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)

AXIL 3000 P, RESISTOL 6218, SARPALO 910, SARPECO 910

Product type 8

Tebuconazole, 3-iodo-2-propynylbutylcarbamate (IPBC), permethrin, 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole (Propiconazole)

Case Number in R4BP: BC-WG023214-46

Evaluating Competent Authority: BE

Date: 12/08/2020

Application type	refMS/ eCA	Case number in the refMS	Decision date	Assessment carried out (i.e. first authorisation / amendment / renewal)	Chapter / page
NA-APP	*BE-CA*	BC-WG023214-46	09.01.2019	Initial assessment	/
NA-MAC	*BE-CA*	BC-UL049493-18	20.01.2020	Effectiveness of AXIL 3000 P for curative treatment of wood against wood-destroying insects (Hylotrupes bajulus L., Lyctus brunneus and Anobium punctatum De Geer) Application of AXIL 3000 P diluted 35% in water by the processes of spraying, injection and brushing with an application rate of 300g/m² of wood for the curative treatment.	See highligt

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1 CONCLUSION

BE eCA considers that the product AXIL 3000 P (additional name RESISTOL 6218, SARPALO 910, SARPECO 910), formulated by BERKEM DEVELOPPEMENT, containing the active substances Tebuconazole (0.75% w/w), IPBC (0.75% w/w), permethrin (1.0% w/w), Propiconazole (0.75% w/w) may be authorized as wood preservative (PT8). The conclusions of each assessment are summarized below.

The biocidal product AXIL 3000 P is a colourless transparent liquid with characteristic odour. At ambient temperature the product has a long term stability for 24 months and is stable under cold and accelerated storage conditions. The product should be protected from direct exposition to light. Physical and compatibility with other products is not relevant. The contact with oxidizing agents has to be avoided. No classification related to physico-chemical risks is necessary.

AXIL 3000 P product is effective against wood-destroying insects including termites and wood destroying fungi (white rot and brown rot fungi) in preventive treatment. The field of use covers use class 1, use class 2 and use class 3.1. The application rate is 100 g/m². The product is intended to be diluted at 10% w/w in water for use class 1, 2 and 3 (softwood) and at 19.2% w/w in water for use class 3 (hardwood) in surface treatment. [redacted]AXIL 3000P is also efficacious in curative insecticide treatment, diluted at 35% and applied at 300 ml/m².

Normal use of AXIL 3000 P by industrial professionals has a sufficiently large safety margin for the fully automated dipping application when using proper PPE (chemical resistant gloves, impermeable coverall). There is no safe use identified when the product is intended to be used on hardwood by automated spraying with a dilution rate at 19.2%. However by limiting the uses with a maximum dilution rate of 10%, a safe use is identified when proper PPE are used (chemical resistant gloves, impermeable coverall) for application by automated spraying.

[redacted]

Normal use of AXIL 3000 P by professionals has a sufficiently large safety margin for the spraying in situ, injection in situ, cleaning of the equipment and brushing in situ when using proper PPE (chemical resistant gloves, impermeable coverall).

Normal use of AXIL 3000 P by professionals has a sufficiently large safety margin for the combined exposure of spraying in situ + cleaning of the equipment and Injection + Brushing + cleaning equipment when using proper PPE (chemical resistant gloves, impermeable coverall).

Due to the exposure to combined active substances in the product, for the scenarios 9+12, use of an additional PPE (respiratory protective equipment with a protection factor of 4) as a risk is identified for the liver when respiratory protection is not worn.

No risk is foreseen for the secondary exposure of professional sanding treated wood posts (chronic exposure). Normal use of AXIL 3000 P has a sufficiently large safety margin for the secondary exposed general public.

The risk characterisation of the biocidal product AXIL 3000 P indicates that:

- Preventive treatments by the industrial processes - automated spraying and short dipping - and the uses of treated wood in UC 1, UC 2 and UC3 do not represent unacceptable risks to the environment if appropriate risk mitigation measures are considered.
- Curative treatments by spraying, brushing and injection in conditions of UC 1 and 2 do not represent unacceptable risks to the environment if appropriate risk mitigation measures are considered.

[redacted]

In view of assessments performed, **the biocidal product AXIL 3000 P is judged efficacious against wood destroying insects and fungi in preventive treatment and is to be applied by fully automated dipping process for all types of wood or by automated spraying with limitation to 10% dilution rate only when using proper PPE (industrial uses). In addition, the biocidal product AXIL 3000 P can be used for curative treatment by professional by spraying or by injection + brushing in situ at a dilution rate of 35% only when using proper PPE.**

2 ASSESSMENT REPORT

2.1 SUMMARY OF THE PRODUCT ASSESSMENT

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier	**Country**
AXIL 3000 P RESISTOL 6218 SARPALO 910 SARPECO 910	Belgium

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	BERKEM DEVELOPPEMENT
	Address	Marais Ouest, F-24680, Gardonne, FR
Authorisation number	BE2018-0023	
Date of the authorisation	09/01/2019	
Expiry date of the authorisation	21/12/2023	

2.1.1.3 Manufacturer of the product

Name of manufacturer	ADKALIS
Address of manufacturer	Marais Ouest F-24680 Gardonne FR
Location of manufacturing sites	Marais Ouest F-24680 Gardonne FR

2.1.1.4 Manufacturers of the active substances

Active substance	Tebuconazole
Name of manufacturer	LANXESS Deutschland GmbH
Address of manufacturer	Kennedyplatz 1 D-50569 Koln, Germany
Location of manufacturing sites	Bayer Corp., Agriculture Division - Hawthorn Road, P.O. Box 4913 MO 64120-001 Kansas City, US.

Active substance	3-iodo-2-propynylbutylcarbamate (IPBC)	
Name of manufacturer	LANXESS Deutschland GmbH	TROY Chemical Company BV
Address of manufacturer	Kennedyplatz 1 D-50569 Koln, Germany	Uiverlaan 12e, 3140 AC Maasluis, Netherlards
Location of manufacturing sites	Shanghai Hui long Chemicals Co., Ltd, Dengta Jiazhu Rd. 201815 District Shangai, China	One Avenue L Newark, 07105 New Jersey, USA

Active substance	Permethrin	
Name of manufacturer	LANXESS Deutschland GmbH	Caldic Denmark A/S (Acting for TAGROS Chemicals India Ltd)
Address of manufacturer	Kennedyplatz 1 D-50569 Köln Germany	Odinsvej 23, DK-8722 Hedensted, Denmark
Location of manufacturing sites	Bilag Industries Limited, Plot #306/3, II Phase, GIDC, Vapi - 396 195, Gujarat, India	Tagros Chemicals India Limited, A4/1&2, SIPCOT Industrial Complex, Kudikadu, Cuddalore, Tamil Nadu, India

Active substance	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole (Propiconazole)	
Name of manufacturer	LANXESS Deutschland GmbH	JANSSEN PMP
Address of manufacturer	Kennedyplatz 1 D-50569 Köln Germany	Turnhoutseweg 30 2340 Beerse, BE
Location of manufacturing sites	CH-1870 Monthey, Switzerland	North Area of Dongsha Chem-Zone Zhangjiagan- 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.

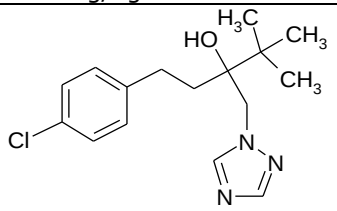
Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

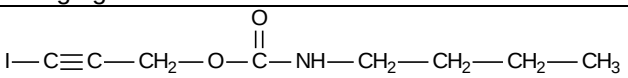
Yes ☐

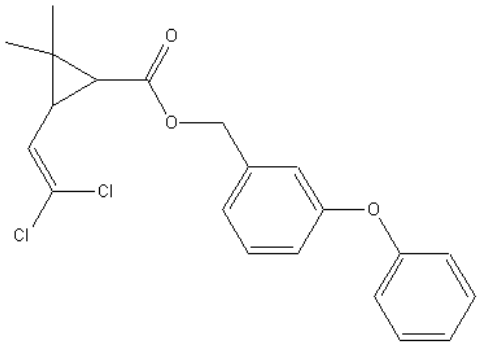
No ☒

2.1.2.1 Identity of the active substances

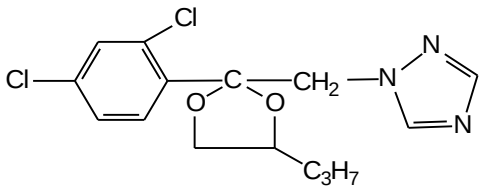
Main constituent(s)	
ISO name	Tebuconazole
IUPAC or EC name	(RS)-1-(4-chlorophenyl)-4,4-dimethyl-3-(1H-1,2,4-triazol-1-ylmethyl)-pentan-3-ol. Ratio (1:1)
EC number	403-640-2

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

Main constituent(s)	
ISO name	Permethrin
IUPAC or EC name	3-phenoxybenzyl(1RS)-cis,trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate or 3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate
EC number	258-067-9
CAS number	52645-53-1
Index number in Annex VI of CLP	613-058-00-2
Minimum purity / content	≥93% w/w sum of all permethrin isomers Cis:trans permethrin % ratio = 22-28:72-78 cis:trans. 1Rcis permethrin content = 5.0 – 10.0% w/w. 1Scis permethrin content = 15.0 – 20.0% w/w. 1Rtrans permethrin content = 45.0 – 55.0% w/w. 1Strans permethrin content = 17.0 – 27.0% w/w.
Structural formula	

Main constituent(s)	
ISO name	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole (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	Min 930 g/kg
Structural formula	

2.1.2.2 Candidate(s) for substitution

The biocidal product AXIL 3000 P contains four active substances: propiconazole, IPBC, tebuconazole and permethrin.

IPBC and propiconazole are not PBT candidates.

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

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). However, tebuconazole is not considered as meeting the exclusion criteria according to Article 5(1). Therefore tebuconazole can be considered to meet the criteria in Article 10(1)d, notably it meets two of the criteria for being PBT in accordance with Annex XIII to regulation (EC) No 1907/2006.

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 (2.2.11).

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Tebuconazole	(RS)-1-(4-chlorophenyl)-4,4-dimethyl-3-(1H-1,2,4-triazol-1-ylmethyl)-pentan-3-ol. Ratio (1:1)	Active substance	107534-96-3	403-640-2	0.75
IPBC	3-Iodo-2-propynyl butyl carbamate	Active substance	55406-53-6	259-627-5	0.75
Permethrin	3-phenoxybenzyl(1RS)-cis,trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate	Active substance	52645-53-1	258-067-9	1
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	0.75

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Alcohol C11, ethoxylated	C11-Oxoalcohol, ethoxylated	Surfactant	127036-24-2	931-927-7	3.56
For the full composition, please see the confidential Annex.					

2.1.2.4 Information on technical equivalence

Two sources listed in 2.1.1.4 are technical equivalences:

- Technical Equivalence IPBC : EU-0017138-0000 for
  Location manufacturing site: Shanghai Hui long Chemicals Co., Ltd, Dengta Jiazhu Rd. 201815 District Shangai, China

- Technical Equivalence propiconazole : EU-0003416-0000 for
  Location manufacturing site : Jiangsu Seven continent Green Chemical Co. Ltd, North Area of Dongsha Chem-Zone - Zhangjiagang, Jiangsu, 215600, China

2.1.2.5 Information on the substance(s) of concern

The biocidal product contains a substance of concern: Alcohol C11, ethoxylated (N°CAS 127036-24-2). This substance participates to the product classification as H318, Eye dam. Category 1.

2.1.2.6 Type of formulation

ME- Micro emulsion

2.1.3 Hazard and precautionary statements

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

Classification	
Hazard category	Eye Dam 1 Skin Sens 1 Aquatic Acute cat. 1 Aquatic Chronic cat. 1
Hazard statement	H318 H317 H400 H410
Labelling	
Signal words	Danger
Hazard statements	Causes serious eye damage May cause an allergic skin reaction Very toxic to aquatic life with long lasting effects
Precautionary statements	P261 Avoid breathing spray. P280 **Wear protective gloves/protective clothing/eye protection/face protection** P305 + P351 + P338 **IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing** P310 **Immediately call a POISON CENTER/doctor** P273 **Avoid release to the environment** P391 **Collect spillage** P501 **Dispose contents/container in accordance with all local, national and international regulations**
Note	-
Risk mitigation measures	1. "Do not apply the product on wood which may come into contact with food, feedstuff or livestock" 2. "Contain permethrin (pyrethroids), may be lethal to cats. Cats must avoid contact with treated object/area" 3. The biocidal product may only be applied to wood, which will not be used above or close to surface waters.. 4. The 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. 5. Application should be conducted within a contained area on impermeable hard standing with bunding and any losses from the application of the product should be collected for reuse or disposal. 6. A non-biocidal topcoat must be applied on treated wood used outdoor, above ground (use class 3.1) to avoid leaching of active substances.

2.1.4 Authorised use

2.1.4.1 Use description

Table 1. Use # 1 – preventive treatment	
Product Type	PT 8 : wood preservatives
Where relevant, an exact description of the authorised use	The Axil 3000 P product is effective against wood-destroying insects including termites and wood destroying fungi (white rot and brown rot fungi) in preventive treatment.
Target organism (including development stage)	- Wood boring insects (representative insect: *Hylotrupes bajulus*, recently hatched larvae) - Termites (*Reticulitermes santonensis* de Feytaud) - White rot fungi (Coriolus versicolor)

<table>
<tr><td></td><td>- Brown rot fungi (Coniophora puteana, Poria placenta, Gloeophyllum trabeum)</td></tr>
<tr><td>Field of use</td><td>- Use class 1: situation in which the wood or wood-based product is inside a construction, not exposed to the weather and wetting
- Use class 2: situation in which the wood or wood-based product is under cover and not exposed to the weather (particularly rain and driven rain) but where occasional, but non persistent, wetting can occur
- Use class 3: situation in which wood or wood-based product is above ground and exposed to the weather (particularly rain). Use in use class 3 is limited to use class 3.1:
o 3.1: wood or wood-based products will not remain wet for long periods. Water will not accumulate</td></tr>
<tr><td>Application methods</td><td>The product AXIL 3000 P could be applied for a surface treatment by fully automated dipping (for all types of wood and use classes 1, 2 and 3.1) and automated spraying (for all types of wood for use class 1 and 2; for softwood only for use class 3.1)</td></tr>
<tr><td>Application rates and frequency</td><td>The application rate is 100 g/m² of the diluted product for surface application (fully automated dipping and automated spraying).
<table>
<tr><th>Application method</th><th>Use class</th><th>Dilution</th><th>Dilution factor</th><th>Type of wood</th></tr>
<tr><td>Automated spraying and fully automated dipping</td><td>1 and 2</td><td>10 %</td><td>10x</td><td>All</td></tr>
<tr><td>Automated spraying and fully automated dipping</td><td>3.1</td><td>10 %</td><td>10x</td><td>Softwood only</td></tr>
<tr><td>Fully automated dipping</td><td>3.1</td><td>19.2%</td><td>5.2x</td><td>Hardwood</td></tr>
</table></td></tr>
<tr><td>Category of users</td><td>Professional user (industrial application)[1]</td></tr>
<tr><td>Pack sizes and packaging material</td><td>Please see the relevant section.</td></tr>
</table>

2.1.4.2 Use-specific instructions for use

The product AXIL 3000 P could be applied for a surface treatment by fully automated dipping (for all types of wood and use classes 1, 2 and 3.1) and automated spraying (for all types of wood for use class 1 and 2; for softwood only for use class 3.1).

The fixation step, following the application is at minimum 4 hours.

The treated wood has to be dried during 24 to 48 hours in ventilated place.

Wood intended to be used in outdoors has to be protected by a resistant paint or varnish.

