5	0.05	0.0030	**6**	**Yes**
	5/ gloves & double coverall	5	0.05	0.0025	**5**	**Yes**
	6/ new gloves per shift & impermeable coverall	5	0.05	0.0018	**4**	**Yes**
	7/ new gloves per shift & double coverall	5	0.05	0.0013	**3**	**Yes**
Laundering work clothes / **Scenario 14**	1/ No PPE (from scen 3)	5	0.05	0.0778	156	No
	2/ Gloves (from scen 3)	5	0.05	0.0078	**16**	**Yes**
	1/ No PPE (from scen 2)	5	0.05	0.0656	131	No
	2/ Gloves (from scen 2)	5	0.05	0.0066	**13**	**Yes**
	1/ No PPE (from scen 1)	5	0.05	0.0029	**6**	**Yes**
Sanding treated wood / Scenario 15	1/ No PPE	5	0.05	0.00319	**1**	**Yes**
	2/ Gloves	5	0.05	0.000538	**1**	**Yes**

Combined scenarios

For each combined scenario, the starting point is the individual scenarios with acceptable risk and, initially, with the least possible protection.
In the following table, the results are provided for permethrin.

Scenarios combined	**Tier**	**Systemic NOAEL mg/kg bw/d**	**$AEL_{long\text{-}te}$ mg/kg bw/d**	**Estimated uptake mg/kg bw/d**	**Estimated uptake/ AEL (%)**	**Acceptable (yes/no)**
Scenarios [1+12+14+15]	Tier 1	5	0.05	0.02139	**42**	**Yes**
Scenarios [2+13+14+15]	Tier 1	5	0.05	0.08239	165	No

	Tier 2	5	0.05	0.06139	123	No
	Tier 3	5	0.05	0.05009	100	Yes/No
	Tier 4	5	0.05	0.04949	**99**	**Yes**
Scenarios [3+13+14+15]	Tier 1	5	0.05	0.08699	174	No
	Tier 2	5	0.05	0.05359	107	No
	Tier 3	5	0.05	0.05094	102	No
	Tier 4	5	0.05	0.03874	**77**	**Yes**
Scenarios [4 +13 + 15]	Tier 1	5	0.05	0.06528	130	No
	Tier 2	5	0.05	0.04428	**89**	**Yes**
Scenarios [5+12+13+14+15]	Tier 1	5	0.05	0.05839	117	No
	Tier 2	5	0.05	0.04709	**94**	**Yes**
Scenarios [6+13+14+15]	Tier 1	5	0.05	0.05929	119	No
	Tier 2	5	0.05	0.05218	104	No
	Tier 3	5	0.05	0.04953	**99**	**Yes**
Scenarios [7+13+14+15]	Tier 1	5	0.05	0.08229	165	No
	Tier 2	5	0.05	0.05969	119	No
	Tier 3	5	0.05	0.05849	117	No
	Tier 4	5	0.05	0.05749	115	No
	Tier 5	5	0.05	0.05609	112	No
	Tier 6	5	0.05	0.05509	110	No
	Tier 7	5	0.05	0.04954	**99**	**Yes**

Scenario [1+12+14+15]:
Tier 1: brushing (S1/T2 gloves & coated coverall) + cleaning brush (S12/T1 no PPE) + laundering work clothes (S14/T1 no PPE) + sanding treated wood (S15/T1 no PPE):

0.011 + 0.0043 + 0.0029 + 0.00319 = **0.02139**

Scenario [2+13+14+15]:
Tier 1: spraying HP (S2/T3 gloves & impermeable coverall) + cleaning equipment (S13/T1 no PPE) + laundering work clothes (S14 from scen 2/T2 gloves) + sanding treated wood (S15/T1 no PPE):

0.0367 + 0.0359 + 0.0066 + 0.00319 = 0.08239

Tier 2: spraying HP (S2/T3 gloves & impermeable coverall) + cleaning equipment (S13/T2 gloves) + laundering work clothes (S14 from scen 2/T2 gloves) + sanding treated wood (S15/T1 no PPE):

0.0367 + 0.0149 + 0.0066 + 0.00319 = 0.06139

Tier 3: spraying HP (S2/T3 gloves & impermeable coverall) + cleaning equipment (S13/T3 gloves & coated coverall) + laundering work clothes (S14 from scen 2/T2 gloves) + sanding treated wood (S15/T1 no PPE):

0.0367 + 0.0036 + 0.0066 + 0.00319 = 0.05009

Tier 4: spraying HP (S2/T3 gloves & impermeable coverall) + cleaning equipment (S13/T4 gloves & impermeable coverall) + laundering work clothes (S14 from scen 2/T2 gloves) + sanding treated wood (S15/T1 no PPE):

0.0367 + 0.0030 + 0.0066 + 0.00319 = **0.04949**

Scenario [3+13+14+15]:
Tier 1: spraying MLP (S3/T4 gloves & double coverall) + cleaning equipment (S13/T1 no PPE) + laundering work clothes (S14 from scen 3/T2 gloves) + sanding treated wood (S15/T1 no PPE):

0.0401 + 0.0359 + 0.0078 + 0.00319 = 0.08699

Tier 2: spraying MLP (S3/T4 gloves & double coverall) + cleaning equipment (S13/T5 gloves & double coverall) + laundering work clothes (S14 from scen 3/T2 gloves) + sanding treated wood (S15/T1 no PPE):

0.0401 + 0.0025 + 0.0078 + 0.00319 = 0.05359

Tier 3: spraying MLP (S3/T4 gloves & double coverall) + cleaning equipment (S13/T5 gloves & double coverall) + laundering work clothes (S14 from scen 3/T2 gloves) + sanding treated wood (S15/T2 gloves):

