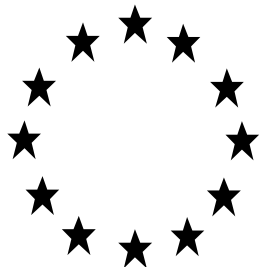
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS



SERPOL GEL II

Product type 8

Propiconazole, IPBC and Permethrin as included in the Union list of approved active substances

Case Number in R4BP: BC-TH023766-28

Evaluating Competent Authority: SPAIN

Date: December 2021

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1 CONCLUSION

Physical-chemical properties and Analytical Methods
SERPOL GEL II is a white gel which pH and density values are 6.5 and 0.831 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 4 years. Therefore, a 4 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 acceptable for the identification and quantification of the active substances in the biocidal product.

Efficacy:
Tests have shown the product to be an effective preservative, use class 2, against subterranean termites, insects, wood rotting basidiomycetes and bluestain in service by surface application (brushing). In addition it has also proven its efficacy as curative treatment against insects and subterranean termites by surface application (brushing).

Human Health
SERPOL GEL II contains the active substances propiconazole (0.85%), IPBC (0.40%) and permethrin (0.35%). The substance aliphatic hydrocarbon (hydrocarbons, C12-C16, isoalkanes, cyclics, <2% aromatics) has been identified as substance of concern.

Based on the classification as Repr. 1B, H360D, the biocidal product cannot be authorised for use by non-professional user (general public) according to article 19 (4) of Regulation (EU) No 528/2012. Therefore, SERPOL GEL II is only authorised for use by trained professional users.

The product contains, in addition to the active substances IPBC and permethrin, the active substance propiconazole. Taking into account the currently legal harmonized classification and labelling of the active substance as Repr 1B; H360D, propiconazole must be considered as a candidate for substitution or exclusion using the criteria in Article 10 (1) and 5 (1) of the Biocides Regulation (EU) No 528/2012 (BPR).

Therefore, in line with Article 23 (1) of the BPR a comparative assessment has been carried out by the ES CA according to the "Technical Guidance Note on comparative assessment of biocidal products" *(TNsG-CA i.e. CA-May15-Doc4.3a-final)*.

According to the CARs and BPC opinons of active substances permethrin and IPBC, are not considered to have endocrine disrupting properties. According to BPC opinion of propiconazole for PT7 (December 2014) the potential for endocrine disruption should be re-assessed once EU harmonised guidelines will be available.

After reviewing the potential ED properties of co-formulants, 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.

Human health exposure assessment and Risk characterisation.

After evaluating the exposure and characterizing the risk to human health of the Serpol Gel II product according to the pattern of use requested by the applicant, the conclusions are:
The risk for trained professional users applying the product SERPOL GEL II by brushing/rolling is acceptable when appropriate PPEs including impermeable coverall and chemical resistant gloves are worn.

The product is not authorized for application by projection or injection, since both application methods involve an unacceptable exposure risk.

For all the secondary exposure scenarios that have been contemplated, the risk is acceptable.

In order to ensure that there would be no consumer exposure from treated wood, the following risk mitigation measure should be added to the product label: "Do not use on wood which may come in direct contact with food, feeding stuff and livestock animals".

Enviromental risk.
The risk characterisation for the environment shows that the intended uses of the biocidal product SERPOL GEL II and the use of treated wood in UC 1 and UC 2 do not pose unacceptable risks to the environment.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier	**Country (if relevant)**
SERPOL GEL II	SPAIN

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	MYLVA S.A.
	Address	Vía Augusta, 48. 08006 Barcelona Spain.
Authorisation number	ES/APP(NA)-2021-08-00790	
Date of the authorisation	20/12/2021	
Expiry date of the authorisation	30/12/2025	

2.1.1.3 Manufacturer of the product

Name of manufacturer	MYLVA S.A.
Address of manufacturer	Vía Augusta, 48. 08006 Barcelona Spain.
Location of manufacturing sites	Sant Galderic 23, Polígono Industrial Ponent, Sant Pol de Mar 08395, Barcelona (Spain)

2.1.1.4 Manufacturer of the active substance

Active substance	**Permethrin**
Name of manufacturer	Caldic Denmark A/S (Denmark) (Acting for Tagros Chemicals India Limited (India))
Address of manufacturer	Odinsvej 23, DK-8722 Hedensted (Denmark)
Location of manufacturing sites	Tagros Chemicals India Limited A4 / 1 & 2 SIPCOT INDUSTRIAL COMPLEX, PACHAYANKUPPAM 607 005 CUDDALORE Tamil Nadu India
Active substance	**Propiconazole**
Name of manufacturer	Janssen PMP, a division of Janssen Pharmaceutica NV
Address of manufacturer	Turnhoutseweg 30, B-2340 Beerse (Belgium)
Location of manufacturing sites	Jiangsu Sevencontinent Green Chemical Co. Ltd. North Area of Dongsha Chem-Zone. 215600 Zhangjiagang China

Active substance	**IPBC**
Name of manufacturer	Troy Chemical Company BV
Address of manufacturer	Uiverlaan 12e, 3145 XN Maassluis (The Netherlands)
Location of manufacturing sites	8 Vreeland Road P.O. Box 955, Florham Park 07932 New Jersey New Jersey (USA)

2.1.2 Product composition and formulation

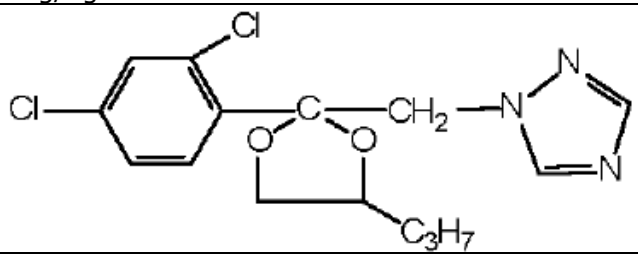
NB: The full composition of the product has been provided in the confidential annex.

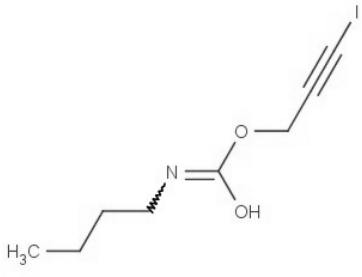
Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes ☐
No ☒

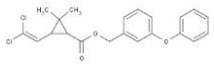
2.1.2.1 Identity of the active substance

The biocidal product has four active substances.

Main constituent(s)	
ISO name	Propiconazole
IUPAC or EC name	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole
EC number	262-104-4
CAS number	60207-90-1
Index number in Annex VI of CLP	613-205-00-0
Minimum purity / content	930 g/kg
Structural formula	

Main constituent(s)	
ISO name	IPBC
IUPAC or EC name	3-iodo-2-propynyl butylcarbamate
EC number	259-627-5
CAS number	55406-53-6
Index number in Annex VI of CLP	616-212-00-7
Minimum purity / content	980 g/kg
Structural formula	

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	
Minimum purity / content	80.0-95.0 %
Structural formula	

2.1.2.2 Candidates for substitution

The biocidal product SERPOL GEL II contains the active substance propiconazole, which meets the criteria for exclusion under article 5 (1) and substitution under Article 10 (1) of the Biocides Regulation (EU) No 528/2012. Therefore in line with Article 23 (1) of the BPR a comparative assessment will beconducted.

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 (pure)
Propiconazole	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole	Active Substance	60207-90-1	262-104-4	0.85 (pure)
IPBC	3-iodo-2-propynyl butylcarbamate	Active Substance	55406-53-6	259-627-5	0.4 (pure)
Naphthalene		Non active substance	91-20-3	202-049-5	0.006
DISOLVENTE ISOPARAFINICO N	Hydrocarbons, C12-C16, isoalkanes, cyclics, <2% aromatics	Non-active substance	Related CAS Nº: 64742-47-8	927-676-8	70.534

2.1.2.4 Information on technical equivalence

The source of Permethrin (Caldic Denmark A/S) is the same as evaluated in the review programme and approved by the Comission, so information about technical equivalence is not relevant.

The source of Propiconazole (Janssen Pharmaceutica NV) is not the same as considered at active substance approval.
The Propiconazole source has been judged as technically equivalent to the approved source by ECHA (asset number EU-0003416-0000 – Decision: TAP-D-1025003-44-00/F).

The source of IPBC (Troy Chemical Company BV) is the same as evaluated in the review programme and approved by the Comission, so information about technical equivalence is not relevant.

2.1.2.5 Information on the substance 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.

Common name	**Classification and Labelling according to Regulation (EC) No 1272/2008**	**CAS number**	**EC number**
Naphthalene	H400, H410	91-20-3	202-049-5

Naphthalene (CAS: 91-20-3), it has been considered as a substance of concern according to art. 3 (1) (f) of Regulation (EU) 528/2012 (see section 8.1.1. of the document "Guidance on the BPR: Volume IV Environment, Assessment & Evaluation (Parts B + C)" version 2.0 of October 2017), the following is clarified. Its inclusion as a priority substance in the field of water policy (Directive 2000/60 / EC), for which a maximum admissible concentration in continental waters of 130 µg/l has been established (Directive 2008/105 / EC), makes that this substance should be considered SoC regardless of its concentration in the biocidal product, and it must be demonstrated that this environmental limit is not exceeded with the application of the biocidal product according to the established scenarios. As the product SERPOL GEL II is for wood UC 1 and UC2, indoor use, 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 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. Therefore the environmental limit of naphthalene is not exceeded with the application of SERPOL GEL II.

Another co-formulant has been authorised as biocidal active substance under BPR regulation. The concentration of this substance in SERPOL GEL II is below 0.1%. However, is being assessed 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 during renewal of product authorization if a Draft Final Competent Authority Report is available. Please see the confidential annex for further details

2.1.2.6 Type of formulation

Gel for direct application (GD)

2.1.3 Hazard and precautionary statements

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

Classification	
Hazard category	Repr 1B; H360D Aquatic Acute 1 Aquatic Chronic 1-
Hazard statement	H360D: May damage the unborn child. H400: Very toxic to aquatic life H410: Very toxic to aquatic life with long lasting effects
Labelling	
Pictogram	GHS08, GHS09
Signal words	Danger
Hazard statements	H360D: May damage the unborn child. H410: Very toxic to aquatic life with long lasting effects. EUH066: Repeated exposure may cause skin dryness or cracking EUH208: Contains "Permethrin, IPBC, propiconazole, 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	P201: Obtain special instructions before use. P202: Do not handle until all safety precautions have been read and understood. P273: Avoid release to the environment P280: Wear protective gloves/ protective clothing/eye protection/face protection/ hearing protection/… P308+P313: IF exposed or concerned: Get medical advice/attention. P391: Collect spillage P405: Store locked up. P501: 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 uses

2.1.4.1 Use description 1

Table 1. Preventive treatment-Superficial application (brushing/rolling)-Trained professional user. Indoors only.

Product Type	PT8

Where relevant, an exact description of the authorised use	SERPOL GEL II is a wood preservative product with insecticidal and fungicidal properties for class of use 1 and 2.
Target organism (including development stage)	Insects: - Wood boring beetles. (*Hylotrupes bajulus*). - Subterranean termites. (*Reticulitermes spp*) Fungi: - Wood rotting basidiomicetes (Brown rot) - Wood discoloring fungi- Bluestain in service.
Field of use	Class of use 1: Situation in which the wood or wood-based product is inside a construction, not exposed to the weather and wetting Class of use 2. Situation in which the wood or wood-based product is under cover and not exposed to the weather (particulary rain and driven rain) but where occasional, but not persistent, wetting can occur.
Application method	Superficial treatment only by brushing/rolling.
Application rates and frequency	Dose rate: 200 g/m^2 treated wood. (250 ml/m^2)
Category of use	Trained professional user.
Pack sizes and packaging material	Plastic bucket (PP) of 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

2.1.4.1.1 Use-specific instructions for use

See section 2.1.5.1

2.1.4.1.2 Use-specific risk mitigation measures

See section 2.1.5.2

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

See section 2.1.5.3.

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

See section 2.1.5.4.

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

See section 2.1.5.5.

2.1.4.2 Use description 2.

Table 2. Curative treatment- Superficial application (brushing/rolling)- Trained professional user.

Product Type	PT8
Where relevant, an exact description of the authorised use	SERPOL GEL II is a wood curative product with insecticidal properties.
Target organism (including development stage)	Insects: - Wood boring beatles. (*Hylotrupes bajulus*).Larvae. - Subterranean termites. (*Reticulitermes spp*)
Field of use	Indoors: in a situation which wood or wood-based products are within a building, not exposed to weather and wetting, although occasionally, but not persistently, wetting can occur.
Application method	Curative treatment by brushing/rolling. Quick action.
Application rates and frequency	Dose rate: 250g/m^2 treated wood (300 ml/m^2)
Category of use	Trained professional user.
Pack sizes and packaging material.	Plastic bucket (PP) of 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

2.1.4.2.1 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 5.5.

2.1.5 General directions for use

2.1.5.1 Instructions for use

Read attached instructions before use. Aerate adequately the place where the product is applied. Only for softwood. Make sure that the timber to be treated is clean and free of any kind of finish or coating. Apply the product by brushing/rolling, without diluting it or mixing it with other products. Apply a uniform layer on the surface of the wood according to dosage in label and let it dry until it is completeley absorbed.

2.1.5.2 Risk mitigation measures

Use protective gloves and impermeable coveralls during the application of the product (material to be specified by the authorisation holder within the product information). Wash hands and exposed skin before meal and after use. Do not use on wood which may come in direct contact with food, feeding stuff and livestock animals. Do not contaminate foodstuffs, eating utensils or food contact surfaces. Ensure adequate ventilation during and after the application, until treated surfaces have dried. Keep children and pets away from treated structures until dried. Store in original packaging under recommended storage conditions. 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. The users should inform if the treatment is ineffective and report straightforward to the registration holder.

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

easy to do. Call a POISON CENTRE or a doctor.

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

2.1.5.4 Instructions for safe disposal of the product and its packaging

Empty containers, unused product and other waste generated during the treatment are considered hazardous waste.

Dispose of in accordance with current regulations.

Do not release into soil, ground, surface water or any kind of sewer.

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

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.
Protect from frost.
Shelf-life: 4 years

2.1.6 Other information

Definitions:

Trained professional: pest control operators, having received specific training in wood preservatives according to the national legislation in force.

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, 500, 650, 750, 1000ml; 1, 2, 5, 7, 7.5, 10, 25, 50, 60, 100, 200L	Plastic (Polypropylene)		Trained professional	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

2.1.8.2 Access to documentation

Mylva, S.A. has submitted a Letter of Access for the active substances Permethrin, Propiconazole and IPBC from owner data dossier at active substance approval company respectively.

All efficacy tests provided have been perfomed with SERPOL GEL II and belong to MYLVA, S.A., so no tetter of access is required to use this tests.

2.2 Assessment of the biocidal product

2.2.1 Intended uses as applied for by the applicant

Table 1. Intended use # 1 – Trained professional user.