2.1.4.3 Use-specific risk mitigation measures

Appropriate and suitable personal protective equipment (PPE) is required: chemical resistant gloves and impermeable coverall:

[1] The relevant user category is industrial. In BE « industrial » user is not allowed, only « professional » user can be targeted.

- Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).
- Wear impermeable coverall during product handling phase (norms specified by the authorisation holder within the product information).

Contact with the skin is to be avoided as the product may produce an allergic reaction.

Do not combine different types of application.

Do not apply the product on wood which may come into contact with food, feedstuff or livestock

Contain permethrin (pyrethroids), may be lethal to cats. Cats must avoid contact with treated object/area.

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

The biocidal product may only be applied to wood, which will not be used above or close to surface waters.

The 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.

Application should be conducted within a contained area on impermeable hard standing with bunding and any losses from the application of the product should be collected for reuse or disposal.

A non-biocidal topcoat must be applied on treated wood used outdoor, above ground (use class 3.1) to avoid leaching of active substances.

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

First aid in general:
Move the affected person into fresh air. Keep warm and at rest. In case of suspected poisoning, you must immediately call a doctor. Tell the doctor that no specific antidote is known, a symptomatic treatment is necessary. NEVER give anything by the mouth to an unconscious person.

General safety and hygiene measures:
Observe the precautions generally taken with chemicals.

If inhaled:
In case of massive inhalation move the patient into the fresh air and keep warm and at rest.
If breathing is irregular or stopped, administer artificial respiration and call a doctor. Give nothing by the mouth.

In case of contact with eyes:
Wash thoroughly with soft, clean water during 15 minutes holding the eyelids open.
Regardless of the initial state, refer the patient to an ophthalmologist and show him the label.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

In case of skin contact:
In case of allergic reaction, seek a medical advice.

Remove contaminated clothing and shoes and wash thoroughly contaminated body parts and hair with soap and water. Destroy or thoroughly clean the soiled clothes and shoes before each re-use.

IF ON SKIN: Wash with plenty of water

In case of swallowing:
If the swallowed quantity is small (no more than one mouthful), rinse the mouth with water and consult a doctor.
Remain at rest. Do not induce vomiting.
Consult a doctor and show him the label.
In case of accidentally swallowing, call a doctor to judge the necessity for monitoring and for a subsequent treatment in hospital. Show the label.

Emergency measures to protect the environment:

Do not discharge the product into drains or into the environment. Prevent entry into waters or soil.

Contain spills by covering with absorbing material.
Store absorbing material used to absorb spills in drums for waste disposal.

Prevent all product entry into drains or waterways.

Place containers or drums for disposal of waste recovered in accordance with applicable regulations.

If the product contaminates waterways, lakes, rivers or drains, alert the competent authorities in accordance with regulatory procedures into force.

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

Completely empty containers. The product residue, washing water, packaging and any other waste related to the treatment should be considered as hazardous waste.

Recycle or dispose of waste in compliance with current legislation, preferably via a certified collector or company. Do not contaminate the ground or water with waste; do not dispose of waste into the environment.

Dispose of empty containers in an incinerator approved for chemicals by the competent authorities. Damaged containers should be placed in specially marked larger ones. Check possibilities of recycling large empty containers.

Codes of wastes (Decision 2001/573/EC; Directive 2006/12/EEC, Directive 94/31/EEC on hazardous waste): 030205 other wood preservatives containing dangerous substances.

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

Storage conditions: Keep container tightly closed in original package in a dry and well-ventilated place. Protect from light.

The contact with oxidizing agents has to be avoided.

At ambient temperature the product has a long term stability for 24 months and is stable under cold and accelerated storage conditions.

2.1.4.7 Use description

Table 2. Use # 2 – curative treatment	
Product Type	PT 8 : wood preservatives
Where relevant, an exact description of the authorised use	The Axil 3000 P product is effective against wood-destroying insects in curative treatment on softwood
Target organism (including development stage)	- Wood boring insects (representative insect: *Hylotrupes bajulus*, recently hatched larvae, *Anobium punctatum De Geer,* larvae)
Field of use	- In conditions of "Use class 1": situation in which the wood or wood-based product is inside a construction, not exposed to the weather and wetting - In conditions of "Use class 2": situation in which the wood or wood-based product is under cover and not exposed to the weather (particularly rain and driven rain) but where occasional, but non persistent, wetting can occur
Application methods	The product AXIL 3000 P could be applied by spraying or brushing or brushing and injection on softwood
Application rates and frequency	The application rate is 300 ml/m² for a product diluted at 35% in water
Category of users	Professional user
Pack sizes and packaging material	Please see the relevant section.

2.1.4.8 Use-specific instructions for use

For the professional user category, the product can be applied by spraying, brushing, brushing + injection for curative treatment with the application rate of 300 ml/m².

For injection the parameters are : 20 ml of diluted product/ hole, 3holes/meter, 9holes/m².

The fixation step, following the application is at minimum 4 hours.

The treated wood has to be dried during 24 to 48 hours in ventilated place.

2.1.4.9 Use-specific risk mitigation measures

Appropriate and suitable personal protective equipment (PPE) is required: chemical resistant gloves, and impermeable coverall:

- Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).
- Wear impermeable coverall during product handling phase (norms specified by the authorisation holder within the product information).

For spraying, an additional personal protective equipment – RPE with a protection factor of 4 is required.

- Wear protective respiratory equipment (RPE) with protection factor 4 during product handling phase (material to be specified by the authorisation holder within the product information).

Contact with the skin is to be avoided as the product may produce an allergic reaction.

Treatments performed by injection must always be combined with treatments applied by brushing

Do not apply the product on wood which may come into contact with food, feedstuff or livestock

Contain permethrin (pyrethroids), may be lethal to cats. Cats must avoid contact with treated object/area.

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

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

First aid in general:
Move the affected person into fresh air. Keep warm and at rest. In case of suspected poisoning, you must immediately call a doctor. Tell the doctor that no specific antidote is known, a symptomatic treatment is necessary. NEVER give anything by the mouth to an unconscious person.

General safety and hygiene measures:
Observe the precautions generally taken with chemicals.

If inhaled:
In case of massive inhalation move the patient into the fresh air and keep warm and at rest.
If breathing is irregular or stopped, administer artificial respiration and call a doctor. Give nothing by the mouth.

In case of contact with eyes:
Wash thoroughly with soft, clean water during 15 minutes holding the eyelids open.
Regardless of the initial state, refer the patient to an ophthalmologist and show him the label.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

In case of skin contact:
In case of allergic reaction, seek a medical advice.
Remove contaminated clothing and shoes and wash thoroughly contaminated body parts and hair with soap and water. Destroy or thoroughly clean the soiled clothes and shoes before each re-use.

IF ON SKIN: Wash with plenty of water

In case of swallowing:
If the swallowed quantity is small (no more than one mouthful), rinse the mouth with water and consult a doctor.
Remain at rest. Do not induce vomiting.
Consult a doctor and show him the label.
In case of accidentally swallowing, call a doctor to judge the necessity for monitoring and for a subsequent treatment in hospital. Show the label.

Emergency measures to protect the environment:

Do not discharge the product into drains or into the environment. Prevent entry into waters or soil.

Contain spills by covering with absorbing material.
Store absorbing material used to absorb spills in drums for waste disposal.

Prevent all product entry into drains or waterways.

Place containers or drums for disposal of waste recovered in accordance with applicable regulations.

If the product contaminates waterways, lakes, rivers or drains, alert the competent authorities in accordance with regulatory procedures into force.

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

Completely empty containers. The product residue, washing water, packaging and any other waste related to the treatment should be considered as hazardous waste.

Recycle or dispose of waste in compliance with current legislation, preferably via a certified collector or company. Do not contaminate the ground or water with waste; do not dispose of waste into the environment.

Dispose of empty containers in an incinerator approved for chemicals by the competent authorities. Damaged containers should be placed in specially marked larger ones. Check possibilities of recycling large empty containers.

Codes of wastes (Decision 2001/573/EC; Directive 2006/12/EEC, Directive 94/31/EEC on hazardous waste): 030205 other wood preservatives containing dangerous substances.

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

Storage conditions: Keep container tightly closed in original package in a dry and well-ventilated place. Protect from light.

The contact with oxidizing agents has to be avoided.

At ambient temperature the product has a long term stability for 24 months and is stable under cold and accelerated storage conditions.

2.1.5 General directions for use

2.1.5.1 Instructions for use

Please refer to 2.1.4.2

2.1.5.2 Risk mitigation measures

Please refer to 2.1.4.3

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

Please refer to 2.1.4.4

2.1.5.4 Instructions for safe disposal of the product and its packaging

Please refer to 2.1.4.5

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

Please refer to 2.1.4.6

2.1.6 Other information

The product is intended to be used on wood or wood-based products up to use class 3.2

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	25 L	HDPE	HDPE closure with PE gasket	professional	Yes
Drum	60 L	HDPE	HDPE closure with PE gasket	professional	Yes
Drum	220 L	HDPE	HDPE closure with PE gasket	professional	Yes
IBC (Intermediate Bulk Container)	640 L	HDPE	HDPE closure with PE gasket	professional	Yes
IBC	1000 L	HDPE	HDPE closure with PE gasket	professional	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

The whole list of data submitted by the applicant is included in the Annex 3.1.

2.1.8.2 Access to documentation

The applicant has submitted seven Letters of Access to granting access to the dossier of active substances:

- Permethrin: one from Lanxess Deutschland GmbH, and one from Tagros Chemicals India ltd.
- Tebuconazole: one from Lanxess Deutschland GmbH
- Propiconazole: one from Lanxess Deutschland GmbH, and one from JANSSEN PMP

- IPBC: one from Lanxess Deutschland GmbH, and one from TROY Chemical Company BV.

2.2 ASSESSMENT OF THE BIOCIDAL PRODUCT

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

Table 3. Use # 1 – Preventive treatment	
Product Type	PT 8 : wood preservatives
Where relevant, an exact description of the authorised use	The Axil 3000 P product is effective against wood-destroying insects including termites and wood destroying fungi (white rot and brown rot fungi) in preventive treatment.
Target organism (including development stage)	Hylotrupes bajulus L. – larvae – House longhorn beetle Lyctus brunneus – larvae – Powder post beetles Anobium punctatum De Geer – larvae – Common furniture beetle Reticulitermes sp. – adults- Termites Coniophora puteana – spores and spore producing structures – Wood rotting fungi Poria placenta – spores and spore producing structures – Wood rotting fungi Gloeophyllum trabeum – spores and spores producing structures – Wood rotting fungi Coriolus versicolor – spores and spore producing structures – Wood rotting fungi
Field of use	Indoor, outdoor Use class 1 to 3
Application methods	Automated spraying - The product application is operated in a closed system. Dipping - The product application is operated in an open system. [redacted]
Application rates and frequency	Automated spraying - 100 g/m² - 10% - 1 application of 1 hour Dipping - 100 g/m² - 19.2% - 1 application of 1 hour [redacted]
Category of users	Professional user (industrial)
Pack sizes and packaging material	Can /Tin - Plastic: HDPE - 25L Drum - Plastic: HDPE - 60L Drum - Plastic: HDPE - 220L IBC (intermediate bulk container) - Plastic: HDPE - 640L IBC (intermediate bulk container) - Plastic: HDPE - 1000L

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Organoleptic observations at 25°C and 20°C (amendment)	Formulation LAB2015_002 (1% permethrin, 0.75% propiconazole, 0.75% tebuconazole, 0.75% IPBC)	Transparent liquid	[redacted]
Colour at 20 °C and 101.3 kPa	Organoleptic observations at 25°C and 20°C (amendment)	Formulation LAB2015_002	Colorless (Gardner color number 1)	[redacted]
Odour at 20 °C and 101.3 kPa	Organoleptic observations at 25°C and 20°C (amendment)	Formulation LAB2015_002	Characteristic odor	[redacted]
Acidity / alkalinity	CIPAC MT 75.3 (2009) 20°C	Formulation LAB2015_002, undiluted and diluted to 1% in water	Lab2015_002 pure: pH= 6.23 1% dilution: pH = 7.27	[redacted]
Relative density / bulk density	ABNT NBR 13826 (2008) OECD 109 (2012): amendment	Formulation LAB2015_002	Density = 1.0189 $g.cm^{-3}$	[redacted]
Storage stability test – **accelerated storage**	OECD 113 (1981) CIPAC MT 46-3 (2009) 54+-2°C, 14 days HPLC/DAD for a.s. dosages	Formulation LAB2015_002	Permethrin: T_0=1.03% T_{2w}=1.03% No variation of active substance concentration Tebuconazole: T_0=0.77% T_{2w}=0.77% No variation of active substance concentration Propiconazole : T_0=0.76% T_{2w}=0.76% No variation of active substance concentration	[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			IPBC : T_0=0.75% T_{2w}=0.73% Variation of 2.7% of active substance concentration (all concentrations of active substances at the beginning of the stability study are within the authorized concentration variation of declared concentrations)	
Storage stability test – **long term storage at ambient temperature**	Storage at ambient temperature HPLC/UV for a.s. dosage	AXIL3000 P, batch N° SC1130539 1% permethrin, 0.75% IPBC, 0.75% propiconazole, 0.75% tebuconazole Analyzed on the commercial packaging: HDPE	Permethrin: T_0=1.03% T_{2y}=1.02% Variation of 1% of active substance concentration Tebuconazole: T_0=0.78% T_{2y}=0.75% Variation of 4% of active substance concentration Propiconazole : T_0=0.74% T_{2y}=0.74%	[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			No variation of active substance concentration IPBC : T_0=0.75% T_{2y}=0.72% Variation of 4% of active substance concentration (all concentrations of active substances at the beginning of the stability study are within the authorized concentration variation of declared concentrations)	
Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3 (2009) 0°C at 7 days	Formulation LAB2015_002	Formation of 0.1 mL of solid matter at the bottom of test tube. After 24 days at ambient temperature, the solid matter is decreased to lower than 0.05 mL.	[redacted]
Effects on content of the active substance and technical characteristics of the biocidal product - **ligh**t	Avoid direct exposition of the product to sunlight	-	-	[redacted]
Effects on content of the active substance and technical	Waived	-	-	[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
characteristics of the biocidal product – **temperature and humidity**				
Effects on content of the active substance and technical characteristics of the biocidal product - reactivity towards container material	-	-	-	[redacted]
Wettability	Waived	-	-	[redacted]
Suspensibility, spontaneity and dispersion stability	Waived	-	-	
Wet sieve analysis and dry sieve test	Waived	-	-	[redacted]
Emulsifiability, re-emulsifiability and emulsion stability	CIPAC MT 36.3 (2009)	Formulation LAB2015_002, diluted at 20% and 1%	<u>Emulsion stability:</u> 20% diluted LAB2015_002 after 30min: 6.69 ml froth formed, no oil and cream detected 1% diluted LAB2015_002 after 30min: no solid matter, oil or cream detected <u>Re-Emulsification stability:</u> 20% diluted LAB2015_002 after 30min: 17.58 ml of foam, no solid matter, oil or cream detected 1% diluted LAB2015_002 after 30min: 6.76	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			ml of foam, no solid matter, oil or cream detected <u>Final Emulsion stability:</u> 20% diluted LAB2015_002 after 4.52 ml of foam formed, no solid matter, oil or cream detected 1% diluted LAB2015_002: no foam, solid matter, oil or cream detected	
Disintegration time	Waived	-	-	[redacted]
Particle size distribution, content of dust/fines, attrition, friability	Waived	-	-	
Persistent foaming	CIPAC MT 47.2 (2009)	Formulation LAB2015_002 (1% permethrin, 0.75% propiconazole, 0.75% tebuconazole, 0.75% IPBC)	<u>20% diluted</u> : 10 seconds : 63.91 mL 1 minute : 40.38 mL After 3 minutes : no foaming <u>1% diluted</u> : No foam after 10 s	[redacted]
Flowability/Pourability/Dustability	Waived	-	-	[redacted]
Burning rate — smoke generators	Waived	-	-	
Burning completeness — smoke generators	Waived	-	-	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Composition of smoke — smoke generators	Waived	-	-	[redacted]
Spraying pattern — aerosols	Waived	-	-	[redacted]
Physical compatibility	Waived	-	-	
Chemical compatibility	Avoid contact with oxidizing agents			
Degree of dissolution and dilution stability	Waived	-	-	[redacted]
Surface tension	EC method A.5 20°C+-0.5°C	Formulation LAB2015_002, diluted at 20% in water	Surface Tension = 25.90 $mN.m^{-1}$	[redacted]
Viscosity	OECD 114, 2012	Formulation LAB2015_002	Kinematic viscosity = 6.13 mm^2s^{-1} at 20°C = 3.49 mm^2s^{-1} at 40°C	[redacted]

