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)

XYLAZEL TOTAL

Product type 8

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

Case Number in R4BP: BC-LT018866-07

Evaluating Competent Authority: Spain CA

Date: November/2021

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1 CONCLUSION

The biocidal product contains four active susbtances (propiconazole, tebuconazole, IPBC and cypermethrin).

Physical-chemical properties.

Xylazel Total is a light yellowish transparent liquid with a density value of 0.82 g/m^3

The formulation was shown to be stable under accelerated conditions (54°C during 2 weeks) and at room temperature during at least 2 years. Therefore, a shelf-life of 24 months can be granted.

The product is not considered to be explosive, oxidizing, pyrophoric or corrosive. However, the flash point obtained showed that the product is flammable and it has to be classified as Flam. Liq. 3 (H226).

Regarding analytical methods, HPLC-UV method can be considered to be acceptable for the determination of the IPBC content and in the same line GC-FID method can be considered to be acceptable for the determination of Tebuconazole, Propiconazole and Cypermethin content.

Conclusion on efficacy assessment:

Xylazel Total is a solvent based wood preservative, for the preventive and curative protection for transformed wood used in joiner, furniture and woodwork, (constructional timber, joints, doors, windows, fences, burgles, etc.), used by an industrial, professional or non professional operator, to prevent the action of basidiomycete and blue stain fungi that cause wood decay and wood-boring beetles like *Hylotrupes Bajulus*, and *Anobium punctatum de Geer.* Wood protection product according to the European standard EN 335, EN 599 and EN 14128.
The test submitted show that Xylazel Total can be authorised to be used by superficial and impregnation application for preventive treatment and by superficial and injection application for curative treatment, both in softwoods.
Uses classes 2 and 3 can be accepted in basidiomycete fungi for superficial and impregnation treatments, and for blue stain fungi for superficial treatment. Only Use Class 2 is authorized due to environmental risk.

- Superficial Preventive application: 200 g of product per m^2 of wood.
- Impregnation Preventive application: 53.45 g of product per m^3 of wood.
- Superficial Curative application: 300 ml of product per m^2 of wood.
- Injection method (via filling of fligh holes). Curative application: 300 mL of product per m^2 of wood (0.4-0.5 mL/hole, 5-7 times).
- Injection method (via pressure injection). Curative application: 50 kg of product per m^3 of wood.

Human health:

In vivo studies of acute oral, dermal and inhalation toxicity, eye and skin irritation and skin sensitisation have been submitted by the applicant according to OECD protocols. No human data are available. According to studies submitted, the biocidal product is not

classified for acute toxicity but it could cause skin irritation and an allergic skin reaction. For other toxicological aspects of the components of the product, information included in data sheets, in website of ECHA or other data base has been used. Low boiling point naphthas included in the composition have been considered as substances of concern (SoC) because some hazard assessment of the biocidal product are due to them and they are present in concentrations greater of 0.1%. In this sense, the biocidal product may cause drowsiness or dizziness and may be fatal if swallowed and enters airways.

Taking into account the Spanish definition of non-professionals and professionals[1] and the necessary PPE to obtain a situation of non-concern from the risk characterization of uses applied for[2], **no Xylazel Total uses for professionls are authorised**. However, professional users could be authorised outside Spain.

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

Summary table: scenarios		
Scenario number	**Scenario and Users (e.g. mixing/ loading)**	**Conclusion**
1.	Double Vacuum-pressure (preventive) Industrial user	A **safe** situation has been identified for industrial double vacuum pressure application of the product when PPEs, gloves and impermeable coverall (PF 90%), are worn**.**
2.	Automated dipping process (preventive) Industrial user	(1) Automated dipping process: A **safe** situation has been identified for industrial automated dipping application of the product when PPE, gloves, are worn.
3.	Automated spray application (preventive) Industrial user	A **safe** situation has been identified for industrial automated spraying application of product when PPE, gloves, are worn**.**
4.	Spray application (preventive and curative) Trained-	An **safe** situation has been identified for trained-professional spaying application of product when PPE, gloves, coated coverall (PF 95%) and mask P3, are

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

2 Spraying: protective chemical resistant gloves and coverall for mixing and loading, gloves, coated coverall (PF 5%), and mask (P3) for application, and gloves and impermeable coveralls (PF 10%) for cleaning spray equipment
Brushing: protective chemical resistant gloves and coverall for mixing and loading and gloves and coated coveralls (PF 5%) for brushing.

	Professional	worn**.**
5.	Brushing (preventive and curative) Trained-professional	A **safe** situation has been identified for trained professional brushing application of product when gloves and coated coverall (PF 95%), are worn.
5(2).	Brushing (preventive and curative) Non-professional	A safe situation has been identified for non-professional brushing application of product.
6.	Injection (preventive and curative) Trained-Professional	A **safe** situation has been identified for trained-professional injection application of product.
7.	Mixing and Loading Trained-professional	A **safe** situation has been identified for trained professional mixing and loading of product.
8.	Cleaning of brush equipment Trained-professional	A **safe** situation has been identified for trained professional cleaning brushes when **gloves** are worn.
9.	Cleaning spray equipment	A **safe** situation has been identified for trained professional cleaning spray equipment when **gloves** are worn.
10.	Cutting and sanding Professional	A **safe** situation has been identified for professional cutting and sanding treated wood.
11.	Cutting and sanding Non-professional	A **safe** situation has been identified for non-professional cutting and sanding treated wood.
12.	Chewing wood off-cut General public	A **safe** situation has been identified for toddler chewing treated wood chips.
13.	Playing on weathered structure and mouthing General public	A **safe** situation has been identified for toddler playing and mouthing on playground weathered wood structure outdoors preventively and curatively treated with the product.
14.	Inhalation residues indoors General public	A **safe** situation has been identified for general public inhaling volatilised residues indoors.
15.	Laundering contaminated work clothing at home General public	A **safe** situation has been identified for general public laundering contaminated work clothing.

Combined Scenarios:

Summary table: Combined scenarios		
Combined Scenario numbers	**Users and Scenarios (e.g. mixing/**	**Conclusion**

	loading)	
(1) + (7) + (15)	Industrials (Trained professionals) Automated double vacuum / M&L / Laundering work clothes	A **safe** situation has been identified for Industrials (Trained professionals) applying the product when gloves and impermeable coverall (PF 90%) for application and clothes and gloves for mixing and loading, are worn.
(2) + (7) + (15)	Industrials (Trained professionals) Automated dipping / M&L / Laundering work clothes	A **safe** situation has been identified for Industrials (Trained professionals) applying the product when gloves for application and clothes and gloves for mixing and loading, are worn.
(3) + (7) + (15)	Industrials (Trained professionals) Automated spraying / M&L / Laundering work clothes	A **safe** situation has been identified for Industrials (Trained professionals) applying the product when gloves for application and clothes and gloves for mixing and loading, are worn.
(4) + (7) + (9) + (15)	Industrials (Trained professionals) Trained professionals Spraying / M&L / Laundering work clothes / Cleaning spray equipment	A **safe** situation has been identified for Trained professionals applying the product when gloves, coated coverall (PF 95%) and mask P3 for application, clothes and gloves for mixing and loading and gloves and impermeable coveralls (PF 90%) for cleaning spray equipment are worn.
(5) + (7) + (8) + (15)	Trained professionals Brushing / M&L / Laundering work clothes / Cleaning brush equipment	A **safe** situation has been identified for Trained professionals applying the product when gloves and coated coverall (PF 95%) for application and clothes and gloves for mixing and loading, are worn.
(5)(2) + (7) + (8) + (15)	Non-professionals Brushing / M&L / Laundering clothes / Cleaning brush equipment	A **safe** situation has been identified for Non-professional applying the product.

Conclusion on environmental risk assessment

For preventive and curative treatment of wood classes 1 and 2, emissions are considered negligible. The risks for the application phase and service life are therefore acceptable for treatment of wood in classes 1 and 2.

For an outdoor application phase for wood in class 3, risks are unacceptable for emissions to the aquatic and terrestrial compartments whatever the type of treatment. Therefore, **the product cannot be authorized for wood in class 3**.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1. Administrative information

Identifier of the product

Identifier[3]	**Country (if relevant)**
XYLAZEL TOTAL	SPAIN

Authorisation holder

Name and address of the authorisation holder	**Name**	XYLAZEL, S.A.
	Address	Poligono Industrial de las Gándaras de Prado-Budiño 36400 – Porriño (Pontevedra)
Authorisation number	ES/APP(NA)-2021-08-00782	
Date of the authorisation	03/11/2021	
Expiry date of the authorisation	31/05/2025	

Manufacturer(s) of the product

Name of manufacturer	AKZO NOBEL COATINGS, S.L.
Address of manufacturer	Poligono Industrial de las Gándaras de Prado-Budiño 36400 – Porriño (Pontevedra)
Location of manufacturing sites	Poligono Industrial de las Gándaras de Prado-Budiño 36400 – Porriño (Pontevedra)

Manufacturer(s) of the active substance(s)

Active substance	**Cypermethrin**
Name of manufacturer	Arysta LifeScience Benelux SPRL
Address of manufacturer	Rue Renory 26 1 BE 4102 Ougree Bélgica
Location of manufacturing sites 1	Gharda Chemical Limited, Plant location: D, 1/2/ MIDC Lote Parshuram Tal. Khed Dist. Ratnagiri, 415 722, Maharashtra, India.
Location of manufacturing sites 2	Dr Reddys Laboratories Limited Plant location: Steanard Lane, Mirfield, West Yorkshire, WF14 8HZ,

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

	UK.
Active substance	**Tebuconazole**
Name of manufacturer	LANXESS Deutschland GmbH
Address of manufacturer	Kennedyplatz 1 50569 Köln Germany
Location of manufacturing sites	Bayer CropScience Corp. P.O. Box 4913 Hawthorn Road, Kansas City MO 64120-001 United States.
Active substance	**3-iodo-2-propynyl carbamate (IPBC)**
Name of manufacturer	Troy Chemical Company BV
Address of manufacturer	Uiverlaan 12e 3145 XN Maassluis Netherlands
Location of manufacturing sites 1	One Avenue L, Newark, 07105 New Jersey United States
Location of manufacturing sites 2	Industriepark 23, 56593, Horhausen Germany
Active substance	**Propiconazole**
Name of manufacturer	LANXESS Deutschland GmbH
Address of manufacturer	Kennedyplatz 1 50569 Köln Germany
Location of manufacturing sites 1	Syngenta Crop Protection AG CH-4002 Basel, Switzerland Plant location: CH-1870 Monthey Switzerland
Location of manufacturing sites 2	Jiangsu Yangnong Chemical Group Co., Ltd Plant location: Wenfeng Road, Yangzhou, Jiangsu 225009, P.R. China
Location of manufacturing sites 3	Jiangsu SevenContinent Green Chemical Co., Ltd Plant location: North Area of Dongsha Chem-Zone, Zhanjiagang, Jiangsu, 215600, P.R. China

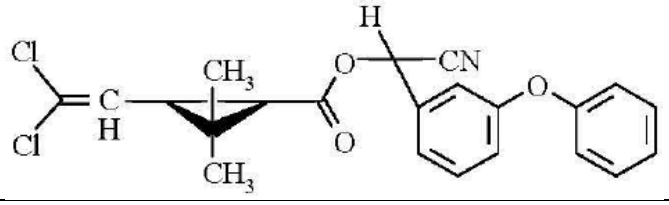
2.1.2. Product composition and formulation

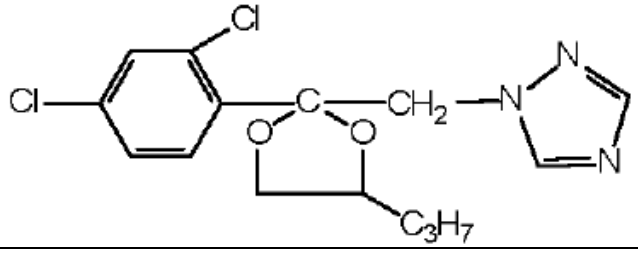
NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

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

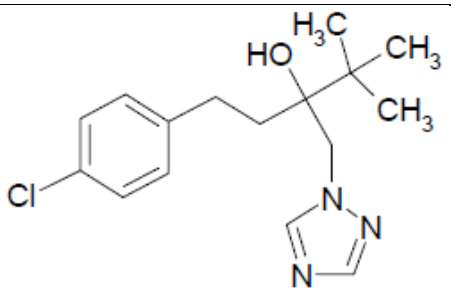
Yes ☐
No X

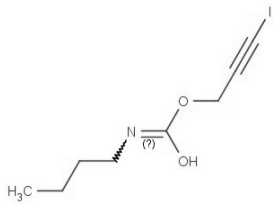
2.1.2.1. Identity of the active substance

Main constituent(s)	
ISO name	Cypermethrin cis/trans; 40/60
IUPAC or EC name	(RS)-α-cyano-3phenoxybenzyl-(1RS)- cis,trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate
EC number	257-842-9
CAS number	52315-07-8, 67375-30-8
Index number in Annex VI of CLP	607-422-00-X
Minimum purity / content	920 g/kg
Structural formula	

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

Main constituent(s)	
ISO name	Tebuconazole
IUPAC or EC name	1-(4-chlorophenyl)-4,4-dimethyl-3-(1,2,4-triazol-1-ylmethyl)pentan-3-ol
EC number	403-640-2

CAS number	107534-96-3
Index number in Annex VI of CLP	603-197-00-7
Minimum purity / content	950 g/kg
Structural formula	

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

2.1.2.2. Candidate(s) for substitution

IPBC, cypermethrin and propiconazole are not PBT candidates.
Annex I Assessment Report for tebuconazole, PT8 states that tebuconazole is considered to be very persistent (vP) and toxic (T) but not bioaccumulative. In conclusion, tebuconazole shall be considered a candidate for substitution using the criteria in Article 10(1).
Under Article 23(1) of Regulation 528/2012 Member States are required to perform a comparative assessment for biocidal products containing an active substance that is a candidate for substitution in accordance with Article 10(1). Please report to the relevant section (2.2.9).

2.1.2.3. Qualitative and quantitative information on the composition of the biocidal product[4]

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Cypermethrin	(RS)-α-cyano-3phenoxybenzyl-(1RS)- cis,trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate	Active Substance	52315-07-8	257-842-9	0.15
Propiconazole	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole	Active Substance	60207-90-1	262-104-4	0.175
Tebuconazole	1-(4-chlorophenyl)-4,4-dimethyl-3-(1,2,4-triazol-1-ylmethyl)pentan-3-ol	Active Substance	107534-96-3	403-640-2	0.175
IPBC	3-iodo-2-propynyl butylcarbamate	Active Substance	55406-53-6	259-627-5	0.60
Solvent naphtha (petroleum), light arom.	Hydrocarbons, C9 aromatics	Solvent	64742-95-6	919-668-5 (Provisional) 265-199-0	13
Naphtha (petroleum), hydrotreated heavy	Hydrocarbons, C10-C13, n-alcanes, cyclical, isoalkanes, <2% aromatics	Solvent	64742-48-9	918-481-9 (Provisional) 265-150-33	72-73

2.1.2.4. Information on technical equivalence

Location of manufacturing sites 2 of active substance Propiconazole:

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. Please note that this is not an ECHA Asset number as given when the process has been handled within R4BP, but it serves the same purpose.

Location of manufacturing sites 3 of active substance Propiconazole: The decision for the technical equivalence is recorded by ECHA under TAP-D-1182636-27-00/F, asset number: EU-0013032-0000, dated February 2016.

4 Please delete as appropriate.

2.1.2.5. Information on the substance(s) of concern

Two substances of the biocidal product has been considered as substances of concern (SoC) because they contribute to the classification of the product.

Please see the confidential annex for further details.

2.1.2.6. Type of formulation

Liquid (ready to use)

2.1.3. Hazard and precautionary statements5

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

Classification	
GHS Pictogram	Danger  GHS08  GHS07  GHS02  GHS09
Hazard category	Flam. Liq. 3 Skin Irrit. 2 Skin Sens. 1B Asp. Tox. 1 STOT-RE 3 Aquatic Acute 1;Aquatic Chronic 1

5 For micro-organisms based products: indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC (Biological Agents at Work).

Hazard statement	H226: Flammable liquid and vapour H315: Causes skin irritation H317: May cause an allergic skin reaction H304 May be fatal if swallowed and enters airways H336 May cause drowsiness or dizziness H400 Very toxic to aquatic life H410 Very toxic to aquatic life with long lasting effects
Labelling	
Signal words	Danger, Warning
Hazard statements	H226 Flammable liquid and vapour H315 Causes skin irritation H317 May cause an allergic skin reaction H304 May be fatal if swallowed and enters airways H336 May cause drowsiness or dizziness H410:Very toxic to aquatic life with long lasting effects
Precautionary statements	P210 Keep away from heat, hot surface, sparks, open flames and other ignition sources. No smoking P233 Keep container tightly closed P261 Avoid breathing dust/fume/gas/mist/vapours/spray P264 Wash … thoroughly after handling. P271 Use only outdoors or in well-ventilated area. P273: avoid release to the environment. P280 Wear protective gloves/protective clothing/eye protection/face protection. P303+P361+P353 IF ON SKIN (or hair) Take off immediately all contaminated clothing. Rinse skin with water. P370+P378 In case of fire: Use ABC powder to extinguish P362+P364 Take off contaminated clothing and wash it before reuse. P391: collect spillage P403 + P233 Store in a well-ventilated place. Keep container tightly closed. P405 Store locked up <u>Trained professionals</u> P501: Dipose of contents/container as hazardous waste to a registered establishment or undertaking, in accordance with current regulations. <u>Non-professionals</u> P501 Dispose of content and / or its container as hazardous waste according to the regulations in force.
Note Additional statements	EUH 208 Contains “propiconazol”. May produce an allergic reaction.

2.1.4. Authorised uses

2.1.4.1. Use description 1

Table 1. Preventive - Superficial application (automated dipping and automated spraying) - Industrial (Trained professional) users.

Product Type	PT08- Wood preservatives

Where relevant, an exact description of the authorised use	Xylazel Total is a solvent based wood protection product, for the preventive protection for transformed wood, used in joinery, furniture and woodwork to prevent the action of wood destroying basidiomycete and blue stain fungi that cause wood decay. Wood protection product for use class 2 according to the European standard EN 335 and EN 599.
Target organism (including development stage)	Wood rotting basidiomycetes: *Coniophora puteana* *Gloeophyllum trabeum* *Poria placenta* Blue stain: *Aureobasidium pullullans.* *Sclerophoma pithyophila*
Field of use	Indoor. Use class 2.
Application method(s)	Surface application method: Closed system: automated dipping or automated spraying treatment.
Application rate(s) and frequency	Surface treatment dose: 200 g/m^2.
Categories of users	Industrial *Only in ES:* *Industrial (Trained professional).*
Pack sizes and packaging material	Can/Tin-Metal: 0.375, 0.750, 2.5, 4, 5, 25 l. Drum-Metal: 200 l. IBC (intermediate bulk container)-Plastic HDPE: 1000 l.

2.1.4.1.1. Use-specific instructions for use

Please refer to section 2.1.5.1

2.1.4.1.2. Use-specific risk mitigation measures

Wear protective chemical resistant gloves and coverall for mixing and loading and protective chemical resistant gloves for application (gloves and coverall material to be specified by the authorisation holder within the product information).

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

Please refer to section 2.1.5.3

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

Please refer to section 2.1.5.4

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

Please refer to section 2.1.5.5

2.1.4.2. Use description 2

Table 2. Preventive - Superficial application (Spraying) - Industrial (Trained professional) users.

Product Type	PT08- Wood preservatives
Where relevant, an exact description of the authorised use	Xylazel Total is a solvent based wood protection product, for the preventive protection for transformed wood, used in joinery, furniture and woodwork to prevent the action of wood destroying basidiomycete and blue stain fungi that cause wood decay. Wood protection product for use class 2 according to the European standard EN 335 and EN 599.
Target organism (including development stage)	Wood rotting basidiomycetes: *Coniophora puteana* *Gloeophyllum trabeum* *Poria placenta* Blue stain: *Aureobasidium pullullans* *Sclerophoma pithyophila*
Field of use	Indoor. Use class 2.
Application method(s)	Spraying treatment.
Application rate(s) and frequency	Surface treatment dose: 200 g/m^2.
Categories of users	Industrial *Only in ES:* Industrial (Trained professionals).
Pack sizes and packaging material	Can/Tin-Metal: 0.375, 0.750, 2.5, 4, 5, 25 l. Drum-Metal: 200 l. IBC (intermediate bulk container)-Plastic HDPE: 1000 l.

2.1.4.2.1. Use-specific instructions for use

Please refer to section 2.1.5.1

2.1.4.2.2. Use-specific risk mitigation measures

Wear protective chemical resistant gloves and coverall for mixing and loading and gloves, coated coverall (PF 95%), and mask (P3) for application, and gloves and impermeable coveralls (PF 90%) for cleaning spray equipment (gloves, coverall and mask material to be specified by the authorisation holder within the product information).

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

Please refer to section 2.1.5.3.

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

Please refer to section 2.1.5.4.

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

Please refer to section 2.1.5.5.

2.1.4.3. Use description 3

Table 3. Preventive - Pressure process (automated double vacuum) - Industrial (Trained professional) users.

Product Type	PT08- Wood preservatives
Where relevant, an exact description of the authorised use	Xylazel Total is a solvent based wood protection product, for the preventive protection for transformed wood, used in joinery, furniture and woodwork to prevent the action of wood destroying basidiomycete fungi that cause wood decay. Wood protection product for use class 2 according to the European standard EN 335 and EN 599.
Target organism (including development stage)	Wood rotting basidiomicetes: *Coniophora puteana* *Gloeophyllum trabeum* *Poria placenta*
Field of use	Indoor. Use class 2
Application method(s)	Vacuum pressure or double vacuum autoclave impregnation.
Application rate(s) and frequency	Impregnation treatment dose: 53.45 Kg/m^3
Category(ies) of users	Industrial *Only in ES:* Industrial (Trained professionals)
Pack sizes and packaging material	Can/Tin-Metal: 0.375, 0.750, 2.5, 4, 5, 25 l. Drum-Metal: 200 l. IBC (intermediate bulk container)-Plastic HDPE: 1000 l.

2.1.4.3.1. Use-specific instructions for use

Please refer to section 2.1.5.1

2.1.4.3.2. Use-specific risk mitigation measures

Wear protective chemical resistant gloves and coverall for mixing and loading and protective chemical resistant gloves and impermeable coverall (FP 90%) for application (gloves and coverall material to be specified by the authorisation holder within the product information).

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

Please refer to section 2.1.5.3.

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

Please refer to section 2.1.5.4.

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

Please refer to section 2.1.5.5.

2.1.4.4. Use description 4

Table 4. Preventive – Superficial application (Spraying) - Trained professionals users.

Product Type	PT08- Wood preservatives
Where relevant, an exact description of the authorised use	Xylazel Total is a solvent based wood protection product, for the preventive protection for transformed wood, used in joinery, furniture and woodwork to prevent the action of wood destroying basidiomycete and blue stain fungi that cause wood decay. Wood protection product for use class 2 according to the European standard EN 335 and EN 599.
Target organism (including development stage)	Wood rotting basidiomycetes: *Coniophora puteana* *Gloeophyllum trabeum* *Poria placenta* Blue stain. *Aureobasidium pullullans* *Sclerophoma pithyophila*
Field of use	Indoor. Use class 2.

Application method(s)	Spraying treatment.
Application rate(s) and frequency	Surface treatment dose: 200 g/m^2.
Category(ies) of users	Professionals Trained professional. *Only in ES:* Trained professionals.
Pack sizes and packaging material	Can/Tin-Metal: 0.375, 0.750, 2.5, 4, 5, 25 l. Drum-Metal: 200 l. IBC (intermediate bulk container)-Plastic HDPE: 1000 l.

2.1.4.4.1. Use-specific instructions for use

Please refer to section 2.1.5.1

2.1.4.4.2. Use-specific risk mitigation measures

Wear protective chemical resistant gloves and coverall for mixing and loading, gloves, coated coverall (PF 95%), and mask (P3) for application, and gloves and impermeable coveralls (PF 90%) for cleaning spray equipment (gloves, coverall and mask material to be specified by the authorisation holder within the product information).

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

Please refer to section 2.1.5.3.

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

Please refer to section 2.1.5.4.

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

Please refer to section 2.1.5.5.

2.1.4.5. Use description 5

Table 5. Preventive – Superficial application (Brushing) - Trained professional users.

Product Type	PT08- Wood preservatives
Where relevant, an exact description of	Xylazel Total is a solvent based wood protection product, for the preventive protection for transformed wood, used in

the authorised use	joinery, furniture and woodwork to prevent the action of wood destroying basidiomycete and blue stain fungi that cause wood decay. Wood protection product for use class 2 according to the European standard EN 335 and EN 599.
Target organism (including development stage)	Wood rotting basidiomycetes: *Coniophora puteana* *Gloeophyllum trabeum* *Poria placenta* Blue stain. *Aureobasidium pullullans* *Sclerophoma pithyophila*
Field of use	Indoor. Use class 2.
Application method(s)	Brushing treatment.
Application rate(s) and frequency	Surface treatment dose: 200 g/m^2.
Category(ies) of users	Professionals Trained professional. *Only in ES:* Trained professional.
Pack sizes and packaging material	Can/Tin-Metal: 0.375, 0.750, 2.5, 4, 5, 25 l. Drum-Metal: 200 l. IBC (intermediate bulk container)-Plastic HDPE: 1000 l.

2.1.4.5.1. Use-specific instructions for use

Please refer to section 2.1.5.1

2.1.4.5.2. Use-specific risk mitigation measures

Wear protective chemical resistant gloves and coverall for mixing and loading and gloves and coated coveralls (PF 95%) for brushing (gloves, coverall and mask material to be specified by the authorisation holder within the product information).

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

Please refer to section 2.1.5.3.

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

Please refer to section 2.1.5.4.

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

Please refer to section 2.1.5.5.

2.1.4.6. Use description 6

Table 6. Preventive– Superficial application (Brushing) – Non-professional users.

Product Type	PT08- Wood preservatives
Where relevant, an exact description of the authorised use	Xylazel Total is a solvent based wood protection product, for the preventive protection for transformed wood, used in joinery, furniture and woodwork to prevent the action of wood destroying basidiomycete and blue stain fungi that cause wood decay. Wood protection product for use class 2 according to the European standard EN 335 and EN 599.
Target organism (including development stage)	Wood rotting basidiomycetes: *Coniophora puteana* *Gloeophyllum trabeum* *Poria placenta* Blue stain. *Aureobasidium pullullans* *Sclerophoma pithyophila*
Field of use	Indoor. Use class 2.
Application method(s)	Brushing treatment.
Application rate(s) and frequency	Surface treatment dose: 200 g/m^2.
Category(ies) of users	Non-Professionals
Pack sizes and packaging material	Can/Tin-Metal: 0.375, 0.750l.

2.1.4.6.1. Use-specific instructions for use

Please refer to section 2.1.5.1.

2.1.4.6.2. Use-specific risk mitigation measures

Please refer to section 2.1.5.2.

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

Please refer to section 2.1.5.3.

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

Please refer to section 2.1.5.4.

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

Please refer to section 2.1.5.5.

2.1.4.7. Use description 7

Table 7. Curative– Superficial application (Brushing) – Non-professional users.

Product Type	PT08- Wood preservatives
Where relevant, an exact description of the authorised use	Xylazel Total is a solvent based wood protection product, for the curative protection for transformed wood, used in joinery, furniture and woodwork to prevent the action of wood destroying wood boring beetles that cause wood decay. Wood protection product for use class 2 according to the European standard EN 335 and EN 599.
Target organism (including development stage)	Wood boring beetles. (*Hylotrupes bajulus*)
Field of use	Indoor.
Application method	Brushing treatment.
Application rate and frequency	Surface treatment dose: 300ml/m^2.
Category of users	Non-Professionals
Pack sizes and packaging material	Can/Tin-Metal: 0.375, 0.750l.

2.1.4.7.1. Use-specific instructions for use

Please refer to section 2.1.5.1.

2.1.4.7.2. Use-specific risk mitigation measures

Please refer to section 2.1.5.2.

2.1.4.7.3. 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 2.1.5.3.

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

Please refer to section 2.1.5.4.

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

Please refer to section 2.1.5.5.

2.1.4.8. Use description 8

Table 8. Curative – Superficial application (Brushing) – Trained professional users.

Product Type	PT08- Wood preservatives
Where relevant, an exact description of the authorised use	Xylazel Total is a solvent based wood protection product, for the curative protection for transformed wood, used in joinery, furniture and woodwork to prevent the action of Wood boring beetles, common furniture beetle and larvae. Wood protection product according to the European standard EN 14128.
Target organism (including development stage)	Wood boring beetles. *Hylotrupes bajulus:* House longhorn beetle, larvae.
Field of use	Indoor
Application method(s)	Brushing treatment
Application rate(s) and frequency	300 mL/m^2 for curative treatment
Category(ies) of users	Professionals Trained professionals *Only in ES:* Trained professional.
Pack sizes and packaging material	Can/Tin-Metal: 0.357, 0.750, 2.5, 4, 5, 25 l. Drum-Metal: 200 l. IBC (intermediate bulk container)-Plastic HDPE: 1000 l.

2.1.4.8.1. Use-specific instructions for use

The product has a fast action of 12 weeks.

2.1.4.8.2. Use-specific risk mitigation measures

Wear protective chemical resistant gloves and coverall for mixing and loading and gloves and coated coveralls (PF 95%) for brushing (gloves, coverall and mask material to be specified by the authorisation holder within the product information).

2.1.4.8.3. 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 2.1.5.3.

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

Please refer to section 2.1.5.4.

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

Please refer to section 2.1.5.5.

2.1.4.9. Use description 9

Table 9. Curative *Anobium punctatum De Geer* - Injection -Trained professional users.

Product Type	PT08- Wood preservatives
Where relevant, an exact description of the authorised use	Xylazel Total is a solvent based wood protection product for the curative protection for transformed wood used in joinery, furniture and woodwork to prevent the action of *Anobium punctatum De Geer*, common furniture beetle and larvae. Wood protection product according to the European standard EN 14128
Target organism (including development stage)	*Anobium punctatum De Geer*: Common furniture beetle, larvae
Field of use	Indoor
Application method(s)	Injection application via filling of fligh holes.
Application rate(s) and frequency	300 ml/m^2 for curative treatments. 0.4-0.5 mL/hole, 5-7 times.
Category(ies) of users	Professionals Trained professional. *Only in ES:* Trained professional.
Pack sizes and packaging material	Can/Tin-Metal: 0.375, 0.750, 2.5, 4, 5, 25 l Drum-Metal: 200 l. IBC (intermediate bulk container)-Plastic HDPE: 1000 l.

2.1.4.9.1. Use-specific instructions for use

The application by injection into flight holes is intended to treat old furniture attacked

by wood boring insects that are painted or varnished, and therefore a surface treatment is not effective.

- Filling of flight holes 5 to 7 times resulting in approx. 0.4 to 0.5 mL (up to 295 mL/m^2).
- The application rate is not restricted to the number of holes.
- The curative treatment only for *Anobium punctatum* with the method of injection via filling of fligh holes has a dose of **300 mL/m^2**.

2.1.4.9.2. Use-specific risk mitigation measures

Wear protective chemical resistant gloves for application (gloves material to be specified by the authorisation holder within the product information).

2.1.4.9.3. 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 2.1.5.3.

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

Please refer to section 2.1.5.4.

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

Please refer to section 2.1.5.5.

2.1.4.10. Use description 10

Table 10. Curative *Hylotrupes bajulus* - Injection - Trained professional users.

Product Type	PT08- Wood preservatives
Where relevant, an exact description of the authorised use	Xylazel Total is a solvent based wood protection product, for the curative protection for transformed wood used in joinery, furniture and woodwork to prevent the action of *Hylotrupes bajulus,* common furniture beetle and larvae. Wood protection product according to the European standard EN 14128
Target organism (including development stage)	*Hylotrupes bajulus*: House longhorn beetle, larvae.
Field of use	Indoor
Application method(s)	Injection application via pressure injection.
Application rate(s) and	50 Kg/m^3

frequency	
Category(ies) of users	Professionals Trained professional. *Only in ES:* Trained professional.
Pack sizes and packaging material	Can/Tin-Metal: 0.375, 0.750, 2.5, 4, 5, 25 l. Drum-Metal: 200 l. IBC (intermediate bulk container)-Plastic HDPE: 1000 l.

2.1.4.10.1. Use-specific instructions for use

Injection application.
Pressure injection is only intended for structural timbers with a thickness greater than 7.5 cm.

The injections must be made in the place where the wood is built-in, and they must be in two lines and directed towards the masonry, as close as possible to it, as well as in any pieces of wood in contact with the walls.

Holes should be drilled in staggered rows on the facing or in line with the edges. The distance between two holes must be no more than 30 cm (15 cm between the holes above and below).

The holes must be drilled at 2/3 the thickness or height of the timber and have a diameter of 9.5 mm. The drills must not leave more than 60 mm at the bottom of the wells.

For pieces of wood thicker than 20 cm where half the perimeter is greater than 30 cm, the wood must be drilled on both sides (double-injection) to ensure that the liquid has better access to the insects and that the wooden structure does not weaken. Holes should be drilled also in staggered rows at a distance of 30 cm.

The holes from one side should be done contrary from the other side, so that they do not coincide in height. If one is up the other must be down and vice versa.

The depth of the holes is half the thickness of the piece of wood and have a diameter of 9.5 mm. It is not necessary to drill the duramen.

Therefore, in 1 m^3 (o 10^6 cm^3), 50Kg of product must be included to be able to support de curative efficacy.

Each hole should be filled with an approximate amount of 206 g of product.

2.1.4.10.2. Use-specific risk mitigation measures

Wear protective chemical resistant gloves for application (gloves material to be specified by the authorisation holder within the product information).

2.1.4.10.3. 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 2.1.5.3.

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

Please refer to section 2.1.5.4.

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

Please refer to section 2.1.5.5.

2.1.5. General directions for use

2.1.5.1. Instructions for use

Read attached instructions before use. It must not be mixed with other chemical products. It can not be applied to wood intended to be in contact with food. The labelling of the product shall be including the sentence: Use biocides safely. Always read the label and product information before use. Aerate adequately the place where the product is applied. Product can be used to treat soft woods.

2.1.5.2. Risk mitigation measures

Impregnated wood must not be in contact with food or feedstuffs. Can be harmful to protected species such as bats, hornets or birds. The presence of protected species in the area to be treated must be assessed prior to use of the product. Appropriate protective measures must be taken if necessary.

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

• <u>Likely direct or indirect adverse effects:</u> **IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. If symptoms: Call 112/ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor.** After inhalation of substances that could cause irritation/breathing difficulties, it is important to keep the person at rest because extensive body labour could make the symptoms more severe. Many persons promptly experience serious breathing difficulties and need medical assistance on their way to the hospital. It is important to call a poison centre or a doctor even if no initial symptoms occur because there may be delayed pronounced symptoms, sometimes without initial indications. **IF SWALLOWED: Rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call a POISON CENTRE or a doctor.**

To decrease symptoms, rinsing of the mouth. The type of drink is not specified as it is of lower importance than having something to drink.

IF ON SKIN: Take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation occurs: Get medical advice.
The applicant can add soap for skin decontamination in relevant cases if the product is less water soluble. If irritation occurs the skin should be washed and medical advice should be sought.

IF IN EYES: Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing for 15 minutes. Call a POISON CENTRE or a doctor.

- First aid measures:

  - Relocate the individual from the exposure source and remove any contaminated/spattered clothing articles, avoiding exposure to yourself and others.
  - Keep the individual calm and at rest, conserve body temperature and control breathing. If necessary, check for pulse and initiate artificial respiration
  - If unconscious; place individual in left sideways position with the head lowered and the knees bent
  - If necessary take the person to a healthcare center, bring packaging or label whenever possible

NEVER LEAVE THE AFFECTED INDIVIDUAL UNATTENDED

- Advice for medical and healthcare personnel:

  - Monitor vital signs and provide symptomatic and supportive treatment.

WHEN ASKING FOR MEDICAL ADVICE KEEP PACKAGING OR LABEL AT HAND AND CALL YOUR LOCAL POISON CONTROL CENTER ☎ **[*INSERT LOCAL NUMBER HERE*]**.

2.1.5.4. Instructions for safe disposal of the product and its packaging

Trained professionals
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 to Decision 2014/955 / EU.
Do not release to soil, ground, surface water or any kind of sewer

Non-professionals
Empty containers, unused product and other waste generated during the treatment are considered hazardous waste. Dispose of in accordance with current regulations.

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

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

Store the product between 5°C and 30°C. Avoid sources of heat, radiation and static electricity. Keep the container closed. Shelf-life: 2 years

2.1.6. Other information

Packaging of product supplied to the general public shall be fitted with child-resistant fastenings and a tactile warning of danger. Definitions: Industrial (Trained professionals) and Trained professionals: pest control operators, having received specific training in management of biocidal products according to the national legislation in force. General public (non-professional user): Users who are not professionals and who apply the product in the context of their private life.

2.1.7. Packaging of the biocidal product

Type of packaging	**Size/volume of the packaging**	**Material of the packaging**	**Type and material of closure(s)**	**Intended user (e.g. professional, non-professional)**	**Compatibility of the product with the proposed packaging materials (Yes/No)**
Can/Tin	0,375 l	Metal	With child-resistant fastening	Industrial (Trained Professionals) Non-professional (general public)	Yes
Can/Tin	0,750 l	Metal	With child-resistant fastening	Industrial (Trained Professionals) Non- porfessional (general public)	Yes
Can/Tin	2,5 l	Metal	With child-resistant fastening	Industrial (Trained Professionals)	Yes
Can/Tin	4 l	Metal	With child-resistant fastening	Industrial (Trained Professionals)	Yes
Can/Tin	5l	Metal	With child-resistant fastening	Industrial (Trained Professionals)	Yes
Can/Tin	25 l	Metal	With child-resistant fastening	Industrial (Trained Professionals)	Yes
Drum	200 l	Metal	Safety closure	Industrial (Trained Professionals)	Yes
IBC	1000 l	Plastic:	Safety	Industrial (Trained Professionals)	Yes

(intermediate bulk container)		HDPE	closure		

* Bearing in mind that the 1000 l package is usually reused in short periods of time, it is necessary to take into account the shelf life of the packaging specified by the manufacturer.

2.1.8. Documentation

2.1.8.1. Data submitted in relation to product application

Toxicological studies about acute toxicity, eye and skin irritation and skin sensitisation were submitted with the biocidal product.

2.1.8.2. Access to documentation

The applicant has submitted four letter of access to the dossier of the active substances:
-Cypermethrin: a letter of access from Agriphar group (now Arysta LifeScience Benelux).
-Tebuconazole: a letter of access from LANXESS Deutschland GmbH.
-IPBC: a letter of access from Troy Chemical Company BV.
-Propiconazole: a letter of access from LANXESS Deutschland GmbH.

2.2. Assessment of the biocidal product

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

Table 2. Use # 1 – Use class 1

Product Type	PT8
Where relevant, an exact description of the authorised use	Xylazel Total is a solvent based wood protection product, for the preventive and curative protection for transformed wood used in joinery, furniture and woodwork to prevent the action of termites and wood-boring beetles like Hylotrupes Bajulus, and different Anobium and Lyctus species. Wood protection product for use class 1 according to the European standard EN 335 and EN 599.
Target organism (including development stage)	Anobium punctatum De Geer: Common furniture beetle, Larvae Hylotrupes bajulus L.: House longhorn beetle, Larvae Lyctus brunneus: Powder post beetles, Larvae Reticulitermes sp.: Termites, Adults
Field of use	Indoor
Application method(s)	Brush treatment, injection, spraying double vacuum autoclave impregnation and dip treatment
Application rate(s) and frequency	200 mL per square meter for preventive treatments and 300 mL per square meter for curative treatments.
Category(ies) of users	Trained professional, Industrial, Professional and General public (non-professional)
Pack sizes and packaging material	Can /Tin-Metal:0.375, 0.750, 2.5, 4, 5, 25 L Drum-Metal:200 L IBC (intermediate bulk container)-Plastic HDPE: 1000 L

Table 2. Use # 2 – Use class 2

Product Type	PT08 - Wood preservatives (Preservatives)
Where relevant, an exact description of the authorised use	Xylazel Total is a solvent based wood protection product, for the preventive and curative protection for transformed wood used in joinery, furniture and woodwork to prevent the action of basidiomycete fungi that cause wood decay, blue stain fungi, termites and wood-boring beetles like Hylotrupes Bajulus, and different Anobium and Lyctus species. Wood protection product for use class 2 according to the European standard EN 335 and EN 599.
Target organism (including development stage)	Anobium punctatum De Geer: Common furniture beetle, Larvae Hylotrupes bajulus L.: House longhorn beetle, Larvae Lyctus brunneus: Powder post beetles, Larvae Reticulitermes sp.: Termites, Adults Basidiomycetes: Wood rotting fungi, Hyphae Blue stain fungi: Blue stain fungi, Hyphae
Field of use	Indoor
Application method(s)	Brush treatment, spraying double vacuum autoclave impregnation and dip treatment
Application rate(s) and frequency	114 mL per square meter for treatment against wood rotting basidiomycetes. 200 mL per square meter for preventive treatments against insects and blue stain. 300 mL per square meter for curative treatments.
Category(ies) of users	Trained professional, Industrial, Professional and General public (non-professional)
Pack sizes and packaging material	Can /Tin-Metal:0.375, 0.750, 2.5, 4, 5, 25 L Drum-Metal:200 L IBC (intermediate bulk container)-Plastic HDPE: 1000 L

Table 3. Use # 3 – Use class 3

Product Type	PT8
Where relevant, an exact description of the authorised use	Xylazel Total is a solvent based wood protection product, for the preventive and curative protection for transformed wood used in joinery, furniture and woodwork to prevent the action of basidiomycete fungi that cause wood decay, blue stain fungi, termites and wood-boring beetles like Hylotrupes Bajulus, and different Anobium and Lyctus species. Wood protection product for use class 3 according to the European standard EN 335 and EN 599.
Target organism (including development stage)	Anobium punctatum De Geer: Common furniture beetle, Larvae Hylotrupes bajulus L.: House longhorn beetle, Larvae Lyctus brunneus: Powder post beetles, Larvae Reticulitermes sp.: Termites, Adults Basidiomycetes: Wood rotting fungi, Hyphae Blue stain fungi: Blue stain fungi, Hyphae
Field of use	Outdoor

Application method(s)	Brush treatment, spraying double vacuum autoclave impregnation and dip treatment
Application rate(s) and frequency	57 kg per cubic meter for treatment against wood rotting basidiomycetes. 200 mL per square meter for preventive treatments against blue stain and termites.
Category(ies) of users	Trained professional, Industrial, Professional and General public (non-professional)
Pack sizes and packaging material	Can /Tin-Metal:0.375, 0.750, 2.5, 4, 5, 25 L Drum-Metal:200 L IBC (intermediate bulk container)-Plastic HDPE: 1000 L

2.2.2. Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa		100 % Xylazel Total	Liquid	IUCLID 3.1
Colour at 20 °C and 101.3 kPa		100 % Xylazel Total	Light yellowish transparent liquid	IUCLID 3.1
Odour at 20 °C and 101.3 kPa		100 % Xylazel Total	During the application the product has an odour to solvent. After drying the product does not smell	IUCLID 3.1
Acidity / alkalinity	Not applicable because it is a ready to use solvent based low viscous liquid that is immiscible in water.			IUCLID 3.2
Relative density / bulk density	Pycnometer method - OECD Guidaeline 109	100 % Xylazel Total	δ = 0.82 g/cm^3 (at 20°C)	Álvarez, R. 2015 – IUCLID 3.3
Storage stability test – **accelerated storage**	CIPAC MT 46.3	100 % Xylazel Total	Tª = 54°C Time: 14 days **IPBC** $[C]_0$ = 0.602% $[C]_F$ = 0.573% Δ[C] = -4.82% **Propiconazole** $[C]_0$ = 0.175% $[C]_F$ = 0.173% Δ[C] = -1.14% **Tebuconazole** $[C]_0$ = 0.175% $[C]_F$ = 0.172% Δ[C] = -1.71% **Cypermethrin**	Ruiz de Gauna, L. 2020

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			$[C]_0$ = 0.152% $[C]_F$ = 0.148% Δ[C] = -2.63% Appearance: after 14 days of storing at 54°C the colour of the liquid has tuned out from transparent to light yellow. Based on the results obtained it can be stated that the product is stable at this accelerated storage conditions.	
Storage stability test – **long term storage at ambient temperature**			Time: 4 years and 8 months at room temperature **Propiconazole** $[C]_0$ = 0.186% $[C]_f$ = 0.172% Δ[C] = -7.53% **Tebuconazole** $[C]_0$ = 0.176% $[C]_f$ = 0.169% Δ[C] = -3.98% **Cypermethrin** $[C]_0$ = 0.161% $[C]_f$ = 0.156% Δ[C] = -3.11% **IPBC** $[C]_0$ = 0.605% $[C]_f$ = 0.587% Δ[C] = -2.98% The results obtained fulfil the Guidance criteria (<10% degradation) Packaging evaluation: It has been evaluated the packaging of 750mL, 2.5L, 5L, 25L, 200L, 1000L*, before and after 2 years	Álvarez, R. 2020 Ruiz de Gauna, B. 2020 Alvarez, R. 2018

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			of storing and it can be stated that none of the packaging has suffered degradation, corrosion, loss of weight. Moreover, after this period of time the appearance of the biocidal product has no suffered any change neither. So it can be concluded that the packaging chosen is suitable for this biocidal product. * Bearing in mind that the 1000L packaging is usually reused in short periods of time, it is necessary to take into account the shelf life of the packaging specified by the manufacturer	
Storage stability test – **low temperature stability test for liquids**	The test has not been carried out because the recommended storage temperature range is from 5 to 30°C.			IUCLID 3.4.1
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Xylazel Total is commercialiced in closed and opaque metallic packages.			Alvarez, R. 2018
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Xylazel Total is commercialiced in closed and opaque metallic packages. Under normal storage conditions Xylazel Total is stable.			Alvarez, R. 2018
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	It has been demonstrated that after 2 years storage the packaging do not suffer any corrosion, degradation or loss of weight.			Alvarez, R. 2018
Wettability	Not applicable			
Suspensibility, spontaneity and dispersion stability	Not applicable			
Wet sieve analysis and	Not applicable			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
dry sieve test				
Emulsifiability, re-emulsifiability and emulsion stability	Not applicable			
Disintegration time	Not applicable			
Particle size distribution, content of dust/fines, attrition, friability	Not applicable			
Persistent foaming	Not applicable			
Flowability/Pourability/ Dustability	Not applicable			
Burning rate — smoke generators	Not relevant			
Burning completeness — smoke generators	Not applicable			
Composition of smoke — smoke generators	Not applicable			
Spraying pattern — aerosols	Not applicable			
Physical compatibility	The product is not intended to be used in conjunction with any other products or active substances.			
Chemical compatibility				
Degree of dissolution and dilution stability	Not applicable			
Surface tension	OECD 115 EEC A5	100 % Xylazel Total	ʊ = 26.9 mN/m (at 20°C) ʊ = 25.5 mN/m (at 25°C)	Margarit. L, 2018
Viscosity	OECD 114	100 % Xylazel Total	2.161 mm^2/s at 20°C 1.635 mm^2/s at 40°C	Serra i Hosta. E, 2015

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

Xylazel Total is a ready to use solvent based low viscous liquid that is immiscible in water. It is composed by a homogeneous solution of an alkyd resin, solvents and additivies. The product is a light yellowish transparent liquid. During the application it has an odour to solvent but after drying the product does not smell.