Product Type(s)	PT8
Where relevant, an exact description of the authorised use	Serpol Gel II is a ready-to-use wood preservative product to be applied indoors as a gel under use class 2. The product is applied by brushing, projection (spraying of a gel product) and injection.
Target organism (including development stage)	Reticulitermes sp. (Adults and Nymphs), *Hylotrupes bajulus* L. (Larvae), *Coniophora puteana* (Hyphae), *Gloephyllum trabeum* (Hyphae), *Poria placenta* (Basidiomycetes), *Aureobasidium pullulan*s spp. (Hyphae), *Sclerophoma pithyophila* (Hyphae)
Field of use	Indoor. Serpol Gel II is a product intended to use as a use class 2 product, which is the situation in which the wood or wood-based product is under cover and not exposed to the weather (particularly rain and driven rain) but where occasional, but not persistent, wetting can occur
Application method(s)	Open system: brush treatment, injection and projection. - Brush treatment: Use a clean brush or a roller to apply the product undiluted and unmixed with other products in the timber to be treated. Apply on clean and dry wood, free from any kind of finish or coating (paint, varnish, oil, etc.) that hamper penetration of Serpol Gel II. For subsequent treatments wait until the application is completely dry. - Injection: Apply the product by injecting it in the core of the timber in order to have a better curative effect on the inside, thus making it easier to the product to penetrate the timber. For subsequent treatments wait until the application is completely dry. - Projection: It consists in the spraying application of the product. Due to the physicochemical properties of a Gel product, particles sprayed are bigger than a liquid product and spraying is considered as a projection of the product. Apply the product undiluted and unmixed with other products in the timber to be treated. Apply on clean and dry wood, free from any kind of

	finish or coating (paint, varnish, oil, etc.) that can hamper the penetration of Serpol Gel II. Apply a uniform layer on the surface of the timber according to dosage indicated and wait until it is completely dry. For subsequent treatments wait until the application is completely dry.
Application rate(s) and frequency	Application dose of 250 ml/m^2 against Hylotrupes and/or Reticulitermes; 30 kg/m^3 against Basidiomycetes. One application according to dosage indicated in the label is enough to protect and cure timber.
Category(ies) of user(s)	Trained professional
Pack sizes and packaging material	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. Plastic

Table 2. Intended use # 2 – Non-trained professional user

Product Type(s)	PT 8
Where relevant, an exact description of the authorised use	Serpol Gel II is a ready-to-use wood preservative product to be applied indoors as a gel under use class 2. The product is applied by brushing, projection (spraying of a gel product) and injection.
Target organism (including development stage)	Reticulitermes sp. (Adults and Nymphs), *Hylotrupes bajulus* L. (Larvae), *Coniophora puteana* (Hyphae), *Gloephyllum trabeum* (Hyphae), *Poria placenta* (Basidiomycetes), *Aureobasidium pullulan*s spp. (Hyphae), *Sclerophoma pithyophila* (Hyphae)
Field of use	Indoor. Serpol Gel II is a product intended to use as a use class 2 product, which is the situation in which the wood or wood-based product is under cover and not exposed to the weather (particularly rain and driven rain) but where occasional, but not persistent, wetting can occur
Application method(s)	Open system: brush treatment, injection and projection. - Brush treatment: Use a clean brush or a roller to apply the product undiluted and unmixed with other products in the timber to be treated. Apply on clean and dry wood, free from any kind of finish or coating (paint, varnish, oil, etc.) that hamper penetration of Serpol Gel II. For subsequent treatments wait until the application is completely dry. - Injection: Apply the product by injecting it in the core of the timber in order to have a better curative effect on the inside, thus making it easier to the product to penetrate the timber. For subsequent treatments wait until the application is completely dry. - Projection: It consists in the spraying application of the product. Due to the physicochemical properties of a Gel product, particles sprayed are bigger than a liquid product and spraying is considered as a projection of the product. Apply the product

	undiluted and unmixed with other products in the timber to be treated. Apply on clean and dry wood, free from any kind of finish or coating (paint, varnish, oil, etc.) that can hamper the penetration of Serpol Gel II. Apply a uniform layer on the surface of the timber according to dosage indicated and wait until it is completely dry. For subsequent treatments wait until the application is completley dry.
Application rate(s) and frequency	Application dose of 250 ml/m^2 against Hylotrupes and/or Reticulitermes; 30 kg/m^3 against Basidiomycetes. One application according to dosage indicated in the label is enough to protect and cure timber.
Category(ies) of user(s)	Professional
Pack sizes and packaging material	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. Plastic

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual inspection at room temperature in a clear glass dish under natural light	Permethrin: 0.35% Propiconazole :0.85% IPBC: 0.40%	Gel	Raphalen, E. 2016
Physical state	ASTM D 4359-90	Permethrin: 0.35% Propiconazole :0.85% IPBC: 0.40%	Liquid	Reig, M. 2020
Colour at 20 °C and 101.3 kPa	Visual inspection at room temperature in a clear glass dish under natural light.	Permethrin: 0.35% Propiconazole :0.85% IPBC: 0.40%	Opaque white	Raphalen, E. 2016
Odour at 20 °C and 101.3 kPa		Permethrin: 0.35% Propiconazole :0.85% IPBC: 0.40%	Odourless	Raphalen, E. 2016
Acidity / alkalinity	CIPAC MT.75	Permethrin: 0.35% Propiconazole :0.85%	pH = 6.5	Raphalen, E. 2016

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
		IPBC: 0.40%		
Relative density / bulk density	OECD Guideline 109 (Density of Liquids and Solids). Pycnometer method.	Permethrin: 0.35% Propiconazole :0.85% IPBC: 0.40%	D_4^{20} = 0.831	Raphalen, E. 2016
Storage stability test – **accelerated storage**	CIPAC MT46.3	Permethrin: 0.35% Propiconazole : 0.85% IPBC: 0.40%	Tª: 54°C time: 14 days • Permetrina: $[C]_0$ = 0.347% $[C]_f$ = 0.351% Δ[C] = +1.15% • IPBC: $[C]_0$ = 0.391% $[C]_f$ = 0.393% Δ[C] = +0.51% • Propiconazol: $[C]_0$ = 0.922% $[C]_f$ = 0.929% Δ[C] = +0.76% The appearance of the test item did not change. The appearance of the commercial packaging did not change. The weight of the test item in its commercial packaging did not change significantly (-0.09%). No sign of corrosion was found. The percentage of decrease of the active substance is within the stablished range by the Guidance.	Raphalen, E. 2016
Storage stability test – **long term storage at**	GIFAP Monograph	Permethrin: 0.35%	Tª: 20°C time: 48 months	Legay, S. 2020

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
ambient temperature	No. 17, CropLife International.	Propiconazole : 0.85% IPBC: 0.40%	• Permetrina: $[C]_0$ = 0.347% $[C]_{12M}$ = 0.361% $\Delta[C]$ = +4.03% $[C]_0$ = 0.347% $[C]_{24M}$ = 0.330% $\Delta[C]$ = -4.9% $[C]_0$ = 0.347% $[C]_{48M}$ = 0.339% $\Delta[C]$ = -2.3% • IPBC: $[C]_0$ = 0.391% $[C]_{12M}$ = 0.392% $\Delta[C]$ = +0.26% $[C]_0$ = 0.391% $[C]_{24M}$ = 0.358% $\Delta[C]$ = -8.44% $[C]_0$ = 0.391% $[C]_{48M}$ = 0.369% $\Delta[C]$ = -5.62% • Propiconazol: $[C]_0$ = 0.922% $[C]_{12M}$ = 0.905% $\Delta[C]$ = -1.84% $[C]_0$ = 0.922% $[C]_{24M}$ = 0.857% $\Delta[C]$ = -7.05% $[C]_0$ = 0.922% $[C]_{48M}$ = 0.903% $\Delta[C]$ = -2.06% pH_0: 6.5 pH_{48M}: 6.9 Packaging: No sign of leakage or deformation or discolouration before and after storage. The weight of the test	

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
			item in its commercial packaging did not change significantly after storing (-0.3%). The percentage of decrease of the active substance is within the stablished range by the Guidance. Therefore, a shelf life of 4 years can be granted.	
Storage stability test – **low temperature stability test for liquids**	The test has not been performed so the sentence "Protect from frost" has been included on the label.			
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	No applicable. The product is not sensitive to light. Furthermore, it is sold in opaque packaging. Therefore, a study of the effect of light is not necessary.			
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	See results storage stability tests.			
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	See results storage stability tests.			
Wettability	No applicable.			
Suspensibility, spontaneity and dispersion stability	No applicable.			
Wet sieve analysis and dry sieve test	No applicable.			
Emulsifiability, re-emulsifiability and emulsion stability	No applicable.			
Disintegration time	No applicable.			
Particle size	No applicable.			

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
distribution, content of dust/fines, attrition, friability				
Persistent foaming	No applicable.			
Flowability/Pourability/ Dustability	No applicable.			
Burning rate — smoke generators	No applicable.			
Burning completeness — smoke generators	No applicable.			
Composition of smoke — smoke generators	No applicable.			
Spraying pattern — aerosols	No applicable.			
Physical compatibility	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.			
Surface tension	OECD Guideline 115 (Surfase Tension os Aqueous Solution) EU Method A.5	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	OECD Guideline 114	The dynamic viscosity varied as following: • At 20°C from 1094000 mPa·s to 72700 mPa·s from 0.3 to 5 rpm and from 73140 mPa·s to 1098000 mPa·s from 5 to 0.3 rpm • At 40°C from 971200 mPa·s to 74850 mPa·s from 0.3 to 5 rpm and from 73800 mPa·s to 1001500 mPa·s from 5 to 0.3 rpm		

Conclusion on the physical, chemical and technical properties of the product
SERPOL GEL II is a white gel which pH and density values are 6.5 and 0.831 g/ml respectively. Based on the viscosity results it can be stated that the product shows a non-newtonian behavior. A 4 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 4 years.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	It has been considered not necessary to test the explosive properties for the formulation SERPOL GEL II based on the criteria established in the Guidance EC A14 related to the determination of the explosive properties of a formulation product. According to this Guidance, it can be expected that the product SERPOL GEL II does not show these explosive properties due to the lack of any ingredient in its formulation that pose molecular structures with explosive properties.			
Flammable gases	Not applicable			
Flammable aerosols	Not applicable			
Oxidising gases	Not applicable			
Gases under pressure	Not applicable			
Flammable liquids	Not relevant as none of the individual ingredients have been identified or classified of having flammable properties.			
Flammable solids	Not applicable			
Self-reactive substances and mixtures	Not applicable			
Pyrophoric liquids	Not relevant as none of the individual ingredients have been identified or classified of having pyrophoric properties			
Pyrophoric solids	Not applicable			
Self-heating substances and mixtures	Not applicable			
Substances and mixtures which in contact with water emit flammable gases	Not applicable			
Oxidising liquids	It has been considered not necessary to test the oxidising properties for the formulation SERPOL GEL II based on the criteria established in the Guidance EC A17 related to the determination of the oxidising properties of a formulated product. According to this Guidance, it can be expected that the product does not show these oxidising properties due to the lack of any ingredient in its formulation that pose molecular structures with oxidising properties.			
Oxidising solids	Not applicable			
Organic peroxides	The study does not need to be conducted because any of the components of the product does not fall under the definition of organic peroxides according to GHS and the relevant UN Manual of test and criteria.			
Corrosive to metals	Test ASTM G-31	Permethrin: 0.35% Propiconazole: 0.85% IPBC: 0.40%	No corrosion attack was occurred after 7 days of exposure at the	García, G. 2021

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			temperature of 55 ºC and the loss mass was 0 %	
Auto-ignition temperatures of products (liquids and gases)	Based on the components it is not expected an auto-ignition reaction. Furthermore, the test is not feasible because the flame goes out.			
Relative self-ignition temperature for solids	Not applicable			
Dust explosion hazard	Not applicable			

Conclusion on the physical hazards and respective characteristics of the product
SERPOL GEL II 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 From 28 to 42 mg/L	Serie 1: $y=5.86\cdot10^4 x - 7.26\cdot10^4$ $R^2=0.997$ Serie 2: $y=5.68\cdot10^4 x - 7.73\cdot10^4$ $R^2=0.995$	No interferences more than 3% at the selected wavelength was detected at the retention time of each active substance.	96.11 % - 99.40 %	97.87 %	0.3245	Raphalen, E. 2016
IPBC	HPLC-UV	n= 5 From 32 to 48 mg/L	Serie 1: $y=1.25\cdot10^3 x + 6.24\cdot10^3$ $R^2=0.993$ Serie 2: $y=1.35\cdot10^3 x - 1.39\cdot10^3$	No interferences more than 3% at the selected wavelength was detected at the retention time of	96.68 % - 104.23 %	100.39 %	0.8122	

			R^2=0.998	each active substance.				
Propiconazole	HPLC-UV	n= 5 From 68 to 102 mg/L	Serie 1: $y=2.65\cdot10^4 x - 1.53\cdot10^4$ R^2=0.999 Serie 2: $y=2.62\cdot10^4 x - 2.29\cdot10^3$ R^2=0.999 All calibration were found to be linear, with determination coefficients (R^2) of 0.99 or greater	No interferences more than 3% at the selected wavelength was detected at the retention time of each active substance.	99.40 % - 102.28 %	100.74 %	0.7445	

Conclusion on the methods for detection and identificationof the product
This analytical method for the determination of each active ingredient in the test item SERPOL GEL II was successfully validated according to SANCO/3030/99 rev.4

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

SERPOL GEL II is a solved-based wood preservative product applied indoors as preventive (class 2) and curative treatments by trained professional, professional and non-professional users.
It is intended to be use by surface applications (brushing) for preventive treatment and by surface application (spraying) and injection application for curative treatment. .

- Superficial preventive application: 200 g of product per m^2 f wood.
- Superficial curative application: 300 ml of product per m^2 f wood.
- Inyection curative application: 30 kg of product per m^3 f wood.

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

SERPOL GEL II is a wood preservative with insecticidal and fungicidal properties against fungi species (i.e.; basidiomycetes), wood boring beetles and termites (*Reticulitermes* spp.)

2.2.5.3 Effects on target organisms, including unacceptable suffering

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.
The product acts as a preventive to fungi and prevents their attack. It causes a decrease in the degree of colonization of these fungi after contact with treated wood.
Unacceptable suffering for fungi, insect larvae and termites cannot be assessed.

2.2.5.4 Mode of action, including time delay

The biocidal product contains 3 active substances: IPBC (carbamate molecule), propiconazole and permethrin (pyrethroide molecule).

According to the FRAC (Fungicide Resitant Action Committee), the mode of action of propiconazole is sterol biosynthesis in membranes, and the mechamism of action is the inhibition of demethylation (DeMethylation Inhibitors). Their common name are Triazoles.

IPBC has a Carbamate structure. The target sites of carbamates in fungui are cell membrane permeability and fatty acids. According to the FRAC, 2019, the risk of resistance formation against carbamate fungicides ir regarded to be low to medium and resistance management is required, in ddition, based on the unspecific mode of action of IPBC, the risk of resistance formation during incan preservation is regarded to be low. (IPBC PAR, 2013),

Regarding Permethrin, according to IRAC, it acts in sodium channel on the modulators of nerve action. Keep sodium channels open, causing hyperexcitation and, in some cases, nerve block. Sodium channels are involved in the propagation of action potentials along nerve axons

2.2.5.5 Efficacy data

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 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	Determination of toxic values.	*Pinus sylvestris*	Subterranean termite *Reticulitermes grassei*	EN 117+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	Wood preservative Preventive treatment	*Pinus sylvestris*	Wood destroying basidiomicetes. *Coniophora puteana* *Gloeophyllum trabeum* *Poria placenta*	EN 113+EN73 (evaporation)	• Superficial treatment (brushing) • 100%(w/w) • Exposure 16 weeks	Toxic values: *Coniophora puteana* 204.84 g/m^2 *Gloeophyllum trabeum* 204.13 g/m^2 *Poria placenta* 207.79 g/m^2	Report nº: 052526-6-a
SERPOL GEL II	Wood preservative Preventive treatment	*Pinus sylvestris*	*Aureobasidium pullulams* *Sclerophoma pithophilla*	EN 152	• Superficial treatment (brushing) 2 coats. • 100%(w/w) • Exposure 109 days • Toxic value: 200.25 g/m^2 • Type C. • Preconditioning: artificial ageing.QUV (cycle 1)	Visual examination after biological essay is 0.5. At the end of test no individual rating ≥2. Minimun stain-free zone: 4.8. Mean stain-free zone:6.7. The data of the speciments of the reference product and control specimens $C_{1.1.}$ validate the assay.	Report nº: 052526-7-a (M2)
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: 176g/ 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	Report nº: 052526-3-a

						control specimens, survive.	
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
SERPOL GEL II	Wood preservative Curative treatment	*Pinus sylvestris*	House longhorn beetle. *Hylotrupes bajulus (L.)*	EN 1390	• Superficial treatment (brushing) • 253.63 g/m^2 / 301.94 ml/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

Conclusion on the efficacy of the product

According to the applicant SERPOL GEL II is intended to be use class 2 as preventive treatment by superficial application and curative treatment by superficial and inyection applications.
The applicant has submitted 7 tests to support these claims.

Preventive treatment. Superficial application (Use class 2):

Subterranean termites (*Reticulitermes spp*):
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 and 2.
-Dose rate by surface treatment: **166.01± 1.32 g/m^2**

Wood destroying basidiomicetes (Brown rot).
The applicant has contributed one test with the UNE 113 standard to support the claim of wood destroying basidiomicetes. It has been developed with ageing procedure EN 73.
According to the test, there is a deviation to the standad: *The test has been done by brushing in one concentration, not by vacuum treatment and not in five concentrations as the standard indicates because the product comes in gel format and it can´t be diluted, as the product is diluted, it will no more be a gel, losing its properties*.
We consider these justification acceptabled.
In this case, at a concentration of 100% without dilution, the corrected mass losses are 0 and, according to the interpretation of the results of point 8.6.4 of the standard, it would be shown that this dilution offers protection.
On the other hand, and as a worst case, we would assimilate the mix-toxic value with the biological reference value according to point 5.2.16 of the EN599-1 standard.
Due to the deviation of the test, point 5.2.15 of the EN599-1 standard does not apply.