Conclusion on the physical, chemical and technical properties of the product
The biocidal product AXIL 3000 P is a colourless transparent liquid with characteristic odour. The pH of the undiluted product is 6.23 and diluted to 1% is 7.27. The relative density is D_4^{20} = 1.0189. At ambient temperature the product has a long term stability for 24 months and is stable under cold and accelerated storage conditions. The product should be protected from direct exposition to light. At 20°C the surface tension is 38.80 mN/m and the viscosity is 6.13 mm^2s^{-1}. At 40°C the viscosity is 4.39 mm^2s^{-1}. Physical and compatibility with other products is not relevant. The contact with oxidizing agents has to be avoided.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	Waived	-	-	[redacted]
Flammable gases	Waived	-	-	
Flammable aerosols	Waived	-	-	
Oxidising gases	Waived	-	-	[redacted]
Gases under pressure	Waived	-	-	
Flammable liquids	CIPAC MT 12.3 (2009) Dir 92/69/EEC (O.J. L383 A)A.9 (1992) Pensky-Martens Closed-cup tester method (9.42.10^4 Pa)	Formulation LAB 2015_002	Flash point > 98.9°C (the boiling temperature of the product)	[redacted]
Flammable solids	Waived	-	-	[redacted]
Self-reactive substances and mixtures	Waived	-	-	
Pyrophoric liquids	Waived	-	-	[redacted]
Pyrophoric solids	Waived	-	-	
Self-heating substances and mixtures	Waived	-	-	
Substances and mixtures which in contact with water emit flammable gases	Waived	-	-	[redacted]
Oxidising liquids	Waived	-	-	[redacted]
Oxidising solids	Waived	-	-	
Organic peroxides	Waived	-	-	
Corrosive to metals	Waived	-	-	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Auto-ignition temperatures of products (liquids and gases)	Waived	-	-	[redacted]
Relative self-ignition temperature for solids	Waived	-	-	[redacted]
Dust explosion hazard	Waived	-	-	[redacted]

Conclusion on the physical hazards and respective characteristics of the product
The flashpoint of the solution is higher than 98.9°C. The product has no self-reacting properties and does not react with air and is not self-heating since it is a liquid at room temperature. It is not able to react with metals and is not corrosive. The product is not oxidizing nor explosive. No classification related to physico-chemical risks is necessary.

2.2.4 Methods for detection and identification

The applicant has submitted two series of validations. Both of them are resumed in the table below, classified by active substance.

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Permethrin	Method based on SOP-M 0048 – 2014 and ANBT 14029 (2005) HPLC with UV/DAD detector	3 fortifications with 6 samples each one : 409.39 $mg.L^{-1}$ 500.70 $mg.L^{-1}$ 593.61 $mg.L^{-1}$	The calibration curve show a linearity in the range from 201.40 $mg.L^{-1}$ to 825.57 $mg.L^{-1}$, with the correlation coefficient > 0.99	There is no interfering peaks at the retention time of active ingredients	98.23 – 101.94	99.62	1.16	LOD:0.04% LOQ:0.12%	[redacted]
Permethrin	HPLC with UV/DAD detector	5 fortifications : 60% 80% 100% 120% 140%	The calibration curve show a linearity in the range from 0.3745 $mg.mL^{-1}$ to 0.9082 $mg.mL^{-1}$, with the correlation coefficient > 0.99	There is no interfering peaks at the retention time of active ingredients	97.8 – 99.4	98.6	0.76	LOD: 0.0438 mg/mL LOQ: 0.0946 mg/mL	[redacted]
Tebuconazole	Method based on SOP-M 0048 –	3 fortifications with 6 samples each one: 205.11 $mg.L^{-1}$	The calibration curve show a	There is no interfering peaks at the retention	98.44 - 101.99	101.06	0.99	LOD:0.001% LOQ:0.004%	[redacted]

	2014 and ANBT 14029 (2005) HPLC with UV/DAD detector	299.76 mg.L^{-1} 396.78 mg.L^{-1}	linearity in the range from 55.72 mg.L^{-1} to 611.97 mg.L^{-1}, with the correlation coefficient > 0.99	time of active ingredients					
Tebuconazole	HPLC with UV/DAD detector	5 fortifications : 60% 80% 100% 120% 140%	The calibration curve show a linearity in the range from 0.2706 mg.mL^{-1} to 0.6861 mg.mL^{-1}, with the correlation coefficient > 0.99	There is no interfering peaks at the retention time of active ingredients	98.3 – 99.7	99.2	1.76	LOD:0.0296 mg/mL LOQ:0.0711 mg/mL	[redacted]
Propiconazole	Method based on SOP-M 0048 – 2014 and ANBT 14029 (2005) HPLC with UV/DAD detector	3 fortifications with 6 samples each one: 211.74 mg.L^{-1} 306.06 mg.L^{-1} 403.37 mg.L^{-1}	The calibration curve show a linearity in the range from 57.71 mg.L^{-1} to 635.21 mg.L^{-1}, with the correlation coefficient > 0.99	There is no interfering peaks at the retention time of active ingredients	99.60 – 101.94	101.32	0.68	LOD:0.002% LOQ:0.006%	[redacted]

Propiconazole	HPLC with UV/DAD detector	5 fortifications : 60% 80% 100% 120% 140%	The calibration curve show a linearity in the range from 0.2678 $mg.mL^{-1}$ to 0.7380 $mg.mL^{-1}$, with the correlation coefficient > 0.99	There is no interfering peaks at the retention time of active ingredients	96.3 – 97.8	97.0	2.09	LOD:0.0370 mg/mL LOQ:0.0823 mg/mL	[redacted]
IPBC	Method based on SOP-M 0048 – 2014 and ANBT 14029 (2005) HPLC with UV/DAD detector	3 fortifications with 6 samples each one: 204.14 $mg.L^{-1}$ 300.56 $mg.L^{-1}$ 392.04 $mg.L^{-1}$	The calibration curve show a linearity in the range from 55.44 $mg.L^{-1}$ to 609.64 $mg.L^{-1}$, with the correlation coefficient > 0.99	There is no interfering peaks at the retention time of active ingredients	98.35 – 101.99	100.56	1.14	LOD:0.16% LOQ:0.52%	[redacted]
IPBC	HPLC with UV/DAD detector	5 fortifications : 60% 80% 100% 120% 140%	The calibration curve show a linearity in the range from 0.2797 $mg.mL^{-1}$ to 0.6826 $mg.mL^{-1}$,	There is no interfering peaks at the retention time of active ingredients	98.4 – 100.00	99.1	1.31	LOD:0.0329 mg/mL LOQ:0.0815 mg/mL	[redacted]

			with the correlation coefficient > 0.99						

Analytical methods for monitoring, for detection in soil, in air, in water, in animal and human body fluids and tissues and residues in food and feeding stuff are described and defined in the CARs of active substances.

Conclusion on the methods for detection and identification of the product
The content in active substances permethrin, tebuconazole, propiconazole and IPBC can be determined in the product using a validated HPLC with an UV/DAD detector. The identity of the analyte is confirmed by comparison of the retention times. The standard regression is linear and the method is repeatable. The mean recovery rates are in the range of 98.6 – 99.62% for permethrin; 99.2-101.06% for tebuconazole, 97 – 101.32% for propiconazole and 99.1-100.56% for IPBC. The limit of quantification (LOQ) is 0.12% for permethrin, 0.001% for tebuconazole, 0.002% for propiconazole and 0.16% for IPBC.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

The product AXIL 3000 P is a concentrated micro-emulsion (ME) for professional use only in wood preservation (PT8). AXIL 3000 P contains 4 active substances with the following concentrations w/w: Permethrin 1%, Propiconazole 0.75%, Tebuconazole 0.75% and IPBC 0.75%.

The product is intended to be used for preventive treatment against fungi and insects for classes 1, 2, 3.1 and 3.2 and can be applied by surface treatment (short dipping, aspersion) [redacted] The targeted wood includes construction wood used outdoor. A top coat is required to be applied after treatment with the product.

Following the MAC application, the product is also intended to be used in curative treatment against wood-destroying insects.

The efficacy claimed by the applicant is "effective against wood rotting basidiomycetes (brown and white rot fungi), xylophage insects and termites in preventive treatment of wood construction". The product is claimed to be efficacious against wood-destroying insects *(Hylotrupes bajulus L., Lyctus brunneus and Anobium punctatum De Geer)* in curative treatment. According to the applicant, for preventive treatment, the product AXIL 3000 P is to be diluted 1.65% to 19.2% w/w with water according to the application method and type of wood. For curative treatment, the product is to be applied diluted at 35% with water, by spraying, injection and brushing with an application rate of 300g/m² of wood. The table below resumes the claim matrix for the product AXIL 3000 P.

Table 2.2.5.1.1 Categories and codes for product for AXIL 3000 P.

User category	Professional user (Industrial application)	A.20
Wood category	Softwood and hardwood	B.10, B.20
Wood product	Solid wood	C.10
Application aim	Preventive treatment Curative treatment	D.40 D.50
Field of use	Use class 1 to 3 included	E.10 – E.30

Method of application	Surface treatment (aspersion and short dipping) [redacted]	F.12, F.14, [redacted]
Target organisms	Brown and white rot fungi, xylophage insects and termites (subterranean)	G.10, G.11, G.30, G.51

Due to the presence of tebuconazole in the product, its use for treatment of wood inside housing areas is not recommended (see CAR for inclusion on to Annex I doc.1).

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

Axil 3000 P is intended to be used in order to protect wood for the following fields of use:

- Use class 1: situation in which the wood or wood-based product is inside a construction, not exposed to the weather and wetting
- Use class 2: situation in which the wood or wood-based product is under cover and not exposed to the weather (particularly rain and driven rain) but where occasional, but non persistent, wetting can occur
- Use class 3: situation in which wood or wood-based product is above ground and exposed to the weather (particularly rain). The use class 3 is subdivided in two sub-categories, and the applicant claims both of them:
    - 3.1: wood or wood-based products will not remain wet for long periods. Water will not accumulate
    - 3.2: wood or wood-based products will remain wet for long periods. Water may accumulate.

Axil 3000P is also intended to be used in curative treatment.

The target organisms claimed for the product AXIL 3000 P are wood-boring insects (tested specie is *Hylotrupes bajulus:* according to the Transitional Guidance on Efficacy Assessment for Product Type 8 Wood Preservatives (March 2015), which was in force when the application for authorisation of AXIL 3000P was submitted, efficacy against *H. bajulus* is sufficient to cover a general claim against wood boring beetles for preventive treatment.), termites (tested specie is *Reticulitermes santonensis*) and fungi, including white rot and brown rot fungi (tested organisms are *Coriolus versicolor*, *Gloeophyllum trabeum*, *Coniophora puteana* and *Poria placenta*).

2.2.5.3 Effects on target organisms, including unacceptable suffering

The following information is available for active substances from the Assessment Reports for inclusion to Annex I for each active substance.

Propiconazole (CAS N° 60207-90-1)

Propiconazole may be used in the preventive treatment of wood against fungi. Propiconazole is a triazole molecule acting by inhibition of demethylation during the ergosterol biosynthesis.

Tebuconazole (CAS N°10734-96-3)

Tebuconazole has been evaluated for its use in wood preservation (Product Type 8 of the Biocidal Products Directive) up to use class 4a and 4b. As a fungicide,

tebuconazole interferes with basic metabolism of the fungal cell wall and contents (see also propiconazole, the other triazole molecule). In combination products e.g., with propiconazole, especially well-balanced efficacy against a broad range of wood rotting fungi can be achieved combined with minimising the amounts of each active.

IPBC (CAS N° 55406-53-6)

IPBC is a fungicide used for wood preservation (PT8) up to and including use class 3. IPBC is active against wood rotting and wood disfiguring fungi by interfering with the cell membrane permeability. IPBC has a carbamate structure. The target sites of carbamates in fungi are cell membrane permeability and fatty acids (according to the information provided by FRAC (Fungicide Resistance Action Committee). IPBC is, in most cases, combined in the formulated products with other active substances like other fungicides (propiconazole, tebuconazole, carbendazim) or insecticides, e.g. permethrin.

Permethrin (CAS N°52645-53-1)

Permethrin has an efficacy against wood-destroying insects (including termites) during both larval and adult life-cycle stages. Permethrin is included into pyrethroids molecule family, responsible for a continuous nerve stimulation of insects ingesting permethrin treated wood, resulting in a lethal effect. From the four active substances present in this biocidal product, permethrin is the only demonstrating an insecticide effect.

The biocidal product AXIL 3000 P, containing the four active substances described above, is intended to be used in preventive treatment against fungi (basidiomycetes) and wood boring insects, including termites.

2.2.5.4 Mode of action, including time delay

The following information is available for active substances from CAR reports for the active substances contained in the AXIL 3000 P product.

Propiconazole (CAS N° 60207-90-1)

Propiconazole-based products can be applied by vacuum-pressure, double-vacuum, spraying, brushing and industrial dipping for constructions outdoors. Wood indoors may be treated by brushing, spraying and professional injection. The targeted fields of use are use class 2 and use class 3.

Tebuconazole (CAS N°10734-96-3)

Tebuconazole – based products can be applied by vacuum pressure, double vacuum, automated spraying, flow coating, dipping and spraying and in situ outdoors brushing. As mentioned in the Assessment Report for inclusion to Annex I, Tebuconazole is not recommended for treatment of wood inside housing areas (with the exception of window frames and external doors, which will usually be treated on or before installation).

IPBC (CAS N° 55406-53-6)

IPBC- containing products can be applied by vacuum pressure, double vacuum, automated spraying, flow coating, dipping and spraying, in situ outdoors brushing.

Permethrin (CAS N°52645-53-1)

Permethrin-based products are intended to be used by automated spraying, vacuum pressure, double vacuum pressure, flow coating and dipping treatment.

According to the applicant and the label claim, the product AXIL 3000 P can be applied by the short dipping and aspersion for surface treatment and by vacuum pressure and double vacuum pressure for penetrative treatment. The application rate depends on the targeted use class and organisms. The fixation step, following the application is at minimum 4 hours. The treated wood has to be dried during 24 to 48 hours in ventilated place. Wood intended to be used in outdoors has to be protected by a resistant paint or varnish.

2.2.5.5 Efficacy data

To support the claims for product AXIL 3000 P, the applicant has submitted two tests to prove the efficacy of the product against wood rot fungi, four tests to prove the efficacy against wood boring insects and four tests to prove the efficacy against termites in particular.

For the insecticide (including termites) claims, the applicant has tested the formulation named [redacted], containing 2% of permethrin, the only active substance responsible for insecticide action. Applicant has provided an analysis report ([redacted]) proving that the concentration of permethrin in the tested formulation is within the variation admitted to not affect the efficacy.

For the fungicide claims, the tested formulation is [redacted], containing 1% of IPBC, propiconazole, tebuconazole and permethrin. Applicant has provided an analysis report ([redacted]) proving that the concentration of permethrin, propiconazole, tebuconazole and IPBC in the tested formulation is within the variation admitted to not affect the efficacy.