The solvents, more than 90% in the formulation, determine in major way the physical and chemical properties like density, viscosity, surface tension…

Regarding the stability, the long-term stability study shows suitable results which fulfil the Guidance criteria and therefore a shelf-life of 2 years can be granted.

Due to the fact that the low temperature storage test has not been carried out the biocidal product should be storage between 5°C and 30°C.

2.2.3. Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	None of the ingredients present in the biocidal product Xylazel Total have explosive properties. Therefore, testing is not deemed necessary.			
Flammable gases	Not applicable			
Flammable aerosols	Not applicable			
Oxidising gases	Not applicable			
Gases under pressure	Not applicable			
Flammable liquids	ASTM-56 (Tag Closed)	100 % Xylazel Total	Tª = 57.5°C Classification: H226	Álvarez.R, 2015
Flammable solids	Not applicable			
Self-reactive substances and mixtures	Not applicable			
Pyrophoric liquids	Not relevant as none of the individual ingredients have been identified or classified of having pyrophoric properties			
Pyrophoric solids	Not applicable			
Self-heating substances and mixtures	Not applicable			
Substances and mixtures which in contact with water emit flammable gases	Not applicable			
Oxidising liquids	None of the ingredients present in the biocidal product Xylazel Total are considered to have oxidising properties. Therefore, testing is not deemed necessary.			
Oxidising solids	Not applicable			
Organic peroxides	Not relevant because there are no organic compounds containing peroxide function in the biocidal product.			
Corrosive to metals	It can be expected that the product does not show corrosiveness to metals containers due to the lack of ingredient in its formulation that pose corrosiveness. Furthermore, the study carried out on the packaging shows that the metal containers do not suffer any degradation after 2 years of storing.			
Auto-ignition temperatures of products (liquids and gases)	Auto-ignition is not expected			
Relative self-ignition temperature for solids	Not applicable			
Dust explosion hazard	Not applicable			

Conclusion on the physical hazards and respective characteristics of the product
The product is not considered to be explosive, oxidizing, pyrophoric or corrosive. However, the flash point shows that the product is flammable and it has be classified as H226. The solvents, more than 90% in the formulation, determine in major way the flammability of Xylazel Total.

2.2.4. Methods for detection and identification

Analytical methods for the analysis of the product as such including the active substance, impurities and residues							
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Recovery rate (%)**		**Limit of quantification (LOQ) or other limits**	**Reference**
				Range	Mean		
IPBC	HPLC-UV	2; calibrated for the range from 0.16 mg/mL to 0.05 mg/mL (5 different concentrations)	R^2 = 0.9993	98.6% – 102.5 %	100.5 %	LOQ = 0.08 mg/mL LOD = 0.05 mg/mL	IUCLID 5
Propiconazole	GC-FID		R^2 = 0.996	99.9% - 101.4 %	100.6 %		
Tebuconazole	GC-FID		R^2 = 0.9992	99.4% - 101%	100.4 %		
Cypermethrin	GC-FID		R^2 = 0.999	100.4 % - 104.3 %	102.1 %		

If the product is found in diferent matrices (water, soil, air or animal/human body fluids) the quantification and detection of active substance contained in the biocidal product are made according to method described for each active substance. The dossier of Xylazel Total includes letter of access (LoA) for each active substance. So, the established procedure to determine active substances will be the registered method for each substance in the ECHA.
In normal conditions to use the biocidal product is not used in a manner that may cause contact with food, but if the product is in contact with food, the quantification and detection of active substances contained in the biocidal product are made according to method described for each active substance.

Conclusion on the methods for detection and identificationof the product
The methods described above proved to be suitable to determine IPBC, Propiconazole, Tebuconazole and Cypermethrine in the biocidal product Xylazel Total.

2.2.5. Efficacy against target organisms

2.2.5.1. Function and field of use

Xylazel Total is a solvent based wood preservative, for the preventive and curative protection for transformed wood used in joiner, furniture and woodwork, (constructional timber, joints, doors, windows, fences, burgles, etc.), used by an industrial or professional and non professional operators, to prevent the action of basidiomycete and blue stain fungi that cause wood decay and wood-boring beetles like *Hylotrupes Bajulus*, and *Anobium punctatum de Geer.* Wood protection product according to the European standard EN 335, EN 599 and EN 14128.

It is intended to be use by superficial and impregnation application for preventive treatment and by superficial and injection application for curative treatment.

- Superficial Preventive application: 200 grams of product per m^2 of wood.
- Impregnation Preventive application: 53.45 grams of product per m^3 of wood.
- Superficial Curative application: 300 ml of product per m^2 of wood.
- Injection method (via filling of fligh holes). Curative application: 300 mL of product per m^2 of wood (0.4-0.5 mL/hole, 5-7 times).
- Injection method (via pressure injection). Curative application: 50 kg of product per m^3 of wood.

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

XYLACEL TOTAL is a wood preservative with insecticidal and fungicidal properties against fungi species (i.e.; basidiomycetes, blue stain) and woodworm.

2.2.5.3. Effects on target organisms, including unacceptable suffering

Wood boring beetle larvae are killed after contact with treated wood.

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

2.2.5.4. Mode of action, including time delay

Cypermethrin is a synthetic pyrethroid that acts preventive against wood-boring beetles, like *Hylotrupes Bajulus*, and different *Anobium* and *Lyctus* species, and against termites. Its action is also creative against wood-boring beetles, like *Hylotrupes Bajulus*, and different *Anobium* and *Lyctus* species. This active substance acts by contact, preventing the transmission of impulses along the nervous system of the insect. It acts in sodium channels on the modulators of nerve action. Keep sodium channels open, causing hyperexcitation and , in some cases, nerve block. Sodium channels are involved in the propagation of action potentials along nerve axons.

Propiconazole and Tebuconazole are triazoles that acts in synergic way against wood rotting basidiomycetes. Triazoles inhibit the cytochrome P450 enzyme 14-α-sterol-demethylase. This enzyme is implicated in the biosynthetic pathway of ergosterol, which is an essential molecule of the fungal cell membrane.

IPBC has a carbamate structure. The target site of carbamates in fungi are cell membrane permeability and fatty acids. IPBC act against blue stain fungi. The mode of action of IPBC is not clearly known, but may be linked to iodine toxicity.

2.2.5.5. Efficacy data

Experimental data on the efficacy of the biocidal product against target organisms							
Test substance	**Field of use envisaged**	**Organisms to be protected**	**Test organisms**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
XYLAZEL TOTAL	Wood preservative Preventive treatment	*Pinus sylvestris*	House longhorn beetle: *Hylotrupes bajulus (L.)*	UNE 56402 (EN 46) +UNE 56406 (EN 73) (Evaporation) The standard was not in force in 2015	•Test system: Superficial application/ dipping treatment •Concentration applied: 100 % (w/w) • Exposure time: 77 days (deviation from the standard) • Solution retention: 201.56 g/m^2	>93% larvae were recovered dead without having made tunnels in the wood. Four larvae were not recovered. At least 70% of the larvae inserted in all untreated control specimens survive. The criterion for biological reference value (100% of mortality at end of the test) is not fulfilled)	Report Nº 11729.2 Report Nº 11729.2-1 (M1)
XYLAZEL TOTAL	Wood preservative Preventive treatment	*Pinus sylvestris*	House longhorn beetle: *Hylotrupes bajulus (L.)*	UNE 56402 (EN 46) + EN 84 (Leaching) The standard was not in force in 2015	•Test system: Superficial application/ dipping treatment •Concentration applied: 100 % (w/w) • Exposure time: 77 days (deviation from the standard) • Solution retention: 207.34 g/m^2	>96% larvae were recovered dead without having made tunnels in the wood. Two larvae were not recovered. At least 70% of the larvae inserted in all untreated control specimens survive. The criterion for biological reference value (100% of mortality at end of the test) is not fulfilled).	Report Nº 11729.2 Report Nº 11729.2-2 (M1)
XYLAZEL TRIPLE ANTITERMITES FORMULA 236/m306	Wood preservative Preventive treatment	*Pinus sylvestris*	House longhorn beetle: *Hylotrupes bajulus (L.)*	UNE 56402 (EN 46) +UNE 56406 (EN 73) (Evaporation) The standar was not in force in 2015	•Test system: Superficial application/ dipping treatment •Concentration applied: 100 % (w/w) • Exposure time: 60 days (deviation from the	100 % larvae were recovered dead without having made tunnels in the wood. At least 70% of the larvae inserted in all untreated control specimens survive.	Report Nº 8944.1 Report Nº 8944.1-3 (M1)

					standard) Solution retention: 200 g/m^2		
XYLAZEL TRIPLE ANTITERMITES FORMULA 236/m306	Wood preservative Preventive treatment	*Pinus sylvestris*	House longhorn beetle: *Hylotrupes bajulus (L.)*	UNE 56402 (EN 46) + EN 84 (Leaching) The standad was not in force in 2015	•Test system: Superficial application/ dipping treatment •Concentration applied: 100 % (w/w) • Exposure time: 60 days (deviation from the standard) • Solution retention: 200 g/m^2	100 % larvae were recovered dead without having made tunnels in the wood. At least 70% of the larvae inserted in all untreated control specimens survive.	Report Nº 8944.1 Report Nº 8944.1-4 (M1)
XYLAZEL TOTAL	Wood preservative Preventive treatment Curative treatment	*Pinus sylvestris*	Subterranean termite *Reticulitermes santonensis*	UNE 56411 (EN118) + UNE 56406 (EN 73) (Evaporation) The standar was not in force in 2015	•Test system: Superficial application/ brush treatment •Concentration applied: 100 % (w/w) • Exposure time: 8 weeks • Solution retention: 155.2 g/m^2	At the end of the study the treated blocks were ranked ≤1. The control blocks were ranked 4 and the number of surviving termites was at least a 50%.	Report Nº 11729.2 Report Nº 11729.2-4 (M1)
XYLAZEL TOTAL	Wood preservative Preventive treatment Curative treatment	*Pinus sylvestris*	Subterranean termite *Reticulitermes santonensis*	UNE 56411 (EN118) +EN84 (Leaching) The standard was not in force in 2015	•Test system: Superficial application/ brush treatment •Concentration applied: 100 % (w/w) • Exposure time: 8 weeks • Solution retention: 153.16 g/m^2	At the end of the study the treated blocks were ranked ≤1. The control blocks were ranked 4 and the number of surviving termites was at least a 50%.	Report Nº 11729.2 Report Nº 11729.2-5 (M1)
XYLAZEL TRIPLE ANTITERMITES FORMULA 236/m306	Wood preservative Preventive treatment Curative treatment	*Pinus sylvestris*	Subterranean termite *Reticulitermes* sp.	UNE 56411 (EN118) + UNE 56406 (EN 73) (Evaporation) The standad was not in force in 2015	•Test system: Superficial application/ brush treatment •Concentration applied: 100 % (w/w) • Exposure time: 8 weeks Toxic values: 161.24 g/m^2	At the end of the study the treated blocks were ranked ≤1. The control blocks were ranked 4 and the number of surviving termites was at least a 50%.	Report Nº 8944.1 Report Nº 8944.1-6 (M1)

XYLAZEL TRIPLE ANTITERMITES FORMULA 236/m306	Wood preservative Preventive treatment Curative treatment	*Pinus sylvestris*	Subterranean termite *Reticulitermes* sp.	UNE 56411 (EN118) +EN84 (Leaching) The standard was not in force in 2015	•Test system: Superficial application/ brush treatment •Concentration applied: 100 % (w/w) • Exposure time: 8 weeks • Solution retention: 162.45 g/m^2	At the end of the study the treated blocks were ranked ≤1. The control blocks were ranked 4 and the number of surviving termites was at least a 50%.	Report Nº 8944.1 Report Nº 8944.1-7 (M1)
XYLAZEL TOTAL	Wood preservative Preventive treatment	*Pinus sylvestris*	Wood destroying basidiomicetes*:* *-Coniophora puteana* *-Gloeophyllum trabeum* *-Poria placenta*	EN 113+EN73 (Evaporation)	• Vacuum impregnation. • Concentration of the product tested: 0, 11.25, 13.13, 15, 16.90 and 18.80% (w/w) • Exposure period: 16 weeks.	***Coniophora puteana*** - Concentration of test product: <11.25% - Retention of test product: 0.00-53.45 Kg/m3 - Mean mass loss at the lower toxic value: 28.79% Mid-toxic value (m.t.v.):26.73 kg/m3 Biological reference value (b.r.v.): 53.45 kg/m3 Critical value: 106.9 g/m2 ***Gloeophyllum trabeums*** - Concentration of test product: <11.25% - Retention of test product: 0.00-53.29 Kg/m3 - Mean mass loss at the lower toxic value: 28.38% m.t.v.: 26.65 kg/m3 b.r.v.: 53.29 kg/m3 Critical value: 106.58 g/m2 ***Poria placenta*** - Concentration of test product: <11.25% - Retention of test product: 0.00-52.50 Kg/m3 - Mean mass loss at the lower toxic value: 23.52%	Report Nº 11729.3 Report Nº 11729.3-1 (M1)

						m.t.v.: 26.25 kg/m3 b.r.v.: 52.50 kg/m3 Critical value: 105 g/m2	
XYLAZEL TOTAL	Wood preservative Preventive treatment	*Pinus sylvestris*	Wood destroying basidiomicetes*:* *-Coniophora puteana* *-Gloeophyllum trabeum* *-Poria placenta*	EN 113+EN84 (Leaching)	• Vacuum impregnation. • Concentration of the product tested: 0, 11.25, 13.13, 15, 16.90 and 18.80% (w/w) • Exposure period: 16 weeks.	***Coniophora puteana*** - Concentration of test product: <11.25% - Retention of test product: 0.00-53.05 Kg/m3 - Mean mass loss at the lower toxic value: 25.07% m.t.v.: 26.52 kg/m3 b.r.v.: 53.05 kg/m3 Critical value: 106.1 g/m2 ***Gloeophyllum trabeums*** - Concentration of test product: <11.25% - Retention of test product: 0.00-52.33 Kg/m3 - Mean mass loss at the lower toxic value: 24.16% m.t.v.: 26.16 kg/m3 b.r.v.: 52.33 kg/m3 Critical value: 104.66g/m2 ***Poria placenta*** - Concentration of test product: <11.25% - Retention of test product: 0.00-52.59 Kg/m3 - Mean mass loss at the lower toxic value: 23.2% m.t.v.: 26.79 kg/m3 b.r.v.: 52.59 kg/m3. Critical value: 105.18 g/m2	Report Nº 11729.3 Report Nº 11729.3-2 (M1)

XYLAZEL TRIPLE ANTITERMITES FORMULA 236/m306	Wood preservative Preventive treatment	*Pinus sylvestris*	Wood destroying basidiomicetes*:* *-Coniophora puteana* *- Gloeophyllum trabeum* *-Poria placenta*	EN 113+EN73 (Evaporation)	• Vacuum impregnation. • Concentration of the product tested: 0, 3, 5, 6.5, 8 and 12.5% (w/w) • Exposure period: 16 weeks.	***Coniophora puteana*** - Concentration of test product: 8-12.5 % - Retention of test product: 38.55-59.27 Kg/m3 - Mean mass loss at the lower toxic value: 20.84% m.t.v.: 48.91 kg/m3 b.r.v.: 59.27 kg/m3 Critical value: 118.54 g/m2 ***Gloeophyllum trabeums*** - Concentration of test product: 6.5-8% - Retention of test product: 31.73-37.53 Kg/m3 - Mean mass loss at the lower toxic value: 6.28% m.t.v.=b.r.v.: 34.63 kg/m3 Critical value: 69.26 g/m2 ***Poria placenta*** - Concentration of test product: 6.5-8% - Retention of test product: 30.93-37.24 Kg/m3 - Mean mass loss at the lower toxic value: 8.82% m.t.v.=b.r.v.: 34.08 kg/m3 Critical value: 68.16 g/m2 This test was not taken into account due to different composition of Xylacel Total	Report Nº 8944.1 Report Nº 8944.1-1 (M1)
XYLAZEL TRIPLE ANTITERMIT	Wood preservative Preventive treatment	*Pinus sylvestris*	Wood destroying basidiomicetes*:*	EN 113+EN84 (Leaching)	• Vacuum impregnation. • Concentration of the product tested: 0, 3, 5, 6.5, 8 and 12.5% (w/w)	***Coniophora puteana*** - Concentration of test product: 8-12.5 % - Retention of test product:	Report Nº 8944.1 Report Nº

ES FORMULA 236/m306			*-Coniophora puteana* - *Gloeophyllum trabeum* *-Poria placenta*		• Exposure period: 16 weeks.	38.34-61.27 Kg/m3 - Mean mass loss at the lower toxic value: 15.69% m.t.v.: 49.80 kg/m3 b.r.v.: 61.27 kg/m3 Critical value: 122.54g/m2 ***Gloeophyllum trabeums*** - Concentration of test product: 8-12.5% - Retention of test product: 38.12-58.15 Kg/m3 - Mean mass loss at the lower toxic value: 8.08% m.t.v.=b.r.v.: 48.13 kg/m3 Critical value: 96.27 g/m2 ***Poria placenta*** - Concentration of test product: 6.5-8% - Retention of test product: 31.22-39.52 Kg/m3 - Mean mass loss at the lower toxic value: 7.84% m.t.v.=b.r.v.: 35.37 kg/m3 Critical value: 70.74 g/m2 This test was not taken into account due to different composition of Xylacel Total	8944.1-2 (M1)
XYLAZEL TOTAL IF-T	Wood preservative Preventive treatment	*Pinus sylvestris*	Blue stain *(Aureobasidium pullullans P268 and Scierophoma pithyophila*	EN 152	•Test system: Superficial application/ brushing procedure (2-coats) •Concentration applied: 100 % (w/w) •Type B ("Xylazel barniz intemperie") •Natural aging: 4 weeks	The visual examination of the surface of the 6 specimens treated with the product is evaluated in 1: non-significant bluish. Test is considered valid.	Report Nº 29527 Report Nº 29527(M1) Report Nº 29527 (M2)

			S231)		• Exposure time: 6 weeks • Retention (toxic values): 197.88±0.91 g/m^2.		
XYLAZEL ANTITERMITES	Wood preservative Preventive treatment	*Pinus sylvestris*	Blue stain *(Aureobasidium pullullans P268 and Scierophoma pithyophila S231)*	UNE 56419-1 (EN 152-1) The standard was not in force in 2015.	•Test system: Superficial application/ brushing procedure •Concentration applied: 100 % (w/w) •Type A •Natural aging: 6 months • Exposure time: 6 weeks • Retention (toxic values): 162.6±0.7 g/m^2.	The visual examination of the surface of the 6 specimens treated with the product is evaluated ≤1: non-significant bluish. The test was not considered valid: the validation specimens were not preformed. This test was not taken into account due to different composition of Xylacel Total	Report Nº 9806.2
XYLAZEL TOTAL	Wood preservative Curative treatment	*Pinus sylvestris*	House longhorn beetle. *Hylotrupes bajulus (L.)*	UNE 56408 (EN 22) The standard was not in force in 2015	• Brushing • 250.6 ± 3.96 g/m2 305.61 ml/m2 •Exposure 12 weeks (Quick action)	The mortality rate is >80% (85.4%) 9 larvae of the untreated control specimens were found alive. The test is valid.	Report Nº 11729.2 Report Nº 11729.2.3 (M1)
XYLAZEL TRIPLE ANTITERMITES FORMULA 236/m306	Wood preservative Curative treatment	*Pinus sylvestris*	House longhorn beetle. *Hylotrupes bajulus (L.)*	UNE 56408 (EN 22) The standard was not in force in 2015	• Brushing • 246.87 g/m2 308.6 ml/m2 •Exposure 12 weeks (Quick action)	The mortality rate is ≤80% (79%) 10 larvae of the untreated control specimens were found alive.	Report Nº 8944.1 Report Nº 8944.1-5 (M1)
XYLAZEL TOTAL	Wood preservative Curative treatment	*Pinus sylvestris*	House longhorn beetle. *Hylotrupes bajulus (L.)*	UNE 1390	• Brushing • 247.28 g/m2 297,92 ml/m2 •Exposure 12 weeks (Quick action)	The mortality rate is >80% (96,66%) 11 larvae of the untreated control specimens were found alive. The test is valid.	Report Nº 088226

Conclusion on the efficacy of the product

The applicant initially provided 17 trials, some were withdrawn. These tests are all included in the efficacy table although some of them will not be taken into account for evaluation.
The applicant has submitted 16 additional tests to support a product for preventive and curative treatment against wood boring beetles, termites, wood destroying basidiomycetes and blue stain fungi.

PREVENTIVE TREATMENT:

Surface treatment:

Wood boring beetles

The applicant has submitted four test against *Hylotrupes bajulus* to support a preventive treatment against Wood Boring Beatles.
We consider that the standard EN46-1:1988 applied was obsolete in 2015 and it has very large deviations from the standard that they should have presented at the time. Therefore, 'Wood boring beetles' claim is not accepted for preventive treatment.
This claim is required for the Use class 1. Therefore, this class is not authorized.
Nor has it been shown that Annex H can be accepted.
Annex H was not accepted due to:
ES initiated an e-consultation with the aim to find a harmonized approach to comply with Annex H of the guideline EN 599-1: +A1: 2013 for PT08, in particular regarding the concept "10 years' successful use" of the product indicated in the mentioned Annex.

Member states indicated the minimum supporting documentation needed to consider the '10 years' successful use as proven, and the minimum quality criteria that this data should fulfil:
-Clients declaration
-Comparison between current and outdated standards.
- Peer reviewed literature and monitoring data.

Subterranean termites

The applicant has submitted four test EN118 against *Reticulitermes sp*. to support a preventive treatment against Subterranean termites.
We consider that the standard EN118:1990 applied, was obsolete in 2015 and that it has very large deviations from the standard that they should have presented at the time. Therefore, claim for subterranean termites preventive use is not accepted.
Nor has it been shown that Annex H can be accepted.

Impregnation treatment

Wood destroying basidiomycetes

The applicant has provided six test (only two of them are acceptable) according EN 113 protocol after both procedure ageing EN 73 and EN 84 for *Coniophora puteana, Gloeophyllum trabeum* and *Poria placenta*. Tests were performed according to impregnation treatment.

	EN113 (EN73).		EN113 (EN84)	
	b.r.v. (*kg/m^3*) (point 5.2.16 of the EN 599-1)	*Critical value (g/m^2)* (point 5.2.15 of the EN 599-1)	*b.r.v. (kg/m^3)* (point 5.2.16 of the EN 599-1)	*Critical value (g/m^2)* (point 5.2.15 of the EN 599-1)
Coniophora puteana	53.45	106.9	53.05	106.1
Gloeophyllum	53.29	106.58	52.33	104.66

trabeum				
Poria placenta	52.50	105	52.59	105.18

The biological reference value for the most aggressive fungi (*Coniophora puteana*) is: **53.45 Kg/m^3**
The critical value for superficial treatment for the most aggressive fungi (*Coniophora puteana*) is: **106.9 g/m^2**

According to the efficacy guide and EN 599-1, to authorize the class of use 2 and 3 , efficacy against brown rot fungi basidiomycetes must be demonstrated as a minimal requirement. Therefore, the product has been shown to be effective against fungi, for superficial and impregnation treatments.
Use classes 2 and 3 can be accepted. But due to environmental risk, only Use Class 2 is authorized.
Surface treatment dose: **106.9 g/m^2**
Impregnation treatment dose: **53.45 kg/m^3**

Surface treatment:
Blue stain fungi
The applicant has provided initially two test according EN-152 against blue stain to support a preventive treatment. In one of them the standard was not in force in 2015 and in the other, the validation specimens were not performed. The report 29527 was amended by Tecnalia twice (M1 and M2 versions) according to different requests. The requirements were met as it is demonstrated in the report that demonstrate the efficacy against blue stain fungi.
Surface treatment dose: **197.88 g/m^2**

CURATIVE TREATMENT:
Surface treatment:
Wood Boring Beetles
The applicant has submitted one test according EN 1390 against *Hylotrupes bajulus* to support a curative treatment against 'Wood boring Beetles'.
Curative dose rate by superficial treatment: 300 mL/m^2
The basic curative norm (EN14128) indicates that insecticidal activity tests should be carried out against *Hylotrupes bajulus* and *Anobium punctatum* or only against the most resistant insect. (section 5.2.3 a and b).
The laboratory has justified that *Hylotrupes bajulus* is more ressistant than *Anobium puctatum.* It is based on the smaller size of *Anobium puctatum*, the laying of eggs in the most superficial layers of the wood and the faster biological cycle with respect to *Hylotrupes bajulus*. This causes the *Annobium* larvae to die earlier, since they need less wood and less exposure time. They also report that they have verified over the years that *Hylotrupes bajulus* is more resistant than *Anobium*. We accept justification of the applicant about that *Hylotrupes bajulus* is the less sensitive target for Xylazel Total. The applicant has only provided tests on this insect and 'Wood boring beetles' claim was accepted for superficial curative treatment.
In conclusion, a general wood boring beetle claim for curative treatment is covered at 200g /m^2 (corresponding to **300 ml/m^2**; at product density 0.67 g/ml)."

Subterranean termites
According to the TNsG, the treatment against termites is designed to kill termites that are already found in the wood and to prevent the degradation of wood; claim for subterranean

termites preventive use is not accepted, therefore, the preventive efficacy test can not be extrapolated for a curative treatment.
Claim for subterranean termites curative use is not accepted.

Injection (method of fligh holes)

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

In any case, specific information regarding this method has been requested.

Old furnitures attacked by wood-boring insects are varnished or painted so that a wood preserver can not penetrate into the wood to kill the insects. Therefore the injection method of flight holes is used.

Curative efficacy against woodworm insects of Xylazel Total when the product is applied via filling (injection) of flight holes in furnitures is not supported by test data. However an effective dose can be derived from the following realistic assumptions:

An average flight hole of *A. punctatum* holds a volume of approx. 0.03 cm^3 (0.2 cm in diameter and 1 cm in depth). According to the product application claim, such a flight hole has to be filled 5 to 7 times (here calculated with 6 fillings), which theoretically would result in 0.188 cm^3 (=0.188 ml) Xylazel Total per flight hole. In contrary to that calculation, the applicant states from practical measurement that filling a flight hole 5 to 7 times results in an application of 0.4 to 0.5 ml per flight hole. This assumption is more realistic than the above calculated 0.188 ml because living larvae produce or have produced tunnels packed with frass, which act as a sponge.

In conclusion, it is realistic that larvae of woodworm insects in their frass-tunnels connected to a flight hole get in contact with 0.4 to 0.5 ml Xylazel Total. A larva of woodworm insects working its way from the interior of the wood to the treated outside comes into contact with the treated wood by an area of approx. 0.03 cm^2 (plain of a flight hole with 0.2 cm in diameter). An effective application rate of 300 ml/m^2 corresponds to approx. 0.03 ml/cm^2. Thus, one larva consumes an effective amount of approx. 0.001 ml of Xylazel Total, which is lethal. With 0.4 ml claimed application (filling per flight hole) this effective amount per larva is achieved by a multiple. That leaves several safety margins for e.g. several larvae having started to tunnel from one flight hole, less frass to soak up the product or even fewer fillings than 5 to 7 times for less deep or smaller flight holes. The advantage of filling flight holes is the direct delivery of the product to the target organisms resulting in a faster kill (after knock down) stopping the damage at an early stage. The application hole injection was submitted for curative treatment for A*. punctatum*.

- Filling of flight holes 5 to 7 times resulting in approx. 0.4 to 0.5 mL (up to 295 mL/m^2).
- The application rate is not restricted to the number of holes.
- Claim for curative treatment is accepted only for *Anobium punctatum* with the method of injection via filling of fligh holes. Dose (**300 mL/m^2**).

Injection (method of pressure:)

Curative treatment, *Hylotrupes bajulus*
Injection application.

When structural timber is affected by wood drestroying insects and the thickness is bigger than 7.5 cm, an injection method is recommended so that Xylazel Total and the structure can be conserved. This ensures that the preservative penetrates into the wood on the surface and can get in contact with the insects. The injections must be made in the place

where the wood is built-in, and they must be in two lines and directed towards the masonry, as close as possible to it, as well as in any pieces of wood in contact with the walls. Holes should be drilled in staggered rows on the facing or in line with the edges. The distance between two holes must be no more than 30 cm (15 cm between the holes above and below). The holes must be drilled at 2/3 the thickness or height of the timber and have a diameter of 9.5 mm. The drills must not leave more than 60 mm at the bottom of the wells. For pieces of wood thicker than 20 cm where half the perimeter is greater than 30 cm, the wood must be drilled on both sides (double-injection) to ensure that the liquid has better access to the insects and that the wooden structure does not weaken. Holes should be drilled also in staggered rows at a distance of 30 cm. The holes from one side should be done contrary from the other side, so that they do not coincide in height. If one is up the other must be down and vice versa. The depth of the holes is half the thickness of the piece of wood and have a diameter of 9.5 mm. It is not necessary to drill the duramen.

The effective dose should be calculated depending on the perimeter of the timber pieces. If a dose of 300 mL/m^2 is needed for curative treatments, it is necessary to apply per hole 300 x (perimeter x 0,15) + 2 x (height x width) mL (the perimeter, height and width expressed in m) of Xylazel Total. For pieces of wood thicker than 20 cm where half the perimeter is greater than 30 cm where the double-injection method is used, (300 x (perimeter x 0,15) + 2 x (height x width) mL)/2 is needed as the injection is done on two sides of the wood, one on the top side and the other on the side. It is assumed that 300 mL/m^2 is applied on the total surface, also considering the internal suface where the holes are drilled.
As a hole has not the sufficient volume to apply the effective dose in one time, it shoud be necessary to inject Xylazel Total up to several times. It is recommended to use a special injection equipment with pressure to apply the calculated dose. For the use of the special injection equipment it is necessary to follow the instructions of the manufacturer.

We assume:
Diameter of injectors: 9.5mm (According to the applicant)
Depth of holes: 5 cm (depth of holes is usually about ¾ of this thickness. We assume the sections is at least 7.5, according to the applicant).
Volume of hole (cilindric): 3,544 ml.
Thanks to curative test against *Hylotrupes bajulus (EN22),* we know that the distance between larvae and the nearest coated face were between 2 and 5 mm. Therefore, 5mm is the maximum distance we know of that penetrates the wood and can kill an *Hylotrupes bajulus* larva.
On the other hand, according to DGfH 2002, information sheet, "*Sonderverfahren zur Behandlung von Gefahrstellen*", the penetration along the fiber is usually 10 to 20 cm and we assumed to be 15 cm. (taking into account the distance between holes is 30cm).
We assume, therefore:
Diameter of injectors: 0.95cm +(15 cm*2)=752,09 cm^2
Depth of holes: 5cm+0.5cm=5.5cm
Volume of hole (cilindric): 4.136,504 cm^3
Volume of the impregnated part: 4.136,504 -3,544 =4.132,96 cm^3

We do not know how much to fill each of the holes, but the applicant has given us that the dose is 300ml/m^2. The toxic value for curative surface treatment is approximately 300 ml/m^2. If we add the penetration of the product to about 5mm, this gives a dose of 50 Kg/m^3.
Therefore, in 1 m^3 (o 10^6 cm^3), 50Kg of product must be included to be able to support de curative efficacy.

This is 206g of the product/hole.

Claim for curative treatment is accepted only for *Hylotrupes bajulus* with the method of pressure injection. Dose **50 Kg/m^3.**

In conclusion, XYLAZEL TOTAL has demonstrated its efficacy:

- For preventive treatment of soft wood by superficial application (brushing, spraying, dipping) at the application of 200 g/m^2 against wood destroying basidiomycetes (demonstrated in *Coniophora puteana, Gloeophyllum trabeum* and *Poria placenta*) and blue stain fungi (demonstrated in *Aureobasidium pullulans* and *Sclerophorma pithyophila*. And by impregnation treatment at the application of 53.45 Kg/m^3. Therefore the efficacy assessment justified that the product meet the requirements for use in preservation of Use Class 2 wood.

- For curative treatment of soft wood by superficial application (brushing) at the application of 300 mL/m^2 against*;* injection application (method of fligh holes) at the application of 300 mL/m^2 against *Anobium punctatum De Geer*; and injection applicaction (method of pressure) at the application of 50 Kg/m^3 against *Hylotrupes bajulus.*

2.2.5.6. Occurrence of resistance and resistance management

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

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

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

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

The number of treatments to wooden structures with carbamates is generally low (in many cases, only one application is made per lifetime of timber structures), resulting in a low selection pressure. IPBC has been used for many years in wood preservation without the reporting of cases of resistance.

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

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

To ensure a satisfactory level of efficacy and avoid the development of resistance, the following recommendations have to be implemented:
-Always read the label or leaflet before use and follow all the instructions provided.
-The users should inform if the treatment is ineffective and report straightforward to the registration holder.

2.2.5.7. Known limitations

No limitations are known.

2.2.5.8. Evaluation of the label claims

Claim matrix:

User category	Industrial Trained professional Non-professional	A.20 A.30 A.10.
Wood category	Softwood	B.10
Wood product	Solid wood	C.10
Application aim	Preventive Curative	D.40 D.50
Field of use	Use class 2	E.20
Method of application rate	Superficial application. Brush Superficial application. Spray Superficial application. Dipping Pressure process. Pressure process/vacuum pressure impregnation Pressure process/double vacuum Injection.	F.10 F.11 F.14 F.30 F.31 F.32 F.20
Target organisms	Wood rotting basidiomycetes (preventive) Blue stain in service. House longhorn beetle.(curative) Common furniture beetle. (curative)	G.10 G.21.2 G.31 G.32

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

Not applicable.

2.2.6. Risk assessment for human health

The biocidal product contains four active susbtances (propiconazole, tebuconazole, IPBC and cypermethrin). *In vivo* studies of acute oral, dermal and inhalation toxicity, eye and skin irritation and skin sensitisation have been submitted by the applicant according to OECD protocols. No human data are available. In addition, an *in vitro* dermal absorption

study according to guideline 428 OECD has been submitted with the biocidal product XYLAZEL TOTAL. The results of this study and the Guidance on Dermal Absorption, EFSA Journal 2017 have been taken into account in the exposure assessment.

For other toxicological aspects of the components of the product, information included in data sheets, in website of ECHA or other data base has been used. Low boiling point naphthas included in the composition have been considered as substances of concern (SoC) because some hazard assessment of the biocidal product are due to them and they are present in concentrations greater of 0.1%. In relation to this, the classification of the biocidal product was carried out taking into account the Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Regulation CLP).

2.2.6.1. Assessment of effects on Human Health

Skin corrosion and irritation

Summary table of animal studies on skin corrosion /irritation					
Method, Guideline, GLP status, Reliability	**Species,Strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Duration of exposure**	**Results** *Average score (24, 48, 72h)/observations and time point of onset, reversibility; other adverse local / systemic effects, histopathological findings*	**Remarks** *(e.g. major deviations)*	**Reference**
OECD 404 GLP Primary Skin Irritation Study in rabbits (4 hours semi-occlusive application)	2 young adult males New Zealand White rabbits	The biocidal product was applied undiluted by topical semi-occlusive application of 0.5 mL to the intact left flank	The first animal showed an irritant effect and in order to confirm these results, another animal was administered. As both animals exhibited approx. the same response, no further testing was needed. Treatment duration was 4 hours and skin reactions were scored at 1, 24, 48 and 72 hours and 7, 10 and 14 days after removing the dressing. The mean values (for all 2 animals together) for each type of lesion at 24, 48 and 72 hours following administration were: Erythema: 3.5 Edema: 3.0 No edema was observed in either animal in the following observations after 72 hours. Erythema decreased progressively disappearing on day 14 in 1 animal and being very slight in the other in the same observation.	-	Harlan Laboratories Study [redacted]

			The application of Xylazel Total to the skin resulted in moderate signs of irritation. No corrosive effects were noted.		

No human data on skin corrosion irritation is available.

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	The application of Xylazel Total to the skin resulted in moderate signs of irritation.
Justification for the value/conclusion	The mean values (for all 2 animals together) for each type of lesion at 24, 48 and 72 hours following administration were: Erythema: 3.5 Edema: 3.0
Classification of the product according to CLP	According to table 3.2.2 in Annex I of CLP Regulation: GHS Pictogram: GHS07 Classification: Skin Irrit. 2 Signal word: Warning Hazard statement: H315: Causes skin irritation

Eye irritation

Summary table of animal studies on serious eye damage and eye irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Dose levels, Duration of exposure**	**Results** *Average score (24, 48, 72h)/observations and time point of onset, reversibility*	**Remarks** *(e.g. major deviations)*	**Reference**
OECD 405 GLP Primary eye irritation study in rabbits	Three young adult males New Zealand White rabbits	The biocidal product Xylazel Total was applied undiluted by instillation of 0.1mL to the right eye	The individual mean scores for corneal opacity and iris were 0 for all 3 animals. The individual mean scores for the conjunctivae were 0, 0 and 0.33 for reddening and 0,0 and 0.33 for chemosis respectively. A period of observation of 14 days were considered. The combined mean values at 24, 48 and 72 hours were: Corneal opacity: 0 Lesion in the iris: 0 Reddening: 0.11 Chemosis: 0.11 No corrosion, no staining of the treated eyes by the test item and no clinical signs wer observed. The effects were reversible and were no longer evident at 48 hours after treatment.	-	Harlan Laboratories Study [redacted]

No human data on serious eye damage and eye irritation is available.

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Not irritating
Justification for the value/conclusion	The combined mean values at 24, 48 and 72 hours were: Corneal opacity: 0 Lesion in the iris: 0 Reddening: 0.11 Chemosis: 0.11
Classification of the product according to CLP	Not irritating to the rabbit eye. No classification according to CLP

Respiratory tract irritation

No human data on respiratory tract irritation is available.

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	Some components of the biocidal product are classified as STOR RE 3 with the hazard statements H335 or H336, category 3. This information has been included in the data sheets of the components and, in the case of the low boiling point naphthas, according to the information of chemical substance in ECHA website and Annex VI of CLP regulation. In addition, other information has been looked up, for example "*Concawe report about the Hazard classification and labelling of petroleum substances in the European Economic Area – 2020*". On the other hand, the *Guidance on the Application of the CLP Criteria; Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures; Version 4.1; June 2015* stablish the following: *"Classification in STOT-SE Category 3 for respiratory tract irritation and narcotic effects does not take potency into account and consequently does not have any guidance values. A pragmatic default generic concentration limit of 20% is suggested, although a lower or higher specific concentration limit may be used where it can be justified".* The applicant has not submitted any information about respiratory tract irritation and, taking into account the guidance, ES CA use the default value of 20%. In addition, regarding the concentration of the substances with these hazard statements, the biocidal product is classified as STOT-RE 3; H336 May cause drowsiness or dizziness.
Classification of the product according to CLP and DSD	STOT-RE 3; H336 May cause drowsiness or dizziness

Data waiving

Information requirement	Respiratory tract irritation study
Justification	The *Guidance on the Application of the CLP Criteria; Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures; Version 4.1; June 2015* stablishes an default value of 20% and ES CA will use this value.

Skin sensitization

Summary table of animal studies on skin sensitisation					
Method, Guideline, GLP status, . Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, duration of exposure Route of exposure** *(topical/intradermal, if relevant)*	**Results** *(EC3-value or amount of sensitised animals at induction dose); evidence for local or systemic toxicity (time course of onset)*	**Remarks** *(e.g. major deviations)*	**Reference**
OECD 429 GLP Local Lymph Node Assay (LLNA) in mice	3 groups each of 4 female mice (CBA/CaOlaHsd). The females were nulliparous and non-pregnant	The biocidal product was dissolved in acetone:olive oil (4+1) and the concentrations of 25; 50 and 100% were used by topical application at the dorsum of each ear lobe (left and right) on 3 consecutive days	The animals did not show any clinical signs. No cases of mortality were observed. The Stimulation Indices (S.I.) of 21.76; 19.61 and 14.39 were determined with the test item at concentrations of 25; 50 and 100% in acetone.olive oil (4+1), respectively. The EC3 value could not be calculated, since all obtained Si´s were above 3. Xylazel Total was found to be a skin sensitiser.	-	Study [redacted]

OECD 429 GLP Local Lymph Node Assay in the mousse: Pooled Method	3 groups each of 4 female mice (CBA/Ca). The females were nulliparous and non-pregnant	The biocidal product was dissolved in acetone:olive oil (4+1) and the concentrations of 25; 50 and 100% were used by topical application (25µL) at the dorsum of each ear lobe (left and right) on 3 consecutive days	There were ni deaths. No signs of systemic were noted in the tes or control animals during the test. The Stimulation Index (S.I.) of 1.06, 2.23 and 3.79 were determined with the test item at concentrations of 25; 50 and 100% in acetone. The EC3 value was calculated to be 75%	No analysis was carried out to determine the homogeneity, concentration or stability of the test item formulation and no information for the purity of the test item was provided but these desviations are considered not to affect the integrity or validity of the study	Study [redacted]

No human data on skin sensitisation is available.

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	The biocidal product was found to be a skin sensitiser in two studies
Justification for the value/conclusion	In the first study, the Stimulation Indices (S.I.) of 21.76; 19.61 and 14.39 were determined with the test item at concentrations of 25; 50 and 100% in acetone.olive oil (4+1), respectively. The EC3 value could not be calculated, since all obtained Si´s were above 3. Therefore a sub-categorization has not been stablished because we do not have enough data for it. In addition, taking into account that the EC3 cannot calculated, we cannot know the potency of the substance (extreme, strong, moderate). This data is important to carry out a qualitative risk assessment to decide on base of exposure assessment, the authorisation of the biocidal product for general public and for non trained professional (please see table 25 and 26 of Guidance on the BPR: Volume III Parts B+C, Version 4.0 December 2017 and Guidance on the Application of the CLP Criteria, Version 5.0 – July 2017) Nevertheless, the applicant have sent a second study where the Stimulation Index (S.I.) of 1.06, 2.23 and 3.79 were determined with the test item at concentrations of 25; 50 and 100% in

	acetone:oil (4:1) and the EC3 value was calculated to be 75%. As the EC3 value is > 2 %, the classification of XYLAZEL TOTAL is skin sensitiser subcategory 1B. According to the table 24 of Guidance on the BPR: Volume III Parts B+C, Version 4.0 December 2017, and in order to carry out a qualitative characterization of local effects, the hazard category of this product is medium and this data is important to decide on base of exposure assessment, the authorisation of the biocidal product for general public and for non trained professional (please see table 25 and 26 of Guidance on the BPR: Volume III Parts B+C, Version 4.0 December 2017 and Guidance on the Application of the CLP Criteria, Version 5.0 – July 2017)
Classification of the product according to CLP and DSD	According to table 3.4.7 in Annex I of CLP Regulation: GHS Pictogram: GHS07 Classification: Skin sensitiser Category 1B Signal word: Warning Hazard statement: H317: May cause an allergic skin reaction In addition, according to CLP; the EUH 208 Contains "propiconazol". May produce an allergic reaction should be included.

Respiratory sensitization (ADS)

No human data on respiratory sensitisation is available.

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not respiratory sensitiser
Justification for the value/conclusion	No study on the respiratory sensitisation of the product has been performed.
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	Respiratory sensitisation study
Justification	No data about respiratory sensitization of the biocidal product was submitted. Nevertheless, the components of XYLAZEL TOTAL are not classified as repiratory sensitizers and, so, the biocidal product is not classified.

Acute toxicity

Acute toxicity by oral route

Summary table of animal studies on acute oral toxicity

Method Guideline GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance Dose levelsType of administration** *(gavage, in diet, other)*	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**Value LD50**	**Remarks** *(e.g. major deviations)*	**Reference**
OECD 420 GLP (Acute Oral Toxicity Study in rats –fixed dose method)	Two studies: - Sighting study: one rat was treated at the dose of 2000 mg/kg. Since no mortality was observed in the sighting study, the main study was carried out - Main study: one group of 5 female Wistar Hannover HsdHan: Wist Rats The females were nulliparous and nonpregnant	Rats were treated with the product Xylazel Total by oral gavage administration at a dosage of 2000 mg/kg bw. The test item was diluted in vehicle (1% Tween 80 in B. Braun water) at a concentration of 0.2 g/mL at administered at a dosing volume of 10 mL/kg	No deaths occurred. No clinical signs were observed. No macroscopic findings were recorded at necropsy	>2000 mg/kg	-	Study [redacted]

No human data on acute oral toxicity is available.