0.0401 + 0.0025 + 0.0078 + 0.000538 = 0.05094

Tier 4: spraying MLP (S3/T5 new gloves per shift & double coverall) + cleaning equipment (S13/T5 gloves & double coverall) + laundering work clothes (S14 from scen 3/T2 gloves) + sanding treated wood (S15/T):

0.0279 + 0.0025 + 0.0078 + 0.00319 = **0.04139** (if S15/T1 No PPE)

0.0279 + 0.0025 + 0.0078 + 0.000538 = **0.03874** (if S15/T2 gloves)

Scenario [4+13+15]:

Tier 1: injection (S4/T1 gloves) + cleaning equipment (S13/T1 no PPE) + sanding treated wood (S15/T1 no PPE):

0.02619 + 0.0359 + 0.00319 = 0.06528

Tier 2: injection (S4/T1 gloves) + cleaning equipment (S13/T2 gloves) + sanding treated wood (S15/T1 no PPE):

0.02619 + 0.0149 + 0.00319 = **0.04428**

Scenario [5+12+13+14+15]:

Tier 1: brushing and injection (S1/T1 gloves & coated coverall) + cleaning brush (S12/T2 gloves)+ cleaning equipment (S13/T2 gloves) + laundering work clothes (S14/T1 no PPE) + sanding treated wood (S15/T1 no PPE):

0.037 + 0.0004 + 0.0149 + 0.0029 + 0.00319 = 0.05839

Tier 2: brushing and injection (S1/T1 gloves & coated coverall) + cleaning brush (S12/T2 gloves)+ cleaning equipment (S13/T3 gloves & coated coverall) + laundering work clothes (S14/T1 no PPE) + sanding treated wood (S15/T1 no PPE):

0.037 + 0.0004 + 0.0036 + 0.0029 + 0.00319 = **0.04709**

Scenario [6+13+14+15]:

Tier 1: spraying HP and injection (S6/T2 new gloves per shift & impermeable coverall) + 2 x cleaning equipment (S13/T6 new gloves per shift & impermeable coverall) + laundering work clothes (S14 from scen 2/T2 gloves) + sanding treated wood (S15/T2 gloves):

0.04855 + 2 x(0.0018) + 0.0066 + 0.000538 = 0.05929

Tier 2: spraying HP and injection (S6/T3 gloves & double coverall) + 2 x cleaning equipment (S13/T5 gloves & double coverall) + laundering work clothes (S14 from scen 2/T2 gloves) + sanding treated wood (S15/T1 no PPE):

0.03739 + 2x(0.0025) + 0.0066 + 0.00319 = 0.05218

Tier 3: spraying HP and injection (S6/T3 gloves & double coverall) + 2 x cleaning equipment (S13/T5 gloves & double coverall) + laundering work clothes (S14 from scen 2/T2 gloves) + sanding treated wood (S15/T2 gloves):

0.03739 + 2x(0.0025) + 0.0066 + 0.000538 = **0.04953**

Scenario [7+13+14+15]:

Tier 1: spraying MLP and injection (S7/T2 new gloves per shift & double coverall) + 2 x cleaning equipment (S13/T2 gloves) + laundering work clothes (S14 from scen 3/T2 gloves) + sanding treated wood (S15/T1 no PPE):

0.0415 + 2 x(0.0149) + 0.0078 + 0.00319 = 0.08229

Tier 2: spraying MLP and injection (S7/T2 new gloves per shift & double coverall) + 2 x cleaning equipment (S13/T3 gloves & coated coverall) + laundering work clothes (S14 from scen 3/T2 gloves) + sanding treated wood (S15/T1 no PPE):

0.0415 + 2 x(0.0036) + 0.0078 + 0.00319 = 0.05969

Tier 3: spraying MLP and injection (S7/T2 new gloves per shift & double coverall) + 2 x cleaning equipment (S13/T4 gloves & impermeable coverall) + laundering work clothes (S14 from scen 3/T2 gloves) + sanding treated wood (S15/T1 no PPE):

0.0415 + 2 x(0.0030) + 0.0078 + 0.00319 = 0.05849

Tier 4: spraying MLP and injection (S7/T2 new gloves per shift & double coverall) + 2 x cleaning equipment (S13/T5 gloves & double coverall) + laundering work clothes (S14 from scen 3/T2 gloves) + sanding treated wood (S15/T1 no PPE):

0.0415 + 2 x(0.0025) + 0.0078 + 0.00319 = 0.05749

Tier 4: spraying MLP and injection (S7/T2 new gloves per shift & double coverall) + 2 x cleaning equipment (S13/T6 new gloves per shift & impermeable coverall) + laundering work clothes (S14 from scen 3/T2 gloves) + sanding treated wood (S15/T1 no PPE):

0.0415 + 2 x(0.0018) + 0.0078 + 0.00319 = 0.05609

Tier 5: spraying MLP and injection (S7/T2 new gloves per shift & double coverall) + 2 x cleaning equipment (S13/T7 new gloves per shift & double coverall) + laundering work clothes (S14 from scen 3/T2 gloves) + sanding treated wood (S15/T1 no PPE):

0.0415 + 2 x(0.0013) + 0.0078 + 0.00319 = 0.05609

Tier 6: spraying MLP and injection (S7/T2 new gloves per shift & double coverall) + 2 x cleaning equipment (S13/T7 new gloves per shift & double coverall) + laundering work clothes (S14 from scen 3/T2 gloves) + sanding treated wood (S15/T1 no PPE):

0.0415 + 2 x(0.0013) + 0.0078 + 0.00319 = 0.05509

Tier 7: spraying MLP and injection (S7/T3 new gloves per shift & double coverall & RPE-FFP1) + 2 x cleaning equipment (S13/T7 new gloves per shift & double coverall) + laundering work clothes (S14 from scen 3/T2 gloves) + sanding treated wood (S15/T1 no PPE):

0.03595 + 2 x(0.0013) + 0.0078 + 0.00319 = **0.04954**

Local effects

Risk characterisation (RC) for local effects is focused in the product and is triggered only when the biocidal product is classified for local effects. Other local effects that do not lead to any classification are not considered as severe enough to require any type of risk assessment for local effects. Product New Serpol Basic is not classified for skin sensitization, but is labelled with EUH208 based on the permethrin and CMIT/MIT concentrations. No other local effects are linked to the product. Based on a co-formulant classification with EUH066 is triggered.

