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

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)

CORPOL MADERA VERDE

Product type 08

Propiconazole, IPBC and Bardap 26 as included in the Union list of approved active substances

Case Number in R4BP: BC-LN036817-20

Evaluating Competent Authority: ES CA

Date: April 2022

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1 CONCLUSION

Physical-chemical properties and Analytical Methods

CORPOL MADERA VERDE is a EC (Emulsifiable Concentrate) product. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. Its technical characteristics are acceptable for an EC formulation. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in a white plastic can (commercial packaging material).

The biocidal product is not classified from the physico-chemical aspect.

The analytical methods provided are fully validated for the determination of the active substances, propiconazole, IBPC and Bardap 26. Methods for the determination of the residues are available in the CAR of the active substances.

Efficacy
The efficacy study has demonstrated the activity of CORPOL MADERA VERDE as temporary preventive wood preservative against blue stain and mould fungi for green wood.

For temporary preservation of green timber, application by immersion of the product in a minimum concentration of 1.5% (v/v) in water for 20 seconds (product retention of 2 g/m^2) is sufficient to prevent infestations of blue stain and mould fungi.
The authorized application methods for this product are by immersion, automated spray and green chain.

Use Classes are not relevant for this product since the temporary treatment is for freshly sawn (green) timber during the drying process of wood.

Human Health
For the classification and labelling of the biocidal product the concentration of active substance and co-formulants in the product is taken into account. No substance of concern for human health have been identified and the classified of the product according to CLP regulation is due to the active substances included..

According to the CAR of each active susbstance, propiconazole is listed in the document of EU Commission on endocrine disrupting chemicals (COMMISSION STAFF WORKING DOCUMENT on implementation of the Community Strategy for Endocrine Disrupters, with insufficient data and does not warrant conclusion of their endocrine disruption potential.
IPBC is not considered to have endocrine disrupting properties.
Based on available experimental results, there is no indication that didecylmethylpoly(oxyethyl)ammonium propionate (Bardap 26) affects the endocrine system. Structural characteristics and SAR do not hint to possible effects of didecylmethylpoly(oxyethyl)ammonium propionate as endocrine disruptor.

After reviewing the potential ED properties of co-formulants, none substances have been identified as having potential endocrine disrupting properties. If these substances are identified as having ED properties in the future, the conditions for granting the biocidal product authorisation will be revised.

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

Summary table risk assessment for human health			
Scenario	**Scenario**	**Conclusion**	**Exposed group**
1.	Mixing and loading	A **safe** situation has been identified for loading of products into vessels or systems in industrial scale when RMM are used.	Professional (trained-professional) users
2.	Dipping application	A **safe** situation has been identified for dipping application when RMM are used.	Professional (trained-professional) users
Combined scenarios 1 + 2	M&L + dipping	A **safe** situation has been identified for M&L and dipping when RMM are used.	Professional (trained-professional) users
3.	Cutting and sanding	A **safe** situation has been identified for Trained for cutting and sanding timber when RMM are used.	Professional (trained-professional) users
Combined scenarios 1 + 2 + 3	M&L + dipping + handling	A **safe** situation has been identified for M&L and dipping and handling timber when RMM are used.	Professional (trained-professional) users
4.	Cutting and sanding	A **safe** situation has been identified for general public for cutting and sanding treated wood.	General public (adult-acute)
5.	Toddler mouthing	A **safe** situation has been identified for toddler chewing treated wood chips.	General public (toddler-acute)
6.	Toddler playing and mouthing	A **safe** situation has been identified for toddler playing and mouthing on playground weathered wood structure outdoors	General public (toddler-chronic)
7.	Toddler inhaling volatile residues	A **safe** situation has been identified for general public inhaling volatilised residues indoors.	General public

All scenarios resulted in acceptable risk. In addition, risk assessment for consumers via residues in food and animal health is not foreseen when RMM are set on the product label.

In addition, we would like to mention that the exposure assessment of the product has been carried out the professional user. Nevertheless, in order to apply national legislation regarding users categories, an art 37 of BPR will be applied in Spain and the product will be granted only for trained professional in our country.

Environmental Risk

CORPOL MADERA VERDE, is a PT-8 intended to be used indoors in sawmills. The biocidal product is used for preventive protection of wood and constructional timbers. The product is intended to be applied only by trained professional users who apply it by automated

dipping, "green chain" or automated spraying methodologies at industrial sites where the wood is treated and then stored under cover. The aim of this wood protection treatment is to prevent mould and blue mould's attack.

Although CORPOL MADERA VERDE is intended to be used as a temporary anti-saptain and the treated wood is going to be storage after the treatment, releases from the subsequent used , i.e., for the life cycle step "service life" have to be assessed with the "assessment of temporary anti-saptain wood preservatives" scenario. According to this scenario, if unacceptable risks for the environment are assessed in one or more UC 3 scenarios and no use on wood intended for pallets is requested by the applicant, the product can only be authorized as a temporary anti-sapstain wood preservative for wood, which is intended to be used in UC 1+2.

As the biocidal product contains 3 actives substances, the assessment must be done for all of the them taking into the account the mixture toxicity. During the active substance assessment for BARDAP 26, a Predicted No Effect Concentration (PNEC) for the sediment and soil compartment could not be derived. Subsequently, the available information does not permit to perform a risk assessment for the sediment and soil compartment for use classes other than 1 and 2.

So, as with the avalaible information is not possible to calculate the risk as UC 3 for the subsequent use of the wood treated with CORPOL MADERA VERDE, no environmental risk assessment has been carried out. In order to reduce the environmental release and because the use classes are not relevant, the following mention has been added to the instructions for use:

- CORPOL MADERA VERDE is ONLY to be used for wood in situation in which the wood or wood based product is inside a contruction, not expose to the weather and wetting or where occasional, but not persistent, wetting can occur.

The following risk mitigation measures must be included in the product label to minimize potential environmental risks derived from product application in industrial premises and storage prior to shipment:

-Prevent any release of the biocidal product to the sewage system or the environment during the product application phase as well as during the storage and the transport of treated timber;
-All industrial application processes must be carried out within a contained area situated on impermeable hard standing with bunding to prevent run-off and a recovery system in place (e.g. sump);
-Application solutions must be collected and reused or disposed of as hazardous waste. They must not be released to soil, ground- and surface water or any kind of sewer;
-Freshly treated timber must be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water and that any losses of the product shall be collected for reuse or disposal;
-Any contaminated water/soil shall be collected, contained and treated as hazardous waste.

2 ASSESSMENT REPORT

2.1.1 Summary of the product assessment

2.1.2 Administrative information

2.1.2.1 Identifier of the product

Identifier[1]	**Country (if relevant)**
CORPOL MADERA VERDE	Spain (rMS)
CORPOL MADERA VERDE	France (cMS)
CORPOL MADERA VERDE	Portugal (cMS)

2.1.2.2 Authorisation holder

Name and address of the authorisation holder	**Name**	QUÍMICA DE MUNGUÍA S.A.
	Address	Derio Bidea, 51 48100 Munguia (Vizcaya)
Authorisation number	ES/APP(NA)-2022-08-00814	
Date of the authorisation	22/04/2022	
Expiry date of the authorisation	28/07/2025	

2.1.2.3 Manufacturer(s) of the product

Name of manufacturer	QUÍMICA DE MUNGUÍA S.A.
Address of manufacturer	Derio Bidea, 51 48100 Munguia (Vizcaya)
Location of manufacturing sites	Derio Bidea, 51 48100 Munguia (Vizcaya)

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

Active substance	Propiconazole
Name of manufacturer	LANXESS Deutschland GmbH
Address of manufacturer	Kennedyplatz, 1. 50569 Köln, Germany
Location 1 of manufacturing sites	Producer 1: Syngenta Crop Protection AG CH-4002 Basilea, Suiza

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

	Plant location: CH-1870 Monthey, Suiza
Location 2 of manufacturing sites	Producer 2: Jiangsu Yangnong Chemical Group Co., Ltd Plant location: Wenfeng Road, Yangzhou, Jiangsu 225009, P.R. China
Location 3 of manufacturing sites	Producer 3: Jiangsu SevenContinent Green Chemical Co., Ltd Plant location North Area of Dongsha Chem-Zone, Zhanjiagang, Jiangsu, 215600, P.R. China

Active substance	3-iodo-2-propynylbutylcarbamate (IPBC)
Name of manufacturer	LANXESS Deutschland GmbH
Address of manufacturer	Kennedyplatz, 1. 50569 Köln, Germany
Location of manufacturing sites	Shanghai Hui Long Chemicals Co., Ltd ZIP: 201815 Dengta Jiazhu Rd. Jiading – district Shanghai – P.R. China

Active substance	Poly(oxy-1,2-ethanediyl), .alpha.-[2-(dide-cylmethylammonio)ethyl]- .omega.- hydroxy-, propanoate (salt) (Bardap 26)
Name of manufacturer	LONZA Cologne GmbH
Address of manufacturer	Nattermannallee 1, 50529 Cologne, Germany
Location 1 of manufacturing sites	Producer 1: Clariant Produkte (Deutschland) GmbH Plant Location: Industrieparkstr. 1, 84504 Burgkirchen Germany
Location 2 of manufacturing sites	Producer 2: WallChemie Plant Location: Am Selder 25, 47906 Kempen Germany

2.1.3 Product composition and formulation

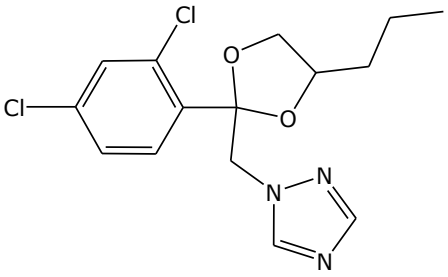
NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

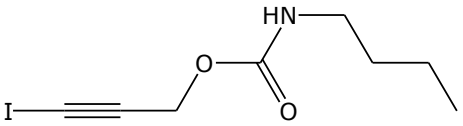
Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

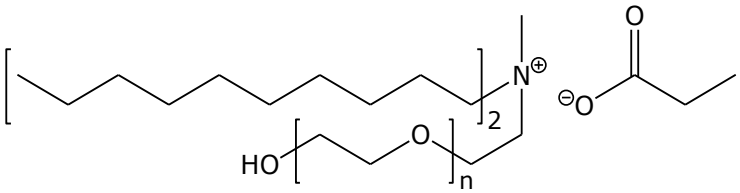
Yes ☐
No ☒

2.1.3.1 Identity of the active substance

Main constituents - Propiconazole

Main constituents - Propiconazole	
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	>93 %
Structural formula	

Main constituents - IPBC	
ISO name	IPBC
IUPAC or EC name	3-Iodo-2-propynylbutylcarbamate
EC number	259-627-5
CAS number	55406-53-6
Index number in Annex VI of CLP	616-212-00-7
Minimum purity / content	≥ 98%
Structural formula	

Main constituents – Bardap 26	
ISO name	Didecylmethylpoly(oxyethyl)ammonium propionate
IUPAC or EC name	Alpha-[2-(didecylmethylammonio)ethyl]-.omega.-hydroxy-poly(oxy-1,2-ethanediyl)propionate
EC number	None assigned
CAS number	94667-33-1
Index number in Annex VI of CLP	
Minimum purity / content	≥86.1% w/w dry weight
Structural formula	

2.1.3.2 Candidate(s) for substitution

There is no indication that IPCB and Didecylmethylpoly(oxyethyl)ammonium propionate would fulfil the exclusion criteria specified in article 5(1), nor the substitution criteria specified in Article 10 (1) of Regulation (EU) No 528/2012.

Regarding the active substance propiconazole, taking into account the classification of reprotox category 1B (H360D), is identified as fulfilling exclusion and substitution criteria in the EU under the biocidal products regulation.

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
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	3 (technical) 2.82 (pure)
IPBC	3-Iodo-2-propynyl butylcarbamate	Active substance	55406-53-6	259-627-5	5 (technical) 4.9 (pure)
Didecylmethylpoly (oxyethyl)ammonium propionate	Alpha-[2-(didecylmethyl ammonio)ethyl]-.omega.-hydroxy-poly(oxy-1,2-ethanediyl)propionate	Active ingredient	94667-33-1	None assigned	3 (technical) 2.1-2.7 (pure)
For further details on full product composition please refer to the Confidential Information.					

2.1.3.4 Information on technical equivalence

The source of IPBC active substance supplied by LANXESS Deutschland GmbH is a technical equivalence (ECHA Decision number: TAP-D1255923-24-00/F dated June 2017- asset number: EU-0017138-0000)

The source of PROPICONAZOLE active substance supplied by LANXESS Deutschland GmbH and manufactured by Producer and Location 1, is the known source from the BPD/BPR process for the active substance Propiconazole. However, there are two sources of PROPICONAZOLE active substance as technical equivalence:

- Location 2 of manufacturing sites The decision for the technical equivalence has been taken by the eMS FIN under the scope of Directive 98/8/EC on July 21, 2017. The decision number is Dnro 717/713/2011.

- Location 3 of manufacturing sites (ECHA Decision number: TAP-D1182636-27-00/F dated February 2016.- asset number: EU-0013032-0000)

2.1.3.5 Information on the substance(s) of concern

According to the definition of a substance of concern laid down in the Guidance on the BPR Volume III Human Health- Assessment & Evaluation– Part B and C Risk Assessment (Version 4.0 December 2017), CORPOL MADERA VERDE does not contain any substance of concern for human health. Please see the confidential annex for further details.

Regarding the environmental assessment, there is a coformulant that cancould be considered as SoC. Please see the confidential annex for further details.

2.1.3.6 Type of formulation

EC – Emulsifiable Concentrate

2.1.4 Hazard and precautionary statements

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

Classification	
Hazard category	Skin Irrit. 2 Eye Dam. 1 STOT RE 2 Skin sens. 1 Repr. 1B Aquatic Acute 1 Aquatic Chronic 1
Hazard statement	**H315** Causes skin irritation **H318** Causes serious eye damage **H373** May cause damage to organs through prolonged or repeated exposure **H317** May cause an allergic skin reaction **H360D** May damage the unborn child **H410** Very toxic to aquatic life with long lasting effects
Labelling	
Pictograms	 GHS08 GHS05 GHS09
Signal words	Danger
Hazard statements	**H315** Causes skin irritation **H318** Causes serious eye damage **H373** May cause damage to organs (state all organs affected, if known) through prolonged or repeated exposure (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)

	H317 May cause an allergic skin reaction **H360D** May damage the unborn child **H410** Very toxic to aquatic life with long lasting effect
Precautionary statements	**P201** Obtain special instructions before use. **P260** Do not breathe mist/vapours/spray **P264** Wash … thoroughly after handling. **P272** Contaminated work clothing should not be allowed out of the workplace. **P280** Wear protective gloves/protective clothing/eye protection/face protection **P310** Immediately call a POISON CENTER/ doctor/... **P302+P352** IF ON SKIN: Wash with plenty of water **P305+P351+P338** IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. **P308+P313** IF exposed or concerned: Get medical advice/attention **P333+P313** If skin irritation or rash occurs: Get medical advice/ attention. Take off immediately all contaminated clothing and wash it before reuse **P273** Avoid release to the environment. **P391** Collect spillage. **P405** Store locked up **P501** Dispose of contents/container as hazardous waste to a registered establishment or undertaking, in accordance with current regulations
Note	

2.1.5 Authorised use(s)

2.1.5.1 Use description

Table 2. Use # 1 - Temporary preventive treatment of green wood

Product Type	PT 8 – Wood preservative
Where relevant, an exact description of the authorised use	Temporary anti-saptain wood preservative, which the wood or wood based product is inside a contruction, not expose to the weather and wetting or where occasional, but not persistent, wetting can occur.
Target organism (including development stage)	Blue stain fungi Mould fungi
Field of use	Indoor use (Use Class not relevant)
Application methods	Superficial application: dipping/green chain/automated spray. Product is not ready-to-use.

Application rates and frequency	Product needs dilution in water before application. Application rate: Product retention: 2 g/m² in water dilution at 1.5% (v/v)Frequency: One application for temporary prevention for freshly sawn wood.
Category of users	Professional (Trained professional) users
Pack sizes and packaging material	Plastic containers (polyethylene): 25, 50, 100, 200, 500 and 1000 L.

2.1.5.1.1 Use-specific instructions for use

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

CORPOL MADERA VERDE is ONLY to be used for wood in situation in which the wood or wood based product is inside a contruction, not expose to the weather and wetting or where occasional, but not persistent, wetting can occur.

CORPOL MADERA VERDE provides temporary preventive protection of freshly felled lumber against colonization by blue stain and moulds during drying of wood in the sawmill.

After treatment by dipping/automated spray/green chain wood should be stored for complete drying in open stacking with wood strips, in a well ventilated, covered and paved area.

For dipping treatment, immerse the wood for at least 20 seconds.
The users should inform if the treatment is ineffective and report straightforward to the registration holder.

Please refer to section 2.1.5. General directions for use.

2.1.5.1.2 Use-specific risk mitigation measures

Please refer to section 2.1.5. General directions for use

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

Please refer to section 2.1.5. General directions for use

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

Please refer to section 2.1.5. General directions for use

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

Please refer to section 2.1.5. General directions for use

2.1.6 General directions for use

2.1.6.1 Instructions for use

Before using the product, read the label carefully.
In order to avoid risks for people or the environment follow the instructions for use.
Properly ventilate the area where the product's treatment is performed.
Do not mix with other chemicals.
Apply the product on the wood to be treated by immersion in the bath.
Dilution: 1,5% (regular conditions)
Do not use in the presence of people or pets.
Do not apply to kitchen tools.
Ventilate where product is applied.
Do not mix with any other chemicals.
Contains Propiconazole, may cause allergic reactions.
In order to avoid direct loss to soil or water, freshly treated wood should be stored after treatment, under cover or on a hard and waterproof surface or both.
The authorization holder should report any observed incidents related to the efficacy to the Competent Authorities (CA).

2.1.6.2 Risk mitigation measures

Environment: -Prevent any release of the biocidal product to the sewage system or the environment during the product application phase as well as during the storage and the transport of treated timber; -All industrial application processes must be carried out within a contained area situated on impermeable hard standing with bunding to prevent run-off and a recovery system in place (e.g. sump). -Application solutions must be collected and reused or disposed of as hazardous waste. They must not be released to soil, ground- and surface water or any kind of sewer; -Freshly treated timber must be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water and that any losses of the product shall be collected for reuse or disposal. -Any contaminated water/soil shall be collected, contained and treated as hazardous waste. **Handling:** Do not use on wood which may come in direct contact with food, feedingstuff and livestock animals Keep children and pets away from treated surfaces until they have dried. Avoid prolonged contact of pets to treated surfaces. Before using the product read the label carefully.

The wood should be treated stacked with separation battens. Once treated, it will remain stacked and trapped protected from the rain to avoid the washout of the protective product. Wood piles should be arranged in such a way that air circulation is favoured to ensure a correct drying process. Recommended period of safety: 24 hours, it will never be less than the time it takes to fix the product.
RMM for industrial uses: "the person responsible for placing the treated wood on the market must ensure that the treated wood is not intended for uses involving contact with food, feed or livestock".

Use Personal Protection Equipment (PPE)
Use clean personal protective equipment in good condition.
Store personal protective equipment in a clean place, away from the work area.
During use, do not eat, drink or smoke. Remove and wash contaminated clothing before reuse. Provide adequate ventilation, especially in closed areas.
Eye protection: Avoid eye and face contact by using glasses and protection screen against drops and liquid splash (UNE-EN 166)
Hand protection: wear protective chemical resistant gloves (glove material to be specified by the authorization holder within the product information)
Body protection: For automated dipping (green chain) and spraying, a protective impermeable coverall (at least category III type 4) shall be worn (coverall material to be specified by the authorization holder within the product information).
For manual dipping, a protective coated coverall (at least category III type 6) shall be worn (coverall material to be specified by the authorization holder within the product information).
Method and precautions concerning fire:
Fire prevention:
Do not allow the access to non-authorized people at the treatment place.
Extinguishing measures:
Extinguish fire with foam, powder, CO_2 or water spray.
Do not use water jet, only to refresh areas and packaging next to the heat source
Specific hazards arising from the substance or preparation.
The fire may product a thick black smoke. The combustion gases of organic materials must always be considered as toxic for inhalation. Do not breathe vapours.
In case of fire, the following sub-products can be formed:

- Carbon monoxide (CO)
- Carbon dioxide (CO_2)
- Hydrogen chloride (HCl)

2.1.6.3 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: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor.

IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance

for medical assistance.
The eyes should also be rinsed repeatedly on the way to the doctor.

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

Emergency measures to protect the environment
Environmental precautions:
Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. Inform to the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and materials for containment and cleaning up:
Channelling large quantities and collect in containers; the rest collect with absorbent material and then dispose them according to local regulations. Wash the small amounts with water. Remove the used water according to local regulations.

2.1.6.4 Instructions for safe disposal of the product and its packaging

Empty containers, unused product, washing water, containers and other waste generated during the treatment are considered hazardous waste. Deliver those wastes to a registered establishment or undertaking, in accordance with current regulations.
Code the waste according Decision 2014/955/EU.
Do not release to soil, ground, surface water or any kind of sewer.

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

Shelf-life: 2 years.
Keep out of direct sunlight and frost.
Keep away from sources of ignition.
Keep always in the original package

2.1.7 Other Information

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

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

At the same time, there are also some restrictions of packaging in relation to those user categories and product types.

2.1.8 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)
Plastic containers	25, 50, 100, 200, 500 and 1000 L	HDPE		Professional (Trained professional)	Yes

2.1.9 Documentation

2.1.9.1 Data submitted in relation to product application

No new data on the active substance itself or on the substances of concern has been submitted in function of this product application. All new information relates to the biocidal product described within this application.
The reference list (including updates) for the studies submitted in support of the BPD dossier has been included in Annex 3.1 whilst the reference list for the studies considered confidential has been included in the confidential PAR.

2.1.9.2 Access to documentation

The applicant supplies the Letters of Access (LoAs) for three active substances included in biocidal product submitted; LANXESS Deutschland GmbH as owner of data dossiers for Propiconazole and IPBC active substances and LONZA Cologne GmbH as owner of data dossier for Bardap 26 active substance.

2.1.10 Assessment of the biocidal product

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

Table 1 1. Use # 1 – Profesional use

Product Type	PT 8 – Wood preservative
Where relevant, an exact description of the authorised use	The product is intended to be applied indoor (classified as use classes 1 and 2 under Norm UNE-EN 335) only by professional users as temporary treatment on fresh sawnwood against blues and molds. The biocidal product is used for preventive protection of wood and constructional timbers.
Target organism (including development stage)	Chromogen fungi and mold.

Field of use	The product is always applied indoor, generally in closed tanks for dipping or spraying application methods. But the treated wood can be destined to be used indoor or outdoor: ***Indoor*** The product is intended to be classified as use classes 1 and 2 under Norm UNE-EN 335 ***Outdoor (service life)*** • when the treated wood does not take contact with the floor or water and always protected and covered from the outdoor-environment (Use class 3.1 under Norm UNE-EN 335). • when the treated wood does not take contact with the floor or water and unprotected from the outdoor-environment, whenever that drained water will be collected and leaded to a STP (Use class 3.2 under Norm UNE-EN 335).
Application method(s)	***Dipping application:*** The product is diluted in water at 1.5% and then the treatment is developed in rafts where the wood is dipped for a short time. ***Green chain:*** The wood is treated as boards which are bathed by an automatic and mechanical process in pools where the product is diluted. ***Automated spraying*** The timber is passed through automated spray tunnels, where the diluted product is applied over the wood.
Application rate(s) and frequency	The treatment is developed only one time as preventive treatment. The product is intended to be applied at 100 grams of diluted product per m^2 of wood for surface treatments. At dipping process, 5 L/m^3 is considered as the most suitable application rate for the final dilution with a regular retention rate of 100cm^3 of product per m^2 of wood.
Category(ies) of users	Professional user
Pack sizes and packaging material	Polyethylene plastic containers, 25, 50, 100, 200, 500 and 1000 liters.