	EN113 (EN73). *Biological reference value*.
Coniphora puteana	204.84 g/m^2
Gloeophyllum trabeum	204.13 g/m^2
Poria placenta	207.79 g/m^2

The critical value (5.2.15.) for superficial treatment for the most aggressive fungui is:
207.79 g/m^2
This dose slightly exceeds the 200g/m^2 indicated by the norm. But we are aware that it is an excessive dose for treating wood-destroying fungi. Therefore the dose will be adjusted to 200g/m^2
-Dose rate by surface treatment: **200 g/m^2**

Blue stain in service.
The applicant has provided a test against blue stain fungi with artificial ageing. The degree of blushiness of both the virulence contro and the referente product validate the assay.
The toxic value by surface treatmen: **200.25g/m^2.**

Wood boring beetles (*Hylotrupes bajulus*)**.**
The applicant has submitted a trial against *Hylotrupes bajulus* with ageing test EN73.
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.
- Dose rate by superficial treatment: **176 g/m^2 or 198.82±1.58 ml/m^2**

Curative treatment.Superficial application:
Subterranean termites (*Reticulitermes spp*).
According to the TNsG, the treatment against termites are designed to kill termites that their are already found in the wood and to prevent the degradation of wood. So preventive efficacy test can be extrapolated for a curative treatment.

Wood boring beetles (*Hylotrupes bajulus*):
The applicant has submitted a tests against *Hylotrupes bajulus*.
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*. (The document is only in spanish language).
- Curative dose rate by superficial treatment: **253.63 g/m^2 or 301.94 ml/m^2.**

Curative treatment. Inyection 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 methodmethod but rather the provision of specific and relevant data, especially in the penetration/diffusion of the product into the holes.

Even thought,the applicant has submitted two trials against termites and wood boring beetes 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 from 3-10 ml. The distance between holes is 15 cm, if the first inyection shows that the product has not penetrated as it should, the injection shoul be repeated.
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/m^3**

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 product could be and therefore we consider that without more information, it is not possible to accept this mode of application.

Conclusion:
Based on the efficacy evaluation, the product may be authorised for use class 2 as prevetive treatment against subterranean termites (*Reticulitermes* sp), wood-boring beetles, bluestain in service, and wood-destroying basidiomycetes (brown rot fungi) by surface treatment brushing/rolling for softwood. Dose rate: 200g/m^2.
In addition the product can be authorised for curative treatment by brushing (dose rate: 300ml/m^2) against subterranean termites (*Reticulitermes* sp) and wood.boring beetles (*Hylotrupes bajulus*) for softwood.

2.2.5.6 Occurrence of resistance and resistance management

Accoding to the FRAC, regarding these kind of substances, resistance is known in various fungal species. Several resistance mechanisms are known incl. target site mutations in cyp51 (erg 11) gene, e.g. V136A, Y137F, A379G, I381V; cyp51 promotor; ABC transporters and others.

Generally wise to accept that cross resistance is present between DMI fungicides active against the same fungus. DMI fungicides are Sterol Biosynthesis Inhibitors (SBIs), but show no cross resistance to other SBI classes. Medium risk.

Resistance to DMIs is mostly characterized by a slow, step-wise erosion of efficacy over several years of intensive use rather than by a rapid loss of control.
- Users must adhere to the manufacturers' recommendations. In many cases, reports of "resistance" have, on investigation, been attributed to cutting recommended use rates, or to poorly timed applications.
- If the performance of SBIs declines and sensitivity testing confirms the presence of less sensitive isolates, SBIs should only be used in mixture or in alternation with effective non-cross-resistant partner fungicides..

The active substance IPBC is not specifically on list of fungicide common names as reference substante for any group from FRAC. Anyway, IPBC has a carbamet molecule and we can make an approach to the carbamate group. According to FRAC carbamates has low to medium risk. Resistance management required.

FRAC focuses mainly on fungicide resistance to products intended for agriculture. In the list of pathogenic species, no wood destroying species are included.

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 cypermethrin 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.

2.2.5.7 Known limitations

NO limitations are known.

2.2.5.8 Evaluation of the label claims

Claim matrix:

User category	Industrial, trained porfessional	A.20; A.30
Wood category	Softwood	B.10
Wood product	Solid wood	C.10
Application aim	Preventive Curative	D.40 D.50
Field of use	Use class 2	E.20
Method of application rate	Superficial application. Brush/rolling Injection.(non authorized)	F.10 F.20
Target organisms	Wood rotting basidiomycetes. Bluestain in service House longhorn beetle. Subterranean termites.	G.10 G.21.2 G.31 G.51

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

Not applicable.

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

No studies on the effects of SERPOL GEL II 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 effects of active substances and critical concentrations are described in their Assessment Reports (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.

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	SERPOL GEL II is neither irritant nor corrosive to the skin.
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 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 substances 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 is 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	SERPOL GEL II is not a skin sensitizer
Justification for the value/conclusion	Based on the classification of the active substances and the different co-formulants and, their respective content in the final formulation. Permethrin, IPBC and propiconazole are classified for skin sensitisation according to annex VI of Regulation (EC) No 1272/2008. However, as their concentrations are 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 for skin sensitisation is not required. Labelling with EUH208 (Contains "Permethrin, IPBC, propiconazole, 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 from 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	SERPOL GEL II is not a respiratory sensitizer.
Justification for the value/conclusion	Based on the classification of the active substances 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 from safety data sheets and other information for each of the individual components in the product. Consequently, classification of the mixture can be made according to the rules laid down in Regulation (EC) No 1272/2008. None of the ingredients are classified as respiratory sensitizers, so the product is not classified.

Acute toxicity

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 Reports of permethrin, IPBC and propiconazole and the SDSs of the other components. According to Assessment Reports of permethrin, IPBC and propiconazole, the LD50 values are 480 mg/kg bw, 300-500 mg/kg bw and 1500 mg/kg respectively. 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 SERPOL GEL II 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 Reports of permethrin, IPBC propiconazole and the SDSs of the other components. IPBC is classified with Acute Tox. 3; H331, while permethrin is classified with Acute Tox. 4; H332. According to the Assessement Reports, the LC_{50} values for IPBC and permethrin are for dust/mist 0.67 mg/l and 4.638 mg/l, respectively 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 SERPOL GEL II 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	SERPOL GEL II 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

No study on dermal absorption of SERPOL GEL II has been submitted. A dermal absorption value of 3, 2 and 10% for Permethrin, Propiconazole and IPBC respectively has been proposed by the applicant for exposure calculations. However ES CA do not accept the justification of the applicant and considers that a demal absoption value of 70% must be used for the exposure calculations.

According to the Guidance on the BPR (Volume III: Human health Part A: Information Requirements, Ver. 1.2, May 2018), *"before new studies are commenced, it should be*

checked whether the intended use is safe when the appropriate default value is applied. If no experimental data are available, studies with similar formulations should be looked for or further information used that may give at least a rough estimate……but in this case strict and transparent rules should be followed as to when another formulation or product can be considered similar"

EFSA Guidance Document on Dermal Absorption (EFSA, 2017) stablishes that dermal absorption data on another (reference) formulation can be used if the formulation for which dermal absorption needs to be determined is closely related. This occurs when all the following conditions are met:

- Content of relevant components in the formulation to be assessed (e.g. other active substance, synergist, safener, wetting agent, surfactant, solvent, emulsifier, preservative, stabiliser, detergent, adhesive, antifreezing substance (= all co-formulants), similar chemical types of co-formulants might be grouped as described below) is within permitted variation ranges of those in the reference formulation. Addition of substances not contained in the reference formulation might be acceptable up to a concentration of ≤ 0.5%, but only if it is shown or scientifically justified that this minor change does not have an impact on physical–chemical or toxicological properties of the formulation. In individual cases, greater variations might be acceptable, for example, replacement of a co-formulant by water or increase of an inert compound
- Co-formulants of both formulations are chemically and physicochemically closely related.
- Additional active substances do not possess properties that may change skin permeability (e.g. irritant and sensitising properties).
- Formulation is of the same or lower skin irritancy based on scores in studies.
- Formulation having the same or no sensitising potential based on classification.
- Active substance concentration is within permitted variations of that in the reference formulation based on the FAO and WHO specifications for pesticides (FAO/WHO, 2016, chapter 4.3.2)

It is considered unlikely that the above criteria will be met when moving from one formulation type to another.

According to the CAR for active substance Permethrin, a dermal absorption value of 3% has been set derived in a human volunteers dermal penetration study. The first two volunteers have been excluded from the derivation as they have a very low recovery and were regarded as outlines compared to the other 4 volunteers. In addition, the values have been normalised to 100% to compensate for the low recovery allowing derivation of a dermal absorption value of 3% as a rounded figure. This value of 3% cannot be accepted since it is not possible establish a similarity between the formulation tested in the study of volunteers provided in the CAR and the product SERPOL GEL II. Furthermore, according to teh guidance on Dermal Absorption, scientifically sound human volunteer *in vivo* data, even if ethically performed, cannot be used. Therefore, according to the BPC opinion on the approval of the active substance permethrin in product type 8, further data may be required, in particular regarding dermal absorption of the products and should be provided by applicants at the product authorization stage.

According to the CAR for active substance IPBC, an *in vitro* study with human skin gave dermal absorption values (including skin residues) of 30, 10, and 1.6% for solvent-based formulations containing 0.6, 2.3, and 17.1% IPBC, respectively and 100% default for solutions containing <0.5%-0.6% IPBC. The proposed 10% value cannot be accepted

since it is not possible establish a similarity between the tested formulations provided in the CAR and the product SERPOL GEL II. Therefore, according to BPC opinion further data may be required, in particular regarding dermal absorption of the products and should be provided by applicants at the product authorization stage.

According to the CAR for active substance propiconazole dermal absorption values used in the calculations are 1 % for the undiluted water based product (10 % a.s., Wocosen 100 SL), and 2% for the dilution (1% a.s.) and the solvent based product (app. 1.4% a.s., Wocosen 12 OL). The proposed 2% value cannot be accepted since it is not possible establish a similarity between the tested formulation provided in the CAR (Wocosen 12 OL) and the product SERPOL GEL II.

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

Data waiving	
Information requirement	Dermal absorption study
Justification	There is no experimental data available on the dermal absorption of SERPOL GEL II 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.
See confidential annex.

Other

SERPOL GEL II 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 971200 mPa s to 74850 mPa s from 0.3 to 5 rpm and from 73800 mPa s to 1001500 mPa s from 5 to 0.3 rpm, and the density is 0.831g/cm^3, the kinematic viscosity measured at 40 °C is far above 20mm^2/s based on theoretical calculation. Therefore SERPOL GEL II 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.
According to the CAR (February 2008) and BPC Opinion for PT13 (December 2014), IPBC 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.
According to BPC opinion for PT7 (December 2014), propiconazole interfers the steroid hormone synthesis but there is not enough data to conclude whether it has endocrine disrupting properties or not. The potential for endocrine disruption should be re-assessed once EU harmonised guidelines will be available.
After examining the possible ED properties of co-formulants, none of the co-formulants contained in the product SERPOL GEL II 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 are identified as having ED properties in the future, the conditions for granting the biocidal product authorisation will be revised.
Please, refer to the confidential annex for more information.

2.2.6.2 Exposure assessment

SERPOL GEL II is a ready-to-use gel wood preservative, applied by brushing and rolling (projection and injection will not be authorized). The product is intended for wood under cover not exposed to the weather but where occasional wetting can occur (Use class 2).
The product should be applied in one application and the following rate, according to the method of application and its aim:

Superficial treatment (brush&rolling) preventive: 200 g/m^2
Superficial treatment (brush&rolling) curative: 300 ml/m^2

Due to the type of wood on which the product will be applied (use class 2), it is expected that the application will be indoors, but in any case, indoor applications have been considered as the worst-case situations for human exposure and the risk derived from these indoor uses cover the human risk under outdoor conditions.

As stated in toxicology section, the product Serpol Gel II is classified as Repr. Cat. 1B (H360D May damage the unborn child) due to the presence of propiconazol in concentration of 0.85%.
According to BPR Art 19.4.b and taking into account Spanish definitions of non-professionals and professionals, the product is only authorized for trained professional users, who have experience and skill in the use of personal protection equipments (PPEs) if that is necessary for their normal work.

Dermal absorption figures are available for all three active substances. However no dermal absoption test was performed with the biocidal product. Therefore, dermal absorption values from assessment of effects on human health of this product will be used for exposure assessment porposes:

Value(s) used in the Risk Assessment – Dermal absorption			
Substance	Permethrine	Propiconazole	IPBC
Value(s)	70%	70%	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)		

An inhalation absorption of 100% is considered for the three active substances

The exposure assessments are based on model calculations using models and default values from Biocides Human Health Exposure Methodology (BHHEM, v1, October 2015), TNsG guides, Recommendations of the Ad hoc WG-HE and HEEG opinions. The protection factors for personal protective equipment (PPE) used for the exposure assessments are defaults from the HEEG opinion 2010 "Default protection factors for protective clothing and gloves".

Human exposure evaluation relates to the use phases of the product and cover primary and secondary exposure.

In line with the TNsG on Human Exposure to Biocidal Products, the ES CA has carried out an exposure assessment for human health based on a tiered approach.

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	n.a.	n.a.	Yes	Yes	n.a.

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

"n.a." (not applicable)

According to Guidance on the Biocidal Products Regulation, vol III Human Health – Assessment & Evaluation (parts B+C) handling of a solid material in a wet state, in the form of a paste or gel or encapsulation may reduce inhalation risk. Primary inhalation exposure route could be considered negligible compared to dermal exposure taken into account the physicochemical properties of the product, which has a high viscosity. However, it has been considered.
Primary oral exposure is ruled out for trained professional users.

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, it might be necessary to calculate the exposure to volatilised residues only from IPBC:

$$\frac{0.328 \,.mw\,.vp}{AEL_{long-term}} = \frac{0.328 * 281.09 * 4.5 * 10^{-3}}{0.2} = 2.07$$

It is higher than 1, therefore the exposure to volatilised residues indoor cannot be considered negligible.
Remark: the mw (molecular weight) and vp (vapour pressure) come from the Assessment Report on IPBC (RMS DK, 22/02/2008).

List of scenarios

Primary and secondary exposure scenarios pertaining to the proposed use of the product 'Serpol Gel II' are detailed in the table below.

Summary table: scenarios			
Scen. No.	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
1.	Brushing and rolling indoors	Primary exposure: Dermal and inhalation exposure while appliying product by brush indoors.	Trained professional
2.	Washing out of a brush	Primary exposure: Washing out of a brush after application of wood preservative.	Trained professional
3.	Injection	Primary exposure: The product is injected in the wood using a wood injector (pressure imprejnation).	Trained professional
4.	Projection (Spraying)	Primary exposure: The product in gel form is sprayed on the wood to be treated.	Trained professional

5.	Laudering work clothes	Secondary exposure: Laudering contaminated work clothes in a domestic automatic washing machine.	Trained professional
6.	Professional sanding treated wood	Secondary exposure: Professional sanding treated timber using a hand-held power sander.	Professional
7.	Non-professional sanding treated wood	Secondary exposure: Non-rofessional sanding treated timber using a hand-held power sander.	General public
8.	Toddler chewing treated wood	Secondary exposure: Toddler chewing treated wood off-cut	General public
9.	Toddler playing on playground structures	Secondary exposure: Toddler playing on playground wethered structures and mouthing	General public
10.	Inhalation volatilased residues indoor	Secondary exposure: This scenario is considered for the General public that stays in a premise where the wood has been treated with the biocide product	General public

The exposure and risk assessment of the general public provided 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, however exposure is covered by the included RMM**: "Keep children and pets away from treated structures until dried".**

In addition, local effects of the SoC "isoparaffin solvent" have not been assessed based on the assumption that it has been completely evaporated when the wood is dried. Therefore, to ensure adequate ventilation, the follow RMM has been assigned: "**Ensure adequate ventilation during and after the application, until treated surfaces have dried."**

Industrial exposure

Serpol Gel II is not intended for industrial use.