Value used in the Risk Assessment – Acute oral toxicity	
Value	LD50 >2000 mg/kg
Justification for the selected value	No deaths occurred. No clinical signs were observed. No macroscopic findings were recorded at necropsy
Classification of the product according to CLP	No classification according to CLP Regulation

Acute toxicity by inhalation

Summary table of animal studies on acute inhalation toxicity

Method, Guideline, GLP status , Reliability	**Species, Strain, Sex, No/group**	**Test substance, form** *(gas, vapour, dust, mist)* **and particle size (MMAD) Actual and nominal concentration, Type of administration** *(nose only / whole body/ head only)*	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**LC50**	**Remarks** *(e.g. major deviations)*	**Reference**
OECD 403 GLP (4-hour acute inhalation toxicity study in the rat)	A group of 5 male and 5 female albino rats (HanRcc:Wist(SPF)) was exposed by nose only, flow-past inhalation for 4 hours	Rats were exposed by nose-only to the biocidal product Xylazel Total at a chemically determined mean concentration of 5.4 mg/L air (s.d.±0.3 mg/L air, n=4)	All animals survived the scheduled observation period. Clinical signs consisted of salivation and restlessness in all animals during exposure. From the end of the exposure onwards, no clinical signs were noted during the remainder of the study. No treatment-related effects on the effects on the body weight development were noted. There were no macroscopical findings at necropsy.	LC50 >5.4 mg/L air (chemically determined mean aerosol concentration)	-	Study [redacted]

No human data on acute inhalation toxicity is available.

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	LC50 >5.4 mg/L air (chemically determined mean aerosol concentration)
Justification for the selected value	All animals survived the scheduled observation period. Clinical signs consisted of salivation and restlessness in all animals during exposure. From the end of the exposure onwards, no clinical signs were noted during the remainder of the study. No treatment-related effects on the effects on the body weight

	development were noted. There were no macroscopical findings at necropsy.
Classification of the product according to CLP	No classification according to CLP Regulation

Acute toxicity by dermal route

Summary table of animal studies on acute dermal toxicity						
Method, Guideline, GLP status, Reliability	**Species, strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Surface area**	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**LD50**	**Remarks** *(e.g. major deviations)*	**Reference**
OECD 402 GLP (Acute Dermal Toxicity Study in rats)	Two studies: - Sighting study: one group of 4 rats (two males and two females). Since no mortality was observed in the sighting study, the main study was carried out - Main study: one group of 10 Hsd: Sprague Dawley SD rats (5 males and 5 females) The females were nulliparous and nonpregnant	The product Xylazel Total was applied on about 10% of the total body surface area. The dose of 2000 mg/kg was applied	No clinical signs were observed in any animal. Slight edema and/or erythema were observed in all animals, with the exception of 1 male, being evident in some of them or erythema until day 3 in males and until day 6 in females. Furthermore, from day 4 in males and 3 in females to day 11 slight desquamation and/or desquamation were observed in all animals. Reddish punctiform areas in the administration area were recorded in 1 female on days 4 and 5 and in 3 toher females in the interval comprising day 7 to 11. In 1 female, a small area in the administration site with severe	>2000 mg/kg	-	Study [redacted]

			desquamation and small wounds was recorded from day 4 to 6 evolving wounds to crusts on day 7. No treatment-related macroscopic findins were recorded at necropsy			

No human data on acute dermal toxicity is available.

Value used in the Risk Assessment – Acute dermal toxicity	
Value	LD50 >2000 mg/kg
Justification for the selected value	No clinical signs were observed. No treatment-related macroscopic findins were recorded at necropsy. No mortality was recorded after administration of the test item at the dose of 2000 mg/kg. The LD50 of XYLAZEL TOTAL was to be higher than that dose when administered by dermal route to rats.
Classification of the product according to CLP	No classification according to CLP Regulation

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption				
Substance	IPBC	Tebuconazole	Cypermethrin	Propiconazole
Value(s)*	14%	24%	2.8%	25%
Justification for the selected value(s)	in vitro study according to OECD 428 guideline. In order to evaluate it, the Guidance on Dermal Absorption, EFSA Journal 2017 was taken into account	in vitro study according to OECD 428 guideline. In order to evaluate it, the Guidance on Dermal Absorption, EFSA Journal 2017 was taken into account	in vitro study according to OECD 428 guideline. In order to evaluate it, the Guidance on Dermal Absorption, EFSA Journal 2017 was taken into account	in vitro study according to OECD 428 guideline. In order to evaluate it, the Guidance on Dermal Absorption, EFSA Journal 2017 was taken into account

Data waiving	
Information requirement	At the beginning the justification of the applicant was that the dermal absorption values of the active substances given in the AR would be used. ES evaluated this justification but said values were referred to biocides with which a *read across* could not be done. The applicant was informed that these values could not be used and that the default values would be chosen considering the EFSA guidelines. Once the

applicant considered this decision by ES CA, the applicant decided to carry out an *in vitro* dermal absorption study.

The *in vitro* study was submitted with the biocidal product according to OECD 428 guideline. In order to evaluate it, the Guidance on Dermal Absorption, EFSA Journal 2017 was taken into account.

The rate and extent of absorption of cypermethrin, 3-iodo-2-propynyl-N-butylcarbamate (IPBC), propiconazole and tebuconazole was investigated following application of XYLAZEL TOTAL (a wood preservative) to excised human skin. Xylazel Total was applied as the commercially available formulation at nominal levels of 12.3 µg/cm2 (cypermethrin), 49.2 µg/cm2 (IPBC), 14.4 µg/cm2 (propiconazole) and 14.4 µg/cm2 (tebuconazole).
Ten flow-through diffusion cells were prepared. Dermatomed membranes (200 - 400 µm thickness) were maintained in the cells at approximately 32°C. The integrity of the membranes was first tested using tritiated water (3H2O). After removal of the residual 3H2O, the Xylazel Total was applied to the unoccluded skin samples as a solution at 6.4 µL per cell (10 µL/cm2).
Eight skin samples were exposed to the Xylazel Total for 6 hours, after which time the remaining dose was washed off the skin with a mild detergent solution. Receptor fluid was collected at 0, 3, 6, 12, 18 and 24 hours after dosing. The solubility of each test item in the receptor fluid was demonstrated to be sufficient for the study and was not rate limiting to the absorption process. At the end of the study, the skin samples were tape stripped to remove residual surface dose and the stratum corneum.
A validated liquid chromatography with tandem mass spectrometry method (LC-MS/MS) was used to determine the amount of cypermethrin, IPBC, propiconazole and tebuconazole in the collected samples.
The mean distribution of each test item is summarised in the following table. Results are expressed as percent cypermethrin, IPBC, propiconazole and tebuconazole applied.

	Cypermethrin	IPBC	Propiconazole	Tebuconazole
Total non-absorbed	88.03	90.17	81.32	81.74
Total absorbed	1.56	2.34	6.45	7.93
Total in stratum corneum	10.41	7.49	12.24	10.51
Total absorbable (total absorbed + total in stratum corneum)	-	9.83	18.68	18.26
Total absorbable + (sd x correction factor, k)	2.8[a]	14	25	24

a Value does not include total in stratum corneum since >75% of total absorption had occurred by 12 hours
k correction factor of 0.84 for eight cells

The directly absorbed test item (that in the receptor fluid, receptor chamber extracts and remaining in the skin after tape stripping) at 24 hours accounted for 1.56% (cypermethrin), 2.34% (IPBC), 6.45% (propiconazole) and 7.76% (tebuconazole), respectively.
For IBPC, propiconazole and tebuconazole less than 75% of total

	absorption had occurred by the midpoint of the study (12 hours). It is therefore considered that the test items remaining in the stratum corneum should be recognised as available for absorption. Therefore, the total amounts of radioactivity considered to be potentially absorbable by 24 hours were 9.83% (IPBC), 18.68% (propiconazole) and 18.26% (tebuconazole), respectively. According to the EFSA guidance where there is variability between replicates i.e. the standard deviation is >25% of the mean value, the value of the standard deviation should be multiplied by a correction factor and added to the overall absorbed value. Therefore, the amount considered as potentially absorbable is 2.8% (cypermethrin), 14% (IPBC), 25% (propiconazole) and 24% (tebuconazole), respectively.
Justification	Please, see above.

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

The biocidal product contains different low boling point naphthas. They are classified in Annex VI according to CLP Regulation as Asp. Tox. 1 with the hazard pictogram GHS08 and the hazard statement H304 May be fatal if swallowed and enters airways.

The CLP Regulation stablishes the following with this hazard:

In order to classify the mixtures when data are not available for the complete mixture, the bridging principles must be used: "*where the mixture itself has not been tested to determine its aspiration toxicity, but there are sufficient data on the individual ingredients and similar tested mixtures to adequately characterise the hazard of the mixture, these data shall be used in accordance with the bridging principles set out in section 1.1.3. However, in the case of application of the dilution bridging principle, the concentration of aspiration toxicant(s) shall be 10 % or more*". Taking into account this criteria and the concentration of this substance in the biocidal product, XYLAZEL TOTAL should be classified as Asp. Tox. 1 with the hazard pictogram GHS08 and the hazard statement H304 May be fatal if swallowed and enters airways.

Available toxicological data relating to a mixture

No other toxicological data of the biocidal product or of the other product with similar composition were submitted. CLP regulation has been used taking into account the different hazard statements of the components of the biocidal product where the study has not been submitted.

Other

Tebuconazole is classified, among other, as Repr. Cat. 2 (H361 Suspected of damaging fertility or the unborn child). Nevertheless, according to CLP Regulation, in order to classify the mixtures when data are not available for the complete mixture, the bridging principles must be used: "*the mixture shall be classified as a reproductive toxicant when at least one ingredient has been classified as a Category 1A, Category 1B or Category 2 reproductive*

toxicant and is present at or above the appropriate generic concentration limit as shown in Table 3.7.2 for Category 1A, Category 1B and Category 2 respectively". The table 3.7.2 stablishes the generic concentration limits in CLP Regulation:

Table 3.7.2

Generic concentration limits of ingredients of a mixture classified as reproduction toxicants or for effects on or via lactation that trigger classification of the mixture

Ingredient classified as:	Generic concentration limits triggering classification of a mixture as:			
	Category 1A reproductive toxicant	Category 1B reproductive toxicant	Category 2 reproductive toxicant	Additional category for effects on or via lactation
Category 1A reproductive toxicant	≥ 0,3 % [Note 1]			
Category 1B reproductive toxicant		≥ 0,3 % [Note 1]		
Category 2 reproductive toxicant			≥ 3,0 % [Note 1]	
Additional category for effects on or via lactation				≥ 0,3 % [Note 1]

Note

The concentration limits in the table above apply to solids and liquids (w/w units) as well as gases (v/v units).

Note 1

If a Category 1 or Category 2 reproductive toxicant or a substance classified for effects on or via lactation is present in the mixture as an ingredient at a concentration above 0,1 %, a SDS shall be available for the mixture upon request.

The concentration to classify *Category 2 reproductive toxicant* should be ≥ 3% but as the concentration of tebuconazole in the product is 0.175%, XYLAZEL TOTAL will not classify with this hazard statement.

IPBC is classified, among other, as STOT RE 1 (H372 Causes damages to organs). Nevertheless, according to CLP Regulation, in order to classify the mixtures when data are not available for the complete mixture, the bridging principles must be used: *"Where the mixture itself has not been tested to determine its specific target organ toxicity, but there are sufficient data on the individual ingredients and similar tested mixtures to adequately characterise the hazards of the mixture, these data shall be used in accordance with the bridging principles set out in section 1.1.3".* The Table 3.9.4 stablishes the generic concentration limits in CLP Regulation:

Table 3.9.4

Generic concentration limits of ingredients of a mixture classified as a specific target organ toxicant that trigger classification of the mixture

Ingredient classified as:	Generic concentration limits triggering classification of the mixture as:	
	Category 1	Category 2
Category 1 Specific Target Organ Toxicant	Concentration ≥ 10 %	1,0 % ≤ concentration < 10 %
Category 2 Specific Target Organ Toxicant		Concentration ≥ 10 % [(Note 1)]

The concentration to classify *Category 1 Specific Target Organ Toxicant* should be ≥ 10% but as the concentration of IPBC in the product is 0.6%, XYLAZEL TOTAL will not classify with this hazard statement.

Cypermethrin is classified, among other, as STOT RE 2 (H373 May cause damage to organs through prolonged or repeated exposure). Nevertheless, according to CLP Regulation, in order to classify the mixtures when data are not available for the complete mixture, the bridging principles must be used: *"Where the mixture itself has not been tested to determine its specific target organ toxicity, but there are sufficient data on the individual ingredients and similar tested mixtures to adequately characterise the hazards of the mixture, these data shall be used in accordance with the bridging principles set out in section 1.1.3".* The Table 3.9.4 stablishes the generic concentration limits in CLP Regulation:

Table 3.9.4

Generic concentration limits of ingredients of a mixture classified as a specific target organ toxicant that trigger classification of the mixture

Ingredient classified as:	Generic concentration limits triggering classification of the mixture as:	
	Category 1	Category 2
Category 1 Specific Target Organ Toxicant	Concentration ≥ 10 %	1,0 % ≤ concentration < 10 %
Category 2 Specific Target Organ Toxicant		Concentration ≥ 10 % [(Note 1)]

The concentration to classify *Category 2 Specific Target Organ Toxicant* should be ≥ 10% but as the concentration of cypermethrin in the product is 0.15%, XYLAZEL TOTAL will not classify with this hazard statement.

Low boiling point naphthas are included in the composition of the biocidal product. These substances can contain benzene, a constituent that is classified as a human carcinogen and a germ cell mutagen (please see Annex VI of CLP Regulation). This classification is not applicable if the concentration of benzene is lower than 0.1% (Note P of the CLP Regulation). In addition, these low boiling point naphthas can contain amounts of toluene and/or n-hexane, constituents that are classified as reprotoxicants. ES CA asked to the applicant about these impurities and an analytical certificated and a limit method of detection was sent: according to that, these substances are lower than 0.1%.

Endocrine disruption assessment

Assessment of the ED properties of the active substances:

The biocidal product contains Cypermethrin, Propiconazole, Tebuconazole and IPBC.

The CAR of cypermethrin indicate*: "The estrogenic potential of cypermethrin cis:trans/40:60 based on ER-mediated mechanisms remains equivocal. Contradictory results were revealed in different studies. In summary, the estrogenic and antiandrogenic effect of cypermethrin cis:trans/40:60 (and pyrethroids in general) depend on the assays or cells used. Results indicate that data obtained with high concentrations (> 10 µM) should be interpreted carefully (solubility of test chemical, cell toxicity). Possibly, cypermethrin cis:trans/40:60 is an oestrogen-like chemical that might act through signalling pathways other than direct ER binding, and as such, might function as an endocrine modulator. However, no definite conclusions can be drawn and there is no data available to the applicant or scientific evidence for endocrine disruption effect"*.

The CAR of propiconazole indicate: "*The dossier evaluated for this assessment report does not warrant conclusion of endocrine disruption potential for propiconazole. In the toxicity tests with mammals there were no effects in test animals which could be related to possible endocrine disruption. The literature review on endocrine disrupting mechanism of action (MoA) of propiconazole revealed that propiconazole has an endocrine MoA by interference of steroid hormone synthesis, however, the relevance of this remains unclear in the light of observed endocrine effects*".

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*".

Regarding the Tebuconazole, the CAR indicate: "*Tebuconazole or the metabolite 1,2,4 triazole are not included in the EU list of substances with evidence (Catefory 1) or potential endocrine disruption (Category 2) (COM (1999) 706). However, tebuconazole is included in table 4 (substances classified as HPV and/or persistent and/or exposure expected in humans and wildlife, with insufficient data). A number of studies investigating the endocrine effects of tebuconazole and other triazoles have been performed recently,*

e.g. Kjaerstad et al. (2010), Cericato et al. (2008), Sancho et al. (2010) showing some potential endocrine disrupting properties of tebuconazole and a number of other triazoles. However the interpretation of the results from these studies has not been fully agreed on but the results from these studies will be considered when criteria for endocrine disrupting substance are developed."

For IPBC, the CAR indicate: "*IPBC is not included in the EU list of potential endocrine disruptors (COM DG ENV, 2000)*".

Therefore, the evaluation of endocrine disruptions properties should be reevaluated in the renewal of active substances.

Assessment of the ED properties of non-active substances (co-formulants):

Since 7 June 2018, date when the Regulation (EU) 2017/2100 came into force, endocrine disruption assessment of co-formulants is mandatory according to the article 19. After reviewing the potential ED properties of co-formulants (please refer to the Confidential Annex), at this moment, based on the available information, ES CA considers that there is no concern regarding the ED properties of these co-formulants (some substances have been identified but no conclusion has been determinated).

Overall conclusion on the biocidal product regarding ED properties:

Based on the existing knowledge and the data provided by the applicant, there is no indication of concern regarding the ED properties of the substances used in the biocidal product because some substances have been identified but no the discussion about them has not been concluded).

If one or several components are identified as having ED properties in the future, the conditions for granting the biocidal product authorisation will be revised.

2.2.6.2. Exposure assessment

As stated in toxicology section, the product XYLAZEL TOTAL is classified as Skin Sens. 1B (H317: May cause an allergic skin reaction). A sub-categorization according to the potency of the substance (extreme, strong, moderate) has been stablished. This data is important to carry out a qualitative risk assessment to decide on base of exposure assessment, the authorisation of the biocidal product for general public and for non trained professional (please see table 25 and 26 of Guidance on the BPR: Volume III Parts B+C, Version 4.0 December 2017 and Guidance on the Application of the CLP Criteria, Version 5.0 – July 2017)

Taking into account Spanish definition of professionals[6], the decision on this category of users will depend on the necessary PPEs to obtain a non-concern situation from risk characterization of exposure scenarios. See section 2.2.6.3.

[6] Professional users (NTP): professionals that use the biocidal products in the context of his profession, that is not pest control operator, and that are unlikely to have received any specific training in biocidal product use according to the national legislation in force. It can be expected that they have some knowledge and skills handling chemicals (if they must use it in their job) and they are able to use correctly some kind of PPE if necessary.

The *in vitro* study was submitted with the biocidal product according to OECD 428 guideline. In order to evaluate it, the Guidance on Dermal Absorption, EFSA Journal 2017 was taken into account.

Therefore, dermal absorption values from assessment of effects on human health of this product will be used for exposure assessment porposes:

Value(s) used in the Risk Assessment – Dermal absorption				
Substance	IPBC	Tebuconazole	Cypermethrin	Propiconazole
Value(s)*	14%	24%	2.8%	25%
Justification for the selected value(s)	in vitro study according to OECD 428 guideline. In order to evaluate it, the Guidance on Dermal Absorption, EFSA Journal 2017 was taken into account	in vitro study according to OECD 428 guideline. In order to evaluate it, the Guidance on Dermal Absorption, EFSA Journal 2017 was taken into account	in vitro study according to OECD 428 guideline. In order to evaluate it, the Guidance on Dermal Absorption, EFSA Journal 2017 was taken into account	in vitro study according to OECD 428 guideline. In order to evaluate it, the Guidance on Dermal Absorption, EFSA Journal 2017 was taken into account

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

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

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group[1]**
1.	Double vacuum.	Primary exposure. Double-Vacuum treatment takes place in sealed	Industrial user

Non-professional users (NP): users who are not professionals and that apply the biocidal product is in his private life.

	(preventive)	chambers without operator's presence. Therefore, operators are dermally exposed through contact with contaminated equipment surfaces and through handling wet treated wood at the beginning or the end of the cycle treatment or by accidental contact with treated wood. In all cases, dermal exposed will be always over a short period.	
2.	Automated dipping process. (preventive)	Primary exposure. After loading the product into vessels systems, the product may be applied to the freshly cut wood automated dipping process.	Industrial user
3.	Automated spray application (preventive)	Primary exposure. The spraying process is done by automated machines in hermetic closed tanks at indoor industrial premises without operator presence during the application.	Industrial user
4.	Spray application (preventive and curative)	Primary exposure. Mixing and loading liquids in reservoir for powered spray application at 4 to 7 bar pressure as a coarse or medium spray, indoors, overhead and downwards. Scenario - medium pressure spray applications.	Trained-Professional
5.	Brushing (preventive and curative)	Primary exposure. This scenario of exposure may be occurring when the trained-professional user applies the product over the wood by using a brush, in absence of general public.	Trained-professional
5(2).	Brushing (preventive and curative)	Primary exposure. This scenario of exposure may be occurring when the non-professional user applies the product over the wood by using a brush.	Non-professional
6.	Injection (preventive and curative)	Primary exposure. The application by injection can be only applied by Trained-professional users as a curative treatment. The product is injected in the wood by means of a syringe, in absence of general public.	Trained-Professional
7.	Mixing and Loading	Primary exposure. The fluid is delivered in a container and is decanted from containers that are manually handled. This task is done by trained professionals where they are exposed during the mixing and loading operations during manual or automated addition.	Trained-professional
8.	Cleaning of brush equipment	Primary exposure scenario of an operator who is washing out of a brush which has been used to apply a conservative biocide.	Trained-professional
9.	Cleaning spray equipment	Primary exposure scenario of an operator who is cleaning the spary equipment which has been used to apply a conservative biocide.	Trained-professional
10.	Cutting and sanding	Secondary exposure. An adult who takes in contact with dry treated wood to move, cutting or sanding it.	Professional
11.	Cutting and sanding	Secondary exposure. An adult who takes in contact with dry treated wood to move, cutting or sanding it.	Non-professional

12.	Chewing wood off-cut	Secondary exposure. Toddler who takes a piece of treated wood and chews it. Therefore, this secondary exposure is foreseeable by ingestion.	General public
13.	Playing on weathered structure and mouthing	Secondary exposure. This scenario is considered for toddler who play on weathered structures. Secondary exposure is foreseeable by dermal and ingestion route.	General public
14.	Inhalation residues indoors	Secondary exposure. This scenario is considered for the General public that stays in a premise where the wood has been treated with the biocide product.	General public
15.	Laundering contaminated work clothing at home	This scenario assumes that the laundering is undertaken in a domestic, automatic washing machine.	Industrial (Trained-professional), Trained-professional, General public

1- Please see the authorised use section. The exposed groups are defined along this assessment as the groups authorised in the refMS. On the authorise use section the reader can find the equivalence of users in other concerned member states.

COMBINED SCENARIOS:

Summary table: COMBINED scenarios			
Scenario number	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
(1) + (7) + (15)	Automated double vacuum / M&L / Laundering work clothes	**Primary exposure** Combined scenarios for application by automated double vacuum and rest of tasks of treatment.	Industrial (Trained professionals)
(2) + (7) + (15)	Automated dipping / M&L / Laundering work clothes	**Primary exposure** Combined scenarios for application by automated dipping and rest of tasks of treatment.	Industrial (Trained professionals)
(3) + (7) + (15)	Automated spraying / M&L / Laundering work clothes	**Primary exposure** Combined scenarios for application by automated spraying and rest of tasks of treatment.	Industrial (Trained professionals)
(3) + (7) + (9) + (15)	Spraying / M&L / Cleaning equipment / Laundering work clothes	**Primary exposure** Combined scenarios for application by spraying vacuum and rest of tasks of treatment.	Industrial (Trained professionals)
(4) + (7) + (9) + (15)	Spraying / M&L / Laundering work clothes / Cleaning spray equipment	**Primary exposure** Combined scenarios for application by spraying and rest of tasks of treatment.	Trained professionals
(5) + (7) + (8) + (15)	Brushing / M&L / Washing brushes / Laundering work clothes	**Primary exposure** Combined scenarios for application by brushing and rest of tasks of treatment.	Trained professionals
(5)(2) + (7) + (8) + (15)	Brushing / M&L / Washing brushes / Laundering work clothes	**Primary exposure** Combined scenarios for application by brushing and rest of tasks of treatment.	Non-professionals

See Annex 3.2 for calculations

Industrial (Trained professionals) exposure

Three scenarios have been considered for the exposure estimation during product application for industrial preventive treatment:

- Pressure process (double vacuum-pressure)
- Immersion / dipping (automated)
- Spray tunnels (automated)

Industrial processes are carried out in facilities with closed or confined areas made of materials resistant to the wood preservative product. Provisions are made for the collection, recycling and reuse of wood preservative collected from the conveyor or drip drying area. The release of wood preservatives from the treatment facility or from the places where treated wood is stored, into a surface water drain or a drain connected to a Wastewater Treatment Plant (STP) is not allowed.

Scenario [1] **Double Vacuum pressure**

Description of Scenario [1]		
Double vacuum pressure preventive treatment takes place in sealed chambers without operator's presence. Therefore, operators are dermally exposed through contact with contaminated equipment surfaces and through handling wet treated wood at the beginning or the end of the cycle treatment or by accidental contact with treated wood. In all cases, dermal exposed will be always over a short period (during the few minutes at the start and the few minutes at the end of the impregnation cycle). Following Recommendation 6 - Methods and models – version 4, Handling model 1 form TNsG 2002 User Guidance - Version 1 is carried out.		
	Parameters	Value
Tier 1	Hand exposure[1]	260 mg/cycle (inside gloves) 88.8 mg/cycle (75thpercentile TNsG 2002)
	Body exposure[1]	158 mg/cycle
	Inhalation[1]	0.6 mg/m3
	Duration[1]	6 cycles, 60 min.
	Dermal absortion	Cypermethrin 2.8%
		Tebuconazol 24%
		Propiconazol 25%
		IPBC 14%
	Body weight[2]	60kg
	Inhalation rate[2]	1.25m^3/h
Tier 2	a) Coverall Permeation [3]	10%

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

[2] HEAdhoc Recommendation no. 14 Default human factor values for use in exposure assessment for biocidal products
[3] HEEG Opinion 9 Default protection factors for protective clothing and gloves. Impermeable coveralls.

Calculations for Scenario [1] Double Vacuum pressure

Relevant calculations are included in Annex 3.2

Summary table: estimated exposure from industrial uses					
Exposure scenario	**Tier / PPE**	**Active substance**	**Estimated inhal uptake mg/kg bw/d**	**Estimated dermal uptake mg/kg bw/d**	**Estimated total uptake mg/kg bw/d**
Scenario [1] Double Vacuum pressure	1	cypermethrin	1,88E-05	1,76E-03	1,77E-03
		tebuconazol	2,19E-05	1,76E-02	1,76E-02
		propiconazol	2,19E-05	1,83E-02	1,83E-02
		IPBC	7,50E-05	3,51E-02	3,52E-02
Scenario [1] Double Vacuum pressure	2a	cypermethrin	1,88E-05	1,16E-03	1,18E-03
		tebuconazol	2,19E-05	1,16E-02	1,16E-02
		propiconazol	2,19E-05	1,21E-02	1,21E-02
		IPBC	7,50E-05	2,32E-02	2,32E-02

Scenario [2] Automated dipping

Description of Scenario [2]		
HEEG opinion 8 (2009) is applied for exposure assessment. Automated dipping preventive treatment 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.		
	Parameters	Value
Tier 1	Hand exposure[1]	260 mg/cycle (inside gloves)
	Body exposure[1]	158 mg/cycle
	Inhalation[1]	0.6 mg/m^3
	Duration[2]	4 cycles
	Dermal absortion	Cypermethrin 2.8%

Description of Scenario [2]		
		Tebuconazol 24%
		Propiconazol 25%
		IPBC 14%
	Body weight[3]	60kg
	Inhalation rate[3]	1.25m^3/h
Tier 2	Coverall Permeation[4]	10%

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

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

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

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

Calculations for Scenario [2] Automated dipping

Relevant calculations are included in Annex 3.2

Summary table: estimated exposure from industrial uses					
Exposure scenario	**Tier / PPE**	**Active substance**	**Estimated inhal uptake mg/kg bw/d**	**Estimated dermal uptake mg/kg bw/d**	**Estimated total uptake mg/kg bw/d**
Scenario [2] Automated dipping	1	cypermethrin	7,50E-05	1,17E-03	1,25E-03
		tebuconazol	8,75E-05	1,17E-02	1,18E-02
		propiconazol	8,75E-05	1,22E-02	1,23E-02
		IPBC	3,00E-04	2,34E-02	2,37E-02
Scenario [1] Automated dipping	2a	cypermethrin	7,50E-05	7,72E-04	8,47E-04
		tebuconazol	8,75E-05	7,72E-03	7,81E-03
		propiconazol	8,75E-05	8,04E-03	8,13E-03
		IPBC	3,00E-04	1,54E-02	1,57E-02

Scenario [3]: Industrial automated spraying

Description of Scenario [3]
Industrial automated spraying preventive scenario, as requested for the applicant, includes the following operations: an operator using a fork-lift truck (or similar) equipment lowers the wood into the spraying tank. Spraying process is carried out by automated machines in hermetic closed tanks without operator presence during the application. Wood is lifted out of the tank by the fork-lift truck (or similar). The wood is then transferred by the fork-lift truck (or similar) to a storage area where it is placed to dry. Reading accross from HEEG opinion 8 – (Defaults and appropriate models to assess human exposure for dipping processes), dermal exposure pattern of automated spraying

is comparable to that of automated dipping process. Based on this assumption the appropriate model to assess the automated spraying process is Handling model 1. This model is used to assess the profesional intermittently handling water-wet or solvent-damp wood and associated equipment after vacuum pressure processes (p. 26 of User Guidance, 2002). For application a default value of 60 minutes was used, by 2 cycles per day.		
	Parameters	Value
Tier 1	Hand exposure[1]	260 mg/cycle (inside gloves)
	Body exposure[1]	158 mg/cycle
	Inhalation[1]	0.6 mg/m3
	Duration[2]	2 cycles
	Dermal absortion	Cypermethrin 2.8%
		Tebuconazol 24%
		Propiconazol 25%
		IPBC 14%
	Body weight[3]	60kg
	Inhalation rate[3]	1.25m^3/h

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

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

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

Calculations for Scenario [3]

Relevant calculations are included in Annex 3.2

Summary table: estimated exposure from industrial uses					
Exposure scenario	**Tier/PPE**	**Active substance**	**Estimated inhal uptake mg/kg bw/d**	**Estimated dermal uptake mg/kg bw/d**	**Estimated total uptake mg/kg bw/d**
Automated spraying	1	cypermethrin	6,25E-06	5,85E-04	5,91E-04
		tebuconazol	7,29E-06	5,85E-03	5,86E-03
		propiconazol	7,29E-06	6,10E-03	6,10E-03
		IPBC	2,50E-05	1,17E-02	1,17E-02

Trained-Professional exposure

For ***in-situ treatments by trained professionals***, XYLAZEL TOTAL is intended to be used for treatment through the following methods:

- Spraying
- Brushing
- Injection

Indoor applications have been considered as the worst-case situations for human exposure and the risk derived from these indoor uses cover the human risk under outdoor conditions.

Scenario [4]: **Trained-professional spraying**

Description of Scenario [4]		
Spraying application is performed by the operator on the wood surfaces by a handheld or knapsack sprayer in absence of general public. Indoor application at premises like parquet, flooring, wood decor (plinths, friezes, baseboards) or carpentry (doors and windows) is considered a worse case for human exposure.. This task is developed for preventive treatments. Following the Biocides Human Health Exposure Methodology, to evaluate the operator exposure for the application method for trained-professionals, spraying model 2 of TNsG 2002, Part 2, has been chosen as the most similar scenario. This model is evaluated for indoor treatments which is considered worst-case scenario for human risk compared to outdoor use. The model includes the tasks for "mixing and loading" and "spray application" at a pressure from 4 to 7 bar.		
	Parameters	Value
Tier 1	Hands exposure[1]	273 (mg/min)
	Body exposure[1]	222 (mg/min)
	Inhalation[1]	76 (mg/m3)
	Duration[1]	80 minutes (by two events of 40 minutes) without distinction between the M&L and application phases.
	Dermal absorption	Cypermethrin 2.8%
		Tebuconazol 24%
		Propiconazol 25%
		IPBC 14%
	Body weight[2]	60kg
	Inhalation rate[2]	1.25m^3/h
Tier 2	Hands exposure[1] (inside gloves)	7.8 (mg/min)
Tier 3	Coverall Permeation[3]	5%
Tier 4	Mask P3 Permeation[4]	2.5%

[1] Biocides Human Health Exposure Methodology

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

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

[5] EN 529-2005

Calculations for Scenario [4]

Relevant calculations are included in Annex 3.2

Summary table: estimated exposure from Spraying					
Exposure scenario	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake mg/kg/d**	**Estimated dermal uptake mg/kg/d**	**Estimated total uptake mg/kg/d**
Spraying	1	cypermethrin	3,17E-03	2,77E-02	3,09E-02
		tebuconazol	3,69E-03	2,77E-01	2,81E-01
		propiconazol	3,69E-03	2,89E-01	2,92E-01
		IPBC	1,27E-02	5,54E-01	5,67E-01
Spraying	2 Gloves	cypermethrin	3,17E-03	1,29E-02	1,60E-02
		tebuconazol	3,69E-03	1,29E-01	1,32E-01
		propiconazol	3,69E-03	1,34E-01	1,38E-01
		IPBC	1,27E-02	2,57E-01	2,70E-01
Spraying	3 Gloves and coverall 5%	cypermethrin	3,17E-03	1,06E-03	4,23E-03
		tebuconazol	3,69E-03	1,06E-02	1,43E-02
		propiconazol	3,69E-03	1,10E-02	1,47E-02
		IPBC	1,27E-02	2,12E-02	3,38E-02
Spraying	4 Gloves and coverall 5% and mask P3	cypermethrin	7,92E-05	1,06E-03	1,14E-03
		tebuconazol	9,24E-05	1,06E-02	1,07E-02
		propiconazol	9,24E-05	1,10E-02	1,11E-02
		IPBC	3,17E-04	2,12E-02	2,15E-02

Scenario [5]: **Trained-professional brushing**

Description of Scenario [5]		
In Trained-professioinal brushing scenario the user applies the product over the wood by using a brush in absence of general public. This task is developed for preventive or curative treatments. According to Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure, following values are used in exposure assessment:		
	Parameters	Value
Tier 1	Hands exposure[1]	0.5417 (mg/m^2)
	Body exposure[1]	0.2382 (mg/m^2)
	Inhalation[1] non-volatile compounds	0.0016 (mg/m^2)
	Duration[1]	240 min
	Application area[1]	31.6 m^2

	Dermal absortion	Cypermethrin 2.8%
		Tebuconazol 24%
		Propiconazol 25%
		IPBC 14%
	Body weight[2]	60kg
	Inhalation rate[2]	1.25m^3/h
Tier 2	Gloves permeation[3]	5%
	Coverall Permeation[3]	10%

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

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

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

Calculations for Scenario [5]

Relevant calculations are included in Annex 3.2

Summary table: estimated exposure from Brushing					
Exposure scenario	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake mg/kgbw/d**	**Estimated dermal uptake mg/kgbw/d**	**Estimated total uptake mg/kgbw/d**
Brushing	1	cypermethrin	1,47E-04	1,73E-03	1,87E-03
		tebuconazol	2,53E-04	1,73E-02	1,75E-02
		propiconazol	2,53E-04	1,80E-02	1,82E-02
		IPBC	2,53E-04	3,45E-02	3,48E-02
Brushing	2 Gloves and coverall 5%	cypermethrin	1,47E-04	1,46E-04	2,94E-04
		tebuconazol	2,53E-04	1,46E-03	1,71E-03
		propiconazol	2,53E-04	1,52E-03	1,78E-03
		IPBC	2,53E-04	2,92E-03	3,18E-03

Scenario [5(2)]: **Non-professional brushing**

Description of Scenario [5]		
In Non-professioinal brushing scenario the user applies the product over the wood by using a brush. This task is developed for preventive or curative treatments. According to Recommendation no. 10 of the BPC Ad hoc Working Group on Human Exposure, following values are used in exposure assessment:		
	Parameters	Value

Tier 1	Hands exposure[1]	1.7 µl/min
	Body exposure[1]	1.12 µl/min
	Inhalation[1] non-volatile compounds	1.63 mg/m^3
	Duration[1]	120 min
	Application area[1]	31.6 m^2
	Dermal absortion	Cypermethrin 2.8%
		Tebuconazol 24%
		Propiconazol 25%
		IPBC 14%
	Body weight[2]	60kg
	Inhalation rate[2]	1.25m^3/h

[1] Recommendation no. 10 of the BPC Ad hoc Working Group on Human Exposure and Biocides Human Health Exposure Methodology

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

Calculations for Scenario [5(2)]

Relevant calculations are included in Annex 3.2

Summary table: estimated exposure from Brushing					
Exposure scenario	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake mg/kgbw/d**	**Estimated dermal uptake mg/kgbw/d**	**Estimated total uptake mg/kgbw/d**
Brushing	1	cypermethrin	1,26E-06	7,07E-04	7,08E-04
		tebuconazol	2,21E-09	7,07E-03	7,07E-03
		propiconazol	3,87E-12	7,36E-03	7,36E-03
		IPBC	2,32E-14	1,41E-02	1,41E-02

Scenario [6]: **Trained-professional Injection**

Description of Scenario [6]
Injection curative scenario, as requested for the applicant, includes two application methods: 1. Injection application via filling of fligh holes for **Anobium punctatum De Geer** - 300 ml/m^2 for curative treatments. - 0.4-0.5 mL/hole, 5-7 times. 2. Injection application via pressure injection for **Hylotrupes bajulus** - 50 Kg/m^3 a) The product is applied in beams with a section greater than 15cm. b) Drill holes of 9 mm in staggered length every 40 cm and up to 2/3 of the

thickness of the piece of woodwork (for example a beam).

c) Place an anti-return injection nozzle, one direction, in each hole. For this use a nylon hammer. Only the injection lug should be visible.
d) Insert the injector of the gun on the nipple of the nozzle. The product of the treatment is pumped directly from the drum by the electric pump.
e) Saturate with product.
f) Uncouple the injection gun

According to Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure, proposed model 30 to assess primary exposure to PT8 for professional borehole pressure impregnation application including mixing and loading (Subsoil treatment Model 2) has been used with parameters showed in the following table:

	Parameters	Value
Tier 1	Hand exposure[1]	8 mg/min (inside gloves)
	Inhalation non-volatile compounds[1]	0.57 mg/m3
	Duration[1]	80 min
	Dermal absortion	Cypermethrin 2.8%
		Tebuconazol 24%
		Propiconazol 25%
		IPBC 14%
	Body weight[2]	60kg
	Inhalation rate[2]	1.25m^3/h

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

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

Calculations for Scenario [6]

Relevant calculations are included in Annex 3.2

Summary table: estimated exposure from Injection					
Exposure scenario	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake mg/kg bw/d**	**Estimated dermal uptake mg/kg bw/d**	**Estimated total uptake mg/kg bw/d**
Injection	1 Gloves	cypermethrin	1,43E-03	2,69E-02	2,83E-02
		tebuconazol	1,66E-03	2,69E-01	2,70E-01
		propiconazol	1,66E-03	2,80E-01	2,82E-01
		IPBC	5,70E-03	5,38E-01	5,43E-01

Scenario [7]: **Mixing and Loading**

Description of Scenario [7]

The fluid is delivered in a container and is decanted from containers that are manually handled. This task is done by trained-professionals where they are exposed during the mixing and loading operations during manual or automated addition. According to HEEG Opinion 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), has been used to calculate the exposure due to liquid manual loading/pouring application for this scenario.		
	Parameters	Value
Tier 1	Dermal exposure under clothes and gloves[1]	1.01 mg/min
	Inhalation exposure[1]	0.94 mg/m3
	Duration[1]	10 min
	Dermal absortion	Cypermethrin 2.8%
		Tebuconazol 24%
		Propiconazol 25%
		IPBC 14%
	Body weight[2]	60kg
	Inhalation rate[2]	1.25m^3/h

[1] HEEG opinion 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.

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

Calculations for Scenario [7]

Relevant calculations are included in Annex 3.2

Summary table: estimated exposure from Mixing and Loading					
Exposure scenario	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake mg/kg/d**	**Estimated dermal uptake mg/kg/d**	**Estimated total uptake mg/kg/d**
Mixing and Loading	1 Gloves and clothes	cypermethrin	4,90E-06	7,07E-06	1,20E-05
		tebuconazol	5,71E-06	7,07E-05	7,64E-05
		propiconazol	5,71E-06	7,36E-05	7,94E-05
		IPBC	1,96E-05	1,41E-04	1,61E-04

Scenario [8]: **Wash out of brushes**

Description of Scenario 8
A post-application task which may lead to some degree of exposure is cleaning the brush used to apply the product. Brush cleaning by trained professionals can be expected to last

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

	Parameters	Value
Tier 1	Body weight[2]	60 kg
	Brush size	200 mL
	Volume of residual solution in brush	1/8 of brush volume = 25 mL
	Volume of each washing solution[1]	400 mL
	Remaining residues in brush after each washing step[1]	10%
	Remaining residues in brush after each squeezing[1]	50%
	Penetration through cleaning cloth during squeezing[1]	10%
	Dermal absorption	Cypermethrin 2.8%
		Tebuconazol 24%
		Propiconazol 25%
		IPBC 14%
Tier 2	Gloves	90% protection

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

[2] HEAdhoc Recommendation no. 14 - Default human factor values for use in exposure assessments for biocidal products (HH WG III, 2017)

Calculations for Scenario [8]

Relevant calculations are included in Annex 3.2

Summary table: estimated exposure from Washing out brushes					
Exposure scenario	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake**	**Estimated dermal uptake mg/kg bw/d**	**Estimated total uptake mg/kg bw/d**
Washing out brushes	1	cypermethrin	-	7,55E-05	7,55E-05
		tebuconazol	-	7,55E-04	7,55E-04
		propiconazol	-	7,87E-04	7,87E-04
		IPBC	-	1,51E-03	1,51E-03
Washing out brushes	2 Gloves	cypermethrin	-	7,55E-06	7,55E-06
		tebuconazol	-	7,55E-05	7,55E-05
		propiconazol	-	7,87E-05	7,87E-05
		IPBC	-	1,51E-04	1,51E-04

Scenario [9]: **Cleaning spray equipment**

Description of Scenario 9		
A post-application task which may lead to some degree of exposure is cleaning the spray equipment used to apply the product. Spray cleaning by trained professionals can be expected to last for no more than 20 minutes and might result in some exposure to hands. To calculate the exposure due to spray equipment, the Recommendation no. 4 of the BPC Ad hoc Working Group on Human Exposure "Cleaning of Spray equipment in antifouling use (PT21)" have been used. During brush cleaning, trained professionals may retain gloves worn during brush application of the product (Tier 2 assessment). No exposure of areas of the body other than the hands is assumed to occur; and exposure via inhalation is considered negligible.		
	Parameters	Value
Tier 1	Hand exposure[1]	28,59mg/min
	Body exposure[1]	15.37 mg/min
	Duration[1]	20 min
	Dermal absortion	Cypermethrin 2.8%
		Tebuconazol 24%
		Propiconazol 25%
		IPBC 14%
Tier 2	Gloves[2]	90% protection
	Impermeable coverall[2]	95% protection

[1] Recommendation no. 4 of the BPC Ad hoc Working Group on Human Exposure "Cleaning of Spray equipment in antifouling use (PT21)"

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

Calculations for Scenario [9]

Relevant calculations are included in Annex 3.2

Summary table: estimated exposure from cleaning spray equipment				
Exposure scenario	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake**	**Estimated dermal uptake mg/kg bw/d**
Cleaning spray equipment	1	cypermethrin	-	6,15E-04
		tebuconazol	-	6,15E-03
		propiconazol	-	6,41E-03
		IPBC	-	1,23E-02
Cleaning spray equipment	2 Gloves and coverall	cypermethrin	-	5,08E-05
		tebuconazol	-	5,08E-04
		propiconazol	-	5,29E-04
		IPBC	-	1,02E-03

Secondary (indirect) Exposure

Industrial, Trained professionals, Professionals and Non-professionals exposure

Considering the human secondary exposure to PT08, the TNsG (2002) makes a distinction between scenarios for preventive and curative products and establish the following classification:

Reference Scenarios for Preventive Products:	Acute phase reference scenarios: - Adult - cutting and sanding treated wood (non-professional) - Toddler - chewing wood off-cut Chronic phase reference scenarios: - Adult - cutting and sanding treated wood (professional) - Adult - inhalation of volatilised residues indoors - Adult - laundering work clothes at home - Toddler - playing on weathered structure and mouthing
Reference Scenarios for Curative Products:	Acute phase reference scenarios: - Not relevant Chronic phase reference scenarios: - Adult/infant - inhalation of volatilized residues indoors. - Adult - laundering work clothes at home

Other secondary exposure scenario that can affect the total exposure to which industrial and trained professional users are also subjected is the scenario of washing work clothes at home when the contracting company does not have a laundry service.

Scenario [10]: **Professional sanding treated wood. Curative**

This scenario has been calculated for curative treatment as a worst case.

Description of Scenario [10]		
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).		
	Parameters	Value
Tier 1	Volume of wood to be sanded in 1h	4,00E+03 cm^3
	Rate of product absorbed in wood (2l/4m^2)	5 mg/cm^2
	Product density	0.820 g/ml
	Wood density	0.4 g/ml
	Dust concentration in air (occupational exposure limit for wood dust)	5 mg/m^3
	Inhalation rate[2]	1.25 m^3/h
	Exposure duration	6 h
	Body weight[2]	60 kg
	Percentage dislodgeable[3]	2%
	Hand surface[2]	420 cm^2
	Transfer to hands	20%
	Dermal absortion	Cypermethrin 2.8%
		Tebuconazol 24%
		Propiconazol 25%
		IPBC 14%

[1] TNsG on Human Exposure to Biocidal Products Part 3, p50-51 as revised by User Guidance version 1 p50-54 (EC, 2002a)

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

[3] *Biocides Human Health Exposure Methodology* 2015, p. 181.