According to the EN 599 norm, Annex A, the application rates can be derived from tested formulations different from the product asking the authorization, with the condition that the variation in co-formulants between the products does not affect the efficacy.

To prove the insecticide action for surface treatment for use class 1,2 and 3, the tests n° [redacted] have been submitted. As proposed in the EN 599-1 (2009), the test follows EN 46 norm, carried after ageing procedure EN 73 for use class 1 and 2; and EN 84 for use class 3, on recently hatched larvae of *Hylotrupes bajulus*. This insect is considered to present the most resistance to permethrine and thus is considered as insect of reference to prove the insecticide action. The application method is brushing procedure. However, eCA Belgium is of opinion that this method could be extended to all usual surface treatment, such as short dipping and aspersion, with the condition to respect the application rate. The results show 100% mortality at the end of the test in comparison with the positive control, where almost 100% of larvae remains alive at the end of the test.

To prove the insecticide action for penetrating treatment for use class 1,2 and 3, the tests n° [redacted] have been submitted. As proposed in the EN 599-1 (2009), the test follows EN 47 norm, carried after ageing procedure EN 73 for use class 1 and 2; and EN 84 for use class 3, on recently hatched larvae of *Hylotrupes bajulus*. The application method is vacuum pressure treatment. The results show 100% mortality at the end of the test in comparison with the positive control, where almost 100% of larvae remains alive at the end of the test. For use class 1 and 2 the preservative retention mean is 0.83 kg/m³ and for use class 3 it is 0.85 kg/m³.

To prove the termiticide action for surface treatment for use class 1,2 and 3 the tests n° [redacted] have been submitted. As proposed in the EN 599-1 (2009), the test follows EN 118 norm, carried after ageing procedure EN 73 for use class 1 and 2; and EN 84 for use class 3, on *Reticulitermes santonensis* de Feytaud . The application method is brushing procedure. The results show no damage > 1 for 5 treated samples and damage = 2 for only

one treated sample. The positive controls demonstrate damage rate of 4, meaning heavy attack.

To prove the termiticide action for penetrating treatment for use class 1, 2 and 3 the tests n° [redacted] have been submitted. As proposed in the EN 599-1 (2009), the test follows EN 117 norm, carried after ageing procedure EN 73 for use class 1 and 2; and EN 84 for use class 3, on *Reticulitermes santonensis* de Feytaud. The application method is vacuum pressure treatment. The results show no damage rating >1 at the application rate of 4.8 kg/m³ for all use classes claimed by the applicant.

To prove the fungicide action for penetrating treatment for use class 2, the test n° [redacted] has been submitted. For the use class 3, the test n° [redacted] has been submitted. As proposed in the EN 599-1 (2009), the test follows EN 113 norm, carried after ageing procedure EN 73 for use class 2; and EN 84 for use class 3, on *Coniophora puteana, Poria placenta, Gloeophyllum trabeum* and *Coriolus versicolor*. The application method is vacuum pressure treatment. According to the results, the mid toxic value for the most tolerant fungus for pine wood is between 3.225 kg/m³ (*Poria placenta*, from the test n° 32/07/9051/01) and for beech wood is 7.215 kg/m³ (*Coriolus versicolor*, from the test n° 32/07/9051/02).

To prove the insecticide curative action, the test n° [redacted] has been submitted against *Anobium punctatum*. As proposed in the EN 14128, the test follows EN 370 norm, carried after ageing procedure EN 73. The EN 370 norm is preferred here because the product to be tested is an aqueous solution and do not penetrated deeply in the wood, by comparison with the solvent-based products. The EN 73 procedure is the only used in combination with the norm EN 370, in the aim to reflect the better a possible ageing of the wood in service. The application method is brushing application. The results show in average 0 hatched beetles from the 72 initially present larvae in the sample treated with 300 g/m² of the ready to use formulation.

Additionally, to prove the insecticide curative action against *Hylotrupes bajulus* by surface treatment the test n° [redacted] has been submitted. As proposed in the EN 14128 norm, it follows the EN 1390 norm, without ageing procedure. The application method is the brushing procedure. Results show in average 90% of mortality, with, however, 2 samples demonstrating 67% of mortality. These two mortality values are below the threshold of 80% specified by the EN 14128 for the EN 1390 norm.

The table below summarize the principal information of the tests provided by the applicant.

Table 2.2.5.5.1 summary of experimental data provided by the applicant

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use and method of application envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Insecticide	*E.10* *E.20* *F.14* *F.12*	[redacted]	*Hylotrupes bajulus* (recently hatched larvae)	EN 46 after EN 73 ageing procedure	Brushing procedure Concentration of the product tested: 5% w/w Retention permethrin : 0.1 g/m² Solution retention: 100 g/m²	100% mortality at the end of the test	[redacted]
Insecticide	*E.20* *E.30* *F.14* *F.12*	[redacted]	*Hylotrupes bajulus* (recently hatched larvae)	EN 46 after EN 84 ageing procedure	Brushing procedure Concentration of the product tested: 5% w/w Retention permethrin : 0.1 g/m² Solution retention: 100 g/m²	100% mortality at the end of the test	[redacted]
Insecticide	*E.10* *E.20* *F.30*	[redacted]	*Hylotrupes bajulus* (recently hatched larvae)	EN 47 after EN 73 ageing procedure	Vacuum pressure treatment Concentration of the product tested: 0 – 0.33% w/w Solution retention: 0 – 2.2 kg/m³	100% mortality at the end of the test with the product retention rate of 0.83 kg/m³	[redacted]

Insecticide	*E.20* *E.30* *F.30*	[redacted]	*Hylotrupes bajulus* (recently hatched larvae)	EN 47 after EN 84 ageing procedure	Vacuum pressure treatment Concentration of the product tested: 0 – 0.33% w/w Solution retention: 0 – 2.3 kg/m³	100% mortality at the end of the test with the product retention rate of 0.85 kg/m³	[redacted]
Termiticide	*E.10* *E.20* *F.12* *F.14*	[redacted]	*Reticulitermes santonensis* de Feytaud	EN 118 after EN 73 ageing procedure	Brushing procedure Concentration of the product tested: 5% w/w Solution retention: 200 g/m²	No damage > 1 (except only one sample) for the retention rate of 200 g/m²	[redacted]
Termiticide	*E.20* *E.30* *F.12* *F.14*	[redacted]	*Reticulitermes santonensis* de Feytaud	EN 118 after EN 84 ageing procedure	Brushing procedure Concentration of the product tested: 5% w/w Solution retention: 200 g/m²	No damage > 1 (except only one sample) for the retention rate of 200 g/m²	[redacted]
Termiticide	*E.10* *E.20* *F.30*	[redacted]	*Reticulitermes santonensis* de Feytaud	EN 117 after EN 73 ageing procedure	Vacuum pressure treatment Concentration of the product tested: 0 – 0.93% w/w Solution retention: 0 – 6.40 kg/m³	The lowest concentration with no damage >1 is 0.71% w/w (corresponding to 4.83 kg/m³ retention rate) The next lowest concentration is 0.55 % w/w (corresponding to 3.89 kg/m³)	[redacted]
Termiticide	*E.20* *E.30*	[redacted]	*Reticulitermes santonensis* de Feytaud	EN 117 after EN 84 ageing procedure	Vacuum pressure treatment	The lowest concentration with no damage >1 is	[redacted]

	F.30				Concentration of the product tested: 0 – 0.93% w/w Solution retention: 0 – 6.5 kg/m³	0.71% w/w (corresponding to 4.79 kg/m³ retention rate) The next lowest concentration is 0.55 % w/w (corresponding to 3.88 kg/m³)	
Fungicide	*E.20* *F.30*	[redacted]	*Coniophora puteana* *Poria placenta* *Gloeophyllum trabeum* *Coriolus versicolor*	EN 113 after EN 73 ageing procedure	Vacuum pressure treatment Concentration of the product tested for pine wood: 0 – 0.59% w/w Concentration of the product tested for beech wood: 0 – 1.80% w/w Solution retention for pine wood: 0 - 4.4 kg/m³ Solution retention for beech wood: 0 – 11.7 kg/m³	The m.t.v for *Coniophora puteana* is 2.8 kg/m³ (tested formulation concentration 0.37% w/w) The m.t.v for *Poria placenta* is between 3.46 and 3.04 kg/m³ (tested formulation concentration 0.44 - 0.39% w/w) The m.t.v for *Gloeophyllum trabeum* is 2.75 kg/m³ (tested formulation concentration 0.37% w/w) The m.t.v for *Coriolus versicolor* is between 7.77 and 6.66 kg/m³ (tested formulation concentration 1.17 - 1.03% w/w)	[redacted]

Fungicide	*E.20* *E.30* *F.30*	[redacted]	*Coniophora puteana* *Poria placenta* *Gloeophyllum trabeum* *Coriolus versicolor*	EN 113 after EN 84 ageing procedure	Vacuum pressure treatment Concentration of the product tested for pine wood: 0 – 0.59% w/w Concentration of the product tested for beech wood: 0 – 1.80% w/w Solution retention for pine wood: 0 – 4.4 kg/m³ Solution retention for beech wood: 0 – 11.7 kg/m³	The m.t.v for *Coniophora puteana* is 2.87 kg/m³ (tested formulation concentration 0.37% w/w) The m.t.v for *Poria placenta* is between 3.42 and 3.03 kg/m³ (tested formulation concentration 0.44 - 0.39% w/w) The m.t.v for *Gloeophyllum trabeum* is 2.88 kg/m³ (tested formulation concentration 0.37% w/w) The m.t.v for *Coriolus versicolor* is between 7.74 and 6.69 kg/m³ (tested formulation concentration 1.17 - 1.03% w/w)	[redacted]
Insecticide Curative	*F.10* *F.11* *F.20*	[redacted]	*Anobium punctatum (De Geer)*	EN 370 after EN 73 ageing procedure	Brushing procedure Solution retention: 300 g/m²	No hatched larvae or beetles at the end of the test	[redacted]
Insecticide Curative	*F.10* *F.11* *F.20*	[redacted]	*Hylotrupes bajulus*	EN 1390 (softwood)	Brushing procedure Concentration of the product tested: 100% w/w	90% mortality in average at the end of the test, vs 0% mortality in untreated controls.	[redacted]

					Solution retention: 300 ml/m²	2 samples show a mortality of 67%	

Tests carried according to the EN 46 protocol after both procedure ageing EN 73 and EN 84 show an efficacy against wood boring insects at the retention rate of 100 g/m² of the tested formulation (2% permethrin), diluted at 5% w/w. From this, the BRV for **insecticide action for the product Axil 3000 P (1% permethrin) in surface treatment is 10 g/m²**.

Tests carried according to the EN 47 protocol after both procedure ageing EN 73 and EN 84 show an efficacy against wood boring insects at the retention rate of 0.85 kg/m³ of tested formulation (2% permethrin). From this, the BRV for **insecticide action for the product Axil 3000 P in penetrative treatment is 1.7 kg/m³[2]**.

Tests carried according to the EN 118 protocol after both procedure ageing EN 73 and EN 84 **show an efficacy** against termites at the retention rate of 200 g/m² of the tested formulation (2% permethrin), diluted at 5% w/w. During the peer review process, it was pointed out that according the EN 599 point 5.2.7 open the possibility for dose reduction, but only when supported by additional evaluation method. It is why the applicant has submitted a field test IRG/WP 18-10931 to support the claimed application rate. As the test demonstrates the efficacy against non-European wood (Kempas, Koompassia malaccensis) and termite (Coptotermes curvignathus) species at 5% dilution of the product requesting the authorisation, half the concentration that will be authorised (10%), it should leave a safety margin for inter-species variation concerning wood and termites. The product AXIL 3000 P is thus effective against termites in surface treatment with application rate of 10 g/m².

Tests carried according to the EN 117 protocol after both procedure ageing EN 73 and EN 84 show an efficacy against termites at the retention rate situated between 3.9 and 4.8 kg/m³ of tested formulation (2% permethrin). From this, the BRV for **termiticide action for the product Axil 3000 P in penetrative treatment is 9.6 kg/m³**.

Tests carried according to the EN 113 protocol after both procedure ageing EN 73 and EN 84 on the tested formulation (1% of each active substance) show an efficacy against fungi at the m.t.v = 3.225 kg/m³ for the softwood and at the m.t.v = 7.215 kg/m³ for the hardwood. From this, the mid toxic value for the **fungicide action for the product Axil 3000 P in penetrative treatment is 4.3 kg/m³ for the pine wood and 9.6 kg/m³ for the beech wood[1].** As explained in EN 599-1:2009 norm, at 5.2.15, in order to derive the critical value, the biological reference value in grams per square meter shall be deemed to be equivalent to twice the biological reference value established in kilograms per cubic metre in the EN 113 test. From this, the toxic value for the **fungicide action for the product Axil 3000 P in surface treatment is 8.6 g/m² for the pine wood and 19.2 g/m² for the beech wood**.

Tests carried according to the EN 370 protocol (curative efficacy against *Anobium punctatum*) show efficacy against these insects at the retention rate of 300 g/m² of tested formulation (0.35% permethrin). For the curative action against Hylotrupes bajulus, the test carried according to the EN 1390 norm show efficacy against these insects at the retention rate of 300 ml/m² of the tested formulation (0.35% permethrin). From this, the BRV for **insecticide curative action for the product AXIL 3000 P (containing 1% of permethrin) in surface treatment is in average 104,89 ml/m².** The claimed product application rate is 300 ml/m², with the product diluted at 35%. Based on the application rate calculated from the submitted tests, the product can be indeed used with the claimed dilution and application rate. The average values of larvae emergency (for *Anobium punctatum*) or larvae mortality (*Hylotrupes bajulus*) show a sufficient efficacy to claim the curative insecticide action.

[2] The penetrative treatment cannot, however be authorized at this stage, even if the efficacy is proven. For further details, please refer to the eco-toxicological assessment.

The applicant has submitted the following dilution rates according to the use class and wood type.

Table 2.2.5.5.2 Summary of efficacious retention rates submitted by the applicant.

Use class	Type of wood	Critic values for surface treatment	Critic values for penetrative treatment (Kg/m³)	
			Without termites	With termites
Use class 1	All	10 g/m²	1.7	9.6
Use class 2	All	10 g/m²	4.3	9.6
Use class 3.1	Softwood	10 g/m²	4.3	9.6
	Hardwood	19.2 g/m²	9.6	9.6
Use class 3.2	Softwood	/	4.3	9.6
	Hardwood	/	9.6	9.6
Curative	Softwood	300 ml/m² (diluted at 35%)	-	

Since the values calculated from the submitted efficacy tests are equal or very slightly below the values (less than 10%) of retention rate proposed by the applicant, the proposed application doses are accepted.

The claimed consumption of the product AXIL 3000 P is 90 to 110 g/m² (average 100 g/m²) or 500 – 600 kg/m³, according to the wood type. Based on the application rates calculated from the submitted tests, the following dilutions are accepted in the aim to reach the claimed consummation:

- Use class 1 and 2, surface treatment : product diluted at **10%** in water (dilution factor 10 times)
- Use class 3.1, surface treatment: product diluted at **10%** in water for softwood (dilution factor 10 times) and at **19.2%** for hardwood (dilution factor 5.2 times)
- Use class 1, 2, 3.1, 3.2, penetrative treatment[2]: product diluted at 1.65% in water for softwood (600 kg/m³) and at 1.92 % in water for hardwood (500 kg/m³). The product shall be dosed by an automatic pump in a system vacuum pressure. The dilution can be deemed to be **2%** (dilution factor 50 times). This is an indicative value, that shall be adapted according the type of wood, the product absorption ability and inherent parameters of vacuum pressure systems.
- Curative treatment: product diluted at **35%** in water, application rate 300 ml/m²

The final instructions for use concerning the dilutions and application rates are summarized in the table below:

Table 2.2.5.5.3 Summary of dilutions to use .