Since NEW SERPOL BASIC is classified, by its SoC "Disolvente isoparafinico N" (Hydrocarbons, C12-C16, isoalkanes, cyclics, <2% aromatics) content, hereinafter isoparaffin solvent, as EUH066 (Repeated exposure may cause skin dryness or cracking), a RC for this local effect is required. For this SoC (belongs to Band A) application of P-statements normally associated with concerned H statements is sufficient. No quantitative risk assessment is performed.
According to the ECHA Guidance Vol III Part B+C a qualitative local risk assessment is necessary for the product labelling EUH066 (Repeated exposure may cause skin dryness or cracking). The related hazard category is "low". For EUH066 no labelling (e.g. P280) according to the CLP regulation is required. The possible effect of skin dryness or cracking

can be prevented by a basic skin care. This means that hand wash and use of skin care products are sufficient. The use of PPE based on EUH066 is not appropriate.
The implicit risk to EUH066 would be covered since, by the total risk characterization, the use of PPEs (gloves and coverall) is mandatory. In any case, in order to take into account the risk of skin dryness or cracking during the handling of product (repeated exposure) and the supplementary information EUH208, the following RMMs or use instructions are added:

- Do not get in eyes, on skin, or on clothing.
- Wash hands thoroughly after handling.

Furthermore, in relation to local effects, pyrethroids like permethrin are known to cause paresthesia (burning and prickling of the skin without irritation) in susceptible persons. This local effect is normally not severe and disappears when direct exposure is terminated. Hence, an appropriate labelling on the packaging is required to inform susceptible persons through the following advice:

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

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**
EUH208, EUH066	Not classified	Potential of skin sensitizing effects due to presence of permethrin and CMIT/MIT	8	Trained professional users	Application of RTU liquid via spraying, brushing, or injection	Skin	Daily. More than few hours per day	Low. Controlled exposure with RMM and use of PPEs	None required, product is not classified as skin sensitizing. Use instructions may include: wash hands after use. By systemic exposure results, indicated PPE are already required.	Acceptable: Yes - Reversible effects - Instructions will be followed by professional users.

Product is classified with EUH208 and EUH066. Use instructions will be followed by professional users, moreover PPE is prescribed due to systemic effects. In conclusion, the risk for local effects is considered acceptable.

Conclusion

For trained professional use, once the combined scenarios have been assessed it can be concluded that:

Acceptable risk levels are obtained when PPE are prescribed for application via **brushing**. **Protective gloves and coated coverall** should be used to obtain safe use.

Acceptable risk levels are obtained when PPE are prescribed for application via **high pressure spraying. Protective gloves and impermeable coverall** should be used to obtain safe use during application and cleaning of the sprayer. In addition, when laundering work clothes, gloves should be worn.

Acceptable risk levels are obtained when PPE are prescribed for application via **medium/low pressure spraying. Protective new gloves per shift and double coverall** should be used during application and cleaning of the sprayer to obtain safe use.

In addition, when laundering work clothes, gloves should be worn. However, based on bilateral discussions held by MS on other occasions, as a general rule and as suggested by HEEG Opinion no. 9, double coverall (99% protection) is only allowed for professional antifouling spraying (PT21). Therefore, given the required protection measures, the **authorization of this use does not proceed**.

Acceptable risk levels are obtained when PPE are prescribed for application via **pressure injection**. **Protective gloves** should be used during application and cleaning of the injector to obtain safe use. Borehole injection should always be combined with a curative superficial treatment.

Acceptable risk levels are obtained when PPE are prescribed for application via **brushing joined pressure injection**. **Protective gloves and coated coverall** should be used to obtain safe use.

Acceptable risk levels are obtained when PPE are prescribed for application via **high pressure spraying joined pressure injection. Protective gloves and double coverall** should be used to obtain safe use during application and cleaning of the equipment. In addition, when laundering work clothes, gloves should be worn. If the same user carries out sanding or sawing operations after the treatment, it is also necessary to wear gloves. However, based on bilateral discussions held by MS on other occasions, as a general rule and as suggested by HEEG Opinion no. 9, double coverall (99% protection) is only allowed for professional antifouling spraying (PT21). Therefore, given the required protection measures, the **authorization of this use does not proceed.**

Acceptable risk levels are obtained when PPE are prescribed for application via **medium/low pressure spraying joined pressure injection. Protective new gloves per shift, double coverall and RPE-FFP1** should be used to obtain safe use during application and cleaning of the equipment. In addition, when laundering work clothes, gloves should be worn. However, based on bilateral discussions held by MS on other occasions, as a general rule and as suggested by HEEG Opinion no. 9, double coverall (99% protection) is only allowed for professional antifouling spraying (PT21). Therefore, given the required protection measures, the **authorization of this use does not proceed**.

Risk for non-professional users

Non-professional users are expected to use the biocidal product once to twice a year. Hence exposure levels are compared to $AEL_{short\text{-}term}$ for risk assessment purposes. No PPEs are worn.

Systemic effects
In the following table, the results are provided for permethrin.