Professional exposure

Scenario [1]: Primary exposure during brush and roller application

This scenario contemplates a trained professional user, who applies the product by brushing, in absence of general public. It can be divided into two different phases:

1a) A loading step is considered assuming a professional 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 (proposed model No 23) based on "Consumer painting model 3"

Description of Scenario 1		
The scenario consists of two phases: loading (1a) and application (1b). The parameters listed in this table are applicable in both phases.		
	Parameters	Value
Tier 1 & Tier 2	Concentration of PERMETHRIN in product	0.35%
	Concentration of PROPICONAZOLE in product	0.85%
	Concentration of IPBC in product	0.40%
	Adult body weight[1]	60 kg
	Inhalation rate[1]	1.25 m^3/hour
	Absorption via inhalation	100%
	Dermal absorption of Permethrin	70%
	Dermal absorption of Propiconazole	70%
	Dermal absorption of IPBC	70%

[1] Recommendation No 14

Description of Scenario 1a		
A trained professional user manually load the product into a tray prior to brush and roller application.		
	Parameters	Value
Tier 1 (without PPEs)	Potential dermal exposure (without gloves); indicative value[1]	101 mg/min
	Potential inahaltion exposure (no RPE); indicative value[1]	0.94 mg/m^3
	Task duration[2]	10 mins
Tier 2 (with PPEs)	Actual dermal exposure (with gloves)[1]	1.01 mg/min

[1] Mixing and loading model 7 (see HEEG opinion 1, p 5-liquid manual loading)
[2] Recommendation No 6 (v4), p11 (assuming it is the same as for a PT8)

Description of Scenario 1b		
Trained professional user treating wooden articles with the product by brush and roller application. Potential exposure via dermal and inhalation route has been calculated assuming an exposure duration of 240 minutes/day equating to an application area of 31.6 m2. Indicative values are normalized to 1 % active substance		
	Parameters	Value

Tier 1 (without PPEs)	Dermal exposure; Normalized to 1% a.s. indicative value[1]	Hands: 0.5417 mg/m^2 Body: 0.2382 mg/m^2
	Inahaltion exposure; Normalized to 1% a.s. indicative value[1]	0.0016 mg/m^2 (non-volatile compounds)
	Task duration[1]	240 mins
	Indicative hand exposure value (no gloves)[2]	0.1896 mg permetrine/m^2 0.4604 mg propiconazole/m^2 0.2167 mg IPBC/m^2
	Indicative potential body exposure value[2]	0.0834 mg permetrine/m^2 0.2025 mg propiconazole/m^2 0.0953 mg IPBC/m^2
	Indicative inhalation value[2]	0.00056 mg permetrine/m^2 0.0014 mg propiconazole/m^2 0.00064 mg IPBC/m^2
Tier 2 (with PPEs)	PPE (gloves&impermeable coveralls)[3]	95% protection (<>5% penetration)

[1] Recommendation No 6 (v4), p 24

[2] Calculated indicative values based on normalised values

[3] HEEG opinion No 9

Calculations for Scenario [1]

Relevant calculations are included in Annex 3.2

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg a.s.)**	**Estimated dermal uptake (mg a.s.)**	**Estimated oral uptake**	**Estimated total systemic uptake (mg/kg bw/day)**
Scenario 1a (loading)					
Permethrin	1	6.85E-04	2.47	No	4.12E-02
Propiconazole	1	1.66E-03	6.01	No	0.1002
IPBC	1	7.83E-04	2.83	No	4.72E-02
Permethrin	2(gloves)	6.85E-04	2.47E-02	No	4.24E-04
Propiconazole	2(gloves)	1.66E-03	6.01E-02	No	1.03E-03
IPBC	2(gloves)	7.83E-04	2.83E-02	No	4.84E-04
Scenario 1b (application)					
Permethrin	1	1.77E-02	6.04	No	0.101
Propiconazole	1	4.30E-02	14.7	No	0.245
IPBC	1	2.02E-02	6.90	No	0.115
Permethrin	2(gloves&impermeable coverall)	1.77E-02	0.512	No	0.009

Propiconazole	2(gloves&impermeable coverall)	4.30E-02	1.24	No	0.021
IPBC	2(gloves&impermeable coverall)	2.02E-02	0.585	No	0.010
Total scenario 1: loading and application					
Permethrin	T1(Load)&T1(App)	0.0184	8.51	No	0.1421
Propiconazole	T1(Load)&T1(App)	0.0447	20.71	No	0.346
IPBC	T1(Load)&T1(App)	0.0209	9.73	No	0.162
Permethrin	T2(Load)&T1(App)	0.0184	6.065	No	0.101
Propiconazole	T2(Load)&T1(App)	0.0446	14.7601	No	0.246
IPBC	T2(Load)&T1(App)	0.0209	6.9283	No	0.116
Permethrin	T2(Load)&T2(App)	0.0184	0.5367	No	0.009
Propiconazole	T2(Load)&T2(App)	0.0446	1.3001	No	0.022
IPBC	T2(Load)&T2(App)	0.0209	0.6133	No	0.011

Note: T1=Tier 1= No PPEs and T2=Tier 2=with PPEs (gloves and impermeable coveralls)

Scenario [2]: Primary exposure during cleaning of brushes after use

After the application of Serpol Gel II the washing out of the brush or roller used for the application is considered, using the model of HEEG opinion 11 (2010) on primary exposure –washing out of a brush which has been used to apply paints.

Description of Scenario [2]		
Serpol Gel II is a non-water based product and therefore, in order to calculate the potential worse-case exposure for an a trained professional washing out a brush which has been used for painting, this exposure scenario can be used. This exposure has been obtained using the calculator format page that is included in the HEEG opinion No 11. Refinement of the scenario is unnecessary, since no risk was identified in Tier 1. For details on the exposure calculation, please refer to Annex **¡Error! No se encuentra el origen de la referencia.**.		
	Parameters	Value
Tier 1	Density of paint	0.831 g/ml
	Concentration of a.s. in paint	Permethrin 0.35% Propiconazole 0.85% IPBC 0.40%
	Dermal absorption	Permethrin 70 % Propiconazole 70 % IPBC 70 %
	Penetration of a.s. through gloves	100%

	Body weight	60 kg
Tier 2	Penetration of a.s. through gloves	10%

Calculations for Scenario [2]

Relevant calculations are included in Annex 3.2

Summary table: estimated exposure from scenario 2			
Exposure scenario	**Tier/PPE**	**Estimated uptake (mg a.s.)**	**Estimated total systemic uptake (mg/kg bw/day)**
Permethrin	1	0.2675	0.0045
Propiconazole	1	0.6497	0.0108
IPBC	1	0.3058	0.0051
Permethrin	2(gloves)	0.0268	0.0004
Propiconazole	2(gloves)	0.0650	0.0011
IPBC	2(gloves)	0.0306	0.0005

Combined scenarios

Combined exposures by same active substance by different tasks may occur. For this assessment, brushing (scen 1) and cleaning of brushes (scen 2) for trained professionals were combined for each active substance.

Combined scenarios (1)+(2): brush + cleaning brushes					
Combined Scenarios	**Tier**	**Active substance**	**Systemic Exposure Scenario (1) mg/kg bw/d**	**Systemic exposure scenario (2) mg/kg bw/d**	**Systemic exposure scenarios (1)+(2) mg/kg bw/d**
Brushing (1) + Washing brushes (2)	(1)Tier1 + (2)Tier1	Permethrin	0.1421	0.0045	0.1466
		Propiconazol	0.346	0.0108	0.3568
		IPBC	0.162	0.0051	0.1671
	(1)Tier2 + (2)Tier1	Permethrin	0.009	0.0045	0.0135
		propiconazol	0.022	0.0108	0.0328
		IPBC	0.011	0.0051	0.0161
	(1)Tier2 + (2)Tier2	Permethrin	0.009	0.0004	0.0094
		Propiconazol	0.022	0.0011	0.0231
		IPBC	0.011	0.0005	0.0115

Scenario [3]: Primary exposure during injection use

The applicant suggests that the application by brushing represents a worse case of exposure, the risk of which would cover the application by injection, since this is carried out in a much more localized way. In any case, according to Recommendation no. 6 (version 4), proposed model 26 to assess primary exposure to PT8 for professional borehole pressure impregnation application including mixing and loading (Subsoil treatment Model 2) has been used with parameters showed in the following table:

Description of Scenario 3		
The biocidal product is applied into pre-drilled holes using a wood injector (pressure imprejnation). The mean volume of the holes would range from 3-10 ml. The distance between holes is 15 cm. If the first injection shows that the product has not penetrated as it should, the injection should be repeated.		
	Parameters	Value
Tier 1	Hand exposure[1]	8 mg/min (inside gloves)
	Inhalation non-volatile compounds[1]	0.57 mg/m^3
	Duration[1]	80 min
	Dermal absortion	Permethrin 70% Propiconazole 70% IPBC 70%
	Body weight[2]	60 kg
	Inhalation rate[2]	1.25 m^3/h
Tier 2	RPE (mask)[3]	APF 40

[1] Ad hoc WG-HE Recommendation No 6 (v4), p 25

[2] Ad hoc WG-HE Recommendation No 14

[3] Biocidal Human Health Exposure Methodology, v1, p 154

Calculations for Scenario [3]

Relevant calculations are included in Annex 3.2

Summary table: estimated exposure from Injection						
Exposure scenario	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake (mg a.s.)**	**Estimated dermal uptake (mg a.s.)**	**Estimated total uptake (mg a.s.)**	**Estimated systemic total uptake mg/kg bw/d**
Injection	1 (with gloves)	Permethrin	3.325E-03	1.57	1.5733	0.02619
		Propiconazole	8.075E-03	3.81	3.8181	0.06360
		IPBC	3.800E-03	1.79	1.7938	0.02993
Injection	2 (with gloves & RPE-APF40)	Permethrin	8.312E-04	1.57	1.5708	0.02613
		propiconazol	2.018E-03	3.81	3.8120	0.06347
		IPBC	9.5E-04	1.79	1.7909	0.02987

Further information and considerations on scenario 3
According to the "Subsoil treatment model 2" used to calculate the exposure, the inhalation route of exposure is very small compared to the dermal one, so, as can be seen, the adoption of respiratory protection measures has practically no influence.

Scenario [4]: Primary exposure during projection use

Proposed by the applicant, this scenario consists in the spraying application of the product. Due to physicochemical properties of a gel product, particles sprayed are bigger than a liquid product and spraying is considered as a projection.
In accordance with HEAdHoc Recommendation No 6 (version 4) proposed model 24, relating to professional spray applications is considered appropriate. This model is based on TNsG Spraying Model 2 (TNsG 2002, part 2, p. 146) and it is appropriate for powered spray application at 4 to 7 bar pressur (medium pressure) as a coarse or medium spray, indoors, overhead and downward direction. It should be noted that this model includes exposure component from mixing and loading and therefore an additional estimate is not required. It is assumed that the exposure duration for spray application is 80 minutes.

Description of Scenario [4]		
Trained professional user treating wooden articles with 'Serpol Gel II' through manual spraying. Potential exposure via dermal and inhalation route has been calculated using TNsG Spraying Model 2 and an exposure duration of 80 mins (by two events of 40 minutes) without distintion between the M&L and application phases. This model is evaluated for indoor treatments which is considered worst-case scenario for human risk compared to outdoor use.		
	Parameters	Value
Tier 1 (No PPEs)	Hands-Indicative dermal exposure[1] (75th percentile value)	273 (mg/min)
	Body-Indicative dermal exposure[1] (75th percentile value)	222 (mg/min)
	Indicative Inhalation exposure (non-volatile compounds)[1] (75th percentile value)	76 (mg/m3)
	Duration[1]	80 min
	Dermal absorption	Permethrin 70% Propiconazole 70% IPBC 70%
	Body weight[2]	60 kg
	Inhalation rate[2]	1.25 m^3/h
Tier 2	Hands-Indicative dermal exposure[1] (inside gloves) (75th percentile value)	7.8 (mg/min)
Tier 3	Double coverall permeation[3]	1%

Tier4	Mask P3 Permeation[4]	2.5%

[1] Ad hoc WG-HE Recommendation No 6 (v4), p 24

[2] Ad hoc WG-HE Recommendation No 14

[3] HEEG opinion No 9

[4] Biocidal Human Health Exposure Methodology, v1, p 154. Note: P3 = APF40 = Permeation 2.5%

Calculations for Scenario [4]

Relevant calculations are included in Annex 3.2

Summary table: estimated exposure from projection (spraying)						
Exposure scenario	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake (mg a.s/d)**	**Estimated dermal uptake (mg a.s/d)**	**Estimated total uptake (mg a.s./d)**	**Estimated systemic total uptake (mg/kg bw/d)**
Spraying	1 (without PPEs)	Permethrin	0.443	97.02	97.463	1.624
		Propiconazol	1.08	235.6	236.697	3.945
		IPBC	0.507	110.9	111.387	1.856
Spraying	2 (with gloves)	Permethrin	0.443	45.04	45.483	0.758
		Propiconazol	1.08	109.4	110.48	1.841
		IPBC	0.507	51.48	51.982	0.866
Spraying	3 (with gloves & double coverall)	Permethrin	0.443	1.964	2.407	0.040
		Propiconazol	1.08	4.770	5.846	0.097
		IPBC	0.507	2.244	2.751	0.046
Spraying	4 (with gloves & double coverall & REP-APF40)	Permethrin	0.0111	1.964	1.975	0.033
		Propiconazol	0.0269	4.770	4.796	0.080
		IPBC	0.0127	2.244	2.257	0.038

Scenario [5]: Secondary exposure for an adult 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 5

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 contamination of the coveralls is based on the trained professional brushing scenario from which the tier that shows safe use is tier 2.
The clothing contamination equals the highest potential body exposure (scenario 1) minus the amount that penetrates through the clothing: 7.53 – (7.53x5/100) = 7.15

Indicative value from model	mg/m^2	0.238200
Applicatio area *	m^2/day	31.6
potential dermal deposit	mg/day	7.53
clothing penetration from model	%	100%
actual dermal product deposit	mg/day	7.53
clothing penetration from model	%	5%
product under coverall	mg/day	0.38
product on coverall	**mg/day**	**7.15**

The sum transfer area is determined by estimating how many times the coverall is touched by the hands while preparing it for laundering. As a first tier, it is assumed that this happens three times, twice with the palms of both hands and once with the total hands surface, the sum transfer area is 1640 cm2. As a worst-case assumption, 30% of the residues in the touched area is transferred to the skin (transfer coefficient).
The scenario is modelled after the CAR for Propiconazole in PT8 (FI CA, 2007).

	Parameter	**Value**
Tier 1	Clothing contamination from brushing[1]	7.15 mg/day
	Days before washing	5 days
	Percentage dislodgeable (transfer coefficient)[2]	30%
	Surface of medium coverall[3]	22700 cm^2
	Sum transfer area[4]	1640 cm^2

[1] Clothing contamination equals the highest potential body exposure (Scanario 1) minus the amount that penetrates through the clothing (5 %), and is expressed as mg a.s./day.
[2] BHHEM, v1, p 173. Cotton, knitwear, plastic, wood Dried fluid 30 % - wet hand
[3] Commonly accepted estimated value

[4] 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.

Calculations for Scenario [5]

Relevant calculations are included in Annex 3.2

Summary table: estimated exposure from Laundery of brushing work clothes					
Exposure scenario	**Active substance**	**Estimated oral uptake**	**Estimated dermal uptake (mg a.s)**	**Estimated total uptake (mg a.s)**	**Estimated systemic total uptake (mg/kg bw/d)**
Laundery of brushing work clothes	Permethrin	-	1.90E-03	1.90E-03	3.16E-05
	Propiconazol	-	4.61E-03	4.61E-03	7.68E-05
	IPBC	-	2.17E-03	2.17E-03	3.62E-05

Combined scenarios

Combined exposures by different tasks may occur. For this assessment, brushing (scen 1), cleaning of brushes (scen 2) and laudering work clothes (scen 5) for trained professionals were combined for each active substance.

Combined scenarios (1)+(2)+(5): brush + cleaning brushes + laudering work clothes					
Tier	**Active substance**	**Systemic Exposure Scenario (1) mg/kg bw/d**	**Systemic exposure scenario (2) mg/kg bw/d**	**Systemic exposure scenario (5) mg/kg bw/d**	**Systemic exposure scenarios (1)+(2)+(5) mg/kg bw/d**
(1)Tier1 + (2)Tier1 + (5)	Permethrin	0.1421	0.0045	3.16E-05	0.1466
	Propiconazol	0.346	0.0108	7.68E-05	0.3568
	IPBC	0.162	0.0051	3.62E-05	0.1671
(1)Tier2 + (2)Tier1 +(5)	Permethrin	0.009	0.0045	3.16E-05	0.0135
	propiconazol	0.022	0.0108	7.68E-05	0.0328
	IPBC	0.011	0.0051	3.62E-05	0.0161
(1)Tier2 + (2)Tier2 + (5)	Permethrin	0.009	0.0004	3.16E-05	0.0094
	Propiconazol	0.022	0.0011	7.68E-05	0.0231
	IPBC	0.011	0.0005	3.62E-05	0.0115

Note: (1)Tier1 = with gloves / (2)Tier1= without gloves / (1)Tier2 = with gloves&impermeable coverall / (2)Tier2= with gloves

Scenario [6]: Secondary exposure for professional users sanding treated wood

Professional (secondary) exposure to 'Serpol Gel II' 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 [6]

The professional user may be instructed to wear a respiratory protection equipment (RPE) when sanding treated wood, but as a worst case no RPE will be used.
A worse scenario for this product is for superficial treatment curative aim, with an application rate of 300 mL/m^2 (at a relative b.p. density of 0.831 g/ml, the application rate is 249.3 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 substances are 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]	4.00E+03 cm^3
	Product application rate (dose)	300 ml/m^2 <> 24.9 mg/cm^2
	Product density	0.831 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	Permethrin 70% Propiconazole 70% IPBC 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%

[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 [6]

Relevant calculations are included in Annex 3.2

Summary table: estimated exposure from Professional sanding treated wood. Curative						
Exposure scenario 6	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake (mg a.s)**	**Estimated dermal uptake (mg a.s)**	**Estimated total uptake (mg a.s)**	**Estimated systemic total uptake mg/kg bw/d**
Professional sanding treated wood.	Tier 1 (No PPEs)	Permethrin	8.25E-03	1.002E-01	1.08E-01	1.81E-03
		Propiconazol	2.00E-02	2.433E-01	2.63E-01	4.39E-03
		IPBC	9.42E-03	1.145E-01	1.24E-01	2.07E-03

Combined scenarios

Combined exposures by same active substance by different tasks may occur. For this assessment, brushing (1), cleanig brushes (2), laundering work clothes (5), and sanding treated wood for trained professionals (6) were combined for each active substance.