Use class	Type of wood	Superficial treatment			Penetrative treatment		
		Dilution (%)	Dilution factor	Application rate	Dilution (%)	Dilution factor	Application rate (kg/m³)
Use class 1	Softwood	10	10 x	100 g/m²	2	50x	600
	Hardwood						500
Use class 2	Softwood						600
	Hardwood						500
Use class 3.1	Softwood						600
	Hardwood	19.2	5.2 x	100 g/m²			500
Use class 3.2	Softwood	-	-	-			600
	Hardwood						500
Curative treatment	Softwood	35	2.86 x	300 ml/m²	-		

In view of available information on active substances and efficacy tests provided by the applicant, eCA Belgium believes that the efficacy of AXIL 3000P is sufficiently demonstrated.

Conclusion on the efficacy of the product

The Axil 3000 P product is effective against wood-destroying insects including termites and wood destroying fungi (white rot and brown rot fungi) in preventive treatment.

The field of use covers use class1, use class 2, use class 3.1 and use class 3.2.

Table 2.2.5.1.1 Categories and codes for product for AXIL 3000P.

User category	Industrial application	A.20
Wood category	Softwood and hardwood	B.10, B.20
Wood product	Solid wood	C.10
Application aim	Preventive treatment Curative treatment	D.40 D.50
Field of use	Use class 1 to 3 included	E.10 – E.30
Method of application	Surface treatment (aspersion and short dipping) [redacted]	F.12, F.14 [redacted]
Target organisms	Brown and white rot fungi, xylophage insects and termites (subterranean)	G.10, G.11, G.30, G.51

For preventive action, the product is intended to be diluted at 10% w/w in water for use class 1, 2 and 3.1 (softwood), in surface treatment (application rate 100 g/m²); at 19.2% w/w in water for use class 3.1 (hardwood), in surface treatment (application rate 100 g/m²); [redacted] This is an indicative value, that shall be adapted according the type of wood, the product absorption ability and inherent parameters of vacuum pressure systems.

For curative action, the product is intended to be diluted at 35% (application rate 300 ml/m²).

Remark:

- the application by spraying is subject to limitation and the penetrative treatment is not approved, even if both are proven to be efficacious. For further details, please see the human exposure and eco-toxicological assessment.
- treatments performed by injection must always be combined with treatments applied by brushing

2.2.5.6 Occurrence of resistance and resistance management

The biocidal product AXIL 3000P contains four active substances: IPBC (carbamate molecule), propiconazole and tebuconazole (triazole molecules) and permethrin (pyrethroide molecule).

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

According to the CAR for propiconazole, the resistance to the triazole fungicides is a normal phenomenon embodied in the natural process of the evolution of biological systems and fungicides of these type have a similar resistance risk but probably different resistance factors. The risk of resistance against triazole fungicide occurrence is regarded to be medium. However, there are no specific resistance prevention measures for biocides identified. It is recommended to pay attention to prevention of the evolution of tolerant fungal strains and report to Competent Authorities any new information on development of fungal resistance to a triazole fungicide.

The use of three different fungicides with two different modes of action (IPBC vs. the triazoles) can be expected to reduce the risk of resistance development in case of this product.

According to the CAR of permethrin, there are no reported cases of resistance occurring for the use of permethrin in wood preservation. However, several cases of resistance have been documented in a wide variety of insects when for the use as a general (PT18). It is recommended to report any observed resistance incidents. Additionally, pest management strategies are advised in the use of permethrin for wood preservation in order to combat any potential for the onset of resistance.

2.2.5.7 Known limitations

According to the applicant, treated wood has to be protected by a coating after biocidal product application and sufficient drying (see also : 2.2.5.4 Mode of action, including time delay). More precisely:

- Treated wood used indoor (use class 1) (carpentries, beams, …) are, in general, protected with a coating like woodstain, paint, varnish before use for decorative and/or durability purpose.

- Treated wood used outdoor (use class 3.1 and 3.2) (window frames, claddings ….) must be protected with a coating like woodstain, paint, varnish. This obligation is mention in our technical documentation.

2.2.5.8 Evaluation of the label claims

As stated at the point 2.2.5.5 and in the conclusion of efficacy of the product, eCA Belgium believes that the efficacy of AXIL 3000 P is sufficiently demonstrated at the doses claimed by the applicant for surface [redacted] treatment in preventive and curative use.

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

Not relevant.

2.2.6 Risk assessment for human health

No human health studies were submitted for this product. There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP). Studies with the biocidal product are scientifically not justified.

2.2.6.1 Assessment of effects on Human Health

(I) Skin corrosion and irritation

Data waiving	
Information requirement	Study scientifically unjustified. [redacted] Classification (Health hazard only): H315 – Skin Irrit. 2, H319 – Eye Irrit. 2.
Justification	There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP).

[1] SDS provided by the applicant (AMP-90** 2-Amino-2-methyl-1-propanol)

Ingredient		**Classification**	**Concentration triggering classification of a mixture**	**Concentration (% w/w)**
Name	**Cas N°**			

[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

[redacted]

This ingredient shall be ≥10% in order to classify the mixture as skin irritant category 2.
So the mixture is not classified for the Skin Corrosion/irritation.

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	[redacted]
Justification for the value/conclusion	In order to classify the mixture as Skin irritant category 2, the ingredient of the mixture classified as skin irritant category 2 should be ≥ 10%
Classification of the product according to CLP and DSD	No classification needed

(II) Eye Irritation

Data waiving	
Information requirement	Study scientifically unjustified. Information on active substance[1]: IPBC (CAS: 55406-53-6) Classification (Health hazard only): H302 – Acute Tox. 4 (oral), H331 – Acute Tox. 3 (inhalation), H317- Skin Sens. 1, H318 – Eye Dam. 1, H372 – STOT RE 1 (Larynx) [redacted] Classification (Health hazard only): H302 – Acute Tox. 4, H318 – Eye Dam. 1. [redacted] Classification (Health hazard only): H319 – Eye Irrit. 2. [redacted] Classification (Health hazard only): H315 – Skin Irrit. 2, H319 – Eye Irrit. 2.
Justification	There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP).

[1] Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation) – ATP06

[2] [redacted]

[4] SDS provided by the applicant (AMP-90** 2-Amino-2-methyl-1-propanol)

Ingredient	Classification	Concentration	Concentration

Name	CAS N°		triggering classification of a mixture	(% w/w)
IPBC	55406-53-6	Eye Dam. 1, H318	3% (cat.1) 1% – 3% (cat.2)	0.75
Alcohol C11, ethoxylated	127036-24-2	Eye Dam. 1, H318	3% (cat.1) 1% – 3% (cat.2)	3.56
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

The concentration of at least one substance classified as H318 is above the concentration triggering the classification of the mixture (3%). Therefore, the mixture is classified for the Serious eye damage/eye irritation with the hazard statement **H318 « Causes serious eye damage»** and with the highly recommended precautionary statement : **P280, P305 + P351 + P338, P310.**

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	The concentration of at least one substances classified as H318 is above the concentration triggering the classification of the mixture (3%).
Justification for the value/conclusion	As the mixture itself has not been tested to determine its eye irritation/damage properties and as there is no data on similar mixtures to adequately characterise the hazards of the mixture, the classification of the mixture has to be done by using the rules laid down in Regulation (EC) No 1272/2008 (CLP).
Classification of the product according to CLP and DSD	Eye Dam. 1 H318

(III) Respiratory tract irritation

Data waiving	
Information requirement	Study scientifically unjustified.
Justification	There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP).

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Conclusion	Not irritating to the respiratory tract
Justification for the conclusion	According to the harmonized classification and labelling of the active substances IPBC, Propiconazole, tebuconazole, and permethrin, the active ingredients are not irritant to the respiratory tract. None of the other ingredients have respiratory tract irritation properties.
Classification of the product according to CLP and DSD	No classification needed

(IV) Skin sensitization

Data waiving	
Information requirement	Study scientifically unjustified. Information on active substance[1]: IPBC (CAS: 55406-53-6) Classification (Health hazard only): H302 – Acute Tox. 4 (oral), H331 – Acute Tox. 3 (inhalation), H317- Skin Sens. 1, H318 – Eye Dam. 1, H372 – STOT RE 1 (Larynx) Information on active substance[2]: Propiconazole (CAS: 60207-90-1) Classification (Health hazard only): H302 – Acute Tox. 4 (oral), H317- Skin Sens. 1 Information on the active substance[3] : Permethrin (CAS: 52645-53-1) Classification (Health hazard only): H302 – Acute Tox. 4, H317 – Skin Sens 1, H332 – Acute Tox. 4.
Justification	There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP).

[1] Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation) – ATP06

[2] Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation) – CLP00

[3] AR for permethrin (RMS: IE, January 2014) and Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation) – CLP00

Ingredient		Classification	Generic concentration limits triggering classification of a mixture	Concentration (% w/w)
Name	**CAS N°**			
IPBC	55406-53-6	Skin Sens. 1, H317	1%	0.75
Propiconazole	60207-90-1	Skin Sens. 1, H317	1%	0.75
Permethrin	52645-53-1	Skin Sens. 1, H317	1%	1

The mixture is classified as a skin sensitizer because the mixture contains an ingredient classified as a skin sensitizer with a concentration present equal or above the appropriate generic concentration limit.

So the mixture is classified for the Skin sensitization with the hazard statement **H317 « May cause an allergic skin reaction »** and with the highly recommended precautionary statement : **P280. P261 is also recommended for the labelling of this product.**

In addition, according "Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008 July 2017 Version 3.0" , the following P-sentences are :

- recommended for professional – P261, P333+P313, P362+P364
- optional for professional – P272
- recommended for inclusion in the SDS – P302+P352
- highly recommended only in exceptional cases where specific treatment is known and required – P321

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Ingredient, Permethrin, Skin Sens 1, H317, concentration in the biocidal product: 1%
Justification for the value/conclusion	The mixture is classified as a skin sensitiser because the mixture contains an ingredient classified as a skin sensitiser with a concentration present equal or above the appropriate generic concentration limit.
Classification of the product according to CLP and DSD	Skin Sens. 1 H317

(V) Respiratory sensitization (ADS)

Data waiving	
Information requirement	Study scientifically unjustified.
Justification	There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP).

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not sensitizing to the respiratory tract
Justification for the value/conclusion	According to the harmonized classification and labelling of the active substances IPBC, Propiconazole, tebuconazole, and permethrin, the active ingredients are not sensitizing to the respiratory tract. None of the other ingredients have respiratory sensitization properties
Classification of the product according to CLP and DSD	No classification needed

(VI) Acute toxicity

a. Acute toxicity by oral route

Data waiving

Information requirement	Study scientifically unjustified. Information on active substance[1]: IPBC (CAS: 55406-53-6) Classification (Health hazard only): H302 – Acute Tox. 4 (oral), H331 – Acute Tox. 3 (inhalation), H317- Skin Sens. 1, H318 – Eye Dam. 1, H372 – STOT RE 1 (Larynx) Information on active substance[2]: Propiconazole (CAS: 60207-90-1) Classification (Health hazard only): H302 – Acute Tox. 4 (oral), H317- Skin Sens. 1 Information on active substance[3]: Tebuconazole (CAS: 60207-90-1) Classification (Health hazard only): H302 – Acute Tox. 4 (oral), H361d – Repr. 2 Information on the active substance[4] : Permethrin (CAS: 52645-53-1) Classification (Health hazard only): H302 – Acute Tox. 4, H317 – Skin Sens 1, H332 – Acute Tox. 4. [redacted] Classification (Health hazard only): H302 – Acute Tox. 4, H318 – Eye Dam. 1.
Justification	There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP).

[1] AR for IPBC (RMS: DK, February 2008) and Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation) – ATP06

[2] AR For Propiconazole (RMS : FI, November 2007) and Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation) – CLP00

[3] AR For Tebuconazole (RMS : DK, November 2007) and Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation) – ATP07

[4] AR for permethrin (RMS: IE, January 2014) and Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation) – CLP00

[5] SDS provided by the applicant (Imbentin-U/100)

Ingredient		**Classification**	**Converted acute toxicity point estimate**	**Concentration (% w/w)**
Name	**CAS N°**			
IPBC	55406-53-6	Acute Tox. 4, H302	500 mg/kg[1]	0.75
Propiconazole	60207-90-1	Acute Tox. 4, H302	500 mg/kg[1]	0.75
Tebuconazol	107534-96-3	Acute Tox. 4, H302	500 mg/kg[1]	0.75
Permethrine	52645-53-1	Acute Tox. 4, H302	500 mg/kg[1]	1
Alcohol C11, ethoxylated	127036-24-2	Acute Tox. 4, H302	500 mg/kg[1]	3.56

[1]*Based on Guidance on the Application of the CLP Criteria, version 5, July 2017. "(d) When only range data (or acute toxicity hazard category information) are available for components in a mixture, they may be converted to point estimates in accordance with Table 3.1.2 when calculating the classification of the new mixture using the formulas in sections 3.1.3.6.1 and 3.1.3.6.2.3."*

The ATE (Acute Toxicity Estimate) of the mixture is determined by calculation from the ATE values for all relevant ingredients according to the following formula :

Toxicity : $\frac{100}{ATE\ mixture} = \sum_n^i \frac{Ci}{ATEi}$

where:
C_i = concentration of ingredient i (% w/w or % v/v)

i = the individual ingredient from 1 to n
n = the number of ingredients
ATE_i = Acute Toxicity Estimate of ingredient i.

So : $\frac{100}{ATE\ mixture} = \frac{0.75+0.75+0.75+1+3.56}{500}$

So ATE mixture = 7.342 mg/kg

The ATE for the mixture is > 2.000 mg/kg, so the mixture is not classified for the acute oral toxicity.

Value used in the Risk Assessment – Acute oral toxicity	
Value	Calculated: 7.342 mg/kg
Justification for the selected value	As the mixture itself has not been tested to determine its acute oral toxicity properties and as there is no data on similar mixtures to adequately characterise the hazards of the mixture, the classification of the mixture has to be done by using the rules laid down in Regulation (EC) No 1272/2008 (CLP).
Classification of the product according to CLP and DSD	No classification needed.

b. Acute toxicity by inhalation

Data waiving	
Information requirement	Study scientifically unjustified. Information on active substance[1]: IPBC (CAS: 55406-53-6) Classification (Health hazard only): H302 – Acute Tox. 4 (oral), H331 – Acute Tox. 3 (inhalation), H317- Skin Sens. 1, H318 – Eye Dam. 1, H372 – STOT RE 1 (Larynx) Information on the active substance[2] : Permethrin (CAS: 52645-53-1) Classification (Health hazard only): H302 – Acute Tox. 4, H317 – Skin Sens 1, H332 – Acute Tox. 4.
Justification	There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP).

[1] AR for IPBC (RMS: DK, February 2008) and Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation) – ATP06

[2] AR for permethrin (RMS: IE, January 2014) and Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation) – CLP00

Ingredient		**Classification**	**Converted acute toxicity point estimate**	**Concentration (% w/w)**
Name	**CAS N°**			
IPBC	55406-53-6	Acute Tox. 3, H331	0.5 mg/l[1]	0.75
Permethrine	52645-53-1	Acute Tox. 4, H332	1.5 mg/l[1]	1

[1]*Based on Guidance on the Application of the CLP Criteria, version 5, July 2017. "(d) When only range data (or acute toxicity hazard category information) are available for components in a mixture, they may be converted to point estimates in accordance with Table 3.1.2 when calculating the classification of the new mixture using the formulas in sections 3.1.3.6.1 and 3.1.3.6.2.3."*

The ATE (Acute Toxicity Estimate) of the mixture is determined by calculation from the ATE values for all relevant ingredients according to the following formula considering vapours :

Toxicity : $\frac{100}{ATE\ mixture} = \sum_n^i \frac{Ci}{ATEi}$

where:

C_i = concentration of ingredient i (% w/w or % v/v)

i = the individual ingredient from 1 to n

n = the number of ingredients

ATE_i = Acute Toxicity Estimate of ingredient i.