Calculations for Scenario [11]

Relevant calculations are included in Annex 3.2

Summary table: estimated exposure from Professional sanding treated wood. Curative

Exposure scenario	Tier/PPE	Active substance	Estimated inhalation uptake mg/kg bw/d	Estimated dermal uptake mg/kg bw/d	Estimated total uptake mg/kg bw/d
Professional sanding treated wood. Curative	Tier 1	cypermethrin	5,81E-05	2,89E-05	8,70E-05
		tebuconazol	6,78E-05	2,89E-04	3,57E-04
		propiconazol	6,78E-05	3,01E-04	3,69E-04
		IPBC	2,32E-04	5,79E-04	8,11E-04

Scenario [11]: **Non-Professional sanding treated wood. Curative**

This scenario has been calculated for curative treatment as a worst case.

Description of Scenario [11]		
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).		
	Parameters	Value
Tier 1	Volume of wood to be sanded in 1h	4,00E+03 cm^3
	Rate of product absorbed in wood (2l/4m^2)	5 mg/cm^2
	Product density	0.820 g/ml
	Wood density	0.4 g/ml
	Dust concentration in air (occupational exposure limit for wood dust)	5 mg/m^3
	Inhalation rate[2]	1.25 m^3/h
	Exposure duration	1 h
	Body weight[2]	60 kg
	Percentage dislodgeable[3]	2%
	Hand surface[2]	420 cm^2
	Transfer to hands	20%
	Dermal absortion	Cypermethrin 2.8%
		Tebuconazol 24%
		Propiconazol 25%
		IPBC 14%

[1] TNsG on Human Exposure to Biocidal Products Part 3, p50-51 as revised by User Guidance version 1 p50-54 (EC, 2002a)

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

[3] *Biocides Human Health Exposure Methodology* 2015, p. 181.

Calculations for Scenario [11]

Relevant calculations are included in Annex 3.2

Summary table: estimated exposure from Non-Professional sanding treated wood. Curative					
Exposure scenario	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake mg/kg bw/d**	**Estimated dermal uptake mg/kg bw/d**	**Estimated total uptake mg/kg bw/d**
Non-Professional sanding treated wood. Curative	Tier 1	cypermethrin	9,69E-06	2,89E-05	3,86E-05
		tebuconazol	1,13E-05	2,89E-04	3,01E-04
		propiconazol	1,13E-05	3,01E-04	3,13E-04
		IPBC	3,87E-05	5,79E-04	6,17E-04

Scenario [12] **Toddler chewing treated wood chip.**

This scenario has been calculated for curative treatment as a worst case.

Description of Scenario [12]		
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
Tier 1	Application rate	300 ml/m^2 24.6mg/cm^2
	Extraction by chewing[1]	10%
	Size of wood composites chip[1]	16cm^3
	Surface of wood composite chip treated[1]	16cm^2
	Cypermetrin oral absorption	57%
	Rest od active substances oral absortion	100%
	Body weight[2]	10 kg

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

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

Calculations for Scenario [12]

Relevant calculations are included in Annex 3.2

This scenario has been calculated for curative treatment as a worst case.

Summary table: estimated exposure from Toddler chewing treated wood chip. Curative.

Exposure scenario	Tier/PPE	Active substance	Estimated oral uptake mg/kg bw/d	Estimated dermal uptake mg/kg bw/d	Estimated total uptake mg/kg bw/d
Toddler chewing wood chip Curative	Tier 1	cypermethrin	3,37E-03		3,37E-03
		tebuconazol	6,80E-03		6,80E-03
		propiconazol	6,89E-03		6,89E-03
		IPBC	2,36E-02		2,36E-02

Scenario [13] **Toddler playing and mouthing on playground weathered wood structure outdoors**

Relevant calculations are included in Annex 3.2

This scenario has been calculated for curative treatment as a worst case.

Description of Scenario [13] Toddler playing and mouthing on playground weathered wood structure outdoors. Curative		
Scenario developed according to TNsG on Human Exposure to Biocidal Products Part 3, pg 51 (EC, 2002a).		
Tier 1	Parameters[1]	Value
	Application rate	300 ml/m^2 24.6mg/cm^2
	Contact surface (hands)[2]	2,31E+02 cm^2
	Hands Contaminated area (%)[1]	20%
	Dislogeable fraction (%)[1]	2%
	Dermal absortion	Cypermethrin 2.8%
		Tebuconazol 24%
		Propiconazol 25%
		IPBC 14%
	Hands surface area mouthing[2]	40% Palms of both hands
	Transfer coefficient of dried product from hand to mouth	50%
	Cypermetrin oral absorption	57%
	Rest of active substances oral absortion	100%
	Body weight[2]	10 kg

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

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

Calculations for Scenario [13]

Relevant calculations are included in Annex 3.2

Summary table: estimated exposure from toddler playing and mouthing on playground weathered wood structure outdoors. Preventive/acute				
Exposure scenario	**Active substance**	**Estimated oral uptake mg/kg bw/d**	**Estimated dermal uptake mg/kg bw/d**	**Estimated total uptake mg/kg bw/d**
Toddler playing and mouthing on playground weathered wood structure outdoors	cypermethrin	9,73E-04	9,56E-05	1,07E-03
	tebuconazol	1,99E-03	9,56E-04	2,95E-03
	propiconazol	1,99E-03	9,96E-04	2,99E-03
	IPBC	6,83E-03	1,91E-03	8,74E-03

Scenario [14]: **General public - Inhalation volatilased residues indoors**

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

Description of Scenario [14]

The exposure assessment due to this scenario has been carried out according to HEEG Opinion 13.
As a Tier-1 screening tool whether inhalation exposure can be neglected or should be included into the risk assessment, the following screening test which is based on the toddler representing the worst case is proposed for each active substance:

Let mw and vp denote the molecular weight (in g/mol) and the vapour pressure (in Pa).For toddler (based on an inhalation rate of 8 m^3/24 hr and bw of 10 kg) and using an AEL in mg a.s./kg bw/d, if

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

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

For the product, there are four active substances:

Active substance	Vapour pressure a.s.	Molecular weight a.s.	AEL long term (mg a.s./kg/bw/d)	Constant	Result	**Negligible / Included**
Cypermethrin	2,30E-07	416,3	0,022	0,328	1,43E-03	negligible
Tebuconazol	1,70E-06	307,8	0,03	0,328	5,72E-03	negligible
Propiconazol	5,60E-05	342,2	0,04	0,328	1,57E-01	negligible

IPBC	4,50E-03	281,1	0,2	0,328	2,07E+00	**included**

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

	Parameters		Value
Tier 1	IPBC	Vapour pressure a.s.	4,50E-03 Pa
		Molecular weight a.s.	281,1 g/mol
	Constante de gases[1]		8,31451 J mol^{-1} K^{-1}
	Temperatura[1] (K)		298 K
	Inhalation rate[1]		8 m^3/24 h
	Body weight[1]		10 Kg

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

Calculations for Scenario [14]

Relevant calculations are included in Annex 3.2

Summary table: estimated exposure from Inhalation volatilased residues indoors				
Exposure scenario	**Active substance**	**Estimated inhalation uptake mg/kg bw/d**	**Estimated dermal uptake mg/kg bw/d**	**Estimated total uptake mg/kg bw/d**
Inhalation volatilased residues indoors	IPBC	4,08E-03		4,08E-03

Scenario [15]: **Laundering of brushing work clothes**

Description of Scenario 15

Exposure to XYLAZEL TOTAL can occur when washing contaminated work clothes. Persons at risk are adults trained-professionals. The exposure is considered acute intermediary, as it does not occur on a daily basis but may be longer-term.
In general, this approach assumes that the washing is carried out in a domestic automatic washing machine, therefore, the exposure will be dermally through the hands, from handling the contaminated clothes before and during the introduction of the clothes in the washing machine. Laundering is considered to be after a five day work week, hence the total amount of product on work clothes is assumed to be five times the daily contamination associated with the application method used and it is assumed that the clothing to be washed is a coverall worn by a trained professional. The contamination of the coveralls is based on the trained professional brushing scenario from which the tier that shows safe use is tier 2.

Indicative value from model	mg/m^2	0,238200
Applicatio area *	m^2/day	31,6
potential dermal deposit	mg/day	7,53
clothing penetration from model	%	100%

actual dermal product deposit	mg/day	7,53
clothing penetration from model	%	10%
product under coverall	mg/day	0,75
product on coverall	**mg/day**	**6,77**

The sum transfer area is determined by estimating how many times the coverall is touched by the hands while preparing it for laundering. As a first tier, it is assumed that this happens three times, twice with the palms of both hands and once with the total hands surface, the sum transfer area is 1640 cm2. As a worst-case assumption, 50% of the residues in the touched area is transferred to the skin (transfer coefficient). The scenario is modelled after the CAR for Propiconazole in PT8 (FI CA, 2007).

	Parameter	**Value**
Tier 1	Clothing contamination from brushing[1]	6.77 mag/day
	Days before washing	5 days
	Percentage dislodgeable (transfer coefficient)[2]	30%
	Surface of medium coated coverall[2]	22700 cm^2
	Sum transfer area[3]	1640 cm^2

[1] Clothing contamination equals the highest potential body exposure (Scanario 5) minus the amount that penetrates through the clothing (10 %), and is expressed as mg a.s./day.

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

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

[4] Based on a surface area of both palms of 410 cm2 and total surface of both hands of 820 cm2; see HEAdhoc Recommendation no. 14 Default human factors values for use in exposure assessment for biocidal products.

Calculations for Scenario [15]

Relevant calculations are included in Annex 3.2

Summary table: estimated exposure from Laundery of brushing work clothes				
Exposure scenario	**Active substance**	**Estimated oral uptake**	**Estimated dermal uptake mg/kg bw/d**	**Estimated total uptake mg/kg bw/d**
Laundery of brushing work clothes	cypermethrin		5,14E-07	5,14E-07
	tebuconazol		5,14E-06	5,14E-06
	propiconazol		5,35E-06	5,35E-06
	IPBC		1,03E-05	1,03E-05

Combined scenarios

Combined exposures by same active substance by different tasks may occur. For this assessment, the following list of combined scenarios for Industrial (trained professionals) and trained professionals were combined for each active substance.

Summary table: COMBINED scenarios			
Scenario number	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
(1) + (7) + (15)	Automated double vacuum / M&L / Laundering work clothes	**Primary exposure** Combined scenarios for application by automated double vacuum and rest of tasks of treatment.	Industrial (Trained professionals)
(2) + (7) + (15)	Automated dipping / M&L / Laundering work clothes	**Primary exposure** Combined scenarios for application by automated dipping and rest of tasks of treatment.	Industrial (Trained professionals)
(3) + (7) + (15)	Automated spraying / M&L / Laundering work clothes	**Primary exposure** Combined scenarios for application by automated spraying and rest of tasks of treatment.	Industrial (Trained professionals)
(4) + (7) + (9) + (15)	Spraying / M&L / Laundering work clothes / Cleaning spray equipment	**Primary exposure** Combined scenarios for application by spraying and rest of tasks of treatment.	Industrial (Trained professionals) Trained professionals
(5) + (7) + (8) + (15)	Brushing / M&L / Washing brushes / Laundering work clothes	**Primary exposure** Combined scenarios for application by brushing and rest of tasks of treatment.	Trained professionals
(5)(2) + (7) + (8) + (15)	Brushing / M&L / Washing brushes / Laundering work clothes	**Primary exposure** Combined scenarios for application by brushing and rest of tasks of treatment.	Non-professionals

Combined Scenarios Automated double vacuum / M&L / Laundering work clothes						
Combined SCENARIOS	**Tier**	**Active substance**	**Systemic Exposure Scnario (1) mg/kg bw/d**	**Systemic Exposure Scnario (7) mg/kg bw/d**	**Systemic Exposure Scnario (15) mg/kg bw/d**	**Systemic exposure combined scenarios mg/kg bw/d**
(1) + (7) + (15)	(1) Tier 1 + (7) Tier1 + (15)	cypermethrin	1,77E-03	1,20E-05	5,14E-07	1,79E-03
		tebuconazol	1,76E-02	7,64E-05	5,14E-06	1,77E-02
		propiconazol	1,83E-02	7,94E-05	5,35E-06	1,84E-02
		IPBC	3,52E-02	1,61E-04	1,03E-05	3,54E-02
	(1) Tier 2a + (7) Tier1 + (15)	cypermethrin	1,18E-03	1,20E-05	5,14E-07	1,19E-03
		tebuconazol	1,16E-02	7,64E-05	5,14E-06	1,17E-02
		propiconazol	1,21E-02	7,94E-05	5,35E-06	1,22E-02
		IPBC	2,32E-02	1,61E-04	1,03E-05	2,34E-02

Combined Scenarios Automated dipping / M&L / Laundering work clothes						
Combined SCENARIOS	**Tier**	**Active substance**	**Systemic Exposure Scnario (1) mg/kg bw/d**	**Systemic Exposure Scnario (7) mg/kg bw/d**	**Systemic Exposure Scnario (15) mg/kg bw/d**	**Systemic exposure combined scenarios mg/kg bw/d**

(2) + (7) + (15)	(2) Tier 1 + (7) Tier1 + (15)	cypermethrin	1,25E-03	1,20E-05	5,14E-07	1,26E-03
		tebuconazol	1,18E-02	7,64E-05	5,14E-06	1,19E-02
		propiconazol	1,23E-02	7,94E-05	5,35E-06	1,24E-02
		IPBC	2,37E-02	1,61E-04	1,03E-05	2,39E-02
	(2) Tier 2a + (7) Tier1 + (15)	cypermethrin	8,47E-04	1,20E-05	5,14E-07	8,60E-04
		tebuconazol	7,81E-03	7,64E-05	5,14E-06	7,89E-03
		propiconazol	8,13E-03	7,94E-05	5,35E-06	8,22E-03
		IPBC	1,57E-02	1,61E-04	1,03E-05	1,59E-02

Combined Scenarios Automated spraying / M&L / Laundering work clothes						
Combined SCENARIOS	**Tier**	**Active substance**	**Systemic Exposure Scnario (1) mg/kg bw/d**	**Systemic Exposure Scnario (7) mg/kg bw/d**	**Systemic Exposure Scnario (15) mg/kg bw/d**	**Systemic exposure combined scenarios mg/kg bw/d**
(3) + (7) + (15)	(3) Tier 1 + (7) Tier1 + (15)	cypermethrin	5,91E-04	1,20E-05	5,14E-07	6,04E-04
		tebuconazol	5,86E-03	7,64E-05	5,14E-06	5,94E-03
		propiconazol	6,10E-03	7,94E-05	5,35E-06	6,19E-03
		IPBC	1,17E-02	1,61E-04	1,03E-05	1,19E-02
	(3) Tier 2a + (7) Tier1 + (15)	cypermethrin	3,81E-04	1,20E-05	5,14E-07	3,94E-04
		tebuconazol	3,76E-03	7,64E-05	5,14E-06	3,84E-03
		propiconazol	3,91E-03	7,94E-05	5,35E-06	4,00E-03
		IPBC	7,53E-03	1,61E-04	1,03E-05	7,70E-03

Combined Scenarios Spraying / M&L / Laundering work clothes / Cleaning spray equipment							
Combined SCENARIOS	**Tier**	**Active substance**	**Systemic Exposure Scnario (4) mg/kg bw/d**	**Systemic Exposure Scnario (7) mg/kg bw/d**	**Systemic Exposure Scnario (15) mg/kg bw/d**	**Systemic Exposure Scnario (9) mg/kg bw/d**	**Systemic exposure combined scenarios mg/kg bw/d**
(4) + (7) + (9) + (15)	(4) Tier 4 + (7) Tier1 + (15) Tier1 + (9) Tier1	cypermeth	1,14E-03	1,20E-05	5,14E-07	6,15E-04	1,77E-03
		tebuconaz	1,07E-02	7,64E-05	5,14E-06	6,15E-03	1,69E-02
		propiconaz	1,11E-02	7,94E-05	5,35E-06	6,41E-03	1,76E-02
		IPBC	2,15E-02	1,61E-04	1,03E-05	1,23E-02	3,40E-02
	(4) Tier 4 + (7) Tier1 + (15) Tier1 +(9) Tier2	cypermeth	1,14E-03	1,20E-05	5,14E-07	5,08E-05	1,20E-03
		tebuconaz	1,07E-02	7,64E-05	5,14E-06	5,08E-04	1,13E-02
		propiconaz	1,11E-02	7,94E-05	5,35E-06	5,29E-04	1,17E-02
		IPBC	2,15E-02	1,61E-04	1,03E-05	1,02E-03	2,27E-02

Combined Scenarios Brushing / M&L / Laundering work clothes / Cleaning brushing equipment

Combined SCENARIOS	Tier	Active substance	Systemic Exposure Scnario (5) mg/kg bw/d	Systemic Exposure Scnario (7) mg/kg bw/d	Systemic Exposure Scnario (8) mg/kg bw/d	Systemic Exposure Scnario (15) mg/kg bw/d	Systemic exposure combined scenarios mg/kg bw/d
(5) + (7) + (8) + (15)	(4) Tier 2 + (7) Tier1 + (8) Tier1 + (15) Tier1	cypermeth	1,87E-03	1,20E-05	7,55E-05	5,14E-07	1,96E-03
		tebuconaz	1,75E-02	7,64E-05	7,55E-04	5,14E-06	1,83E-02
		propiconaz	1,82E-02	7,94E-05	7,87E-04	5,35E-06	1,91E-02
		IPBC	3,48E-02	1,61E-04	1,51E-03	1,03E-05	3,64E-02
	(4) Tier 2 + (7) Tier1 + (8) Tier2 + (15) Tier1	cypermeth	2,94E-04	1,20E-05	7,55E-05	5,14E-07	3,82E-04
		tebuconaz	1,71E-03	7,64E-05	7,55E-04	5,14E-06	2,55E-03
		propiconaz	1,78E-03	7,94E-05	7,87E-04	5,35E-06	2,65E-03
		IPBC	3,18E-03	1,61E-04	1,51E-03	1,03E-05	4,86E-03

Non-professional Combined Scenarios Brushing / M&L / Laundering work clothes / Cleaning brushing equipment							
Combined SCENARIOS	Tier	Active substance	Systemic Exposure Scnario (5) mg/kg bw/d	Systemic Exposure Scnario (7) mg/kg bw/d	Systemic Exposure Scnario (8) mg/kg bw/d	Systemic Exposure Scnario (15) mg/kg bw/d	Systemic exposure combined scenarios mg/kg bw/d
(5)(2) + (7) + (8) + (15)	Tier 1	cypermeth	7,08E-04	3,08E-04	7,55E-05	5,14E-07	1,09E-03
		tebuconaz	7,07E-03	4,84E-04	7,55E-04	5,14E-06	8,31E-03
		propiconaz	7,36E-03	4,90E-04	7,87E-04	5,35E-06	8,64E-03
		IPBC	1,41E-02	1,46E-03	1,51E-03	1,03E-05	1,71E-02

Summary of exposure assessment

Scenarios and values to be used in risk assessment				
Scenario number	Exposed group	Tier/PPE	Active substance	Estimated total uptake mg/kg bw/d
1.	Industrial user (Trained professionals)	Tier1 gloves	cypermethrin	1,77E-03
			tebuconazol	1,76E-02
			propiconazol	1,83E-02
			IPBC	3,52E-02
		Tier2 gloves + coverall 10%	cypermethrin	1,18E-03
			tebuconazol	1,16E-02
			propiconazol	1,21E-02
			IPBC	2,32E-02
2.	Industrial user (Trained professionals)	Tier1 gloves	cypermethrin	1,77E-03
			tebuconazol	1,76E-02
			propiconazol	1,83E-02

			IPBC	3,52E-02
		Tier2 gloves + coverall 10%	cypermethrin	1,18E-03
			tebuconazol	1,16E-02
			propiconazol	1,21E-02
			IPBC	2,32E-02
3.	Industrial user (Trained professionals)	Tier1 gloves	cypermethrin	5,91E-04
			tebuconazol	5,86E-03
			propiconazol	6,10E-03
			IPBC	1,17E-02
4.	Industrial user (Trained professionals) Trained-Professional	Tier1	cypermethin	3,09E-02
			tebuconazol	2,81E-01
			propiconazol	2,92E-01
			IPBC	5,67E-01
		Tier2 gloves	cypermethrin	1,60E-02
			tebuconazol	1,32E-01
			propiconazol	1,38E-01
			IPBC	2,70E-01
		Tier3 gloves and coverall 5%	cypermethrin	4,23E-03
			tebuconazol	1,43E-02
			propiconazol	1,47E-02
			IPBC	3,38E-02
		Tier2 gloves, coverall 5% and mask P3	cypermethrin	1,14E-03
			tebuconazol	1,07E-02
			propiconazol	1,11E-02
			IPBC	2,15E-02
5.	Trained-professional	Tier1	cypermethrin	2,16E-03
			tebuconazol	2 ,98E-02
			propiconazol	3,11E-02
			IPBC	1,75E-02
		Tier2 gloves and coverall 5%	cypermethrin	3,49E-04
			tebuconazol	3,21E-03
			propiconazol	3,33E-03
			IPBC	1,98E-03
6.	Trained-Professional	Tier1 gloves	cypermethrin	2,83E-02
			tebuconazol	2,70E-01

			propiconazol	2,82E-01
			IPBC	5,43E-01
7.	Trained-professional	Tier1 gloves and coverall	cypermethrin	1,20E-05
			tebuconazol	7,64E-05
			propiconazol	7,94E-05
			IPBC	1,61E-04
8.	Trained-professional	Tier1	cypermethrin	7,55E-05
			Tebuconazol	7,55E-04
			Propiconazol	7,87E-04
			IPBC	1,51E-03
		Tier2 gloves	cypermethrin	7,55E-06
			tebuconazol	7,55E-05
			propiconazol	7,87E-05
			IPBC	1,51E-04
9.	Trained-professional	Tier1	cypermethrin	6,15E-04
			tebuconazol	6,15E-03
			propiconazol	6,41E-03
			IPBC	1,23E-02
		Tier2 gloves and coverall	cypermethrin	5,08E-05
			tebuconazol	5,08E-04
			propiconazol	5,29E-04
			IPBC	1,02E-03
10.	Professional	Tier1	cypermethrin	8,70E-05
			tebuconazol	3,57E-04
			propiconazol	3,69E-04
			IPBC	8,11E-04
11.	Non-professional	Tier1	cypermethrin	3,86E-05
			tebuconazol	3,01E-04
			propiconazol	3,13E-04
			IPBC	6,17E-04
12.	General public	Tier1	cypermethin	3,37E-03
			tebuconazol	6,80E-03
			propiconazol	6,89E-03
			IPBC	2,36E-02
13.	General public	Tier1	cypermethrin	1,07E-03

			tebuconazol	2,95E-03
			propiconazol	2,99E-03
			IPBC	8,74E-03
14.	General public	Tier1	IPBC	4,08E-03
15.	Industrial (Trained professionals), Trained professionals, General public	Tier1	cypermethrin	5,14E-07
			tebuconazol	5,14E-06
			propiconazol	5,35E-06
			IPBC	1,03E-05

Combined Scenarios:

Scenarios and values to be used in risk assessment				
Combined Scenarios numbers	**Exposed group**	**Tier/PPE**	**Active substance**	**Estimated total uptake mg/kg bw/d**
(1) + (7) + (15)	Industrial user (Trained professionals)	(1) Tier 1 gloves + (7) Tier1 gloves and coverall + (15)	cypermethrin	1,79E-03
			tebuconazol	1,77E-02
			propiconazol	1,84E-02
			IPBC	3,54E-02
		(1) Tier 2a gloves and impermeable coverall (FP 10%)+ (7) Tier1 gloves and coverall + (15)	cypermethrin	1,19E-03
			tebuconazol	1,17E-02
			propiconazol	1,22E-02
			IPBC	2,34E-02
(2) + (7) + (15)	Industrial user (Trained professionals)	(2) Tier 1 gloves+ (7) Tier1 gloves and coverall + (15)	cypermethrin	1,26E-03
			tebuconazol	1,19E-02
			propiconazol	1,24E-02
			IPBC	2,39E-02
		(2) Tier 2a gloves and impermeable coverall (FP 10%) + (7) Tier1 gloves and coverall + (15)	cypermethrin	8,60E-04
			tebuconazol	7,89E-03
			propiconazol	8,22E-03
			IPBC	1,59E-02
(3) + (7) + (15)	Industrial user (Trained professionals)	(3) Tier 1 gloves + (7) Tier1 gloves and coverall+ (15)	cypermethrin	6,04E-04
			tebuconazol	5,94E-03
			propiconazol	6,19E-03
			IPBC	1,19E-02
		(3) Tier 2a gloves and impermeable coverall (FP	cypermethrin	3,94E-04
			tebuconazol	3,84E-03

		10%) + (7) Tier1 gloves and coverall + (15)	propiconazol	4,00E-03
			IPBC	7,70E-03
(4) + (7) + (15) + (9)	Industrial user (Trained professionals) Trained-Professional	(4) Tier 4 gloves, coverall 5% and mask P3 + (7) Tier1 gloves and coverall + (15) Tier1 + (9)	cypermethin	1,77E-03
			tebuconazol	1,69E-02
			propiconazol	1,76E-02
			IPBC	3,40E-02
		(4) Tier4 gloves, coverall 5% and mask P3 + (7) Tier1 gloves and coverall + (15) Tier2 + (9) gloves and coverall	cypermethrin	1,20E-03
			tebuconazol	1,13E-02
			propiconazol	1,17E-02
			IPBC	2,27E-02
(5) + (7) + (8) + (15)	Trained-professional	(5) Tier 2 gloves and coverall 5% + (7) Tier1 gloves and clothes + (8) Tier1 + (15)	cypermethrin	1,96E-03
			tebuconazol	1,83E-02
			propiconazol	1,91E-02
			IPBC	3,64E-02
		(4) Tier2 gloves and coverall 5% + (7) Tier1 gloves and clothes + (8) Tier2 gloves + (15)	cypermethrin	3,82E-04
			tebuconazol	2,55E-03
			propiconazol	2,65E-03
			IPBC	4,86E-03
(5)(2) + (7) + (8) + (15)	Non-professional	Tier 1	cypermethrin	1,09E-03
			tebuconazol	8,31E-03
			propiconazol	8,64E-03
			IPBC	1,71E-02

2.2.6.3. Risk characterisation for human health

Reference values to be used in Risk Characterisation

	Cypermethrin	**Tebuconazol**	**Propiconazol**	**IPBC**
AEL long term (mg/kg bw/day)	0,022	0,03	0,04	0.2
AEL medium term (mg/kg bw/day)	0,05			
AEL short term (mg/kg bw/day)	0,088	0,03	0.3	0.35

Value(s) used in the Risk Assessment – Dermal absorption				
Substance	Cypermethrine	Tebuconazole	Propiconazole	IPBC
Value(s)*	2.8%	24%	25%	15%
Justification for the selected value(s)	in vitro study according to OECD 428 guideline. In	in vitro study according to OECD 428 guideline. In	in vitro study according to OECD 428 guideline. In	in vitro study according to OECD 428 guideline. In

	order to evaluate it, the Guidance on Dermal Absorption, EFSA Journal 2017 was taken into account	order to evaluate it, the Guidance on Dermal Absorption, EFSA Journal 2017 was taken into account	order to evaluate it, the Guidance on Dermal Absorption, EFSA Journal 2017 was taken into account	order to evaluate it, the Guidance on Dermal Absorption, EFSA Journal 2017 was taken into account

Value(s) used in the Risk Assessment – Oral absorption				
Substance	Cypermethrine	Tebuconazole	Propiconazole	IPBC
Value(s)*	57%	(>98%) 100%[1]	(86%) 100%[1]	(>90%)100%[1]
Justification for the selected value(s)	Cypermethrin Assessment Report cis:trans/40:60 PT08 Belgium 2013 Tebuconazol Assessment Report PT08 Denmark 2007 Propiconazol Assessment Report PT08 Finland 2007 IPBC Assessment Report PT08 Denmark 2008			

[1] The 'Guidance on the BPR: Volume III Parts B+C' (Version 4.0, December 2017) notes (p. 66) that "…when the oral absorption rate exceeds 80%, the default value of 100% should be applied for the derivation of AELs and internal exposure levels."

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

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

See Annex 3.2 for calculations.

Risk assessment for Primary Exposure

Risk for industrial users

Systemic effects

Scenario 1 Automated Double Vacuum

Task/ Scenario	**Tier**	**Active substance**	**AEL mg/kg bw/d**	**Estimated uptake mg/kg bw/d**	**Estimated uptake/ AEL (%)**	**Acceptable (yes/no)**
Scenario [1] Automated Double	1 Gloves	cypermethrin	0,022	1,77E-03	8,07%	YES
		tebuconazol	0,03	1,76E-02	58,59%	YES
		propiconazol	0.04	1,83E-02	45,77%	YES

Vacuum		IPBC	0,2	3,52E-02	17,59%	YES
Scenario [1] Automated Double Vacuum	2a Gloves and coverall 10%	cypermethrin	0,022	1,18E-03	5,35%	YES
		tebuconazol	0,03	1,16E-02	38,68%	YES
		propiconazol	0,04	1,21E-02	30,22%	YES
		IPBC	0,2	2,32E-02	11,62%	YES

Combined exposure to several active substances within the biocidal product

According to Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation (Parts B+C) Version 4.0 December 2017, risk characterisation from combined exposure to several active substances in product has been carried out.

Task/ Scenario	Tier	Active substance	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	HQi	HI=∑ Hqi	Acceptable (yes/n
Automated Double Vacuum	1	cypermethrin	0,022	1,77E-03	8,07%	0,08	>1	NO
		tebuconazol	0,03	1,76E-02	58,59%	0,59		
		propiconazol	0,04	1,83E-02	45,77%	0,46		
		IPBC	0,2	3,52E-02	17,59%	0,18		
Automated Double Vacuum	2a	cypermethrin	0,022	1,18E-03	5,35%	0,05	<1	YES
		tebuconazol	0,03	1,16E-02	38,68%	0,39		
		propiconazol	0,04	1,21E-02	30,22%	0,30		
		IPBC	0,2	2,32E-02	11,62%	0,12		

Scenario [2] Automated dipping

Systemic effects

Task/ Scenario	Tier	Active substance	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Automated dipping	1 Gloves	cypermethrin	0,022	1,25E-03	5,66E+00	YES
		tebuconazol	0,03	1,18E-02	3,93E+01	YES
		propiconazol	0,04	1,23E-02	3,07E+01	YES
		IPBC	0,2	2,37E-02	1,19E+01	YES
Automated dipping	2a Gloves and	cypermethrin	0,022	8,47E-04	3,85E+00	YES
		tebuconazol	0,03	7,81E-03	2,60E+01	YES

	coverall 10%	propiconazol	0,04	8,13E-03	2,03E+01	YES
		IPBC	0,2	1,57E-02	7,87E+00	YES

Combined exposure to several active substances within the biocidal product

According to Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation (Parts B+C) Version 4.0 December 2017, risk characterisation from combined exposure to several active substances in product has been carried out.

Task/ Scenario	Tier	Active substance	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	HQi	HI=∑ Hqi	Acceptable (yes/n
Automated dipping	1	cypermethrin	0,022	1,25E-03	5,66E+00	5,66E-02	<1	YES
		tebuconazol	0,03	1,18E-02	3,93E+01	3,93E-01		
		propiconazol	0,04	1,23E-02	3,07E+01	3,07E-01		
		IPBC	0,2	2,37E-02	1,19E+01	1,19E-01		
Automated dipping	2a	cypermethrin	0,022	8,47E-04	3,85E+00	3,85E-02	<1	YES
		tebuconazol	0,03	7,81E-03	2,60E+01	2,60E-01		
		propiconazol	0,04	8,13E-03	2,03E+01	2,03E-01		
		IPBC	0,2	1,57E-02	7,87E+00	7,87E-02		

Scenario [3] Industrial automated spraying

Systemic effects

Task/ Scenario	Tier	Active substance	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Automated spraying	1 Gloves	cypermethrin	0,022	5,91E-04	2,69E+00	YES
		tebuconazol	0,03	5,86E-03	1,95E+01	YES
		propiconazol	0,04	6,10E-03	1,53E+01	YES
		IPBC	0,2	1,17E-02	5,86E+00	YES

Combined exposure to several active substances within the biocidal product

According to Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation (Parts B+C) Version 4.0 December 2017, risk characterisation from combined exposure to several active substances in product has been carried out.

Task/ Scenario	Tier	Active substance	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	HQi	HQi>1 HQI<1	HI=∑ Hqi	Acceptable
Automated spraying	1	cypermethrin	0,022	1,83E-02	2,69E+00	2,69E+00	<1	3,57E-01	YES
		tebuconazol	0,03	3,13E-02	1,95E+01	1,95E+01	<1		
		propiconazol	0,04	3,13E-02	7,63E+00	1,53E+01	<1		
		IPBC	0,2	3,13E-02	5,86E+00	5,86E+00	<1		

Risk for trained professional users

Systemic effects

Scenario [4] Trained-professional Spraying

Task/ Scenario	Tier	Active substance	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Trained-professional Spraying	1	cypermethrin	0,022	3,09E-02	1,40E+02	NO
		tebuconazol	0,03	2,81E-01	9,36E+02	NO
		propiconazol	0,04	2,92E-01	7,31E+02	NO
		IPBC	0,2	5,67E-01	2,84E+02	NO
Trained-professional Spraying	2 Gloves	cypermethrin	0,022	1,60E-02	7,29E+01	YES
		tebuconazol	0,03	1,32E-01	4,41E+02	NO
		propiconazol	0,04	1,38E-01	3,44E+02	NO
		IPBC	0,2	2,70E-01	1,35E+02	NO
Trained-professional Spraying	3 Gloves and coverall 5%	cypermethrin	0,022	4,23E-03	1,92E+01	YES
		tebuconazol	0,03	1,43E-02	4,76E+01	YES
		propiconazol	0,04	1,47E-02	3,68E+01	YES
		IPBC	0,2	3,38E-02	1,69E+01	YES
Trained-professional Spraying	4 Gloves and coverall 5% and mask P3	cypermethrin	0,022	1,14E-03	5,17E+00	YES
		tebuconazol	0,03	1,07E-02	3,56E+01	YES
		propiconazol	0,04	1,11E-02	2,78E+01	YES
		IPBC	0,2	2,15E-02	1,07E+01	YES

Combined exposure to several active substances within the biocidal product

According to Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation (Parts B+C) Version 4.0 December 2017, risk characterisation from combined exposure to several active substances in product has been carried out.

Task/ Scenario	Tier	Active substance	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	HQi	HQi>1 HQI<1	HI=∑ Hqi	Acceptable
Trained-professional Spraying	1	cypermethrin	0,022	3,09E-02	1,40E+02	1,40E+00	>1	>1	NO
		tebuconazol	0,03	2,81E-01	9,36E+02	9,36E+00	>1		
		propiconazol	0,04	2,92E-01	7,31E+02	7,31E+00	>1		
		IPBC	0,2	5,67E-01	2,84E+02	2,84E+00	>1		
Trained-professional Spraying	2	cypermethrin	0,022	1,60E-02	7,29E+01	7,29E-01	<1	>1	NO
		tebuconazol	0,03	1,32E-01	4,41E+02	4,41E+00	>1		
		propiconazol	0,04	1,38E-01	3,44E+02	3,44E+00	>1		
		IPBC	0,2	2,70E-01	1,35E+02	1,35E+00	>1		
Trained-professional Spraying	3	cypermethrin	0,022	4,23E-03	1,92E+01	1,92E-01	<1	>1	NO
		tebuconazol	0,03	1,43E-02	4,76E+01	4,76E-01	<1		
		propiconazol	0,04	1,47E-02	3,68E+01	3,68E-01	<1		
		IPBC	0,2	3,38E-02	1,69E+01	1,69E-01	<1		
Trained-professional Spraying	4	cypermethrin	0,022	1,14E-03	5,17E+00	5,17E-02	<1	<1	YES
		tebuconazol	0,03	1,07E-02	3,56E+01	3,56E-01	<1		
		propiconazol	0,04	1,11E-02	2,78E+01	2,78E-01	<1		
		IPBC	0,2	2,15E-02	1,07E+01	1,07E-01	<1		

Scenario [5] Trained-professional brushing

Task/ Scenario	Tier	Active substance	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Trained-professional Brushing	1	cypermethrin	0,022	1,87E-03	8,51E+00	YES
		tebuconazol	0,03	1,75E-02	5,83E+01	YES
		propiconazol	0,04	1,82E-02	4,56E+01	YES
		IPBC	0,2	3,48E-02	1,74E+01	YES
Trained-professional	2 Gloves and	cypermethrin	0,022	2,94E-04	1,33E+00	YES
		tebuconazol	0,03	1,71E-03	5,71E+00	YES

Brushing	coverall 5%	propiconazol	0,04	1,78E-03	4,44E+00	YES
		IPBC	0,2	3,18E-03	1,59E+00	YES

Combined exposure to several active substances within the biocidal product

According to Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation (Parts B+C) Version 4.0 December 2017, risk characterisation from combined exposure to several active substances in product has been carried out.

Task/ Scenario	Tier	Active substance	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	HQi	HQi>1 HQI<1	HI=Σ Hqi	Acceptable
Trained professional brushing	1	cypermethrin	0,022	1,87E-03	8,51E+00	8,51E-02	<1	1,30E+00	NO
		tebuconazol	0,03	1,75E-02	5,83E+01	5,83E-01	<1		
		propiconazol	0,04	1,82E-02	4,56E+01	4,56E-01	<1		
		IPBC	0,2	3,48E-02	1,74E+01	1,74E-01	<1		
Trained professional brushing	2	cypermethrin	0,022	2,94E-04	1,33E+00	1,33E-02	<1	1,31E-01	YES
		tebuconazol	0,03	1,71E-03	5,71E+00	5,71E-02	<1		
		propiconazol	0,04	1,78E-03	4,44E+00	4,44E-02	<1		
		IPBC	0,2	3,18E-03	1,59E+00	1,59E-02	<1		

Scenario [6] Trained-professional Injection

Task/ Scenario	Tier	Active substance	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Trained-professional Injection	1 Gloves	cypermethrin	0,022	4,72E-04	2,14	YES
		tebuconazol	0,03	4,51E-03	15,03	YES
		propiconazol	0,04	4,69E-03	11,74	YES
		IPBC	0,2	9,06E-03	4,53	YES

Combined exposure to several active substances within the biocidal product

According to Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation (Parts B+C) Version 4.0 December 2017, risk characterisation from combined exposure to several active substances in product has been carried out.

Task/ Scenario	Tier	Active substance	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	HQi	HQi>1 HQI<1	HI=∑ Hqi	Acceptable
Trained professional injection	1	cypermethrin	0,022	4,72E-04	2,14	2,14E-02	<1	3,34E-01	YES
		tebuconazol	0,03	4,51E-03	15,03	1,50E-01	<1		
		propiconazol	0,04	4,69E-03	11,74	1,17E-01	<1		
		IPBC	0,2	9,06E-03	4,53	4,53E-02	<1		

Scenario [7] Mixing and Loading

Task/ Scenario	Tier	Active substance	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Mixing and Loading	1 Clothes and gloves	cypermethrin	0,022	1,20E-05	0,05	YES
		tebuconazol	0,03	7,64E-05	0,25	YES
		propiconazol	0,04	7,94E-05	0,20	YES
		IPBC	0,2	1,61E-04	0,08	YES

Combined exposure to several active substances within the biocidal product

According to Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation (Parts B+C) Version 4.0 December 2017, risk characterisation from combined exposure to several active substances in product has been carried out.

Task/ Scenario	Tier	Active substance	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	HQi	HQi>1 HQI<1	HI=∑ Hqi	Acceptable
Mixing and Loading	1	cypermethrin	0,022	1,20E-05	0,05	5,44E-04	<1	5,88E-03	YES
		tebuconazol	0,03	7,64E-05	0,25	2,55E-03	<1		
		propiconazol	0,04	7,94E-05	0,20	1,98E-03	<1		
		IPBC	0,2	1,61E-04	0,08	8,05E-04	<1		

Scenario [8] Washing out of brushes

Task/ Scenario	Tier	Active substance	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Washing	1	cypermethrin	0,022	7,55E-05	3,43E-01	YES

out of brushes		tebuconazol	0,03	7,55E-04	2,52E-00	YES
		propiconazol	0,04	7,87E-04	1,97E-00	YES
		IPBC	0,2	1,51E-03	7,55E-01	YES
Washing out of brushes	2 Gloves	cypermethrin	0,022	7,55E-06	3,43E-02	YES
		tebuconazol	0,03	7,55E-05	2,52E-01	YES
		propiconazol	0,04	7,87E-05	1,97E-01	YES
		IPBC	0,2	1,51E-04	7,55E-02	YES

Combined exposure to several active substances within the biocidal product

According to Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation (Parts B+C) Version 4.0 December 2017, risk characterisation from combined exposure to several active substances in product has been carried out.

Task/ Scenario	Tier	Active substance	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	HQi	HQi>1 HQI<1	HI=∑ Hqi	Acceptable
Washing out of brushes	1	cypermethrin	0,022	7,55E-05	3,43E-01	3,43E-03	<1	5,58E-02	YES
		tebuconazol	0,03	7,55E-04	2,52E-00	2,52E-02	<1		
		propiconazol	0,04	7,87E-04	1,97E-00	1,97E-02	<1		
		IPBC	0,2	1,51E-03	7,55E-01	7,55E-03	<1		
Washing out of brushes	2	cypermethrin	0,022	7,55E-06	3,43E-02	3,43E-04	<1	5,58E-03	YES
		tebuconazol	0,03	7,55E-05	2,52E-01	2,52E-03	<1		
		propiconazol	0,04	7,87E-05	1,97E-01	1,97E-03	<1		
		IPBC	0,2	1,51E-04	7,55E-02	7,55E-04	<1		

Scenario [9] Cleaning spray equipment

Task/ Scenario	Tier	Active substance	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Cleaning spray equipment	1	cypermethrin	0,022	6,15E-04	2,80	YES
		tebuconazol	0,03	6,15E-03	20,51	YES
		propiconazol	0,04	6,41E-03	16,03	YES
		IPBC	0,2	1,23E-02	6,15	YES
Cleaning spray	2 Gloves and	cypermethrin	0,022	5,08E-05	0,23	YES
		tebuconazol	0,03	5,08E-04	1,69	YES

equipment	coverall 5%	propiconazol	0,04	5,29E-04	1,32	YES
		IPBC	0,2	1,02E-03	0,51	YES

Combined exposure to several active substances within the biocidal product

According to Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation (Parts B+C) Version 4.0 December 2017, risk characterisation from combined exposure to several active substances in product has been carried out.

Task/ Scenario	Tier	Active substance	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	HQi	HQi>1 HQI<1	HI=∑ Hqi	Acceptable
Cleaning spray equipment	1	cypermethrin	0,022	6,15E-04	2,80	2,80E-02	<1	4,55E-01	YES
		tebuconazol	0,03	6,15E-03	20,51	2,05E-01	<1		
		propiconazol	0,04	6,41E-03	16,03	1,60E-01	<1		
		IPBC	0,2	1,23E-02	6,15	6,15E-02	<1		
Cleaning spray equipment	2	cypermethrin	0,022	5,08E-05	0,23	2,31E-03	<1	3,75E-02	YES
		tebuconazol	0,03	5,08E-04	1,69	1,69E-02	<1		
		propiconazol	0,04	5,29E-04	1,32	1,32E-02	<1		
		IPBC	0,2	1,02E-03	0,51	5,08E-03	<1		

Risk for Non-professional users

Systemic effects

Scenario [5(2)] Non-professional brushing

Task/ Scenario	Tier	Active substance	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Non-professional Brushing	1	cypermethrin	0,022	7,08E-04	3,22E+00	YES
		tebuconazol	0,03	7,07E-03	2,36E+01	YES
		propiconazol	0,04	7,36E-03	1,84E+01	YES
		IPBC	0,2	1,41E-02	7,07E+00	YES

Combined exposure to several active substances within the biocidal product

According to Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation (Parts B+C) Version 4.0 December 2017, risk characterisation from combined exposure to several active substances in product has been carried out.

Task/ Scenario	Tier	Active substance	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	HQi	HQi>1 HQI<1	HI=Σ Hqi	Acceptable
Non-professional brushing	1	cypermethrin	0,022	7,08E-04	3,22E+00	3,22E-02	<1	5,22E-01	YES
		tebuconazol	0,03	7,07E-03	2,36E+01	2,36E-01	<1		
		propiconazol	0,04	7,36E-03	1,84E+01	1,84E-01	<1		
		IPBC	0,2	1,41E-02	7,07E+00	7,07E-02	<1		

Risk assessment for Secondary Exposure

Risk for Industrial (trained professional), trained professiona, profesional and non-professional users

Systemic effects

Scenario [10] Professional sanding treated wood. Curative

Task/ Scenario	Tier	Active substance	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Professional sanding treated wood. Curative	1	cypermethrin	0,022	8,70E-05	3,96E-01	YES
		tebuconazol	0,03	3,57E-04	1,19E+00	YES
		propiconazol	0,04	3,69E-04	9,23E-01	YES
		IPBC	0,2	8,11E-04	4,06E-01	YES

Combined exposure to several active substances within the biocidal product

Task/ Scenario	Active substance	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	HQi	HQi>1 HQi<1	HI=∑ HQi	Acceptable
Professional sanding treated wood.	cypermethrin	0,022	8,70E-05	3,96E-01	3,96E-03	<1	2,91E-02	YES
	tebuconazol	0,03	3,57E-04	1,19E+00	1,19E-02	<1		
	propiconazol	0,04	3,69E-04	9,23E-01	9,23E-01	<1		

Curative	IPBC	0,2	8,11E-04	4,06E-01	4,06E-01	<1		

Scenario [11] Non- Professional sanding treated wood. Curative

Task/ Scenario	Tier	Active substance	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Non- Prof sanding treated wood. Curative	1	cypermethrin	0,088	3,86E-05	4,39E-02	YES
		tebuconazol	0,03	3,01E-04	1,00E+00	YES
		propiconazol	0,3	3,13E-04	1,04E-01	YES
		IPBC	0,35	6,17E-04	1,76E-01	YES

Combined exposure to several active substances within the biocidal product

Task/ Scenario	Active substance	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	HQi	HQi>1 HQI<1	HI=∑ Hqi	Acceptable
Non-Professional sanding treated wood. Curative	cypermethrin	0,088	3,86E-05	4,39E-02	4,39E-04	<1	1,33E-02	YES
	tebuconazol	0,03	3,01E-04	1,00E+00	1,00E-02	<1		
	propiconazol	0,3	3,13E-04	1,04E-01	1,04E-03	<1		
	IPBC	0,35	6,17E-04	1,76E-01	1,76E-03	<1		

Scenario [12] Toddler chewing treated wood chip

Scenario [12a] Toddler chewing treated wood chip. Curative.