2.1.12 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual method	Propiconazole, 3.0% w/w IPBC, 5.0 % w/w	Liquid	Report nº 402/16/1258F-e

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		DMPAP, 3.0 % w/w		(2017)
Colour at 20 °C and 101.3 kPa	Visual method	Propiconazole, 3.0% w/w IPBC, 5.0 % w/w DMPAP, 3.0 % w/w	Transparent yellow liquid	Report nº 402/16/1258F-e (2017)
Odour at 20 °C and 101.3 kPa	Not guideline followed	Propiconazole, 3.0% w/w IPBC, 5.0 % w/w DMPAP, 3.0 % w/w	Not specified	Report nº 402/16/1258F-e (2017)
Acidity / alkalinity	CIPAC method MT 75.3	Propiconazole, 3.0% w/w IPBC, 5.0 % w/w DMPAP, 3.0 % w/w	7.08 at 20 ±2ºC (Initial) (undiluted product) 6.23 at 20 ±2ºC (After 14 days at 54ºC) (undiluted product)	Report nº 402/16/1258F-e (2017)
Relative density / bulk density	OECD 109	Propiconazole, 3.0% w/w IPBC, 5.0 % w/w DMPAP, 3.0 % w/w	1.051 at 20.0 ± 0.5·ºC	Report nº 402/16/1258F-e (2017)
Storage stability test – **accelerated storage**	CIPAC MT 46.3	Propiconazole, 3.0% w/w IPBC, 5.0 % w/w DMPAP, 3.0 % w/w	Temperatura 54ºC ± 2°C (14 days) PROPICONAZOLE (% w/w) $[C]_0$ =3.0 % $[C]_f$ = 3.03% Δ[C] = +1.0% < 10% IPBC (% w/w) $[C]_0$ =4.92 % $[C]_f$ = 4.48% Δ [C] = -8.9% < 10% DMPAP (% w/w) $[C]_0$ = 2.98% $[C]_f$ = 2.89% Δ [C] = -3.0% < 10% The appearance of the commercial packaging and the weight of the test item in the commercial packaging did not change significantly.	Report nº 402/16/1258F-e (2017)
Storage stability test –	GIFAP Nº 17	Propiconazole, 3.0% w/w	PROPICONAZOLE (% w/w) Results 6 months	Report nº COA-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
long term storage at ambient temperature		IPBC, 5.0 % w/w DMPAP, 3.0 % w/w	$[C]_0$ =3.0 % $[C]_f$ = 3.08 % Δ [C] = +2.66% < 10% <u>Results 12 months</u> $[C]_0$ =3.0 % $[C]_f$ = 3.02 % Δ [C] = +0.66% < 10% <u>Results 18 months</u> $[C]_0$ =3.0 % $[C]_f$ = 3.10 % Δ [C] = +3.33% < 10% <u>Results 24 months</u> $[C]_0$ =3.0 % $[C]_f$ = 3.08 % Δ [C] = +2.66% < 10% IPBC (% w/w) <u>Results 6 months</u> $[C]_0$ =4.92 % $[C]_f$ = 4.88% Δ [C] = -0.81% < 10% <u>Results 12 months</u> $[C]_0$ =4.92 % $[C]_f$ = 4.94% Δ [C] = +0.40% < 10% <u>Results 18 months</u> $[C]_0$ =4.92 % $[C]_f$ = 4.85 % Δ [C] = -1.42% < 10% <u>Results 24 months</u> $[C]_0$ =4.92 % $[C]_f$ = 4.84 % Δ [C] = -1.62% < 10% DMPAP (% w/w) <u>Results 6 months</u>	402/16/1258F/3/m/T24M-e (2020)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			$[C]_0$ =2.98 % $[C]_f$ = 3.11 % Δ [C] = +4.36% < 10% <u>Results 12 months</u> $[C]_0$ =2.98 % $[C]_f$ = 2.89 % Δ [C] = -3.02% < 10% <u>Results 18 months</u> $[C]_0$ =2.98 % $[C]_f$ = 2.75 % Δ [C] = -7.71% < 10% <u>Results 24 months</u> $[C]_0$ =2.98 % $[C]_f$ = 2.92 % Δ [C] = -2.01% < 10% Results show that the product is stable after 24 months at ambient temperature.	
Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3	Propiconazole, 3.0% w/w IPBC, 5.0 % w/w DMPAP, 3.0 % w/w	The test item was physically stable after 7 days at 0 ± 2°C. No deposit or phase partition was observed.	Report nº 402/16/1258F-e (2017)
Effects on content of the active substance and technical characteristics of the biocidal product – **light**	-	-	The product is stored in darkness at room temperature, so no effect of light is expected.	-
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	-	-	Stability at elevated and decreased temperatures confirmed by the respective storage stability test. Humidity does not affect the properties of the product as t he product is water based.	-
Effects on			The product is stable in its	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	-	-	container.	-
Wettability	-	-	Not applicable for this type of product.	-
Suspensibility, spontaneity and dispersion stability	-	-	Not applicable for this type of product.	-
Wet sieve analysis and dry sieve test	-	-	Not applicable for this type of product.	-
Emulsifiability, re-emulsifiability and emulsion stability	CIPAC MT 36.3/CIPAC MT18	Propiconazole, 3.0% w/w IPBC, 5.0 % w/w DMPAP, 3.0 % w/w	Test item dilution: 1.5% w/w in water before accelerated storage at 54ºC; 1.5% w/w in water after accelerated storage at 54ºC Initial emulsification: Uniform; Uniform Emulsion stability on standing: No free oil, cream, solid matter after standing for 30 min, 2h and 24h.; No free oil, cream, solid matter after standing for 30 min, 2h and 24h. Re-emulsification after standing for 24h: No free oil, cream, solid matter after standing for 30 s; No free oil, cream, solid matter after standing for 30 s Final emulsion stability: No free oil, cream, solid matter after standing for 30 min,; No free oil, cream, solid matter after standing for 30 min	Report nº 402/16/1258F-e (2017)
Disintegration time	-	-	Not applicable for this type of product.	-
Particle size istribution, content of dust/fines,	-	-	Not applicable for this type of product.	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
attrition, friability				
Persistent foaming	CIPAC MT 47.2/CIPAC MT18	Propiconazole, 3.0% w/w IPBC, 5.0 % w/w DMPAP, 3.0 % w/w	The result of persistent foaming test was a volume of foam greater than 60 mL. (observed after 1 minute, at 20 ºC, before and after the accelerated procedure)	Report nº 402/16/1 258F-e (2017)
Flowability/Pourability/Dustability	-	-	Not applicable for this type of product	-
Burning rate — smoke generators	-	-	Not applicable for this type of product	-
Burning completeness — smoke generators	-	-	Not applicable for this type of product	-
Composition of smoke — smoke generators	-	-	Not applicable for this type of product.	-
Spraying pattern — aerosols	-	-	Not applicable for this type of product.	-
Physical compatibility	-	-	Not applicable. The product is not intended to be used in combination with other products.	-
Chemical compatibility	-	-	Not applicable. The product is not intended to be used in combination with other products.	-
Degree of dissolution and dilution stability	-	-	Not applicable for this type of product.	-
Surface tension	OECD Guideline 115/EU Method A.5	Propiconazole, 3.0% w/w IPBC, 5.0 % w/w DMPAP, 3.0 % w/w	31.09 mN/m at 20 ºC.	Report nº 402/16/1 258F-e (2017)
Viscosity	OECD 114/CIPAC MT 192	Propiconazole, 3.0% w/w IPBC, 5.0 % w/w DMPAP, 3.0 % w/w	Dynamic viscosity: 99.6 mPa.s at 20ºC 36.2 mPa.s at 40ºC	Report nº 402/16/1 258F-e (2017)

Conclusion on the physical, chemical and technical properties of the product
The product "CORPOL MADERA VERDE" is a EC (Emulsifiable Concentrate) product. All

studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is a transparent yellow liquid. There is no effect of high temperature on the stability of the formulation, since after 2 weeks at 54 ºC, neither the active ingredient content nor the technical properties were changed.

The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in a white plastic can (commercial packaging material). Its technical characteristics are acceptable for an EC formulation.

2.1.13 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	Differential Scanning Calorimety (DSC)	Propiconazole, 3.0% w/w IPBC, 5.0 % w/w DMPAP, 3.0 % w/w	The DSC test proves that the product does not have explosive properties.	Report nº 402/21/1220F/a-e
Flammable gases	-	-	Not applicable. The product is a liquid.	-
Flammable aerosols	-	-	Not applicable. The product is a liquid.	-
Oxidising gases	-	-	Not applicable. The product is a liquid.	-
Gases under pressure	-	-	Not applicable. The product is a liquid.	-
Flammable liquids	NF EN ISO 2719/EC method A.9	Propiconazole, 3.0% w/w IPBC, 5.0 % w/w DMPAP, 3.0 % w/w	The flash point of the test item was >99º·C under the conditions of the test. The product does not need to be classified as 'flammable liquid', since flash point is >60°C	Report nº 402/16/1258F-e (2017)
Flammable solids	-	-	Not applicable. The product is a liquid.	-
Self-reactivesubstances and mixtures	Differential Scanning Calorimety (DSC)	Propiconazole, 3.0% w/w IPBC, 5.0 % w/w DMPAP, 3.0 % w/w	The DSC test proves that the product does not have explosive properties.	Report nº 402/21/1220F/a-e
Pyrophoric liquids	-	-	Not applicable. The product is a liquid without pyrophoric properties.	-
Pyrophoric solids	-	-	Not applicable. The product is	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			a liquid.	
Self-heating substances and mixtures	-	-	Not applicable. According to the UN Manual of Tests and Criteria, 7th revised edition (2019) Appendix 6, A6.5.3.1, the classification procedure for pyrophoric solids and liquids need not be applied when experience, in production or handling, shows that the substance does not ignite spontaneously on coming into contact with air at normal temperatures (i.e. the substance is known to be stable at room temperature for prolonged periods of time). Furthermore, the absence of self-heating properties of the products in this product is confirmed by experience in production and handling, and by stability studies.	-
Substances and mixtures which in contact with water emit flammable gases	-	-	Not applicable.	-
Oxidising liquids	-	-	The study does not need to be conducted because there are no chemical groups present in the molecule which are associated with oxidising properties and hence, the classification procedure does need to be applied.	-
Oxidising solids	-	-	Not applicable. The product is a liquid.	-
Organic peroxides	-	-	Not applicable. The study does not need to be conducted because the substance does not fall under the definition of organic peroxides according to GHS and the relevant UN manual of test and criteria	-
Corrosive to metals	UN Test C.1	Propiconazole, 3.0% w/w	No corrosion attack was occurred after 28 days of	Report nº 402/21/121

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		IPBC, 5.0 % w/w DMPAP, 3.0 % w/w	exposure at the temperature of 55 ºC and the loss mass was lower than 51.5 %.	8F/a-e (2022)
Auto-ignition temperatures of products (liquids and gases)	EC Method A.15	Propiconazole, 3.0% w/w IPBC, 5.0 % w/w DMPAP, 3.0 % w/w	The product was found not to self-ignite below 400°C.	Report nº RT87WQ (2017)
Relative self-ignition temperature for solids	-	-	Not applicable. The product is a liquid.	-
Dust explosion hazard	-	-	Not applicable. The product is a liquid.	-

Conclusion on the physical hazards and respective characteristics of the product
CORPOL Madera verde product (EC) has no oxidizing, no organic peroxides and explosive properties. The flash point of the product was >99º·C, therefore the product does not need to be classified as 'flammable liquid'. Hence, the product does not require classification under Regulation (EC) No 1272/2008 for physical hazards.

2.1.14 Methods for detection and identification

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of quantification (LOQ) or other limits	Reference
					Range	Mean	RSD		
Propiconazole	HPLC	Recovery rates at each spiking level: 100% at 60 mg/L - RSD (mean rel. stand. dev. %): 1.13% (n=6)	The method/detector response was linear (coefficient of determination, r2= 0.99) within the range from 48 to 72 mg/L (Propiconazole (60 mg/L))	The method is specific. No interfering substances reported.	[99.77 - 100.3]	100.0	0.39	Not specified	Report nº 402/16/1258F-e (2017)
IPBC	HPLC	Recovery rates at each spiking level: 99.66% at 100 mg/L;	The method/detector response was linear	The method is specific. No interfering	[99.41 - 99.91]	99.66	0.39	Not specified	Report nº 402/16/1258F-e (2017)

		- RSD (mean rel. stand. dev. %): 1.57% (n=6)	(coefficient of determination, r2= 0.99) within the range from 80 to 120 mg/L (IPBC (100 mg/L))	substances reported.					
DMPAP	IC	Recovery rates at each spiking level: 99.41% at 100 mg/L; - RSD (mean rel. stand. dev. %): 0.84% (n=6)	The method/detector response was linear (coefficient of determination, r2= 0.99) within the range from 80 to 120 mg/L (DMPAP (100 mg/L))	The method is specific. No interfering substances reported.	[99.05 - 99.77]	99.41	0.56	Not specified	Report nº 402/16/1258F-e (2017)

Analytical methods for monitoring									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Please refer to the respective active substance's CAR for further methods									

Analytical methods for soil									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Please refer to the respective active substance's CAR for further methods									

Analytical methods for air									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Please refer to the respective active substance's CAR for further methods									

Analytical methods for water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Please refer to the respective active substance's CAR for further methods									

Analytical methods for animal and human body fluids and tisues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Please refer to the respective active substance's CAR for further methods									

Analytical methods for monitoring of active substances and residues in food and feeding stuff									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Please refer to the respective active substance's CAR for further methods									

Conclusion on the methods for detection and identificationof the product
According to guideline SANCO/3030/99 the analytical methods provided are fully validated for the determination of the active substances: propiconazole, IPBC and DMPAP.

2.1.15 Efficacy against target organisms

2.1.15.1 Function and field of use

CORPOL MADERA VERDE is a temporary wood preservative (PT 8) for trained professional users.

The product is used for preventive treatment against blue stain and mould fungi for green wood (i.e. freshly sawn timber) during the drying process of wood in the sawmill.

The treatment with CORPOL MADERA VERDE is performed by immersion (dipping) and by spraying of green wood at industrial facilities.

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

CORPOL MADERA VERDE is a preventive wood preservative for green wood.

CORPOL MADERA VERDE provides temporary control of wood discolouring fungi (blue stain and mould fungi).

2.1.15.3 Effects on target organisms, including unacceptable suffering

CORPOL MADERA VERDE contains three active substances: propiconazole, IPBC and Bardap 26.

Propiconazole acts as a fungicide by stoping cellular growth.

IPBC acts as a fungicide by impairing cell membrane permeability and fatty acids metabolism.

Bardap 26 acts as a fungicide by impairing the cell wall permeability, disturbs membrane-bound ion-translocation mechanisms, and may facilitate the uptake of other biocides.

2.1.15.4 Mode of action, including time delay

CORPOL MADERA VERDE contains three active substances: propiconazole, IPBC and Bardap 26, with different modes of action.

Propiconazole is a triazole fungicide, also known as a DMI, or demethylation inhibiting fungicide due to its binding with and inhibiting the 14-alpha demethylase enzyme from demethylating a precursor to ergosterol. Without this demethylation step, the ergosterols are not incorporated into the growing fungal cell membranes, and cellular growth is stopped.

IPBC is a fungicide that belongs to the group of carbamates. IPBC is commonly used as a mildewcide in water-based architectural coating films and for wood preservatives. The principal mode of action is thought to be through the iodine moiety. Oxidation of the sulfhydryl group of the amino acid cysteine results in loss of the ability to connect protein chains by disulfide (-S-S-) bridges, an important factor in the synthesis of proteins.

Bardap 26 is a cationic surfactant-type active substance. Since it is surface active, it has fair wetting properties and reacts strongly with cell walls of microorganisms. Due to its interaction with phospholipid-bilayer structures, it severely alters the cell wall permeability, disturbs membrane-bound ion-translocation mechanisms, and may facilitate the uptake of other biocides as Propiconazole or IPBC.

2.1.15.5 Efficacy data

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Fungicide - Temporary preventive treatment	Industrial sites Industrial operators Green wood	CORPOL MADERA VERDE	Bluestain fungi Mould fungi	CEN/TS 15,082:2006 Field study	*Pinus sylvestris* (softwood), freshly shawn timber Dipping procedure Exposure: 20 seconds of immersion in diluted product Tested concentrations of CORPOL in water dilution: 1.5, 2, 2.5, 3% v/v Reference product, tested dilutions 1.5, 3% v/v	Average (overall) fungal attack intensity (cromogen + mould fungi): -open stacking: 0, 0.04, 0.02, 0 Controls: 2.82 (>2.50, valid) Ref. product at 1.5%: 0.76 (>0.75, valid) -closed stacking: 1.58, 1.54, 2, 1.50 Controls: 3.96 (>3.50, valid) Reference product at 1.5%: 1.26 (>1, valid) Solution retentions (mean of 10 samples per concentration tested): 1.7, 1.9, 1.9, 2 g/m²	[redacted] Report no. 19100-a

Conclusion on the efficacy of the product

Efficacy against fungi was tested following the CEN/TS 15,082:2005 standard on freshly sawn timber of *Pinus sylvestris* (softwood) by immersion in product dilutions for 20 seconds. In the study four concentrations of CORPOL MADERA VERDE diluted in water were tested (i.e. 1.5, 2, 2.5, 3% v/v). Fungal attack intensity (blue stain and mould fungi) was observed after the treatment of green wood.

The solution absorbed by each sample was measured and the equivalent product retention was estimated. Mean product retention after immersion in the four dilutions tested was ca. 2 g/m².

Aditionally wood samples were tested with negative controls (0% v/v dilution) and with a reference product (at 1.5% and 3% v/v dilutions) as indicated by the standard. The effect results obtained in the controls and the reference product (at 1.5% v/v) samples showed that the study can be considered valid, according to the standard criteria.

The results showed very good efficacy against blue stain and mould fungi (i.e. rate of 0, equivalent to 0% cover of overall fungal attack) at the four product dilutions when green wood was stored in open stacking (pilled up with wood strips). When green wood was stored in closed stacking (without wood strips) efficacy was lower (i.e. rate 1.5-2 intensity, equivalent to 10-25% cover of fungal attack). The lower efficacy was due to mould fungi attack (rated as 1.5-2 intensity), while sapstain fungi attack intensity was rated as 0 with all tested dilutions.

The fungicide effect of CORPOL MADERA VERDE did not increase largely with increasing concentrations tested, compared to the reference product. The fungicide effect was more related to the later stacking conditions (open or close) of green wood when left to dry.

According to the test, the product is applied by immersion, but the applicant has also requested the methods of application by automated spraying and green chain, therefore these methods will also be authorized.

Therefore, the treatment of green wood with CORPOL MADERA VERDE applied by dipping, automated spray and green chainat a minimum concentration rate of 1.5% (v/v) in water is effective against blue stain and mould fungi. For best efficacy the treated wood should stored in open stacking (with wood strips) in a well ventilated and covered area.

Since the application of CORPOL MADERA VERDE is a temporary preventive treatment, Use Class is not relevant.

2.1.15.6 Occurrence of resistance and resistance management

Propiconazole

According to the CAR resistance to fungicides is a normal phenomenon embodied in the natural process of the evolution of biological systems and all demethylation inhibitor have a similar resistance risk but resistance factors may be different.

However, there are no specific resistance cases to propiconazole reported and the activity of all four isomers of propiconazole may reduce the formation of resistance.
IPBC

According to the CAR of this active substance, the risk of resistance formation against Carbamate fungicides is regarded to be low to medium by FRAC (Fungicide Resistance Action Committee).

There is no evidence showing that any organism has developed resistance to IPBC in the field of wood protection.

BARDAP 26 (Didecylmethylpoly(oxyethyl)ammonium propionate)

According to the CAR of this active substance, from practical experiences with standalone-biocides in this field of application, it is known that a local formation of "resistant" fungus strains at the application site may occur.

For this reason didecylmethylpoly(oxyethyl)ammonium propionate or other biocides are normally not used as unique biocide in anti sapstain formulations. This preservative type is always made up of two or three different biocides to avoid adaptations or resistances. Additional investigations on exposure of domestic microbial communities to quaternary ammonium biocidal substances do not result in increased antimicrobial resistance (McBain A.J. et al., 2004).

Since CORPOL MADERA VERDE is made up of three active substances, it is not excepted that resistance may arise. Nevertheless 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.

2.1.15.7 Known limitations

There are not limitations known.

2.1.15.8 Evaluation of the label claims

The following matrix of categories and codes for product are applicable to CORPOL MADERA VERDE:

Table 2.2.5.8 Categories and codes for product for CORPOL MADERA VERDE

User category	Trained professional users (Industrial users)	A.20
Wood category	Softwood	B.10
Wood product	Green wood (newly sawn timber)	C.10
Application aim	Temporary preventive treatment / green wood	D.20
Field of use	Green wood (Use Class not relevant)	-
Method of application	Superficial application / spray treatment	F.11

	Superficial application / dipping treatment	F.14
Target organisms	Blue stain fungi Mould fungi	G.21.2 G.22

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

The product is not intended to be authorised for use with other biocidal product(s)

2.1.16 Risk assessment for human health

CORPOL MADERA VERDE contains three active substances: Propiconazole (3%), IPBC (5%) and didecylmethylpoly(oxyethyl)ammonium propionate (3%) and other co-formulants.

No studies on the effects of CORPOL MADERA VERDE 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). Active substances effects and critical concentrations are described in the propiconazole, IPBC and Bardap 26 assessment report. Information on co-formulants are found on the ECHA dissemination website and the SDSs submitted. Therefore new studies with the biocidal product are scientifically not justified.

2.1.16.1 Assessment of effects on Human Health

There are not studies on the effects of CORPOL MADERA VERDE on human health submitted for this product. However 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). 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	CORPOL MADERA VERDE is classified as Skin Irrit. 2
Justification for the value/conclusion	According to the notifications provided by companies to ECHA in REACH registrations and data sheet, the active substance Bardap 26 is classified as Skin Corr 1B (H314). Taking into account the concentration of this active substance in the product and the Table 3.2.3 of CLP regulation, the product . is classified as Skin Irritant cat. 2 (H315).
Classification of the product according to CLP	Skin Irrit. 2 (H315)

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	CORPOL MADERA VERDE is classified as Eye Dam. 1.
Justification for the value/conclusion	Two active substances are classified as Eye Dam 1 (H318): IPBC and Bardap 26. In addition, one component is also classified as Eye Dam. 1 but the concentration of this component in the product is less than the generic concentration limit stablished in CLP regulation. Taking into account that concentration of active substances in the product and considering the Table 3.3.3 of CLP regulation, the product is classified as as Eye Damage cat. 1 (H318)
Classification of the product according to CLP	Eye Dam. 1 (H318)

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	
Value/conclusion	CORPOL MADERA VERDE is not a respiratory tract irritant
Justification for the conclusion	Based on the classification of active substances and the different co-formulants 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 classification 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	CORPOL MADERA VERDE is a Skin sensitizer 1
Justification for the value/conclusion	Based on the classification of active susbstances and the different co-formulants and, their respective content in the final formulation.Two active substances are classified as Skin Sensitizer 1 (H317) according to annex VI of Regulation (EC) No 1272/2008. Based on their concentrations, the biocidal product is classified as skin sensitizer 1 according to the rules laid down in Regulation (EC) No 1272/2008 (CLP) (Table 3.4.5).
Classification of the product according to CLP	Skin sensitizer 1 (H317)

Data waiving	
Information requirement	Skin sensitization study.
Justification	For the biocidal product the composition is known. Sufficient data on the intrinsic properties of the components are available from safety data sheets and other information for each of the individual components in the product. 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	CORPOL MADERA VERDE is not a respiratory sensitizer
Justification for the value/conclusion	Based on the classification of 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 acute dermal toxicity 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	For the biocidal product the composition is known. Sufficient data on the intrinsic properties of the components are available from safety

	data sheets and other information for each of the individual components in the product. Consequently, classification of the mixture can be made according to the rules laid down in Regulation (EC) No 1272/2008. None of the ingredients are classified as respiratory sensitizers, so the product is not classified.

Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	DL50: >2000 mg/kg bw
Justification for the selected value	The active substances (Propiconazole, IPBC and Bardap 26) are classified as Acute Tox. 4 via the oral route (H302). The ATE_{oral} obtained is 6250 mg/kg bw (i.e. >2000 mg/kg). According to the data available and the CLP criteria (Regulation EC 1272/2008) the product is not classified as acute toxicant by the oral route.
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	CL50: >5mg/l
Justification for the selected value	Only the active substance IPBC is classified as Acute Tox. 3 via the oral route (H331). The ATE_{inhal} obtained is 10 (i.e. >5 mg/L) The calculated inhalation ATE for CORPOL MADERA VERDE 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 and DSD	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	CORPOL MADERA VERDE is not classified for acute dermal toxicity
Justification for the selected value	Based on the classification of 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 acute dermal toxicity. Therefore, the product does not meet the criteria for classification according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP and DSD	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.

Specific target organ toxicity – repeated exposure

Value used in the Risk Assessment – STOT RE	
Value	CORPOL MADERA VERDE is classified as Specific target organ toxicity-repeated exposure cat. 2
Justification for the selected value	There is one STOT-RE Category 1(H372) ingredient in a concentration of < 10%. Therefore the mixture is not classified as STOT-RE 1. There is one STOT-RE Cat. 1 ingredient in a concentration of ≥1% and ≤10%, therefore STOT-RE Cat. 2(H373) is warranted for the mixture.
Classification of the product according to CLP	STOT RE 2 (H373)

Data waiving	
Information	Specific target organ toxicity (repeated exposure) study

requirement	
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.

Reproductive toxicity

Value used in the Risk Assessment – Reproductive toxicity	
Value	CORPOL MADERA VERDE is classified as Reproductive Toxicant cat. 1B
Justification for the selected value	There is one active substance (Propiconazole) classified as Reproductive toxicant cat. 1B in a concentration of >0.3% (w/w). Therefore the mixture is classified as Repr. 1B.
Classification of the product according to CLP	Repr. 1B (H360D)

Data waiving	
Information requirement	Reproductive 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

According to the BPR guidance, values for dermal absorption should be obtained following the EFSA Guidance on Dermal Absorption (2017).

There are not experimental studies available on the dermal absorption of CORPOL MADERA VERDE. Thus default values for the formulation under consideration should be used for the risk assessment.

Default values depend on the formulation category and the concentration status. CORPOL MADERA VERDE is an organic solvent-based Emulsifiable Concentrate containing 3% of Propiconazole, 5% of IPBC and 3% of Bardap 26.

For the use as wood preservative, the product needs dilution in water at the rate of 3% (v/v).

Value(s) used in the Risk Assessment – Dermal absorption

Substance	Propiconazole	Bardap 26	IPBC
Value(s)*	70% dilution 25% concentrate	70% dilution 25% concentrate	70% dilution 25% concentrate
Justification for the selected value(s)	Applicant proposed to select default values from the EFSA Guidance on Dermal Absorption (2017) for Soluble Concentrates. However ES CA has concluded that CORPOL MADERA VERDE is an Emulsifiable Concentrate (EC). Thus default values for EC solvent-based formulations are proposed instead. It should be noted that the CAR of propiconazole concluded that for this a.s. the dermal absorption value are 1% and 2% for the concentrates and dilutions, respectively, on the basis of *in vivo* and *in vitro* studies. Thus the default value suggested by the guidance is a worst-case value.	Applicant proposed to select default values from the EFSA Guidance on Dermal Absorption (2017) for Soluble Concentrates. However ES CA has concluded that CORPOL MADERA VERDE is an Emulsifiable Concentrate (EC). Thus default values for EC solvent-based formulations are proposed instead. It should be noted that the CAR of Bardap 26 concluded that for this a.s. the dermal absorption value is 9.4% for the diluted product in water. This value comes from read-across of studies with the structural analogue, Didecyldimethylammoniu m Chloride. Thus the default value suggested by the guidance is a worst-case value.	Applicant proposed to select 100% of dermal absorption for solutions containing <0.5%-0.6% IPBC. ES CA believes that in the absence of dedicated studies with CORPOL MADERA VERDE, deafulst values of the EFSA Guidance on Dermal Absorption (2017) should be used. It should be noted that the CAR of IPBC concluded that for this a.s. the dermal absorption value are 30, 10, and 1.6% for solvent-based formulations containing 0.6, 2.3, and 17.1% IPBC, respectively, according to an *in vitro* study with human skin.

Data waiving	
Information requirement	Dermal absorption study
Justification	There is no experimental data available on the dermal absorption of CORPOL MADERA VERDE since no study has been conducted thus far. As a result, risk assessment calculations for human exposure have been made according to the EFSA guidance on dermal absorption (EFSA Journal, 2017;15(6):4873) using a default value of 70% dermal absorption for this product.

Endocrine disrupting properties

Endocrine disrupting properties assessment of active substance and co-formulants is mandatory from 7 June 2018, date when the Regulation (EU) 2017/2100 came into force, according to the article 19 of BPR.
None of the former substances has been identified as having potential endocrine disruptive 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.
Propiconazole had been in written consultation in the ED EG, and in follow-up discussion in the plenary all the experts agreed that an ED mode of action for aromatase inhibition leading to reproductive dysfunction in fish can be postulated and thus the ED criteria for non-target organisms are met. The ED EG agreed that there is also enough data for ED

identification with regard to human health, except for one expert who proposed requesting further information.
Taking into account these information, if these substances are identified as having ED properties in the future, the conditions for granting the biocidal product authorisation will be revised.
Please, refer to the confidential annex for more information

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

The biocidal product CORPOL MADERA VERDE contains three active substances and other coformulants. The active substances are Propiconazole (3% w/w), IPBC (5% w/w), and Bardap 26 (3% w/w). the classification of the product is due to these active substances.

Please see more information in the Confidential Annex.

According to Annex A of the document "Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation (Parts B+C) Version 2.1 February 2017": a qualitative exposure and risk assessment should be done in order to determine whether P-statements normally associated with concerned H statements are sufficient or whether other risk mitigation measures should be applied. The qualitative risk assessment can be found in the section 2.2.6.3 Risk characterization for human health.

Available toxicological data relating to a mixture

There are not toxicological studies available conducted with the mixture.

2.1.16.2 Exposure assessment

The scenarios used in this assessment are described in the TNsG on Human Exposure to Biocidal Products Part 3, p50-51 as revised by User Guidance version 1 p50-54 (EC, 2002a). This scenarios are in accordance with ECHA Guidance document "Biocides Human Health Exposure Methodology, first ed. (October 2015) and later harmonized in the Recommendations of the BPC Ad hoc Working Group on Human Exposure.

The biocidal product CORPOL MADERA VERDE, containing 3 active substances, is used as wood preservative by immersion/spraying of the timber in dissolved product. The product is delivered in form of concentrate containing 3% propiconazole, 5% IPBC and 3% Bardap 26. For use purposes it is diluted in water at 1.5%. Therefore final concentration of each active substance is as follows:

Active substance	In biocidal product (%)	Use solution (%) worst case (1.5%)
Propiconazole	3	0.045
IPBC	5	0.075
Bardap 26	3	0.045

For temporary preservation of green timber, application by immersion/spraying of the product in dilution of 1.5% in water for 20 seconds (product retention of 2 g/m^2) is sufficient to prevent infestations of blue stain and mould fungi.

The biocidal product is intended for **professional** use only. Adult users can get exposed during application of the product, through inhalation and dermal contact. Primary oral

exposure is considered not to be relevant. Secondary exposure is possible for the general public, when entering a room after treatment. Here dermal and inhalation exposure is relevant. For children, also oral exposure needs to be considered.

The SoCs detected in the biocidal product are not included in the exposure assessment according to the conclusions detailed in the Assessment of effects on Human Health (section 2.2.6.1).

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

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure** **Description of scenario**	**Exposed group**
1.	mixing and loading	Primary exposure loading of product into vessels or systems in industrial scale - inhalation and dermal routes.	Professional (trained-professional) users
2.	Dipping	Primary exposure dipping and cleaning out dipping tank - inhalation and dermal routes.	Professional (trained-professional) users
3.	adult sandig	Secondary exposure sanding treated wood from impregnated timber - inhalation and dermal routes.	Professional (trained-professional) users
4.	adult sandig	Secondary exposure sanding treated wood from impregnated timber - inhalation and dermal routes.	non professionals
5.	Toddler mouthing	secondary exposure chewing wood off-cut – oral route	non professionals
6.	Toddler playing and mouthing	secondary exposure playing on playground structure outdoors – dermal and oral routes.	non professionals
7.	Toddler inhaling volatile residues	secondary exposure inhaling volatile residues at home- inhalation route	Non professionals

Industrial exposure

No industrial exposure is foreseen.

Professional exposure (trained professional exposure – primary exposure)

Scenario [1]: Mixing and Loanding

Description of Scenario [1]			
It is assumed that most facilities have automated systems and therefore mixing and loading is not of concern (HEEG OPINION 18 - For exposure assessment for professional operators undertaking industrial treatment of wood by fully automated dipping): Where the wood preservative fluid is delivered by tanker and is transferred from the tanker into the dip tank using connecting hosing then, it could be assumed, providing the operator wears suitable PPE, exposure of the operator's skin is minimal and does not need to be quantified. However as worst case scenario and in order to include in this assessment the non fully automated facilities, HEEG Opinion on the use of available data and models for the assessment of the exposure of operators during the loading of products into vessels or systems in industrial scale - Agreed at TM I08) will be used. In order to be as much concordant to active substances assessments and being an acceptable possibility acoording to HEEG Opinion nº 1 on the use of available data and models for the assessment of the exposure of operators during the loading of products into vessels or systems in industrial scale, Mixing & loading model 7; TNSG part 2 p.142 (corrected) was used. Furthermore, this models also provides inhalatory exposure. Tier 1 assessment should be carried out considering no personal protective equipment or 100% penetration through protective clothes. For inhalation uptake 100% figure was used as well. Due to moderate physical activity the inhalation rate a value of 1.25 m^3/hour was used for calculations. In Tier 2 assessment, values from model are used. Dermal penetration is assumed as 70% as a worst case default. Exposure of each active substance is related to its relative contribution to the product. The biocidal product is assumed as undiluted for this process		
	Parameters	**Value**	**Justification / reference**
Tier 1	Propiconazole concentration	3%	Applicant's data
	IPBC comcentration	5%	Applicant's data
	Body weight, adult	60 kg	Recommendation no. 14 (2017)
	Exposure duration	10 min	Recommendation no. 6 (2020)
	Dermal exposure		
	Dermal exposure, without gloves	101 mg/min	HEEG Opinion 1 (2008)

Description of Scenario [1]			
	Dermal absorption	70%	Guidance on dermal absorption (2017)
	Inhalation exposure		
	Inhalation	0.94 mg/m^3	HEEG Opinion 1 (2008)
	Inhalation rate, adult	1.25m^3/h	Recommendation no. 14 (2017)
	Inhalation absorption	100%	Default value
Tier 2	Clothes and gloves penetration	1%	HEEG Opinion 1 (2008)
	Dermal exposure, under clothes and gloves	1.01 mg/min	HEEG Opinion 1 (2008)

Calculations for Scenario [1]

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake mg/kg bw/d**	**Estimated dermal uptake mg/kg bw/d**	**Estimated oral uptake mg/kg bw/d**	**Estimated total uptake mg/kg bw/d**
Propiconazole					
Scenario [1]	1 / no PPE	9.79E-05	3.54E-01	--	3.54E-01
Scenario [1]	2 / gloves and coverall	9.79E-05	3.54E-03	--	3.63E-03
IPBC					
Scenario [1]	1 / no PPE	1.63E-04	5.89E-01	--	5.89E-01
Scenario [1]	2 / gloves and coverall	1.63E-04	5.89E-03	--	6.05E-03

See Annex 3.2 for more information.

Further information and considerations on scenario [1]

Based on the conclusion of WGII2015, the systemic risk characterization was not considered necessary and only risk characterization for local effect should be presented for Bardap 26. Thus in this PAR only a local effect risk assessment of the a.s. Bardap 26 is performed (see Local effects in 2.2.6.3 Risk Characterisation for human health).

Scenario [2]: Dipping

Description of Scenario [2]
HEEG opinion 8 (2009) is applied for exposure assessment. Two different processes might occur depending on the whether it is a manual or automated facility. Manual dipping is defined as manual dipping of wooden articles in open tanks (p. 27 of the User Guidance, 2002 - including mixing/diluting formulations, handling wet articles, machine minding and

Description of Scenario [2]

loading/unloading). This models were agreed at the Human Health Working Group I on 28 January 2015 and later harmonized in Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure 'Methods and models to assess exposure to biocidal products in different product types' (2020).
In manual dipping operations, the operator lifts and places – by hand – the wooden article into the dipping tank. The operator then pushes, using a post, the wooden article under the wood preservative in the dipping tank and/or uses a broom to brush the wood preservative onto the wooden article (the article is still in the dipping tank as the preservative is brushed on the wood). The operator then lifts by his/her gloved hand the wooden article from the dipping tank and stacks the article to dry. The operator gets relatively highly contaminated by the wood preservative, as demonstrated by a video recording of this operation (UK HSE). Duration is assumed as 30 minutes. For exposure assessment Dipping Model 1 is used, including dermal and inhalatory exposure.

Automated dipping includes the following operations: an operator using a fork-lift truck or similar equipment lowers the wood into the dipping tank or transfers the wood to a bathing tray. The wood stays in the wood preservative for a few minutes or for a few hours before being lifted out of the tank by the fork-lift truck (or similar). The wood is then transferred by the fork-lift truck (or similar) to a storage area where it is placed to dry. For duration a default value of 60 minutes was used, by 4 cycles per day. Handling Model 1 for dermal exposure is used. Negligible inhalatory exposure to aerosols is assumed.
According to the HEEG opinion 8 - Defaults and appropriate models to assess human exposure for dipping processes (PT 8), inhalation exposure resulting from aerosol formation should be negligible.
The called treatment "Green chain" is considered quite similar to a dipping process and therefore, the exposure assessment of "green chain" is covered by the dipping scenario. At this scenario, freshly cut wood boards are passed one by one by a bathtub where the diluted product is placed. All this process is done automatically and this is the reason by which this process is regarded quite similar to dipping process and its assessment is covered by the dipping scenario.
The application by spraying is claimed as automated. The phases of exposure will be close to the phases of exposure for automated dipping. Therefore, this scenario covers also the use application by automated spraying.

Tier 1 assessment should be carried out considering no personal protective equipment or 100% penetration through protective clothes. For inhalation uptake 100% figure was used as well. Due to moderate physical activity the inhalation rate a value of 1.25 m^3/hour was used for calculations.
In Tier 2 assessment, values from model are used.
Dermal penetration is assumed as 70% as a worst case default. Exposure of each active substance is related to its relative contribution to the product. The biocidal product is assumed as diluted for this process

***Scenario [2a]:* Manual Dipping**

	Parameters	**Value**	**Justification / reference**
Tier 1	Propiconazole concentration	0.045%	Applicant's data
	IPBC comcentration	0.075%	Applicant's data

Description of Scenario [2]			
	Body weight, adult	60 kg	Recommendation no. 14 (2017)
	Exposure duration	30 min	HEEG Opinion 8 (2009)
	Dermal exposure		
	Hands	2570 mg/min	HEEG Opinion 8 (2009)
	Body	178 mg/min	HEEG Opinion 8 (2009)
	Dermal absorption	70%	Guidance on dermal absorption (2017)
	Inhalation exposure		
	Inhalation	<1 mg/m^3	HEEG Opinion 8 (2009)
	Inhalation rate, adult	1.25m^3/h	Recommendation no. 14 (2017)
	Inhalation absorption	100%	Default value
Tier 2	Hands (inside gloves)	25.7 mg/min	HEEG Opinion 8 (2009)
***Scenario [2b]:* Automated Dipping**			
	Parameters	**Value**	**Justification / reference**
Tier 1	Propiconazole concentration	0.045%	Applicant's data
	IPBC comcentration	0.075%	Applicant's data
	Body weight, adult	60 kg	Recommendation no. 14 (2017)
	Exposure duration	4 cycles	HEEG Opinion 8 (2009)
	Dermal exposure		
	Hands	108000 mg/cycle	HEEG Opinion 8 (2009)
	Body	8570 mg/cycle	HEEG Opinion 8 (2009)
	Dermal absorption	70%	Guidance on dermal absorption (2017)
Tier 2	Hands (inside gloves)	1080 mg/cycle	HEEG Opinion 8 (2009)
	Coverall penetration	5%	HEEG Opinion 9 (2010)

Calculations for Scenario [2]

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake** mg/kg bw/d	**Estimated dermal uptake** mg/kg bw/d	**Estimated oral uptake** mg/kg bw/d	**Estimated total uptake** mg/kg bw/d
Propiconazole					
Scenario [2a]	1 / no PPE	4.69E-06	4.33E-01	--	4.33E-01

Scenario [2a]	2 / gloves and coverall	4.69E-06	6.85E-03	--	6.86E-03
Scenario [2b]	1 / no PPE	--	2.45	--	2.45
Scenario [2b]	2 / gloves and coverall	--	3.17E-02	--	3.17E-02
IPBC					
Scenario [2a]	1 / no PPE	7.81E-06	7.21E-01	--	7.21E-01
Scenario [2a]	2 / gloves and coverall	7.81E-06	1.14E-02	--	1.14E-02
Scenario [2b]	2 / gloves and coverall	--	4.08	--	4.08
Scenario [2b]	2 / gloves and coverall	--	5.28E-02	--	5.28E-02

See Annex 3.2 for more information.

Further information and considerations on scenario [2]

Based on the conclusion of WGII2015, the systemic risk characterization was not considered necessary and only risk characterization for local effect should be presented for Bardap 26. Thus in this PAR only a local effect risk assessment of the a.s. Bardap 26 is performed (see Local effects in 2.2.6.3 Risk Characterisation for human health).

Combined scenarios

Combined exposures by same active substance by different tasks may occur. For this assessment mixing and loading and automated dipping was combined for each active substance.

Summary table: combined estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake mg/kg bw/d**	**Estimated dermal uptake mg/kg bw/d**	**Estimated oral uptake mg/kg bw/d**	**Estimated total uptake mg/kg bw/d**
Propiconazole					
Scenario [1, 2b]	1 / no PPE	9.79E-05	2.80	--	2.80
Scenario [1, 2b]	2 / gloves and coverall	9.79E-05	3.52E-02	--	3.53E-02
IPBC					
Scenario [1, 2b]	1 / no PPE	1.63E-04	4.67	--	4.67
Scenario [1, 2b]	2 / gloves and coverall	1.63E-04	5.87E-02	--	5.89E-02

See Annex 3.2 for more information.

Professional exposure (trained professional exposure – secondary exposure)

Scenario [3]: Sanding treated wood from dipping impregnated timber

Description of Scenario [3]			
The scenario is described in the TNsG on Human Exposure to Biocidal Products Part 3, p50-51 as revised by User Guidance version 1 p50-54 (EC, 2002a). The area of wood to be sanded was calculated considering a piece of wood with a length of 250 cm and a height of 4 cm. It has been considered that the exposure comes from the outer layer of the piece of wood (thickness of 1 cm).			
	Parameters	**Value**	**Justification / reference**
Tier 1	Propiconazole concentration	0.045%	Applicant's data
	IPBC comcentration	0.075%	Applicant's data
	Rate of product absorbed in wood (1.9E-03 L/m^2)	0.2 mg/cm^2	Applicant's data (Section 2.2.5)
	Product density	1.051 g/mL	Applicant's data (Section 2.2.2)
	Body weight, adult	60 kg	Recommendation no. 14 (2017)
	Exposure duration	6 h	Assumption
	Inhalation exposure		
	Volume of wood to be sanded in 1h	4.00E+03 cm^3	TNsG
	Wood density	0.4 g/mL	MOTA, 2013 from TM III 2008.
	Dust concentration in air (occupational exposure limit for wood dust)	5 mg/m^3	TNsG
	Inhalation rate	1.25 m^3/h	Recommendation no. 14 (2017)
	Inhalation absorption	100%	Default value
	Dermal exposure		
	Percentage dislodgeable	2%	Biocides Human Health Exposure Methodology 2015, p. 171.
	Hand surface	410 cm^2	Recommendation no. 14 (2017)
	Transfer to hands	20%	TNsG
	Dermal absorption	70%	Guidance on dermal absorption (2017)

Calculations for Scenario [3]

Summary table: systemic exposure from professional uses

Exposure scenario	Tier/PPE	Estimated inhalation uptake mg/kg bw/d	Estimated dermal uptake mg/kg bw/d	Estimated oral uptake mg/kg bw/d	Estimated total uptake mg/kg bw/d
Propiconazole					
Scenario [3]	1 / no PPE	1.42E-05	1.72E-04	--	1.86E-04
Scenario [3]	2 / gloves	1.42E-05	1.72E-05	--	3.14E-05
IPBC					
Scenario [3]	1 / no PPE	2.36E-05	2.87E-04	--	3.11E-04
Scenario [3]	2 / gloves	2.36E-05	2.87E-05	--	5.23E-05

See Annex 3.2 for more information.

Further information and considerations on scenario [3]

Based on the conclusion of WGII2015, the systemic risk characterization was not considered necessary and only risk characterization for local effect should be presented for Bardap 26. Thus in this PAR only a local effect risk assessment of the a.s. Bardap 26 is performed (see Local effects in 2.2.6.3 Risk Characterisation for human health).

Combined scenarios

Summary table: combined estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake mg/kg bw/d**	**Estimated dermal uptake mg/kg bw/d**	**Estimated oral uptake mg/kg bw/d**	**Estimated total uptake mg/kg bw/d**
Propiconazole					
Scenario [2a, 3]	1 / no PPE	1.89E-05	4.33E-01	--	4.33E-01
Scenario [2a, 3]	2 / gloves and coverall	1.89E-05	6.87E-03	--	6.89E-03
Scenario [1, 2b, 3]	1 / no PPE	1.12E-04	2.80	--	2.80
Scenario [1, 2b, 3]	2 / gloves and coverall	1.12E-04	3.52E-02	--	3.53E-02
IPBC					
Scenario [2a, 3]	1 / no PPE	3.14E-05	7.22E-01	--	7.22E-01
Scenario [2a, 3]	2 / gloves and coverall	3.14E-05	1.14E-02	--	1.15E-02
Scenario [1, 2b, 3]	1 / no PPE	1.87E-04	4.67	--	4.67
Scenario [1, 2b, 3]	2 / gloves and coverall	1.87E-04	5.87E-02	--	5.89E-02

See Annex 3.2 for more information.