So considering vapours : $\frac{100}{ATE\ mixture} = \frac{0.75}{0.5} + \frac{1}{1.5}$

So ATE mixture = 46 mg/l

The ATE for the mixture is > 5 mg/l, so the mixture is not classified for the acute inhalation toxicity.

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Calculated: 46 mg/l
Justification for the selected value	As the mixture itself has not been tested to determine its acute oral toxicity properties and as there is no data on similar mixtures to adequately characterise the hazards of the mixture, the classification of the mixture has to be done by using the rules laid down in Regulation (EC) No 1272/2008 (CLP).
Classification of the product according to CLP and DSD	No classification needed

c. Acute toxicity by dermal route

Data waiving	
Information requirement	Study scientifically unjustified.
Justification	There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP).

Ingredient		**Classification**	**Converted acute toxicity point estimate**	**Concentration (% w/w)**
Name	**Cas N°**			
None of the ingredients have acute dermal toxicity properties				

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not applicable. None of the ingredients have acute dermal toxicity properties

Justification for the selected value	According to the harmonized classification and labelling of the active substance permethrin, the active ingredient have no acute dermal toxicity properties. None of the other ingredients have acute dermal toxicity properties.
Classification of the product according to CLP and DSD	No classification needed

(VII) Specific target organ toxicity – single exposure

Narcotic effects

Data waiving	
Information requirement	Study scientifically unjustified. [redacted] Classification (Health hazard only): H336 – STOT SE 3.
Justification	There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP).

[1] SDS provided by the applicant (SOLVENON* PM)

Ingredient		**Classification**	**Generic concentration limits triggering classification of a mixture**	**Concentration (% w/w)**
Name	**Cas N°**			
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

The mixture is not classified as H336 ‘May cause drowsiness or dizziness’ because the concentration of the concerned ingredient is not above the generic concentration limit triggering the classification of the mixture fixed to be at 20%.

Value used in the Risk Assessment – STOT SE – Narcotic effects	
Value	[redacted]
Justification for the selected value	In order to classify the mixture as STOT SE 3, the concern ingredient of the mixture classified as STOT SE 3 should be ≥ 20%.
Classification of the product according to CLP and DSD	No classification needed

(VIII) Reproductive toxicity

Data waiving	
Information requirement	Study scientifically unjustified Information on active substance[1]: Tebuconazole (CAS: 60207-90-1) Classification (Health hazard only): H302 – Acute Tox. 4 (oral), H361d – Repr. 2
Justification	There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP).

[1] AR For Tebuconazole (RMS : DK, November 2007) and Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation) – ATP07

Ingredient		**Classification**	**Generic concentration limits triggering classification of a mixture**	**Concentration (% w/w)**
Name	**Cas N°**			
Tebuconazole	107534-96-3	Repr. 2, H361d	≥ 3%	0.75

The mixture is not classified as H361d 'Suspected of damaging the unborn child' because the concentration of the concerned ingredient is not above the generic concentration limit triggering the classification of the mixture fixed to be at 3%.

Value used in the Risk Assessment –Reproductive toxicity	
Value	Tebuconazole: 0.75%
Justification for the selected value	The concentration of the concerned ingredient is not above the generic concentration limit triggering the classification of the mixture fixed to be at 3%.
Classification of the product according to CLP and DSD	No classification needed

(IX) Specific target organ toxicity – repeated exposure

Data waiving	
Information requirement	Study scientifically unjustified. Information on active substance[1]: IPBC (CAS: 55406-53-6) Classification (Health hazard only): H302 – Acute Tox. 4 (oral), H331 – Acute Tox. 3 (inhalation), H317- Skin Sens. 1, H318 – Eye Dam. 1, H372 – STOT RE 1 (Larynx)

Justification	There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP).

Ingredient		**Classification**	**Generic concentration limits triggering classification of a mixture**	**Concentration (% w/w)**
Name	**Cas N°**			
IPBC	55406-53-6	STOT RE1, H372	Category 1: ≥ 10% Category 2: ≥ 1% and < 10%	0.75

The mixture is not classified as H372 'Causes damage to organs (larynx) through prolonged or repeated exposure' or H373 'May cause damage to organs (larynx) through prolonged or repeated exposure' because the concentration of the concerned ingredient is not above the generic concentration limit triggering the classification of the mixture fixed to be at 1%.

Value used in the Risk Assessment – Specific target organ toxicity - repeated	
Value	IPBC: 0.75%
Justification for the selected value	The concentration of the concerned ingredient is not above the generic concentration limit triggering the classification of the mixture fixed to be at 1%.
Classification of the product according to CLP and DSD	No classification needed

(X) Information on dermal absorption

No dermal absorption studies with the biocidal product have been performed.

A. Dermal absorption of propiconazole

The BE CA proposes a default dermal absorption of 75%. Please refer to the confidential annex for more information.

B. Dermal absorption of Tebuconazole

The BE CA proposes a default dermal absorption of 75%. Please refer to the confidential annex for more information.

C. Dermal absorption of IPBC

The BE CA proposes a default dermal absorption of 75%. Please refer to the confidential annex for more information.

D. Dermal absorption of Permethrin

The BE CA proposes a dermal absorption of 10%. Please refer to the confidential annex for more information.

	Value(s) used in the Risk Assessment – Dermal absorption			
Concentrated and diluted product				
Substance	Propiconazole	Tebuconazole	IPBC	Permethrin
Values	75%	75%	75%	10%

	Value(s) used in the Risk Assessment – Inhalation absorption and oral absorption			
Substance	Propiconazole	Tebuconazole	IPBC	Permethrin
Value for inhalation absorption	100% (default)	100% (default)	100% (default)	100% (default)
Value for oral absorption	100% (default)	100% (default)	100% (default)	100% (default)

UPDATED Dec 2019 – NA-MAC- new information for dermal absorption:

The applicant provided 3 new studies of percutaneous absorption according to OECD guideline 428 on their product. The percutaneous absorption of permethrin, propiconazole and tebuconazole were studied. For IBPC, no new data was provided. Therefore, the previous conclusion was not reviewed and remains valid. Please refer to the confidential annex for more information.

	Value(s) used in the Risk Assessment – Dermal absorption			
Concentrated product				
Substance	Propiconazole	Tebuconazole	IPBC	Permethrin
Values	25%	25%	75%	25%
Diluted product (35%)				
Substance	Propiconazole	Tebuconazole	IPBC	Permethrin
Values	16%	15%	75%	12%

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

Apart from the active substance permethrin, the biocidal product contains a substance of concern: Alcohol C11, ethoxylated (N°CAS 127036-24-2). This substance participates to the product classification as H318, Eye dam. Category 1.

The applicant provided the Safety Data Sheet (SDS) of the substance [redacted]. According the information provided the substance is a polymer with a proposed classification as Acute Tox. 4 (H302) and Eye Dam. 1 (H318).

Proposed classification/labelling in accordance with Regulation (EC) N° 1272/2008:

Danger Category Pictogram(s) Signal word(s)	Acute Tox. 4, Eye Dam. Cat.1 GHS05, GHS07 Danger	
H statements	H302 H318	Harmful if swallowed Causes serious eye damage

There is no limit values available.

(XII) Available toxicological data relating to a mixture

Not applicable.

2.2.6.2 Exposure assessment

AXIL 3000 P is a wood preservative for industrial use only which has 3 functions: fungicide, insecticide and anti-termite. Its fields of use are Use classes 1, 2, 3.1 [redacted] to protect wood construction (joinery, window frames, sidings, etc). The biocidal product is a water-based concentrate that will be diluted in water. The product is intended to be applied by industrial spraying process, by industrial dipping process [redacted]

UPDATED Dec 2019 – NA-MAC

The applicant apply for a major change in the authorization of the product AXIL 3000 P, additional uses have been requested: AXIL 3000 P is a wood preservative for professional use which is intended for curative treatment of wood against wood-destroying insects. Its field of use is to protect construction wood in conditions of use classes 1 and 2. The biocidal product is a concentrate water-based to be diluted 35% w/w with water. The curative treatment is performed by double spraying and by Injection + Brushing processes.

AXIL 3000 P contains four active substances : Propiconazole, Tebuconazole, IPBC, each of them at 0.75% w/w and Permethrin at 1% w/w.

AXIL 3000P contains one substance of concern: alcohol C11, ethoxylated (N°CAS: 127036-24-2). This substance participates to the classification of the product as eye damage category 1 (H318).

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

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	n.a.	yes	Yes	yes	n.a.
Dermal	Yes	yes	n.a.	yes	Yes	yes	n.a.
Oral	No	no	n.a.	no	No	yes	no

Primary exposure:

Industrial use :

Spraying :

This type of superficial application process is typically used in sawmills and carpentry / joinery shops. Concentrates of the wood preservative are diluted, with water, to prepare a ready for use treatment solution. The wood, whether in debarked logs or fully or partly machined timber are moved through one or more longitudinal or transversal boxes on a continuously moving conveyor system. The product is applied as a spray which is usually as a coarse spray using a particle spray size to ensure the wetting of the timber with the correct amount of wood preservative. The spray boxes are relatively contained and splashguards surround the spraying boxes to eliminate any droplets of spray from entering the rest of the mill area and may have local exhaust ventilation. After the timber has been treated it is stacked or sorted, either mechanically or manually, either dries on the conveyor belt or in the post treatment drip dry conditioning area before being moved off-site to manufacturers or used on site.
The treatment apparatus is typically established in a contained or bunded area fabricated from materials resistant to the wood preservative product. Provision is made for the collection, recycling and reuse of wood preservative collected from the conveyor or drip dry area. Mixing, loading and application of the product are fully automated process.

Mixing and Loading
The mixing and loading is a fully automated process (pumping process) in a closed system. The product AXIL 3000P is delivered in 640L and 1000L containers or in 60 and 220L drums or in 25L cans. There is no manual interaction needed. Mixing occurs in a tank to which the product and water are automatically supplied in the required quantities via hoses. It is considered that the Mixing and Loading process is not associated with significant exposure to the operator. No exposure calculation is needed.

Application
Automated spraying, flow coating (deluge) is an industrial automated process. The wood is mechanically moved through one or more longitudinal or transversal boxes on a continuously moving conveyor system. The product is applied as a spray which is usually as a coarse spray using a particle spray size to ensure the wetting of the wood with the correct amount of wood preservative. The spray boxes are relatively contained and splashguards surround the spraying boxes to eliminate any droplets of spray from entering the rest of the area and may have local exhaust ventilation. After the treatment of the wood, before removing treated wood from the system, excessive treatment solution is allowed to drain off. A potential source of exposure might be via evaporation of the product from opening the system after treatment. However, the active substances contained in AXIL 3000P have very low volability (IPBC Vp 2.36 10^{-3} Pa at 25°C, Tebuconazole Vp 1.7 10^{-6} Pa at 20°C, Propiconazole Vp 5.6 10^{-5} Pa at 25°C, Permethrin Vp 2.16 10^{-6} Pa at 20°C) and the process occurs at ambient temperature. No separate exposure calculation is made for this activity.
The model applied for post-application handling may cover potential exposure during the treatment process itself. The exposure calculation for the application stage is covered by post application.

Post-application: Handling of treated (wet) articles
Post-application exposure to the product may occur during the manual handling of treated (wet) wood. Unloading of the wood occurs mechanically on a continuously moving conveyor system. After treatment, the wood is transported mechanically to the storage place. The handling phase includes a cycle of loading, waiting, unloading and removal of treated timber to storage. Dermal contamination can occur through direct contact with the surface of treated wood and through contact with ancillary equipment and the contaminated process system.

Dipping :

Dipping and immersion are superficial application processes and are typically used in sawmills and carpentry / joinery shops. They are batch processes and are usually automatic in operation. In either case they involve the submerging of a pack or single piece (only in small scale operations) of wood into a dipping tank filled with ready for use wood preservative solution. Packs of wood are typically loaded on automatic equipment (e.g. a hydraulic mast) and lowered into the dipping tank. The immersion period lasts anything from a very short period of a few minutes to over one hour depending on the end use application of the treated commodity and the application rate of AXIL 3000P. After the required immersion period the packs or pieces of wood, which are slightly raised at one end to aid liquid run off, are hoisted out of the liquid and usually held above the open tank for excess liquid to fall back into the dipping tank and be re-used. When the excess liquid has been drained, the pieces or packs of wood are moved to a post treatment conditioning location which is usually bunded and the timber is allowed to dry before being moved off-site or used on site. Any further drips are contained and recycled. Some installations may have local exhaust ventilation. Mixing, loading and application of the product are fully automated process.

Mixing and Loading

The mixing and loading is a fully automated process (pumping process) in a closed system. The product AXIL 3000P is delivered in 640L and 1000L containers or in 60 and 220L drums or in 25L cans. There is no manual interaction needed. Mixing occurs in a tank to which the product and water are automatically supplied in the required quantities via hoses. It is considered that the Mixing and Loading process is not associated with significant exposure to the operator. No exposure calculation is needed.

Application

The application process itself occurs in a large tank, which is opened. Loading and unloading with wood occurs mechanically by forklift trucks. For the actual dipping process timber stacks are loaded onto a forklift integrated in the dipping system. Before removing treated wood from the dipping system, excessive treatment solution is allowed to drain off above the tank. Afterwards it is transported mechanically to the storage place. A potential source of exposure might be via evaporation of the product from the open dipping tank. However, the active substances contained in AXIL 3000P have very low volability (IPBC Vp 2.36 10^{-3} Pa at 25°C, Tebuconazole Vp 1.7 10^{-6} Pa at 20°C, Propiconazole Vp 5.6 10^{-5} Pa at 25°C, Permethrin Vp 2.16 10^{-6} Pa at 20°C) and the process occurs at ambient temperature. No separate exposure calculation is made for this activity. However, the model applied for post-application handling may cover potential exposure during the treatment process itself. The exposure calculation for the application stage is covered by post application.

Post-application: Handling of treated (wet) articles

Post-application exposure to the product may occur during the manual handling of treated (wet) wood. Timber to be treated is generally stacked to large batches which are transported mechanically by forklift trucks. After treatment, they remain on the forklift above the tank for a certain while (initial drying), before they are transported mechanically by a forklift truck to the storage place for final drying and fixation. The handling phase includes a cycle of loading, waiting, unloading and removal of treated timber to storage. Dermal contamination can occur through direct contact with the surface of treated wood and through contact with ancillary equipment and the contaminated process system.

[redacted]

[redacted]

Professional use:

The product is not intended to be used by professional users. No primary exposure is foreseen.

Additional professional uses (MAC – DEC 2019):

Brushing

Mixing and loading:

According the applicant information, the first step is a dilution of the concentrated product AXIL 3000 P in order to obtain a ready-to-use product. The dilution is operated by pouring the concentrate in the dilution drum containing water (dilution rate: 35%). This dilution is done by the professional user in its own facility. Then the professional user brings the ready-to-use product to the location where the application will be done.

Application :

During application by brushing, the diluted product is directly be applied on wood buy a brush.

Post-application

After the treatment there is no contact of treated articles and operators because there is no handling of treaded articles as the application is operated in-situ. Only accidental exposure of operator could occur during this period.

Cleaning

During the cleaning process operator could be exposed to residual product in the brush.

Injection (must always be combined with an application by brushing) :

Mixing and loading:

According the applicant information, the first step is a dilution of the concentrated product AXIL 3000 P in order to obtain a ready-to-use product. The dilution is operated by pouring the concentrate in the dilution drum containing water (dilution rate: 35%). This dilution is done by the professional user in its own facility. Then the professional user brings the ready-to-use product to the location where the application will be done.

Application :

During application by injection process, the ready to use product is moved from the drum to the wood to be treated through the injection system.