Combined Scenarios: Brushing (1) + Cleaning brushes (2) + Laudering (5) + Sanding profess (6)							
Combined scaniros	**Tier**	**Active substance**	**Systemic Exposure Scenario (1) mg/kg bw/d**	**Systemic Exposure Scenario (2) mg/kg bw/d**	**Systemic Exposure Scenario (5) mg/kg bw/d**	**Systemic Exposure Scenario (6) mg/kg bw/d**	**Systemic exposure combined scenarios mg/kg bw/d**
(1) + (2) + (5) + (6)	(1)Tier1 + (2)Tier1 +(5) + (6)	Permethrin	0.101	0.0045	3.16E-05	1.81E-03	0.1073
		Propiconazol	0.246	0.0108	7.68E-05	4.39E-03	0.2613
		IPBC	0.116	0.0051	3.62E-05	2.07E-03	0.1232
	(1)Tier2 + (2)Tier2 + (5) + (6)	Permethrin	0.009	0.0004	3.16E-05	1.81E-03	0.0112
		propiconazol	0.022	0.0011	7.68E-05	4.39E-03	0.0276
		IPBC	0.011	0.0005	3.62E-05	2.07E-03	0.0136

Note: (1)Tier1 = T2(Load)&T1(App) from scenario 1 and (1)Tier2 = T2(Load)&T2(App) from scenario 1

Non-professional exposure

Serpol Gel II is not authorised for non-professional use.

Exposure of the general public

Scenario [7]: Secondary exposure for non-professionals during sanding and cutting treated wood

Secondary exposure to 'Serpol Gel II' 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 [7]

The scenario is identical to the sanding of wood by professional (Scenario 6), however no PPE is worn and the duration of exposure is shorter (only one hour).

In our case, a worse scenario is for superficial treatment curative aim, with an application rate of 300 mL/m^2 (at a relative b.p. density of 0.831 g/ml, the application rate is 249.3 g/m^2).
The duration of a sanding task for non-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.

Inhalation route:
A non-professional adult is sanding the surface of treated wood (4 cm x 4 cm x 2.5 m, surface area of 4032 cm²) (TNsG 2002, Part 3, p.50). The active substances are 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/m³.

Dermal route (hands):
The surface area of both palms of hands is 410 cm² 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]	4.00E+03 cm^3
	Product application rate (dose)	300 ml/m^2 <> 24.9 mg/cm^2
	Product density	0.831 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	Permethrin 70% Propiconazole 70% IPBC 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 [7]

Relevant calculations are included in Annex 3.2

Summary table: estimated exposure from non-professional sanding treated wood. Curative						
Exposure scenario 6	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake (mg a.s)**	**Estimated dermal uptake (mg a.s)**	**Estimated total uptake (mg a.s)**	**Estimated systemic total uptake mg/kg bw/d**
Non-rofessional sanding treated wood.	Tier 1 (No PPEs)	Permethrin	1.37E-03	1.002E-01	0.102	1.69E-03
		Propiconazol	3.34E-03	2.433E-01	0.247	4.11E-03
		IPBC	1.57E-03	1.145E-01	0.116	1.93E-03

Scenario [8]: 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 Serpol Gel II 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 8

In our case, a worse scenario is for superficial treatment curative aim, with an application rate of 300 mL/m^2 (at a relative b.p. density of 0.831 g/ml, the application rate is 249.3 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	Oral absorption[3]	Permethrin: 100%
		Propiconazole: 100%
		IPBC: 100%
	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)	300 ml/m^2 <> 24.9 mg/cm^2

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

[2] HEAdhoc Recommendation no. 14

[3] According to the CAR of propiconazol for PT8 (Finland 2007) its oral absorption value is 86% and according to the CAR of IPBC for PT8 (DK 2008) its oral absorption is > 90%. However according to current guidance (Guidance on BPR, vol III Part B+C, version 4.0, December 2017, notes p.66) when the oral absorption rate exceeds 80%, the default value of 100% should be applied for the derivation of AELs and internal exposure levels.

Calculations for Scenario [8]

Relevant calculations are included in Annex 3.2

Summary table: estimated exposure from Toddler chewing treated wood chip. Curative.						
Exposure scenario 8	**Tier/PPE**	**Active substance**	**Estimated oral uptake (mg a.s)**	**Estimated dermal uptake (mg a.s)**	**Estimated total uptake (mg a.s)**	**Estimated systemic total uptake mg/kg bw/d**
Toddler chewing wood chip	Tier 1	Permethrin	0.140	n.a	0.140	0.0140
		Propiconazol	0.339	n.a	0.339	0.0339
		IPBC	0.160	n.a	0.160	0.0160

Scenario [9]: 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 superficial treatment for curative purposes, with an application rate of 300 mL/m^2 (at a relative b.p. density of 0.831 g/ml, the application rate is 249.3 g/m^2).
Following the indications of TNsG, it is considered a secondary exposure from a chronic point of view.

Description of Scenario 9		
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)	300 ml/m^2<>24.93 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 absorptions (all a.s.)	70%
	Oral absorptions (all a.s.)	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 9

Relevant calculations are included in Annex 3.2

Summary table: estimated exposure from toddler playing on playground wethered structures and mouthing after curative treatment (scenario 9).						
Exposure scenario 9	**Tier/PPE**	**Active substance**	**Estimated oral uptake (mg a.s)**	**Estimated dermal uptake (mg a.s)**	**Estimated total uptake (mg a.s)**	**Estimated systemic total uptake mg/kg bw/d**
Toddler	Tier 1	Permethrin	0.01206	0.05629	0.06835	0.00684

playing on playground structure		Propiconazol	0.02929	0.1367	0.16600	0.01660
		IPBC	0.01379	0.06433	0.07812	0.00781

Scenario [10]: 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 [10]

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.

For the product, there are three active substances:

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
Propiconazol	5.60E-05	342.2	0.04	0.328	1.57E-01	negligible
IPBC	4.50E-03	281.1	0.2	0.328	2.07E+00	**included**

Based on the results table above, the inhalation exposure of IPBC should be included in the risk assessment.

Chronic exposure to wood preservatives may arise from indoor remedial treatment. As a worst case, inhalation exposure was taken as 100% of the saturated vapour pressure/concentration (SVC) according to HEEG opinion 13: a person is exposed to the saturated vapour concentration of the active substance for 24 hours a day. This is the worst-case scenario as it is not possible for the air to hold more than the saturated vapour concentration of the active substance at a given ambient temperature and it is not possible for a person to be exposed more than 24 hours per day. The calculation is highly

conservative and is designed as a screeing tool for identifying a risk. According to TNsG 2002, part 3, p 50 a more realistic assumption that wood installed in moderately ventilated room (1% of SVC). The toddler is presented as the worst case since the ratio between body weight and inhatation rate is highest for the toddler.			
	Parameters		Value
Tier 1	IPBC	Vapour pressure a.s.	4.50E-03 Pa
		Molecular weight a.s.	281.09 g/mol
	Constante de gases[1]		8.31451 J mol^{-1} K^{-1}
	Temperatura[1] (K)		298 K
	Inhalation rate[1]		8 m^3/24 h
	Body weight[1]		10 Kg

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

Calculations for Scenario [10]

Relevant calculations are included in Annex 3.2

Summary table: estimated exposure from Inhalation volatilased residues indoors					
Exposure scenario 10: **Inhalation volatilased residues indoors**	**Active substance**	**Estimated inhalation uptake (mg/d)**	**Estimated dermal uptake**	**Estimated total uptake (mg/d)**	**Estimated systemic total uptake mg/kg bw/d**
Toddlers	IPBC	4.08E-02	n.a	4.08E-02	4.08E-03
Infants	IPBC	2.76E-02	n.a	2.76E-02	3.45E-03
Childs	IPBC	6.13E-02	n.a	6.13E-02	2.56E-03
Adults	IPBC	8.17E-02	n.a	8.17E-02	1.36E-03

Monitoring data

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

Dietary exposure

Indirect exposure via food, drinking water or livestoke is not foreseen from the proposed use of 'Serpol Gel II'. The following risk mitigation measure is required:

- 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 propiconazole, IPBC and 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 propiconazole, IPBC and 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.

Propiconazole:

Summary table of other (non-biocidal) uses			
	Sector of use	**Intended use**	**Reference value(s)**
1.	Plant protection products	The approval of the active substance propiconazole was not renewed by Commission Implementing Regulation (EU) 2018/1865	(1)

(1) COMMISSION REGULATION (EU) 2021/155 of 9 February 2021 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for carbon tetrachloride, chlorothalonil, chlorpropham, dimethoate, ethoprophos, fenamidone, methiocarb, omethoate, propiconazole and pymetrozine in or on certain products

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation

The rationale for setting the AELs of the active substances propiconazole, IPBC and permethrin can be found in the respective CA reports. The reference doses and the relevant NOAEL-values from which they are derived are summarised in the following table.

Reference	Study	NOAEL (LOAEL)	AF[1]	Correction for oral absorption	Value
IPBC[3]					
$AEL_{short-term}$	90 days gavage study	35 mg/kg bw/d	100	No[2]	0.35 mg/kg bw/d
$AEL_{long-term}$	104 weeks chronic/cacinogenicity in rats	20 mg/kg bw/d	100	No[2]	0.2 mg/kg bw/d
Permethrin[4]					
$AEL_{short-term}$	2 year study in rat (oral exposure, acute effect)	59.4 mg/kg/ bw/d	100	No[2]	0.5 mg/kg bw/d
$AEL_{medium-term}$	12 month study in dog	5 mg/kg bw/d	100	No[2]	0.05 mg/kg bw/d
$AEL_{long-term}$	12 month study in dog	5 mg/kg/ bw/d	100	No[2]	0.05 mg/kg bw/d
Propiconazole[5]					
$AEL_{short-term}$	Delevopmental study in rat	30 mg/kg/ bw/d	100	No[2]	0.3 mg/kg bw/d
$AEL_{long-term}$	2-year rat study	3.6 mg/kg/ bw/d	100	No[2]	0.04 mg/kg bw/d

[1] Inter/intra species variation

[2] IPBC: >90% oral absorption. Permethrin: Extensive and rapid. Propiconazole: 86% oral absoption within 48 h, however according to 'Guidance on the BPR: Volume III Parts B+C' (Version 4.0, December 2017) notes (p. 66) that "…when the oral absorption rate exceeds 80%, the default value of 100% should be applied for the derivation of AELs and internal exposure levels."

[3] CAR-IPBC PT8 (DK, 22 February 2008)

[4] CAR-Permethrin PT8 (Ireland, April 2014)

[5] CAR-Propiconazole PT7 (Finland, January 2015)

Value(s) used in the Risk Assessment – Dermal absorption			
Substance	Permethrin	Propiconazole	IPBC
Value(s)	70%	70%	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)		

Value(s) used in the Risk Assessment – Oral absorption			
Substance	Permethrin	Propiconazole	IPBC
Value(s)	100%	(86%) 100%	(>90%)100%
Justification for the selected value(s)	The 'Guidance on the BPR: Volume III Parts B+C' (Version 4.0, December 2017) notes (p. 66) that "…when the oral absorption rate exceeds 80%, the default value of 100% should be applied for the derivation of AELs and internal exposure levels."		

The product contains 3 different active substances; therefore a risk assessment from combined exposure to several active substances should be performed according to the Guidance on the Biocidal Product Regulation, vol III (Part B+C).

The first step (**Tier 1**) of this approach is to verify acceptability for each substance used in the product, corresponding to the comparison of the exposure values to the AEL of each substance as stated above and leading to the calculation of Hazard Quotients (HQ), corresponding to estimation of exposure/AEL. If for one substance, the exposure is above the AEL, risk is unacceptable.

In a second step (**Tier 2**), additive effects were considered by summing up the HQ of each active substance, leading to the calculation of a HI (Hazard Index).
If HI ≤ 1 the risk related to use of the mixture will be considered acceptable;
If HI > 1 a refinement is needed.

In a third step (Tier 3), which is more complex but considered to be more realistic regarding the risks to be assessed, if necessary it is divided in 3 stepsof refinement:

- **Tier 3A**: Combined exposure assessment by grouping the substances with common target organ/mode of action (with the non refined AEL of each substance);
- **Tier 3B**: Combined exposure assessment with specific AEL by target organ/mode of action;
- **Tier 3C**: Combined exposure assessment by considering mechanism of action (if available)

Local effects

Risk characterisation (RC) for local effects is triggered only when the biocidal product is classified for local effects. RC for local effects is not required when the active substance and/or co-formulants in a product are classified for local effects but are present at concentrations that do not trigger classification of the product according to the CLP criteria.

For PRIMARY EXPOSURE: Since SERPOL GEL II is classified, by its SoC (aliphatic hydrocarbon (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.
In any case, the implicit risk to EUH066 would be covered since, both by the classification of the product H360D and by the total risk characterization, the use of PPEs (gloves and impermeable coverall) is mandatory.

For SECONDARY EXPOSURE: Local exposure and risk assessment EUH066 is not relevant as it is attributed to the SoC (isoparaffin solvent), which is assumed to be completely evaporated when the wood is dried.

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

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**".

Risk for industrial users

Serpol Gel II is not intended for industrial use.

Risk for professional users

Professional users can be expected to be chronically exposed to Serpol Gel II in both primary and secondary scenarios, and therefore the $AEL_{long\ term}$ values are used in the risk assessment calculations for all scenarios for this type of user. The risk characterization (RC) of the proposed scenarios is shown below

Scenario [1] RC for brushing

The scenario consists of two phases: loading (1A) and application (1B).

Systemic effects

Task/ Scenario 1	**Tier**	**Active substance**	**$AEL_{chronic}$ mg/kg bw/d**	**Estimated total systemic uptake mg/kg bw/d**	**Estimated total systemic uptake/ AEL (%)**	**Acceptable (yes/no)**
Trained-professional Brushing (1A+1B)	1 (No PPEs)	Permethrin	0.05	0.1421	284.2	No
		Propiconazol	0.04	0.346	865	No
		IPBC	0.2	0.162	8.1	Yes
Trained-professional Brushing (1A+1B)	T2(load)& T1(applic)	Permethrin	0.05	0.101	203	No
		Propiconazol	0.04	0.246	615	No
		IPBC	0.2	0.116	58	Yes
Trained-professional Brushing (1A+1B)	T2(load)& T2(applic)	Permethrin	0.05	0.009	18	**Yes**
		Propiconazol	0.04	0.022	56	**Yes**
		IPBC	0.2	0.011	5	**Yes**

Note: T1=Tier 1= No PPEs and T2=Tier 2=with PPEs (gloves and impermeable coveralls)

Combined exposure to several active substances within the biocidal product

Task/ Scenario 1	Tier	Active substance	$AEL_{chronic}$ mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	HQ_i	$HQ_i>1$ $HQ_i<1$	HI= $\sum HQ_i$	Acceptable
Brushing (1A+1B)	T2(load)& T2(applic)	Permethrin	0.05	0.009	18	0.18	<1	0.79	Yes
		Propiconazol	0.04	0.022	56	0.56	<1		
		IPBC	0.2	0.011	5	0.05	<1		

The Hazard Quotient (HQ) is defined by the ratio of internal exposure and AEL. The risk for individual active substances is considered acceptable when HQ<1. This is the case.
No synergistic effects have been identificated between the substances contained in the product.

To evaluate the combined exposure of all substances in the mixture, the Hazard Index (HI) is defined, being the sum of the HQs for each substance.
If HI ≤1 the risk related to use of the mixture will be considered acceptable.

Conclusion

The risk is considered acceptable for brushing of product by trained-professional when gloves and impermeable coverall are worn

Scenario [2] RC for cleaning of brushes after use

Systemic effects

Task/ Scenario 2	Tier	Active substance	$AEL_{chronic}$ mg/kg bw/d	Estimated total systemic uptake mg/kg bw/d	Estimated total systemic uptake/ AEL (%)	Acceptable (yes/no)
Cleaning of Brushes	1 (No PPEs)	Permethrin	0.05	0.0045	8.9	Yes
		Propiconazol	0.04	0.0108	27.1	Yes
		IPBC	0.2	0.0051	2.5	Yes
Cleaning of Brushes	2 (gloves)	Permethrin	0.05	0.0004	0.9	Yes
		Propiconazol	0.04	0.0011	2.7	Yes
		IPBC	0.2	0.0005	0.25	Yes

Combined exposure to several active substances within the biocidal product

Task/ Scenario 2	Tier	Active substance	$AEL_{chronic}$ mg/kg bw/d	Estimated total systemic uptake mg/kg bw/d	Estimated total systemic uptake/ AEL (%)	HQ_i	$HQ_i>1$ $HQ_i<1$	HI= $\sum HQ_i$	Acceptable
Cleaning of brushes	T1 (no PPEs)	Permethrin	0.05	0.0045	8.9	0.089	<1	0.385	Yes
		Propiconazol	0.04	0.0108	27.1	0.271	<1		
		IPBC	0.2	0.0051	2.5	0.025	<1		
Cleaning of brushes	T2 (gloves)	Permethrin	0.05	0.0004	0.9	0.009	<1	0.039	Yes
		Propiconazol	0.04	0.0011	2.7	0.0271	<1		
		IPBC	0.2	0.0005	0.25	0.0025	<1		

Conclusion

The risk is considered acceptable for cleaning brushes by trained-professional even when no PPEs are worn.