Non-professional exposure

No non-professional exposure is foreseen.

Exposure of the general public

Preserved wood is not placed on the market until the product is dry. The product is suitable for indoor use. The reference scenarios modelled are as follows:

- Acute phase reference scenarios
  - Adult cutting and sanding treated wood - inhalation and dermal route.
  - Toddler acute chewing wood off-cut - ingestion route.
- Chronic phase reference scenarios
  - Adult inhalation of volatilised residues indoors - inhalation route.
  - Toddler playing on weathered structure and mouthing - dermal and ingestion.

Indirect exposure via the environment is considered to be of minor importance as the release to the environment is limited.

Scenario [4]: Sanding treated wood from dipping impregnated timber

Description of Scenario [4]			
The scenario is described in the TNsG on Human Exposure to Biocidal Products Part 3, p50-51 as revised by User Guidance version 1 p50-54 (EC, 2002a). The area of wood to be sanded was calculated considering a piece of wood with a length of 250 cm and a height of 4 cm. It has been considered that the exposure comes from the outer layer of the piece of wood (thickness of 1 cm).			
	Parameters	**Value**	**Justification / reference**
Tier 1	Propiconazole concentration	0.045%	Applicant's data
	IPBC comcentration	0.075%	Applicant's data
	Rate of product absorbed in wood (1.9E-03 L/m^2)	0.2 mg/cm^2	Applicant's data (Section 2.2.5)
	Product density	1.051 g/mL	Applicant's data (Section 2.2.2)
	Body weight, adult	60 kg	Recommendation no. 14 (2017)
	Exposure duration	1 h	Assumption
	Inhalation exposure		
	Volume of wood to be sanded in 1h	4.00E+03 cm^3	TNsG
	Wood density	0.4 g/mL	MOTA, 2013 from TM III 2008.
	Dust concentration in air (occupational exposure limit for wood dust)	5 mg/m^3	TNsG
	Inhalation rate	1.25 m^3/h	Recommendation no. 14 (2017)
	Inhalation absorption	100%	Default value
	Dermal exposure		

Description of Scenario [4]			
	Percentage dislodgeable	2%	Biocides Human Health Exposure Methodology 2015, p. 171.
	Hand surface	410 cm^2	Recommendation no. 14 (2017)
	Transfer to hands	20%	TNsG
	Dermal absorption	70%	Guidance on dermal absorption (2017)

Calculations for Scenario [5]

Summary table: systemic exposure from indirect exposure					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake mg/kg bw/d**	**Estimated dermal uptake mg/kg bw/d**	**Estimated oral uptake mg/kg bw/d**	**Estimated total uptake mg/kg bw/d**
Propiconazole					
Scenario [4]	1 / no PPE	2.36E-06	1.72E-04	--	1.75E-04
IPBC					
Scenario [4]	1 / no PPE	3.94E-06	2.87E-04	--	2.91E-04

See Annex 3.2 for more information.

Further information and considerations on scenario [4]

Based on the conclusion of WGII2015, the systemic risk characterization was not considered necessary and only risk characterization for local effect should be presented for Bardap 26. Thus in this PAR only a local effect risk assessment of the a.s. Bardap 26 is performed (see Local effects in 2.2.6.3 Risk Characterisation for human health).

Scenario [5]: Toddler chewing treated wood chip (acute exposure)

Description of Scenario [5]			
According to TNsG on Human Exposure to Biocidal Products Part 3, p42 as revised by User Guidance version 1 p50-54 (EC, 2002a).			
	Parameters	**Value**	**Justification / reference**
Tier 1	Propiconazole concentration	0.045%	Applicant's data
	IPBC comcentration	0.075%	Applicant's data
	Application rate	0.2 mg/cm^2	Applicant's data
	Extraction by chewing	10%	TNsG
	Size of wood composites chip	48 cm^2	TNsG
	Oral absorption	100%	Default value
	Body weight	10 kg	Recommendation no. 14 (2017)

Calculations for Scenario [5]

Summary table: systemic exposure from indirect exposure					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake** mg/kg bw/d	**Estimated dermal uptake** mg/kg bw/d	**Estimated oral uptake** mg/kg bw/d	**Estimated total uptake** mg/kg bw/d
Propiconazole					
Scenario [6]	1 / no PPE	--	--	1.44E-03	1.44E-03
IPBC					
Scenario [6]	1 / no PPE	--	--	2.40E-03	2.40E-03

See Annex 3.2 for more information.

Further information and considerations on scenario [5]

Based on the conclusion of WGII2015, the systemic risk characterization was not considered necessary and only risk characterization for local effect should be presented for Bardap 26. Thus in this PAR only a local effect risk assessment of the a.s. Bardap 26 is performed (see Local effects in 2.2.6.3 Risk Characterisation for human health).

Scenario [6]: Toddler playing on playground structure outdoors and mouthing (chronic exposure via dermal route and ingestion)

Description of Scenario [6]			
According to TNsG on Human Exposure to Biocidal Products Part 3, p42 as revised by User Guidance version 1 p50-54 (EC, 2002a).			
	Parameters	**Value**	**Justification / reference**
Tier 1	Propiconazole concentration	0.045%	Applicant's data
	IPBC comcentration	0.075%	Applicant's data
	Application rate	0.2 mg/cm^2	Applicant's data
	Body weight	10 kg	Recommendation no. 14 (2017)
	Dermal exposure		
	Contact surface	230.4 cm^2	Recommendation no. 14 (2017)
	Contaminated area	20%	TNsG
	Dislogeable fraction	2%	TNsG
	Dermal absortion	70%	Guidance on dermal absorption (2017)
	Oral exposure		
	Hand surface area mouthing	50 cm^2	TNsG
	Extraction by chewing	10%	TNsG

Description of Scenario [6]			
	Oral absorption	100%	Default value

Calculations for Scenario [6]

Summary table: systemic exposure from indirect exposure					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake mg/kg bw/d**	**Estimated dermal uptake mg/kg bw/d**	**Estimated oral uptake mg/kg bw/d**	**Estimated total uptake mg/kg bw/d**
Propiconazole					
Scenario [6]	1 / no PPE	--	5.81E-04	4.50E-03	5.08E-03
IPBC					
Scenario [6]	1 / no PPE	--	9.68E-04	7.50E-03	8.47E-03

See Annex 3.2 for more information.

Further information and considerations on scenario [6]

Based on the conclusion of WGII2015, the systemic risk characterization was not considered necessary and only risk characterization for local effect should be presented for Bardap 26. Thus in this PAR only a local effect risk assessment of the a.s. Bardap 26 is performed (see Local effects in 2.2.6.3 Risk Characterisation for human health).

Scenario [7]: Inhalation of volatilised residues indoors (chronic exposure via inhalation)

Professional and general public may be exposed to volatilised residues from treated wood installed indoors. However, based on the document, HEEG opinion 13 on Assessment of Inhalation Exposure of volatilised biocide active substance, it might not be necessary to calculate the exposure to volatilised residues:

- For propiconazole:

  $0.328*(Mw*Vp)/AEL_{long\text{-}term} = 0.157 \leq 1$

  Remark: the mw (molecular weight), vp (vapour pressure) and $AEL_{long\text{-}term}$ come from the Assessment Report on Propiconazole.
- IPBC:

  $0.328*(Mw*Vp)/AEL_{long\text{-}term} = 0.0151 \leq 1$

  Remark: the mw (molecular weight), vp (vapour pressure) and $AEL_{Long\text{-}term}$ come from the Assessment Report on IPBC.
- Bardap 26:

  $0.328*(Mw*Vp)/DNEL_{long\text{-}term} = 3.62E\text{-}04 \leq 1$

  Remark: the mw (molecular weight), vp (vapour pressure) and $DNEL_{Long\text{-}term}$ come from the Assessment Report on Bardap 26 and ECHA database.
- Co-formulant:

  $0.328*(Mw*Vp)/DNEL_{long\text{-}term} = 12.1 > 1$

  Remark: the mw (molecular weight), vp (vapour pressure) and $DNEL_{Long\text{-}term}$ come from the MSDS and ECHA database.

The result of this equation is lower than 1 for active substances. The **exposure to volatilised residues indoor** can be considered **negligible** for general public for these active substances.

The result of this equation is higher than 1 for one co-formulant. The **exposure to volatilised residues** indoor cannot be considered negligible for professionals and general public but this exposure is not calculated according to the assessment of effects on human health conclusions.

Description of Scenario [7]			
Chronic inhalation exposure to volatilised residues indoors has been assessed for adult considering the scenario "assessment of Inhalation Exposure of Volatilised Biocide Active Substance" from the Opinion n°13 of HEEG with calculation of the Saturated Vapour Concentration (SVC) for 24 hours (worst-case) following this formula: SVC = Mw x vp : R x T (mg/m^3) The exposure is calculated with the following formula : Exposure = SVC x inhalation rate / body weight (mg/kg bw/d)			
	Parameters	**Value**	**Justification / reference**
Tier 1	Vapour pressure (Vp): Propiconazole IPBCl Bardap 26 Co-formulant	 5.60E-05 Pa 2.36E-05 Pa 1.80E-06 Pa 40 Pa	Applicant's data ARs ECHA web
	Molecular weight (Mw): Propiconazole IPBCl Bardap 26 Co-formulant	 342.2 g/mol 391.29 g/mol 429.726 g/mol 120.28 g/mol	Applicant's data ARs ECHA web
	Gas constant (R)	8.31451 J*mol^{-1}*K^{-1}	HEEG opinion 13 (2011)
	Temperature (T)	293 K	HEEG opinion 13 (2011)
	Body weight: Adult Child Toddler Infant	 60 kg 23.9 kg 10 kg 8 kg	Recommendation no. 14 (2017)
	Inhalation rate: Adult Child Toddler Infant	 16 m^3/24h 12 m^3/24h 8 m^3/24h 5.4 m^3/24h	Recommendation no. 14 (2017)

Calculations for Scenario [7]
No calculations are needed.

Further information and considerations on scenario [7]
According to the Guidance on the BPR Volume III Human Health- Assessment & Evaluation– Part B and C Risk Assessment (Version 4.0 December 2017), SoCs contained in the product are 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.

Combined scenarios
Not applicable.

Monitoring data

No monitoring studies have been performed with the formulated product as they are not considered necessary.

Dietary exposure

No dietary exposure is foreseeable because the product is not intended to be used on premises where food is kept or located and no residue is foreseen.

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

During the product/formulation and disposal of the biocidal product, human are not exposed to the product residues as the process is automated and the operator is segregated from the product source. Therefore, no risk assessment is needed at this regard. Moreover, all the steps of the manufacturing process at QUIMUNSA manufacturing plant are performed according to the instructions given in the Directive 98/24/EC - risks related to chemical agents at work.

Aggregated exposure

Not applicable as this product is not intended to be used under a different biocidal product type such as PT8.

Summary of exposure assessment

Scenarios and values to be used in risk assessment				
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier / PPE**	**Estimated total uptake Propiconazole** mg/kg bw/d	**Estimated total uptake IPBC** mg/kg bw/d
Primary exposures				
1. Mixing and Loading	Professional (trained professional) users	Tier 1	3.54E-01	5.89E-01
		Tier 2	3.63E-03	6.05E-03
2a. Manual dipping	Professional (trained professional) users	Tier 1	4.33E-01	7.21E-01
		Tier 2	6.86E-03	1.14E-02
2b. Automated dipping	Professional (trained professional) users	Tier 1	2.45	4.08
		Tier 2	3.17E-02	5.28E-02
1, 2b. Combined	Professional (trained	Tier 1	2.80	4.67

Scenarios and values to be used in risk assessment				
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier / PPE**	**Estimated total uptake Propiconazole mg/kg bw/d**	**Estimated total uptake IPBC mg/kg bw/d**
scenarios	professional) users	Tier 2	3.53E-02	5.89E-02
Secondary exposures				
3. Adult amateur sanding/processing of treated wood composites	Professional (trained professional) users	Tier 1	1.86E-04	3.11E-04
		Tier 2	3.14E-05	5.23E-05
2a, 3. Combined scenarios	Professional (trained professional) users	Tier 1	4.33E-01	7.22E-01
		Tier 2	6.89E-03	1.15E-02
1, 2b, 3. Combined scenarios	Professional (trained professional) users	Tier 1	2.80	4.67
		Tier 2	3.53E-02	5.89E-02
4. Adult amateur sanding/processing of treated wood composites	Adult amateur (general public)	Tier 1	1.75E-04	2.91E-04
5. Toddler chewing wood composite chips treated	Toddler (general public)	Tier 1	1.44E-03	2.40E-03
6. Toddler playing on playground structure and mouthing (chronic)	Toddler (general public)	Tier 1	5.08E-03	8.47E-03
7. Inhalation of volatilised residues indoors (chronic)	Adult, Toddler & Child (general public)	Tier 1	--	--

2.1.16.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation

- ***Propiconazole***

Reference	**Study**	**NOAEL (LOAEL)** [mg/kg bw/day]	**AF**	**Value** [mg/kg bw/day]
AELshort-term	Developmental toxicity study in rat	30	100	0.3
AELmedium-term	2-generation rat study	8	100	0.08
AELlong-term	2-year rat study	3.6	100	0.04
ARfD(*)	Developmental toxicity study in rat	30	100	0.3
ADI(*)	2-year rat study	3.6	100	0.04

(*)Not required since no exposure of foodstuffs should occur during and after treatment.

- ***IPBC***

Reference	Study	NOAEL (LOAEL) [mg/kg bw/day]	AF	Value [mg/kg bw/day]
AELshort-term	90 day gavage rat	35	100	0.35
AELmedium-term	-	-	100	-
AELlong-term	2 years oral rat	20	100	0.2
ARfD(*)	-	-	-	-
ADI(*)	-	-	-	-

(*)Not required since no exposure of foodstuffs should occur during and after treatment.

- ***Bardap 26***

Reference	Study	NOAEL (LOAEL) [mg/kg bw/day]	AF	Value [mg/kg bw/day]
AELshort-term	Not relevant	--	--	--
AELmedium-term	Not relevant	--	--	--
AELlong-term	Not relevant	--	--	--
ARfD(*)	Not applicable	--	--	--
ADI(*)	Not applicable	--	--	--

(*)Not required since no exposure of foodstuffs should occur during and after treatment.

According to Bardap26's CAR there is not relevant value to evaluate the systemic effects, instead of that, local effects are considered more suitable to assess the human exposure. Therefore, the dermal NOAEC value of 0.045 mg/cm^2 is equivalent to a dermal NOAEC of 0.3% and an oral NOAEC value of 0.3 mg/mL which is considered equivalent to an oral NOAEC of 0.03% is used for human secondary exposure (infant and children).

Maximum residue limits or equivalent

MRLs or other relevant reference values	Reference	Relevant commodities	Value
MRL (propiconazole)	Reg. (EU) 2017/626 (previous) Reg. (EU) 2021/155 (applicable) [Plant Protection Products]	All commodities	0.01-0.05

Risk for industrial users

No risk is considered for these users.

Risk for professional (trained professional) users

Systemic effects

Task/ Scenario	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Propiconazole					
1. Mixing and Loading	1	0.04	3.54E-01	883.99	**No**
	2	0.04	3.63E-03	9.08	Yes

2a. Manual dipping	1	0.04	4.33E-01	1082.04	**No**
	2	0.04	6.86E-03	17.14	Yes
2b. Automated dipping	1	0.04	2.45	6119.93	**No**
	2	0.04	3.17E-02	79.20	Yes
1, 2b. combined scenarios	1	0.04	2.80	7003.92	**No**
	2	0.04	3.53E-02	88.28	Yes
3. Adult sanding/handling treated wood	1	0.04	1.86E-04	0.47	Yes
	2	0.04	3.14E-05	0.08	Yes
2a, 3. combined scenarios	1	0.04	4.33E-01	1082.50	**No**
	2	0.04	6.89E-03	17.22	Yes
1, 2b, 3. combined scenarios	1	0.04	2.80	7004.39	**No**
	2	0.04	3.53E-02	88.36	Yes
IPBC					
1. Mixing and Loading	1	0.2	5.89E-01	294.66	**No**
	2	0.2	6.05E-03	3.03	Yes
2a. Manual dipping	1	0.2	7.21E-01	360.68	**No**
	2	0.2	1.14E-02	5.71	Yes
2b. Automated dipping	1	0.2	4.08	2039.98	**No**
	2	0.2	5.28E-02	26.40	Yes
1, 2b. combined scenarios	1	0.2	4.67	2334.64	**No**
	2	0.2	5.89E-02	29.43	Yes
3. Adult sanding/handling treated wood	1	0.2	3.11E-04	0.16	Yes
	2	0.2	5.23E-05	0.03	Yes
2a, 3. combined scenarios	1	0.2	7.22E-01	1082.50	**No**
	2	0.2	1.15E-02	5.74	Yes
1, 2b, 3. combined scenarios	1	0.2	4.67	2334.80	**No**
	2	0.2	5.89E-02	29.45	Yes

The estimated systemic exposure of workers is below the reference value during wood preservative tasks when PPE is used. The estimated systemic exposure is acceptable when worker is wearing gloves and coveralls.

Assuming one person is performing some tasks, the combined exposure was estimated. The estimated systemic exposure of worker is below the reference value only when gloves and coveralls are worn.

Due to sensitizing properties (Skin sens. 1), irritant eye properties (Eye dam. 1), irritant skin properties (Skin Irrit. 2) and the presence of Bardap26 in the biocidal product, any dermal exposure to the biocidal product must be prevented using the technical and organizational RMM adequate for very high hazard chemicals and appropriate PPE must be used (see next chapter for details).

Local effects

According to the criteria of the Regulation 1272/2008, BP is proposed to be classified as a skin sensitizer category 1 (H317),a severe eye irritant category 1 (H318) and an irritant to skin category 2 (H315), therefore, a qualitative assessment of local effects is performed in this section. Furthermore, the local effects assessment is necessary for the active substance Bardap 26.

Professional (trained professional) use – Primary/secondary exposure

Hazard						Exposure				Risk
Hazard Category	**Effects in terms of C&L**	**Additional relevant hazard information**	**PT**	**Who is exposed?**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant RMM&PPE**	**Conclusion on risk**
Very High	Skin sens. 1 (H317) Eye dam. 1, (H318) Skin Irrit. 2 (H315)		8	Professional (trained professional) users	Mixing and loading, dipping application, spraying application and handling treated wood	Skin Eyes RT	daily	100% b.p. and 1.5% b.p.	**all measures to eliminate exposure as much as possible, such as:** **Technics** - Very high level of containment required, except for short term exposures e.g. taking samples; - Design closed system to allow for easy maintenance; - If possible keep equipment under negative pressure; - Regular cleaning of equipment and work area; **Organisation** - Control staff entry to work area; - Ensure all equipment well maintained; - Permit to work for maintenance work; - Management/supervision in place to check that the RMMs in place are being used correctly and OCs followed; - Training for staff on good practice; - Procedures and training for emergency decontamination and disposal; - Good standard of personal hygiene - Recording of any 'near miss' situations. Sensitisers - Pre-employment screening and appropriate health surveillance	Acceptable: + Minimisation of manual phases. + Low frequency + Used for short duration + Low amount used per event; + Professionals using PPE; + Professionals following instructions for use; + Good standard of personal hygiene.

									Personal protective equipment - All skin and mucous membranes with potential exposure protected with appropriate PPE - Chemical googles	

The biocidal product has been allocated to the "Very High" hazard category according to the classification as a strong skin sensitizer (Skin sens 1 - H317) and a severe eye irritant (Eye dam. 1 – H318) following the hazard categories proposed in the Guidance for Human Health Risk Assessment & evaluation (Volume III – Part B + C).

Use of the product in the proposed manner is acceptable and is expected to occur at professional sites. The PPE, which have to be used for protection from the sensitize potential of the preserved product, are described as follows.

Exposure controls
Personal protective equipment

- Substance/task appropriate gloves.
- Skin coverage with appropriate barrier material based on potential for contact with chemicals.
- Eye protection.

Respiratory protection is not considered necessary when loading in adequately ventilated areas due to the low vapour pressure of the active substances. Further, airborne particles are not expected to be formed during operations.

Organisation:

- General safety and hygiene measures:

Avoid contact with the skin, eyes and clothing. Wearing of closed work clothing is recommended. When using, do not eat, drink or smoke. Hands and/or face should be washed before breaks and at the end of the shift. At the end of the shift the skin should be cleaned and skin-care agents applied. Gloves must be inspected regularly and prior to each use. Replace if necessary (e.g., pinhole leaks).

Conclusion

The estimated systemic exposure of workers to acive substances Propiconazole, IPBC and Bardap 26 is below the reference value during preserved tasks when RMM for high hazard class chemicals are implemented and worker is wearing gloves, coverall and face mask in order to prevent any contact with the biocidal product.
Finally, considering recent EU discussion about BP dossiers and treated articles, the following RMM for industrial uses should be included in the label: "the person responsible for placing the treated wood on the market must ensure that the treated wood is not intended for uses involving contact with food, feed or livestock".

Risk for non-professional users

No risk is considered for these users.

Risk for the general public

Systemic effects

Task/ Scenario	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Propiconazole					
4. Adult amateur sanding/processing of	1	0.3	1.75E-04	0.06	Yes

treated wood (acute)					
5. Toddler chewing wood composite chips treated (acute)	1	0.3	1.44E-03	0.48	Yes
6. Toddler playing on playground structure and mouthing (chronic)	1	0.04	5.08E-03	12.70	Yes
IPBC					
4. Adult amateur sanding/processing of treated wood (acute)	1	0.35	2.91E-04	0.08	Yes
5. Toddler chewing wood composite chips treated (acute)	1	0.35	2.40E-03	0.69	Yes
6. Toddler playing on playground structure and mouthing (chronic)	1	0.2	8.47E-03	4.23	Yes

Local effects
Indirect dermal exposure to biocidal product is possible through contact with dried treated articles. Therefore, the RMM is proposed:

- "Do not use on wood which may come in direct contact with food, feedingstuff and livestock animals"

Conclusion
Based on the results obtained in the risk assessment, the exposure of bystanders results in levels of exposure lower than the relevant reference values.

Risk for consumers via residues in food

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

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

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

Cumulative risk assessment is performed according to Guidance on the BPR: Volume III, Assessment & Evaluation (Parts B+C), Version 2.1 – February 2017, (pp 261 & Appendix 4.7, pp 293).