Task/ Scenario	Tier	Active substance	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Toddler chewing treated wood chip. Curative.	1	cypermethrin	0,088	3,37E-03	3,82E+00	YES
		tebuconazol	0,03	6,80E-03	2,27E+01	YES
		propiconazol	0,3	6,89E-03	2,30E+00	YES
		IPBC	0,35	2,36E-02	6,75E+00	YES

Combined exposure to several active substances within the biocidal product

Task/ Scenario	Active substance	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	HQi	HQi>1 HQI<1	HI=∑ Hqi	Acceptable
Toddler chewing treated wood chip. Curative.	cypermethrin	0,088	3,37E-03	3,82E+00	3,82E-02	<1	3,55E-01	YES
	tebuconazol	0,03	6,80E-03	2,27E+01	2,27E-01	<1		
	propiconazol	0,3	6,89E-03	2,30E+00	2,30E-02	<1		
	IPBC	0,35	2,36E-02	6,75E+00	6,75E-02	<1		

The **Risk is accesptable** for Toddler chewing treated wood chid curative, then, risk is also acceptable for scenario 12b, Toddler chewing treated wood chip. Preventive.

Scenario [13] Toddler playing and mouthing on playground weathered wood structure outdoors

Scenario [13b] Toddler playing and mouthing on playground weathered wood structure outdoors. Curative

Task/ Scenario	Tier	Active substance	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Toddler P&M. Curative	1	cypermethrin	0,088	1,07E-03	4,86E+00	YES
		tebuconazol	0,03	2,95E-03	9,83E+00	YES
		propiconazol	0,3	2,99E-03	7,47E+00	YES
		IPBC	0,35	8,74E-03	4,37E+00	YES

Combined exposure to several active substances within the biocidal product

Task/ Scenario	Active substance	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	HQi	HQi>1 HQI<1	HI=∑ Hqi	Acceptable
Toddler P&M. Preventive	cypermethrin	0,088	1,07E-03	4,86E+00	4,86E-02	<1	2,65E-01	NO
	tebuconazol	0,03	2,95E-03	9,83E+00	9,83E-02	<1		
	propiconazol	0,3	2,99E-03	7,47E+00	7,47E-02	<1		
	IPBC	0,35	8,74E-03	4,37E+00	4,37E-02	<1		

Scenario [14] General public - Inhalation volatilased residues indoors

Task/ Scenario	Tier	Active substance	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Inhalation volatilased residues indoors Toddler		IPBC	0,2	4,08E-03	2,04E+00	YES

Scenario [15]: Laundering work clothes

Task/ Scenario	Tier	Active substance	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Laundering of brushing work clothes	1	cypermethrin	0,022	5,14E-07	2,00E-03	YES
		tebuconazol	0,03	5,14E-06	1,70E-03	YES
		propiconazol	0,04	5,35E-06	1,30E-03	YES
		IPBC	0,2	1,03E-05	5,00E-03	YES

Combined exposure to several active substances within the biocidal product

Task/ Scenario	Active substance	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	HQi	HQi>1 HQI<1	HI=∑ Hqi	Acceptable
Laundering of brushing work clothes	cypermethrin	0,022	5,14E-07	2,00E-03	2,00E-05	<1	3,80E-05	YES
	tebuconazol	0,03	5,14E-06	1,70E-03	1,70E-05	<1		
	propiconazol	0,04	5,35E-06	1,30E-03	1,30E-05	<1		
	IPBC	0,2	1,03E-05	5,00-E03	5,00-E05	<1		

Combined scenarios

Combined Scenarios Industrial (Trained professionals)

Automated double vacuum / M&L / Laundering work clothes

Combined Scenarios Automated double vacuum / M&L / Laundering work clothes

Task/ Scenario	Tier	Active substance	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	HQi	HQi>1 HQI<1	HI=∑ Hqi	Acceptable
(1) + (7) + (15)	(1) Tier 1 + (7) Tier1 + (15)	cypermethri	0,022	1,79E-03	8,12E-00	8,12E-02	<1	1,31E+0	NO
		tebuconazol	0,03	1,77E-02	5,89E+01	5,89E-01	<1		
		propiconazo	0,04	1,84E-02	4,60E+01	4,60E-01	<1		
		IPBC	0,2	3,54E-02	1,77E+01	1,77E-01	<1		
	(1) Tier 2a + (7) Tier1 + (15)	cypermethri	0,022	1,19E-03	5,41E+ 00	5,41E-02	<1	8,65E-01	YES
		tebuconazol	0,03	1,17E-02	3,90E+01	3,90E-01	<1		
		propiconazo	0,04	1,22E-02	3,04E+01	3,04E-01	<1		
		IPBC	0,2	2,34E-02	1,17E+01	1,17E-01	<1		

Automated dipping / M&L / Laundering work clothes

Combined Scenarios Automated dipping / M&L / Laundering work clothes									
Task/ Scenario	Tier	Active substance	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	HQi	HQi>1 HQI<1	HI=∑ Hqi	Acceptable
(2) + (7) + (15)	(2) Tier 1 + (7) Tier1 + (15)	cypermethri	0,022	1,26E-03	5,72E+00	5,72E-02	<1	8,81E-01	YES
		tebuconazol	0,03	1,19E-02	3,96E+01	3,96E-01	<1		
		propiconazo	0,04	1,24E-02	3,09+-01	3,09E-01	<1		
		IPBC	0,2	2,39E-02	1,19E+01	1,19E-01	<1		
	(2) Tier 2a + (7) Tier1 + (15)	cypermethri	0,022	8,60E-04	3,91+-00	3,91E-02	<1	5,87E-01	YES
		tebuconazol	0,03	7,89E-03	2,63E+01	2,63E-01	<1		
		propiconazo	0,04	8,22E-03	2,05E-+1	2,05E-01	<1		
		IPBC	0,2	1,59E-02	7,96E002	7,96E-02	<1		

Automated spraying / M&L / Laundering work clothes

Combined Scenarios Automated spraying / M&L / Laundering work clothes									
Task/ Scenario	Tier	Active substance	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	HQi	HQi>1 HQI<1	HI=∑ Hqi	Acceptable

(3) + (7) + (15)	(3) Tier 1 + (7) Tier1 + (15)	cypermethri	0,022	6,04E-04	2,75E+00	2,75E-02	<1	4,40E-01	YES
		tebuconazol	0,03	5,94E-03	1,98E-01	1,98E+01	<1		
		propiconazo	0,04	6,19E-03	1,55E-01	1,55E+01	<1		
		IPBC	0,2	1,19E-02	5,95E-02	5,95E+00	<1		
	(3) Tier 2a + (7) Tier1 + (15)	cypermethri	0,022	3,94E-04	1,79E-02	1,79E+00	<1	2,84E-01	YES
		tebuconazol	0,03	3,84E-03	1,28E-01	1,28E+01	<1		
		propiconazo	0,04	4,00E-03	1,00E-01	1,00E+01	<1		
		IPBC	0,2	7,70E-03	3,85E-02	3,85E+00	<1		

Combined Scenarios Trained professionals

Spraying / M&L / Laundering work clothes / Cleaning spray equipment

Combined Scenarios Spraying / M&L / Laundering work clothes / Cleaning spray equipment									
Task/ Scenario	**Tier**	**Active substance**	**AEL mg/kg bw/d**	**Estimated uptake mg/kg bw/d**	**Estimated uptake/ AEL (%)**	**HQi**	**HQi>1 HQI<1**	**HI=∑ Hqi**	**Acceptable**
(4) + (7) + (9) + (15)	(4) Tier 4 + (7) Tier1 + (15) Tier1 + (9) Tier1	cypermethri	0,022	1,77E-03	1,77E-03	1,77E-03	<1	1,25E+0	NO
		tebuconazol	0,03	1,69E-02	1,69E-02	1,69E-02	<1		
		propiconazo	0,04	1,76E-02	1,76E-02	1,76E-02	<1		
		IPBC	0,2	3,40E-02	3,40E-02	3,40E-02	<1		
	(4) Tier 4 + (7) Tier1 + (15) Tier1 +(9) Tier2	cypermethri	0,022	1,20E-03	1,20E-03	1,20E-03	<1	8,37E-01	YES
		tebuconazol	0,03	1,13E-02	1,13E-02	1,13E-02	<1		
		propiconazo	0,04	1,17E-02	1,17E-02	1,17E-02	<1		
		IPBC	0,2	2,27E-02	2,27E-02	2,27E-02	<1		

Brushing / M&L / Laundering work clothes / Cleaning spray equipment

Combined Scenarios Brushing / M&L / Laundering work clothes / Cleaning spray equipment									
Task/ Scenario	**Tier**	**Active substance**	**AEL mg/kg bw/d**	**Estimated uptake mg/kg bw/d**	**Estimated uptake/ AEL (%)**	**HQi**	**HQi>1 HQI<1**	**HI=Σ Hqi**	**Acceptable**

(5) + (7) + (8) + (14)	(4) Tier 2 + (7) Tier1 + (8) Tier1 + (14) Tier1	cypermeth	0,022	1,96E-03	8,91E-02	8,91E-02	<1	1,36E+00	NO
		tebuconaz	0,03	1,83E-02	6,11E-01	6,11E-01	<1		
		propiconaz	0,04	1,91E-02	4,77E-01	4,77E-01	<1		
		IPBC	0,2	3,64E-02	1,82E-01	1,82E-01	<1		
	(4) Tier 2 + (7) Tier1 + (8) Tier2 + (14) Tier1	cypermeth	0,022	3,82E-04	1,73E-02	1,73E-02	<1	1,93E-01	YES
		tebucona	0,03	2,55E-03	8,50E-02	8,50E-02	<1		
		propiconaz	0,04	2,65E-03	6,62E-02	6,62E-02	<1		
		IPBC	0,2	4,86E-03	2,43E-02	2,43E-02	<1		

<u>Combined Scenarios Non-professionals</u>

Brushing / M&L / Laundering work clothes / Cleaning brush equipment

Non-professional Combined Scenarios Brushing / M&L / Laundering work clothes / Cleaning brush equipment									
Task/ Scenario	**Tier**	**Active substance**	**AEL mg/kg bw/d**	**Estimated uptake mg/kg bw/d**	**Estimated uptake/ AEL (%)**	**HQi**	**HQi>1 HQI<1**	**HI=Σ Hqi**	**Acceptable**
(5)(2) + (7) + (8) + (15)	Tier 1	cypermeth	0,022	1,09E-03	4,96E-00	4,96E-02	<1	6,28E-01	YES
		tebuconaz	0,03	8,31E-03	2,77E+01	2,77E-01	<1		
		propiconaz	0,04	8,64E-03	2,16E+01	2,16E-01	<1		
		IPBC	0,2	1,71E-02	8,56E-00	8,56E-02	<1		

Risk assessment of effect due to presence of non-active substance(s) (i.e. substance(s) of concern SoCs)

According to *Guidance on the BPR: Volume III Parts B+C Version 4.0 December 2017; Annex A: Substances of Concern – Proposed Human Health (Toxicology) Assessment Scheme for Authorisation of Biocidal Products*, a risk assessment has been performed for all SoCs in the biocidal product.

- Two SoCs meeting criterion (1) have been identified in product:

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Solvent naphtha (petroleum), light arom.	Hydrocarbons, C9 aromatics	Solvent	64742-95-6	919-668-5 (Provisional) 265-199-0	13

Naphtha (petroleum), hydrotreated heavy	Hydrocarbons, C10-C13, n-alcanes, cyclical, isoalkanes, <2% aromatics	Solvent	64742-48-9	918-481-9 (Provisional) 265-150-33	72-73

These (toxicological) SoCs are present in the biocidal product at concentrations leading or contributing to the classification of the product according to Directive 1999/45/EC or the CLP Regulation.

- Asp. Tox. 1 H304 May be fatal if swallowed and enters airways

The SoCs are assigned to product hazard classification band A:

Band	**Classification of biocidal product according to CLP Regulation due to classified SoC**	**Associated evaluation/risk management requirements**
A	Acute Tox 4 (H332, H312, H302) STOT SE 2 (H371) **Asp Tox 1 (H304)** EUH066 **STOT SE 3 (H336)** **Eye Irrit 2 (H319)** STOT SE 3 (H335) **Skin Irrit 2 (H315)**	Application of P-statements normally associated with concerned H-statements

It is proposed that for these SoCs, appropriate risk mitigation measures, in the form of the the precautionary (P)-statements normally associated with the concerned hazard (H)-statements under the CLP Regulation, have to be applied:

- P261 Avoid breathing dust/fume/gas/mist/vapours/spray
- P271 Use only outdoors or in well-ventilated area.

One SoCs meeting criterion (5) have been identified in product:
This criterion identifies substances for which there are EU IOELVs. The requirements of band C should apply to these SoCs.

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**	**IOELV**
Xylene (this substance is included in the co-formulant Polikyd AS 624/60D)	1,2-xylene; 1,3-xylene; 1,4-xylene	Solvent	1330-20-7	215-535-7	0,134	**Long term** 50 ppm 221 mg/m^3 **Short term** 100 ppm 442 mg/m^3 Skin notation

Regarding the dermal route, xylene has skin notation, that means this route had to be assessed, but in this case and taking into account the PPEs that have to be used due to the presence of active substances, no dermal exposure to xylene is expected for uses authorised.

Regarding the inhalation route, the inhalation exposure has been calculated with respect to xylene without taking into account the RMM in the scenarios in which there is inhalation, and compare with the value of the IOELV.
If the result of the evaluation is acceptable, by not taking into account the MMR that will be used due to the presence of active substances, we will be well below a risk situation and we will be able to consider this route of entry to the organism negligible.
In case we had a risk situation in any of them, we would make an evaluation with the MMR for that scenario.

See annex 3.2 for calculations.

Results are showed in table below:

XYLENE SCENARIO INHALATION EXPOSURE COMPARATION						
Tier 1 Xylazel Total						
INHALATION EXPOSURE SCENRIO	**Product concentration in air prod mg /m³**	**Xylene concentr in air mg/m³**	**Xylene Long term mg/m3**	**Xylene/ Long term**	**Xylene/ Long term (%)**	**ACCEPTABLE/ NON-ACCEPTABLE**
Automated double vacuum	0,6	8,04E-04	221	3,64E-06	3,64E-04	YES
Automated dipping	0,6	8,04E-04	221	3,64E-06	3,64E-04	YES
Spray industrial	0,6	8,04E-04	221	3,64E-06	3,64E-04	YES
Spray Trained professioinal	76	1,02E-01	221	4,61E-04	4,61E-02	YES
Brashing trained prof	0,0016	2,14E-06	221	9,70E-09	9,70E-07	YES
Injection	0,57	7,64E-04	221	3,46E-06	3,46E-04	YES
M&L	0,94	1,26E-03	221	5,70E-06	5,70E-04	YES
Sanding	3,10E-13	4,15E-16	221	1,88E-18	1,88E-16	YES

As can be seen, the situation is far below a risk situation, so it is concluded no risk is expected due to presence of xylene in product inhalation via.

However, taking into account Xylene is a volatile substance and primary exposure by inhalation of vapours is possible for the users (vapour pressure 821 Pa at 20 °C) ConsExpo was used to assess it.

The exposure to xylene via inhalation is estimated using ConsExpo Web with the exposure to vapour model using the brushing treatment scenario. The exposure level depends on a number of parameters such as application frequency and room volume. A room volume of 1 m^3 to reflect the personal breathing zone, a release area of 31.6 m^2 (representing the product application surface form brushing), a ventilation rate of 1.5 per hour relevant for professional use, a product amount of 7774 g assuming a brushing curative treatment , a mass transfer coefficient of 2.18E+05 m/h using Langmuir's method, an application

duration of 120 minutes in line with the duration chosen for brushing scenario and an emission duration of 240 minutes per day were are assumed.
An important parameter for the ConsExpo Web exposure to vapour model is the Molecular weight matrix and in the product XYLAZEL TOTAL the matrix is Naphtha (petroleum), hydrotreated heavy (Hydrocarbons, C10-C13, n-alcanes, cyclical, isoalkanes, <2% aromatics) [7] that has not a defined molecular weight. Using C_{11} chain length (undecane) as a substance of reference, molecular weight of 158 g/mol has been used.

This results in a mean event concentration and peak concentration of 6.8 × 10^1 mg/m^3 which is below the 8-hour-TWA of 221 mg/m^3, and short-term exposure level STEL (15 mins) of 442 mg/m^3.
The concentration of xylene in air is calculated to be 68 mg/m^3 and the resulting risk index is 31% (68/221 x 100) for a 8 hours TWA. The estimated exposure is thus lower than the available IOELV value for xylene. Taking this into account, the xylene evaporation vapours exposure to is considered acceptable.

Altogether the exposure to xylene is not considered to cause adverse health effects to the users when using XYLAZEL TOTAL in accordance to the use instructions. Due to its volatility xylene evaporates quickly after application from manure. Therefore, secondary exposure to xylene is considered negligible.

See annex 3.2 for calculations.

Conclusion

Taking into account the Spanish definition of professionals[8] and the necessary PPE to obtain a situation of non-concern from the risk characterization of uses applied for[9], no Xylazel Total uses for professionls are authorised.

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

Summary table: scenarios		
Scenario number	**Scenario and Users (e.g. mixing/ loading)**	**Conclusion**

[7] A complex combination of hydrocarbons obtained by treating a petroleum fraction with hydrogen in the presence of a catalyst. It consists of hydrocarbons having carbon numbers predominantly in the range of C6 through C13 and boiling in the range of approximately 65°C to 230°C (149°F to 446°F).

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

[9] Spraying: protective chemical resistant gloves and coverall for mixing and loading, gloves, coated coverall (PF 5%), and mask (P3) for application, and gloves and impermeable coveralls (PF 10%) for cleaning spray equipment
Brushing: protective chemical resistant gloves and coverall for mixing and loading and gloves and coated coveralls (PF 5%) for brushing.

1.	Double Vacuum-pressure (preventive) Industrial user	A **safe** situation has been identified for industrial double vacuum pressure application of the product when PPEs, gloves and impermeable coverall (PF 10%), are worn**.**
2.	Automated dipping process (preventive) Industrial user	(2) Automated dipping process: A **safe** situation has been identified for industrial automated dipping application of the product when PPE, gloves, are worn.
3.	Automated spray application (preventive) Industrial user	A **safe** situation has been identified for industrial automated spraying application of product when PPE, gloves, are worn**.**
4.	Spray application (preventive and curative) Trained-Professional	An **safe** situation has been identified for trained-professional spaying application of product when PPE, gloves, coated coverall (PF 5%) and mask P3, are worn**.**
5.	Brushing (preventive and curative) Trained-professional	A **safe** situation has been identified for trained professional brushing application of product when gloves and coated coverall (PF 5%),are worn.
5(2).	Brushing (preventive and curative) Non-professional	A **safe** situation has been identified for Non-professional brushing application of product.
6.	Injection (preventive and curative) Trained-Professional	A situation has been identified for trained-professional injection application of product.
7.	Mixing and Loading Trained-professional	A **safe** situation has been identified for trained professional mixing and loading of product.
8.	Cleaning of brush equipment Trained-professional	A **safe** situation has been identified for trained professional cleaning brushes when **gloves** are worn.
9.	Cleaning spray equipment	A **safe** situation has been identified for trained professional cleaning spray equipment when **gloves** are worn.
10.	Cutting and sanding Professional	A **safe** situation has been identified for professional cutting and sanding treated wood.
11.	Cutting and sanding Non-professional	A **safe** situation has been identified for non-professional cutting and sanding treated wood.
12.	Chewing wood off-cut General public	A **safe** situation has been identified for toddler chewing treated wood chips.
13.	Playing on weathered structure and	A **safe** situation has been identified for toddler playing and mouthing on playground weathered wood

	mouthing General public	structure outdoors preventively and curatively treated with the product.
14.	Inhalation residues indoors General public	A **safe** situation has been identified for general public inhaling volatilised residues indoors.
15.	Laundering contaminated work clothing at home General public	A **safe** situation has been identified for general public laundering contaminated work clothing.

Combined Scenarios:

Summary table: Combined scenarios		
Combined Scenario numbers	**Users and Scenarios (e.g. mixing/ loading)**	**Conclusion**
(1) + (7) + (15)	Industrials (Trained professionals) Automated double vacuum / M&L / Laundering work clothes	A **safe** situation has been identified for Industrials (Trained professionals) applying the product when gloves and impermeable coverall (PF 10%) for application and clothes and gloves for mixing and loading, are worn.
(2) + (7) + (15)	Industrials (Trained professionals) Automated dipping / M&L / Laundering work clothes	A **safe** situation has been identified for Industrials (Trained professionals) applying the product when gloves for application and clothes and gloves for mixing and loading, are worn.
(3) + (7) + (15)	Industrials (Trained professionals) Automated spraying / M&L / Laundering work clothes	A **safe** situation has been identified for Industrials (Trained professionals) applying the product when gloves for application and clothes and gloves for mixing and loading, are worn.
(4) + (7) + (9) + (15)	Industrials (Trained professionals) Trained professionals Spraying / M&L / Laundering work clothes / Cleaning spray equipment	A **safe** situation has been identified for Trained professionals applying the product when gloves, coated coverall (PF 5%) and mask P3 for application, clothes and gloves for mixing and loading and gloves and impermeable coveralls (PF 10%) for cleaning spray equipment are worn.
(5) + (7) + (8) + (14)	Trained professionals Brushing / M&L / Laundering work	A **safe** situation has been identified for Trained professionals applying the product when gloves and coated coverall (PF 5%) for application and clothes

	clothes / Cleaning brush equipment	and gloves for mixing and loading, are worn.
(5)(2) + (7) + (8) + (14)	Non- professionals Brushing / M&L / Laundering work clothes / Cleaning brush equipment	A **safe** situation has been identified for Non-professionals applying the product.

2.2.7. Risk assessment for animal health

There is no foreseen risks for animals, therefore this assessment has not been performed.

2.2.8. Risk assessment for the environment

ES-CA:

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

This environmental risk study aims to assess whether the use of the biocidal product Xylazel Total may cause unacceptable risks to the environment.

The evaluation has been set under the guideline of the "ECHA Transitional Guidance on mixture toxicity assessment for biocidal products for the environment".

The product is composed by the following active substances:

Active substance	**% w/w**	**Pvap (Pa)**
Cypermethrin (RS)-α-cyano-3phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate - CAS: 52315-07-8	0,15	6·10-7 (25ºC)
Propiconazole 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole - CAS: 60207-90-1	0,175	5,6·10-5 (25 °C)
Tebuconazole 1-(4-Chlorophenyl)-4,4-dimethyl-3-(1,2,4-triazol-1-ylmethyl)-3-pentanol - CAS: 107534-96-3	0,175	1.7E-06 (20°C)
IPBC 2-propenyl butyl carbamate - CAS: 55406-53-6	0,6	0.00236 (25 °C)

There are no expected interations nor synergies between actives substances. As a first tier of the assessment, the summation of RQ is considered. In case an unacceptable risk may exist, further refinement of the PEC will be performed.

2.2.8.1. Effects assessment on the environment

Tebuconazole

Reference	Study	NOEC	AF	Value
$PNEC_{wat}$	21d daphnia	0,01 mg/l/	10	0,03 mg/l
$PNEC_{sus.sed}$	Chironomus riparius EC_{10}	54.5 mg a.s. /$kg_{sus.sed}$	100	0.55 mg / $kg_{sus.sed}$
$PNEC_{stp}$		32 mg/l	100	0.32mg/l
$PNEC_{soil}$	56d Earthworm reproduction	5.7 mg/kg $_{dry\ soil}$	50	0.114 mg/kg dry soil (0.1 mg/ kg wwt)

Propiconazole

Reference	Study	NOEC	AF	Value
$PNEC_{wat}$				1,6 µg/l
$PNEC_{sed}$				0,054 mg/kg wet sediment
$PNEC_{stp}$				1 mg /l
$PNEC_{soil}$				0,02 mg/kg wwt

Cypermethrin

Reference	Study	NOEC	AF	Value
$PNEC_{wat}$	Fish (Chronic test)	0,01 µg/1	10	0,001 µg/1
$PNEC_{sed}$	equilibriurn method	-	-	0,125 mg/Kg
$PNEC_{stp}$	microbial activity inhibition test	163 mg/l	100	1,63 mg/l
$PNEC_{soil}$		5.2 mg/Kg wwt	50	0,1 mg/kg wwt

IPBC

Reference	Study	NOEC /EC	AF	Value
$PNEC_{wat}$	algae	0,0046 mg/l	10	0,0005 mg/l
$PNEC_{sed}$	equilibrium method	-	-	0,0005 mg/l
$PNEC_{stp}$		44,00 mg/l	100	0,44 mg/l
$PNEC_{soil}$	plant test	4,92 mg/kg wwt	100	0,005 mg/kg wwt

ES -CA:

The PNEC values for IPBC/PBC have been taken from the Assessment Report for PT 8 and also including updates in the Assessment Report for PT13 (January 2015). For Cypermethrin the PNEC values have been taken from the Assessment Report for PT18 (January 2017). For Tebuconazole the PNEC values have been taken from the Assessment Report for PT8 (November, 2007). For propiconazole/1,2,4-triazole the PNEC values have been taken from the Assessment Report for propiconazole in PT7 (January 2015), because new data has been included compared to the Assessment Report for propiconazole in PT8 (December 2007).

The PNEC values used in the risk assessment are the following:

Summary table on PNEC values for active substances and their relevant metabolites

Active substance	PNEC water [mg.l^{-1}]	PNEC sediment [mg.kg^{-1}wwt]	PNEC soil [mg.kg^{-1}wwt]	PNEC STP [mg.l^{-1}]	PNEC oral,bird [mg.kg^{food}]	PNEC oral,mammal [mg.kg^{food}]
Tebuconazole	1.00E-03	5.50E-01	1.00E-01	3.20E-01	n.r.	n.r.
Propiconazole	6.80E-03	5.40E-02	1.00E-01	1.00E+02	n.r.	n.r.
IPBC	5.00E-04	Covered by surface water	4.40E-03	4.40E-01	n.r.	n.r.
Cypermethrin	4.00E-6	5.00E-2(1)	7.00E-02	1.63 E+00	3.33E+01	3.33E+00
1,2,4-triazole	n.r	n.r	8.20E-03(2)	n.r	n.r.	n.r.
PBC	4.13E-02	2.10E-01	1.49E-01	4.40E-01	n.r.	n.r.
Iodine/Iodate/Iodide	0.59 / 58.5 / 0.83 (µg iodine/L)	Covered by surface water	0.0118 / 0.304 /0.0043 (mg iodine/kg wwt)	2.90	n.r.	n.r.

n.r.: not relevant for the concerned compartment
(1) EPM-A factor of 10 has to be added to the PEC/PNEC ratios
(2) From AR (2015) Propiconazole (PT7).

Besides PBC and 1,2,4-triazole, another transformation product from IPBC is iodine which is not a xenobiotic substance but an essential dietary trace element and is ubiquitously present in the environment. Because of iodine's natural presence in the environment, background values have to be taken into account in the environmental risk assessment. An overview on the background concentrations of iodine in the relevant environmental compartments is given in the table below. This has been taken from the Assessment Report for iodine (PT1,3,4,22), December 2013.

Background concentration of iodine in the environment	
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 (river and lake)	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

Xylazel Total is a mixture of different substances. These substances are solved in organic solvents, chemically stable and non reactive. According to CLP, the data for the individual substances of the mixture should normally be used as a basis for the hazard identification of the mixture.
The active substances are authorized according to BPD/BPR and were evaluated for similar uses that are intended for Xylazel Total.

Xylazel Total is a mixture of different substances. These substances are solved in organic solvents, chemically stable and non reactive. According to CLP, the data for the individual substances of the mixture should normally be used as a basis for the hazard identification of the mixture.

The active substances are authorized according to BPD/BPR and were evaluated for similar uses that are intended for Xylazel Total.

Substance	CLP - Pictograms	CL50 fish (mg/kg)	CL50 algae (mg/kg)	CL50 Dapnia (mg/L)
Tebuconazole	Aquatic Chronic 2: H411	4.4	5.3	2.8
Propiconazole	Aquatic Acute 1, H400 Aquatic Chronic 1, H410	4.3	0.016	10.2
Cypermethrine	Aquatic Acute 1, H400 Aquatic Chronic 1, H410	0.00283	0.00471	0.033
IPBC	Aquatic Acute 1, H400 Aquatic Chronic 2, H411	0.067	0.022	0.16

The hazard to environment is evaluated according to CLP.

According to the eco-toxicological data of the substances, Xylazel Total is considered: Aquatic Acute 1: Hazardous to the aquatic environment, acute hazard, Category 1 Aquatic Chronic 1: Hazardous to the aquatic environment, long-term hazard, Category To evaluate the risk using Xylazel Total it is necessary to calculate the release or these substances to the to environment, taking in account the intended uses of the product.

ES -CA:

Harmonised environmental classification of the active substances

The environmental classification of the active substances is the following:

Classification for the active substances			
Active substance	**Env. Classification**	**M-Factor**	**Concentration of a.s. in the product (%)**
Tebuconazole (1)	H400, H410	M=1 M(chronic)=10	0.175
Propiconazole (2)	H400, H410	M=1 M(chronic)=1	0.175
IPBC (3)	H400, H410	M=10 M(chronic)=1	0.60
Cypermethrin (4)	H400, H410	M=100000 M(chronic)=100000	0.15

(1) Current entry in Annex VI, CLP Regulation, ATP 7.
(2) Current entry in Annex VI, CLP Regulation, ATP13.
(3) Current entry in Annex VI, CLP Regulation, ATP6.
(4) No M-factor was shown in the harmonised classification, but the M-factor noted here is based on RAC Opinion. The proposed classification is Aquatic Acute 1, H400 with an acute M-factor of 100 000 and Aquatic Chronic 1, H410, with a chronic M-factor of 100 000.

Environmental classification of the substance(s) of concern

The biocidal product contains a substance that influences the environmental classification so this substance is subtance of concern.

Classification for the substances of concern			
Component	**Env. Classification**	**M-Factor**	**Concentration of a.s. in the product (%)**

Naphtha (petroleum)	H411	-	>70

Environmental classification of the biocidal product

Regarding the ecotoxicological properties, the formulation is very toxic to aquatic organisms. According to Regulation (EC) No 1272/2008 the product is classified as Aquatic Acute 1 (H400: Very toxic to aquatic life)/Aquatic Chronic 1 (H410: Very toxic to aquatic life with long lasting effects) with the signal word "Warning".

Conclusion on the environmental classification and labelling of the product

Classification:

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

Labelling:
Warning H410

Precautionary statements

P273 – Avoid release to the environment

P391 – Collect spillage

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

PBT-assessment:
According to the PT08-AR of tebuconazole (2007), tebuconazole does not fulfil the PBT nor the vPvB criteria. Nonetheless, the substance is candidate for substitution, as it fulfils the P and T criteria.
According to the PT07-AR of propiconazole (2015), propiconazole does not fulfil the PBT nor the vPvB criteria. Nonetheless, the substance fulfils the P criteria.
According to the PT18-AR of Cypermethrin (2017), Cypermethrin does not fulfil the PBT nor the vPvB criteria.
According to the PT13-AR of IPBC (2015), IPBC and PBC do not fulfil the PBT nor the vPvB criteria.

ED-assessment:
According to the PT08-AR of tebuconazole (2007), the PT07-AR of Propiconazole (2015), the PT018-AR of Cypermethrin (2017), the PT13-AR of IPBC (2015) no definitive conclusions can be drawn concerning the endocrine disruption activity of each active substance. Nevertheless, a number of scientific publications mention potential endocrine disruption activity of propiconazole , tebuconazole and IPBC. These effects will be assessed more in detail at the renewal stage of these biocidal active substances approval in the frame of the EU Regulation No 528/2012 (initially scheduled in 2019), 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 these active substances were identified as ED, the conditions for the product authorisation will have to be revised.

Please refer to Confidential Annex.

Further Ecotoxicological studies

Not available. The active substances detemine the effects against microorganisms and other non-target organism.
Futher information is in the available data of these approved substance.

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

No data is available. The active substances detemine the effects against microorganisms and other non-target organism.
Futher information is in the available data of these approved substance.

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

Xylazel Total is a wood preservative against insects an fungi. The active substances detemine the effects against microorganisms and other non-target organism.
Futher information is in the available data of these approved substance.

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

No data is available. The active substances detemine the effects against microorganisms and other non-target organism.
Futher information is in the available data of these approved substance.

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

No relevant.

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

Xylazel Total is a solvent based wood preservative that can be released to the environment during the treatment of the wood.
Industrial application of Xylazel Total must be made within a confined or on a hard impermeable surface area with protective barriers. Freshly treated wood have to be stored, after treatment, under roof or on impermeable hard surface, or both modes to avoid direct discharge to soil or water. Occasional discharges must be collected for reuse or disposal.
Outdoor wood should be treat in protected areas from rainwater to avoid discharge to the environment.
Leaching of the active substances can occure when treated wood is is exposed to outdoor environment.
Xylazel Total applications must be top-coated by using as a wood stain, varnish or paint to avoid leaching of the active substances when the treated wood is exposed to outdoor environment.
Using a topcoat has prove to be an adequate mitigation measure to protect the soil compartments.
The values PEC/PNEC for the scenario "house" were calculated for each active substance.

The values PEC/PNEC for the scenario "house" were calculated for each active substance. These values are under 1, so that it is expected that the risk for use class 3 of Xylazel Total with a top-coat is acceptable.

ES-CA:

***Industrial application of* the biocidal product and storage of the wood**

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

In-service life

Emissions may take place due to leaching from constructions built from industrially treated wood. During the Arona Leaching Workshop in June 2005, it was agreed that a long-term assessment of in-service uses of wood should be carried out. For automated spraying and short dipping an assessment of cumulative leaching from treated wood in-service over a 15 years period was applied. For double vacuum an assessment of cumulative leaching from treated wood in-service over a 20 years period should be applied and for "In- situ" application an assessment of cumulative leaching from treated wood in-service over a 5 years period was applied. Hence, the assessment times are 30 days (TIME 1) for short term consideration and 5, 15 or 20 years (service life) for the longer time period (TIME 3). A further TIME 2 value of 365 days is calculated as well (not used for decision making) as agreed by the Environment Working Group.

Please refer to section "Fate and distribution in exposed environmental compartment" for further details.

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

No further information available.

Leaching behaviour (ADS)

Leaching behaviour has been assessed in a laboratory Test Report Order no. 2214094 (Entwicklungs- und Prueflabor Holztechnologie GmbH).

> "A set of 30 specimens from Scots pine sapwood (25 x 15 x 50 mm³) was prepared according to requirements of EN 113. The end grains were sealed by threefold brushing with Sigillon D/D 2-K (Wildschek & Co, Switzerland). Specimens were exposed in the conditioning room (20°C/65 % relative air humidity) for drying and conditioning until further use.
> The side faces of all specimens were brushed with the preservative product "Xylazel Total Tratamiento Protector de la Madera" twice. The required quantity

of 240 mL/m2, supplied by the Client, was realized by applying a product mass of 0.76 g to 0.84 g per specimen (calculated on the basis of a product density of 0.83 g/cm³, a treated area of 40 cm² per specimen and a tolerance of ± 5 %).
After drying, the end product "Xylazel Plus Satinado Incoloro" was applied by two brushing steps. The required quantity of 145 mL/m2, supplied by the Client, was realized by applying a product mass of 0.51 g to 0.57 g per specimen (calculated on the basis of a product density of 0.93 g/cm³, a treated area of 40 cm² per specimen and a tolerance of ± 5 %).
After four weeks of drying and fixation, half of the specimens were leached with water according to EN 84 realizing 4 water exchanges within a period of 14 days. The other (not leached) specimens were exposed in the conditioning room [20/65]. Samples from the leaching water were collected. Leached specimens were dried for two weeks. Afterward, chemical analysis was performed."

The manufacturer proposes the use of the topcoat "Xylazel Plus Satin Colourless" to avoid releases due to leaching, as a risk reduction measure.
To carry out the evaluation, data on leaching behaviour provided by the test performed by the laboratory Entwicklungs- und Prueflabor (report No. 2,214,094) are used.

Leaching values attached in section 3.2. show that emission after 3rd day stabilzes. According to document "*leaching workshop, 2005 page 14"* : "*the duration of the test must be sufficient to enable a flux profile against time to be determined"* since flux profile was determined, 14 days values are used as for the initial period assessment (30 days).

For extrapolation of 30 day values to 365 days, it is adviced to multpli 30 day values by 10. (*leaching workshop, 2005 page 14).*

ES- CA:

The applicant performed a leaching test for XYLAZEL TOTAL which was performed according to (OECD 2009, Nº107), however ES-CA is of the opinion that this test does not fulfil with the validity criteria due to the following deficiencies:

- The analytical measurements of all active substances were carried out but only data for propiconazole and IPBC were obtained. For tebuconazole and cypermetrin the data were below the determination limit. The leaching water fraction was analyzed with a gas chromatograph using ECD detection (GC-ECD).

According to section 2.2.4 of this dossier, the methods of detection used in the analytical test of Xylazel Total (liquid product ready for use, report nº 051988_1 and 051988_2) were HPLC-UV for IPBC and GC-FID for tebuconazole, propiconazole and cypermethrin.

The method used in this report is not considered appropriate.

- The report does not specify the testing regime and the wood orientation (horizontal or vertical). Three main immersion regimes are recommended in the guideline. The Applicant must always be able to scientifically justify the selected testing regime according to the application method of the preservative, the use class and intended use pattern of the treated wood.
- According to the guideline the preservative is applied to the test specimens by the method specified for the preservative, which may be by a penetrating treatment process or a superficial application process (e.g., dip, spray or brush). According to the intended uses XYLAZEL TOTAL class 3 can be applicated by brushing, dipping and vacuum impregnation however this test was carried out only for the superficial treatment.
- The experimental data obtained from the laboratory study are not sufficient and do not

have sufficient resolution to make a good regression.

In the 2nd EU Leaching Workshop default leached quantities were defined, in case no leaching test is available. In this case there is a leaching test but due to deficiencies of the test, ES-CA considers more apppropiate to use defaults leached quantities. Taken into account that the application rate of XYLAZEL TOTAL is 140ml/m2 according to intended used for fungi, the defaults values of leached quantities are the following:

Time 1 (30days): 50% of the applied substance leaches out
Time 2 (365 days): 75% of the applied substance leaches out
Time 3 (service life): 100% of the applied substance leaches out

The new Time 2 of 365 days is currently only used for a validation/impact assessment and it should not be used for decision making (according to the follow up of the 2nd EU Leaching workshop).

Testing for distribution and dissipation in soil (ADS)

Information for distribution and dissipation in soil of active substances and its corresponding metabolite was extracted from active substace's assessment report, as remarked in *"Method, Guideline, GLP status, Reliability"*.

Distribution

Summary table of the adsorption/desorption in soil									
Method, Guideline, GLP status, Reliability	Soil	Adsorbed AS [%]	K_a	K_{aOC}	K_d K_{dOC} K_a/K_d	Kf	l/n	Remarks	Reference
Assessment report: Cypermethtin cis:trans/ 40:60 PT8, 12 July 2013	*Soil 1*	ND	ND	Koc = 80653 - 574360 mL/g	Kd = 3871-8976	ND	ND	Values referent to Cypermethtin adsorption	
Assessment report: IPBC PT8, 22 February 2008	*Soil 2*	ND	Ka= 0.67-2.46	KaOC = 61.0 - 309	Kd= 3.43-31.3 KdOC= 457-4065	ND	ND	Values referent to IPBC adsorption	
Assessment report: Propiconazole PT8, 29 November 2007	*Soil 3*	ND	ND	KaOC= 382 - 1789	Kdoc= 455-2279	ND	ND	Values referent to Propiconazole adsorption	
Assessment report: Tebuconazole PT8, 29 November 2007	*Soil 4*	ND	Ka= 12.7	Koc= 992 Koc,ads = 992 mL/g	ND	ND	ND	None	

				Koc,des =1300 mL/g					

K_a = Adsorption coefficient

K_{aOC} = Adsorption coefficient based on organic carbon content

K_d = Desorption coefficient

K_{dOC} = Desorption coefficient based on organic carbon content

K_a/ K_d = Adsorption / Desorption distribution coefficient

Summary table of adsorption/desorption of metabolite/transformation- or reaction product in soil							
Method, Guideline, GLP status, Reliability	Soil	Adsorbed AS [%]	K_a	K_{aOC}	K_d K_{dOC} K_a/K_d	Remarks	Reference[1]
Assessment report: Propiconazole PT8, 29 November 2007	*Soil 1*	ND	ND	KaOC= 13 - 202	ND	Values referent to 1,2,4-triazole	
Assessment report: Propiconazole PT8, 29 November 2007	*Soil 2*	ND	ND	KaOC= 101-166	ND	Values referent to CGA 118 245	

Although other metabolites were described, no data of distribution in soil was provided in the assessment report.

Dissipation

Summary table on half lives in soil					
Process	DT_{50} measured in test (20º)	DT_{50} at 12°C	Rate constant at 12°C	Remarks	Reference[1]
Degradation (aerobic)	72d	137d	ND	Values referent to active substance	Assessment report: Propiconazole PT8, 29 November 2007
Degradation	6-24d	17.2d	ND	Values referent to active substance	Assessment report: Cypermethtin cis:trans/40:60 PT8, 12 July 2013 Assessment report: Cypermethtin
Soil photolysis	29.6d	ND	ND	Values referent to active substance	
Degradation (anaerobic)	46d	87.2d	ND	Values referent to active	

Summary table on half lives in soil					
Process	DT_{50} measured in test (20º)	DT_{50} at 12°C	Rate constant at 12°C	Remarks	Reference[1]
				substance	cis:trans/40:60 PT8, 12 July 2013 Assessment report: Cypermethtin cis:trans/40:60 PT8, 12 July 2013
Degradation (aerobic)	> 365d	ND	ND	Values referent to active substance	Assessment report: Tebuconazole PT8, 29 November 2007
Degradation (field study)	77d	ND	ND	Values referent to active substance	Assessment report: Tebuconazole PT8, 29 November 2007
Degradation (aerobic)	2.1h (22º)	5h	ND	Values referent to active substance	Assessment report: IPBC PT8, 22 February 2008

Summary table of identified relevant metabolites and transformation- or reaction products in soil				
Process	Metabolite/ transformation- or reaction product	[%] of active substance	Remarks	Reference
Photolisis is a minor route	Not applicable	Not applicable	Not applicable	Assessment report: Cypermethtin cis:trans/40:60 PT8, 12 July 2013
Aerobic and anaerobic degradation produces metabolization of three metabolites.These lead to bound residues and mineralization to dioxide.	3-phenoxybenzoic (3-PBA)	Max.10.2%	DT50=58d (Anaerobic,20ºC)	
	TDCVC	Max.13,6%	ND	
	CDCVC	Max.3.6%	ND	
	CO2	ND	ND	
Hydrolytically stable	Not applicable	Not applicable	Not applicable	Assessment report:

Summary table of identified relevant metabolites and transformation- or reaction products in soil				
Process	Metabolite/ transformation- or reaction product	[%] of active substance	Remarks	Reference
Photolytically stable	Not applicable	Not applicable	Not applicable	Propiconazole PT8, 29 November 2007
Anaerobic degradation	Not applicable	Not applicable	Not applicable	
Aerobic degradation	1,2,4-triazole	>10%	DT50= 9.3d (20ºC)	
	CGA 118 245:	>10%	DT50= 1d (20ºC)	
Hydrolisis aerobic soil: Further metabolism produced its degradetion to CO2.	PBC	>10%	DT50= 10d	Assessment report: IPBC PT8, 22 February 2008
Anaerobic degradaetion	Stable	Not applicable	DT50=10d	Assessment report: Tebuconazole PT8, 29 November 2007
Aerobic degradaetion	1,2,4-Triazole	Max. 9%		
Photolysis	Stable	Not applicable		

Conclusion used in Risk Assessment –Distribution and dissipation in soil	
Value/conclusion	Metabolites will not contribute to soil hazards
Justification for the value/conclusion	Regarding the terrestrial compartment, cypermethrin cis:trans/40:60 is characterised by a koc value ranged from 80653 to 574360, indicating a high potential to adsorb to the soil particles, reducing the bioavailability. Identified metabolites were 3-Phenoxybenzoic acid, TDCVC and CDCVC. No ecotxociological information was provided for 3-phenoxybenzoic and TDCV 3-PBA in the aquatic compartirment. Since it was not considered a metabolite of concern in Assessment report: Cypermethtin cis:trans/ 40:60 PT8, 12 July 2013, no further assessment was developed. According to assessment report for Propiconazole, both metabolites are degreded fater than the parent substance.Metabolites are more mobile than propiconazole (koc of 129), but main route still been adsoption. Toxicity values (LC50) for soil organisms (earthworms) are below 1000 mg/kg dw. Therefore, metabolites are not considered to be dangerous to soil compartment. (OK).