Scenario [3] RC for injection

Systemic effects

Task/ Scenario 3	Tier	Active substance	$AEL_{chronic}$ mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Trained-professional Injection	1 (gloves)	Permethrin	0.05	0.02618	52.38	Yes
		Propiconazol	0.04	0.063601	159	No
		IPBC	0.2	0.02993	14.97	Yes
Trained-professional Injection	2 (gloves & RPE-APF40)	Permethrin	0.05	0.02613	52.27	Yes
		Propiconazol	0.04	0.06347	158.7	No
		IPBC	0.2	0.02986	14.93	Yes

According to the "Subsoil treatment model 2" used to calculate the exposure, the inhalation route of exposure is very small compared to the dermal one, so, as can be seen, the adoption of respiratory protection measures has practically no influence.

When the risk is assessed substance by substance, the risk is **unacceptable** even if PPEs are worn. In this context, no additional risk characterization is performed.

An unsafe situation has been identified for trained prefessioinal injection application of product even when wearing PPEs, then**, this use will not be authorised.**

Scenario [4] RC for proyection (spraying)

Systemic effects

Task/ Scenario 4	**Tier**	**Active substance**	**$AEL_{chronic}$ mg/kg bw/d**	**Estimated uptake mg/kg bw/d**	**Estimated uptake/ AEL (%)**	**Acceptable (yes/no)**
Trained-professional Spraying	1 (No PPE)	Permethrin	0.05	1.624	3248.78	No
		Propiconazol	0.04	3.945	9862.36	No
		IPBC	0.2	1.856	1031.36	No
Trained-professional Spraying	2 (gloves)	Permethrin	0.05	0.758	1516.14	No
		Propiconazol	0.04	1.841	4602.56	No
		IPBC	0.2	0.866	481.31	No
Trained-professional Spraying	3 (gloves + double coverall 1%)	Permethrin	0.05	0.040	80.24	Yes
		Propiconazol	0.04	0.097	243.59	No
		IPBC	0.2	0.046	25.47	Yes
Trained-professional Spraying	4 (gloves + double coverall 1% + RPE-APF40)	Permethrin	0.05	0.033	65.83	Yes
		Propiconazol	0.04	0.080	199.85	No
		IPBC	0.2	0.038	20.90	Yes

When the risk is assessed substance by substance, the risk is **unacceptable** even if PPEs are worn. In this context, no additional risk characterization is performed.
An unsafe situation has been identified for trained prefessioinal spraying application of product even when wearing PPEs, then**, this use will not be authorised.**

Combined Scenariso [1+2+5+6] RC for trained professional brushing + cleaning brushes+ laudering work clothes + sanding treated timber.

In addition to the risk of primary exposure due to scenarios 1 (brushing) and 2 (brush cleaning), this risk characterization includes the risk of secondary exposure originated in scenarios 5 (laudering work clothes) and 6 (sanding by professional).

Systemic effects

Task/ Scenario	**Tier**	**Systemic NOAEL mg/kg**	**$AEL_{chronic}$ mg/kg bw/d**	**Estimated uptake mg/kg**	**Estimated uptake/ AEL**	**Acceptable (yes/no)**

		bw/d		bw/d	(%)	
Permethrin						
1. Brushing/ rolling	1	5	0.05	0.101	202.7	No
1. Brushing/ rolling	2	5	0.05	0.009	18.5	Yes
2. Washing brush/roller	1	5	0.05	0.0045	8.9	Yes
2. Washing brush/roller	2	5	0.05	0.0004	0.9	Yes
5. Laudering work clothes	1	5	0.05	3.16E-05	0.06	Yes
6. Profes-sional sanding	1	5	0.05	1.81E-03	3.6	Yes
Propiconazole						
1. Brushing/ rolling	1	3.6	0.04	0.246	615	No
1. Brushing/ rolling	2	3.6	0.04	0.022	56.1	Yes
2. Washing brush/roller	1	3.6	0.04	0.0108	27	Yes
2. Washing brush/roller	2	3.6	0.04	0.0011	2.7	Yes
5.Laudering work clothes	1	3.6	0.04	7.68E-05	0.19	Yes
6. Profes-sional sanding	1	3.6	0.04	4.39E-03	10.97	Yes
IPBC						
1. Brushing/ rolling	1	20	0.2	0.116	57.9	Yes
1. Brushing/ rolling	2	20	0.2	0.011	5.3	Yes
2. Washing brush/roller	1	20	0.2	0.0051	2.5	Yes
2. Washing brush/roller	2	20	0.2	0.0005	0.25	Yes
5. Laudering work clothes	1	20	0.2	3.62E-05	0.02	Yes
6. Profes-sional sanding	1	20	0.2	2.07E-03	1.03	Yes

Combined exposure to several active substances within the biocidal product

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)

Permethrin 1+2+5+6	2/1*	5	0.05	0.0112	22.4	Yes
Propiconazole 1+2+5+6	2/1*	3.6	0.04	0.0272	68	Yes
IPBC 1+2+5+6	2/1*	20	0.2	0.0128	6.4	Yes

*Tier 2 (gloves & impermeable coverall) for scenario 1&2 and tier 1 for the remaining scenarios.

The Hazard Quotient (HQ) is defined by the ratio of internal exposure and AEL. The risk for individual active substances is considered acceptable when HQ<1. This is the case.
No synergistic effects have been identificated between the substances contained in the product.

To evaluate the combined exposure of all substances in the mixture, the Hazard Index (HI) is defined, being the sum of the HQs for each substance.
If HI ≤1 the risk related to use of the mixture will be considered acceptable.

Task/ Scenarios 1+2+5+6	**Tier**	**Active substance**	**$AEL_{chronic}$ mg/kg bw/d**	**Estimated uptake mg/kg bw/d**	**Estimated uptake/ AEL (%)**	**HQ_i**	**$HQ_i>1$ $HQ_i<1$**	**HI= $\sum HQ_i$**	**Acceptable**
	*	Permethrin	0.05	0.0112	22.4	0.224	<1	0.968	YES
		Propiconazol	0.04	0.0272	68	0.68	<1		
		IPBC	0.2	0.0128	6.4	0.064	<1		

*Tier 2 (gloves & impermeable coverall) for scenario 1&2 and tier 1 (no PPEs) for the remaining scenarios.

Conclusion
The ready-to-use (RTU) product containing 0.4% w/w IPBC, 0.35% w/w Permethrin and 0.85% w/w Propiconazole is used by trained professionals for wood preservation by **brushing and rolling**. Washing out of a brush is performed after application of the wood preservative.
In addition, the secondary exposure to professional workers sanding of treated wood and laudering work clothes are assessed.

Professional users are expected to follow a minimum of instructions. It is assumed that professional users wear coveralls and gloves on a daily basis. Under normal, the product Serpol Gel II does not pose an unacceptable health risk for professional users wearing PPE during application.
In addition the secondary exposure to professional workers (sanding of treated wood) is assessed. The calculation of the risk through secondary exposure to wood preserved with Serpol Gel II shows an acceptable risk for workers during sanding of treated wood without PPE.

The professional user can be expected to be cronically exposed to Serpol Gel II at the workplace from several work tasks. A combination of the relevant scenarios to form a worst case, did not lead to an unacceptable risk.

Risk for non-professional users

This product is not authorised for non-professional use.

Risk for the general public

The risk to which the general public is exposed is due to a possible **secondary exposure**.

Scenario [7] RC for non-professional sanding treated wood

Systemic effects

Task/ Scenario 7	**Tier**	**Active substance**	**AEL mg/kg bw/d**	**Estimated Systemic uptake mg/kg bw/d**	**Estimated Systemic uptake/ AEL (%)**	**Acceptable (yes/no)**
Non-Professional sanding treated wood	1	Permetrina	0.5	1.69E-03	0.338	Yes
		Propiconazol	0.3	4.11E-03	1.37	Yes
		IPBC	0.35	1.93E-03	0.553	Yes

Combined exposure to several active substances within the biocidal product

Task/ Scenario 7	**Active substance**	**AEL_{acute} mg/kg bw/d**	**Estimated systemic uptake mg/kg bw/d**	**Estimated systemic uptake/ AEL (%)**	**HQi**	**HQi>1 HQI<1**	**HI=∑ Hqi**	**Acceptable**
Non-Professional sanding treated wood.	Permetrina	0.5	1.69E-03	0.338	0.00338	<1	0.0226	YES
	Propiconazol	0.3	4.11E-03	1.37	0.0137	<1		
	IPBC	0.35	1.93E-03	0.553	0.00553	<1		

The **Risk is accesptable** for non-professionals sanding treated wood.

Scenario [8] RC for toddler chewing treated wood chip

Systemic effects

Task/ Scenario 8	Tier	Active substance	AEL_{acute} mg/kg bw/d	Estimated Systemic uptake mg/kg bw/d	Estimated Systemic uptake/ AEL (%)	Acceptable (yes/no)
Toddler chewing treated wood chip	1	Permetrina	0.5	0.0140	2.79	Yes
		Propiconazol	0.3	0.0339	11.3	Yes
		IPBC	0.35	0.0160	4.56	Yes

Combined exposure to several active substances within the biocidal product

Task/ Scenario 8	Active substance	AEL_{acute} mg/kg bw/d	Estimated systemic uptake mg/kg bw/d	Estimated systemic uptake/ AEL (%)	HQi	HQi>1 HQI<1	HI=∑ Hqi	Acceptable
Toddler chewing treated wood chip	Permetrina	0.5	0.0140	2.79	0.0279	<1	0.1865	YES
	Propiconazol	0.3	0.0339	11.3	0.113	<1		
	IPBC	0.35	0.0160	4.56	0.0456	<1		

The Risk is accesptable for toddler chewing treated wood chip.

Scenario [9] RC for toddler playing and mouthing on playground weathered treated wood structures

Systemic effects

Scenario 9 (After curative aim treatment)

Task/ Scenario	Tier	Active substance	$AEL_{chronic}$ mg/kg bw/d	Estimated Systemic uptake mg/kg bw/d	Estimated Systemic uptake/ AEL (%)	Acceptable (yes/no)
Toddler p&m on playground structures	1	Permetrina	0.05	0.00684	13.67	Yes
		Propiconazol	0.04	0.01660	41.5	Yes
		IPBC	0.2	0.00781	3.91	Yes

When the risk is assessed substance by substance, the risk is acceptable**.**

Risk assessed by substances combination is also acceptable:

Task/ Scenario	Active substance	AEL_{chron} mg/kg bw/d	Estimated systemic uptake mg/kg bw/d	Estimated systemic uptake/ AEL (%)	HQi	HQi>1 HQI<1	HI=∑ Hqi	Acceptable
Toddler p&m on playground structures	Permetrina	0.05	0.00684	13.67	0.137	<1	0.591	YES
	Propiconazol	0.04	0.01660	41.5	0.415	<1		
	IPBC	0.2	0.00781	3.91	0.039	<1		

The Risk is **acceptable** for toddler playing and mouthing on playground weathered treated wood structures

Scenario [10] RC for inhalating volatilased residues indoors.

Systemic effects

Only volatile residues from IPBC have been taken into account.

Task/ Scenario 10	General public	Active substance	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Inhalation volatilased residues indoors	Toddler	IPBC	0.2	4.08E-03	2.4	Yes
	Infant	IPBC	0.2	3.45E-03	1.72	Yes
	Child (6 to 12 years)	IPBC	0.2	2.56E-03	1.28	Yes
	Adult	IPBC	0.2	1.36E-03	0.68	Yes

Final conclusion

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

Summary table: scenarios		
Scenario number	**Scenario and Users (e.g. mixing/ loading)**	**Conclusion**
1.	Brushing by trained professionals	A **safe** siutation has been identified for Trained professional brushing when gloves and impermeable coverall are worn.

2.	Cleaning of brushes by trained professionals	A **safe** situation has been identified for trained professional cleaning brushes when **gloves** are worn.
3.	Injection by trained professionals	An **unsafe** situation has been identified this application method even when using PPE, therefore **the uses of which this scenario is part will not be authorized.**
4.	Projection (spray application) by trained professionals	An **unsafe** situation has been identified for the application of Trained-Professional spaying even when using PPE, therefore **the uses of which this scenario is part will not be authorized.**
5.	Laundering contaminated work clothing	A **safe** situation has been identified
6.	Cutting and sanding Professional	A **safe** situation has been identified for professionals cutting and sanding treated wood.
7.	Cutting and sanding Non-professional	A **safe** situation has been identified for non-professionals cutting and sanding treated wood.
8.	Chewing wood off-cut General public	A **safe** situation has been identified for toddler chewing treated wood chips.
9.	Playing on weathered structure and mouthing General public	A **safe** situation has been identified for toddler playing and mouthing on playground weathered wood structures.
10.	Inhalation residues indoors General public	A **safe** situation has been identified for general public inhaling volatilased residues indoors.
Combined scenarios. (1) + (2) + (5) +(6)	Trained professionals Brushing / /Washing brushes / Laundering work clothes / Sanding treated wood	A **safe** situation has been identified for trained professionals mixing and loading, brushing, washing brushes, laundering work clothes and sanding treated wood when gloves and impermeable coveralls for brushing and gloves for washing brushes are worn.

CONCLUSION:

The risk for trained professional users applying the product by brushing/rolling is acceptable when appropriate PPEs including impermeable coverall and chemical resistant gloves are worn.

The product is not authorized for application by projection or injection, since both application methods involve an unacceptable exposure risk.

For all secondary exposure scenarios that have been contemplated, the risk is acceptable

2.2.7 Risk assessment for animal health

Serpol Gel II is not intended for applications where contact with feed or livestocks may arise, considering the RMM as included in the general risk mitigation section of the authorised use(s): " Do not use on wood which may come in direct contact with food, feeding stuff and livestock animals."

Considering its authorised uses, the Serpol Gel II is to be applied for curative and preventive treatment when wood or wood-based product is under cover and not exposed to the weather but where occasional, but not persistent, wetting can occur. Depending on the local surroundings, an access of pets and cats in particular to these sites cannot be excluded.
In order to avoid accidental poisoning, the following RMM is included in the general risk mitigation section of the authorised use(s): "Keep children and pets away from treated structures until dried" and "Avoid prolonged contact of pets, specifically cats, with treated structures."
Consequently, a risk assessment for animal health is not relevant.

2.2.8 Risk assessment for the environment

2.2.8.1 Effects assessment on the environment

ES CA:
According to the recommendations of the manufacturer, Serpol Gel II is a ready to use wood preservative product by brush treatment, injection and projection and must be used only for indoor treatments (UC 1 y UC 2) by trained professionals and professionals. It contains Propiconazole 0.85%, IPBC 0.40% and Permethrin 0.35% as active substances, and . Thus, related emissions to the environment are considered negligible. (OECD SERIES ON EMISSION SCENARIO DOCUMENTS Number 2, Revised Emission Scenario Document for Wood Preservatives, 2013).

	Permethrin	**Propiconazole**	**IPBC**
PNEC water (µg/L)	0.00047	1.6	0.0005
PNEC microorganisms STP (mg/L)	0.00495	1.0	0.44
PNEC sediment (µg/kg wwt)	0.001 (mg/kg dwt)	0.054	-
PNEC soil (mg/kg wwt)	>0.0876	0.02	0.005
PNEC oral bird (mg/kg food)	>16.7		
PNEC oral small mammal (mg/kg	120		

food)			

In case of Propiconazole and IPBC no data is required for exposure of birds to active ingredients and no PNEC has been derived.

ES CA:

The product contains permethrin, propiconazole and IPBC as active substances. The toxicity data for the active substances and their metabolites can be obtained from the ASs Assessment Report. The summarised PNECs for the active substances and its metabolites are presented below.

..

*As log Kow(IPBC/PBC) < 5, the risk assessment conducted for the aquatic compartment also cover the sediment compartment (please see TGD (2015) section 3.5.2.).
**new agreed PNEC soil is 0,198 mg/kg dwt, corresponding to 0,175 mg/kg wwt.