Preliminary step:

The evaluation of propiconazole did indicate that propiconazole is moderately toxic via oral administration, the liver being its target organ, and that it is a moderate skin sensitiser. In addition, propiconazole is repr. 1B according to CLP (H360D). Propiconazole interfers the steroid hormone synthesis but there is not enough data to conclude whether it has endocrine disrupting properties or not. In addition, the RAC opinion specify for propiconazole that "a variety of studies on potentially endocrine disrupting effects have been published in the open scientific literature: impairments in serum testosterone levels, testes and foetus weight, anogenital distance, oestrus cyclicity and sperm quality,

suggesting endocrine mediated effects. However, RAC also notes that such observations did not alter fertility in the 2-generation Guideline study,that the reported effects are reversible in some cases and finally, effects reported in individual studies were not further confirmed in others with similar approaches. Thus, RAC does not consider the effects reported in these studies to be consistent enough to warrant classification".. Nevertheless, a number of scientific publications mention potential endocrine disruption activity of propiconazole. These effects will be assessed more in detail at the renewal stage of this active substance approval in the frame of the EU Regulation No 528/2012 and according to the criteria mentioned in the Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009. In case this active substance was identified as ED, the conditions for the product authorisation will have to be revised.
IPBC is of moderate acute toxicity by the oral route and of low toxicity by the dermal route. IPBC is classified toxic by inhalation. The substance is not irritating to skin but is a severe eye irritant and a skin sensitizer. In the short term studies the liver and kidney were the main target organs. Repeated exposure by inhalation of solid IPBC resulted in histopathological findings (hyperplasia or squamous metaplasia and necrosis of the underlying cartilage) in the central region of the larynx and was regarded as a local and not systemic effect. IPBC was neither carcinogenic, neurotoxic or genotoxic. IPBC is not toxic to reproduction or a developmental toxicant.
The main critical effects associated with didecylmethylpoly(oxyethyl)ammonium propionate (Bardap 26) are due to its corrosive prosperities. The active substance induces severe erythema, desquamation and corrosive eschar in the rabbit skin, and therefore it is classified as corrosive to skin. No systemic effects in the absence of local effects were observed in any of the studies. Therefore, only a local risk assessment was considered necessary for the use of didecylmethylpoly(oxyethyl)ammonium propionate.

Given their mode of action we can assume that there is no indication of synergy within substances.

A summary of systemic exposures for the scenarios assessed are shown in section 2.2.6.2.

TIER 1 and TIER 2:

Tier 1 is an intermediary step to verify risk acceptability for each active ingredient used in the product, as currently performed. It is followed by Tier 2, which involves assessing the combined exposure to the substances of the mixture/biocidal product.

For the toxicological section, primary exposure of professionals (trained professionals) has been considered and exposure estimations were compared to the chronic AEL for Propiconazole and IPBC. Secondary exposure of professionals (trained professionals) has been considered and exposure estimations were compared to the long term AEL for Propiconazole and IPBC. Secondary exposure for adults/toddlers was performed according to a long/short term scenarios using chronic/acute AEL.

Results of Tier 1 / 2 assessments are shown in the following table.

Primary exposure: Professional (Trained professional), chronic exposure

M&L without PPE	**Propiconazole**	**IPBC**	**conclusion**
Tier 1	884 %AEL	295 %AEL	Not Acceptable
Tier 2	8.84	2.95	Not acceptable
	HI = 11.79		
M&L with PPE	**Propiconazole**	**IPBC**	**conclusion**

Tier 1	9.08 %AEL	3.03 %AEL	acceptable
Tier 2	0.0908	0.0303	acceptable
	HI = 0.1211		
Manual Dipping without PPE	**Propiconazole**	**IPBC**	**conclusion**
Tier 1	1082 %AEL	361 %AEL	Not acceptable
Tier 2	10.82	3.61	Not acceptable
	HI = 14.43		
Manual Dipping with PPE	**Propiconazole**	**IPBC**	**conclusion**
Tier 1	71 %AEL	24 %AEL	Acceptable
Tier 2	0.71	0.24	acceptable
	HI = 0.95		
Automated dipping without PPE	**Propiconazole**	**IPBC**	**conclusion**
Tier 1	6120 %AEL	2040 %AEL	Not acceptable
Tier 2	61.20	20.40	Not acceptable
	HI = 81.60		
Automated dipping with PPE	**Propiconazole**	**IPBC**	**conclusion**
Tier 1	79.20 %AEL	26.40 %AEL	Acceptable
Tier 2	0.792	0.264	Not acceptable
	HI = 1.056		
M&L + AD without PPE	**Propiconazole**	**IPBC**	**conclusion**
Tier 1	7004 %AEL	2335 %AEL	Not acceptable
Tier 2	70.04	23.35	Not acceptable
	HI = 93.39		
M&L + AD with PPE	**Propiconazole**	**IPBC**	**conclusion**
Tier 1	88 %AEL	29 %AEL	Not Acceptable
Tier 2	0.88	0.29	Not acceptable
	HI = 1.17		

Secondary exposure: Professional (Trained professional), chronic exposure

Sanding/Handling without PPE	**Propiconazole**	**IPBC**	**conclusion**
Tier 1	0.47 %AEL	0.16 %AEL	acceptable
Tier 2	0.0047	0.0016	acceptable
	HI = 0.0063		
Sanding/Handling with PPE	**Propiconazole**	**IPBC**	**conclusion**
Tier 1	0.08 %AEL	0.03 %AEL	acceptable
Tier 2	0.0008	0.0003	acceptable
	HI = 0.0011		
MD + S/H without PPE	**Propiconazole**	**IPBC**	**conclusion**
Tier 1	1083 %AEL	361 %AEL	Not acceptable
Tier 2	10.83	3.61	Not acceptable
	HI = 14.44		
MD + S/H with PPE	**Propiconazole**	**IPBC**	**conclusion**
Tier 1	71 %AEL	24%AEL	acceptable
Tier 2	0.71	0.24	acceptable
	HI = 0.95		

M&L + AD + S/H without PPE	Propiconazole	IPBC	conclusion
Tier 1	7004 %AEL	2335 %AEL	Not acceptable
Tier 2	70.04	23.35	Not acceptable
	HI = 93.39		
M&L + AD + S/H with PPE	**Propiconazole**	**IPBC**	**conclusion**
Tier 1	88 %AEL	29 %AEL	acceptable
Tier 2	0.88	0.29	Not acceptable
	HI = 1.17		

Indirect exposure: adult, acute exposure

	Propiconazole	IPBC	conclusion
Tier 1	0.06 %AEL	0.08 %AEL	acceptable
Tier 2	0.0006	0.0008	acceptable
	HI = 0.0014		

Indirect exposure: toddler, acute exposure

	Propiconazole	IPBC	conclusion
Tier 1	0.48 %AEL	0.69 %AEL	acceptable
Tier 2	0.0048	0.0069	acceptable
	HI = 0.0117		

Indirect exposure: toddler, chronic exposure

	Propiconazole	IPBC	conclusion
Tier 1	12.7 %AEL	4.23 %AEL	acceptable
Tier 2	0.127	0.0423	acceptable
	HI = 0.1693		

Conclusion:

For professional (trained professional) use:

TIER I: Risk assessment is not acceptable for each substance individually in the product without PPE but is acceptable with gloves and coverall for all tasks and combined tasks studied.

TIER 2: Mixture Risk assessment is not acceptable in T2 without PPE but is acceptable with gloves and coverall with the exception of the automatic dipping application and its combined tasks. Therefore, a tier 3 should be performed for these scenarios.

For the indirect exposure:

TIER I: Risk assessment is acceptable for each substance individually in the product.

TIER 2: Mixture risk assessment is acceptable in T2.

TIER 3: this tier is performed according:

1. A summary of the critical AELs and NOAELS for each substance is detailed in the following table:

Target organ / mode of action	**NOAELs Propiconazole (AEL)**	**NOAELs IPBC (AEL)**
	Chronic AEL: 0.04 mg/kg bw/d (2-year dietary rats) **Acute AEL: 0.3 mg/kg**	**Chronic AEL: 0.2 mg/kg bw/d (2-year dietary rats)** **Acute AEL: 0.35 mg/kg**

	bw/d (developmental rat)	**bw/d (90 day gavage rat)**
Liver (chronic)	4 mg/kg bw/d (0.04 mg/kg bw/d)	20 mg/kg bw/d (0.2 mg/kg bw/d)
Thyroid (chronic)	NA	NA
Kidney (chronic)	NA	20 mg/kg bw/d (0.2 mg/kg bw/d)
Eye (cataract) (chronic)	NA	NA
Fertility (chronic)	8 mg/kg bw/d (0.08 mg/kg bw/d)	30 mg/kg bw/d (0.3 mg/kg bw/d)
Malformation (acute)	30 mg/kg bw/d (0.3 mg/kg bw/d)	40 mg/kg bw/d (0.4 mg/kg bw/d)
Neurotoxicity (acute)	NA	120 mg/kg bw/d (1.20 mg/kg bw/d)

2. Grouping substances by target organs (without refining AEL) as first step (tier 3a):

Automated dipping application chronic	**HQ Propiconazole**	**HQ IPBC**	**HI**
Liver (chronic)	0.792	0.264	1.056
Thyroid (chronic)	--	--	--
Kidney (chronic)	--	0.264	0.264
Eye (cataract) (chronic)	--	--	--
Fertility (chronic)	0.792	0.264	1.056

M&L + AD combined scenarios chronic	**HQ Propiconazole**	**HQ IPBC**	**HI**
Liver (chronic)	0.88	0.29	1.17
Thyroid (chronic)	--	--	--
Kidney (chronic)	--	0.29	0.29
Eye (cataract) (chronic)	--	--	--
Fertility (chronic)	0.88	0.29	1.17

M&L + AD + S/H combined scenarios chronic	**HQ Propiconazole**	**HQ IPBC**	**HI**
Liver (chronic)	0.88	0.29	1.17
Thyroid (chronic)	--	--	--
Kidney (chronic)	--	0.29	0.29
Eye (cataract) (chronic)	--	--	--
Fertility (chronic)	0.88	0.29	1.17

According to this table de Tier 3a is not acceptable for fertility toxicity.

3. If risk assessment is not acceptable for a group, by refining AEL for the target organ/mode of action specific of the group (Tier 3b):

	Propiconazole	**IPBC**
Liver (chronic)	4 mg/kg bw/d (0.04 mg/kg	20 mg/kg bw/d (0.2 mg/kg

	bw/d)	bw/d)

Automated dipping application chronic	**HQ Propiconazole**	**HQ IPBC**	**HI**
Liver (chronic)	0.792	0.0132	0.8052

M&L + AD combined scenarios chronic	**HQ Propiconazole**	**HQ IPBC**	**HI**
Liver (chronic)	0.88	0.0145	0.8945

M&L + AD + S/H combined scenarios chronic	**HQ Propiconazole**	**HQ IPBC**	**HI**
Liver (chronic)	0.88	0.0145	0.8945

	Propiconazole	**IPBC**
Fertility (chronic)	8 mg/kg bw/d (0.08 mg/kg bw/d)	30 mg/kg bw/d (0.3 mg/kg bw/d)

Automated dipping application chronic	**HQ Propiconazole**	**HQ IPBC**	**HI**
Fertility (chronic)	0.099	0.0088	0.1078

M&L + AD combined scenarios chronic	**HQ Propiconazole**	**HQ IPBC**	**HI**
Fertility (chronic)	0.11	0.0097	0.1197

M&L + AD + S/H combined scenarios chronic	**HQ Propiconazole**	**HQ IPBC**	**HI**
Fertility (chronic)	0.11	0.0097	0.1197

After organ AEL refinement, risk assessment (HI) is acceptable for automated dipping application and the combined tasks associated.

2.1.17 Risk assessment for animal health

The contact of treated wood (pallets, boxes) with animals is unlikely The product CORPOL MADERA VERDE is intended to be used indoors in industrial sites without animal presence, hence, no animal exposure is foreseeable.

In addition, to prevent any exposure of animals the following RMMs are included:

- Do not use on wood which may come in direct contact with food, feedingstuff and livestock animals
- Keep children and pets away from treated surfaces until they have dried.
- Avoid prolonged contact of pets to treated surfaces.

2.1.18 Risk assessment for the environment

ES CA:
The risk assessment for the environment is reported as submitted by the Applicant. The ES CA assessment is presented in separate boxes on a green background.

ESD for PT-8 with its calculation sheets has been followed to evaluate the potential risk of the product in the environment. The product is intended to be applied at sawmills in preventive wood preservation treatments by automated dipping (and "green chain") and automated spraying processes. Two life cycle stages have been considered for environmental risk assessment:

1. Product application where dipping application is considered as industrial preventive process and storage of treated wood.

2. Treated wood in service (service life) where the risk of leaching product to the environment is taken into account. This risk depends on the use class of the treated wood. Following label instructions, the treated wood should be kept under cover and fully protected from the weather (use classes 1 and 2). On the other hand, in those cases where the treated wood will be not covered and not in contact with the ground (Use class 3), a cover resin must be applied just after treatment with CORPOL MADERA VERDE. This last scenario involves the possibility to release product residues to the environment and in function of the contaminated compartment, three sub-scenarios are considered by the ESD PT-8:

   a) Wooden house (for soil)
   b) Bridge over Pond (for surfacewater)
   c) Noise barrier (for STP and soil)

All of these scenarios cover the use classes (since 1 to 3) of the treated wood after the product application. According to these scenarios, the environmental compartment to which the product may be released during the application or during the service life into the wood is provided in the following table:

Identification of relevant receiving compartments based on the exposure pathway											
Scenarios			**Fresh-water**	**Freshwater sediment**	**Sea-water**	**Seawater sediment**	**STP**	**Air**	**Soil**	**Ground-water**	**Other: Secondary poisoning**
Application*	Dipping		2º	2º	n.r	n.r.	1º**	1º	2º	2º	n.r.
	Spraying		2º	2º	n.r	n.r.	1º**	1º	2º	2º	n.r.
Life cycle stage	Use Classes (UC) 1 & 2		n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.
	UC 3	House	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	1º	2º	n.r.
		Bridge	1º	2º	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.

Identification of relevant receiving compartments based on the exposure pathway											
Scenarios			Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other: Secondary poisoning
		over pond									
		Noise barrier	2º	2º	n.r.	n.r.	1º		1º or 2º	2º	n.r.

n.r. = Not relevant

* no storage process in regarded in the scenario of application due to label's requirements of the product.

** Worse case situation as residue after application and storage must be disposed as hazardous waste.

ES CA:

The risk assessment provided by the applicant for the product CORPOL MADERA VERDE was not considered acceptable by ES-CA. The environmental exposure assessment of the product CORPOL MADERA VERDE containing Propiconazole, IPBC and Bardap 26 and formulated as a wood preservative, was assessed in accordance with the Guidance on the Biocidal Products Regulation (Volume IV Environment, version 2.0, October 2017) and the technical agreements for biocides (ENV TAB Entry 199, July 2021).. This assessment was likewise performed following the recommendations of the Revised Emission Scenario Document for Wood Preservatives (OECD, 2013)

The product "CORPOL MADERA VERDE" is a fungicide, which is intended to be applied at sawmills in preventive wood preservation treatments by automated dipping (and "green chain") and automated spraying processes.

According to OECD (2013), industrial emissions are considered to occur during the treatment process including post-treatment conditioning as well as during storage of treated wood prior to shipment. No quantitative exposure assessment has been carried out for the life cycle stages "production" and "formulation of the biocidal product" as environmental exposure due to manufacturing of the active substance is covered by other legislation and will therefore not be considered here.

Industrial local floors are cemented, so run-off is generally collected and recycled via drip pads. Release of the collected waste water to a sewage treatment plant (STP) is nowadays not permitted anymore in EU member state countries, and the corresponding emission pathway (facility drain to surface water via STP) has not been considered, providing specific risk mitigation measures instead to minimize the environmental concern at this stage.

CORPOL MADERA VERDE is intended to be used in wood treated as a temporary antisaptain, so an assessment for the emission during service life needs to be performed according to the TAB-ENV 109 entry. The assessment of temporary anti-sapstain wood-preservatives was first discussed at ENV WG-I-2018. It was agreed to substitute the tiered assessment approach for temporary anti-sapstain preservatives from the 2nd EU Leaching Workshop in Varese (2013) by the approach described in the TAB-ENV 199: PT 8 - Assessment of temporary anti-sapstain wood-preservatives.

According with the active substances' CARs, the following predicted no effect concentration values (PNECs) have been estimated for each environmental compartment and for each active substance:

PNEC values obtained from the CAR of each active substance				
Compartment	***Units***	**Active substance**		
		Propiconazole	**IPBC**	**Bardap26**
PNEC for micro-organisms in a STP (PNECstp)	*[mg.l^{-1}]*	1	0.44	0.168
PNEC for surface water (PNECsw)	*[mg.l^{-1}]*	1.60E-03	0.0005	0.01
PNEC for fresh-water sediment organisms (PNECsed)	*[mg.l^{-1}]*	0.054	3.93E-03*	1.415E-3**
PNEC for terrestrial organisms (PNECsoil)	*[mg.kgwwt^{-1}]*	0.02	0.005	4.23x10^{-4}***
PNEC for secondary poisoning of birds and mammals	*[mg.kg^{-1}]*	0.0747**	1.33**	0.54 for birds 16.7 for mammals

* Value obtained from EUSES program. According to IPBC's CAR, the risk to the sediment is the same as that described for surface water. Therefore the risk of the sediment should not be considered further.

** Values obtained from EUSES program.

*** This data obtained from EUSES program should be carefully taken in account, according to Bardap26's CAR, due to the lack of initial terrestrial effects data a reliable PNEC for the soil compartment cannot be derived.

Aquatic compartment

$PNEC_{stp}$, $PNEC_{surfacewater}$ and $PNEC_{sediment}$ values obtained from each active substance's CAR have been summarized in the table above.

Atmosphere

According to the TGD on Risk Assessment (ECB Part II, 2003), there is currently no appropriate guidance to calculate a PNECair. The physical-chemical properties of Propiconazole and Bardap26 in the environment, such as vapour pressure (<0.1 mPa) and molecular weight (between 281.1 and 429.726 g/mol), indicate that none of the them will readily volatilise into the atmosphere at ambient temperature and pressure. On the other hand, IPBC may be regarded as slightly volatile, but as it is mentioned on the respective active substance's CAR, Residues in air were not necessary because IPBC is not volatile and spray applications only involve non-respirable particles. In view of that, the atmospheric half-life is estimated to be between 8 and 42 hrs. Therefore, it is not expected that any active substances will be present in air for extended periods and the long range transport and re-deposition of any of them is expected to be negligible. Thus, in conclusion, due to the rapid degradation of CORPOL MADERA VERDE's active substances in the atmosphere, no risk is expected from its use either on the atmosphere, birds or non-target insects. In addition, it is important to bear in mind that the product is intended to be used only in indoor premises, so the presence of volatile residue in the outdoor environment is really unlikely, despite the treated wood can be placed outside (always dry).

Terrestrial compartment

PNECsoil values obtained from each active substance's CAR have been summarized in the table above.

Non compartment specific effects relevant to the food chain (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 concentration in 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.

In order to avoid unnecessary vertebrate testing, we consider that the data submitted in support of the approval of the active substance present in the formulation is sufficient to address this endpoint as it can be considered to represent the worst case.

ES CA:

The product "CORPOL MADERA VERDE" is a fungicide, which is intended to be used as wood protector product by temporary treatment of fresh lumber against blues and molds for use by trained professional users. The application method is both automated spraying and dipping application.

No additional studies on fate and/or effects of the active substances or the products were provided for the product authorisation. Therefore, the product has been assessed according to the information provided in the CARs for the three active substances. For propiconazole (and 1,2,4-triazole), updated PNEC values are available in the CAR for PT7 and PT9. These will be used, as they represent the newest data. For IPBC, PNEC-values from PT8 has been used (these are confirmed in CARs for other PTs).
For the case of for Bardap26 (didecylmethylpoly(oxyethyl)ammonium propionate), for sediment-dwelling and soil organisms no data are available, but only for DDAC. Since didecylmethylpoly(oxyethyl)ammonium propionate is not biodegradable, the read across to sediment and soil data (typically from static tests) available for DDAC was not accepted. Likewise, as Bardap26 is a surfactant, the Equilibrium Partioning Method cannot be used either to calculated a Predicted No Effect Concentration (PNEC) values. Therefore, a PNEC for the sediment and soil compartment could not be derived.

PNEC values obtained from the CAR of each active substance

Compartment	***Units***	**Active substance**		
		Propiconazole	**IPBC**	**Bardap26**
PNEC for micro-organisms in a STP (PNECstp)	*[mg.l^{-1}]*	100	0.44	0.168
PNEC for surface water (PNECsw)	*[mg.l^{-1}]*	6.80E-03	0.0005	0.001
PNEC for fresh-water sediment organisms (PNECsed)	*[mg.l^{-1}]*	0.054	3.93E-03*	Not derived

PNEC for terrestrial organisms (PNECsoil)	*[mg.kgwwt^{-1}]*	0.1	0.005	Not derived
PNEC for secondary poisoning of birds and mammals	*[mg.kg^{-1}]*	0.0747**	1.33**	0.54 for birds 16.7 for mammals

* Value obtained from EUSES program. According to IPBC's CAR, the risk to the sediment is the same as that described for surface water. Therefore the risk of the sediment should not be considered further.
** Values obtained from EUSES program.

In the CAR for propiconazole in PT 7 and 9, two relevant metabolites are determined in the soil. One metabolite is considered to degrade faster than the parent compound, but for the other metabolite, 1,2,4-triazole, it is necessary to conduct an environmental risk assessment.

Two metabolites from IPBC are considered in the environmental risk assessment, i.e. PBC and iodine. For iodine, the background level has to be taken into consideration as the substance is not xenophobic, but is present in the environment as an essential trace element. These values are found in the CAR for iodine.

PNEC-values for relevant metabolites			
Compartment	**1,2,4-triazole**	**PBC**	**Iodine/iodate/iodide**
Surface water (ug/L)	Not relevant*	41.3	0.59 / 58.5 / 0.83
Soil (mg/kg wwt)	0.01	0.169	0.0118 / 0.304 / 0.0043
STP (mg/L)	Not relevant*	IPBC in considered worst case	2.9
Sediment (mg/kg wwt)	Not relevant*	Covered by surface water	Covered by surface water

*1,2,4-triazole is a soil metabolite, and it is thus not relevant to consider risk to any other compartment.

Background levels of iodine	
Compartment	Background level (as iodine)
Soil	Typically 0.5 - 20 mg/kg dw but with extremes up to 98 mg/kg Global mean value of 5 mg/kg
Groundwater	Mean concentration: 1 µg/l Range: < 1-70 µg/l with extremes up to 400 µg/l
Freshwater	0.5 - 20 µg/l

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

No studies have been performed with the formulated product and the classification presented in this report relies on the ecotoxicity data available for the coformulants.

ES CA:

CORPOL MADERA VERDE contains three active substances which are classified for their environmental effects as follows:

- Propiconazole (3%), classified as Aquatic Acute 1 M=1, Aquatic Chronic 1 M=1 according to the entry in Annex VI of Regulation (EC) No. 1272/2008.

- IPBC (5%), classified as Aquatic Acute 1 M=10, Aquatic Chronic 1 M=1 according to the entry in Annex VI of Regulation (EC) No. 1272/2008.
- Bardap 26 (3%), classified as Aquatic Chronic 1 M=10 according to the BPC opinion find on the ECHA website.

With the different a.s. concentrations and the classification of co-formulants, the biocidal product is classified according to CLP regulation as Aquatic Acute 1, Aquatic Chronic 1 (H410).

CORPOL MADERA VERDE has several other co-formulants in the formulation. ES CA analised the information available on the co-formulants (i.e. Safety Data Sheets, C&L Inventory, REACH Registration dossiers, REACH Evaluation Reports and CARs of approved biocidal active substances). Some of the co-formulants are not classified for environmental hazards and therefore do not contribute to the classification or possible risks of the mixture. But some co-formulants carry environmental hazard classification. However they are below the concentration limits specified in Regulation (EC) No. 1272/2008 leading the product to be regarded as hazardous. Therefore it doesn`t contribute to the classification of the biocidal product for environmental hazards.

Only one of the coformulants is suspected of being SoC due to the environmental classification and the amount in which it is found in the product. Please see the confidential annex for further details.

Further Ecotoxicological studies

No further data is available on the product. Please refer to the data on the respective active substances' CARs.