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL_{acute} mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Brushing / **Scenario 8**	1	50	0.5	0.201	**40**	**Yes**
	2*	50	0.5	0.081	**16**	**Yes**
Spraying / **Scenario 9**	1	50	0.5	0.489	**98**	**Yes**
	1	50	0.5	0.804	161	No

Brushing & injection / **Scenario 11**	2*	50	0.5	0.161	**32**	**Yes**
Cleaning of brush / **Scenario 12**	1	50	0.5	0.0043	**9**	**Yes**

* *Tier 2: Brushing calculated with refined approach, but no PPE is used.*

Combined scenarios

Scenarios combined	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenarios [8+12]	1	50	0.5	0.2053	**41**	**Yes**
Scenarios [11+12]	1	50	0.5	0.8083	162	No
	2	50	0.5	0.1653	**33**	**Yes**

Scenario [8+12]:
Tier 1: brushing (S1/T1 No PPE) + cleaning brush (S12/T1 No PPE)
0.201 + 0.0043 = **0.2053**

Scenario [11+12]:
Tier 1: brushing and injection (S1/T1 No PPE) + cleaning brush (S12/T1 No PPE)
0.804 + 0.0043 = 0.8083
Tier 2: brushing & injection (S1/T2 refined approach No PPE) + cleaning brush (S12/T1 No PPE) 0.161 +0.0043 = **0.1653**

Local effects

Product New Serpol Basic is not classified for skin sensitization, but is labelled with EUH0208 based on the permethrin and CMIT/MIT concentrations. No other local effects are linked to the product. Based on a co-formulant classification with EUH066 is triggered.
According to the ECHA Guidance Vol III Part B+C a qualitative local risk assessment is necessary for the product labelling EUH066 (Repeated exposure may cause skin dryness or cracking). The related hazard category is "low". For EUH066 no labelling according to the CLP regulation is required. The possible effect of skin dryness or cracking can be prevented by a basic skin care. This means that hand wash and use of skin care products are sufficient. The use of PPE based on EUH066 is not appropriate.
In order to take into account the risk of skin dryness or cracking during the handling of product (repeated exposure) and the supplementary information EUH208, the following RMMs or use instructions are added:

- Do not get in eyes, on skin, or on clothing.
- Wash hands thoroughly after handling.

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
EUH208, EUH066	Not classified	Potential of skin sensitizing	8	Non-professional users	Application of RTU liquid via	Skin	Once or twice per year	Low. Controlled exposure	None required, product is	Acceptable: Yes

		effects due to presence of permethrin and CMIT/MIT			spraying, brushing, or injection			with RMM and instructions of use.	not classified as skin sensitizing. Use instructions may include: wash hands after use.	- Reversible effects - Low frequency of use.

Conclusion

For non-professional use, it can be concluded that:

Acceptable risk levels are obtained without the need for PPE for application via **brushing**.

Acceptable risk levels are obtained without the need for PPE for application via **spraying**, but it is also necessary that the sprayer will be disposed off after use.

Acceptable risk levels are obtained without the need for PPE for application via **brushing joined injection.**

Risk for the general public

General remark: the results reflect the concentration of 0.35% of permethrin and, as a worse case, the highest-end-retention application rate of 552 mL/m2 of the RTU product.

Systemic effects
In the following table, the results are provided for permethrin.

Task/ Scenario	**Tier**	**Systemic NOAEL mg/kg bw/d**	**AEL mg/kg bw/d**	**Estimated uptake mg/kg bw/d**	**Estimated uptake/ AEL (%)**	**Acceptable (yes/no)**
Bystander sanding treated wood/ **Scenario 16**	1/ No PPE	50	0.5 (Acute)	0.00299	**1**	**Yes**
Toddler chewing treated wood / **Scenario 17**	1/ No PPE	50	0.5 (Acute)	0.0246	**5**	**Yes**
Toddler playing on playground wethered structures / **Scenario 18**	1/ No PPE	5	0.05 (Chronic)	0.01207	**24**	**Yes**
Inhalation volatilased residues / **Scenario 19**	1/ No PPE	5	0.05 (Chronic)	Negligible	Negligible	**Yes**

Combined scenarios
Not relevant

Local effects

Local exposure and risk assessment is not relevant for the secondary exposure scenarios, since it can be assumed that the solvent "Disolvente isoparafinico N" is completely evaporated when the wood is dried and therefore no local adverse effects are expected.

Conclusion
In all general public exposure scenarios, no exceedance of the corresponding reference value for permethrin was observed and, thus, the risk is acceptable when the product is used in accordance with the instructions described in the PAR / SPC.
It should be noted that the exposure and risk assessment of the general public in the PAR applies only to dried residues. Potential contact to wet surfaces was not assessed. For adults it can be assumed that they generally avoid contact to wet treated surfaces. However, for younger children and for pets this cannot be assumed. To avoid contact to wet surfaces by children and pets, the following RMM was therefore assigned:

- N-315: Keep uninvolved persons, children and pets away from treated surfaces/areas until dried

Risk for consumers via residues in food

New Serpol Basic is not intended for applications where contact with feedingstuffs may arise. Consequently, the transfer of potential residues of the biocidal product to food of animal origin via feedingstuffs is not relevant. In this sense, the following RMM has been incorporated:

- Do not use on wood which may come in direct contact with food, feeding stuff and livestock animals.

Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product

A combined risk characterisation is not relevant, as permethrin is the only active substance present in the biocidal product New Serpol Basic. Furthermore, the substance of concern "Disolvente isoparafinico N" does not trigger a quantitative risk assessment according to the Guidance on the Biocidal Products Regulation.

2.2.7 Risk assessment for animal health

(NA-AAT) January 2023: As a result of the comment phase opened during the MRS procedure with Greece, this section 2.2.7 has been amended, in order to include certain harmonized and commonly accepted RMMs for products containing pyrethrins / pyrethroids.