Summary table on PNEC values for metabolites					
Compartment	**PNEC**				
Metabolites of	**Propiconazole**	**IPBC**		**PERMETHRIN**	
	1,2,4-triazole	PBC	Iodine/Iodate/Iodide	DCVA	PBA
STP	Not relevant, 1,2,4-triazole is a soil metabolite	The one for IPBC is used as a worst case	2900 / - / - (µg iodine/l)	Not relevant, permethrin is not degraded in the STP.	Not relevant, permethrin is not degraded in the STP.
Surface water	Not relevant, 1,2,4-triazole is a soil metabolite	41,3 µg/l	0,59 / 58,5 / 0,83 (µg iodine/l)	0,015 mg/l	0,010 mg/l
Sediment	Not relevant, 1,2,4-triazole is a soil metabolite	Covered by surface water*	Covered by surface water**	0,055 mg/kg dwt 0,012 mg/kg wwt	0,042 mg/kg dwt 0,009 mg/kg wwt
Soil	0,01 mg/kg wwt	0,149 mg/kg wwt	0,0118 / 0,304 / 0,0043 (mg iodine/kg wwt)	4,6 mg/kg wwt	1,44 mg/kg wwt

*As log Kow(IPBC/PBC) < 5, the risk assessment conducted for the aquatic compartment also cover the sediment compartment (please see TGD (2015) section 3.5.2.).
**PNECsediment derived by equilibrium partitioning from PNECsurface water.

Besides one substance of concern for the environment was identified. Naphthalene (CAS: 91-20-3) is a substance of concern according to art. 3 (1) (f) of Regulation (EU) 528/2012 (see section 8.1 of the document "Guidance on the BPR: Volume IV Environment, Assessment & Evaluation (Parts B + C)" version 2.0 of October 2017), the following is clarified. Its inclusion as a priority substance in the field of water policy (Directive 2000/60 / EC), for which a maximum admissible concentration in continental waters of 130 µg / l has been established (Directive 2008/105 / EC). Therefore the environmental limit of naphthalene is not exceeded with the application of SERPOL GEL II.

Another co-formulant has been authorised as biocidal active substance under BPR regulation. The concentration of this substance in SERPOL GEL II 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 during renewal of product authorization if a Draft Final Competent Authority Report is available. Please see the confidential annex for further details.

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

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 SERPOL GEL II is based on the environmental classification of its active substances 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*).

Harmonised env. classification for the active substances			
Substance	**Env. classification**	**M-factor**	**Concentration of a.s. in the product (%)**
Propiconazole	H400, H410	M(acute)=10 M(chronic)=1,	0,85
IPBC	H400, H410	M(acute)=10 M(Chronic)=1	0,40
Permethrin	H400, H410	M=1000	0,35

Harmonised env. classification for the substance of concern			
Substance	**Env. classification**	**M-factor**	**Concentration in the product (%)**
Naphthalene	H400, H410	M(acute)=1 M(Chronic)=1	0,00625

Considering the ecotoxicological properties and classification of the active substances and their corresponding M- factors, these data are enough to classify SERPOL GEL II 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.

Data waiving	
Information requirement	Ecotoxicological studies
Justification	Ecotoxicological studies for Serpol Gel II have not been performed. Please refer to the Letters of access granted by R2 Group A/S, Janssen Pharmaceutica NV and Troy Chemical Company to MYLVA S.A. for the information regarding the ecotoxicological studies performed in the active ingredients Permethrin, Propiconazole and IPBC.

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.

]

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

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 SERPOL GEL II. The product was not tested for potential endocrine disruption properties. The product SERPOL GEL II contains the active substance permethrin, propiconazole and IPBC and various co-formulates (see confidential annex).

For the active substances, 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. This substance has been authorised as biocidal active substance under BPR regulation,and it's being assess as ED and has been identified as a potencial ED by United States EPA. However, a Draft 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 to have ED properties or not Therefore, it will be considered during the renewal of the product authorization, if a Draft Final Competent Authority Report is available. This is further assessed in the frame of the REACH Regulation. 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 SERPOL GEL II can proceed.. Please see the confidential annex for further details.

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

Please refer to section Fate and distribution in exposed environmental compartments.

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.

However, as the product SERPOL GEL 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.

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

No data is available.

ES CA:
No additional data are required.

Leaching behaviour (ADS)

A test was performed to investigate the leaching behaviour of Permethrin, Propiconazole and IPBC from vertically exposed surfaces painted with Serpol Gel II under field and outdoor conditions (natural rain) without top coat applied.
The average acumulated amount of Permethrin, Propiconazole and IPBC during the study period was 0.0555 mg/m^2, 186.85 mg/m^2 and 33.51 mg/m^2 respectively.

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)

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.

Acute aquatic toxicity

Data waiving	
Information requirement	Acute aquatic toxicity
Justification	The product is not intended to be sprayed near to surface waters. Please see report "Toxicological profile for humans and animals on: SERPOL GEL II"

Chronic aquatic toxicity

Data waiving	
Information requirement	Chronic aquatic toxicity
Justification	The product is not intended to be sprayed near to surface waters. Please see report "Toxicological profile for humans and animals on: SERPOL GEL II"

Measured aquatic bioconcentration

Data waiving	
Information requirement	Measured aquatic bioconcentration
Justification	The product is not intended to be sprayed near to surface waters.

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

General information

Assessed PT	PT 8 (UC 1 and 2)
Assessed scenarios	Scenario 1: Brushing and rolling indoors. Scenario 2: Spraying indoors.
ESD(s) used	ESD for PT 8: Revised Emission Scenario Document for Wood Preservatives (OECD series No. 2, 2013)
Approach	Scenario 1: Average consumption Scenario 2: Average consumption
Distribution in the environment	Please, refer to Assessment Report of Permethrin, Assessment Report of Propiconazole and Assessment Report of IPBC.
Groundwater simulation	Please refer to leaching study: Ref. 676377_Leaching_Mylva rev4
Confidential Annexes	NO
Life cycle steps assessed	Scenario 1 and 2: Production: No Formulation No Use: Yes Service life: Yes

ES CA:
Regarding the distribution in the environment and groundwater simulation, SERPOL GEL II is a ready tuo use product for indoor use only UC1 and UC2 and therefore exposure to environmental compartments are consider neglegible (OECD Emission Scenario Document for Wood Preservatives, 2013).

Emission estimation

In line with statements made within the "OECD Emission Scenario Document (ESD) for Wood Preservatives" (2003) and its 2013 revision, no assessment of in-service losses and risks arising from timber in UC 1 & 2 needs 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 zero for all compartments.

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. and UC 2 situation in which the wood or wood-based product is under cover and fully protected from the weather but where occasional but not persistent wetting may occur). 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 and UC 2 are negligible and risks to environmental compartments are considered as zero.

There is only one aspect in the environmental risk assessment of SERPOL GEL II 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 uses 1 and 2: 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.

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway									
	Freshwater	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
Scenario 1	NO	NO	NO	NO	NO	NO	NO	NO	NO
Scenario 2	NO	NO	NO	NO	NO	NO	NO	NO	NO

Calculated PEC values

Not applicable.

Primary and secondary poisoning

Primary poisoning

Primary poisoning was not assessed.

Secondary poisoning
The potential impact of substances on top predators is based on the accumulation of hydrophobic chemicals through food chains and should in principle be assessed by comparing the measured or estimated concentration in the tissues and organs of the top predators with the no-effect concentrations for these predators expressed as the internal dose. Data on internal concentrations in wildlife animals are hardly ever available and most no-effect levels are expressed in terms of concentrations of the food that the organisms consume (i.e. mg/kg food). Therefore, the actual assessment is based on a comparison of the predicted concentration in the food of the top predator and the predicted no-effect concentration which is based on studies with laboratory animals.

For substances with a log K_{ow} ≥ 4.5, uptake routes such as intake of contaminated food or sediment are considered to be of importance.

Permethrin:
The Log K_{ow} and some of the estimated BCF values would indicate permethrin has a strong potential to bioconcentrate following uptake via water/porewater (e.g. in fish/worms) and subsequently bioaccumulate through the food chain, resulting in toxic concentrations in predatory birds or mammals ingesting biota containing the chemical. A study Spehar R.L., 1983, was carried out to assess the toxicity of the synthetic pyrethroid, Permethrin, in early life-stages of fathead minnows and snails. This information is presented as a scientific peer-reviewed paper in Aquatic Toxicology Volume 3, Issue 2, February 1983, Pages 171–182. The BCF values reported were 2800 L/Kg for fathead minnows and 800 L/Kg for snails. Data is not lipid normalised and non- GLP. Please refer to Assessment Report of Permethrin and to the letter of access.
However, due to the proposed use patterns, the wood preservative product Serpol Gel II no data is required for exposure of birds to active ingredients and no PNEC has been derived.

Propiconazole and IPBC:
In case of Propiconazole and IPBC (log K_{ow} of 3.72 and 2.81 respectively), an assessment of the potential for secondary poisoning in birds and mammals through the consumption of aquatic and terrestrial biota exposed to this two active ingredients is not deemed necessary. Due to the proposed use patterns of Serpol Gel II, a wood preservative product, no data is required for exposure of birds to active ingredients and no PNEC has been derived.

2.2.8.3 Risk characterisation

Atmosphere

The pattern of use of Serpol Gel II (UC2) as a wood preservative product excludes direct contamination of air. Volatilization of permethrin is considered to be negligible based on the vapour pressure (2.155 x 10-6 Pa at 20°C, 25:75 cis:trans) and Henry constant (4.6 x 10-3 - > 4.5 x 10-2 Pa m3 mol-1). Propiconazole is very slightly volatile. With the estimated half-life less than 2 days in troposphere propiconazole is not regarded as a persistent contaminant in the air. Propiconazole is not expected to have long-range atmospheric transport or contribute to global warming, ozone depletion or acidification on the basis of the physical and chemical properties. Results indicate that emissions of IPBC are extremely low. PECair is not relevant for IPBC due to the low vapour pressure of the active substance.

Additionally, due to the intended use of the product Serpol Gel II, as a wood preservative product, directly emission to the air is considered negligible.

Aquatic compartment

The risk to the hydrosphere is characterised in this section. The environmental exposure of permethrin, propiconazole and IPBC, formulated as a ready to use gel wood preservative product was assessed in accordance with the Technical Guidance Documents (TGDs) and relevant OECD exposure scenario document for pt8 products.
Serpol Gel II is a preventive and curative wood preservative product to be used under Use Class 2, which is the situation in which the wood or wood-based product is under cover and not exposed to the weather (particularly rain and driven rain) but where occasional, but not persistent, wetting can occur. Pattern of use of Serpol Gel II excludes direct contamination of water as the product is not exposed directly to water nor to the rain. As a wood preservative product ready to use, to be used in situ, it is recommended to avoid direct contact of the product with soil as a risk mitigation measure in order to exclude direct contamination of water.

Regarding the metabolites of the active substances, they are not considered to be ecotoxicologically relevant in the aquatic compartment. The aquatic metabolits of Permethrin are 3-(2,2-dichlorovinyl)-2,2-dimethyl-(1-cyclopropane)carboxylate (DCVA) and 3-phenoxybenzoic acid (PBA), which are far less toxic to aquatic organisms than the parent active ingredient (Assessment report of Permethrin, PT8, April 2014). Propiconazole have neither major metabolites nor ecotoxicologically relevant ones (Assessment report of Propiconazole, PT8, November 2007).Finally, PBC is a relevant metabolite of IPBC in water, sediment and soil but, due to its relative short half-life, PBC is regarded as a transient metabolite, which its ecotoxicity for fish, algae and invertebrates is 300-1000 times lower compared to IPBC (Assessment report of IPBC, PT8, February 2008).

Terrestrial compartment

Serpol Gel II is a wood preservative product to be applied on wood by brushing, spraying and injection in use class 2 by professional users. The product is not intended for direct application to soil or plants. Exposure to soil is considered negligible according to *"OECD Emission Scenario Document (ESD) for Wood Preservatives" (2003)* and its 2013 revision.

Toxicity tests on organisms present in the soil such as earthworms, collembolans, mites, etc. were assessed and accepted in the Assessment Report for three active substances, Permethrin, Propiconazole and IPBC.

Regarding the metabolites of the active substances, they are not considered to be ecotoxicologically relevant in the terrestrial compartment. The terrestrial metabolits of Permethrin are 3-(2,2-dichlorovinyl)-2,2-dimethyl-(1-cyclopropane)carboxylate (DCVA) and FPB-acid (4-fluoro-3-phenoxybenzoic acid), which are far less toxic to soil macro-organisms than permethrin. Regarding the PBA, a very conservative QSAR estimation was performed, giving a 1-day LC_{50} of 3400 mg/kg dry wt soil for 3-phenoxybenzoic acid in earthworms, further supporting the indication that PBA is not toxic to soil organisms. (Assessment report of Permethrin, PT8, April 2014). As in the aquatic compartment, Propiconazole have neither major metabolites nor ecotoxicologically relevant ones in the terrestrial compartment (Assessment report of Propiconazole, PT8, November 2007).Finally, PBC is a relevant metabolite of IPBC in water, sediment and soil but, due to its relative short half-life, PBC is regarded as a transient metabolite, which its ecotoxicity for fish, algae and invertebrates is 300-1000 times lower compared to IPBC (Assessment report of IPBC, PT8, February 2008).

Groundwater

Please see terrestrial compartment

Primary and secondary poisoning

Conclusion:
The potential impact of substances on top predators is based on the accumulation of hydrophobic chemicals through food chains and should in principle be assessed by comparing the measured or estimated concentration in the tissues and organs of the top predators with the no-effect concentrations for these predators expressed as the internal dose. Data on internal concentrations in wildlife animals are hardly ever available and most no-effect levels are expressed in terms of concentrations of the food that the organisms consume (i.e. mg/kg food). Therefore, the actual assessment is based on a comparison of the predicted concentration in the food of the top predator and the predicted no-effect concentration which is based on studies with laboratory animals.

For substances with a log Kow ≥ 4.5, uptake routes such as intake of contaminated food or sediment are considered to be of importance.

Permethrin
The Log Kow and some of the estimated BCF values would indicate permethrin has a strong potential to bioconcentrate following uptake via water/porewater (e.g. in fish/worms) and subsequently bioaccumulate through the food chain, resulting in toxic concentrations in predatory birds or mammals ingesting biota containing the chemical. A study Spehar R.L., 1983, was carried out to assess the toxicity of the synthetic pyrethroid, Permethrin, in early life-stages of fathead minnows and snails. This information is presented as a scientific peer-reviewed paper in Aquatic Toxicology Volume 3, Issue 2, February 1983, Pages 171–182. The BCF values reported were 2800 L/Kg for fathead minnows and 800 L/Kg for snails. Data is not lipid normalised and non- GLP. Please refer to Assessment Report of Permethrin and to the letter of access.
However, due to the proposed use patterns, the wood preservative product Serpol Gel II no data is required for exposure of birds to active ingredients and no PNEC has been derived.

Propiconazole and IPBC:
In case of Propiconazole and IPBC (log Kow of 3,72 and 2,81 respectively), an assessment of the potential for secondary poisoning in birds and mammals through the consumption of aquatic and terrestrial biota exposed to this two active ingredients is not deemed necessary. Due to the proposed use patterns of Serpol Gel II, a wood preservative product, no data is required for exposure of birds to active ingredients and no PNEC has been derived.

Mixture toxicity

Please see report "Toxicological profile for humans and animals on: SERPOL GEL II".

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

Aggregated exposure (combined for relevant emmission sources)

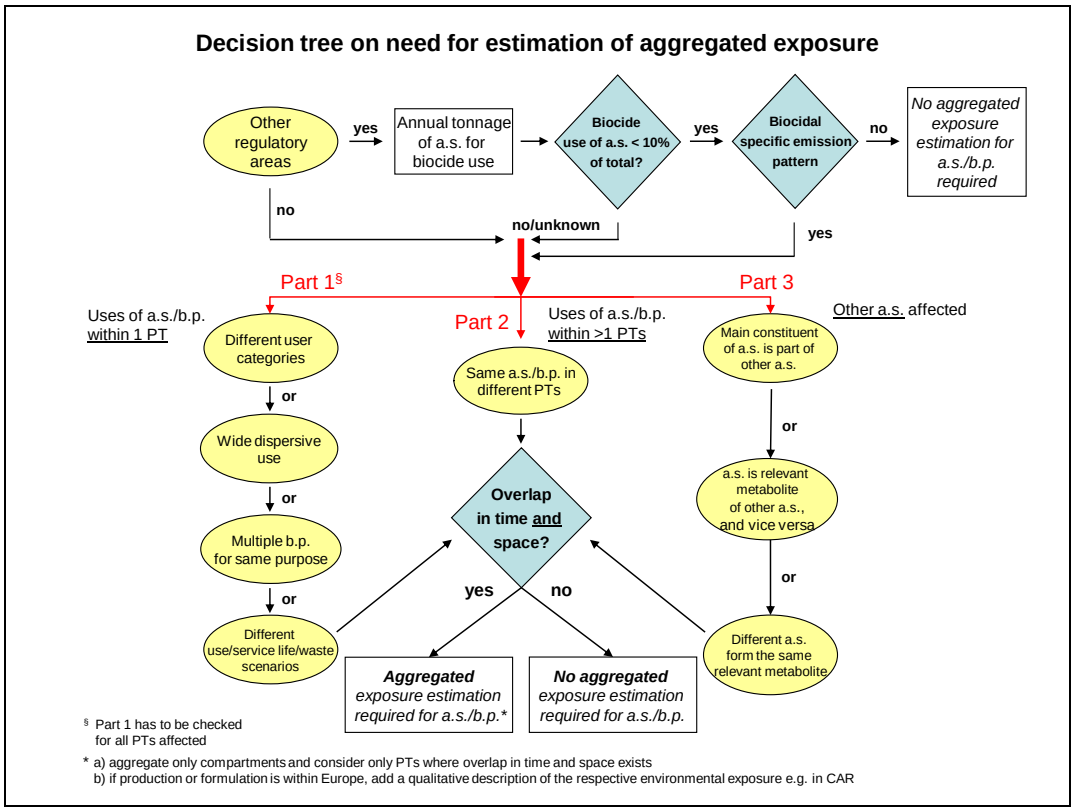


Figure 1: Decision tree on the need for estimation of aggregated exposure

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
The risk quotient is well below the trigger value which indicates an acceptable risk according to the proposed use pattern, with the top coat.
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, see risks mitigation measures for authorized uses.