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

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

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

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

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

No data is available and is not required as the biocidal product is not in the form of bait or granules.

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

Not applicable.

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 CORPOL MADERA VERDE. The product was not tested for potential endocrine disruption properties. CORPOL MADERA VERDE contains the active substances propiconazole, IPBC, Bardap26 and various co-formulants (see confidential annex).

For the active substancess, no ED assessment is required because for active substances that 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 any co-formulate triggered an alert for ED property.

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

The product is intended to be used indoors as preventive treatment. Either wood or wood-based product treated with this product are always under cover, fully protected from the weather and not exposed to wetting or also where occasional but not persistent wetting may occur. Therefore, according to ISO 21887 and the "*OECD Series on emission scenario documents*" (2013), the product is classified as Use Class 1 and 2 and according to the same references, the potential emissions to the outer environment from treated wood derived from the use of this UC1+2 product are considered negligible. Hence, environmental risk assessment is considered unnecessary in the present report because no concern is derived from the correct use of this product for the environment.

ES CA:

The environmental exposure assessments of the active substances were determined with the Emission Scenario Document (ESD) developed for Product Type 08 (wood preservatives) by OECD: OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 2, Emission Scenario Document for Wood Preservatives. The emission scenarios estimate the emission of wood preservatives from two stages of their life cycle:

-Application and storage of treated wood prior to shipment;

-Treated wood in service.

The application at industrial sites and storage of treated wood scenarios have not been assessed and emissions were not calculated because these stages are subjected to specific regulation within the EU. Therefore, product application and **freshly treated timber must be stored on impermeable hard standing to prevent direct losses to soil or water and any losses must be collected for reuse or disposal.**

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

No data is available. Please refer to the data on the active substances.

Leaching behaviour (ADS)

No data is available. Please refer to the data on the active substances.

Testing for distribution and dissipation in soil (ADS)

No data is available. Please refer to the data on the active substances.

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

No data is available. Please refer to the data on the active substances.

Testing for distribution and dissipation in air (ADS)

No data is available. Please refer to the data on the active substances.

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)

No data is required as the biocidal product is not intended to be applied 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)

No data is required as the biocidal product is not intended to be used outside.

2.1.18.1 Exposure assessment

CORPOL MADERA VERDE, is a PT-8 intended to be used indoors in sawmills. The biocidal product is used for preventive protection of wood and constructional timbers. The product is intended to be applied only by professional users who apply it by automated dipping, "green chain" or automated spraying methodologies at industrial sites where the wood is treated and then stored under cover. Under these conditions, the wood dries off naturally

by losing its humidity and no leaching of any substance of concern occurs to the environment. The aim of this wood protection treatment is to prevent mould and blue mould's attack. Two life cycle stages have been considered for environmental risk assessment: Product application and treated wood in service (service life).

1. *Product application* is considered as industrial preventive process and storage of treated wood. At this first stage, the product is diluted in water between 2.5% and 1.5%. Then the diluted product may be applied by:

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

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

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

Use Classes (UC) 1 and 2 are the main UCs intended to be covered by CORPOL MADERA VERDE. This involves the use of the product on wood to be used indoors out of weather conditions. On the other hand, the product can also be applied for UC 3 as long as a cover resin is used after product's application. The layer of resin will help to remain the product in the treated wood and avoid its release to the environment by leaching process at adverse weather conditions.

2. *Treated wood in service (service life)*. Once the treatment has finished, the treated wood may be destined to be used as different uses. According to ESD PT-8 there are 5 types of "Use classes". The treated wood by CORPOL MADERA VERDE may be intended to be used for the following use classes:

- Indoor (Use classes 1 and 2 under Norm UNE-EN 335).
- Outdoor when the treated wood does not take contact with the floor or water and is not protected nor covered from the outdoor-environment (e.g.; wooden house, bridge over the pond,…(Use class 3.1 under Norm UNE-EN 335). This intended use requires using a coat of a resin product which must be applied after the product application. The use of the resin avoids the drift of the product by leaching and keeps the product further time in the treated wood. Depending on the used resin the retention time in wood varies. Hence, this scenario involves a combined exposure which is not developed in the current dossier because it always depends on the used resin to cover the product. This is an exceptional case of use which requires the use of an additional product and it must be mentioned on the product's label..
- Outdoor when the treated wood does not take contact with the floor or water and unprotected from the outdoor-environment, whenever that drained water will be collected and leaded to a STP (e.g.; noise barrier. Use class 3.2 under Norm UNE-EN 335). As in the case before, this use requires to use a coated resin which must

be applied after product application so the remains' time of product in the treated wood will be always depended on the used resin (This information must be mentioned in label's product).

All of these scenarios cover the use classes (since 1 to 3) of the treated wood after the product application.

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

ES CA:
Please note that the product CORPOL MADERA VERDE is intended to be used as a temporary anti-saptain and the treated wood is going to be storage after the treatment, so releases from the subsequent used have to be assessed with the "assessment of temporary anti-saptain wood preservatives" scenario (ENV-TAB 199). According to this scenario, if unacceptable risks for the environment are assessed in one or more UC 3 scenarios and no use on wood intended for pallets is requested by the applicant, the product can only be authorized as a temporary anti-sapstain wood preservative for wood, which is intended to be used in UC 1+2.

As no reliable risk assessment could be performed for soil and sediment organisms due to the lack of ecotoxicological data for the substance BARDAP 26, it is not possible to calculate the risk as UC 3 for the subsequent use of the wood treated with CORPOL MADERA VERDE, so no environmental risk assessment has been carried out for the service life stage of the biocidal product. In order to reduce the environmental release and because the use classes are not relevant, the following mention has been added to the instructions for use:

• CORPOL MADERA VERDE is ONLY to be used for wood in situation in which the wood or wood based product is inside a contruction, not expose to the weather and wetting or where occasional, but not persistent, wetting can occur.

General information

Assessed PT	PT 8 – Wood preservative
Assessed scenarios	[1] Stage - Product application and storage before shipping Scenario [1.1]: Automated dipping treatment Sub-scenario [1.1.1]: Application Sub-scenario [1.1.2]: Storage before shipping Scenario [1.2]: Automated spraying Sub-scenario [1.2.1]: Application Sub-scenario [1.2.2]: Storage before shipping [2] Stage – Service life Scenario [2.1]: Use classes 1 and 2 where the treated wood is placed under cover and fully protected from the weather.* Scenario [2.2]: Use class 3 (Situation in which the wood or wood-based product is not covered and not in contact with the ground. It is either

	continually exposed to the weather or is protected from the weather but subject to frequent wetting (e.g. bridge over pond). Three example of scenarios can be assessed for this type of use class: - Wooden house or fence (Use class 3.1) - Bridge over pond (Use class 3.1) - Noise barrier (Use class 3.2)
ESD(s) used	*Emission Scenario Documents for Product Type 8*
Approach	***Scenario 1.1.1:*** Automated dipping treatment*. (this scenario also involves "green chain" application which is regarded as a type of dipping application (ENV/JM/MONO(2013)21)).* *Depending on risk conditions, the product is diluted at 1.5% or 2.5% before the application. Hence, the active substance concentrations are:* o *Propiconazole: 3% in product formulation, 7.5x10^{-4}% in use-application (at worse case considering 2.5% dilution).* o *IPBC: 5% 5% in product formulation, 1.25x10^{-3}% in use-application (at worse case considering 2.5% dilution).* o *Bardap26: 3% in product formulation, 7.5x10^{-4}% in use-application (at worse case considering 2.5% dilution).* ***Scenario 1.1.2:*** Storage treated wood after Automated dipping treatment. ***Scenario 1.2.1:*** Automated spraying*.* *Depending on risk conditions, the product is diluted at 1.5% or 2.5% before the application. Hence, the active substance concentrations are:* o *Propiconazole: 3% in product formulation, 7.5x10^{-4}% in use-application (at worse case considering 2.5% dilution).* o *IPBC: 5% 5% in product formulation, 1.25x10^{-3}% in use-application (at worse case considering 2.5% dilution).* o *Bardap26: 3% in product formulation, 7.5x10^{-4}% in use-application (at worse case considering 2.5% dilution).* ***Scenario 1.2.2:*** Storage treated wood after Automated dipping treatment. ***Scenario 2.1***: Service life for Use Class 3 in a wooden house ***Scenario 2.2***: Service life for Use Class 3 in a noise barrier. ***Scenario 2.3***: Service life for Use Class 3 in a bridge over pond
Distribution in the environment	Calculations based on ECHA's excel sheets have been used to estimate the environmental emissions. Outputs of these estimations can be found in section 13 of IUCLID dossier and in Annex 3.2 of the current dossier.
Groundwater simulation	FOCUS PEARL model was performed.
Confidential Annexes	Yes

Life cycle steps assessed	- *Scenarios 1.1 and 1.2:* Production: No Formulation No Use: Yes Service life: No - *Scenarios 2.1, 2.2 and 2.3:* Production: No Formulation No Use: No Service life: Yes
Remarks	*All emission scenarios have been developed by following the ESD – PT8*

*This scenario (Use classes 1 or 2) is regarded negligible for preventive products at environmental exposure.

ES CA:

Assessed PT	PT 8 – Wood preservative
Assessed scenarios	Stage - Product application and storage before shipping Scenario [1.1]: Automated dipping treatment Sub-scenario [1.1.1]: Application Sub-scenario [1.1.2]: Storage before shipping Scenario [1.2]: Automated spraying Sub-scenario [1.2.1]: Application Sub-scenario [1.2.2]: Storage before shipping
ESD(s) used	Emission Scenario Document for Product Type 8: OECD Series on Emission Scenario Documents No 2, Revised ESD for Wood Preservatives (September 2013).
Approach	Average consumption
Distribution in the environment	Guidance on the BPR: Volume IV Environment, Assessment & Evaluation (Parts B+C)" version 2.0 October 2017. Technical Agreements for Biocides (TAB) – July, 2021
Groundwater simulation	No
Confidential Annexes	No
Life cycle steps assessed	- *Scenarios 1.1 and 1.2:* Production: No Formulation No Use: Yes Service life: No
Remarks	-

Emission estimation

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

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

Stage 1 - Application

Scenario [1.1] – Dipping and store treatment

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

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

Because of the great dilution of the product (2.5%), the density of the final applied formulation is regarded next to 1 kg/m^3. As it was mentioned before, no leaching data is regarded because the product is intended to be applied in wood to be used in class 1 and 2. If the wood treated with this product is intended to be used as class 3.1 or 3.2, a coat of resin product must be applied after the product application and leeching test must be developed with the coat in order to determine the retention of the product in the wood during the service life.

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

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

Input parameters for calculating the local emission from automated dipping process			
Input	**Value**	**Unit**	**Remarks**
Scenario: **1.1.1 – Automated dipping (application)**			
Application rate of biocidal product	5	L/m^3	
Quantity of a substance applied per m^3 of wood			
- Propiconazole	0.00375	Kg/m^3	
- IPBC	0.00625	Kg/m^3	

Input parameters for calculating the local emission from automated dipping process			
Input	**Value**	**Unit**	**Remarks**
Scenario: **1.1.1 – Automated dipping (application)**			
- Bardap26	0.00375	Kg/m^3	
Volume of wood treated per day	100	m^3/d	
Fraction released to facility drain	0.03	[-]	(water solubility > 100 mg/l)
Fraction released to air	0.001	[-]	(vapour pressure at 20ºC < 0.005Pa)

As it was mentioned before the product is intended to be used in wood which are intended to be used as use classes 1 or 2 where the treated wood will be always covered and fully protected from the weather. This entails that storage step (minimum 24 hrs) must be done in sealed places where residues from drain must be collected and disposal by safe means under regional normative in order to avoid any release to the environment. Therefore, storage of treated wood prior to shipping (including removal processes in the receiving environmental compartment, soil) should not release any residue to the environment so it should not has to be assessed in the current dossier. At anyway in order to cover all worse cases, storage treatment under dipping application process has been also assessed as scenario 1.1.2.

Input parameters for calculating the local emission from automated dipping process			
Input	**Value**	**Unit**	**Remarks**
Scenario: **1.1.2 – Automated dipping (storage)**			
Effective surface area of treated wood, considered to be exposed to rain, per 1 m^2 storage area (i.e. soil)	11	$m^2.m^{-2}$	
Surface area of the storage place	700	m^2	
Duration of the initial assessment period	30	d	
Duration of a longer assessment period	7300	d	Value agreed at the WG IV 2015 (Tolyfluanid discussion) (20 years)
Average daily flux i.e. the average quantity of a substance that is daily leached out of 1 m^2 of treated wood during 14 day storage period.			Tier 1: worst-case assumption where 50% of the active substance is assumed to leach after an initial time period of 30 days and 100% of the active substance is assumed to leach after a given longer time period = (Qa.i.*50% /30days)/40 factor
- Propiconazole	1.56E-06	$kg.m^{-2}.d^{-1}$	
- IPBC	2.60E-06	$kg.m^{-2}.d^{-1}$	
- Bardap26	1.56E-06	$kg.m^{-2}.d^{-1}$	
Bulk density of wet soil	1700	Kg/m^3	
Soil depth	0.5	m	

Input parameters for calculating the local emission from automated dipping process			
Input	**Value**	**Unit**	**Remarks**
Scenario: **1.1.2 – Automated dipping (storage)**			
Fraction of rainwater running off the storage site	0.5	[-]	
Flow rate of surface water (creek/river)	25920	$m^3.d^{-1}$	This value corresponds to 0.3 $m^3.s^{-1}$ which is the default value for a small creek.
First order rate constant for removal from soil	3.54E-04	d^{-1}	Taken from EUSES
Soil-water partitioning coefficient	27.2	$m^3.m^{-3}$	Taken from EUSES

Scenario [1.2] – Automated spraying

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

The product is applied as a spray which is usually as a coarse spray using a particle spray size to ensure the wetting of the timber with the correct amount of wood preservative.

The spray boxes are relatively contained and splashguards surround the spraying boxes to eliminate any droplets of spray from entering the rest of the mill area and may have local exhaust ventilation.

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

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

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

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

Input parameters for calculating the local emission from automated spraying process			
Input	**Value**	**Unit**	**Remarks**
Scenario: **1.2.1 – Automated spraying (application)**			
Area of wood treated per day in a			
- Large plant	20000	m^2/d	(considered as

Input parameters for calculating the local emission from automated spraying process			
Input	**Value**	**Unit**	**Remarks**
Scenario: **1.2.1 – Automated spraying (application)**			
			worse case)
- Small plant	2000	m^2/d	
Application rate of the product	0.1	L/m^2	
Concentration of substance in diluted product			
- Propiconazole	0.075	%	
- IPBC	0.125	%	
- Bardap26	0.075	%	
Quantity of a substance applied per m^2 of wood			
- Propiconazole	7.5E-8	Kg/m^2	
- IPBC	1.25E-7	Kg/m^2	
- Bardap26	7.5E-8	Kg/m^2	
Fraction released to facility drain	0.03	[-]	(water solubility > 100 mg/l)
Fraction released to air	0.001	[-]	(vapour pressure at 20ºC < 0.005Pa)
Fraction of spray drift deposition	0.001	[-]	

As in the scenario before, the environmental risk derived from the storage of treatment wood during the application and before shipping has been taken in account as a worse case for the automated spraying application:

Input parameters for calculating the local emission from automated spraying process			
Input	**Value**	**Unit**	**Remarks**
Scenario: **1.2.2 – Automated spraying (storage)**			
Effective surface area of treated wood, considered to be exposed to rain, per 1 m^2 storage area (i.e. soil)	11	$m^2.m^{-2}$	
Surface area of the storage place in a large plant	790	m^2	
Duration of the initial assessment period	30	d	
Duration of a longer assessment period	7300	d	Value agreed at the WG IV 2015 (Tolyfluanid discussion) (20 years)
Average daily flux i.e. the average quantity of a substance that is daily leached out of 1 m^2 of treated wood during 3 day storage period			Tier 1: worse-case assumption where 50% of the active substance is assumed to leach after an initial time
- Propiconazole	1.25E-09	$kg.m^{-2}.d^{-1}$	

Input parameters for calculating the local emission from automated spraying process			
Input	**Value**	**Unit**	**Remarks**
Scenario: **1.2.2 – Automated spraying (storage)**			
- IPBC	6.25E-09	$kg.m^{-2}.d^{-1}$	period of 30 days and 100% of the active substance is assumed to leach after a given longer time period = (Qa.i.*50% /30days)
- Bardap26	1.25E-09	$kg.m^{-2}.d^{-1}$	
Volume of treated wood stacked per m^2 of storage area (i.e. soil)	2	$m^3.m^{-2}$	
Bulk density of wet soil	1700	Kg/m^3	
Soil depth	0.5	m	
Fraction of rainwater running off the storage site	0.5	[-]	
Flow rate of surface water (creek/river)	25920	$m^3.d^{-1}$	This value corresponds to 0.3 $m^3.s^{-1}$ which is the default value for a small creek.

Stage 2 – *Treated wood in service (service life)*

Following the ESD PT-8, there is no scenario for treated wood in service (covering service life) for Use classes 1 and 2 which can be considered no of concern for the environment from dipping or automated spraying applications. In view of that, emissions to outdoor air are considered negligible and no environmental risk is foreseen from this stage 2 of treated wood in service for Use classes 1 or 2 (out of weather exposure).

On the other hand, in the case where the product will be applied on intended wood to be used as Use class 3.1 or 3.2, it must be applied with a cover resin that must be applied just after CORPOL MADERA VERDE application. This mixture of products will change the drifting and leaching properties of the product from the treated wood so specific tests of leaching should be done with the combined mixture to assess the environmental risk for these specific use classes. In addition, in the case where treated wood is exposed to the environment (Use class 3.1 or 3.2), the likely drain from leaching must be collected to STP. Taking into account these assumptions, there is no need to assess the environmental risk for the service life scenarios in the present dossier. However, in order to cover intended uses a rough approach has been done following the Guidance on BPR: Vol IV Environment Parts B+C (Ver. 2. Oct 2017) where a Tier 1 is recommended when no reliable leaching data exists. This first approach is a worst-case assumption where 50% of the active substance is assumed to leach after initial period of 30 days and 100% of the active substance is assumed to leach after a given longer time period (equal to the life time). In order to cover all the uses class 3, the following scenarios of service life have been taken in account:

- Wooden house – Scenario [2.1]
- Noise barrier – Scenario [2.2]
- Bridge over pond – Scenario [2.3]

In addition is important to bear that following BARDAP's CAR, BARDAP 26 is only assessed for wood preservative product in UC 1 and 2, which is the same intended use of CORPOL MADERA VERDE.

ES CA:

Scenario 1 (Product application and storage of treated wood prior to shipment - Dipping)

Application and storage phases

No emission values are presented for these stages as they are subjected to specific regulation within the EU. However, risk mitigation measures are included in the product label to minimize potential environmental risks derived from product application in industrial premises and storage prior to shipment (please see section 2.2.8.3).

Scenario 2 (Product application and storage of treated wood prior to shipment – Automated spraying)

Application and storage phases

No emission values are presented for these stages as they are subjected to specific regulation within the EU. However, risk mitigation measures are included in the product label to minimize potential environmental risks derived from product application in industrial premises and storage prior to shipment (please see section 2.2.8.3).

Fate and distribution in exposed environmental compartments

The following table shows some of the input parameters considered in the environmental assessment for each active substance:

Input parameters (only set values) for calculating the fate and distribution in the environment				
Input	**Value**			**Unit**
	Propiconazole	**IPBC**	**Bardap26**	
Molecular mass	342.2	281.1	429.726*	g/mol
Melting (freezing) point	-23	65.8-66.5	No freezing point down to −50 °C	°C
Boiling point	>250	No boiling point	180-195	°C
Vapour pressure	$5.6x10^{-5}$	$2.36 - 4.5x10^{-3}$	$4x10^{-6}$	Pa at 25ºC
Water solubility	100 (at 20°C (99.1%; pH 6.9)	168 (at 20°C, pH 7)	$1x10^{6}$ (Completely miscible)	mg/l
Log Octanol/water partition coefficient (Kow)	3.72 at 25ºC and pH 6.6	<3	-	Log 10
Henry's Law Constant	$9.2x10^{-5}$	$3.38\ x10^{-3}$ – $6.45x10^{-3}$	$3.03\ x10^{-11}$	$Pa/m^3/mol$ (25ºC)

Input parameters (only set values) for calculating the fate and distribution in the environment				
Input	**Value**			**Unit**
	Propiconazole	**IPBC**	**Bardap26**	
Biodegradability	No readily biodegradable	No readily biodegradable		
Degradation in soil	DT_{50} = 129 d from FOMC	DT_{50lab} = 2.1 hours at 22ºC	No data available	days
Degradation in water compartment	DT_{50} = 1206 days at 12 °C (pH 7)	DT_{50} = 702 days at 12 °C (pH 7)		days
Rate constant for degradation in air	Although there is a photo-oxidative degradation in air (DT_{50}= 10.2 and 42 hours). Fate and behaviour in air is not regarded relevant because there is no relevant release of the compound to the air compartment. The substance is considered very slightly volatile.	DT_{50} = 15 hours. (therefore is not considered persistent in air)	DT_{50} = 8.314 hours. (0.346 days) (therefore is not considered persistent in air)	days
K_{oc}	944	126	562314	-
Other degradation and transformation rates	Default values are used as input according to the ECHA Guidance on the Biocidal Product Regulations, as implemented in EUSES 2.1.1 and ECHA Excel spreadsheet for PT-8.			

n.a. = not available

* monomer

All of these scenarios cover the use classes (since 1 to 3) of the treated wood after the product application. According to these scenarios, the environmental compartment to which the product may be released during the dipping application or during the service life into the wood is provided in the following table:

Identification of relevant receiving compartments based on the exposure pathway											
Scenarios			**Fresh-water**	**Freshwater sediment**	**Sea-water**	**Seawater sediment**	**STP**	**Air**	**Soil**	**Ground -water**	**Other: Secondary poisoning**
Application*	Dipping		2º	2º	n.r	n.r.	1º**	1º	2º	2º	n.r.
	Spraying		2º	2º	n.r	n.r.	1º**	1º	2º	2º	n.r.
Life cycle stage	Use Classes (UC) 1 & 2		n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.
	UC 3	House	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	1º	2º	n.r.
		Bridge over pond	1º	2º	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.
		Noise barrier	2º	2º	n.r.	n.r.	1º		1º or 2º	2º	n.r.

n.r. = Not relevant

* no storage process in regarded in the scenario of application due to label's requirements of the product.

** Worse case situation as residue after application and storage must be disposed as hazardous waste.

It is assumed that emissions from sawmills can only be produced by air or by facility drain during the application (application task + storage). Therefore, under the assumption that the product cannot be applied and storage on unpaved areas (covered from weather conditions), the emission by facility drain is considered as a worse case released to STP and then to surface waters. However, it should be taken into account that this release is not allowed by law.