Specific exposure and risk assessment for pets and domestic animals has not been performed. For the private area it is expected that animals can be exposed to the active substance after treatment. It can be assumed that the health risk for these animals (except cats) is comparable to those of toddlers and children. Therefore, no specific measures are required for these animals if the biocidal product is used as intended. However, cats are more sensitive against pyrethroids. Due to a slower metabolisation intoxications by pyrethroids are common. Thus, particularly the access of cats to treated surfaces has to be avoided.
The following use instructions and risk mitigation measures are proposed:

- Assure no animals are present during the treatment
- N-333: Contains permethrin, may be dangerous/toxic to pets (e.g. cats, bees, fish and other aquatic organisms).
- N-335: Keep cats away from treated surfaces. Due to their particular sensitivity to permethrin, the product can cause severe adverse reactions in cats.

2.2.8 Risk assessment for the environment

ES CA
Please notice that the risk assessment for the environment (section 2.2.8) is reported as provided by the applicant. The ES CA position is presented in green boxes.

The biocidal product New Serpol Basic with the active substance Permethrin (0,35 % w/w) is used as a wood preservative beetles and their larvae. It is a ready-to-use product intended for the curative and preventive treatment of timber in Use Class 1 (UC1), situation in which the wood-based product is inside a construction, not exposed to the weather and wetting, only indoors.
The product is intended to be applied by professional and non-professional users by spraying, brushing and injection.
An environmental risk assessment has been performed using relevant active substance and the relevant metabolites data as reported in the CAR. No new information compared to the CAR has been provided.

ES CA
In line with the "OECD Emission Scenario Document (ESD) for Wood Preservatives" 2013, no assessment of in-service losses and risks arising from timber in UC 1 & 2 need to be made as "the potential emissions from treated wood to the outer environment are considered negligible" and as such, environmental risk is considered to be negligible for all compartments.

In addition to the active substances Permethrin, the product contains other substances which are not considered as substance of concern for the environment. Thus, related emissions to the environment are considered negligible.

2.2.8.1 Effects assessment on the environment

Effects assessment is performed based on the active substance Permethrin, as well as its metabolites, based on the assessment reports in PT8 and PT18 (CAR 2014; Rapporteur: Ireland). The product doesn't contain any substances of concern for the environment and therefore the assessment is only focused in the active substance and its metabolites, 3-(2,2-dichlorovinyl)-2,2-dimethyl-(1-cyclopropane)carboxylate (DCVA) and 3-Phenoxybenzoic Acid (PBA).
The PNEC values used in the assessment are derived using the data from the CAR for which a letter of access has been granted.

Surfacewater
Detailed data on the environmental effect assessment and PNEC derivation of the active substance permethrin and its metabolite DCVA and PBA can be found in the CAR for PT8 and PT18 (2014).
The lowest NOEC values of 0.0047 µg/L was derived from a study with Daphnia magna (CAR 2014). An AF of 10 was applied as long-term tests with species from three trophic levels are available.

- $PNEC_{water}$ permethrin = 0.00047 µg/L
- $PNEC_{water}$ DCVA = 0.015 mg/L

- $PNEC_{water}$ PBA > 0.10 mg/L

Conclusion: Metabolites (DCVA and PBA) are far less toxic than the parent active ingredient and are not considered to be relevant.

Sediment

Detailed data on the environmental effect assessment and PNEC derivation of the active substance permethrin and its metabolite DCVA and PBA can be found in the CAR for PT8 and PT18 (2014).

- $PNEC_{sediment}$ permethrin = 0.001 mg/kg dwt ($2.17x10^{-4}$ mg/kg wwt)
- $PNEC_{sediment}$ DCVA = 0.055 mg/kg dwt (0.012 mg/kg wwt)
- $PNEC_{sediment}$ PBA = 0.042 mg/kg dwt (0.09 mg/kg wwt)

Conclusion: Metabolites (DCVA and PBA) are far less toxic than the parent active ingredient and are not considered to be relevant.

STP microorganisms

The effect of permethrin on aerobic biological sewage treatment processes was assessed according by determining respiration inhibition of the micro-organisms present in activated sludge.

Since testing was conducted using concentrations above the water solubility and no inhibition was observed, the NOEC for permethrin is set equal to the water solubility of 4.95 µg/l. The PNEC microorganisms (STP) reported in the AR (2014) was 4.95 µg/l.

Soil

Detailed data on the environmental effect assessment and PNEC derivation of the active substance permethrin and its metabolite DCVA and PBA can be found in the CAR for PT8 and PT18 (2014).

For the active substance permethrin in PT8/PT18 a new study has been provided for the compartment soil (March 2017 Addendum). In the long-term study on Folsomia candida the 28d-EC10 value (reproduction) was 579 mg/kg soil dwt, resulting in an EC50 >9.9 mg/kg dwt. An assessment factor of 50 is applied as there are results from two long term studies for two species of two trophic levels for the derivation of $PNEC_{soil}$.

- $PNEC_{soil}$ permethrin = 0.001 mg/kg dwt ($2.17x10^{-4}$ mg/kg wwt)

Conclusion: No metabolites are relevant for the soil compartment.

ES CA:
New agreed PNEC soil for permethrin is 0,198 mg/kg dwt, corresponding to 0,175 mg/kg wwt.
Metabolites:
DCVA_PNEC soil (wet weight) = 4.6 mg/kg wwt
PBA_PNEC soil (wet weight) = 1.44 mg/kg wwt.

Groundwater

For the groundwater the limit is stablished by the Drinking Water Directive as 1 µg/L.

Conclusion: No metabolites are relevant for the soil compartment.

Athmosphere

Exposure to the athmosphere is not relevant due to the low vapour pressure ($2.16x10^{-6}$ Pa×m^3/mol at 20 °C) a low Henry's Law constant and a high adsorption potential of the active substance.
Conclusion: No exposure is expected to the athmosphere.