	PBC was identified as a relevant metabolite of IPBC soil, above the limit of 10%. Due to a relative short half-life of PBC, can be considered a transient metabolite. Ecotoxicity is a factor of 300 – 1000 lower for fish, invertebrates and algae compared to IPBC. Risk assessment on PBC is not considered further. (OK). Tebuconazole is not metabolised rapidly in soil in laboratory experiments, the half-life for primary degradation is greater than one year. In field studies the dissipation half lives are 77 days. An accumulation of Tebuconazole in soil is not anticipated when tebuconazole is used as a wood preservative. Has a low mobility potential. 1,2,4-Triazole is the primary metabolite from the degradation of tebuconazole (max 9%). The dissipation half-life of this metabolite in aerobic soil is estimated to be about 10 days. Since it doesn't reach 10%, no further assessment is required. (OK)

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

Distribution

Although the product is not expected to be applied closed to water sources or sediment, informationa bout distribution in water/sediment systems was extracted and exposed below.

According to chapter 4, page 32 of Assessment report: IPBC PT8, 22 February 2008" 78% of the active substance would remain in the water phase and less than 10% in the sediment.

Metabolites distribution assessment in sediment/water systems showed that in anaerobic aquatic environments, PBC was degraded to 2-propenyl butyl carbamate (2-PBC) and 2 unidentified degradates (less than 10%), CO2 and possibly CH4.

In anaerobic aquatic environments (sediment/water), PBC was degraded to 2-propenyl butyl carbamate (2-PBC) and 2 unidentified degradates (less than 10%), CO2 and possibly CH4.

The metabolite 2-PBC is only formed at a percentage > 10% in the water phase under anaerobic conditions.

88.6% of PBC will remain in surface water while a 20.9% will remain in sediment.

Distribution for 2-PBC is described as 35.9% in surface water and 8.8% in sediment.

Assessment report: Cypermethtin cis:trans 40:60 PT8, 12 July 2013 distribution values expressed in chapter 4, shows the following environmental fate:

- Active substance: After 100 days, 9% will remain in water phase while 7% will remain in sediment.

- On the other hand, after the same period, distribution of metabolites in water-sediment system would be as follows:

    - 3-Phenoxybenzoic acid: Up to 21% in water and 11% in sediment.
    - TDCVC: Up to 44% in water and 20% sediment.
    - CDCVC: Up to 22% in water and 15% in sediment.

Fate and behaviour in the environment for Tebuconazole is exposed in chapter 4 of document Assessment report: Tebuconazole PT8, 29 November 2007.
Tebuconazole is stable to hydrolysis, it's not readily, inherent or ultimately biodegradable in water.

No major metabolites were found for degradation in water.

Assessment report: Propiconazole PT8, 29 November 2007 exposes that Propiconazol is stable to Hydrolisis and photo-oxidative degradation, no major metabolites are formed.

After a 175 days study, distribution in water phase was estimated in 2% and 81.7% in sediment.

Dissipation

Summary table on half lives in water and sediments					
Compartment /process	DT_{50} measured in test	DT_{50} at 12°C	Rate constant at 12°C	Remarks	Reference[1]
Total water/sediment system	54d	ND	ND	-	Assessment report: Tebuconazole PT8, 29 November 2007
Biodegradation in surface water	198d	ND	ND	-	
Hydrolysis	>29d (25ºC)	98.9d	ND	pH=7	*Assessment report: Cypermethtin cis:trans/ 40:60 PT8, 12 July 2013*
Water	0.5d (20ºC)	0.948d	ND	-	
Sediment	14.3d	27d	ND	-	
Water/Sediment system	10.9d	18.5d	ND	-	
Water	5.5-6.4d	ND	ND	-	*Assessment report: Propiconazole PT8, 29 November 2007*
Water/sediment system	485-636d	ND	ND	-	
Hydrolysis	248d (25ºC)	702d	ND	pH=7	*Assessment report: IPBC*

Summary table on half lives in water and sediments					
Compartment /process	DT_{50} measured in test	DT_{50} at 12°C	Rate constant at 12°C	Remarks	Reference[1]
Anaerobic Water/sediment system	1.5h (22ºC)	3.3h	ND	Nonsterile	*PT8, 22 February 2008*
Anaerobic Water/sediment system	13.3h (22ºC)	30h	ND	Sterile	

Summary table of identified metabolites /transformation- or reaction products in water and sediments				
Compartment	Metabolite/ transformation- or reaction product	[%] of Metabolite	Remarks	Reference[1]
Water/sediment	PBC	ND	DT50= 11.5d (22ºC) DT50=26d (12ºC)	*Assessment report: IPBC PT8, 22 February 2008*
Water/sediment	TDCVC	ND	DT50= 114.3d (20ºC) DT50= 273.6d (12ºC)	Assessment report: Cypermethtin cis:trans/ 40:60 PT8, 12 July 2013
Water/sediment	CDCVC	ND	DT50= 187.5d (20ºC) DT50= 355.6d (12ºC)	
Water/sediment	3-PBA	ND	DT50= 12.9d (20ºC) DT50= 24.5dmust (12ºC)	
Water/sediment	No major metabolites were found in water/sediment systems.	< 10%	Not applicable	Assessment report: Tebuconazole PT8, 29 November 2007
Water/sediment	No major metabolites were found in water/sediment systems	<10%	Not applicable	*Assessment report: Propiconazole PT8, 29 November*

Summary table of identified metabolites /transformation- or reaction products in water and sediments				
Compartment	Metabolite/ transformation- or reaction product	[%] of Metabolite	Remarks	Reference[1]
				2007

Conclusion used in Risk Assessment –distribution and dissipation in water and sediment	
Value/conclusion	
Justification for the value/conclusion	Metabolates Tebuconazole and Propiconazole are below 10% and no further assessment is required, though, TDCVC, PBC and 3-PBA are above the limit value and must be considered major metabolites. PBC toxicity values (NOEC) for aquatic compartiment, considering the most sensitive organisms (algae) are far above >1 mg/l. No toxicity is expected. No ecotxociological information was provided for TDCVC and 3-PBA in the aquatic compartirment. Since it was not considered a metabolite of concern in Assessment report: Cypermethtin cis:trans/ 40:60 PT8, 12 July 2013, no further assessment was developed.

Testing for distribution and dissipation in air (ADS)

Summary table on half lives in air			
	Value	Unit	Remarks
Molecular weight	281.1	g/mol	Assessment report: IPBC PT8, 22 February 2008
Melting point	65.8-66.5	°C	
Boiling point	ND	°C	
Vapour pressure at 25°C	2.36 -4.5E-03	Pa	
Henry's Law Constant (20 °C)	3.38-6.45E-03	Pa/m3/mol	

Summary table on half lives in air			
	Value	Unit	Remarks
Molecular weight	307.8	g/mol	Assessment report: Tebuconazole PT8, 29 November 2007
Melting point	105	°C	
Boiling point	ND	°C	
Vapour pressure at 25°C	1.7E-06	Pa	
Henry's Law Constant (20 °C)	1E-05	Pa/m3/mol	

Summary table on half lives in air			
	Value	Unit	Remarks
Molecular weight	416.3	g/mol	Assessment report: Cypermethtin
Melting point	47.3	°C	

Boiling point	ND	°C	cis:trans/40:60 PT8, 12 July 2013
Vapour pressure at 25°C	6.0E-07	Pa	
Henry's Law Constant (20 °C)	0.024	Pa/m3/mol	

Summary table on half lives in air			
	Value	Unit	Remarks
Molecular weight	342.2	g/mol	Assessment report: Tebuconazole PT8, 29 November 2007
Freezing point	-23	°C	
Boiling point	> 250	°C	
Vapour pressure at 25°C	5.6E-05	Pa	
Henry's Law Constant (20 °C)	9.2E-05	Pa/m3/mol	

Summary table of half lives identified relevant metabolites and transformation products in air

No data provided for metabolites.

Dissipation

Summary table on (estimated) half lifes in air					
Model	**Light protection (yes/no)**	**Estimated daily (24h) OH concentration [OH/cm³]**	**Overall OH rate constant [cm³/molecule ec]**	**Half-life [hr]**	**Reference**
Photo-oxidative degradation	ND	ND	ND	15	Assessment report: IPBC PT8, 22 February 2008
Photo-oxidative degradation	ND	0.5E+06	ND	17.990	Assessment report: Cypermethtin cis:trans/40:60 PT8, 12 July 2013
Photo-oxidative degradation	ND	5E10+05	ND	10.2-42	Assessment report: Propiconazole PT8, 29 November 2007
Photo-oxidative degradation	ND	ND	ND	3.8 days	Assessment report: Tebuconazole PT8, 29 November 2007

Conclusion used in Risk Assessment –distribution and dissipation in air

Value/conclusion	Emision to air is not considered a potencial hazard.
Justification for the value/conclusion	According to photo-oxidative degradation values assessment for every active substance contained in the product, and considering that vapour pressure is very low in all cases, the product is not expected to emitted or remain in air.

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

The product will always be applied far from water sources and in paved soil.

Because of it, no emission to surface water by overspray is expected.

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

Not applicable

ES-CA:

A summary of the environmental behaviour of the active substances and their relevant metabolites is presented below. All the data are from Doc IIA as well as from Doc IIB for the active substances Cypermethrin, Tebuconazole, Propiconazole and IPBC.

Parameter / Variable	Unit	Cypermethrin	Tebuconazole	Propiconazole	1,2,4-triazole(*)	IPBC	PBC(***)	Iodine(****)
Molar mass	[g/mol]	416.3	307.8	342.2	69.1	281.1	155.2	253.81
Vapour pressure - Vp	[Pa]	2.3E-07	1.70E-06	5.6E-05	0.220	2.36E-03	1.88E+01	40.7
Water solubility – WS	[$mg.L^{-1}$]	4.00E-03	29	100	700	168	2860	290
K_{oc}	[$L.kg^{-1}$]	575 000	992	944	89	134.5	198.1	n.r.
DT_{50} (soil)	[d at 12°C]	17.2	77	82	114.7 (**)	1.96E-01	9.50	n.r.
DT_{50} (surface water – degradation + dissipation)	[d at 12°C]	0.95	43	12	n.r.	1.29E-01	31.2	n.r.
DT_{50} (aquatic – degradation only)	[d at 12°C]	18.5 (whole system)	198 (degradation in water)	1206 (whole system)	n.r.	2.04E-01	31.4	n.r.
BCF in fish	[$L.kg^{-1}$]	417	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.

BCF in earthworm	[L.kg^{-1}]	3380	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.
STP fraction								
$F_{STP, water}$	[-]	0.0915	0.89	0.9	n.r.	0.963	0.967	0.80
$F_{STP, sludge}$	[-]	0.61	0.109	0.1	n.r.	0.0364	0.0241	0.20

n.r. – Not relevant for the environmental risk assessement of the product

(*) – Relevant metabolite of tebuconazole and propiconazole in soil with a maximum of 9% and 43.23 % of applied radioactivity, respectively.

(**) – Calculated according to the arrehnius equation with a DT_{50} at 20°C of 60.5 days.

(***) – Relevant metabolite of IPBC in all environmental compartments assuming 100% of applied radioactivity.

(****) – Relevant metabolite of IPBC in all environmental compartments with a transformation rate in:

- Surface water – iodine to iodide 100% - iodine to iodate 100%
- Soil *via* the STP- iodine to iodide 14% - iodine to iodate 100%

Soil *via* direct release - iodine to iodide 100% - iodine to iodate 100%

2.2.8.2. Exposure assessment

Before scenario development recommended uses of the product and against indications are exposed below:

Use	Scenario	Affected compartments	Observations
Industrial preventive processes and storage of treated wood	Dipping Vacuum pressure treatment/double vacuum.	air	The air compartment is not considered due to low vapour pressure of all relevant substances (Pvap<0.005Pa) and therefore no emissions to atmosphere are expected to occur. This compartment for industrial application and storage is not further assessed.
		facility drain	The releases to the facility drain are not permitted according to national laws10. This compartment for industrial application and storage is not further assessed.

10 "OECD DOCUMENTS SERIES ON EMISSION SCENARIO Emission Scenario Number 2 Revised Document for Wood Preservatives (2013)"
93. The distribution of the emissions in air, public sewage treatment plant (STP) or surface water is not discussed. This distribution will be dealt with in national and regional exposure assessment schemes.

		soil	The soil compartment is not considered because the industrial area and storage's zone pavement must be sealed 11to avoid filtrations into the local soil. This compartment for industrial application and storage is not further assessed.
		surface water	The surface water compartment is not considered because the industrial area and storage's zone protected from rainfall and potential run-off to adjacent surface water bodies. This compartment for industrial application and storage is not further assessed.
In situ treatment (curative / preventive)	House, Brushing – amateur / professional	surface water	The manufacturer recommends not to apply the product nearby a body of water. This compartment for professional/amateur application is not further assessed.
		soil	The soil compartment is not considered because the application must be done in a paved area and correctly sealed to avoid filtrations into the local soil (i.e. indoors). This compartment for amateur/professional application is not further assessed.
Life cycle stage	Treated wood in service: House	soil	Leaching from treated wood is considered (use class 3).
	Treated wood in service: Urban areas	Freshwater	Leaching from treated wood is considered (use class 3).
	Treated wood in service: Bridge over water source	Water Sediment	Leaching from treated wood is considered (use class 3).
	Storage of treated wood prior to shipping	Soil Freshwater	Leaching from treated wood is considered (use class 3).

ES-CA:

11 "OECD DOCUMENTS SERIES ON EMISSION SCENARIO Emission Scenario Number 2 Revised Document for Wood Preservatives (2013)"
90. On European level, where the industrial application of wood preservatives is regulated by local authorities, it can be assumed that most storage places are sealed to prevent any direct release to soil. In the case that the storage place is sealed and run-off from storage places will be collected and disposed of by save means, 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 needs to be assessed.

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 relevant exposure scenarios for each stage of the wood preservative life cycle have been summarised in the tables below.

- Industrial application and storage

The use of wood preservative XYLAZEL TOTAL in the industrial premises involves two life cycle stages: application and post-application storage. Two different methods of application are used: dipping and double-vacuum pressure.

Table 2.2.8.2.-1. Environmental exposure assessment scheme for industrial use.

Application use	**Treatment**	**Emission scenario**	**Compartment**
Preventive Industrial application	Dipping	Application	STP (facility drain)
		Leaching during storage	Soil, Surfacewater
	Double vacuum	Application	STP (facility drain)
		Leaching during storage	soil, Surfacewater

- In-situ application

The product XYLAZEL TOTAL is intended to be used as wood preservative with preventive treatment performed in situ by professionals and amateurs. Evaluated scenarios following OECD guide are:

- House (brushing)
- Fence (brushing)
- Bridge (brushing)

Brushing treatment is considered the principal method for in-situ applications in Europe. During this kind of application, product loses can occur by drip or accidental spills. In this sense and following the guide's recommendations, different emission fraction spill to the environment for amateur and professional user have been considered (0.3 for professional and 0.5 for amateur -worse case-).
In the following table, a summary of *in situ* applications is showed:

Table 2.2.8.2.-2. Scheme of environmental exposure assessment for *in-situ* application.

Application use	**Treatment**	**Emission scenario**	**Compartment**
Preventive *in-situ* application by professional and amateur users	Brushing	Bridge	Surface water
	Brushing	Fence	Soil
	Brushing	House	Soil

- Service life

Apart from the application stage, service life should be also considered as an additional emission

pathway to the environment. Environment emissions from treated wood are due to leaching process during wood's service life. Table below summarises the relevant exposure scenario considered for this life cycle stage.

Table 2.2.8.2.-3. Scheme of environmental exposure assessment for service life wooden treated.

Application use	Treatment	Emission scenario		Compartment
SERVICE LIFE (Outdoor)	Leaching Wooden house	Time 1 (30 days)	Surface Industrial treatment	Soil
			Deep Industrial treatment	
			Surface *In situ* treatment	
		Time 3	Surface *In situ* treatment (5 years)*	
			Surface Industrial treatment (15 years)	
			Deep treatment (20 years)	
	Leaching Fence (brushed)	Time 1 (30 days)	Surface Industrial treatment	Soil
			Deep Industrial treatment	
			Surface *In situ* treatment	
		Time 3	Surface *In situ* treatment (5 years)*	
			Surface Industrial treatment (15 years)	
			Deep treatment (20 years)	
	Leaching Noise barrier	Time 1 (30 days)	Surface Industrial treatment	Soil, STP
			Deep Industrial treatment	
			Surface *In situ* treatment	
		Time 3	Surface *In situ* treatment (5 years)*	
			Surface Industrial treatment (15 years)	
			Deep treatment (20 years)	
	Leaching Bridge	Time 1 (30 days)	Surface Industrial treatment	Surface water
			Deep Industrial treatment	
			Surface *In situ* treatment	
		Time 3	Surface *In situ* treatment (5 years)*	
			Surface Industrial treatment (15 years)	
			Deep treatment (20 years)	

The following assumptions have been made when performing this exposure assessment:

- Taken into account that the application rate of XYLAZEL TOTAL is 140ml/m2 according to intended used for fungi, the defaults values of leached quantities are the following:

Time 1 (30days): 50% of the applied substance leaches out
Time 2 (365 days): 75% of the applied substance leaches out
Time 3 (service life): 100% of the applied substance leaches out

The new Time 2 of 365 days is currently only used for a validation/impact assessment and it should not be used for decision making (according to the follow up of the 2nd EU Leaching workshop).

General information

Assessed PT	PT 8
Assessed scenarios	Scenario 2: House scenario : Application
	Scenario 2: Treated wood in service: House

	Scenario 3: Direct emision to surface water in urban areas
	Scenario 4: Bridge over pond: Application
	Scenario 5: Treated wood in service: Bridge over pond
	Scenario 6: Storage prior to shipping
ESD(s) used	OECD DOCUMENTS SERIES ON EMISSION SCENARIO Emission Scenario Number 2 Revised Document for Wood Preservatives (2013) *The assessment of direct emission to surface water in urban areas*. *Leaching from paints, plasters, and fillers applied in urban areas.*
Approach	Scenario 1: Average consumption Scenario 2: Average consumption Scenario 3: Average consumption Scenario 4: Average consumption Scenario 5: Average consumption Scenario 6: Average consumption
Distribution in the environment	Guidance for BPR: Volume IV Part B Risk Assessment (active substances) version 1.0 April 2015
Groundwater simulation	Leaching behaviour extrapolated from laboratory test
Confidential Annexes	NO
Life cycle steps assessed	Scenario 1 - 3 Production: No Formulation No Use: No Service life: Yes
Remarks	

ES-CA:

Assessed PT	PT8
Assessed scenarios	Scenario 1: Industrial processes – short dipping. Scenario 2: Industrial processes –double vacuum. • Product application • Storage of treated wood prior to shipping Scenario 3: In-situ treatment for professional and amateur (preventive)-brush. Scenario 4: In-service leaching from treated wood • House • Fence • Bridge over pond • Noise Barrier (The pre-treatment of the wood for use as noise barrier is not included in the application; but in order to evaluate the possible risk for STP the calculations

	regarding in-service leaching from noise barrier are included)
ESD(s) used	Emission Scenario Document for Product Type 8: revised Emission Scenario Document for Wood Preservatives, (OECD 2013)
Approach	Average consumption
Distribution in the environment	Calculated based on Vol. IV, Part B
Groundwater simulation	A FOCUS-PEARL-4.4.4 groundwater modelling was performed for active substances and their relevant metabolites. In the modelling the house number of 16 per hectare and the fraction of house surface exposed to weather (0.5) were applied according to the revised OECD ESD for wood preservatives (2013).
Confidential Annexes	No
Life cycle steps assessed	Production: No Formulation No Use: Yes Service life: Yes
Remarks	The product is intended to be used for the UC 1, UC 2 and UC 3. According to the OECD ESD PT 08 no emission scenarios are available for UC 1 and UC 2, since the potential emissions from treated wood to the outer environment are considered negligible. Therefore, no emission and exposure calculation are performed for the UC 1 and UC 2.

Emission estimation

During House scenario assessment, two steps must be considered:

- In-situ treatment: During application the main receiving compartment is considered to be soil via product losses due to spills and drips brushing (corresponding to scenario 1).

- Service-life: The primary receiving compartment is considered to be soil via run-off. It is considered that leaching of substances as a result of rainfall occurs only from the outer side of the wood (corresponding to scenario 2).

Input parameters for calculating the local emission				
Input	**Symbol**	**Value**		**Unit**
Application rate of the product	Qapplic,product	0.24		l/m2
Content of substance in product	f,active substance	IPBC	0.006	-
		Tebuconazole	0.00175	
		Cypermethrin	0.0015	
		Propiconazole	0.00175	
Density of product	RHO,product	850		kg/m3
Duration of the long-term assessment period	Time2	365		d
Cumulative quantity of substance leached out of 1	Q*leach,time1	IPBC	5E-05	kg/m2
		Propiconazole	1.6E-08	

m2 of treated wood over the initial assessment period (30d)		Cypermethrin and Tebuconazole	8E-07	
Cumulative quantity of substance leached out of 1 m² of treated wood over a longer assessment period (365d)	Q*leach,time2	IPBC	3.9E-10	kg/m2
		Propiconazole	3.2E-19	
		Cypermethrin and Tebuconazole	6.78E-08	

ES-CA:

XYLAZEL TOTAL is a solvent-based wood preservative containing 0.15% Cypermethrin, 0.175% Tebuconazole, 0.175% Propiconazole and 0.60% IPBC.

Input parameters for calculating the local emission

Input	Symbol	Value		Unit
Application rate of biocidal product (brush treatment-preventive)	Qapplic,product	0.137		l/m2
Application rate of biocidal product (dip treatment and vacuum impregnation-preventive)	Qapplic,product	53		Kg/m3
Content of substance in product	f,active substance	IPBC	0.006	-
		Tebuconazole	0.00175	
		Cypermethrin	0.0015	
		Propiconazole	0.00175	
Density of product	RHO,product	850		kg/m3
Cumulative quantity of substance leached out of 1 m2 of treated wood over the initial assessment period (30d)	Q*leach,time1	IPBC	321	mg/m2
		Propiconazole	94	
		Cypermethrin	80	
		Tebuconazole	94	
Cumulative quantity of substance leached out of 1 m² of treated wood over a longer assessment period (365d)	Q*leach,time2	IPBC	482	mg/m2
		Propiconazole	140	
		Cypermethrin	120	
		Tebuconazole	140	
Cumulative quantity of substance leached out of 1 m² of treated wood over a longer assessment period (service life)	Q*leach,time3	IPBC	642	mg/m2
		Propiconazole	187	
		Cypermethrin	161	
		Tebuconazole	187	

Input parameters		
First order rate constant for removal from soil (*k*) (k=Ln2/DT_{50})		
Tebuconazole	0.009	[d^{-1}]
Propiconazole	0.009	[d^{-1}]
IPBC	3.540	[d^{-1}]
Cypermethrin	0.040	[d^{-1}]
Fraction released to facility drain ($F_{facilitydrain}$)		
Tebuconazole	0.003	[-]
Propiconazole	0.03	[-]
IPBC	0.03	[-]
Cypermethrin	0.0001	[-]
Fraction released to air (F_{air})		
Tebuconazole	0.001	[-]
Propiconazole	0.001	[-]
IPBC	0.001	[-]
Cypermethrin	0.001	[-]

Scenario [1]

Input parameters and model calculations were extracted from ESD PT8 *"OECD series on emission scenario documents, number, table 4.11, page 63".*

Input parameters for calculating the local emission				
Input	**Symbol**	**Value**		**Unit**
Application rate of the product	Qapplic,product	0.24		l/m2
Content of substance in product	f,active substance	IPBC	0.006	-
		Tebuconazole	0.00175	
		Cypermethrin	0.0015	
		Propiconazole	0.00175	
Density of product	RHO,product	850		kg/m3

In-situ treatment

Professional use (Fsoil,brush=0.03)

IPBC:

$$Esoil, brush = Area, house \cdot Qapplic, product \cdot fai \cdot RHOproduct \cdot Fsoil, brush \cdot 10\text{-}3$$

$$Esoil, brush = 125 \cdot 0.24 \cdot 0.006 \cdot 850 \cdot 0.03 \cdot 10 - 3 = 0.045\ kg/d$$

$$Clocalsoil, = \frac{Esoil, brush}{Vsoil \cdot RHOsoil}$$

$$Clocalsoil, = \frac{0.045}{13 \cdot 1700} = 2.03E - 06\ kg/kgwwt$$

Tebuconazole and Cypermethrin:

$$Esoil, brush = Area, house \cdot Qapplic, product \cdot fai \cdot RHOproduct \cdot Fsoil, brush \cdot 10\text{-}3$$

$$Esoil, brush = 125 \cdot 0.24 \cdot 0.00175 \cdot 850 \cdot 0.03 \cdot 10 - 3 = 0.013\ kg/d$$

$$Clocalsoil, = \frac{Esoil, brush}{Vsoil \cdot RHOsoil}$$

$$Clocalsoil, = \frac{0.013}{13 \cdot 1700} = 5.88E - 07\ kg/kgwwt$$

Propiconazole:

$$Esoil, brush = Area, house \cdot Qapplic, product \cdot fai \cdot RHOproduct \cdot Fsoil, brush \cdot 10\text{-}3$$

$$Esoil, brush = 125 \cdot 0.24 \cdot 0.00175 \cdot 850 \cdot 0.03 \cdot 10 - 3 = 0.013\ kg/d$$

$$Clocalsoil, = \frac{Esoil, brush}{Vsoil \cdot RHOsoil}$$

$$Clocalsoil, = \frac{0.013}{13 \cdot 1700} = 5.88E - 07\ kg/kgwwt$$

Note: Only values corresponding to the non-professional use were used for the calculations of the scenario, as a worst case.

Non-professional use (Fsoil,brush=0.05)

IPBC:

$$Esoil, brush = Area, house \cdot Qapplic, product \cdot fai \cdot RHOproduct \cdot Fsoil, brush \cdot 10\text{-}3$$

$$Esoil, brush = 125 \cdot 0.24 \cdot 0.006 \cdot 850 \cdot 0.05 \cdot 10 - 3 = 0.076\ kg/d$$

$$Clocalsoil, = \frac{Esoil, brush}{Vsoil \cdot RHOsoil}$$

$$Clocalsoil, = \frac{0.076}{13 \cdot 1700} = 3.43E - 06\ kg/kgwwt$$

Tebuconazole and Cypermthin:

$$Esoil, brush = Area, house \cdot Qapplic, product \cdot fai \cdot RHOproduct \cdot Fsoil, brush \cdot 10\text{-}3$$

$$Esoil, brush = 125 \cdot 0.24 \cdot 0.00175 \cdot 850 \cdot 0.05 \cdot 10 - 3 = 0.022\ kg/d$$

$$Clocalsoil, = \frac{Esoil, brush}{Vsoil \cdot RHOsoil}$$

$$Clocalsoil, = \frac{0.022}{13 \cdot 1700} = 9.95E - 07\ kg/kgwwt$$

Propiconazole:

$$Esoil, brush = Area, house \cdot Qapplic, product \cdot fai \cdot RHOproduct \cdot Fsoil, brush \cdot 10\text{-}3$$

$$Esoil, brush = 125 \cdot 0.24 \cdot 0.0015 \cdot 850 \cdot 0.05 \cdot 10 - 3 = 0.019\ kg/d$$

$$Clocalsoil, = \frac{Esoil, brush}{Vsoil \cdot RHOsoil}$$

$$Clocalsoil, = \frac{0.019}{13 \cdot 1700} = 8.5E - 07\ kg/kgwwt$$

Scenario [2]

Service-life

Input parameters and model calculations were extracted from ESD PT8 *"OECD series on emission scenario documents, number, table 4.39, page 114".*

Input parameters for calculating the local emission				
Cumulative quantity of substance leached out of 1 m2 of treated wood over the initial assessment period (30d)	Q*leach,time1	IPBC	5E-05	kg/m2
		Propiconazole	1.6E-08	
		Cypermethrin and Tebuconazole	8E-07	
Cumulative quantity of substance leached out of 1 m² of treated wood over a longer assessment period (365d)	Q*leach,time2	IPBC	3.9E-13	kg/m2
		Propiconazole	3.2E-22	
		Cypermethrin and Tebuconazole	6.7E-11	

IPBC:

$$Qleach,time1 = Area,house \cdot Q*leach,time1$$

Qleach,time1 = 125 ·5E-05 = 6.37E-03 kg/d

Qleach,time2 = Area,house · Q*leach,time2

Qleach,time2 = 125 · 3.9E-13 = 4.87E-11 kg/d

$$Clocalsoil, leach, time1 = \frac{Qleach, time1}{Vsoil \cdot RHOsoil} =$$

$$Clocalsoil, leach, time1 = \frac{6.37E-03}{13 \cdot 1700} = 2.88E-07\ kg/kgwwt$$

$$Clocalsoil, leach, time2 = \frac{Qleach, time2}{Vsoil \cdot RHOsoil} =$$

$$Clocalsoil, leach, time2 = \frac{4.87E-11}{13 \cdot 1700} = 2.17E-15\ kg/kgwwt$$

Tebuconazole and Cypermthrin:

Qleach,time1 = Area,house · Q*leach,time1

Qleach,time1 = 125 · 8E-07 = 1.025E-04 kg/d

Qleach,time2 = Area,house · Q*leach,time2

Qleach,time2 = 125 · 6.7E-11 = 8.37E-09 kg/d

$$Clocalsoil, leach, time1 = \frac{1.025E-04}{13 \cdot 1700} = 4.63E-09\ kg/kgwwt$$

$$Clocalsoil, leach, time2 = \frac{8.37E-09}{13 \cdot 1700} = 3.78E-13\ kg/kgwwt$$

Propiconazole:

Qleach,time1 = Area,house · Q*leach,time1

Qleach,time1 = 125 · 1.6E-08 = 2E-06 kg/d

Qleach,time2 = Area,house · Q*leach,time2

Qleach,time2 = 125 · 3.2E-22 = 4E-20 kg/d

$$Clocalsoil, leach, time1 = \frac{2E-06}{13 \cdot 1700} = 9.04E-11\ kg/kgwwt$$

$$Clocalsoil, leach, time2 = \frac{4E-20}{13 \cdot 1700} = 1.80E-24\ kg/kgwwt$$

Note: Only values corresponding to the initial assessment period (30d) were used for the calculations of the scenario, as a worst case.

Scenario [3]

Direct emission to surface water in urban areas can be calculated with lixiviation data according to document "*Leaching from paints, plasters, and fillers applied in urban areas Version 5, November 2013, for endorsement at TMIV-2013"* included in document "*Manual of Techical Agreements of the Biocides Techincal Meeting (MOTA) V.6, section 5.2.6 "*

Input information was extracted from the following table (Table 1 attached in document "*Leaching from paints, plasters, and fillers applied in urban areas Version 5, November 2013, for endorsement at TMIV-2013":* Service life and number of houses that contributes to leaching for the situation when both initial and longer assessment period leaching data is available.

Data for the application of "paints applied on window and door frames, and doors was used."

application	**service life (d) ($T_{service\ life}$)**	**area (m²) (AREA)**	**time over which leaching is calculated (days)**		**number of houses from which the actives are leaching (-)**	
			initial ($T_{initial}$)	**longer (T_{longer})**	**initial ($N_{houses,\ initial}$)**	**longer ($N_{houses,\ longer}$)**
Indoor applications						
joint fillers (bathroom)	3650	0.24	30	3620	33	3968
sealants (bathroom)	3650	0.12	30	3620	33	3968
Outdoor applications						
paints applied on façade	1825	125	30	1795	66	1934
paints applied on window and door frames, and doors	1825	5.57[1]	30	1795	66	1934
plasters applied on façades outdoors	9125	125	30	9095	14	1986
joint sealants applied outdoors	1825	0.31[2]	30	1795	66	1934
joint fillers applied outdoors	9125	35	30	9095	14	1986
roof membranes	See 'Use-based approaches for the estimations of environmental exposure in case of roof membranes' discussed during TMII-2013.					

[1] Surface taken from appendix 6 of the revised ESD for wood preservatives (window and door surfaces for a single-floor 125 m² house);

[2] Surface based on window and door frame perimeters calculated from the dimensions for a single floor 125 m² house as specified in appendix 6 of the revised ESD for wood preservatives.

Input parameters for calculating the local emission				
Cumulative quantity of substance leached out of 1 m2 of treated wood over the initial assessment period (30d)	Q*leach,time1	IPBC	5E-08	kg/m2
		Propiconazole	1.6E-11	
		Cypermethrin and Tebuconazole	8E-10	
Cumulative quantity of substance leached out of 1 m² of treated wood over a longer assessment period (365d)	Q*leach,time2	IPBC	3.9E-13	kg/m2
		Propiconazole	3.2E-22	
		Cypermethrin and Tebuconazole	6.7E-11	

$$N_{houses,initial} = \frac{T_{initial}}{T_{servicelife}} \cdot N_{house} \cdot f_{house}$$

$$N_{houses,longer} = \frac{T_{longer}}{T_{servicelife}} \cdot N_{house} \cdot f_{house}$$

$$E_{local} = \frac{(N_{house,initial} \cdot Q_{leach,time1} \cdot AREA)}{T_{initial}} + \frac{(N_{house,longer} \cdot Q_{leach,time2} \cdot AREA)}{T_{longer}}$$

$$Nhouse, intial = \frac{30}{1825} \cdot 66 \cdot 1 = 1.08$$

$$Nhouse, longer = \frac{1795}{1825} \cdot 1934 \cdot 1 = 1902.20$$

IPBC:

$$\text{Elocal} = \frac{1.08 \cdot 5\text{E-}08 \cdot 5.57}{30} + \frac{1902.20 \cdot 3.9\text{E-}13 \cdot 5.57}{1795} = 1\text{E-}05 \text{ kg/d}$$

$$\text{Clocaleff} = \frac{1E-05}{2.0E+06} = 5 \cdot 10^{-12} \text{ kg/l} = 5\text{E-}09 \text{ mg/l}$$

Propiconazole:

$$\text{Elocal} = \frac{1.08 \cdot 1.6\text{E-}11 \cdot 5.57}{30} + \frac{1902.20 \cdot 3.2\text{E-}22 \cdot 5.57}{1795} = 3.20\text{E-}12 \text{ kg/d}$$

$$\text{Clocaleff} = \frac{3.2\text{E-}12}{2.0\text{E+}06} = 1.6 \cdot 10^{-18} \text{ kg/l} = 1.6\text{E-}15 \text{ mg/l}$$

Tebuconazole and Cypermethrin:

$$Elocal = \frac{1.08 \cdot 8E-10 \cdot 5.57}{30} + \frac{1902.20 \cdot 6.78E-11 \cdot 5.57}{1795} = 5.60E-10 \text{ kg/d}$$

$$\text{Clocaleff} = \frac{5.60E-10}{2.0E+06} = 2.82 \cdot 10^{-16} \text{ kg/l} = 2.82\text{E-}13 \text{ mg/l}$$

During "Bridge over pond" scenario assessment, two steps must be considered:

- In-situ treatment: During application the main receiving compartment is considered to be freshwater via product losses due to spills and drips brushing (corresponding to scenario 4).

- Service-life: The primary receiving compartment is considered to be soil via run-off. It is considered that leaching of substances as a result of rainfall occurs only from the outer side of the wood (corresponding to scenario 2).

Scenario [4]

The scenario describes a wooden bridge or walkway on poles with a railing.

Input parameters were extracted from document "*OECD series on emission scenario documents, Number 2, Revised Emission Scenario Document for Wood Preservatives, section 4.2.4.3, page 64, Table 4.13"*

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: Treated wood in service: Bridge over pond			
Qapplic,product	0.240	l·m^2	
Fai	Tebuconazole: 0.00175	-	
	Cypermethrin: 0.0015		
	Propiconazole: 0.00175		
	IPBC: 0.006		
RHO,product	850	kg·m^3	
Fwater,brush	0.03[1]	-	
	0.05[1]		

1 Value corresponding to professional use

2 Value corresponding to professional use

In-situ treatment

$$Ewater,brush = Area,bridge \cdot Qapplic,product \cdot fai \cdot RHOproduct \cdot Fwater.brush \cdot 10^{-3}$$

Tebuconazole and Cypermthrin

$$Ewater,brush,prof.= 10 \cdot 0.240 \cdot 0.00175 \cdot 850 \cdot 0.03 \cdot 10^{-3} = 1.071E\text{-}4 \text{ kg/d}$$

$$Ewater,brush,prof.= 10 \cdot 0.240 \cdot 0.00175 \cdot 850 \cdot 0.05 \cdot 10^{-3} = 1.78E\text{-}4 \text{ kg/d}$$

$$Clocal,water,brush,prof. = \frac{Ewater,brush}{Vwater} = \frac{1.071E-4}{1000} = 1.07E\text{-}07 \text{ mg/l}$$

$$Clocal,water,brush,amat. = \frac{Ewater,brush}{Vwater} = \frac{1.78E-4}{1000} = 1.78E\text{-}7 \text{ mg/l}$$

Propiconazole

$$Ewater,brush,prof.= 10 \cdot 0.240 \cdot 0.0015 \cdot 850 \cdot 0.03 \cdot 10^{-3} = 9.18E\text{-}5 \text{ kg/d}$$

$$Ewater,brush,prof.= 10 \cdot 0.240 \cdot 0.0015 \cdot 850 \cdot 0.05 \cdot 10^{-3} = 1.53E\text{-}4 \text{ kg/d}$$

$$Clocal,water,brush,prof. = \frac{Ewater,brush}{Vwater} = \frac{9.18E-5}{1000} = 9.18E\text{-}8 \text{ mg/l}$$

$$Clocal,water,brush,amat. = \frac{Ewater,brush}{Vwater} = \frac{1.53E-4}{1000} = 1.53E\text{-}7 \text{ mg/l}$$

IPBC

$$Ewater,brush,prof.= 10 \cdot 0.240 \cdot 0.006 \cdot 850 \cdot 0.03 \cdot 10^{-3} = 3.6E\text{-}4 \text{ kg/d}$$

$$Ewater,brush,prof.= 10 \cdot 0.240 \cdot 0.006 \cdot 850 \cdot 0.05 \cdot 10^{-3} = 6.12E\text{-}4 \text{ kg/d}$$

$$Clocal,water,brush,prof. = \frac{Ewater,brush}{Vwater} = \frac{3.6E-4}{1000} = 3.6E\text{-}7 \text{ mg/l}$$

$$Clocal,water,brush,amat. = \frac{Ewater,brush}{Vwater} = \frac{6.12E-4}{1000} = 6.12E\text{-}7 \text{ mg/l}$$

Note: Only values corresponding to amateur users were used, as a worst case.

Scenario [5]

The scenario describes a wooden bridge or walkway on poles with a railing.

Input parameters were extracted from document "*OECD series on emission scenario documents, Number 2, Revised Emission Scenario Document for Wood Preservatives, section 4.2.4.3, page 64, Table 4.18"*

Input parameters for calculating the local emission				
Input	**Value**		**Unit**	**Remarks**
Scenario: Treated wood in service: Bridge over pond				
Duration of the long-term assessment period	365		d	
Cumulative quantity of substance leached out of 1m^2 of treated wood over the initial assessment period	Tebuconazole	8E-07	kg·m^3	
	Cypermethrin	8E-07		
	Propiconazole	1.61E-08		
	IPBC	5E-05		
Cumulative quantity of substance leached out of 1m^2 of treated wood over a longer assessment period	Tebuconazole	6.78E-08	kg·m^3	
	Cypermethrin	6.78E-08		
	Propiconazole	3.2E-19		
	IPBC	3.9E-10		

Tebuconazole and Cypermethrin

$$Qleach,time1 = Areabridge \cdot Q^*leach,time1 =$$

$$Qleach,time1 = 10 \cdot 8E\text{-}07 = 8E\text{-}06 \text{ kg}$$

$$Qleach,time2 = Areabridge \cdot Q^*leach,time2 =$$

$$Qleach,time2 = 10 \cdot 6.78E\text{-}08 = 6.78E\text{-}07 \text{ kg}$$

$$Clocal,water,leach,time1 = \frac{Qleach,time1}{V,water} = \frac{8E-06}{1000} = 8E\text{-}09 \text{ kg/kgwwt}$$

$$Clocal,water,leach,time2 = \frac{Qleach,time2}{V,water} = \frac{6.78E-07}{1000} = 6.78E\text{-}10 \text{ kg/kgwwt}$$

Propiconazole

$$Qleach,time1 = Areabridge \cdot Q^*leach,time1 =$$

Qleach,time1= 10 · 1.61E-08= 1.61E-07 kg

Qleach,time2=Areabridge · Q*leach,time2=

Qleach,time2= 10 · 3.2E-19= 3.2E-18 kg

$$Clocal,water,leach,time1=\frac{Qleach,time1}{V,water}= \frac{1.61E-07}{1000} = 1.61E-10 \text{ kg/kgwwt}$$

$$Clocal,water,leach,time2=\frac{Qleach,time2}{V,water}= \frac{3.2E-18}{1000} =3.2E-21 \text{kg/kgwwt}$$

IPBC

Qleach,time1=Areabridge · Q*leach,time1=

Qleach,time1= 10 · 5E-05= 5E-04 kg

Qleach,time2=Areabridge · Q*leach,time2=

Qleach,time2= 10 · 3.9E-10= 3.9E-09 kg

$$Clocal,water,leach,time1=\frac{Qleach,time1}{V,water}= \frac{5E-04}{1000} =5.7E-07 \text{ kg/kgwwt}$$

$$Clocal,water,leach,time2=\frac{Qleach,time2}{V,water}= \frac{3.9E-09}{1000} =3.9E-12 \text{ kg/kgwwt}$$

Note: Only values corresponding to the initial assessment period (30d) were used for the calculations of the scenario, as a worst case.

Scenario [6]

Local emissions from industrially treated wood during storage prior to shipment are referred to as 'the cumulative quantity (Qleach,storage) of a substance emitted from the stored treated wood over a certain assessment period.

According to OECD (2000c), local emissions and concentrations resulting from industrially treated wood during storage prior to shipment (Qleach,storage) are considered for two time periods: – 30 days for an initial assessment – > 30 days for a longer assessment period.