Post-application

After the treatment there is no contact of treated articles and operators because there is no handling of treaded articles as the application is operated in-situ. Only accidental exposure of operator could occur during this period.

Cleaning

During the cleaning process operator could be exposed to residual product in the system.

Spraying

Mixing and loading:

According the applicant information, the first step is a dilution of the concentrated product AXIL 3000 P in order to obtain a ready-to-use product. The dilution is operated by pouring the concentrate in the dilution drum containing water (dilution rate: 35%). This dilution is done by the professional user in its own facility. Then the professional user brings the ready-to-use product to the location where the application will be done.

Application :

During application by spraying process, the ready to use product is moved from the drum to the wood to be treated through the spraying system. According the instruction of use, the wood to be treated may need to be sprayed two times.

Post-application

After the treatment there is no contact of treated articles and operators because there is no handling of treaded articles as the application is operated in-situ. Only accidental exposure of operator could occur during this period.

Cleaning

During the cleaning process operator could be exposed to residual product in the system.

Illustration of the application process of AXIL 3000 P (as provided by the applicant).

- Injection process on in situ roof framing :

- Spraying process on in situ roof framing :

Non-professional use:

The product is not intended to be used by non-professional users. No primary exposure is foreseen.

Secondary exposure:

General consideration:

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

- For propiconazole

$$\frac{0.328\,.mw\,.vp}{AEL_{long-term}} = \frac{0.328 * 342.2 * 5.6 * 10^{-5}}{0.08} = 7.86 * 10^{-2}$$

Remark: the mw (molecular weight) and vp (vapour pressure) come from the Assessment Report on Propiconazole (RMS FI, November 2007).

- For tebuconazole

$$\frac{0.328\,.mw\,.vp}{AEL_{long-term}} = \frac{0.328 * 307.8 * 1.7 * 10^{-6}}{0.03} = 5.72 * 10^{-3}$$

Remark: the mw (molecular weight) and vp (vapour pressure) come from the Assessment Report on Tebuconazole (RMS DK, November 2007).

- For IPBC

$$\frac{0.328\,.mw\,.vp}{AEL_{long-term}} = \frac{0.328 * 281.1 * 4.5 * 10^{-3}}{0.2} = 2.07$$

Remark: the mw (molecular weight) and vp (vapour pressure) come from the Assessment Report on IPBC (RMS DK, February 2008).

- For Permethrin:

$$\frac{0.328\,.mw\,.vp}{AEL_{long-term}} = \frac{0.328 * 391.29 * 2.155 * 10^{-6}}{0.05} = 5.53 * 10^{-3}$$

Remark: the mw (molecular weight) and vp (vapour pressure) come from the Assessment Report on Permethrin (RMS IE, April 2014).

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

The result of this equation is higher than 1 for IPBC. The **exposure to volatilised residues** indoor cannot be considered negligible for professional and general public for these active substances. This exposure is therefore considered into the scenarios **for IPBC only**.

According the efficacy assessment of this product, the maximum application rate is 100 g/m² for preventive treatment. This value would be used for the secondary exposure.

Following the requested for major change, the application rate is 300 mL/m^2 for curative treatment. The treatment by injection must always be combined with a superficial treatment, brushing in this case. The application rate for injection is 20mL/hole, 9holes/m2 according the applicant. However, according the applicant and the instructions of use, the maximum application rate is 300 mL/m^2. Therefore the secondary exposure assessment has been reviewed accordingly.

Industrial secondary exposure is foreseen mainly during the cleaning/maintenance of the system. Any sort of maintenance/repair work on the system (hoses, valves etc.) may potentially lead to exposure. Cleaning may also potentially lead to exposure. However it is assumed that this type of tasks will be done by others professionals compared to application tasks (primary exposure). The exposure is considered lower than the exposure resulting of the application of the product. As no model are available in order to estimate the exposure, if PPE are required for the application task, it is advice to use the same PPE for the potentially secondary exposure.

Professional secondary exposure is foreseen for this product when activities are performed on the treated wood. The exposed professional for this type of work is supposed different than the professional doing the primary exposure. This task will induce an inhalation and dermal exposure.

General public secondary exposure is possible for this product. There are different situations where indirect exposure may be expected.

- Acute exposure
    - Non-professional user manipulating the treated wood (Processing treated dried wood)
    - Toddler chewing wood off-cut
- Chronic exposure: toddler playing and mouthing weathered playground structure outdoors.

(I) List of scenarios

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure** **Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
1.	Automated spraying - deluge	**Primary exposure :** Professional deluging	Industrial
2.	Automated dipping	**Primary exposure :** Professional automated dipping	Industrial
2bis.	Fully automated dipping	**Primary exposure :** Professional fully automated dipping	Industrial
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
4.	Processing Treated dried wood	**Secondary exposure:** Professional sanding treated dried wood Remark: reviewed following higher application rate for curative treatment.	Professional
5.	Processing Treated dried wood	**Secondary exposure:** Adult non-professional – sanding treated wood posts (acute exposure) Remark: reviewed following higher application rate for curative treatment.	General public
6.	Chewing wood off-cut	**Secondary exposure:** toddler chewing wood offcut (acute exposure) Remark: reviewed following higher application rate for curative treatment.	General public
7.	Playing and mouthing playground structure	**Secondary exposure**: toddler playing and mouthing weathered playground structure outdoors (chronic exposure) Remark: reviewed following higher application rate for curative treatment.	General public
8.	Inhalation volatized residues (IPBC only)	**Secondary exposure** : General public - Inhalation volatized residues indoors (chronic exposure)	General public Adult, child, toddler, infant
9.	Spraying	**Primary exposure:** application of product by spraying Mixing and Loading is included into the model.	Professionals
10.	Injection	**Primary exposure:** application of product by borehole pressure impregnation Mixing and Loading is included into the model.	Professionals

11.	Brushing	**Primary exposure:** Mixing and Loading **+** application of product by brushing	Professionals
12.	Spraying	**Primary exposure:** post-application, Cleaning of the spray equipment	Professionals

(II) Industrial exposure

Scenario 1: Automated spraying - deluge

Description of Scenario 1: Automated spraying - deluge		
According to the Biocides Health Exposure Methodology, version no 1 of October 2015 and according to Recommendation no 6, Methods and models to assess exposure to biocidal products in different product types, version 3: Model no 28 – Professional deluging – Dipping model 1.		
	Parameters	Value
Tier 1 (No PPE)	% of active substance in the biocidal product Permethrin Tebuconazole Propiconazole IPBC	 1% 0.75% 0.75% 0.75%
	Dilution of the applied product	19.2% (worst case)
	Body weight[1]	60 kg
	Inhalation rate[1]	1.25 m^3/h
	Indicative body dermal exposure[2]	178 mg/min
	Potential dermal exposure on hands (no gloves)[3]	2570 mg/min
	Penetration through PPE (body) = no PPE[1]	100%
	Dermal absorption : Permethrin Tebuconazole Propiconazole IPBC	 10% 75% 75% 75%
	Indicative inhalation exposure (non-volatile compounds)[2]	< 1 mg/m^3
	Exposure duration[2]	60 min
	Penetration through RPE	100%
Tier 2 a (PPE - gloves)	Indicative dermal exposure on hands (inside gloves)[2]	25.7 mg/min
Tier 2 b (PPE – gloves and impermeable coveralls	Relative penetration of clothing – impermeable coveralls[1]	5 %
Tier 2 c (PPE – gloves, impermeable coveralls and respiratory protective equipment	Relative penetration of respiratory protection – filtering half masks / FFP1[1]	25 %

[1] Biocide Human Health Exposure Methodology, version 1, October 2015

[2] Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure, Methods and models to assess exposure to biocidal products in different product types, version 3, February 2017

[3] Calculated according HEEG opinion on the assessment of Potential & Actual Hand Exposure, 2008, using a multiplication factor of 100 for the conversion of actual to potential hand exposure.

Calculations for scenario 1 - Automated spraying - Deluge

Please for details calculations refer to annex 3.2.

Estimated exposure from application of product by Automated spraying - Deluge						
Exposure scenario	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake (µg/kg bw/d)**	**Estimated dermal uptake (µg/kg bw/d)**	**Estimated oral uptake (µg/kg bw/d)**	**Estimated total uptake (µg/kg bw/d)**
Scenario 1: Automated spraying - Deluge	1 /No PPE	Permethrin Tebuconazole Propiconazole IPBC	0.040 0.030 0.030 0.030	527.616 2967.840 2967.840 2967.840	- - - -	527.656 2967.870 2967.870 2967.870
	2a / Gloves	Permethrin Tebuconazole Propiconazole IPBC	0.040 0.030 0.030 0.030	39.110 219.996 219.996 219.996	- - - -	39.150 220.026 220.026 220.026
	2b / Gloves + impermeable coveralls	Permethrin Tebuconazole Propiconazole IPBC	0.040 0.030 0.030 0.030	6.643 37.368 37.368 37.368	- - - -	6.683 37.398 37.398 37.398
	2c / Gloves + impermeable coveralls + filtering half masks (FFP11)	Permethrin Tebuconazole Propiconazole IPBC	0.010 0.007 0.007 0.007	6.643 37.368 37.368 37.368	- - - -	6.653 37.375 37.375 37.375

*Scenario 1bis : Automated spraying – deluge (limitation to **maximum 10% dilution rate**)*

Description of Scenario 1: Automated spraying - deluge		
According to the Biocides Health Exposure Methodology, version no 1 of October 2015 and according to Recommendation no 6, Methods and models to assess exposure to biocidal products in different product types, version 3: Model no 28 – Professional deluging – Dipping model 1.		
	Parameters	Value
Tier 1 (No PPE)	% of active substance in the biocidal product Permethrin Tebuconazole Propiconazole IPBC	 1% 0.75% 0.75% 0.75%
	Dilution of the applied product	**10% (refinement).**
	Body weight[1]	60 kg
	Inhalation rate[1]	1.25 m^3/h
	Indicative body dermal exposure[2]	178 mg/min
	Potential dermal exposure on hands (no gloves)[3]	2570 mg/min
	Penetration through PPE (body) = no PPE[1]	100%
	Dermal absorption : Permethrin Tebuconazole Propiconazole IPBC	 10% 75% 75% 75%
	Indicative inhalation exposure (non-volatile compounds)[2]	< 1 mg/m^3
	Exposure duration[2]	60 min
	Penetration through RPE	100%
Tier 2 a (PPE - gloves)	Indicative dermal exposure on hands (inside gloves)[2]	25.7 mg/min
Tier 2 b (PPE – gloves and impermeable coveralls	Relative penetration of clothing – impermeable coveralls[1]	5 %
Tier 2 c (PPE – gloves, impermeable coveralls and respiratory protective equipment	Relative penetration of respiratory protection – filtering half masks / FFP1[1]	25 %

[1] Biocide Human Health Exposure Methodology, version 1, October 2015

[2] Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure, Methods and models to assess exposure to biocidal products in different product types, version 3, February 2017

[3] Calculated according HEEG opinion on the assessment of Potential & Actual Hand Exposure, 2008, using a multiplication factor of 100 for the conversion of actual to potential hand exposure.

Calculations for scenario 1bis - Automated spraying – Deluge (limitation to maximum 10% dilution rate)

Please for details calculations refer to annex 3.2.

Estimated exposure from application of product by Automated spraying - Deluge						
Exposure scenario	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake (µg/kg bw/d)**	**Estimated dermal uptake (µg/kg bw/d)**	**Estimated oral uptake (µg/kg bw/d)**	**Estimated total uptake (µg/kg bw/d)**
Scenario 1bis: Automated spraying – Deluge / limitation to maximum 10% dilution rate	1 /No PPE	Permethrin Tebuconazole Propiconazole IPBC	0.021 0.016 0.016 0.016	274.800 1545.750 1545.750 1545.750	- - - -	274.821 1545.766 1545.766 1545.766
	2a / Gloves	Permethrin Tebuconazole Propiconazole IPBC	0.021 0.016 0.016 0.016	20.370 114.581 114.581 114.581	- - - -	20.391 114.597 114.597 114.597
	2b / Gloves + impermeable coveralls	Permethrin Tebuconazole Propiconazole IPBC	0.021 0.016 0.016 0.016	3.460 19.452 19.452 19.452	- - - -	3.481 19.478 19.478 19.478
	2c / Gloves + impermeable coveralls + filtering half masks (FFP11)	Permethrin Tebuconazole Propiconazole IPBC	0.005 0.004 0.004 0.004	3.460 19.452 19.452 19.452	- - - -	3.465 19.466 19.466 19.466

Scenario 2 and 2bis: Automated dipping and fully automated dipping

Description of Scenario 2: Automated dipping		
According to the Biocides Health Exposure Methodology, version no 1 of October 2015 and according to Recommendation no 6, Methods and models to assess exposure to biocidal products in different product types, version 3: Model no 19/20 – Professional automated dipping, immersion of wooden articles / Fully automated dipping – Handling model 1 for dermal exposure. The default values form the water-based products are used. According to the HEEG opinion 8, inhalation exposure resulting from aerosol formation should be negligible. For non-volatile compounds, the assessment of vapour is not necessary.		
	Parameters	Value
Tier 1 (No PPE)	% of active substance in the biocidal product Permethrin Tebuconazole Propiconazole IPBC	 1% 0.75% 0.75% 0.75%
	Dilution of the applied product	19.2% (worst case)
	Body weight[1]	60 kg
	Inhalation rate[1]	1.25 m^3/h
	Indicative body dermal exposure[2]	8570 mg/cycle
	Potential dermal exposure on hands (no gloves)[3]	108 000 mg/cycle
	Penetration through PPE (body) = no PPE[1]	100%
	Dermal absorption : Permethrin Tebuconazole Propiconazole IPBC	 10% 75% 75% 75%
	Indicative inhalation exposure (non-volatile compounds)[2]	negligible
	Exposure duration[2]	4 dipping cycle per day
	Penetration through RPE	100%
Tier 2 a (PPE - gloves)	Indicative dermal exposure on hands (inside gloves)[2]	1080 mg/cycle
Tier 2 b (PPE – gloves and impermeable coveralls	Relative penetration of clothing – impermeable coveralls[1]	5 %

[1] Biocide Human Health Exposure Methodology, version 1, October 2015

[2] Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure, Methods and models to assess exposure to biocidal products in different product types, version 3, February 2017

[3] Calculated according HEEG opinion on the assessment of Potential & Actual Hand Exposure, 2008, using a multiplication factor of 100 for the conversion of actual to potential hand exposure.

Description of Scenario 2bis: Fully automated dipping		
According to the Biocides Health Exposure Methodology, version no 1 of October 2015 and according to Recommendation no 6, Methods and models to assess exposure to biocidal products in different product types, version 3: Model no 19/20 – Professional automated dipping, immersion of wooden articles / Fully automated dipping – Handling model 1 for dermal exposure. The default values form the water-based products are used. Fully automated dipping (model 20): According to the HEEG opinion 18 - for exposure assessment for professional operators undertaking industrial treatment of wood by fully automated dipping where all steps in the treatment and drying process are mechanised and no manual handling takes place the dermal exposure is assumed to decrease by a factor of 4. According to the HEEG opinion 8, inhalation exposure resulting from aerosol formation should be negligible. For non-volatile compounds, the assessment of vapour is not necessary.		
	Parameters	Value
Tier 1 (No PPE)	% of active substance in the biocidal product Permethrin Tebuconazole Propiconazole IPBC	 1% 0.75% 0.75% 0.75%
	Dilution of the applied product	19.2% (worst case)
	Body weight[1]	60 kg
	Inhalation rate[1]	1.25 m^3/h
	Indicative body dermal exposure[2]	8570 mg/cycle
	Potential dermal exposure on hands (no gloves)[3]	108 000 mg/cycle
	Penetration through PPE (body) = no PPE[1]	100%
	Dermal absorption : Permethrin Tebuconazole Propiconazole IPBC	 10% 75% 75% 75%
	Indicative inhalation exposure (non-volatile compounds)[2]	negligible
	Exposure duration[2]	4 dipping cycle per day
	Penetration through RPE	100%
	Fully automated dipping (Recomm. No 6 v3, No 20), HEEG opinion 18: professional operators undertaking industrial treatment of wood by fully automated dipping where all steps in the treatment and drying process are mechanised and no manual handling takes place	Dermal exposure is assumed to decrease by a factor of 4.
Tier 2 a (PPE - gloves)	Indicative dermal exposure on hands (inside gloves)[2]	1080 mg/cycle

Tier 2 b (PPE – gloves and impermeable coveralls	Relative penetration of clothing – impermeable coveralls[1]	5 %

[1] Biocide Human Health Exposure Methodology, version 1, October 2015

[2] Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure, Methods and models to assess exposure to biocidal products in different product types, version 3, February 2017

[3] Calculated according HEEG opinion on the assessment of Potential & Actual Hand Exposure, 2008, using a multiplication factor of 100 for the conversion of actual to potential hand exposure.