Other effects
According to the BPR guidance Vol IV part B+C an assessment of secondary poisoning is performed if a substance shows bioaccumulation potential.
The log Kow = 4.7 reveals a potential for bioaccumulation for the active substance permethrin (log Kow ≥ 3). Moreover, according to the CAR 2014, some of the estimated BCF values indicate a potential of permethrin to bioconcentrate following uptake via water/porewater through the food chain. Therefore, the secondary poisoning must be assessed.
For risk assessment a $PNEC_{oral\ bird}$ = 16.7 mg a.s./kg food and a $PNEC_{oral\ mammal}$ = 120 mg a.s./kg food was concluded in the permethrin CAR PT8 and PT 18 (2014).

Summary of effects assessment
The PNEC values for permethrin and the relevant metabolites are summarized in the following table.

Compartment	Permethrin	DCVA	PBA
$PNEC_{surfacewater}$ (µg/L)	0.00047	15	>10
$PNEC_{sediment}$ (mg/kg dwt)	0.001	0.055	0.042
$PNEC_{STP}$ (mg/L)	0.00495	-	-
$PNEC_{soil}$ (mg/kg wwt)	0.175	4.6	1.44
$PNEC_{groundwater}$ (µg/L)	1	-	-
$PNEC_{oral\ bird}$ (mg/kg food)	>16.7	-	-
$PNEC_{oral\ small\ mammal}$ (mg/kg food)	120	-	-

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 contains 0.35% Permethrin and 0.00135% Mixture of CMIT/MIT as ingredients likely to lead to classification regarding environmental properties. Permethrin is classified as aquatic acute (H400) and aquatic chronic (H410) with a general M factor of 1000, contributing to the classification according to M factor multiplication as set out in the Regulation EC 1272/2008 with a percentage of 350%. The concentration of the active substance itself (>25%) leads to classification as Aquatic Acute Category 1 H400 and Aquatic Chronic Category 1 H410. Mixture of CMIT/MIT is classified as aquatic acute (H400) and aquatic chronic (H410) with a general M factor of 100 for both, contributes to the classification with a percentage of 0.135%, not leading to classification of the product with regards to the environment.
None of the coformulants meet the PBT/vPvB criteria.

ES CA:
The calculation method according to Regulation (EC) No. 1272/2008 was used in order to conclude on the hazard identification of the biocidal product. The environmental classification of NEW SERPOL BASIC is based on the environmental classification of its active substance

and co-formulants based on summation method (*4.1.3.5.5 of Guidance on the Application of the CLP Criteria Version 5.0- July 2017*).

Substance name	CAS	Max % (w/w)	CLP Classification concerning environmental hazards
Permethrin	52645-53-1	0.35	Aquatic Acute, H400 (M=100) Aquatic Chronic, H410 (M=10000)

Considering the ecotoxicological properties and classification of the active substance and its corresponding M- factors, these data are enough to classify NEW SERPOL BASIC as 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 pictogram for environmental hazard and signal word "Warning".

Further Ecotoxicological studies

No data is available.

ES CA:
No additional data are required.

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

No data is available.

ES CA:
No additional data are required.

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

No data is available.

ES CA:
No additional data are required.

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

No data is available.

ES CA:
No additional data are required.

ES CA:
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.

No further ecotoxicological studies are available for the product NEW SERPOL BASIC. The product was not tested for potential endocrine disruption properties. The product NEW SERPOL BASIC contains the active substance permethrin and various co-formulates (see confidential annex).

For the active substance, no ED assessment is required because for active substances which have been approved, the EU assessment should be followed.

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

- ECHA data for identification of ED and PBT, under REACH, 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, one co-formulant triggered an alert for ED properties, because has been identified as a potential ED by United States EPA. This substance is being assessed as biocidal active substance under BPR regulation, including ED assessment. However, a Final Competent Authority Report is not available yet. Based on the existing knowledge and the data provided in substances CAR it is not possible to conclude whether this co-formulant should be considered as an ED. If one or several components are identified as having ED properties in the future, the conditions for granting the biocidal product authorisation will be revised. Based on this information, the ES CA considers that the authorisation of the biocidal product NEW SERPOL BASIC can proceed.
Please see the confidential annex for further details.

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

New Serpol Basic is a ready-to-use product to be applied indoors in household, commercial and public environments. The product is intended for the curative and preventive treatment of timber in Use Class 1 (UC1), situation in which the wood-based product is inside a construction, not exposed to the weather and wetting, only indoors.

Exposure to the receiving environmental compartments such as soil, water and air depends on the physical-chemical properties of the active substance as well as its formulation type, mode of application, use and disposal.
Different release pathways are envisaged depending on the mode of application of the product according to the Revised Emission Scenario Document for Wood Preservatives (PT8) ENV/JM/MONO(2013)21, in which a general overview is provided on the environmental compartments to which wood preservatives may be released during the respective applications or during service life.

According to the ESD p. 22 there are three different stages of emission:

- Life cycle stage: Product application.
- Life cycle stage: Treated wood in service (= service life).
- Additional (niche) scenarios.

During in-situ treatment of timber (curative / preventive) emissions are only expected for Use Class 3 (UC3), situation in which the wood or wood-based product is above ground and exposed to the weather (particularly rain). No environmental exposure is expected when treating timber in UC1.
For treated wood in service, the potential emissions from UC1 treated wood to the outer environment are considered negligible.
Due to the low vapour pressure of the active substance (2.16×10^{-6} Pa×m^3/mol at 20 °C) it is not expected that any volatile losses of permethrin to the air compartment would occur either before, during or after application of the product, including during the possible additional (niche) scenario Indoor fumigation.

Therefore, no risk for the environment is expected from the use of New Serpol Basic.

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

No data is available.

ES CA:
Product is for interior use only and therefore exposure to environmental compartments is not possible (OECD Emission Scenario Document for Wood Preservatives, 2013).