Input parameters for calculating the local emission			
Input	**Symbol**	**Value**	**Unit**

Scenario: Treated wood during storage				
Duration of a longer assessment period	TIME2	365		d
Average daily flux	$FLUX_{storage, spray}$	IPBC	1.92E-07	$kg \cdot m^{-2} \cdot d^{-1}$
		Propicona.	3.28E-08	
		Cypermeth.	5.7E-10	
		Tebuconaz.	5.7E-10	
Time storage	$Time_{storage}$	14		d
Surface area of the storage place[1]	$Area_{storage}$	790		m^2
Soil depth	DEPTHsoil	0.5		m
Vsoil		395		m3

[1]Large plants were considered for the scenario calculation as a worst-case.

$$Vsoil = Area,storage \cdot DEPTHsoil = 790 \cdot 0.5 = 395 m^3$$

$$FLUXstorage,spray = \frac{Qleach,0-3}{TIMEstorage}$$

$$FLUXstorage,spray = \frac{2.7E-06}{14} = 1.9E-07$$

$$FLUXstorage,spray = \frac{0.46E-06}{14} = 3.28E-08$$

$$FLUXstorage,spray = \frac{0.008E-06}{14} = 5.71E-10$$

IPBC

$$Qleach,storage,time1 = FLUXstorage,spray \cdot Area_{wood\text{-}expo} \cdot Area_{storage} \cdot TIME1$$

$$Qleach,storage,time1 = 1.9E\text{-}07 \cdot 11 \cdot 790 \cdot 30 = 0.04 \text{ kg}$$

$$Qleach,storage,time2 = FLUXstorage,spray \cdot Area_{wood\text{-}expo} \cdot Area_{storage} \cdot TIME2$$

$$Qleach,storage,time2 = 1.9E\text{-}07 \cdot 11 \cdot 790 \cdot 365 = 0.6 kg$$

Emission to soil

$$Clocalsoil,time1 = \frac{Qleach,storage,time1 \cdot (1-Frunoff)}{Vsoil \cdot RHOsoil}$$

$$Clocalsoil,time1 = \frac{0.04 \cdot (1\text{-}0.5)}{395 \cdot 1700} = 2.9E\text{-}08 \ kg \cdot kg_{wwt}$$

$$\text{Clocalsoil,time2} = \frac{Qleach,storage,time2\cdot(1-Frunoff)}{Vsoil\cdot RHOsoil}$$

$$\text{Clocalsoil,time2} = \frac{0.6\cdot(1\text{-}0.5)}{395\cdot 1700} = \text{4.4E-07 kg}\cdot\text{kg}_{wwt}$$

Emission to surface water

$$Elocal,surfacewater,time1 = \frac{Qleach,storage,time1\cdot Frunoff}{TIME1}$$

$$Elocal,surfacewater,time1 = \frac{0.04\cdot 0.5}{30} = 6.6E-04 \text{ kg/d}$$

$$Elocal,surfacewater,time2 = \frac{Qleach,storage,time2\cdot Frunoff}{TIME2}$$

$$\text{Elocal, surfacewater, time2} = \frac{0.6\cdot 0.5}{365} = \text{8.2E-04 kg/d}$$

$$Clocalsurfacewater,time1 = \frac{Elocalsurfacewater,time1}{FLOWsurfacewater}$$

$$Clocalsurfacewater,time1 = \frac{6.6e-04}{0.3} = \text{2.2E-03 mg/l}$$

$$Clocalsurfacewater,time2 = \frac{Elocalsurfacewater,time2}{FLOWsurfacewater}$$

$$Clocalsurfacewater,time2 = \frac{8.2E-04}{0.3} = \text{2.7E-03 mg/l}$$

Propiconazole

$$\text{Qleach,storage,time1} = \text{FLUXstorage,spray} \cdot \text{Area}_{\text{wood-expo}} \cdot \text{Area}_{\text{storage}} \cdot \text{TIME1}$$

$$\text{Qleach,storage,time1} = \text{3.28E-08} \cdot 11 \cdot 790 \cdot 30 = \text{8.55E-03 kg}$$

$$\text{Qleach,storage,time2} = \text{FLUXstorage,spray} \cdot \text{Area}_{\text{wood-expo}} \cdot \text{Area}_{\text{storage}} \cdot \text{TIME2}$$

$$\text{Qleach,storage,time2} = \text{3.28E-08} \cdot 11 \cdot 790 \cdot 365 = \text{0.6kg}$$

Emission to soil

$$\text{Clocalsoil,time1} = \frac{Qleach,storage,time1 \cdot (1-Frunoff)}{Vsoil \cdot RHOsoil}$$

$$\text{Clocalsoil,time1} = \frac{8.5E-03 \cdot (1-0.5)}{395 \cdot 1700} = \text{6.3E-09 kg·kg}_{\text{wwt}}$$

$$\text{Clocalsoil,time2} = \frac{Qleach,storage,time2 \cdot (1-Frunoff)}{Vsoil \cdot RHOsoil}$$

$$\text{Clocalsoil,time2} = \frac{0.6 \cdot (1-0.5)}{395 \cdot 1700} = \text{4.46E-07 kg·kg}_{\text{wwt}}$$

Emission to surface water

$$Elocal, surfacewater, time1 = \frac{Qleach, storage, time1 \cdot Frunoff}{TIME1}$$

$$Elocal, surfacewater, time1 = \frac{8.55\text{E}-03}{30} = 2.85E-04 \text{ kg/d}$$

$$Elocal, surfacewater, time2 = \frac{Qleach, storage, time2 \cdot Frunoff}{TIME2}$$

$$\text{Elocal, surfacewater, time2} = \frac{0.6 \cdot 0.5}{365} = \text{8.21E-04 kg/d}$$

$$Clocalsurfacewater, time1 = \frac{Elocalsurfacewater, time1}{FLOWsurfacewater}$$

$$\text{Clocalsurfacewater, time1} = \frac{2.85\text{E-}04}{0.3} = \text{9.8E-04 mg/l}$$

$$Clocalsurfacewater, time2 = \frac{Elocalsurfacewater, time2}{FLOWsurfacewater}$$

$$Clocalsurfacewater, time2 = \frac{8.21E-04}{0.3} = 2.7E-03 \text{ mg/l}$$

Tebuconazole and Cypermethrin

$$\text{Qleach,storage,time1} = \text{FLUXstorage,spray} \cdot \text{Area}_{\text{wood-expo}} \cdot \text{Area}_{\text{storage}} \cdot \text{TIME1}$$

Qleach,storage,time1 = 5.7E-010 · 11 · 790 · 30 = 1.4E-04 kg
Qleach,storage,time2 = FLUXstorage,spray ·$Area_{wood-expo}$ · $Area_{storage}$ · TIME2

Qleach,storage,time2 = 5.7E-010 · 11 · 790 · 365 = 1.8E-03 kg

Emission to soil

$$Clocalsoil,time1 = \frac{Qleach,storage,time1 \cdot (1-Frunoff)}{Vsoil \cdot RHOsoil}$$

$$Clocalsoil,time1 = \frac{= 1.4E-04 \cdot (1-0.5)}{395 \cdot 1700} = 1.04E\text{-}10 \text{ kg·kg}_{wwt}$$

$$Clocalsoil,time2 = \frac{Qleach,storage,time2 \cdot (1-Frunoff)}{Vsoil \cdot RHOsoil}$$

$$Clocalsoil,time2 = \frac{1.8E-03 \cdot (1-0.5)}{395 \cdot 1700} = 1.34E\text{-}09 \text{ kg·kg}_{wwt}$$

Emission to surface water

$$Elocal, surfacewater, time1 = \frac{Qleach, storage, time1 \cdot Frunoff}{TIME1}$$

$$Elocal, surfacewater, time1 = \frac{1.4E-04 \cdot 0.5}{30} = 2.33E-06 \text{ kg/d}$$

$$Elocal, surfacewater, time2 = \frac{Qleach, storage, time2 \cdot Frunoff}{TIME2}$$

$$Elocal, surfacewater, time2 = \frac{1.8E-03 \cdot 0.5}{365} = 2.6E\text{-}06 \text{ kg/d}$$

$$Clocalsurfacewater, time1 = \frac{Elocalsurfacewater, time1}{FLOWsurfacewater}$$

$$Clocalsurfacewater, time1 = \frac{2.33E-06}{0.3} = 7.76E\text{-}06 \text{ mg/l}$$

$$Clocalsurfacewater, time2 = \frac{Elocalsurfacewater, time2}{FLOWsurfacewater}$$

$$Clocalsurfacewater, time2 = \frac{2.6E-06}{0.3} = 8.66E-06 \text{ mg/l}$$

ES-CA:

Based on the industrial application the followings scenarios can be considered:

Scenario 1: *Industrial processes – short dipping*
Scenario 2: *Industrial processes –double vacuum.*

- Product application
- Storage of treated wood prior to shipping

No risk assessment has been conducted for the industrial application (including storage), based on mandatory risk mitigation measures for wood treatment plants:"Industrial application shall be conducted within a contained area on impermeable hard standing with bunding and freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water, and that any losses of the product shall be collected for reuse or disposal". This will be stated on the label.

Scenario 3: *In-situ treatment for professional and amateur (preventive)-brush.*

Input parameters for calculating the local emission and concentration

Input		Nomenclature	Value	Unit	Remarks
Scenario: Application – House scenario, fence and bridge					
Treated wood area	House	$AREA_{house}$	125	$[m^2 \cdot d^{-1}]$	D
	Fence		2		
	Bridge over pond		10		
Application rate of the product		$Q_{applic.product}$	**See above**		S
Content of a substance in product		f_{ai}	**See above**		S
Density of product		$RHO_{product}$	850	$[kg.m^{-3}]$	S
Fraction of product lost to soil/water during application	Professional	$F_{soil.brush}$ / $F_{water.brush}$	0.03		D
	Amateur		0.05		
(wet) soil volume	House	V_{soil}	13	$[m^3]$	D
	Fence		0.25		
Water volumen under bridge		V_{water}	1000	$[m^3]$	D
Bulk density of wet soil		RHO_{soil}	1700	$[kg_{wwt}.m^{-3}]$	D

- **Calculations**

The local emissions to soil during the day of application are calculated according to the equations 4.37 and 4.39 and the concentration in local soil according to the equations 4.38 and 4.40 from the revised ESD PT8 as following:

$\mathbf{E_{soil.brush\ house}} = AREA_{house} * Q_{applic.product} * f_{ai} * RHO_{product} * F_{soil.brush} * 10^{-3}$
$\mathbf{Clocal_{soil,brush\ house}} = E_{soil,brush\ house} * 10^6 / (V_{soil} * RHO_{soil})$

$\mathbf{E_{soil.brush\ fence}} = AREA_{fence} * Q_{applic.product} * f_{ai} * RHO_{product} * F_{soil.brush} * 10^{-3}$
$\mathbf{Clocal_{soil,brush\ fence}} = E_{soil,brush\ fence} * 10^6 / (V_{soil} * RHO_{soil})$

In the case of bridge over pond the primary receiveing environmental compartment is considered to be a static surface water. So, the emision of substance and the local concentration to water

during the day of application are calculated according to equations 4.41 and 4.42 from the revised ESD PT8 as following:

$\mathbf{E_{water,brush\ bridge}}$ = $AREA_{bridge}$ * $Q_{applic,product}$ * f_{ai} * $RHO_{product}$ * $F_{water,brush}$ * 10^{-3}
$\mathbf{Clocal_{water,brush\ bridge}}$ = $E_{water,brush\ bridge}$ * 1000 / V_{water}

The results are presented in the following table:

Output House scenario		
Active substance	Concentration in local soil at the end of the day of application [mg· kg_{wwt}]-Preventive	
	Professional	Non-professional
Tebuconazole	$3.46 \cdot 10^{-2}$	$5.76 \cdot 10^{-2}$
Propiconazole	$3.46 \cdot 10^{-2}$	$5.76 \cdot 10^{-2}$
IPBC	$1.19 \cdot 10^{-1}$	$1.98 \cdot 10^{-1}$
Cypermethrin	$2.96 \cdot 10^{-2}$	$4.94 \cdot 10^{-2}$
Output Fence scenario		
Tebuconazole	$2.88 \cdot 10^{-2}$	$4.80 \cdot 10^{-2}$
Propiconazole	$2.88 \cdot 10^{-2}$	$4.80 \cdot 10^{-2}$
IPBC	$9.86 \cdot 10^{-2}$	$1.64 \cdot 10^{-1}$
Cypermethrin	$2.47 \cdot 10^{-2}$	$4.11 \cdot 10^{-2}$
Output Bridge over pond scenario		
Active substance	Concentration in local water at the end of the day of application [mg· l^{-1}]-Preventive	
Tebuconazole	$6.11 \cdot 10^{-5}$	$1.02 \cdot 10^{-}$
Propiconazole	$6.11 \cdot 10^{-5}$	$1.02 \cdot 10^{-4}$
IPBC	$2.10 \cdot 10^{-4}$	$3.49 \cdot 10^{-4}$
Cypermethrin	$5.24 \cdot 10^{-5}$	$8.73 \cdot 10^{-5}$

Scenario 4: *In-service leaching from treated wood*

During service life of UC 3 treated wood, emission into the environment can occur due to leaching of active substances out of the wood due to rainfall.
Emissions due to leaching of the active substances out of the wood may occur into the soil, the surface water and into the Sewage Treatment Plant (STP) after run-off.
The calculated concentrations (Clocal) in the receiving environmental compartments represent the concentration at the end of the assessment time period taking into account removal processes of the substance from the receiving compartment for example due to degradation, volatilisation, or leaching to groundwater.

House

The input parameters for calculating the local emission and concentration into the soil following leaching are presented in the following table.

Input parameters for calculating the local emission and concentration					
Input	**Nomenclature**		**Value**	**Unit**	**Remarks**
Scenario: Service life – House scenario					
Treated wood area	$AREA_{house}$		125	[m^2]	D
Duration of the initial assessment period	*TIME1*		30	[d]	D
Duration of the long-term assessment period	*TIME3*	Surface *In situ* treatment	1825	[d]	D
		Surface Industrial treatment	5475		
		Deep Industrial treatment	7300		
Cumulative quantity of substance leached out of 1 m^2 of treated wood over the initial assessment period	$Q^*_{leach,time1}$	IPBC	321	[$mg.m^{-2}$]	S
		Propiconazole	94		
		Cypermethrin	80		
		Tebuconazole	94		
Cumulative quantity of substance leached out of 1 m^2 of treated wood over a longer assessment period	$Q^*_{leach,time3}$	IPBC	642	[$mg.m^{-2}$]	S
		Propiconazole	187		
		Cypermethrin	161		
		Tebuconazole	187		
(wet) soil volume	V_{soil}		13	[m^3]	D
Bulk density of wet soil	RHO_{soil}		1700	[$kg_{wwt}.m^{-3}$]	D
First order rate constant for removal from soil	*k*		**See above**	[d^{-1}]	S

D=default, S=based on information of applicant

$Q^*_{leach,time3}$ in this case is independent of the duration of the long-term assessment period because default values was considered.

- **Calculations**

The local emissions into the soil are calculated according to the equations 3.5 and 3.6 from the revised ESD PT8 as following:

*Esoil,leach,time1 = AREAhouse . Q*leach, time1 / TIME 1*

*Esoil,leach,tim32 = AREAhouse . Q*leach, time3 / TIME 3*

The local concentrations into the soil are calculated according to the equations 3.11 and 3.12 from the revised ESD PT8 as following:

$$\boldsymbol{C}local_{soil,TIME1} = [E_{soil,leach,TIME1}/(V_{soil} \cdot RHO_{soil} \cdot k)] - [E_{soil,leach,TIME1}/(V_{soil} \cdot RHO_{soil} \cdot k)] \cdot (e^{-TIME1 \cdot k})$$

$\mathbf{C}local_{soil,TIME3} = [E_{soil,leach,TIME3}/(V_{soil} \cdot RHO_{soil} \cdot k)] - [E_{soil.leach.TIME3}/(V_{soil} \cdot RHO_{soil} \cdot k)] \cdot (e^{-TIM32 \cdot k})$

Fence

The input parameters for calculating the local emission and concentration into the soil following leaching are presented in the following table.

Input parameters for calculating the local emission and concentration					
Input	**Nomenclature**		**Value**	**Unit**	**Remarks**
Scenario: Service life – Fence					
Leachable wood area	$AREA_{fence}$		2	[m^2]	D
Duration of the initial assessment period	*TIME1*		30	[d]	D
Duration of the long-term assessment period	*TIME3*	Surface *In situ* treatment	1825	[d]	D
		Surface Industrial treatment	5475		
		Deep Industrial treatment	7300		
Cumulative quantity of substance leached out of 1 m^2 of treated wood over the initial assessment period	$Q^*_{leach,time1}$	IPBC	321	[$mg.m^{-2}$]	S
		Propiconazole	94		
		Cypermethrin	80		
		Tebuconazole	94		
Cumulative quantity of substance leached out of 1 m² of treated wood over a longer assessment period	$Q^*_{leach,time3}$	IPBC	642	[$mg.m^{-2}$]	S
		Propiconazole	187		
		Cypermethrin	161		
		Tebuconazole	187		
(wet) soil volume	V_{soil}		0.25	[m^3]	D
Bulk density of wet soil	RHO_{soil}		1700	[$kg_{wwt}.m^{-3}$]	D
First order rate constant for removal from soil	*k*		**See above**	[d^{-1}]	S

D=default, S=based on information of applicant

$Q^*_{leach,time3}$ in this case is independent of the duration of the long-term assessment period because default values was considered.

- **Calculations**

The local emissions into the soil are calculated according to the equations 3.5 and 3.6 from the revised ESD PT8 as following:

*Esoil,leach,time1 = AREAfence . Q*leach, time1 / TIME 1*

*Esoil,leach,time3 = AREAfence . Q*leach, time3 / TIME 3*

The local concentrations into the soil are calculated according to the equations 3.11 and 3.12 from the revised ESD PT8 as following:

$C_{localsoil,TIME1} = [E_{soil,leach,TIME1}/(Vs_{oil} * RHO_{soil} * k)] - [E_{soil,leach,TIME1}/(V_{soil} * RHO_{soil} * k) - C_{localsoil.brush\ fence}] * e^{-TIME1*k}$

$C_{localsoil,TIME3} = [E_{soil,leach,TIME3}/(V_{soil} * RHO_{soil} * k)] - [E_{soil,leach,TIME3}/(V_{soil} * RHO_{soil} * k) - C_{localsoil.brush\ fence}] * e^{-TIME3*k}$

Bridge over pond scenario

The input parameters for calculating the local emission and concentration into the surface water following leaching are presented in the following table.

Input parameters for calculating the local emission					
Input	**Nomenclature**		**Value**	**Unit**	**Remarks**
Scenario: Service life – Bridge over pond scenario					
Treated wood area	$AREA_{bridge}$		10	[m^2]	D
Duration of the initial assessment period	*TIME1*		30	[d]	D
Duration of the long-term assessment period	*TIME3*	Surface *In situ* treatment	1825	[d]	D
		Surface Industrial treatment	5475		
		Deep Industrial treatment	7300		
Cumulative quantity of substance leached out of 1 m^2 of treated wood over the initial assessment period	$Q^*_{leach,time1}$	IPBC	321	[$mg.m^{-2}$]	S
		Propiconazole	94		
		Cypermethrin	80		
		Tebuconazole	94		
Cumulative quantity of substance leached out of 1 m² of treated wood over a longer assessment period	$Q^*_{leach,time3}$	IPBC	642	[$mg.m^{-2}$]	S
		Propiconazole	187		
		Cypermethrin	161		
		Tebuconazole	187		
Water volume under bridge	V_{water}		1000	[m^3]	D

D=default, S=based on information of applicant

$Q^*_{leach,time3}$ in this case is independent of the duration of the long-term assessment period because default values was considered.

- **Calculations**

The local emissions into the water (the cumulative quantity of substance leached over 30 days and 15 years, $Q_{leach,time}$) are calculated according to the equations 4.61 and 4.62 from the revised ESD PT8 as following:

$$Qleach,time1 = AREAbridge \cdot Q^*leach,\ time1$$
$$Qleach,time3 = AREAbridge \cdot Q^*leach,\ time3$$

The local concentrations into the water are calculated according to the equations 4.63/4.64/4.65/4.66 from the revised ESD PT8 as following:

$$\boldsymbol{C}local_{water,leach,TIME1} = Qleach,time1 \cdot 0.001 / V_{water}$$

$$\boldsymbol{C}local_{water,leach,TIME3} = Qleach,time3 \;.\; 0.001 \;/\; V_{water}$$
$$\boldsymbol{C}local_{water.total.TIME1} = \boldsymbol{C}local_{water.leach.TIME1}$$
$$\boldsymbol{C}local_{water,total,TIME3} = \boldsymbol{C}local_{water,leach,TIME3}$$

Noise barrier scenario

The noise barrier scenario describes a noise barrier that is made of poles with planks in between. The medium size of a noise barrier in an urbanized area is assumed to be 1000 m long and 3 m high. It is assumed that 30% of the emissions of active substances due to leaching end up directly in the adjacent soil and 70% of the emissions are collected in the gutter and sewer, and finally enter a STP.

The input parameters for calculating the local emission and concentration into the soil and the STP following leaching are presented in the following table.

Input parameters for calculating the local emission and concentration

Input	Nomenclature		Value	Unit	Remarks
Scenario: Service life – Noise barrier scenario					
Treated wood area	$AREA_{noise\text{-}barrier}$		3000	[m^2]	D
Duration of the initial assessment period	*TIME1*		30	[d]	D
Duration of the long-term assessment period	*TIME3*	Surface *In situ* treatment	1825	[d]	D
		Surface Industrial treatment	5475		
		Deep Industrial treatment	7300		
Cumulative quantity of substance leached out of 1 m^2 of treated wood over the initial assessment period	$Q^*_{leach,time1}$	IPBC	321	[$mg.m^{-2}$]	S
		Propiconazole	94		
		Cypermethrin	80		
		Tebuconazole	94		
Cumulative quantity of substance leached out of 1 m^2 of treated wood over a longer assessment period	$Q^*_{leach,time3}$	IPBC	642	[$mg.m^{-2}$]	S
		Propiconazole	187		
		Cypermethrin	161		
		Tebuconazole	187		
(wet) soil volume	V_{soil}		250	[m^3]	D
Bulk density of wet soil	RHO_{soil}		1700	[$kg_{wwt}.m^{-3}$]	D
Fraction released to soil	F_{soil}		0.3	[-]	D
Fraction released to the STP	F_{STP}		0.7	[-]	D
First order rate constant for removal from soil	k		**See above**	[d^{-1}]	S

D=default, S=based on information of applicant

$Q^*_{leach,time3}$ in this case is independent of the duration of the long-term assessment period because default values was considered.

The local daily emissions into the STP are calculated according to the equations 3.5 and 3.6 from the revised ESD PT08 as following:

*ESTP,time 1 = AREAnoise-barrier x FSTP x Q*leach, time1 / Time 1*
*ESTP,time 3 = AREAnoise-barrier x FSTP x Q*leach, time3 / Time 3*

The local emissions into the soil are calculated according to the equations 3.5 and 3.6 from the revised ESD PT08 as following:

*Esoil,leach,time 1 = AREAnoise-barrier x FSTP x Q*leach, time1 / Time 1*
*Esoil,leach,time 3 = AREAnoise-barrier x FSTP x Q*leach, time3 / Time 3*

The local concentrations into the soil are calculated according to the equations 3.11 and 3.12 from the revised ESD PT8 as following:

$$\boldsymbol{C}local_{soil.TIME1} = [E_{soil.leach.TIME1}/(V_{soil} \cdot RHO_{soil} \cdot k)] - [E_{soil,leach,TIME1}/(V_{soil} \cdot RHO_{soil} \cdot k)] \cdot (e^{-TIME1 \cdot k})$$

$$\boldsymbol{C}local_{soil,TIME3} = [E_{soil,leach,TIM32}/(V_{soil} \cdot RHO_{soil} \cdot k)] - [E_{soil.leach.TIME3}/(V_{soil} \cdot RHO_{soil} \cdot k)] \cdot \cdot (e^{-TIME3 \cdot k})$$

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
Scenario 1	No	No	No	No	No	No	Yes	No	No
Scenario 2	No	No	No	No	No	No	Yes	No	No
Scenario 3	Yes	No	No	No	No	No	No	No	No
Scenario 4	Yes	No	No	No	No	No	No	No	No
Scenario 5	No	No	No	No	No	No	Yes	No	No
Scenario 6	Yes	No	No	No	No	No	Yes	No	No

ES-CA:

The relevant environmental compartments for each substance and identified metabolites are specified in the table below

Phase	**STP**	**Surface water**		**Sediment**		**Soil**		**Groundwater**		**Secondary Poisoning**
		Direct Release	**Via STP**	**Direct Release**	**Via STP**	**Direct Release**	**Via STP**	**Direct Release**	**Via STP**	
Propiconazole	Y	Y	Y	Y	Y	Y	Y	Y	Y	N
Tebuconazole	Y	Y	Y	Y	Y	Y	Y	Y	Y	N

Cypermethrin	Y	Y	Y	Y	Y	Y	Y	N	N	Y
IPBC	Y	Y	N	N	N	Y	N	Y	N	N
PBC	Y	Y	Y	Y	Y	Y	Y	Y	Y	N
1,2,4-triazole	N	N	N	N	N	Y	N	Y	Y	N

In the table below the relevant parameters from the active substance dossiers of all active substances are presented. For a general assessment of the environmental fate and behaviour of all four active substances refer to the active substances CAR.

Input parameters (only set values) for calculating the fate and distribution in the environment for the active substances

Input	Unit	Tebuconazole	Propiconazole	IPBC	Cypermethrin
Molecular weight	g/mol	307.8	342.2	281.1	416.3
Vapour pressure (at 20 °C)	Pa	1.7E-06	5.6E-05	2.36E-03	2.3E-07
Water solubility (at 20 °C)	mg/l	2.9E+01	1.00E+02	1.68E+2	4E-03
Log Octanol/water partition coefficient	Log 10	3.49	3.72	2.81	5.45
Organic carbon/water partition coefficient (Koc)	l/kg	992	944	135	575000
Henry's Law Constant (at 20 °C)	$Pa/m^3/mol$	1.00E-05	9.2E-05	6.45E-03	2.4E-02
Biodegradability		Not biodegradable	Not biodegradable	Not biodegradable	Not biodegradable

Input	Unit	1.2.4-Triazole	PBC
Molecular weight	g/mol	69.1	155.2
Vapour pressure (at 20 °C)	Pa	2.2E-01	1.88E+01
Water solubility (at 20 °C)	mg/l	7.0E+05	2.86E+05

	Organic carbon/water partition coefficient (Koc)	l/kg	89	198.1	
	Fraction transformed (soil)	-	0.09 (Tebuconazole) 0.43 (Propiconazole)	1 (IPBC)	

Calculated PEC values

$PEC_{local,soil} = C_{local,soil} + PEC_{regional,nat.\ soil}$

$PEC_{regional,nat.\ soil}$ is assumed to be negligible in front of the $C_{local,soil}$.

Summary table on calculated PEC values				
	PEC_{water}		PEC_{soil}	
	[mg/l]		[kg/kgwwt]	
Scenario 1: House: Insitu treatment	-		IPBC	3.43E-06
			Tebucona.	9.95E-07
			Propicona.	$8.5E-07$
			Cyperme.	9.95E-07
Scenario 2: House: Service life	-		IPBC	$2.88E-07$
			Tebucona.	$4.63E-09$
			Propicona.	$9.04E-11$
			Cyperme.	$4.63E-09$
Scenario 3: Urban areas	IPBC	5E-09	-	
	Tebucona.	2.82E-13		
	Propicona.	1.6E-12		
	Cyperme.	2.82E13		
Scenario 4: Bridge over pond: In-situ treatment	IPBC	6.12E-07	-	
	Tebuc. and Cyper.	1.78E-07		
	Propicona.	1.53E-07		
Scenario 5: Bridge over pond: Service life	-		IPBC	5.7E-07
			Tebucona.	8E-09
			Propicona.	1.61E-10
			Cyperme.	8E-09
Scenario 6: Treated wood during storage	IPBC	4.4E-07	IPBC	2.7E-03
	Tebucona.	8.6E-06	Tebucona.	1.34E-09
	Propicona.	2.7E-03	Propicona.	4.46E-07
	Cyperme.	8.6E-06	Cyperme.	1.34E-09

ES-CA:

In the present risk assessment, only the risk derived from the wood classified as Use Class (UC) 3 has been considered as the risks derived from wood UC 1 and 2 are considered insignificant.

Aquatic PEC values are summarised in the following tables:

Propiconazole			**$PEC_{Surface\ water}$ (mg/l)**	**PEC_{STP} (mg/l)**	**$PEC_{Sediment}$ (mg/kg_{wwt})**	**PEC_{soil} (mg/kg_{wwt})**	**$PEC_{groundwater}$ (mg/l)**
Preventive							
Aplication-Brushing	House	Professional				3.46E-02	2.06E-03
		Non-professional				5.76E-02	3.44E-03
	Fence	Professional				2.88E-02	1.71E-03
		Non-professional				4.80E-02	2.86E-03
	Bridge	Professional	6.11E-05		1.30E-03		
		Non-professional	1.02E-04		2.17E-03		
Service life-Surface Treatment Industrial	House (Time 1)					4.69E-01	2.33E-02
	House (Time 3)					2.26E-02	1.35E-03
	Fence (Time 1)					3.90E-01	2.33E-02
	Fence (Time 3)					1.88E-02	1.12E-03
	Noise Barrier (Time 1)		2.96E-04	2.96E-03	6.30E-03	1.13E-03	3.92E-05
	Noise Barrier (Time 3)		3.22E-06	3.23E-05	6.86E-05	1.23E-05	4.27E-07
	Bridge over pond (Time 1)		2.85E-04		6.07E-03		
	Bridge over pond (Time 3)		5.89E-06		1.26E-04		
Service life-Surface Treatment In situ	House (Time 1)					4.69E-01	2.33E-02
	House (Time 3)					6.79E-02	4.05E-03
	Fence (Time 1)					3.90E-01	2.33E-02
	Fence (Time 3)					5.65E-02	3.37E-03
	Noise Barrier (Time 1)		2.96E-04	2.96E-03	6.30E-03	1.13E-03	3.92E-05
	Noise Barrier (Time 3)		9.66E-06	9.68E-05	2.06E-04	3.69E-05	1.28E-06
	Bridge over pond (Time 1)		2.85E-04		6.07E-03		
	Bridge over pond (Time 3)		1.76E-05		3.74E-04		
Service life-Deep Industrial	House (Time 1)					4.69E-01	2.33E-02
	House (Time 3)					1.70E-02	1.01E-03
	Fence (Time 1)					3.90E-01	2.33E-02
	Fence (Time 3)					1.41E-02	8.41E-04
	Noise Barrier (Time 1)		2.96E-04	2.96E-03	6.30E-03	1.13E-03	3.92E-05
	Noise Barrier (Time 3)		2.42E-06	2.42E-05	5.15E-05	9.26E-06	3.20E-07
	Bridge over pond (Time 1)		2.85E-04		6.07E-03		

	Bridge over pond (Time 3)	4.42E-06		9.43E-05		

Tebuconazole			**$PEC_{Surface\ water}$ (mg/l)**	**PEC_{STP} (mg/l)**	**$PEC_{Sediment}$ (mg/kg_{wwt})**	**PEC_{soil} (mg/kg_{wwt})**	**$PEC_{groundwater}$ (mg/l)**
Preventive							
Aplication-Brushing	House	Professional				3.46E-02	1.96E-03
		Non-professional				5.76E-02	3.27E-03
	Fence	Professional				2.88E-02	1.63E-03
		Non-professional				4.80E-02	2.72E-03
	Bridge	Professional	6.11E-05		1.37E-03		
		Non-professional	1.02E-04		2.28E-03		
Service life-Surface Treatment Industrial	House (Time 1)					4.66E-01	2.64E-02
	House (Time 3)					2.15E-02	1.22E-03
	Fence (Time 1)					3.88E-01	2.20E-02
	Fence (Time 3)					1.79E-02	1.01E-03
	Noise Barrier (Time 1)		2.92E-04	2.93E-03	6.53E-03	1.21E-03	3.89E-05
	Noise Barrier (Time 3)		3.19E-06	3.19E-05	7.12E-05	1.32E-05	4.22E-07
	Bridge over pond (Time 1)		4.03E-04		9.00E-03		
	Bridge over pond (Time 3)		2.10E-05		4.69E-04		
Service life-Surface Treatment In situ	House (Time 1)					4.66E-01	2.64E-02
	House (Time 3)					6.44E-02	3.65E-03
	Fence (Time 1)					3.88E-01	2.20E-02
	Fence (Time 3)					5.36E-02	3.04E-03
	Noise Barrier (Time 1)		2.92E-04	2.93E-03	6.53E-03	1.21E-03	3.89E-05
	Noise Barrier (Time 3)		9.55E-06	9.57E-05	2.13E-04	3.96E-05	1.27E-06
	Bridge over pond (Time 1)		4.03E-04		9.00E-03		
	Bridge over pond (Time 3)		6.15E-05		1.37E-03		
Service life-Deep Industrial	House (Time 1)					4.66E-01	2.64E-02
	House (Time 3)					1.61E-02	9.13E-04
	Fence (Time 1)					3.88E-01	2.20E-02
	Fence (Time 3)					1.34E-02	7.60E-04
	Noise Barrier (Time 1)		2.92E-04	2.93E-03	6.53E-03	1.21E-03	3.89E-05
	Noise Barrier (Time 3)		2.39E-06	2.39E-05	5.34E-05	9.93E-06	3.18E-07
	Bridge over pond		4.03E-04		9.00E-03		

	(Time 1)					
	Bridge over pond (Time 3)	1.58E-05		3.53E-04		

Cypermethrin			**$PEC_{Surface\ water}$ (mg/l)**	**PEC_{STP} (mg/l)**	**$PEC_{Sediment}$ (mg/kg_{wwt})**	**PEC_{soil} (mg/kg_{wwt})**	**$PEC_{groundwater}$ (mg/l)**
Preventive							
Aplication-Brushing	House	Professional				2.96E-02	2.92E-06
		Non-professional				4.94E-02	4.87E-06
	Fence	Professional				2.47E-02	2.43E-06
		Non-professional				4.11E-02	4.05E-06
	Bridge	Professional	5.24E-05		1.97E+01		
		Non-professional	8.73E-05		3.28E+01		
Service life-Surface Treatment Industrial	House (Time 1)					2.63E-01	2.59E-05
	House (Time 3)					4.13E-03	4.07E-05
	Fence (Time 1)					2.18E-01	2.15E-05
	Fence (Time 3)					3.43E-03	3.38E-07
	Noise Barrier (Time 1)		7.14E-06	2.56E-04	2.68E+00	3.69E-03	8.63E-08
	Noise Barrier (Time 3)		7.88E-08	2.83E-06	2.96E-02	4.07E-05	9.53E-10
	Bridge over pond (Time 1)		3.48E-05		1.31E+00		
	Bridge over pond (Time 3)		4.02E-07		1.51E-02		
Service life-Surface Treatment In situ	House (Time 1)					2.63E-01	2.59E-05
	House (Time 3)					1.24E-02	1.22E-06
	Fence (Time 1)					2.18E-01	2.15E-05
	Fence (Time 3)					1.03E-02	1.02E-06
	Noise Barrier (Time 1)		7.14E-06	2.56E-04	2.68E+00	3.69E-03	8.63E-08
	Noise Barrier (Time 3)		2.36E-7	8.46E-6	8.85E-03	1.22E-04	2.85E-09
	Bridge over pond (Time 1)		3.48E-05		1.31E+00		
	Bridge over pond (Time 3)		1.21E-06		4.52E-02		
Service life-Deep Industrial	House (Time 1)					2.63E-01	2.59E-05
	House (Time 3)					3.10E-03	3.05E-07
	Fence (Time 1)					2.18E-01	2.15E-05
	Fence (Time 3)					2.58E-03	2.54E-07
	Noise Barrier (Time 1)		7.14E-06	2.56E-04	2.68E+00	3.69E-03	8.63E-08
	Noise Barrier (Time 3)		5.90E-08	2.12E-06	2.21E-03	3.05E-05	7.14E-10

	Bridge over pond (Time 1)	3.48E-05		1.31E+00		
	Bridge over pond (Time 3)	3.02E-07		1.13E-02		

IPBC			**$PEC_{Surface\ water}$ (mg/l)**	**PEC_{STP} (mg/l)**	**$PEC_{Sediment}$ (mg/kg_{wwt})**	**PEC_{soil} (mg/kg_{wwt})**	**$PEC_{groundwater}$ (mg/l)**
Preventive							
Aplication-Brushing	House	Professional				1.19E-01	4.76E-02
		Non-professional				1.98E-01	7.93E-02
	Fence	Professional				9.86E-02	3.96E-02
		Non-professional				1.64E-01	6.60E-02
	Bridge	Professional	2.10E-04		7.77E-04		
		Non-professional	3.49E-04		1.29E-03		
Service life-Surface Treatment Industrial	House (Time 1)					1.71E-02	6.85E-03
	House (Time 3)					1.87E-04	7.51E-05
	Fence (Time 1)					1.42E-02	5.70E-03
	Fence (Time 3)					1.56E-04	6.25E-05
	Noise Barrier (Time 1)		1.08E-03	1.08E-02	4.01E-03	1.43E-05	9.60E-07
	Noise Barrier (Time 3)		1.18E-05	1.18E-04	4.39E-05	1.57E-07	1.05E-08
	Bridge over pond (Time 1)		1.98E-05		7.34E-05		
	Bridge over pond (Time 3)		2.18E-07		8.09E-07		
Service life-Surface Treatment In situ	House (Time 1)					1.71E-02	6.85E-03
	House (Time 3)					5.62E-04	2.25E-04
	Fence (Time 1)					1.42E-02	5.70E-03
	Fence (Time 3)					4.68E-04	1.87E-04
	Noise Barrier (Time 1)		1.08E-03	1.08E-02	4.01E-03	1.43E-05	9.60E-07
	Noise Barrier (Time 3)		3.56E-05	3.56E-04	1.32E-04	4.72E-07	3.16E-08
	Bridge over pond (Time 1)		1.98E-05		7.34E-05		
	Bridge over pond (Time 3)		6.55E-07		2.43E-06		
Service life-Deep Industrial	House (Time 1)					1.71E-02	6.85E-03
	House (Time 3)					1.41E-04	5.63E-05
	Fence (Time 1)					1.42E-02	5.70E-03
	Fence (Time 3)					1.17E-04	4.69E-05
	Noise Barrier (Time 1)		1.08E-03	1.08E-02	4.01E-03	1.43E-05	9.60E-07
	Noise Barrier		8.91E-06	8.91E-05	3.30E-05	1.18E-07	7.90E-09

	(Time 3)					
	Bridge over pond (Time 1)	1.98E-05		7.34E-05		
	Bridge over pond (Time 3)	1.64E-07		6.07E-07		

Note: Noise Barrier scenario - Indirect emissions via the STP

Relevant degradation products and their assessment for the soil compartment

Degradation of **IPBC** yields the primary degradate propargyl butyl carbamate (PBC) as well as iodine.Emissions of PBC (degradation product of IPBC) are calculated assuming 100% formation fraction of IPBC to PBC at time 0, using the ratio between the molar mass of PBC and IPBC of 0.552 in soil and water.
Moreover IPBC is quickly degraded in the environment in iodine, released as iodine radical, which is not stable in soil and can be considered as a "transient metabolites". The final reaction end-products would be iodide and iodate. According to the conclusions of the AR for IPBC PT06 (27/09/2013), a quantitative assessment should not be a requirements for the final reaction end-products of IPBC. Moreover this present evaluation is covered by the qualitative assessment proposed in the AR for IPBC PT06.
In addition, the background concentrations of iodine in the environment (and particularly in the soil compartment: see table below) are much higher than what could be calculated after degradation of the IPBC of the product XYLAZEL TOTAL.

Background concentration of iodine in the environment	
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

The assessment of 1,2,4-triazole was proposed only for emission to soil. The emission calculation for the metabolite takes into account the maximal level of formation fraction of the substances in soil (9% and 43% for **tebuconazole** and **propiconazole** respectively, as defined for the approval of these substances) and the molar mass of each component. An assessment 1,2,4-triazole is also proposed for soil compartment.

PBC			**$PEC_{Surface\ water}$ (mg/l)**	**PEC_{STP} (mg/l)**	**$PEC_{Sediment}$ (mg/kg_{wwt})**	**PEC_{soil} (mg/kg_{wwt})**	**$PEC_{groundwater}$ (mg/l)**
Preventive							
Aplication-Brushing	House	Professional				6.57E-02	1.82E-02
		Non-professional				1.09E-01	3.03E-02
	Fence	Professional				5.44E-02	1.51E-02
		Non-professional				9.05E-02	2.51E-02
	Bridge	Professional	1.16E-04		4.29E-04		
		Non-professional	1.93E-04		7.12E-04		
Service life-	House (Time 1)					9.44E-03	2.61E-03

Surface Treatment Industrial	House (Time 3)				1.03E-04	2.86E-05
	Fence (Time 1)				7.84E-03	2.17E-03
	Fence (Time 3)				8.61E-05	2.38E-05
	Noise Barrier (Time 1)	6.00E-04	6.01E-03	3.06E-03	2.25E-04	1.17E-05
	Noise Barrier (Time 3)	6.56E-06	6.57E-05	3.34E-05	2.46E-06	1.28E-07
	Bridge over pond (Time 1)	1.09E-05		4.05E-05		
	Bridge over pond (Time 3)	1.20E-07		4.47E-07		
Service life-Surface Treatment In situ	House (Time 1)				9.44E-03	2.61E-03
	House (Time 3)				3.10E-04	8.59E-05
	Fence (Time 1)				7.84E-03	2.17E-03
	Fence (Time 3)				2.58E-04	7.15E-05
	Noise Barrier (Time 1)	6.00E-04	6.01E-03	3.06E-03	2.25E-04	1.17E-05
	Noise Barrier (Time 3)	1.97E-05	1.97E-04	1.00E-04	7.39E-06	8.83E-07
	Bridge over pond (Time 1)	1.09E-05		4.05E-05		
	Bridge over pond (Time 3)	3.62E-07		1.34E-06		
Service life-Deep Industrial	House (Time 1)				9.44E-03	2.61E-03
	House (Time 3)				7.78E-05	2.15E-05
	Fence (Time 1)				7.84E-03	2.17E-03
	Fence (Time 3)				6.46E-05	1.79E-05
	Noise Barrier (Time 1)	6.00E-04	6.01E-03	3.06E-03	2.25E-04	1.17E-05
	Noise Barrier (Time 3)	4.94E-06	4.94E-05	2.51E-05	1.85E-06	9.60E-08
	Bridge over pond (Time 1)	1.09E-05		4.05E-05		
	Bridge over pond (Time 3)	9.05E-08		3.35E-07		

1,2,4-Triazole			**$PEC_{Surface\ water}$ (mg/l)**	**PEC_{STP} (mg/l)**	**$PEC_{Sediment}$ (mg/kg_{wwt})**	**PEC_{soil} (mg/kg_{wwt})**	**$PEC_{groundwater}$ (mg/l)**
Preventive							
Aplication-Brushing	House	Professional				3.81E-03	1.02E-04
		Non-professional				6.34E-03	1.71E-04
	Fence	Professional				3.17E-03	8.53E-05
		Non-professional				5.28E-03	1.42E-04
	Bridge	Professional					
		Non-professional					

Service life-Surface Treatment Industrial	House (Time 1)				5.15E-02	1.39E-03
	House (Time 3)				2.46E-03	6.64E-05
	Fence (Time 1)				4.29E-02	1.15E-03
	Fence (Time 3)				2.05E-03	5.52E-05
	Noise Barrier (Time 1)				1.26E-04	3.39E-06
	Noise Barrier (Time 3)				1.37E-06	3.69E-08
	Bridge over pond (Time 1)					
	Bridge over pond (Time 3)					
Service life-Surface Treatment In situ	House (Time 1)				5.15E-02	1.39E-03
	House (Time 3)				7.40E-03	1.99E-04
	Fence (Time 1)				4.29E-02	1.15E-03
	Fence (Time 3)				6.16E-03	1.66E-04
	Noise Barrier (Time 1)				1.26E-04	3.39E-06
	Noise Barrier (Time 3)				4.11E-06	1.11E-07
	Bridge over pond (Time 1)					
	Bridge over pond (Time 3)					
Service life-Deep Industrial	House (Time 1)				5.15E-02	1.39E-03
	House (Time 3)				1.85E-03	4.99E-05
	Fence (Time 1)				4.29E-02	1.15E-03
	Fence (Time 3)				1.54E-03	4.14E-05
	Noise Barrier (Time 1)				1.26E-04	3.39E-06
	Noise Barrier (Time 3)				1.03E-06	2.78E-08
	Bridge over pond (Time 1)					
	Bridge over pond (Time 3)					

Primary and secondary poisoning

Primary poisoning

A direct uptake of the product is unlikely.

Secondary poisoning

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

A secondary exposure of man to **IPBC** relevant to the food chain can be excluded due to the minimum amount which reaches the soil. In addition, the log K_{ow} is less than 3 and the soil area of concern is very small.

Although the log Kow of **Propiconazole** (log K_{ow} = 3.7) reveals a slight potential for bioaccumulation, the assessment of secondary poisoning is not requested according to the active substance Assessment Report for the use of propiconazole in wood preservatives.

According to the BCF in earthworm equal to 28 and the BCF in fish equal to 78, **Tebuconazole** is not expected to bioaccumulate to terrestrial and aquatic organisms. Therefore, an assessment of secondary poisoning doesn't need to be performed.

ES-CA considers that secondary poisoning is relevant only for the active substance cypermethrin.
For the aquatic food chain**,** the scenario "direct emissions during service life - Bridge over the pond scenario" is taken into account as worst case with a $Clocal_{water,TWA\ TIME1}$ of 3.48E-05 $mg.L^{-1}$.
For the terrestrial food chain, the scenario "Direct emissions to soil – House - Service life of treated wood" is taken into account with a $Clocal_{soil.TWA\ TIME1}$ of 2.63E-01 $mg.kg^{-1}_{wwt}$.
In accordance with the equations of the ECHA guidance vol.IV, part B (2015), $PEC_{oral,predator}$ for both food chain were calculated as followed:

Parameter / variable	**Symbol**	**Unit**	**Value**
Aquatic food chain:			
Predicted environmental concentration during episode	$PEC_{local,water}$	$[mg.l^{-1}]$	3.48E-05
Bioconcentration factor for fish on wet weight basis	BCF_{fish}	$[l.kg^{-1}_{wet\ fish}]$	417
Biomagnification factor in fish	BMF	[-]	2
Predicted environmental concentration in food (considering that predators feed at 50% on local level)	**$PEC_{oral,predator}$**	**$[mg.kg^{-1}_{wet\ fish}]$**	**2.90E-02**
Terrestrial food chain :			
log of partition coefficient n-octanol-water	Log K_{ow}	[-]	5.45
Bioconcentration factor for earthworm on wet weight basis	$BCF_{earthworm}$	$[l.kg^{-1}_{wet\ earthworm}]$	3.38E+03
Concentration in porewater	$C_{porewater}$	$[mg.l^{-1}]$	2.15E-05
Concentration in soil	C_{soil}	$[mg.kg^{-1}_{wwt}]$	2.63E-01
Fraction of gut loading in worm	F_{gut}	$[kg_{dwt}.kg^{-1}_{wwt}]$	0.1
Conversion factor for soil concentration wet-dry weight soil	$CONV_{soil}$	$[kg_{wwt}.kg^{-1}_{dwt}]$	1.13
Predicted environmental concentration in food (considering that predators feed at 50% on local level)	**$PEC_{oral,predator}$**	**$[mg.kg^{-1}_{wet\ earthworm}]$**	**2.67E-02**

2.2.8.3. Risk characterisation

Atmosphere

Conclusion: According to air distribution assessment and considering low vapour pressure values of the product's active substances, emission to air is considered negligible.

Sewage treatment plant (STP)

Conclusion: Since emission to STP though sewage water is forbidden in industrial areas and product's labels strongly discourages professional and amateur elimitation of the product through sewage water, emission to STP is considered negligible.

Aquatic compartment

Calculated PEC/PNEC values		
	PEC/PNEC$_{freshwater}$	
Scenario 1	IPBC	1E-05
	Tebuconazole	9.4E-11
	Propiconazole	1E-09
	Cypermethrine	2.82E-07
Scenario 2	IPBC	1.224E-04
	Tebuconazole	5.9E-06
	Propiconazole	1E-09
	Cypermethrine	0.17
Scenario 5	IPBC	8.8E-04
	Tebuconazole	2.8E-04
	Propiconazole	1.6E-02
	Cypermethrine	8.6E-02

Conclusion: After developing proposed model, product emissions (PEC) to the compartment will not overtake PNEC values. RQProduct <1

After assessing emission to surface water compartment for all active substances included in the product, it was concluded that combine emission of all substances will be acceptable.

Terrestrial compartment

Calculated PEC/PNEC values		
	PEC/PNEC$_{soil}$	
Scenario 1	IPBC	6.92E-04
	Tebuconazole	9.95E-07
	Propiconazole	$8.5E-07$
	Cypermethrine	9.95E-07
Scenario 2	IPBC	5.7E-05
	Tebuconazole	2.47E-12
	Propiconazole	8E-11
	Cypermethrine	2.47E-12
Scenario 5	IPBC	1.14E-04
	Tebuconazole	7.01E-08
	Propiconazole	8E-09
	Cypermethrine	7.01E-08
Scenario 6	IPBC	0.54

	Tebuconazole	1.34E-08
	Propiconazole	2.23E-05
	Cypermethrine	1.34E-08

Conclusion: After assessing emission to soil compartment for all active substances included in the product, considering developed leaching assays and distribution in soil for all substances, it was concluded that combine emission of all substances will be acceptable.

Groundwater

Conclusion: The product is no expected to leach to groundwater.

After assessment of distribution in soil for all active substances, considering DT50 and Koc values, it was concluded that the product is expected to be highly retained to soil compartment. Because of this low mobility, no emission to groundwater is expected.