ES CA:

Identification of relevant receiving compartments based on the exposure pathway

	Fresh-water		Freshwater sediment		STP	Soil		Ground-water		Other
	Direct Release	*Via* STP	Direct Release	*Via* STP		Direct Release	*Via* STP	Direct Release	*Via* STP	
Scenario 1.1	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.r
Scenario 1.2	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.r

n.a.: not assessed

n.r.: not relevant

Calculated PEC values

Stage 1 - Application

Scenario [1.1] – Dipping treatment

Please see in the table below the PECs obtained for each environmental compartment at scenario of automated dipping application:

PEC values derived from Dipping application and storage before shipping				
Compartments	**Units**	**Active substance**		
		Propiconazole	**IPBC**	**Bardap26**
Scenario [1.1.1] - During application stage				
Annual average local PEC in air	[mg.m^{-3}]	9.425E-08	1.571E-07	9.425E-08
PEC for micro-organisms in the STP	[mg.l^{-1}]	5.625E-03	9.375E-03	5.625E-03
Local PEC in surface water during initial emission episode	[mg.l^{-1}]	2.022E-06	3.373E-06	7.625E-07
Local PEC in fresh-water sediment during emission episode	[mg.kgwwt^{-1}]	4.115E-05	2.485E-05	1.830E-02
Local PECoral,fish Concentration in fish for secondary poisoning (freshwater)	[mg.kgwwt^{-1}]	3.64E-04	1.65E-04	6.18E-05
Scenario [1.1.2] - During storage stage				
Local PEC in surface water during:				
Time 1 – initial emission episode	[mg.l^{-1}]	2.321E-04	3.868E-04	2.321E-04
Time 2 – over a longer duration		2.321E-04	3.868E-04	2.321E-04
Local PEC in fresh-water sediment during:				
Time 1 – initial emission episode	[mg.kgwwt^{-1}]	4.722E-03	2.849E-03	5.569E+00
Time 2 – over a longer duration		4.722E-03	2.849E-03	5.569E+00
Local PEC in agric. soil (total) averaged over each time				

Time 1 – initial emission episode	[mg.kgwwt^{-1}]	3.033E-07	5.055E-07	3.033E-07
Time 2 – over a longer duration		7.381E-05	1.230E-04	7.381E-05
Local PEC in pore water of agricultural soil				
Time 1 – initial emission episode	[mg.l^{-1}]	1.896E-08	9.261E-08	1.557E-11
Time 2 – over a longer duration		4.613E-06	2.253E-05	3.789E-09
Local PECoral,fish Concentration in fish for secondary poisoning (freshwater)	[mg.kgwwt^{-1}]	4.18E-02	1.89E-02	1.88E-02
Predicted Environmental Concentration in food for terrestrial secondary poisoning	[mg.kgwwt^{-1}]	1.12E-06	1.86E-04	7.52E-06

Scenario [1.2] – Spraying treatment

Please see in the table below the PECs obtained for each environmental compartment at scenario of automated spraying application:

PEC values derived from spraying application and storage before shipping				
Compartments	**Units**	**Active substance**		
		Propiconazole	**IPBC**	**Bardap26**
Scenario [1.2.1] - During application stage				
Annual average local PEC in air	[mg.m^{-3}]	7.540E-10	1.257E-09	7.540E-10
PEC for micro-organisms in the STP	[mg.l^{-1}]	2.250E-05	3.750E-05	2.250E-05
Local PEC in surface water during initial emission episode	[mg.l^{-1}]	2.022E-06	3.373E-06	7.625E-07
Local PEC in fresh-water sediment during emission episode	[mg.kgwwt^{-1}]	4.115E-05	2.486E-05	1.830E-02
Local PECoral,fish Concentration in fish for secondary poisoning (freshwater)	[mg.kgwwt^{-1}]	3.64E-04	1.65E-04	6.18E-05
Scenario [1.2.2] - During storage stage				
Local PEC in surface water during:				
Time 1 – initial emission episode	[mg.l^{-1}]	2.095E-07	3.492E-07	2.095E-07
Time 2 – over a longer duration		2.095E-07	3.492E-07	2.095E-07
Local PEC in fresh-water sediment during:				
Time 1 – initial emission episode	[mg.kgwwt^{-1}]	4.264E-06	2.574E-06	5.028E-03
Time 2 – over a longer duration		4.264E-06	2.574E-06	5.028E-03
Local PEC in agric. soil (total) averaged over each time				
Time 1 – initial emission episode	[mg.kgwwt^{-1}]	2.426E-10	4.044E-10	2.426E-10
Time 2 – over a longer duration		5.904E-08	9.841E-08	5.904E-08
Local PEC in pore water of agricultural soil				
Time 1 – initial emission episode	[mg.l^{-1}]	1.517E-11	2.528E-11	1.246E-14
Time 2 – over a longer duration		3.690E-09	6.150E-09	3.031E-12
Local PECoral,fish Concentration in fish for secondary poisoning (freshwater)	[mg.kgwwt^{-1}]	3.77E-05	5.11E-05	1.70E-05
Predicted Environmental Concentration in food for terrestrial secondary poisoning	[mg.kgwwt^{-1}]	8.96E-10	1.72E-07	6.01E-09

It is important to bear in mind, that the product formulation is considered a water based product and in addition the product is diluted before its application, hence there is a really low percentage which can evaporate and further, soil deposition.

Stage 2 – Service life

Due to the long time that the treated wood is intended to be used, according to ESD PT8, degradation rates in soil and aquatic compartments have been regarded in the respective scenario assessment for service life.

Scenario [2.1] – Wooden house

The following table shows the outputs obtained for a service life scenario of treated wood used for a wooden house considering removal processes in the soil:

PEC values derived from service life at wooden house				
Compartments	**Units**	**Active substance**		
		Propiconazole	**IPBC**	**Bardap26**
Local PEC in agric. soil (total) averaged over each time				
Time 1 – initial emission episode	[mg.kgwwt^{-1}]	2.599E-07	3.516E-04	2.110E-04
Time 2 – over a longer duration		2.849E-09	3.123E-04	1.874E-04
Local PEC in pore water of agricultural soil				
Time 1 – initial emission episode	[mg.l^{-1}]	1.248E-03	6.442E-05	1.083E-08
Time 2 – over a longer duration		1.368E-05	5.720E-05	9.619E-09
Predicted Environmental Concentration in food for terrestrial secondary poisoning	[mg.kgwwt^{-1}]	8.85E-03	2.75E-04	3.04E-05

Scenario [2.2] – Noise barrier

The following table shows the outputs obtained for a service life scenario of treated wood used for a noise barrier considering removal processes in soil and aquatic compartments:

PEC values derived from service life at noise barrier				
Compartments	**Units**	**Active substance**		
		Propiconazole	**IPBC**	**Bardap26**
PEC for micro-organisms in the STP	[mg.l^{-1}]	1.181E-06	1.969E-06	1.181E-06
Local PEC in surface water during:				
Time 1 – initial emission episode	[mg.l^{-1}]	1.180E-07	1.968E-07	4.448E-08
Time 2 – over a longer duration		1.293E-09	2.157E-09	4.874E-10
Local PEC in fresh-water sediment during:				
Time 1 – initial emission episode	[mg.kgwwt^{-1}]	2.400E-06	1.450E-06	1.067E-03
Time 2 – over a longer duration		2.631E-08	1.589E-08	1.170E-05
Local PEC in agric. soil (total) averaged over each time				
Time 1 – initial emission episode	[mg.kgwwt^{-1}]	9.732E-08	1.317E-04	7.899E-05
Time 2 – over a longer duration		1.067E-09	1.169E-04	7.015E-05
Local PEC in pore water of agricultural soil				
Time 1 – initial emission episode	[mg.l^{-1}]	4.673E-04	2.412E-05	4.055E-09
Time 2 – over a longer duration		5.122E-06	2.142E-05	3.601E-09
Local PECoral,fish Concentration in fish for secondary poisoning (freshwater)	[mg.kgwwt^{-1}]	2.62E-06	1.18E-06	3.60E-06
Predicted Environmental Concentration in food for terrestrial secondary poisoning	[mg.kgwwt^{-1}]	3.31E-03	2.82E-04	1.14E-05

Scenario [2.3] – Bridge over pond

The following table shows the outputs obtained for a service life scenario of treated wood used for a noise barrier considering removal processes at aquatic compartment:

PEC values derived from service life at bridge over pond scenario				
Compartments	**Units**	**Active substance**		
		Propiconazole	**IPBC**	**Bardap26**
Local PEC in surface water during:				
Time 1 – initial emission episode	[mg.l^{-1}]	1.875E-04	3.125E-04	1.875E-04
Time 2 – over a longer duration		3.745E-04	6.242E-04	3.745E-04
Local PEC in fresh-water sediment during:				

PEC values derived from service life at bridge over pond scenario				
Compartments	**Units**	**Active substance**		
		Propiconazole	**IPBC**	**Bardap26**
Time 1 – initial emission episode	[mg.kgwwt^{-1}]	3.815E-03	2.303E-03	4.499
Time 2 – over a longer duration		7.621E-03	4.600E-03	8.987
Local PECoral,fish Concentration in fish for secondary poisoning (freshwater)	[mg.kgwwt^{-1}]	5.06E-02	2.29E-02	2.28E-02

Primary and secondary poisoning

The first step in an assessment of secondary poisoning risk is to consider whether a chemical has the potential to bioaccumulate. Following the respective ARs of each active substances, only BARDAP26 is considered of concern by bioaccumulation. On the other hand, a secondary exposure of animals to IPBC relevant to the food chain can be excluded due to the minimum amount which reaches the soil (in fact, no data in the IPBC's AR is available . In addition, the log K_{ow} is less than 3 and the soil area of concern is very small. This last assumption can be extrapolated for the product. In addition is important to bear in mind that no direct exposure is intended to occur due that when the treated wood is located no animal's contact is available for Use Classes 1 and 2. Hence, only when the product is applied with a coated resin at Use classes 3 (e.g.: wooden house, noise barrier, bridge over pond,…) a low possibility of contact can occur. These conditions have been assessed in the current dossier as a worse cases for secondary poisoning at aquatic and terrestrial compartments.

The following table shows the bioconcentration factors (BCF) that have been used in the Predicted Environmental concentrations for each active substance:

Parameter	**Active substance**		
	Propiconazole	**IPBC**	**Bardap26**
bioconcentration factor for fish on wet weight basis (L/kgwwt)	180	48.8*	81
bioconcentration factor for earthworms (L/kgwwt)	64	8.59*	0.852*

* values obtained from EUSES program

ES CA:

Not relevant for CORPOL MADERA VERDE.

2.1.18.2 Risk characterisation

The risk characterization ratio (RCR) is calculated as a quotient between the Predicted Environmental Concentrations (PECs) and the Predicted Non-Effect-Concentrations (PNECs) for the different compartments such as air, surface water, sediment, Sewage Treatment Plants (STP), soil (agricultural and grassland) and groundwater. If RCR for any environmental compartment is >1, there is a potential risk for this compartment.

According with the active substances' CARs, the following predicted no effect concentration values (PNECs) have been estimated for each compartment and for each active substance:

PNECs	***Units***	**Active substance**

		PROPICONAZOLE	IPBC	BARDAP 26
PNECstp	[mg.l^{-1}]	1	0.44	0.168
PNECwater	[mg.l^{-1}]	1.60E-03	0.0005	0.01
PNECsed	[mg.kgwwt^{-1}]	0.054	3.93E-03*	1.41E-03*
PNECsoil	[mg.kgwwt^{-1}]	0.02	0.005	4.23E-04*
PNECgw	[mg.l^{-1}]	1.00E-04	1.00E-04	1.00E-04
PNECbirds	[mg.kg$_{food}^{-1}$]	0.0747*	1.33*	0.54
PNECmammals	[mg.kg^{-1}]	0.0747*	1.33*	16.7

* value taken from EUSES

Taken into account the above values, the risk due to each active substance at each scenario was calculated for the main environmental compartments.

Atmosphere

Conclusion: With regard to exposure scenarios, no environmental risk exposure is foreseen for the atmosphere. The application of the product is done in closed and sealed tanks where the evaporation is not considered of concern. In addition, the physical-chemical properties of each active substance in the environment, such as vapour pressure (<0.1 mPa) and molecular weight (between 281.1 and 429.726 g/mol), indicate that none of the active substance will readily volatilise into the atmosphere at ambient temperature and pressure.

In addition, there is not $PNEC_{air}$ available for some of the active substances to be compared to the PEC_{air} of the product. However, considering the low volatility of the active substances, and following the assessment report of Regulation (EU) n°528/2012 concerning the making available on the market and use of biocidal products (July, 2013); emissions to the air compartment are expected to be low with no risk associated to the air compartment.

Sewage treatment plant (STP)

The following table shows the derived risk from the corresponding PEC for scenario:

Summary table on calculated PEC/PNEC values from STP						
Scenarios		**Active substance**	**PEC_{STP} (mg/L)**	**$PNEC_{STP}$ (mg/L)**	**PEC_{STP}/ $PNEC_{STP}$**	**RISK**
Stage 1: Application	Scenario [1.1.1] Automated Dipping	Propiconazole	5.625E-03	1	5.63E-03	No
		IPBC	9.375E-03	0.44	2.13E-02	No
		Bardap26	5.625E-03	0.168	3.35E-02	No
	Scenario [1.2.1]. Automated spraying	Propiconazole	2.250E-05	1	2.25E-05	No
		IPBC	3.750E-05	0.44	8.52E-05	No
		Bardap26	2.250E-05	0.168	1.34E-04	No
Stage 2: Service life	Scenario [2.2] Noise barrier	Propiconazole	1.181E-06	1	1.18E-06	No
		IPBC	1.969E-06	0.44	4.48E-06	No
		Bardap26	1.181E-06	0.168	7.03E-06	No

Total $RCR_{product}$ is calculated as the sum of each $RCR_{substance}$ for STP compartment:

Scenarios	$RCR_{product}$	Risk

Stage 1: Application	Scenario [1.1.1] Automated Dipping	6.04E-02	No
	Scenario [1.2.1]. Automated spraying	2.42E-04	No
Stage 2: Service life	Scenario [2.2] Noise barrier	1.27E-05	No

Conclusion:

No risk is foreseen for STP compartment by the use of CORPOL MADERA VERDE at application or service life scenarios.

Surface water

Summary table on calculated PEC/PNEC values from surfacewater							
Scenarios			**Active substance**	**PEC_{sw} (mg/L)**	**$PNEC_{sw}$ (mg/L)**	**PEC_{sw}/ $PNEC_{sw}$**	**RISK**
Stage 1: Application	Scenario [1.1.1] Automated Dipping application		Propiconazole	2.02E-03	1.60E-03	1.26E-03	No
			IPBC	3.37E-03	0.0005	6.75E-03	No
			Bardap26	7.63E-04	0.01	7.63E-05	No
	Scenario [1.1.2] storage after Dipping application	Time 1	Propiconazole	2.32E-01	1.60E-03	1.45E-01	No
			IPBC	3.87E-01	0.0005	7.74E-01	No
			Bardap26	2.32E-01	0.01	2.32E-02	No
		Time 2	Propiconazole	2.32E-01	1.60E-03	1.45E-01	No
			IPBC	3.87E-01	0.0005	7.74E-01	No
			Bardap26	2.32E-01	0.01	2.32E-02	No
	Scenario [1.2.1] Automated spraying application		Propiconazole	2.02E-03	1.60E-03	1.26E-03	No
			IPBC	3.37E-03	0.0005	6.75E-03	No
			Bardap26	7.63E-04	0.01	7.63E-05	No
	Scenario [1.2.2] storage after spraying application	Time 1	Propiconazole	2.10E-04	1.60E-03	1.31E-04	No
			IPBC	1.05E-03	0.0005	2.10E-03	No
			Bardap26	2.10E-04	0.01	2.10E-05	No
		Time 2	Propiconazole	2.10E-04	1.60E-03	1.31E-04	No
			IPBC	1.05E-03	0.0005	2.10E-03	No
			Bardap26	2.10E-04	0.01	2.10E-05	No
Stage 2: Service life	Scenario [2.2] Noise barrier	Time 1	Propiconazole	1.18E-04	1.60E-03	7.38E-05	No
			IPBC	1.97E-04	0.0005	3.94E-04	No
			Bardap26	4.45E-05	0.01	4.45E-06	No
		Time 2	Propiconazole	1.29E-06	1.60E-03	8.08E-07	No
			IPBC	2.16E-06	0.0005	4.31E-06	No

Summary table on calculated PEC/PNEC values from surfacewater							
Scenarios			**Active substance**	**PEC_{sw} (mg/L)**	**$PNEC_{sw}$ (mg/L)**	**PEC_{sw}/ $PNEC_{sw}$**	**RISK**
			Bardap26	4.87E-07	0.01	4.87E-08	No
	Scenario [2.3] Bridge over pond	Time 1	Propiconazole	1.88E-01	1.60E-03	1.17E-01	No
			IPBC	3.13E-01	0.0005	6.25E-01	No
			Bardap26	1.88E-01	0.01	1.88E-02	No
		Time 2	Propiconazole	3.75E-01	1.60E-03	2.34E-01	No
			IPBC	6.24E-01	0.0005	1.25E+00	Yes
			Bardap26	3.75E-01	0.01	3.75E-02	No

Total $RCR_{product}$ is calculated as the sum of each $RCR_{substance}$ for surfacewater compartment:

Scenarios			**$RCR_{product}$**	**Risk**
Stage 1: Application	Scenario [1.1.1] Automated Dipping application		8.09E-03	No
	Scenario [1.1.2] storage after Dipping application	Time 1	9.42E-01	No
		Time 2	9.42E-01	No
	Scenario [1.2.1] Automated spraying application	Time 1	8.09E-03	No
		Time 2	8.09E-03	No
	Scenario [1.2.2] storage after spraying application	Time 1	2.25E-03	No
		Time 2	2.25E-03	No
Stage 2: Service life	Scenario [2.2] Noise barrier	Time 1	4.72E-04	No
		Time 2	5.17E-06	No
	Scenario [2.3] Bridge over pond		1.52	Yes

Conclusion:

Under a worse case, where the label instructions are not followed and no cover resin is applied after product application on wood to be used as use class 3, a slight risk is foreseen for the scenario [2.3], bridge over pond. On the other hand, no risk at surfacewater compartment is foreseen for the rest of scenarios.

Sediment

Summary table on calculated PEC/PNEC values from sediment							
Scenarios			**Active substance**	**PEC_{sed} (mg/ kgwwt)**	**$PNEC_{sed}$ (mg/ kgwwt)**	**PEC_{sed}/ $PNEC_{sed}$**	**RISK**
Stage 1: Application	Scenario [1.1.1] Automated Dipping application		Propiconazole	4.12E-05	0.054	7.62E-04	No
			IPBC	2.49E-05	3.93E-03	6.32E-03	No
			Bardap26	1.83E-02	1.41E-03	1.30E+01	**Yes**
	Scenario [1.1.2] storage after Dipping application	Time 1	Propiconazole	4.72E-03	0.054	8.74E-02	No
			IPBC	2.85E-03	3.93E-03	7.25E-01	No
			Bardap26	5.57E+00	1.41E-03	3.95E+03	**Yes**
		Time 2	Propiconazole	4.72E-03	0.054	8.74E-02	No
			IPBC	2.85E-03	3.93E-03	7.25E-01	No
			Bardap26	5.57E+00	1.41E-03	3.95E+03	**Yes**
	Scenario [1.2.1] Automated spraying application		Propiconazole	4.12E-05	0.054	7.62E-04	No
			IPBC	2.49E-05	3.93E-03	6.33E-03	No
			Bardap26	1.83E-02	1.41E-03	1.30E+01	**Yes**
	Scenario [1.2.2] storage after spraying application	Time 1	Propiconazole	4.26E-06	0.054	7.90E-05	No
			IPBC	7.72E-06	3.93E-03	1.96E-03	No
			Bardap26	5.03E-03	1.41E-03	3.57E+00	**Yes**
		Time 2	Propiconazole	4.26E-06	0.054	7.90E-05	No
			IPBC	7.72E-06	3.93E-03	1.96E-03	No
			Bardap26	5.03E-03	1.41E-03	3.57E+00	**Yes**
Stage 2: Service life	Scenario [2.2] Noise barrier	Time 1	Propiconazole	2.40E-06	0.054	4.44E-05	No
			IPBC	1.45E-06	3.93E-03	3.69E-04	No
			Bardap26	1.07E-03	1.41E-03	7.57E-01	No
		Time 2	Propiconazole	2.63E-08	0.054	4.87E-07	No
			IPBC	1.59E-08	3.93E-03	4.04E-06	No
			Bardap26	1.17E-05	1.41E-03	8.30E-03	No
	Scenario [2.3] Bridge over pond	Time 1	Propiconazole	3.82E-03	0.054	7.06E-02	No
			IPBC	2.30E-03	3.93E-03	5.86E-01	No
			Bardap26	4.50E+00	1.41E-03	3.19E+03	**Yes**
		Time 2	Propiconazole	7.62E-03	0.054	1.41E-01	No
			IPBC	4.60E-03	3.93E-03	1.17E+00	**Yes**
			Bardap26	8.99E+00	1.41E-03	6.37E+03	**Yes**

Total $RCR_{product}$ is calculated as the sum of each $RCR_{substance}$ for sediment compartment:

Scenarios			$RCR_{product}$	Risk
Stage 1: Application	Scenario [1.1.1] Automated Dipping application		13.0	**Yes**
	Scenario [1.1.2] storage after Dipping application	Time 1	3.95E+03	**Yes**
		Time 2	3.95E+03	**Yes**
	Scenario [1.2.1] Automated spraying application	Time 1	13.0	**Yes**
		Time 2	13.0	**Yes**
	Scenario [1.2.2] storage after spraying application	Time 1	3.57	**Yes**
		Time 2	3.57	**Yes**
Stage 2: Service life	Scenario [2.2] Noise barrier	Time 1	7.57E-01	No
		Time 2	8.30E-03	No
	Scenario [2.3] Bridge over pond		6.38E+03	**Yes**

Conclusion:

Under the assumption that there are product's losses to the environment during the application treatment, an unacceptable risk for sediment compartment is foreseen by both application methods (dipping and spraying) either during application or storage tasks. During the service life of the product, only the scenario of the bridge over pond shows risk whereas the scenario of the noise barrier is considered out of risk for sediment compartment.

Soil

Summary table on calculated PEC/PNEC values from soil							
Scenarios			**Active substance**	**PEC_{soil} (mg/ kg)**	**$PNEC_{soil}$ (mg/ kg)**	**PEC_{soil}/ $PNEC_{soil}$**	**RISK**
Stage 1: Application	Scenario [1.1.2] storage after Dipping application	Time 1	Propiconazole	3.03E-07	0.02	1.52E-05	No
			IPBC	5.06E-07	0.005	1.01E-04	No
			Bardap26	3.03E-07	4.23E-04	7.17E-04	No
		Time 2	Propiconazole	7.38E-05	0.02	3.69E-03	No
			IPBC	1.23E-04	0.005	2.46E-02	No
			Bardap26	7.38E-05	4.23E-04	1.74E-01	No
	Scenario [1.2.2] storage after spraying application	Time 1	Propiconazole	2.43E-10	0.02	1.21E-08	No
			IPBC	1.21E-09	0.005	2.43E-07	No
			Bardap26	2.43E-10	4.23E-04	5.74E-07	No
		Time 2	Propiconazole	5.90E-08	0.02	2.95E-06	No
			IPBC	2.95E-07	0.005	5.90E-05	No
			Bardap26	5.90E-08	4.23E-04	1.40E-04	No
Stage 2: Service life	Scenario [2.1] wooden house	Time 1	Propiconazole	2.60E-07	0.02	1.30E-05	No
			IPBC	3.52E-04	0.005	7.03E-02	No
			Bardap26	2.11E-04	4.23E-04	4.99E-01	No
		Time 2	Propiconazole	2.85E-09	0.02	1.42E-07	No
			IPBC	3.12E-04	0.005	6.25E-02	No

Summary table on calculated PEC/PNEC values from soil							
Scenarios			**Active substance**	**PEC_{soil} (mg/ kg)**	**$PNEC_{soil}$ (mg/ kg)**	**PEC_{soil}/ $PNEC_{soil}$**	**RISK**
			Bardap26	1.87E-04	4.23E-04	4.43E-01	No
	Scenario [2.2] Noise barrier	Time 1	Propiconazole	9.73E-08	0.02	4.87E-06	No
			IPBC	1.32E-04	0.005	2.63E-02	No
			Bardap26	7.90E-05	4.23E-04	1.87E-01	No
		Time 2	Propiconazole	1.07E-09	0.02	5.34E-08	No
			IPBC	1.17E-04	0.005	2.34E-02	No
			Bardap26	7.02E-05	4.23E-04	1.66E-01	No

Total $RCR_{product}$ is calculated as the sum of each $RCR_{substance}$ for soil compartment:

Scenarios			**$RCR_{product}$**	**Risk**
Stage 1: Application	Scenario [1.1.2] storage after Dipping application	Time 1	8.33E-04	No
		Time 2	2.03E-01	No
	Scenario [1.2.2] storage after spraying application	Time 1	8.28E-07	No
		Time 2	2.02E-04	No
Stage 2: Service life	Scenario [2.1] wooden house	Time 1	5.69E-01	No
		Time 2	5.05E-01	No
	Scenario [2.2] Noise barrier	Time 1	2.13E-01	No
		Time 2	1.89E-01	No

Conclusion:

No risk is foreseen for soil compartment under any of the considered scenarios in the current dossier.