However, as the product NEW SERPOL BASIC contains permethrin and "OECD Emission Scenario Document (ESD) for Wood Preservatives" indicates that *"For indoor treatments by spraying, brushing and injection…Indoor treatments may need to be considered in the exposure assessment for bats in countries where bats are protected animals (e.g. in most European countries) [Chadwick J et al., 1992; Mitchell-Jones AJ et al., 1989]. Bats are exposed to treated wood via contact."* Please refer to section emission estimation for further details
No additional data are required.

Leaching behaviour (ADS)

Not applicable as the product is intended to be used under use class 1. However, a leaching study for the product SERPOL GEL II, containing the same amount of permethin has been taken into account. Please see "Effects and Exposure Assessment for the Biocidal Product NEW SERPOL BASIC".

ES CA:
Product is for interior use only and therefore exposure to environmental compartments is not possible (OECD Emission Scenario Document for Wood Preservatives, 2013).
No additional data are required.

Testing for distribution and dissipation in soil (ADS)

No data is available.

ES CA:
Product is for interior use only and therefore exposure to environmental compartments is not possible (OECD Emission Scenario Document for Wood Preservatives, 2013).
No additional data are required.

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

No data is available.

ES CA:
Product is for interior use only and therefore exposure to environmental compartments is not possible (OECD Emission Scenario Document for Wood Preservatives, 2013).
No additional data are required.

Testing for distribution and dissipation in air (ADS)

No data is available.

ES CA:
Product is for interior use only and therefore exposure to environmental compartments is not possible (OECD Emission Scenario Document for Wood Preservatives, 2013).
No additional data are required.

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)

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

ES CA:
Product is for interior use only and therefore exposure to environmental compartments is not possible (OECD Emission Scenario Document for Wood Preservatives, 2013).
No additional data are required.

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 to be sprayed ouside.

ES CA:
Product is for interior use only and therefore exposure to environmental compartments is not possible (OECD Emission Scenario Document for Wood Preservatives, 2013).
No additional data are required.

2.2.8.2 Exposure assessment

The environmental exposure assessment is based on the Revised Emission Scenario Document for Wood Preservatives (PT8) ENV/JM/MONO(2013)21. Where necessary the

"Guidance on the Biocidal Products Regulation" (Volume IV Environment – Part B Risk Assessment (active substances); Version 1.0; April 2015) is also taken into consideration.
The ready-to-use biocidal product (0.35 % w/w permethrin) is intended for the curative and preventive treatment of timber via spraying, brushing or injection in UC1.

General information

Assessed PT	PT 8
Assessed scenarios	None
ESD(s) used	Revised Emission Scenario Document for Wood Preservatives (PT8) ENV/JM/MONO(2013)21
Approach	Qualitative assessment of relevant life cycle stages
Distribution in the environment	Assessed based on the Guidance on the Biocidal Products Regulation, Volume IV Environment, Part B Risk Assessment (active substances, version 1, ECHA, 2015)
Groundwater simulation	Not required
Confidential Annexes	No
Life cycle steps assessed	Production: No Formulation: No Use (application): Yes (qualitative) Storage: Yes (qualitative) Service life: Yes (qualitative)

Emission estimation

The biocidal product is intended for trained professional, professional and non-professional applications. Emissions to the environment can generally occur during in-situ applications and the service life of the treated wood.
New Serpol Basic is a ready-to-use-product used for treatment of wood only indoors where the wood or wood-based product is inside a construction, not exposed to the weather and wetting (UC1). The product is intended for preventive curative treatment of wood against insects by brushing, spraying or injection. The product contains 0.35% permethrin and is applied at a rate of 250 mL/m^2 for superficial treatments or 10 mL/hole, 6 holes/linear m (360 mL/m^2) for injection treatment.

Emission during production and formulation

Environmental emission estimation for formulation has not been performed as it is not regulated under BPR No 528/2012.

Emission during in-situ-application

The product is only used for the treatment of wood that is installed under the conditions of UC1. According to revised ESD PT 8 (2013), potential emissions to the environment regarding in situ-treatment of wood in UC1 are considered negligible. A prerequisite is that product and packaging waste are collected and reused or disposed in accordance with local/regional/national/international regulations. They must not be released to soil, groundand surface water or any kind of sewer.

Conclusion: Emissions to the environment are considered negligible for in-situ-treatment of wood in UC1. The following instruction for use is part of the authorisation:

- The disposal shall be made in accordance with local legislation.
- Dispose the product residue on an authorized point waste collection.

Emission during storage of treated wood

Emissions to the environment can potentially occur during storage of wood after application of New Serpol Basic if the treated wood is not installed, e.g. treatment of wooden furniture and smaller wooden items. However, according to the intended uses, no significant emissions to the environment are expected because the wood is inside a construction, not exposed to the weather and wetting (UC1). Therefore, no emission and exposure calculation is performed.

Conclusion: Potential emissions to the environment during storage of treated timber in UC1 are considered negligible.

Emission during service life of treated wood

No emission scenarios for wood in service are available for UC 1 according to the revised ESD, since the potential emissions from treated wood to the outer environment are considered negligible.

Conclusion: Emissions to the environment during service life are considered negligible for treated timber that is used according to UC1.

ES CA

It is accepted in the PT 8 ESD (2013 version) that in-service leaching losses from timber protected from weather (rain and driven rain) will be negligible and thus risks to environmental compartments will be zero.

When product is applied in-situ, then there is potential for losses to floor but, when applied indoors (UC 1, situation in which the wood or wood-based product is under cover, fully protected from the weather and not exposed to wetting), no emissions during application are expected to reach environmental compartments.

As a consequence, no calculations have been undertaken in this PAR on the basis that application and in-service losses in UC 1 are negligible and risks to environmental compartments are considered as zero.