Overall conclusion on the risk assessment for the environment of the product
After assessing emission to all compartments, it was concluded that emisions will not overtake environmental limit values (PNEC). Therefore, it was concluded risk for the environment was acceptable.

ES-CA:

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

If the PEC/PNEC ratio is below 1, this is interpreted as an acceptable risk to the environment.

Calculated PEC/PNEC values are summarized below, values above 1 are marked with red color.

Propiconazole			**PEC/PNEC** Surface water	**PEC/PNEC** STP	**PEC/PNEC** Sediment	**PEC/PNEC** soil	**PECgw (µg/l)**
Preventive							
Aplication-Brushing	House	Professional				0.3460	2.0600
		Non-professional				0.5760	3.4400
	Fence	Professional				0.2880	1.7100
		Non-professional				0.4800	2.8600
	Bridge	Professional	0.0090				
		Non-professional	0.0150				
Service	House (Time 1)					4.6900	23.3000

life-Surface Treatment Industrial	House (Time 3)				0.2260	1.3500
	Fence (Time 1)				3.9000	23.3000
	Fence (Time 3)				0.1880	1.1200
	Noise Barrier (Time 1)	0.0435	0.0000		0.0113	0.0392
	Noise Barrier (Time 3)	0.0005	0.0000		0.0001	0.0004
	Bridge over pond (Time 1)	0.0419				
	Bridge over pond (Time 3)	0.0009				
Service life-Surface Treatment In situ	House (Time 1)				4.6900	23.3000
	House (Time 3)				0.6790	4.0500
	Fence (Time 1)				3.9000	23.3000
	Fence (Time 3)				0.5650	3.3700
	Noise Barrier (Time 1)	0.0435	0.0000		0.0113	0.0392
	Noise Barrier (Time 3)	0.0014	0.0000		0.0004	0.0013
	Bridge over pond (Time 1)	0.0419				
	Bridge over pond (Time 3)	0.0026				
Service life-Deep Industrial	House (Time 1)				4.6900	23.3000
	House (Time 3)				0.1700	1.0100
	Fence (Time 1)				3.9000	23.3000
	Fence (Time 3)				0.1410	0.8410
	Noise Barrier (Time 1)	0.0435	0.0000		0.0113	0.0392
	Noise Barrier (Time 3)	0.0004	0.0000		0.0001	0.0003
	Bridge over pond (Time 1)	0.0419				
	Bridge over pond (Time 3)	0.0007				

Tebuconazole			**PEC/PNEC** Surface water	**PEC/PNEC** STP	**PEC/PNEC** Sediment	**PEC/PNEC** soil	**PECgw (µg/l)**
Preventive							
Aplication-Brushing	House	Professional				0.3460	1.9600
		Non-professional				0.5760	3.2700
	Fence	Professional				0.2880	1.6300
		Non-professional				0.4800	2.7200
	Bridge	Professional	0.0611		0.0025		
		Non-professional	0.1020		0.0041		
Service	House (Time 1)					4.6600	26.4000

life-Surface Treatment Industrial	House (Time 3)				0.2150	1.2200
	Fence (Time 1)				3.8800	22.0000
	Fence (Time 3)				0.17790	1.0100
	Noise Barrier (Time 1)	0.2920	0.0092	0.0119	0.0121	0.0389
	Noise Barrier (Time 3)	0.0032	0.0001	0.0001	0.0001	0.0004
	Bridge over pond (Time 1)	0.4030		0.0164		
	Bridge over pond (Time 3)	0.0210		0.0009		
Service life-Surface Treatment In situ	House (Time 1)				4.6600	26.4000
	House (Time 3)				0.6440	3.6500
	Fence (Time 1)				3.8800	22.0000
	Fence (Time 3)				0.5360	3.0400
	Noise Barrier (Time 1)	0.2920	0.0092	0.0119	0.0121	0.0389
	Noise Barrier (Time 3)	0.0096	0.0003	0.0004	0.0004	0.0013
	Bridge over pond (Time 1)	0.4030		0.0164		
	Bridge over pond (Time 3)	0.0615		0.0025		
Service life-Deep Industrial	House (Time 1)				4.6600	26.4000
	House (Time 3)				0.1610	0.9130
	Fence (Time 1)				3.8800	22.0000
	Fence (Time 3)				0.1340	0.7600
	Noise Barrier (Time 1)	0.2920	0.0092	0.0119	0.0121	0.0389
	Noise Barrier (Time 3)	0.0024	0.0001	0.0001	0.0001	0.0003
	Bridge over pond (Time 1)	0.4030		0.0164		
	Bridge over pond (Time 3)	0.0158		0.0006		

Cypermethrin			**PEC/PNEC** Surface water	**PEC/PNEC** STP	**PEC/PNEC** Sediment	**PEC/PNEC** soil	**PECgw (µg/l)**
Preventive							
Aplication-Brushing	House	Professional				0.4229	0.0029
		Non-professional				0.7057	0.0049
	Fence	Professional				0.3529	0.0024
		Non-professional				0.5871	0.0041
	Bridge	Professional	13.1000		3940.0000		
		Non-professional	21.8250		6560.0000		
Service	House (Time 1)					3.7571	0.0259

life-Surface Treatment Industrial	House (Time 3)				0.0590	0.0407
	Fence (Time 1)				3.1143	0.0215
	Fence (Time 3)				0.0490	0.0003
	Noise Barrier (Time 1)	1.7850	0.0002	536.0000	0.0527	0.0001
	Noise Barrier (Time 3)	0.0197	0.0000	5.9200	0.0006	0.0000
	Bridge over pond (Time 1)	8.7000		262.0000		
	Bridge over pond (Time 3)	0.1005		3.0200		
Service life-Surface Treatment In situ	House (Time 1)				3.7571	0.0259
	House (Time 3)				0.1771	0.0012
	Fence (Time 1)				3.1143	0.0215
	Fence (Time 3)				0.1471	0.0010
	Noise Barrier (Time 1)	1.7850	0.0002	536.0000	0.0527	0.0001
	Noise Barrier (Time 3)	0.0590	0.0000	1.7700	0.0017	0.0000
	Bridge over pond (Time 1)	8.7000		262.0000		
	Bridge over pond (Time 3)	0.3025		9.0400		
Service life-Deep Industrial	House (Time 1)				3.7571	0.0259
	House (Time 3)				0.0443	0.0003
	Fence (Time 1)				3.1143	0.0215
	Fence (Time 3)				0.0369	0.0003
	Noise Barrier (Time 1)	1.7850	0.0002	536.0000	0.0527	0.0001
	Noise Barrier (Time 3)	0.0148	0.0000	0.4420	0.0004	0.0000
	Bridge over pond (Time 1)	8.7000		262.0000		
	Bridge over pond (Time 3)	0.0755		2.2600		

IPBC			**PEC/PNEC** Surface water	**PEC/PNEC** STP	**PEC/PNEC** Sediment	**PEC/PNEC** soil	**PECgw (µg/l)**
Preventive							
Aplication-Brushing	House	Professional				27.0455	47.6000
		Non-professional				45.0000	79.3000
	Fence	Professional				22.4091	39.6000
		Non-professional				37.2727	66.0000
	Bridge	Professional	0.4200		0.4195		
		Non-professional	0.6980		0.6965		
Service	House (Time 1)					3.8864	6.8500

life-Surface Treatment Industrial	House (Time 3)				0.0425	0.0751
	Fence (Time 1)				3.2273	5.7000
	Fence (Time 3)				0.0355	0.0625
	Noise Barrier (Time 1)	2.1600	0.0245	2.1650	0.0033	0.0010
	Noise Barrier (Time 3)	0.0236	0.0003	0.0237	0.0000	0.0000
	Bridge over pond (Time 1)	0.0396		0.0396		
	Bridge over pond (Time 3)	0.0004		0.0004		
Service life-Surface Treatment In situ	House (Time 1)				3.8864	6.8500
	House (Time 3)				0.1277	0.2250
	Fence (Time 1)				3.2273	5.7000
	Fence (Time 3)				0.1064	0.170
	Noise Barrier (Time 1)	2.1600	0.0245	2.1650	0.0033	0.0010
	Noise Barrier (Time 3)	0.0712	0.0008	0.0713	0.0001	0.0000
	Bridge over pond (Time 1)	0.0396		0.0396		
	Bridge over pond (Time 3)	0.0013		0.0013		
Service life-Deep Industrial	House (Time 1)				3.8864	6.8500
	House (Time 3)				0.0320	0.0563
	Fence (Time 1)				3.2273	5.7000
	Fence (Time 3)				0.0266	0.0469
	Noise Barrier (Time 1)	2.1600	0.0245	2.1650	0.0033	0.0010
	Noise Barrier (Time 3)	0.0178	0.0002	0.0178	0.0000	0.0000
	Bridge over pond (Time 1)	0.0396		0.0396		
	Bridge over pond (Time 3)	0.0003		0.0003		

PBC			**PEC/PNEC** Surface water	**PEC/PNEC** STP	**PEC/PNEC** Sediment	**PEC/PNEC** soil	**PECgw (µg/l)**
Preventive							
Aplication-Brushing	House	Professional				0.4409	18.1872
		Non-professional				0.7335	30.2611
	Fence	Professional				0.3653	15.0694
		Non-professional				0.6076	25.0648
	Bridge	Professional	0.0028		0.0020		
		Non-professional	0.0047		0.0034		
Service	House (Time 1)					0.0634	2.6135

life-Surface Treatment Industrial	House (Time 3)				0.0007	0.0286
	Fence (Time 1)				0.0526	2.1702
	Fence (Time 3)				0.0006	0.0238
	Noise Barrier (Time 1)	0.0145	0.0137	0.0146	0.0015	0.0117
	Noise Barrier (Time 3)	0.0002	0.0001	0.0002	0.0000	0.0001
	Bridge over pond (Time 1)	0.0003		0.0002		
	Bridge over pond (Time 3)	0.0000		0.0000		
Service life-Surface Treatment In situ	House (Time 1)				0.0634	2.6135
	House (Time 3)				0.0021	0.0859
	Fence (Time 1)				0.0526	2.1702
	Fence (Time 3)				0.0017	0.0715
	Noise Barrier (Time 1)	0.0145	0.0137	0.0146	0.0015	0.0117
	Noise Barrier (Time 3)	0.0005	0.0004	0.0005	0.0000	0.0009
	Bridge over pond (Time 1)	0.0003		0.0002		
	Bridge over pond (Time 3)	0.0000		0.0000		
Service life-Deep Industrial	House (Time 1)				0.0634	2.6135
	House (Time 3)				0.0005	0.0215
	Fence (Time 1)				0.0526	2.1702
	Fence (Time 3)				0.0004	0.0179
	Noise Barrier (Time 1)	0.0145	0.0137	0.0146	0.0015	0.0117
	Noise Barrier (Time 3)	0.0001	0.0001	0.0001	0.0000	0.0001
	Bridge over pond (Time 1)	0.0003		0.0002		
	Bridge over pond (Time 3)	0.0000		0.0000		

1,2,4 Triazole			**PEC/PNEC** Surface water	**PEC/PNEC** STP	**PEC/PNEC** Sediment	**PEC/PNEC** soil	**PECgw (µg/l)**
Preventive							
Aplication-Brushing	House	Professional				0.4641	0.1025
		Non-professional				0.7727	0.17006
	Fence	Professional				0.3863	0.0853
		Non-professional				0.6439	0.1422
	Bridge	Professional					
		Non-professional					
Service	House (Time 1)					6.2841	1.3876

life-Surface Treatment Industrial	House (Time 3)				0.3005	0.0664
	Fence (Time 1)				5.2268	1.1542
	Fence (Time 3)				0.2500	0.0552
	Noise Barrier (Time 1)				0.0154	0.0034
	Noise Barrier (Time 3)				0.0002	0.0000
	Bridge over pond (Time 1)					
	Bridge over pond (Time 3)					
Service life-Surface Treatment In situ	House (Time 1)				6.2841	1.3876
	House (Time 3)				0.9023	0.1992
	Fence (Time 1)				5.2268	1.1542
	Fence (Time 3)				0.7509	0.1658
	Noise Barrier (Time 1)				0.0154	0.0034
	Noise Barrier (Time 3)				0.0005	0.0001
	Bridge over pond (Time 1)					
	Bridge over pond (Time 3)					
Service life-Deep Industrial	House (Time 1)				6.2841	1.3876
	House (Time 3)				0.2259	0.0499
	Fence (Time 1)				5.2268	1.1542
	Fence (Time 3)				0.1874	0.0414
	Noise Barrier (Time 1)				0.0154	0.0034
	Noise Barrier (Time 3)				0.0001	0.0000
	Bridge over pond (Time 1)					
	Bridge over pond (Time 3)					

Atmosphere

The product XYLAZEL TOTAL is a liquid product and the active substances Cypermethrin, Tebuconazole, Propiconazole and IPBC show very low vapour pressure.

Only negligible exposure to the atmosphere is expected and no threat to the atmosphere is expected.

Sewage treatment plant (STP)

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

Aquatic compartment

For the aquatic compartment (surface-water and sediment), risks were identified during the application phase (brushing) and during the service life for the bridge over pond scenario and Noise Barrier scenario (Indirect emissions via the STP) . Those risks are primarily due to the high toxicity

of Cypermethrin to aquatic and sediment organisms.

Terrestrial compartment

Considering that the calculated PEC/ PNEC ratios of IPBC are above 1 for soil, brushing application phase are cause of concern for the terrestrial compartment, unless direct releases to soil is prevented by covering the soil during application.

During service life of treated wood, considering that calculated PEC/PNEC ratios for terrestrial compartment is above 1 and below 10 only in TIME 1, the risks are considered acceptable if the active subtances are considered separately.

Groundwater

The estimations of releases of active substances, and their relevant degradation products for the groundwater compartment, were calculated with the FOCUS PEARL v.4.4.4 software.
According to the paragraph 578 of the PT08-ESD (2013), the estimation of releases to groundwater is relevant for susbstance with:

- K_{oc} < 500 $l.kg^{-1}$ and
- $DT50_{soil}$ > 21 d**.**

Considering that:

Substance	**K_{oc} [$l.kg^{-1}$]**	**$DT50_{soil,12°C}$ [d]**
Tebuconazole	992	77
Propiconazole	944	82
1,2,4-triazole (*)	89	114.7 (**)
Cypermethrin	575000	17.2
IPBC	134.5	1.96E-01
PBC(***)	198.1	9.50

(*) – Relevant degradation product of tebuconazole and propiconazole in soil, with a maximum formation rate of 9% and 43.23% of applied radioactivity, respectively.
(**) – Calculated according to the arrhenius equation with a DT_{50} at 20°C of 60.5 days.
(***) – Relevant metabolite of IPBC in all environmental compartments assuming 100% of applied radioactivity.

Estimations of releases to groundwater is considered relevant by ES-CA for the following substances:

- Tebuconazole;
- Propiconazole;
- IPBC;
- PBC;
- 1,2,4-triazole.

According to the PT08-ESD (2013), a groundwater assessment is only necessary for the house scenario, which can be considered to be the worst case for soil exposure, thus covering all other scenarios.
Consequently to the environmental risk assessment performed for the application phase, it is recommended on the label to cover the soil during the application by brushing. Then, no emission into the soil occurs during the application. Therefore, only emissions into the soil during the service-life of the treated wood due to leaching are taken into account to estimate the contamination of the groundwater.

The scenario for the groundwater exposure assessment for wood preservatives described in the supplement of the appendix 4 of the PT08-ESD, based on leaching values.

Input parameter	**Unit**	**Value**				
		Tebuconazole	**Propiconazole**	**IPBC**	**PBC**	**1,2,4-triazole**
Physicochemical parameters						
Molar mass	$g.mol^{-1}$	307.8	342.2	281.1	155.2	69.1
Water solubility (25 °C)	$mg.l^{-1}$	29	100	168	2860	700 000
Molar enthalpy of dissolution	$kJ.mol^{-1}$	27				
Saturated vapour pressure	Pa	1.70E-06 (20°C)	5.60E-05 (25°C)	2.36E-03 (25°C)	1.88E+01 (25°C)	2.20E-01 (20°C)
Molar enthalpy of vaporisation	$kJ.mol^{-1}$	95				
Diffusion coefficient in water (20 °C)	$m^2.d^{-1}$	4.3E-05				
Diffusion coefficient in air (20 °C)	$m^2.d^{-1}$	0.43				
Degradation parameters						
Half-life (12°C, pF2)	d	77	82	1.96E-01	9.50	114.7
Arrhenius activation energy	$kJ.mol^{-1}$	65.4				
Exponent of moisture correction function	-	0.7				
Sorption parameters						
K_{oc} value	$l.kg^{-1}$	992	944	134.5	198.1	89
K_{om}value (20°C)	$ml.g^{-1}$	575.41	547.56	78.02	114.91	51.62
Freundlich exponent 1/n	-	1				
Method of subroutine description	-	pH independent				
Crop related parameters						
Crop uptake factor	-	0				
Application Schemes						
Q*leach, TIME2 (5	$kg.m^{-2}$	1.87E-04	1.87E-04	6.42E-04	n.r.	n.r.

years)						
Total leachable area	$m^2.ha^{-1}$	2 000				
Fraction of house surface exposed to weather	-	0.5				
Service life	year	5				
Number of application per year	-	10				
Dosage per FOCUS application	$kg.ha^{-1}.applicaton^{-1}$	3.74E-03	3.74E-03	1.28E-02	n.r.	n.r.
Fraction transformed	-	n.r.	n.r.	n.r.	1 (IPBC)	0.09 (Tebuconazole) 0.43 (Propiconazole)
Application type	-	To the soil surface				
Repeat interval for years	-	1				
Date	-	10/01/1901				
		15/02/1901				
		24/03/1901				
		29/04/1901				
		05/06/1901				
		11/07/1901				
		17/08/1901				
		22/09/1901				
		29/10/1901				
		04/12/1901				
Crops Application						
Crop(s)	-	Grassland				
Selected Locations		CHATEAUDUN				
		HAMBURG				
		JOIKIONEN				
		KREMSMUENSTER				
		OKEHAMPTON				
		PIACENZA				
		PORTO				
		SEVILLA				
		THIVA				

n.r.: not relevant

The results are listed in the table below.

Scenario	Tebuconazole [µg.l^{-1}]	Propiconazole [µg.l^{-1}]	1,2,4-triazole [µg.l^{-1}]	IPBC [µg.l^{-1}]	PBC [µg.l^{-1}]
CHATEAUDUN	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
HAMBURG	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
JOIKIONEN	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
KREMSMUENSTER	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
OKEHAMPTON	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
PIACENZA	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
PORTO	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
SEVILLA	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
THIVA	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001

Primary and secondary poisoning

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

	PEC/PNEC$_{birds}$ ($PNEC_{oral,bird}$ = 33.3 mg/kg food)	**PEC/PNEC$_{mammals}$** ($PNEC_{oral,small\ mammal}$ = 3.33 mg/kg food)
Via fish	8.71E-04	8.71E-04
Via earthworm	8.02E-04	8.02E-04

Based on these PEC/PNEC ratios, it can be concluded that the use of the product will not pose a significant risk to the top predators.

Mixture toxicity

As the product XYLAZEL TOTAL consists of more than one active substance, the risk assessment for the product can be based on data of the active substances, when considering the mixture toxicity assessment for biocidal products (Guidance on the BPR: Volume IV Environment, Assessment & Evaluation (Parts B+C) 2017).
Screening step

Screening Step 1: Identification of concerned environmental compartments

The screening step identifies, if exposure of environmental compartments can be expected from the application of XYLAZEL TOTAL and if so, which environmental compartments are likely to be at risk. The wood treated with the product in use class 3 (wood not covered, not in contact with ground, exposed to the weather or subject to frequent wetting) the active substances might enter the environment during in-situ treatment and/or leaching from treated wood during service life. Therefore, the risk assessment for XYLAZEL TOTAL is based on data of the active substances, including the mixture toxicity assessment for products.

Screening Step 2: Identification of relevant substances

XYLAZEL TOTAL contains four active substances. The concentrations in the product are 0.6 % for IPBC, 0.175% for tebuconazole, 0.175 for propiconazole and 0.15% for cypermethrin. For the assessment of mixture toxicity, the respective relevant metabolites have to be considered as well.

Some ingredients of XYLAZEL TOTAL are classified as hazardous to the environment according to regulation (EC) No 1272/2008.

However, Naphtha and Solven Naphtha (SoC) are a petroleum products and the PNEC cannot be possible established since the majority of its mass is comprised of chemical components that cannot be accurately described by a chemical structure and for which there is an absence of ecotoxicological data.

According to Figure 29 from section 9 of BPR Guideline (Mixture Toxicity Assesment), we have not PEC/PNEC for all relevant substances in all relevant environmental compartments and the test with the mixture carried out by the applicant has not an appropriate reliability (see section Further Ecotoxicological studies) and do not give information about the SoCs. So, a qualitative assessment is carried out by ES-CA for this coformulant.

The following data is obtained from REACH dossier of Naphtha and Solvent Naphtha.

EL50/48h = 4.5 mg/l (daphnia magna) (OECD Guideline 202)

EL50/72h = 3.1 mg/l (pseudokirchnerella subcapitata) (OECD Guideline 201)

LL50/96h = 10 mg/l (oncorhynchus mykiss) (OECD Guideline 203)

LL50/96h = 8.2 mg/l (pimephales promelas) (OECD Guideline 203)

Comparing this data with the ecotoxicological data from de active subtances, the toxicity of the active substances is higher and the environmental risk assessment for the product based on the four active substances and metabolites would cover the toxicity from the coformulant.

Subtance	IPBC	Cypermethrin	Propiconazole	Tebuconazole
Content in the product (%)	0,6	0,15	0,175	0,175
Aquatic compartment				
Algae EC50(72h) [mg/L]	0,022		9	5,3
Daphnid EC50(48h) [mg/L]	0,16	0,00471	0,51	2,79
Fish LC50(96h) [mg/L]	0,067	0,00283	2,6	4,4
AlgaeNOEC(72h) [mg/L]	0,0046		0,46	0,56
Daphnid NOEC (21d) [mg/L]	0,05	0,00004	0,11	0,01
Fish NOEC (28d) [mg/L]	0,0084	0,000463	0,068	0,01
Soil Compartment				
Earthworms LC50(96h)mg/kg ww	885	100		470

Screening Step 3: Screen on synergistic interactions

The product contains 4 active substances (IPBC, tebuconazole, propiconazole and cypermethrin) and no substances of concern for the environment. The toxicity of the single active substances is known. Potential indications for synergistic interactions/effects are summarised in Annex 3 of the Guidance on the BPR: Volume IV Environment, Assessment & Evaluation (Parts B+C) 2017. In this Annex possible synergistic effects are described for fungicides, which act as ergosterol biosynthesis inhibitors (EBI fungicides) and pyrethroids. As tebuconazole belongs to the class of EBI fungicides and cypermethrin is a pyrethroid substance, literature was screened on indications of synergisms between these substances. The literature research revealed one study12 on Daphnia magna with

tebuconazole and a pyrethroid (alpha-cypermethrin), showing no synergistic interaction, but additive behaviour. Furthermore, the tested concentrations of tebuconazole were far above the environmental concentrations expected from the use of the product XYLAZEL TOTAL.

In the first tier a PEC/PNEC summation based on effect data (most sensitive organism) for the individual substances is performed for each environmental compartment of concern.

[(PEC/PNEC)product = Σ (PEC/PNEC)individual substances] for each environmental compartment

(PEC/PNEC)product values for each environmental compartment of concern are summarized below.

ΣPEC/PNEC			**PEC/PNEC** Surface water	**PEC/PNEC** STP	**PEC/PNEC** Sediment	**PEC/PNEC** soil	**PECgw (µg/l)**
Preventive							
Aplication-Brushing	House	Professional				29.0653	69.9126
		Non-professional				48.3639	116.4466
	Fence	Professional				24.0896	58.0972
		Non-professional				40.0713	96.7910
	Bridge	Professional	13.5929		3940.4481		
		Non-professional	22.6447		6560.7442		
Service life-Surface Treatment Industrial	House (Time 1)					23.3410	60.5770
	House (Time 3)					0.8437	2.7807
	Fence (Time 1)					19.4010	54.3459
	Fence (Time 3)					0.7020	2.2719
	Noise Barrier (Time 1)		4.2951	0.0475	538.3081	0.0962	0.0942
	Noise Barrier (Time 3)		0.0471	0.0005	5.9453	0.0011	0.0010
	Bridge over pond (Time 1)		9.1848		262.1686		
	Bridge over pond (Time 3)		0.1228		3.0236		
Service life-Surface Treatment In situ	House (Time 1)					23.3410	60.5770
	House (Time 3)					2.5323	8.2114
	Fence (Time 1)					19.4010	54.3459
	Fence (Time 3)					2.1071	6.8353
	Noise Barrier (Time 1)		4.2951	0.0476	538.3081	0.0962	0.0942
	Noise Barrier (Time 3)		0.1416	0.0016	1.8459	0.0032	0.0036
	Bridge over pond (Time 1)		9.1848		262.1686		
	Bridge over pond (Time 3)		0.3679		9.0507		
Service life-Deep Industrial	House (Time 1)					23.3410	60.5770
	House (Time 3)					0.6337	2.0510

	Fence (Time 1)				19.4010	54.3459
	Fence (Time 3)				0.5263	1.7074
	Noise Barrier (Time 1)	4.2951	0.0475	528.3081	0.0962	0.0942
	Noise Barrier (Time 3)	0.0354	0.0004	0.4610	0.0008	0.0008
	Bridge over pond (Time 1)	9.1848		262.1686		
	Bridge over pond (Time 3)	0.0923		2.2627		

According to the Guidance on the BPR: Volume IV Environment, Assessment & Evaluation (Parts B+C, 2017), the summation of the active substances as well as the summation of the relevant metabolites showed an unacceptable risk for the environment for the scenarios "in-situ application" for the house, fence and bridge-over-pond scenario. These risks can be reduced by the requirement that the ground should be covered before painting with the product and application of the product is not allowed near surface waters, hence direct emissions during the application are avoided. However, an unacceptable risk for soil, sediment and water during service life due to the use of product XYLAZEL TOTAL is indicated for Time 1(30 days) and due to PEC/PNEC soil is greater than 10 the risk is unacacceptable.

In the risk assessmnent carried out by ES-CA, only the application rate of 106g/m^2 for fungi was taken into account, due to this risk assessment represents an unacceptable risk for the environment, the risk assessment for the application rate of 200g/m^2 for blue stain fungi was not carried out.

Aggregated exposure (combined for relevant emmission sources)

Not relevant.

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

The risk characterisation indicates that the uses of the biocidal product XYLAZEL TOTAL by the industrial processes - dipping and vacuum impregnation – and by in situ processes -brush for the uses of treated wood in UC 1 and UC 2 do not represent unacceptable risks to the environment. However, **for the uses of treated wood in UC3 represent unacceptable risks to the environment and this use can not be authorized.**

According to the PT8 scenario, for indoor treatments by spraying, brushing and injection, no scenarios are proposed in this document because related emissions to the environment are considered to be negligible. Indoor treatment may need to be considered in the exposure assessemnt for bats in countries where bats are protected animals. So the following Risk Mitigation Measurement is added "Can be harmful to protected species such as bats, hornets or birds. The presence of protected species in the area to be treated must be assessed prior to use of the product. Appropriate protective measures must be taken if necessary".

2.2.9. Measures to protect man, animals and the environment

Xylazel Total is a skin irritant and skin sensitizer sub-category 1B. May be fatal if swallowed and enters airways. Repeated exposure may cause skin dryness or cracking. The product is a flammable liquid. As a result of combustion or thermal decomposition reactive sub-products are created that can become highly toxic and, consequently, can present a serious health risk.

Under normal conditions of storage, Xylazel Total is stable for 2 years.
Conditions for safe storage: Avoid sources of heat, radiation, static electricity and contact with food. Keep container closed. Technical measures for storage: Minimum Temp.:5 º C Maximun Temp.: 30º C

Conditions for safe storage, including any incompatibilities:
Due to the danger of this product for the environment it is recommended to use it within an area containing contamination control barriers in case of spillage, as well as having absorbent material in close proximity.
Technical recommendations to prevent environmental risks:
Do not eat or drink during the process, washing hands afterwards with suitable cleaning products.

Technical recommendations to prevent ergonomic and toxicological risks:
Transfer in well ventilated areas, preferably through localized extraction. Fully control sources of ignition (mobile phones, sparks,…) and ventilate during cleaning operations. Avoid the existence of dangerous atmospheres inside containers, applying inertization systems where possible. Transfer at a slow speed to avoid the creation of electrostatic charges. Against the possibility of electrostatic charges: ensure a perfect equipotential connection, always use groundings, do not wear work clothes made of acrylic fibres, preferably wearing cotton clothing and conductive footwear. Comply with the essential security requirements for equipment and systems defined in Directive 94/9/EC (ATEX 100) and with the minimum requirements for protecting the security and health of workers under the selection criteria of Directive 1999/92/EC (ATEX 137).

Technical recommendations for the prevention of fires and explosions:
Comply with the current legislation concerning the prevention of industrial risks. Keep containers hermetically sealed. Control spills and residues, destroying them with safe methods. Avoid leakages from the container. Maintain order and cleanliness where dangerous products are used.

Extinguishing media:
If possible use polyvalent powder fire extinguishers (ABC powder), alternatively use foam or carbon dioxide extinguishers (CO2). IT IS RECOMMENDED NOT to use tap water as an extinguishing agent.

Special hazards arising from the substance or mixture:
As a result of combustion or thermal decomposition reactive sub-products are created that can become highly toxic and, consequently, can present a serious health risk.

Advice for firefighters:
Depending on the magnitude of the fire it may be necessary to use full protective clothing and individual respiratory equipment. Minimum emergency facilities and equipment should be available (fire blankets, portable first aid kit,...) in accordance with Directive 89/654/EC.

First aid instructions:
By inhalation:
This product is not classified as dangerous through inhalation,however, it is recommended in case of intoxication symptoms to remove the person affected from the area of exposure, provide clean air and keep at rest. Request medical attention if symptoms persist.

By skin contact:
Remove contaminated clothing and footwear, rinse skin or shower the person affected if appropriate with plenty of cold water and neutral soap. In serious cases see a doctor. If the product causes burns or freezing, clothing should not be removed as this could worsen the injury caused if it is stuck to the skin. If blisters form on the skin, these should never be burst as this will increase the risk of infection
By eye contact:
Rinse eyes thoroughly with lukewarm water for at least 15 minutes. Do not allow the person affected to rub or close their eyes. If the injured person uses contact lenses, these should be removed unless they are stuck to the eyes, as this could cause further damage. In all cases, after cleaning, a doctor should be consulted as quickly as possible with the MSDS of the product.
By ingestion/aspiration:
Do not induce vomiting, but if it does happen keep the head up to avoid inhalation. Keep the person affected at rest. Rinse out the mouth and throat, as they may have been affected during ingestion

Personal precautions, protective equipment and emergency procedures:
Isolate leaks provided that there is no additional risk for the people performing this task. Evacuate the area and keep out those without protection. Personal protection equipment must be used against potential contact with the spilt product. Above all prevent the formation of any vapour-air flammable mixtures, through either ventilation or the use of an inertization agent. Destroy any source of ignition. Eliminate electrostatic charges by interconnecting all the conductive surfaces on which static electricity could form, and also ensuring that all surfaces are connected to the ground.

Environmental precautions:
Avoid at all cost any type of spillage into an aqueous medium. Contain the product absorbed appropriately in hermetically sealed containers. Notify the relevant authority in case of exposure to the general public or the environment.
Methods and material for containment and cleaning up:
It´s recommend: Absorb the spillage using sand or inert absorbent and move it to a safe place. Do not absorb in sawdust or other combustible absorbents.

The product is to use according the technical instructions and intended uses. Xylazel Total is a wood preservative and does not be used for other applications.

2.2.10. Assessment of a combination of biocidal products

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

Not applicable

2.2.11. Comparative assessment

ES-CA:

The biocidal product contains four active substances, of which tebuconazole is considered to meet the criteria for substitution listed in article 10(1) of Regulation 528/2012. Therefore in accordance with Article 23 of Regulation 528/2012 a comparative assessment should be carried out for the

biocidal product. Nevertheless, taking into account that a proposal no authorisation is considered, the comparative assessment cannot be done.

Product XYLAZEL TOTAL is a wood preservative (PT 8) which contains the active substances indicate above. The product is to be used by industrial and professional users as a preventive treatement for wood, indoor and outdoor (use class 1, 2 and 3). Preventive treatments are performed by superficial application and deep treatment.

Table 2.2.11.-1 Intended uses of the biocidal product: Preventive treatment

Product Type	8 Wood preservatives
Where relevant, an exact description of the authorised use	Preventive
Target organism (including, where relevant) development stage)	- Basidiomycetes - Blue stain.
Field(s) of use	Indoor Use class 2
Application method(s)	- Automated dipping - Automated spraying - Spraying - Brushing - Double vacuum pressure
Category(ies) of users	Industrial users Trained Professional users

Table 2.2.11.-2 Intended uses of the biocidal product: Curative treatment

Product Type	8 Wood preservatives
Where relevant, an exact description of the authorised use	Curative
Target organism (including, where relevant) development stage)	- Anobium punctatum De Geer-Common furniture beetle-Larvae - Hylotrupes bajulus L.-House longhorn beetle-Larvae
Field(s) of use	Indoor
Application method(s)	- Brushing - Injection
Category(ies) of users	Trained Professional users

2.2.11.2 Mapping of existing alternatives to the relevant BP

2.2.11.2.1 Identified eligible alternative BPs

The product XYLAZEL TOTAL has been only compared with alternative products authorised in Spain, as the searchable SPCs and a corresponding search tool in the Register for Biocidal Products (R4BP) is currently not available, Spanish CA has used the information available to the ES CA on the 13nd of Mayl 2021 of the biocidal products authorised under the Directive 98/8/EC or Regulation (EU) No 528/2012. In Spain 95 products PT8 have been authorised, 16 products

cotain tebuconazole and 43 products contain Propiconazole, but considering that propiconazole was classified as reprotoxic 1B after 1st december of 2019 accordingly with regulation (EU) 2018/1480, products containing propiconazole are not classified as appropriate alternatives. Considering the fungicide and insecticide activity, no alternatives has been found.

2.2.11.2.2. Identified eligible non chemical alternatives

Considering that tebuconazole was authorized under the BPD, no public consultation was carried out by ECHA in the context of the tebuconazole approval. Consequently, no non-chemical alternatives were proposed to replace the use of this substance.

2.2.11.3 Screening phase

Consideration on whether the CFS(s) 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.

Tebuconazole is not considered as meeting the exclusion criteria according to Article 5(1).

Conclusion of the screening phase:

As no alternatives have been found, the comparative assessment is finalised at this stage. The product XYLAZEL TOTAL is authorised for a period not exceeding 5 years in accordance with Article 23 (6).

3. ANNEXES

3.1. List of studies for the biocidal product

IUCLID section	Author	Year	Title	Report no.	Owner company
IUCLID 3.1	[redacted]	[redacted]	Appearance	-	-
IUCLID 3.2	[redacted]	[redacted]	Acidity/Alkalinity	-	-
-	[redacted]	[redacted]	Relative density	-	Xylazel, S.A
-	[redacted]	[redacted]	Accelerate stability test	089357	Tecnalia
-	[redacted]	[redacted]	Storage stability test (M1)	-	Xylazel, S.A
-	[redacted]	[redacted]	Storage stability test	051988-2 (M1)	Tecnalia
-	[redacted]	[redacted]	Xylazel Total – Ensayos de estabilidad	-	Xylazel, S.A
IUCLID 3.4.1	[redacted]	[redacted]	Low temperature stability test	-	-
-	[redacted]	[redacted]	Surface tension	BA18027	Cambium
-	[redacted]	[redacted]	Viscosidad	-	IQS
-	[redacted]	[redacted]	Flash Point	-	Xylazel, S.A
IUCLID 5	[redacted]	[redacted]	Analytical Methods	-	-
IUCLID 6	[redacted]	[redacted]	Eficacia preventiva frente a *Hylotrupes bajulus* UNE 56402:1996	Report Nº 11729.2	CIDEMCO
IUCLID 6	[redacted]	[redacted]	Determinación de la eficacia preventiva contra larvas recien nacidas de *Hylotrupes bajulus (Linnaeus*). Método según UNE 56402:1996 (EN 46:1988)	Report Nº 11729.2-1 (M1)	TECNALIA
IUCLID 6	[redacted]	[redacted]	Determinación de la eficacia preventiva contra larvas recien nacidas de *Hylotrupes bajulus (Linnaeus*). Método según UNE 56402:1996 (EN 46:1988)	Report Nº 11729.2-2 (M1)	TECNALIA
IUCLID 6	[redacted]	[redacted]	Eficacia curativa frente *Hylotrupes bajulus*. UNE 56408:1982	Report Nº 11729.2-3 (M1)	TECNALIA
IUCLID 6	[redacted]	[redacted]	Determinación de la eficacia preventiva contra *Reticulotermes santonensis* de Feytaud. Método según UNE 56411:1992 (EN 118:1990)	Report Nº 11729.2-4 (M1)	TECNALIA
IUCLID 6	[redacted]	[redacted]	Determinación de la eficacia preventiva contra *Reticulotermes santonensis* de Feytaud. Método según UNE 56411:1992 (EN 118:1990)	Report Nº 11729.2-5 (M1)	TECNALIA
IUCLID 6	[redacted]	[redacted]	Eficacia preventiva hongos	Report Nº	CIDEMCO

			basidiomicetos EN113:1996	11729.3	
IUCLID 6	[redacted]	[redacted]	Método de ensayo para la determinación de la eficacia preventiva contra los basidiomicetos destructores de la madera. Determinación de valores tóxicos según norma EN 113:1996.	Report Nº 11729.3-1 (M1)	TECNALIA
IUCLID 6	[redacted]	[redacted]	Método de ensayo para la determinación de la eficacia preventiva contra los basidiomicetos destructores de la madera. Determinación de valores tóxicos según norma EN 113:1996.	Report Nº 11729.3-2 (M1)	TECNALIA
IUCLID 6	[redacted]	[redacted]	Eficacia preventiva frente a hongos basidiomicetos. EN113:1996	Report Nº 8944.1	CIDEMCO
IUCLID 6	[redacted]	[redacted]	Método de ensayo para la determinación de la eficacia preventiva contra los basidiomicetos destructores de la madera. Determinación de valores tóxicos según norma EN 113:1996.	Report Nº 8944.1-1 (M1)	TECNALIA
IUCLID 6	[redacted]	[redacted]	Método de ensayo para la determinación de la eficacia preventiva contra los basidiomicetos destructores de la madera. Determinación de valores tóxicos según norma EN 113:1996.	Report Nº 8944.1-2 (M1)	TECNALIA
IUCLID 6	[redacted]	[redacted]	Determinación de la eficacia preventiva contra larvas recien nacidas de *Hylotrupes bajulus (Linnaeus*). Método según UNE 56402:1996 (EN 46:1988)	Report Nº 8944.1-3 (M1)	TECNALIA
IUCLID 6	[redacted]	[redacted]	Determinación de la eficacia preventiva contra larvas recien nacidas de *Hylotrupes bajulus (Linnaeus*). Método según UNE 56402:1996 (EN 46:1988)	Report Nº 8944.1-4 (M1)	TECNALIA
IUCLID 6	[redacted]	[redacted]	Eficacia curativa frente *Hylotrupes bajulus* UNE56408:1982 (EN22:1974)	Report Nº 8944.1-5 (M1)	TECNALIA
IUCLID 6	[redacted]	[redacted]	Determinación de la eficacia preventiva contra *Reticulotermes santonensis* de Feytaud. Método según UNE 56411:1992 (EN 118:1990)	Report Nº 8944.1-6 (M1)	TECNALIA
IUCLID 6	[redacted]	[redacted]	Determinación de la eficacia preventiva contra *Reticulotermes santonensis* de Feytaud. Método según UNE 56411:1992 (EN 118:1990)	Report Nº 8944.1-7 (M1)	TECNALIA
IUCLID 6	[redacted]	[redacted]	Determinación de la eficacia protectora de un tratamiento de protección de la madera en servicio contra el azulado: EN 152:2011	Report Nº 29527	TECNALIA

IUCLID 6	[redacted]	[redacted]	Determinación de la eficacia protectora de un tratamiento de protección de la madera en servicio contra el azulado: EN 152:2011	Report Nº 29527(M1)	TECNALIA
IUCLID 6	[redacted]	[redacted]	Determinación de la eficacia protectora de un tratamiento de protección de la madera en servicio contra el azulado: EN 152:2011	Report Nº 29527(M2)	TECNALIA
IUCLID 6	[redacted]	[redacted]	Eficacia preventiva frente a hongos del azulado: EN 152-1:1988	Report Nº 9806.2	CIDEMCO
IUCLID 6	[redacted]	[redacted]	Determinación de la eficacia curativa contra *Hylotrupes bajulus (Linnaeus)* según la norma UNE-EN 1390:2007	Report Nº 088226	TECNALIA

3.2. Output from exposure assessment tools

Human health assessment

Exposure-Risk characterisation - XY

SoC -XYLENE- XYLAZEL TOTAL (EN).

Environmental assessment

Leaching assessment:

leaching_results.xlsx

3.3. New information on the active substance

Not appicable

3.4. Residue behaviour

It is a low volatil product. As a result of combustion or thermal decomposition reactive sub-products are created that can become highly toxic and, consequently, can present a serious health risk. Evacuate the area and keep out those without protection. Personal protection equipment must be used against potential contact with the spilt product. Above all prevent the formation of any vapour-air flammable mixtures, through either ventilation or the use of an inertization
Agent. Destroy any source of ignition. Eliminate electrostatic charges by interconnecting all the conductive surfaces on which static electricity could form, and also ensuring that all surfaces are connected to the ground.

Avoid at all cost any type of spillage into an aqueous medium. Contain the product absorbed appropriately in hermetically sealed
Containers. Notify the relevant authority in case of exposure to the general public or the environment. Xylazel total is a not miscible with water product with a lower relative density. It can be emusify by especial emusifier. Solvents are volatile, the remaining products are te active substances and the alkyd resin. It is important to look ata the properties of the active substances in water.

Avoid at all cost any type of spillage. Contain the product absorbed appropriately in hermetically sealed
Containers. Notify the relevant authority in case of exposure to the general public or the environment. Absorb the spillage using sand or inert absorbent and move it to a safe place. Do not absorb in sawdust or other combustible.absorbents. Xylazel total is a not miscible with water product with a lower relative density. It can be emusify by especial emusifier. Solvents are volatile, the remaining products are te active substances and the alkyd resin. It is important to look ata the properties of the active substances in water.
Contaminated soil can be treated like the product.

Consult the authorized waste service manager on the assessment and disposal operations in accordance with annex 1 and annex
2 (directive 2008/98/ec). As under 15 01 (2000/532/ec) of the code and in case the container has been in direct contact with
The product, it will be processed the same way as the actual product. Otherwise, it will be processed as non-dangerous residue.
We do not recommended disposal down the drain.
Xylazel total is a mixture of organic compounds that can be separate by chemical and phisical procedures.

Absorb the spillage using sand or inert absorbent and move it to a safe place. Do not absorb in sawdust or other combustible.absorbents.

Avoid at all cost any type of spillage. Contain the product absorbed appropriately in hermetically sealed
Containers. Due to the danger of this product for the environment it is recommended to use it within an area containing contamination control barriers in case of spillage, as well as having absorbent material in close proximity.
Do not eat or drink during the process, washing hands afterwards with suitable cleaning products.

Transfer in well ventilated areas, preferably through localized extraction. Fully control sources of ignition (mobile phones, sparks,…) and ventilate during cleaning operations. Avoid the existence of dangerous atmospheres inside containers, applying inertization systems where possible. Transfer at a slow speed to avoid the creation of electrostatic charges. Against the possibility of electrostatic charges: ensure a perfect equipotential connection, always use groundings, do not wear work clothes made of acrylic fibres, preferably wearing cotton clothing and conductive footwear. Comply with the essential security requirements for equipment and systems defined in directive 94/9/ec (atex 100) and with the minimum requirements for protecting the security and health of workers under the selection criteria of directive 1999/92/ec (atex 137).
Comply with the current legislation concerning the prevention of industrial risks. Keep containers hermetically sealed. Control spills and residues, destroying them with safe methods. Avoid leakages from the container. Maintain order and cleanliness where dangerous products are used.

If it is possible, better to use reclying procedures. Avoid at all cost any type of spillage. Contain the product absorbed appropriately in hermetically sealed
Containers. Due to the danger of this product for the environment it is recommended to use it within an area containing contamination control barriers in case of spillage, as well as having absorbent material in close proximity.
Do not eat or drink during the process, washing hands afterwards with suitable cleaning products.

Transfer in well ventilated areas, preferably through localized extraction. Fully control sources of ignition (mobile phones, sparks,…) and ventilate during cleaning operations. Avoid the existence of dangerous atmospheres inside containers, applying inertization systems where possible. Transfer at a slow speed to avoid the creation of electrostatic charges. Against the possibility of electrostatic charges: ensure a perfect equipotential connection, always use groundings, do not wear work clothes made of acrylic fibres, preferably wearing cotton clothing and conductive footwear. Comply with the essential security requirements for equipment and systems defined in directive 94/9/ec (atex 100) and with the minimum requirements for protecting the security and health of workers under the selection criteria of directive 1999/92/ec (atex 137).
Comply with the current legislation concerning the prevention of industrial risks. Keep containers hermetically sealed. Control spills and residues, destroying them with safe methods. Avoid leakages from the container. Maintain order and cleanliness where dangerous products are used.
Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe way. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. In accordance with annex ii of regulation (ec) nº1907/2006 (reach) the community or state provisions related to waste management are stated.

Does not exist special procedures for cleaning application equipment. It is possible to clean the equipment with organic solvents or special detergents.

3.5. Summaries of the efficacy studies (B.5.10.1-xx)[13]

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

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