Groundwater

Summary table on calculated PEC/PNEC values from groundwater							
Scenarios			**Active substance**	**PEC_{gw} (mg/ L)**	**$PNEC_{gw}$ (mg/L)**	**PEC_{gw}/ $PNEC_{gw}$**	**RISK**
Stage 1: Application	Scenario [1.1.2] storage after Dipping application	Time 1	Propiconazole	1.90E-08	1.00E-04	1.90E-04	No
			IPBC	9.26E-08		9.26E-04	No
			Bardap26	1.56E-11		1.56E-07	No
		Time 2	Propiconazole	4.61E-06		4.61E-02	No
			IPBC	2.25E-05		2.25E-01	No
			Bardap26	3.79E-09		3.79E-05	No
	Scenario [1.2.2] storage after spraying application	Time 1	Propiconazole	1.52E-11		1.52E-07	No
			IPBC	7.58E-11		7.58E-07	No
			Bardap26	1.25E-14		1.25E-10	No
		Time 2	Propiconazole	3.69E-09		3.69E-05	No
			IPBC	1.85E-08		1.85E-04	No
			Bardap26	3.03E-12		3.03E-08	No

Summary table on calculated PEC/PNEC values from groundwater							
Scenarios			**Active substance**	**PEC_{gw} (mg/ L)**	**$PNEC_{gw}$ (mg/L)**	**PEC_{gw}/ $PNEC_{gw}$**	**RISK**
Stage 2: Service life	Scencario [2.1] wooden house	Time 1	Propiconazole	1.25E-03		1.25E+01	**Yes**
			IPBC	6.44E-05		6.44E-01	No
			Bardap26	1.08E-08		1.08E-04	No
		Time 2	Propiconazole	1.37E-05		1.37E-01	No
			IPBC	5.72E-05		5.72E-01	No
			Bardap26	9.62E-09		9.62E-05	No
	Scencario [2.2] Noise barrier	Time 1	Propiconazole	4.67E-04		4.67E+00	**Yes**
			IPBC	2.41E-05		2.41E-01	No
			Bardap26	4.06E-09		4.06E-05	No
		Time 2	Propiconazole	5.12E-06		5.12E-02	No
			IPBC	2.14E-05		2.14E-01	No
			Bardap26	3.60E-09		3.60E-05	No

Total $RCR_{product}$ is calculated as the sum of each $RCR_{substance}$ for groundwater compartment:

Scenarios			**$RCR_{product}$**	**Risk**
Stage 1: Application	Scenario [1.1.2] storage after Dipping application	Time 1	1.12E-03	No
		Time 2	2.71E-01	No
	Scenario [1.2.2] storage after spraying application	Time 1	9.10E-07	No
		Time 2	2.21E-04	No
Stage 2: Service life	Scenario [2.1] wooden house	Time 1	13.1	**Yes**
		Time 2	7.09E-01	No
	Scenario [2.2] Noise barrier	Time 1	4.91	**Yes**
		Time 2	2.65E-01	No

Conclusion:

Without considering label's instructions, only PEC groundwater values calculated by excel ESD PT8 programme for service life scenario at time 1 for wooden house and noise barrier are above the maximum permissible concentration of 0.1 µg/l given in Directive 80/778/EEC (amended by 98/83/EC). It is important to bear in mind that the use of coat resin is required when the treated wood is intended to be used as use class 3. The use of this coat will notably reduce the product's leaching from the treated wood and hence, this groundwater concentration will be signally reduced. In addition is important to bear in mind that no risk is foreseen for groundwater compartment when Time 2 is regarded.

On the other hand it is necessary to point out that the active substance, BARDAP26, is only accepted for wood preservative products in Use classes 1 and 2.

ES CA:

No risk assessment has been performed for the stages of product application at industrial sites and storage of treated wood prior to shipment, as they are subjected to specific regulation within the EU. However, the following risk mitigation measures are included in

the product label to minimize potential environmental risks derived from product application in industrial premises and storage prior to shipment:

-Prevent any release of the biocidal product to the sewage system or the environment during the product application phase as well as during the storage and the transport of treated timber;
-All industrial application processes must be carried out within a contained area situated on impermeable hard standing with bunding to prevent run-off and a recovery system in place (e.g. sump).
-Application solutions must be collected and reused or disposed of as hazardous waste. They must not be released to soil, ground- and surface water or any kind of sewer;
-Freshly treated timber must be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water and that any losses of the product shall be collected for reuse or disposal.
-Any contaminated water/soil shall be collected, contained and treated as hazardous waste.

No risk assessment has been performed for the subsequent use of the wood treated with CORPOL MADERA VERDE, as no PNECs for the sediment and soil compartments can be derived for the substance BARDAP 26. In order to reduce the environmental release, the following mention has been added to the instructions for use:

• CORPOL MADERA VERDE is ONLY to be used for wood in situation in which the wood or wood based product is inside a contruction, not expose to the weather and wetting or where occasional, but not persistent, wetting can occur.

Primary and secondary poisoning (non-compartment specific effects relevant to the food chain)

- For freshwater

Summary table on calculated PEC/PNEC values from secondary poisoning at freshwater						
Scenarios		**Active substance**	**$PEC_{oral,fish}$ (mg/ kgwwt)**	**$PNEC_{oral,fish}$ (mg/ kgwwt)**	**$PEC_{oral,fish}$/ $PNEC_{oral,fish}$**	**RISK**
Stage 1: Application	Scenario [1.1.1] Automated dipping application	Propiconazole	3.64E-04	0.0747	4.87E-03	No
		IPBC	1.65E-04	1.33	1.24E-04	No
		Bardap26	6.18E-05	0.54	1.14E-04	No
	Scenario [1.1.2] storage after Dipping application	Propiconazole	4.18E-02	0.0747	5.60E-01	No
		IPBC	1.89E-02	1.33	1.42E-02	No
		Bardap26	1.88E-02	0.54	3.48E-02	No
	Scenario [1.2.1] Automated spraying application	Propiconazole	3.64E-04	0.0747	4.87E-03	No
		IPBC	1.65E-04	1.33	1.24E-04	No
		Bardap26	6.18E-05	0.54	1.14E-04	No

Summary table on calculated PEC/PNEC values from secondary poisoning at freshwater						
Scenarios		**Active substance**	**$PEC_{oral,fish}$ (mg/ kgwwt)**	**$PNEC_{oral,fish}$ (mg/ kgwwt)**	**$PEC_{oral,fish}$/ $PNEC_{oral,fish}$**	**RISK**
	Scenario [1.2.2] storage after spraying application	Propiconazole	3.77E-05	0.0747	5.05E-04	No
		IPBC	5.11E-05	1.33	3.84E-05	No
		Bardap26	1.70E-05	0.54	3.15E-05	No
Stage 2: Service life	Scenario [2.2] Noise barrier	Propiconazole	2.62E-06	0.0747	3.51E-05	No
		IPBC	1.18E-06	1.33	8.87E-07	No
		Bardap26	3.60E-06	0.54	6.67E-06	No
	Scenario [2.3] Bridge over pond	Propiconazole	5.06E-02	0.0747	6.77E-01	No
		IPBC	2.29E-02	1.33	1.72E-02	No
		Bardap26	2.28E-02	0.54	4.22E-02	No

- For terrestrial

Summary table on calculated PEC/PNEC values from secondary poisoning at soil						
Scenarios		**Active substance**	**$PEC_{oral,worm}$ (mg/ kgwwt)**	**$PNEC_{oral,worm}$ (mg/ kgwwt)**	**$PEC_{oral,worm}$/ $PNEC_{oral,worm}$**	**RISK**
Stage 1: Application	Scenario [1.1.2] storage after Dipping application	Propiconazole	1.12E-06	0.0747	1.50E-05	No
		IPBC	1.86E-04	1.33	1.40E-04	No
		Bardap26	7.52E-06	16.7	4.50E-07	No
	Scenario [1.2.2] storage after spraying application	Propiconazole	8.96E-10	0.0747	1.20E-08	No
		IPBC	1.72E-07	1.33	1.30E-07	No
		Bardap26	6.01E-09	16.7	3.60E-10	No
Stage 2: Service life	Scenario [2.1] Wooden house	Propiconazole	8.85E-03	0.0747	1.18E-01	No
		IPBC	2.75E-04	1.33	2.07E-04	No
		Bardap26	3.04E-05	16.7	1.82E-06	No
	Scenario [2.2] Noise barrier	Propiconazole	3.31E-03	0.0747	4.43E-02	No
		IPBC	2.82E-04	1.33	2.12E-04	No
		Bardap26	1.14E-05	16.7	6.81E-07	No

Total $RCR_{product}$ is calculated as the sum of each $RCR_{substance}$ for each compartment:

- For freshwater

Scenarios		**$RCR_{product}$**	**Risk**
Stage 1: Application	Scenario [1.1.1] Automated dipping application	5.11E-03	No
	Scenario [1.1.2] storage after Dipping application	6.09E-01	No
	Scenario [1.2.1] Automated spraying application	5.11E-03	No
	Scenario [1.2.2] storage after spraying application	5.75E-04	No
Stage 2: Service life	Scenario [2.2] Noise barrier	4.26E-05	No
	Scenario [2.3] Bridge over pond	7.37E-01	No

- For terrestrial

Scenarios		$RCR_{product}$	Risk
Stage 1: Application	Scenario [1.1.2] storage after Dipping application	1.56E-04	No
	Scenario [1.2.2] storage after spraying application	1.42E-07	No
Stage 2: Service life	Scenario [2.1] Wooden house	1.19E-01	No
	Scenario [2.2] Noise barrier	4.46E-02	No

Conclusion:

No risk exposure is foreseen for secondary poisoning both aquatic or terrestrial compartment.

ES CA:

Not relevant.

Mixture toxicity

ES CA:

Not relevant.

Aggregated exposure (combined for relevant emmission sources)

ES CA:

No overlap in time and space of this product is expected and therefore, no additional aggregated exposure is calculated.

Overall conclusion on the risk assessment for the environment of the product

In aquatic compartment for all scenarios, the PEC/PNEC values are only higher than 1 for surface water at bridge over pond scenario indicating an unacceptable risk. On the other hand, for sediment compartment all scenarios (with the exception of noise barrier) are regarded at risk. This risk for sediment is due to the higher partition coefficient organic carbon-water (K_{oc}) of the active substance BARDAP26. Anyway, in order to reduce emissions from the storage phases for aquatic compartment, the dipping and spraying treatment must be performed only by those plants where significant losses can be contained (e.g. no drain connections to storm drains or STP) and appropriately recycled/disposed.

It is important to highlight that no risk is predicted for the microorganisms in sewage treatment plant.

Therefore, as for other PT8 CA reports, risk mitigation measures are proposed to restrict the storage of pre-treated timber to areas of impermeable hard standing so as to prevent direct exposure of the water compartment and allow the recovery of the losses for

recycling or appropriate disposal. Moreover, due to the PEC/PNEC ratios higher than 1 for the aquatic compartment, it is proposed to restrict the dipping and spraying treatment allowing it only to those plants where significant losses can be contained (e.g., no drain connections to storm drains or STP) and appropriately recycled/disposed.

Soil compartment and secondary poisoning are considered under an acceptable risk. Moreover, groundwater compartment is regarded of concern for service life scenarios of use class 3 when the use of a coat resin is not taking into account. In view of that the use of a resin coat must always be used when the product is applied in wood to be used as use class 3.

ES CA:

Overall conclusion on the risk assessment for the environment of the product

CORPOL MADERA VERDE is a biocidal product used for preventive protection of wood and constructional timbers. The product is applied by automated dipping, "green chain" or automated spraying methodologies at industrial sites where the wood is treated and then stored under cover. This application is considered of no concern when the following risk mitigation measures to avoid releases are taken:

-Prevent any release of the biocidal product to the sewage system or the environment during the product application phase as well as during the storage and the transport of treated timber;

-All industrial application processes must be carried out within a contained area situated on impermeable hard standing with bunding to prevent run-off and a recovery system in place (e.g. sump).

-Application solutions must be collected and reused or disposed of as hazardous waste. They must not be released to soil, ground- and surface water or any kind of sewer;

-Freshly treated timber must be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water and that any losses of the product shall be collected for reuse or disposal.

-Any contaminated water/soil shall be collected, contained and treated as hazardous waste.

These risk mitigation measures must be included in the product label to minimize potential environmental risks derived from product application in industrial premises and storage prior to shipment.

On the other hand, releases from the subsequent used have to be assessed with the "assessment of temporary anti-saptain wood preservatives" scenario (ENV-TAB 199). According to this, if unacceptable risks for the environment are assessed in one or more UC 3 scenarios and no use on wood intended for pallets is requested by the applicant, the product can only be authorized as a temporary anti-sapstain wood preservative for wood, which is intended to be used in UC 1+2.

As the risk assessment for UC3 uses cannot be performed due to the lack of sediment and soil PNECs of one of the product substances (BARDAP 26), and in order to reduce the environmental release, the following mention has been added to the instructions for use:

• CORPOL MADERA VERDE is ONLY to be used for wood in situation in which the wood or wood based product is inside a contruction, not expose to the weather and wetting or where occasional, but not persistent, wetting can occur.

2.1.19 Measures to protect man, animals and the environment

See risk mitigation measures for authorized uses

Recommended methods and precautions concerning storage of biocidal product; shelf life of product:

The product is stored in a pressure container. Protect from sunlight and do not expose to temperatures exceeding 50°C. Do not pierce or burn, even after use. Do not spray on a naked flame or any incandescent material. Keep away from any source of ignition. Do not smoke. Keep out of reach of small children. Use only in well ventilated areas. Do not breathe vapour. Keep always in the original package

Recommended methods and precautions concerning handling and transport

Handling:

Before using the product read the label carefully.

The wood should be treated stacked with separation battens. Once treated, it will remain stacked and trapped protected from the rain to avoid the washout of the protective product. Wood piles should be arranged in such a way that air circulation is favoured to ensure a correct drying process. Recommended period of safety: 24 hours, it will never be less than the time it takes to fix the product.

Indications for the transport

- ONU number: UN1950
- Official Classification of Transport: Flammable aerosols.
- Class of dangerous goods: 2
- Group of packaging: -
- Dangerous for the environment: Yes
- Special precautions for users: -

Recommended methods and precautions concerning fire:

Fire prevention:

Do not allow the access to not authorized people at the treatment place.

Extinguishing measures:

Extinguish fire with foam, powder, CO_2 or water spray.

Do not use water jet, only to refresh areas and packaging next to the heat source

Specific hazards arising from the substance or preparation.

The fire may product a thick black smoke. The combustion gases of organic materials must always be considered as toxic for inhalation. Do not breathe vapours.

In case of fire, the following sub-products can be formed:

- Carbon monoxide (CO)
- Carbon dioxide (CO_2)
- Hydrogen chloride (HCl)

Recommendations for the firefighters
Use masks with chemical filters, in enclosed spaces use self-contained breathing apparatus.

Particulars of likely direct or indirect effects

The product is intended to be applied on wood which is located and stored in indoor premises or under roof (Use Classes 1 and 2), hence it is not directly exposed to the environmental conditions and no releases to the environment are foreseeable. On the other hand, there is a chance to be used as Use Class 3, as long as it is used with a cover resin wich must be applied after application product over the wood, then the treated wood may be placed outdoor but always trying to be out of direct adverse weather conditions (Use Class 3).

Conditions to avoid:

- Avoid contact with strong acids and alkalis and organic matter.

Main symptoms and effects, acute and delayed:

- The clinical manifestations that can occur in case of exposure and contact are: Irritation to caustic burn in skin, eyes, mucous membranes, respiratory and gastrointestinal tract with intense pain and risk of gastric perforation.
- Chemical pneumonia due to aspiration and metabolic acidosis.
- Contact dermatitis and sensitization

Hazardous decomposition products:

- No decomposition products are generated if stored and handled correctly. Carbon monoxide, carbon dioxide, nitrogen oxides, iodine vapours and other toxic gases can be formed in case of fire or thermal decomposition, therefore, in case of fire or combustion, avoid inhalation of the fumes.

First aid instructions

IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor.

IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.

The eyes should also be rinsed repeatedly on the way to the doctor.

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

Emergency measures to protect the environment

Environmental precautions:
Avoid dispersal of spilt material and runoff and contact with soil,waterways,drains and sewers. Inform to the relevant authorities if the product has caused environmental pollution (sewers,waterways,soil or air).

Methods and materials for containment and cleaning up:
Channelling large quantities and collect in containers;dispose them according to local regulations. Wash the small amounts with water. Remove the used water according to local regulations.

Instructions for safe disposal of the product and its packaging

Product:

The residues of product should be managed according to current regulations through authorized waste managers. Waste must not be disposed through sewage systems.

Containers:

The management of waste is carried out without endangering human health and without harming the environment, and especially without creating risks for water, air, soil, fauna or flora

Empty containers should be managed according to current regulations through authorized waste managers.

2.1.20 Assessment of a combination of biocidal products

Not applicable as the biocidal product is not intended to be authorised for the use with other biocidal products.

2.1.21 Comparative assessment

The product contains, in addition to the active substances IPBC and didecylmethylpoly(oxyethyl)ammonium propionate, 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-LN036817-20
Evaluating Competent Authority: ES CA
Applicant: QUÍMICA DE MUNGUÍA
(Prospective) Authorisation holder: QUÍMICA DE MUNGUÍA

2. Administrative information of the BP

Trade name(s): CORPOL MADERA VERDE

Product type(s): 08 (wood preservative)

Active substance(s): Propiconazole (60207-90-1), IPBC (CAS: 55406-53-6), Didecylmethylpoly(oxyethyl)ammonium propionate (CAS: 94667-33-1)

3. Intended uses for the relevant BP in the application

The wood protection product (PT8) CORPOL MADERA VERDE contains the active substances propiconazole, IPBC and Didecylmethylpoly(oxyethyl)ammonium propionate. The product is used by trained professional users for Temporary preventive treatment for green timber by superficial application (dipping/green chain/automated spray) against blue stain fungi and mould fungi.

Table 1. Preventive treatment-superficial application (dipping/green chain/automated spray) Trained professional user.

Product Type	PT8
Where relevant, an exact description of the authorised use	CORPOL MADERA VERDE is a temporary preventive treatment for green timber with fungicidal properties for outdoor use.
Target organism (including development stage)	Wood discoloring fungi- Ascomycetes and Deuteromycetes - -Blue stain fungi - -Mould fungi
Field of use	Outdoor
Application method	Superficial treatment by dipping/green chain/automated spray.
Category of use	Trained professional user.

Mode of Action of the active substances:

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.

Didecylmethylpoly(oxyethyl)ammonium propionate acts as a fungistatic and an insecticide. It is a cationic surfactant-type active substance. Since it is surface active, it has fair wetting properties and reacts strongly with cell walls of micro-organisms. Due to its interaction with phospholipid-bilayer structures, it severely alters the cell wall permeability, disturbs membrane-bound ion-translocation mechanisms, and may facilitate the uptake of other biocides.

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	F: lipid synthesis or	28	Low to medium

	fungi and wood destroying fungi	transport / membrane integrity or function F4: cell membrane permeability, fatty acid (proposed)		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 creosote, 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 CORPOL MADERA VERDE which is under evaluation.

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 CORPOL MADERA VERDE 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 CORPOL MADERA VERDE 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.

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 105 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). 101 of them are authorised for trained professional users. Of them, no biocidal products have been authorised in Spain for the same intended uses in CORPOL MADERA VERDE which is authorised by trained professional users for temporary preventive treatment for green timber by superficial application (dipping/green chain/automated spray) against blue stain fungi and mould fungi.
There are currently 3 biocidal products authorised for trained professional users for preventive green wood protection. All of them are authorised for dipping use, one of them is authorised for green chain use but none of them are authorised for automatic spraying use.
All of them are authorised against blue stain fungi but only two of them against mould fungi.
Two of them contain propiconazole and one contain granulated copper.

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 CORPOL MADERA VERDE containing propiconazole.

No biocidal products have been authorised in Spain for the same intended uses in CORPOL MADERA VERDE 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 CORPOL MADERA VERDE should be authorised for a period not exceeding 5 years in accordance with Article 23(6) of Regulation (EU) No 528/2012.

3 ANNEXES

3.1.1 List of studies for the biocidal product

Section No.	Author(s)	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data Protection Claimed (Y/N)	Owner
2.2.5	[redacted]	[redacted]	Title: Determination of the preservative effectiveness against sapstain fungi and mould fungi on freshly sawn timber - Field Test Test facility: CIDEMCO-Tecnalia, Spain Report No. 19100-a	Yes	QUÍMICA DE MUNGUÍA, S.A.
2.2.2	[redacted]	[redacted]	Title: Physico-chemical properties, validation of the analytical method and chemical analyses of the biocidal product CORPOL MADERA VERDE before and after an accelerated storage procedure for 14 days at 54 2ºC, in compliance with CIPAC MT 46.3 method.	Yes	QUÍMICA DE MUNGUÍA, S.A.
2.2.2	[redacted]	[redacted]	Title: Determination of the expiry date: testing at 24 months.	Yes	QUÍMICA DE MUNGUÍA, S.A.
2.2.3	[redacted]	[redacted]	Title: Determination of the corrosive properties of the item "CORPOL MADERA VERDE" during 28 days according to the UN Test C.1. (Aluminium and Steel specimens)	Yes	QUÍMICA DE MUNGUÍA, S.A
2.2.3	[redacted]	[redacted]	Title: Corpol Madera Verde: Auto ignition Temperature (Liquids and Gases)	Yes	QUÍMICA DE MUNGUÍA, S.A.
2.2.3	Legay, S.	[redacted]	Title: Differential Scanning Calorimetry (DSC) measurement on the test item Corpol Madera Verde	Yes	QUÍMICA DE MUNGUÍA, S.A

3.1.2 Output tables from exposure assessment tools

Human Exposure Calculations_CORPC

3.1.3 New information on the active substance

3.1.4 Residue behaviour

3.1.5 Summaries of the efficacy studies (B.5.10.1-xx)[2]

Please see table on Efficacy data on section 2.2.1.5

3.1.6 Confidential annex

Please see confidential annex.

3.1.7 Other