There is only one aspect in the environmental risk assessment of NEW SERPOL BASIC to take into account. In the ESD for PT 8 products, 4.2 Emission estimation for professional and amateur in situ treatments (curative and preventive) (page 60) is said that. ”For indoor treatments by spraying, brushing and injection…Indoor treatments may need to be considered in the exposure assessment for bats in countries where bats are protected animals (e.g. in most European countries) [Chadwick J et al., 1992; Mitchell-Jones AJ et al., 1989]. Bats are exposed to treated wood via contact.”. As the product contains permethrin, therefore it is necessary to include the following risk mitigation measure for all uses: 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.

Calculated PEC values

Significant emissions to the environmental compartments, regarding the formulation and in-situ application of the product, as well as the use of treated timber are not expected if the respective instructions for use are applied. Therefore, no PEC values have to be derived.

Primary and secondary poisoning

Primary poisoning
Not relevant for PT8.

Secondary poisoning
According to the BPR guidance Vol IV part B (2015) for substances with a log Kow ≥ 4.5 (permethrin Kow = 4.7), uptake routes such as intake of contaminated food or sediment are considered to be of importance.
However, for wood of UC1 no emission scenarios are presented since for this wood classes the potential emissions from treated wood to the environment are considered negligible.

ES CA:
No additional data are required.

2.2.8.3 Risk characterisation

The product is applied in-situ to wood by brushing, spraying or injection. The application takes place under the conditions of UC1. Therefore, emission to the environment are considered to be negligible during product application, storage of treated wood and service life of treated timber.

Atmosphere

Air compartment isn't considered in the emission scenario due to the physico-chemical properties of the active substance.

Aquatic compartment

Conclusion: No emission expected. No unacceptable risk for the aquatic compartment is anticipated during any life cycle step.

Terrestrial compartment

Conclusion: No emission expected. No unacceptable risk for the terrestrial compartment is anticipated during any life cycle step.

Groundwater

Conclusion: No emission expected. No unacceptable risk for the groundwater compartment is anticipated during any life cycle step.

Primary and secondary poisoning

Conclusion: No emission expected. No unacceptable risk for the primary and secondary poisoning is anticipated during any life cycle step.

Mixture toxicity

Not relevant as there's no several active substances or substances of concern.

ES CA:
As emissions of the active substances have been considered to be negligible in relation to in-service and application losses of NEW SERPOL BASIC (UC 1 y UC 2), no assessment of mixture toxicity has been carried out.

Aggregated exposure (combined for relevant emmission sources)

Not required.

ES CA:
Aggregated exposure for the product and its a.s. and/or SoCs has not been assessed as a harmonised guidance on how to conduct aggregated exposure has not been agreed yet and no appropriate guidance is currently available.

Overall conclusion on the risk assessment for the environment of the product
No emission expected. No unacceptable risk for the environment is anticipated during any life cycle step.

ES CA
No concern is derived from the correct use of this product for the environment.

2.2.9 Measures to protect man, animals and the environment

Please, regarding this section, see the risk mitigation measures included in the description of each use authorised in the SPC/PAR.

2.2.10 Assessment of a combination of biocidal products

New Serpol Basic is intended to be used directly and without other Biocidal products.

2.2.11 Comparative assessment

NO applicable

3 ANNEXES

3.1 List of studies for the biocidal product

Author	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published
[redacted]	[redacted]	NEW SERPOL BASIC: Determination of physico-chemical properties. Study number: CH 1000/2018
[redacted]	[redacted]	Determination of wheteher the sample NEW SERPOL BASIC is a solid or a liquid.
[redacted]	[redacted]	NEW SERPOL BASIC: Determination of the accelerated storage stability and corrosion characteristics. Study number: CH 1002/2018
[redacted]	[redacted]	NEW SERPOL BASIC: Four years storage stability and corrosion characteristics Final Interim report after two years of storage. Final Interim Report CH – 1003/2018
[redacted]	[redacted]	NEW SERPOL BASIC: Validation of the analytical method for the determination of permethrin ingredient content. Study number: CH 1001/2018
[redacted]	[redacted]	Determination of the eradicant action against *Hylotrupes bajulus (Linnaeus)* larvae according to EN 1390: 2006. TECNALIA Research and Innovation Report Nº 052526 -1-a
[redacted]	[redacted]	Determination of preventive action against Reticulotermes species according to EN 118: 2013. TECNALIA Research and Innovation Report Nº 052526 -2-a
[redacted]	[redacted]	Determination of preventive action against *Hylotrupes bajulus (Linnaeus)* – Part 1: Larvicidal effect according to EN 46-1: 2010+ERRATUM 2012. TECNALIA Research and Innovation Report Nº 052526 -3-a
[redacted]	[redacted]	Determination of toxic values against *Reticulotermes* species according to EN 117: 2012. TECNALIA Research and Innovation Report Nº 052526 -4-a
[redacted]	[redacted]	Determination of toxic values against larvae of Hylotrupes bajulus (Linnaeus) according to UNE-EN 47: 2007/AC: 2007. TECNALIA Research and Innovation Report Nº 052526 -5-a
[redacted]	[redacted]	Wood preservatives- Determination of the preventive action against recently hatched larvae of *Hylotrupes bajulus (Linnaeus)* – Part 1: Application by surface treatment (laboratory method). UNE-EN 46-1: 2016. TECNALIA Research and Innovation Report Nº 076190-a (M1)
xxx	xxx	NEW SERPOL BASIC: Physical-Chemical Properties (Auto-ignition Temperature, Explosive Properties by Preliminary Differential Scanning Calorimetry (DSC) Analysis, Flash Point and Boiling Point)

3.2 Output tables from exposure assessment tools

HUMAN HEALTH EXPOSURE

Exp Non-prof 28-07-2021(Final).xls

Exp Prof & secondary 28-07-202

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)[1]

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

3.6 Confidential annex

See confidential annex document.

3.7 Other

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