2.2.10 Assessment of a combination of biocidal products

For biocidal products that are intended to be authorised for the use with other biocidal products.

2.2.11 Comparative assessment
Background

The product contains, in addition to the active substances IPBC and permethrin, the active substance propiconazole.
Based on the Assessment Report for active substance approval of propiconazole shall not be considered as a candidate for substitution. However, taking into to account the currently legal harmonized classification and labelling in accordance of CLP Regulation, propiconazole is classified as Repr. 1B, H360D therefore, it shall be considered as a candidate for exclusion or substitution using the criteria in Article 5 (1) and 10 (1) of the Biocides Regulation (EU) No 528/2012 (BPR). Therefore, in line with Article 23 (1) of the BPR this comparative assessment has been carried out by the ES CA according to the *Technical Guidance Note on comparative assessment of biocidal products (TNsG-CA i.e. CA-May15-Doc4.3a-final).*
For this comparative assessment the Spanish CA used the data from R4BP database on January 2021.
In accordance with the *Technical Guidance Note on comparative assessment of biocidal products (CA-May-15-Doc-4.3a-final)* the products were only compared to the alternatives authorised in Spain.

1. Application administrative details

Procedure: NA-APP

Purpose: Authorisation

Case Number in R4BP: BC-TH023766-28

Evaluating Competent Authority: ES CA

Applicant: MYLVA S.A.

(Prospective) Authorisation holder: MYLVA S.A.

2. Administrative information of the BP

Trade name(s): SERPOL GEL II

Product type(s): 08 (wood preservative)

Active substance(s): Propiconazole (60207-90-1), IPBC (CAS: 55406-53-6), Permethrin (CAS: 52645 53 1)

3. Intended uses for the relevant BP in the application

The wood protection product (PT8) SERPOL GEL II contains the active substances propiconazole, IPBC and permethrin. The product is used by trained professional users for preventive wood protection in use class 2 only by brushing against wood discolouring fungi, wood destroying basidiomycetes and wood boring beetles and curative treatment against wood boring beetles by brushing.
The product is a gel.
Table 1, 2and 3 lists the intended uses of the biocidal products, which determines the focus of the comparative assessment.

Table 2. Preventive treatment-superficial application (brushing)-Trained professional user.

Product Type	PT8
Where relevant, an exact description of the authorised use	SERPOL GEL II is a wood preservative product with insecticidal and fungicidal properties for class of use 2.
Target organism (including development stage)	Insects: - Wood boring beatles. (*Hylotrupes bajulus*). - Subterranean termites. (*Reticulitermes spp*) Fungi: - Wood rotting basidiomicetes (*Gloeophyllum trabeum, Poria placenta* and *Coniophora puteana*) - Wood discoloring fungi- Bluestain in service.
Field of use	Class of use 2. Situation in which the wood or wood-based product is under cover and not exposed to the weather (particulary rain and driven rain) but where occasional, but not persistent, wetting can occur.
Application method	Superficial treatment only by brushing.
Category of use	Trained professional user.

Table 2. Curative treatment- Superficial application (brushing)- Trained professional user.

Product Type	PT8
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Insects: - Wood boring beatles. (*Hylotrupes bajulus*).Larvae. - Subterranean termites. (*Reticulitermes spp*)
Field of use	Indoors. Outdoors.
Application method	Curative treatment by brushing/rolling.
Category of use	Trained professional user.

Mode of Action of the active substances:
Permethrin is responsible for the insecticidal activity only. Propiconazole and IPBC are responsible only for fungicidal activity.
The active substance propiconazole inhibits the fungal growth and has no obvious effect on spore germination or penetration of the pathogen. As other triazole fungicides, propiconazole inhibits the C 14 demethylation step in the ergosterolbiosynthesis of fungi. Propiconazole is effective against wood decay. It is effective against the wood rotting fungus *P. placenta*, but is less effective against the wood rotting fungi *C. puteana* or *G. trabeum*.
The active substance IPBC is a carbamate fungicide. The target sites of carbamates in fungi are cell membrane permeability and fatty acids, which leads to disruption of basic cell functions. IPBC has some activity against brown wood-rotting fungi but its efficacy largely lies with its activity against blue-stain (wood staining) fungi. IPBC is usually not

used stand-alone but in combination with propiconazole (and or tebuconazole) to achieve efficacy against wood decay.
As an insecticide, Permethrin when formulated as a wood preservative is an axonic poison, binding to voltage-gated sodium channels in nerves. By binding to these channels, the substance group of pyrethroids prevent the channels from closing which cause prolonged sodium channel activation. The nervous system is irreversibly damaged leading to death.

4. Mapping of existing alternatives to the relevant BP

4.1.- Identified eligible alternative BPs

According to the information available in R4BP on January.2021, there are about 2930 active authorisations under product type 8 (wood protection) throughout the whole Union including mutual recognitions and same product authorizations. However, only products authorised under Biocidal Products Directive and Biocidal Products Regulation in Spain have been considered for comparative assessment (in line with CA-May15-Doc.4.3.a-Final).
A total of 79 products containing IPBC, propiconazole, tebuconazole, boric acid, fenpropimorph, creosote, granulated copper, sulfuryl fluoride, hydrogen cyanide permethrin and cypermethrin are authorised in Spain. Of these, IPBC, propiconazole, tebuconazole, boric acid, fenpropimorph, creosote and granulated cooper are effective against fungi. The Fungicide Resistance Action Committee (FRAC), an international scientific committee with an overview of the global position, has provided the following information on the potential for resistance; this has been derived from experience with plant protection products rather than wood preservative products.

Table 4 Mode of action and risk of resistance formation for PT8 fungicidal substances in authorised biocidal products

Active substance	Target organism (from Annex I AR)	Mode of action	FRAC code	Risk of resistance formation
Boric acid	Wood-destroying fungi, wood boring insects and termites	Inhibition of metabolism	Not reported	No information in CAR
Fenpropimorph	blue-stain, wood discolouring fungi and wood destroying basidiomycetes	G: sterol biosynthesis in membranes G2: Δ14-reductase and Δ8-Δ7-isomerase in sterol biosynthesis *(erg24, erg2)*	**5**	Low to medium risk (resistance management required)
Tebuconazole	Wood-destroying fungi	G: sterol biosynthesis in membranes G1: C14-demethylase in sterol biosynthesis *(erg11/cyp51)*	3	Medium risk (resistance management required)
Propiconazole	Wood-disfiguring fungi and wood destroying fungi	G: sterol biosynthesis in membranes G1: C14-demethylase in sterol biosynthesis *(erg11/cyp51)*	3	Medium risk (resistance management required)

IPBC	Wood-disfiguring fungi and wood destroying fungi	F: lipid synthesis or transport / membrane integrity or function F4: cell membrane permeability, fatty acid (proposed)	28	Low to medium risk (resistance management required)
Granulated copper	wood destroying fungi wood boring beetles and termites	M: Chemicals with multi-site activity: multi-site Contact activity. Inorganic copper (different salts). Also applies to organic copper complexes	M 01	Low risk without any signs of resistance developing to the fungicides. In the CAR it is recommended to include a second active substance in biocidal products as some fungi show increased tolerance towards copper
Creosote	Wood rotting basidiomycetes Soft rot micro-fungi	Multi-site action	Not reported	No information in CAR

4.2.- Identified eligible non-chemical alternatives

Not relevant in the screening phase. However, considering that propiconazole was authorised under the BPD, no public consultation was carried out by ECHA in the context of the approval. Consequently, no non-chemical alternatives were proposed to replace the use of the active substance propiconazol.

5. Screening phase of comparative assessment

5.1.- Description of the assessment of the adequate chemical diversity in authorised BPs to minimise the occurrence of resistance and conclusion.

Propiconazole, tebuconazole, boric acid, fenpropimorph, and creosote are themselves candidates for substitution and hence, products containing these active substances should not be included in this comparative assessment.

As boric acid and creosota, due to their harmonized classification as Toxic for Reproduction Cat. 1B and carcinogenic Cat 1B respectively fulfill one of the exclusion criteria of the BPR, those active substances are not further considered as a viable alternative to propiconazol.

The only product containing fenpropimorph (which is a candidate for substitution itself) authorised in Spain also contains boric acid and propiconazole and accordingly cannot be an alternative to the propiconazole-containing product SERPOL GEL II which is under evaluation.

Products based on sulfuryl fluoride and hydrogen cyanide are fumigation products acting as insecticide products. Therefore, all the fumigation products are not considered as

eligible alternative for wood preservative products and are therefore not included in this comparative assessment.

Since products containing only permethrin and/or cypermethrin act as insecticide products, these products cannot be alternatives for wood preservative products. Therefore, these products have not been included in this comparative assessment.

Other products containing cypermethrin or permethrin additionally contain propiconazole and/or tebuconazole (which is a candidate for substitution itself) and accordingly cannot be alternatives for the propiconazole containing product SERPOL GEL II under assessment.

The only product containing granulated copper authorised in Spain contains tebuconazole (which is a candidate for substitution itself) and propiconazole and accordingly cannot be alternative for the propiconazole containing product SERPOL GEL II which is under assessment.

Accordingly, the only alternatives for the protection of wood against fungi in Spain are IPBC containing products. Therefore, there is potentially one available mode of action-active substance (IPBC) combination for the intended uses of the biocidal product.

As paragraph 57 of the TNsG for comparative assessment states that at least three different and independent active substance/mode of action combinations should remain available through authorised biocidal products for a given use, the Spanish CA concludes that there are currently no alternatives in order to replace the product SERPOL GEL II containing propiconazole.

On the other hand, as mentioned above, IPBC has some activity against brown wood-rotting fungi but its efficacy largely lies with its activity against blue-stain (wood staining) fungi and thus, IPBC is usually not used stand-alone but in combination with other fungicides (propiconazole and/or tebuconazole) to achieve efficacy against wood decay.

In addition, no products containing only IPBC plus an active substance against insects have been authorised in Spain.

5.2.- Consideration on whether the Candidate(s) for substitution meet(s) at least one of the exclusion criteria listed in Article 5 (1) but can benefit from derogation in accordance with Article 5(2) of the BPR

Based on the Assessment Report for active substance approval, as well as taking into account the currently legal harmonized classification and labelling as Repr Tox 1B; H360D of the active substance propiconazole is considered as meeting the substitution criteria in Article 10 (1) and further the exclusion criteria according to Article 5 (1).

5.3.- Conclusion of the screening phase

It is proposed that the comparative assessment for propiconazole must be taken forward to Tier IB (quantitative analysis) in line with section 6.2 of *the technical Guidance Note on comparative assessment of biocidal product* (CA-May15-Doc4.3a-final)

6. TIER IB: detail comparison

According to the information available to the ES CA, there are 79 biocidal products authorised in Spain under Product Type 8 (Wood Preservatives) of the Biocidal Products Directive and Biocidal Products Regulation (including Mutual Recognitions and same product authorisations). Of them, no biocidal products have been authorised in Spain for the same intended uses in SERPOL GEL II which is authorised by trained professional users for preventive wood protection in use class 2 only by brushing against wood discolouring

fungi, wood destroying basidiomycetes and wood boring beetles and curative treatment against wood boring beetles by brushing.
There are currently 6 biocidal products authorised for trained professional users for preventive wood protection in use class 2 by brushing against wood boring beetles, wood destroying fungi but not against wood discolouring fungi and curative treatment against wood boring beetles by brushing and injection application. They all contain propiconazole.
Also, there are also 5 products authorised for trained professional users for preventive wood protection in use class 2, by brushing against wood discolouring fungi, wood destroying basidiomycetes and wood boring beetles but curative treatment is not allowed. They all contain propiconazole.
Therefore, there is no alternative product available for detailed comparison according to point 6.2.2 of the *technical Guidance Note on comparative assessment of biocidal product (CA-May15-Doc4.3a-final).*

7. Overall conclusion

The Spanish CA concludes that there are currently no alternatives in order to replace the product SERPOL GEL II containing propiconazole.
The IPBC containing products, which could be an alternative regarding the fungicidal activity, would lack the insecticidal activity.
Even if tebuconazole had been considered as an alternative active substance at the screening phase (which is a candidate for substitution itself), the tebuconazole containing products with insecticidal activity also contains propiconazole in all products.
No biocidal products have been authorised in Spain for the same intended uses in SERPOL GEL II so there is no alternative product available for detailed comparison according to point 6.2.2 of *the technical Guidance Note on comparative assessment of biocidal product.*
Taking into account that the outcome of the comparative assessment is not sufficiently conclusive to conclude that the criteria of Article 23(3) of BPR are met, the comparative assessment is finalised at this stage and ES CA proposes that the biocidal product SERPOL GEL II should be authorised for a period not exceeding 5 years in accordance with Article 23(6) of Regulation (EU) No 528/2012.

3 ANNEXES

3.1 List of studies for the biocidal product

Author(s)	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published
[redacted]	[redacted]	SERPOL GEL II. Determination of preventive action against *Hylotrupes bajulus* (Linnaeus) – Part 1: Larvicidal effect according to EN 46-1:2010+ERRATUM 2012. Sponsor: MYLVA, SA. Laboratory: TECNALIA. Study Code: 052526-3-a
[redacted]	[redacted]	SERPOL GEL II Determination of the toxic values against larvae of *Hylotrupes bajulus* (Linnaeus) according to UNE-EN 47:2007/AC:2007. Sponsor: MYLVA, S.A. Laboratory: TECNALIA. Study code: 052526-5-a
[redacted]	[redacted]	SERPOL GEL II. Determination of preventive action against *Reticulitermes* species according to EN 118:2013. Sponsor: MYLVA, S.A. Laboratory: TECNALIA. Study code: 052526-2-a
[redacted]	[redacted]	SERPOL GEL II. Determination of toxic values against *Reticulitermes* species according to EN 117:2012. Sponsor: MYLVA, S.A. Laboratory: TECNALIA. Study code: 052526-4-a
[redacted]	[redacted]	SERPOL GEL II. Test method for determining the protective effectiveness against wood destroying basidiomycetes. Determination of the toxic values based in EN 113:1996/A1:2004 Sponsor: MYVA, S.A. Laboratory: TECNALIA Study code: 29825-7-a
[redacted]	[redacted]	SERPOL GEL II. Determination of the protective effectiveness of a preservative treatment against blue stain in wood service, according to EN 152:2011. Sponsor: MYLVA S.A. Laboratory:TECNALIA Study code: 052526-7-a

[redacted]	[redacted]	SERPOL GEL II. Determination of the eradicant action against *Hylotrupes bajulus* (Linnaeus) larvae according to EN 1390:2006. Sponsor: MYLVA S.A. Laboratory:TECNALIA Study code: 052526-1-a
[redacted]	[redacted]	Physico-chemical properties, validation of the analytical method and chemical analyses of the biocidal product SERPOL GEL II before and after an accelerated storage procedure for 14 days at 54°C±2°C in compliance with CIPAC MT 46.3 method. Final Report No:402/15/1202F-e
[redacted]	[redacted]	Determination of whetheher the sample Serpol GeL II is a solid or a liquid.
[redacted]	[redacted]	Storage stability during 4 years at ambient temperature according to Technical Monograph No.17 (CropLife) on the biocidal product "SERPOL GEL II" Draft report No:402/15/1202F/j-e
[redacted]	[redacted]	Immersion corrosion testing S/ASTM-G 31 Sponsor: MYLVA, S.A. Laboratory:Metaltest Study code: E-01430.00004

3.2 Output tables from exposure assessment tools

Human Health exposure

HH Exposure calculations 28-05-2

3.3 New information on the active substance

Not applicable.

3.4 Residue behaviour

Not relevant.

3.5 Summaries of the efficacy studies

See summary table of efficacy tests. Section 2.2.5.5.