Calculations for scenario 2 and 2bis: Automated dipping and fully automated dipping

Please for details calculations refer to annex 3.2.

Estimated exposure from application of product by Automated dipping						
Exposure scenario	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake (µg/kg bw/d)**	**Estimated dermal uptake (µg/kg bw/d)**	**Estimated oral uptake (µg/kg bw/d)**	**Estimated total uptake (µg/kg bw/d)**
Scenario 2: Automated dipping	1 /No PPE	Permethrin Tebuconazole Propiconazole IPBC	- - - -	1492.096 8393.040 8393.040 8393.040	- - - -	1492.096 8393.040 8393.040 8393.040
	2a / Gloves	Permethrin Tebuconazole Propiconazole IPBC	- - - -	123.520 694.800 694.800 694.800	- - - -	123.520 694.800 694.800 694.800
	2b / Gloves + impermeable coveralls	Permethrin Tebuconazole Propiconazole IPBC	- - - -	19.309 108.612 108.612 108.612	- - - -	19.309 108.612 108.612 108.612
Scenario 2bis : **Fully** automated dipping	1 /No PPE	Permethrin Tebuconazole Propiconazole IPBC	- - - -	373.024 2098.260 2098.260 2098.260	- - - -	373.024 2098.260 2098.260 2098.260
	2a / Gloves	Permethrin Tebuconazole Propiconazole IPBC	- - - -	30.880 173.700 173.700 173.700	- - - -	30.880 173.700 173.700 173.700
	2b / Gloves + impermeable coveralls	Permethrin Tebuconazole Propiconazole IPBC	- - - -	4.827 27.153 27.153 27.153	- - - -	4.827 27.153 27.153 27.153

[redacted]

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[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

(III) Professional exposure

Scenario 9 : Professional spraying in situ

Description of Scenario : application of product by spraying

This scenario is based on the scenario available in Biocides Human Health Exposure Methodology (Oct. 2015) for the assessment of professional using a PT 8. The default exposure values in this document have been updated by Recommendation 6 (version 3, Feb. 2017) of the Ad hoc Working Group on Human Exposure.

Mixing and Loading is included into the model.

Professional spray treatment – Spraying model 2 – Task: 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.

In a tier 2, PPE are taken into consideration into the model :

- Gloves (Tier 2a)
- impermeable coveralls (Tier 2b)
- Respiratory protective equipment (Tier 2c) – *filtering half masks FFP1*

	Parameters	Value
Tier 1 (No PPE)	% of active substance in the biocidal product Permethrin Tebuconazole Propiconazole IPBC	 0.35% 0.2625% 0.2625% 0.2625%
	Body weight[1]	60 kg
	Inhalation rate[1]	1.25 m^3/h
	Dermal absorption : Permethrin Tebuconazole Propiconazole IPBC	 12% 15% 16% 75%
	Indicative dermal exposure on hands (no gloves)[2]	273 mg/min
	Indicative dermal exposure on body (no protection)[2]	222 mg/min
	Indicative inhalation exposure (non-volatile compounds)[2]	76 mg/min
	Exposure duration[2]	40 min/event
	Relative penetration of clothing (no PPE considered)[1]	100%
	Number of events per day[2]	2 events /days
Tier 2 a (PPE - gloves)	Indicative dermal exposure on hands (inside gloves)[2]	7.8 mg/min
Tier 2 b (PPE – gloves and impermeable coveralls	Relative penetration of clothing – impermeable coveralls[1]	5 %

Tier 2 c (PPE – gloves, impermeable coveralls and respiratory protective equipment	Relative penetration of respiratory protection – filtering half masks / FFP1[1]	25 %

[1] Biocide Human Health Exposure Methodology, version 1, October 2015

[2] Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure, Methods and models to assess exposure to biocidal products in different product types, version 3, February 2017

Calculations for scenario 9 – Professional spraying in situ

Please for details calculations refer to annex 3.2.

Estimated exposure from application of product by spraying						
Exposure scenario	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake (µg/kg bw/d)**	**Estimated dermal uptake (µg/kg bw/d)**	**Estimated oral uptake (µg/kg bw/d)**	**Estimated total uptake (µg/kg bw/d)**
Scenario 9 – application of product by spraying	1 /No PPE	Permethrin Tebuconazole Propiconazole IPBC	7.39 5.54 5.54 5.54	277.20 259.88 277.20 1299.38	- - - -	284.59 265.42 282.74 1304.92
	2a / Gloves	Permethrin Tebuconazole Propiconazole IPBC	7.39 5.54 5.54 5.54	128.69 120.65 128.69 603.22	- - - -	136.08 126.19 137.23 608.77
	2b / Gloves + impermeable coveralls	Permethrin Tebuconazole Propiconazole IPBC	7.39 5.54 5.54 5.54	10.58 9.92 10.58 46.61	- - - -	17.97 15.46 16.13 55.15
	2c / Gloves + impermeable coveralls + filtering half masks (FFP11)	Permethrin Tebuconazole Propiconazole IPBC	1.85 1.39 1.39 1.39	10.58 9.92 10.58 46.61	- - - -	12.43 11.31 11.97 51.00

Scenario 10: Professional injection in situ (by borehole impregnation)

Description of Scenario 10 : application of product by borehole impregnation

This scenario is based on the scenario available in Biocides Human Health Exposure Methodology (Oct. 2015) for the assessment of professional using a PT 8. The default exposure values in this document are the same than in Recommendation 6 (version 3, Feb. 2017) of the Ad hoc Working Group on Human Exposure.

Mixing and Loading is included into the model.

Professional borehole pressure impregnation – Subsoil treatment model 2 – Task: Mixing and loading, and treating soil by watering and subsoil by infection, spraying foundations and sub-building crawl space.

In a tier 2, PPE are taken into consideration into the model :

- Gloves (Tier 2a)
- impermeable coveralls (Tier 2b)
- Respiratory protective equipment (Tier 2c) – *filtering half masks FFP1*

	Parameters	Value
Tier 1 (No PPE)	% of active substance in the biocidal product Permethrin Tebuconazole Propiconazole IPBC	 0.35% 0.2625% 0.2625% 0.2625%
	Body weight[1]	60 kg
	Inhalation rate[1]	1.25 m^3/h
	Dermal absorption : Permethrin Tebuconazole Propiconazole IPBC	 12% 15% 16% 75%
	Indicative dermal exposure on hands (no gloves)[2]	80 mg/min
	Indicative inhalation exposure (non-volatile compounds)[2]	0.57 mg/min
	Exposure duration[2]	80 min/event
	Number of events per day[2]	1 event /days
Tier 2 a (PPE - gloves)	Indicative dermal exposure on hands (inside gloves)[2]	8.0 mg/min

Tier 2 b (PPE – gloves and impermeable coveralls	Relative penetration of clothing – impermeable coveralls[1]	5 %
Tier 2 c (PPE – gloves, impermeable coveralls and respiratory protective equipment	Relative penetration of respiratory protection – filtering half masks / FFP1[1]	25 %

[1] Biocide Human Health Exposure Methodology, version 1, October 2015

[2] Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure, Methods and models to assess exposure to biocidal products in different product types, version 3, February 2017

***Calculations for Scenario** 10 : professional injection in situ*

Please for details calculations refer to annex 3.2.

Estimated exposure from application of product by injection						
Exposure scenario	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake (µg/kg bw/d)**	**Estimated dermal uptake (µg/kg bw/d)**	**Estimated oral uptake (µg/kg bw/d)**	**Estimated total uptake (µg/kg bw/d)**
Scenario 10 – application of product by borehole impregnation	1 /No PPE	Permethrin Tebuconazole Propiconazole IPBC	0.06 0.04 0.04 0.04	448 420 448 2100	- - - -	448.06 420.04 448.04 2100.04
	2a / Gloves	Permethrin Tebuconazole Propiconazole IPBC	0.06 0.04 0.04 0.04	4.48 4.2 4.48 21	- - - -	4.54 4.24 4.52 21.04
	2b / Gloves + impermeable coveralls	Permethrin Tebuconazole Propiconazole IPBC	0.06 0.04 0.04 0.04	4.48 4.2 4.48 21	- - - -	4.54 4.24 4.52 21.04
	2c / Gloves + impermeable coveralls + filtering half masks (FFP11)	Permethrin Tebuconazole Propiconazole IPBC	0.01 0.01 0.01 0.01	4.48 4.2 4.48 21	- - - -	4.49 4.21 4.49 21.01

Scenario 11: Professional brushing application in situ

Description of Scenario 11 - application of product by brushing

This scenario is based on the scenario available in Biocides Human Health Exposure Methodology (Oct. 2015) for the assessment of professional using a PT 8. The default exposure values in this document are the same than in Recommendation 6 (version 3, Feb. 2017) of the Ad hoc Working Group on Human Exposure.

Mixing and Loading is NOT included into the model. It is considered that for Pouring/Mixing and loading of packages superior to 20 L), RISKOFDERM Toolkit : connecting lines, is an appropriate model according HEEG opinion 1 - Mixing loading model 7 alternatives.

In a tier 2, PPE are taken into consideration into the model :

- Gloves (Tier 2a)
- impermeable coveralls (Tier 2b)
- Respiratory protective equipment (Tier 2c) – *filtering half masks FFP1*

	Parameters	Value
Tier 1 (No PPE)	% of active substance in the biocidal product Permethrin Tebuconazole Propiconazole IPBC	 0.35% 0.073% 0.073% 0.073%
	Penetration through PPE: no PPE	100%
	Dermal penetration Permethrin Tebuconazole Propiconazole IPBC	 12% 15% 16% 75%
	Inhalation rate[1]	1.25 m^3/hour
	Body weight[1]	60 kg
Mixing and Loading task		
Tier 1 (No PPE)	Task duration[1]	10 min
	Indicative dermal exposure on hands (no gloves)[2]	0.92 mg/min
Brushing task		
	Daily working time[1]	240 min
	Indicative dermal exposure on body (no protection)[1]	0.2382 mg/m^2 (indicative values normalized to 1 % active)

	Indicative dermal exposure on hands (no gloves)[1]	0.5417 mg/m^2 (indicative values normalized to 1 % active)
	Indicative inhalation exposure[1]	0.0016 mg/m^2 (indicative values normalized to 1 % active)
	Application area[1]	31.6 m^2
Tier 2 a (PPE - gloves)	Relative penetration of clothing – impermeable coveralls[1]	10 %
Tier 2 b (PPE – gloves and impermeable coveralls	Relative penetration of clothing – impermeable coveralls[1]	5 %

[1] Biocides Human Health Exposure Methodology, Oct 2015

[2] HEEG opinion 1 - Mixing loading model 7 alternatives, 2008.

Calculations for Scenario 11

Please for details calculations refer to annex 3.2.

Estimated exposure from application of product by brushing						
Exposure scenario	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake (µg/kg bw/d)**	**Estimated dermal uptake (µg/kg bw/d)**	**Estimated oral uptake (µg/kg bw/d)**	**Estimated total uptake (µg/kg bw/d)**
Scenario 11 – application of product by brushing	1 /No PPE	Permethrin Tebuconazole Propiconazole IPBC	0.005 0.004 0.004 0.004	17.316 16.233 17.316 81.168	- - - -	17.32 16.24 17.32 81.17
	2a / Gloves	Permethrin Tebuconazole Propiconazole IPBC	0.005 0.004 0.004 0.004	6.474 6.070 6.474 30.345	- - - -	6.48 6.07 6.48 30.35
	2b / Gloves + impermeable coveralls	Permethrin Tebuconazole Propiconazole IPBC	0.005 0.004 0.004 0.004	1.468 1.376 1.468 6.888	- - - -	1.47 1.38 1.47 6.88

Scenario 12: Primary exposure - Post-application, Cleaning of the spray/injection equipment

Description of Scenario 12 : post-application, Cleaning of the spray equipment		
This scenario is based on information provided in the document Biocides Human Health Exposure Methodology (Oct. 2015) and on Recommendation no. 4 of the BPC Ad hoc Working Group on Human Exposure, Cleaning of spray equipment in antifouling use (PT21), agreed at the Human Health Working Group IV on 17 September 2014. It assessed the cleaning of the spray equipment. In a tier 2, PPE are taken into consideration into the model : - Gloves (Tier 2a) - impermeable coveralls (Tier 2b) - Respiratory protective equipment (Tier 2c) – *filtering half masks FFP1*		
	Parameters	Value
Tier 1 (No PPE)	% of active substance in the biocidal product Permethrin Tebuconazole Propiconazole IPBC	 0.35% 0.2625% 0.2625% 0.2625%
	Body weight[1]	60 kg
	Inhalation rate[1]	1.25 m^3/h
	Dermal absorption : Permethrin Tebuconazole Propiconazole IPBC	 12% 15% 16% 75%
	Indicative dermal exposure on hands (no gloves)[2]	35.87 mg/min
	Indicative dermal exposure on body (no protection)[2]	19.28 mg/min
	Exposure duration[2]	20 min/event
	Relative penetration of clothing (no PPE considered)[1]	100%
	Number of events per day[2]	1 event /days
Tier 2 a (PPE - gloves)	Relative penetration of gloves – gloves[1]	10 %
Tier 2 b (PPE – gloves and impermeable coveralls	Relative penetration of clothing – impermeable coveralls[1]	5 %

Tier 2 c (PPE – gloves, impermeable coveralls and respiratory protective equipment	Relative penetration of respiratory protection – filtering half masks / FFP1[1]	25 %

[1] Biocide Human Health Exposure Methodology, version 1, October 2015

[2] Recommendation no. 4 of the BPC Ad hoc Working Group on Human Exposure, Cleaning of spray equipment in antifouling use (PT21), agreed at the Human Health Working Group IV on 17 September 2014

Calculations for Scenario 12

Please for details calculations refer to annex 3.2.

Estimated exposure from post-application, Cleaning of the spray equipment						
Exposure scenario	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake (µg/kg bw/d)**	**Estimated dermal uptake (µg/kg bw/d)**	**Estimated oral uptake (µg/kg bw/d)**	**Estimated total uptake (µg/kg bw/d)**
Scenario 12 – post-application, Cleaning of the spray equipment	1 /No PPE	Permethrin Tebuconazole Propiconazole IPBC	- - - -	7.73 7.25 7.73 36.25	- - - -	7.73 7.25 7.73 36.25
	2a / Gloves	Permethrin Tebuconazole Propiconazole IPBC	- - - -	3.21 3.01 3.21 15.03	- - - -	3.21 3.01 3.21 15.03
	2b / Gloves + impermeable coveralls	Permethrin Tebuconazole Propiconazole IPBC	- - - -	0.64 0.60 0.64 2.99	- - - -	0.64 0.60 0.64 2.99
	2c / Gloves + impermeable coveralls + filtering half masks (FFP11)	Permethrin Tebuconazole Propiconazole IPBC	- - - -	0.64 0.60 0.64 2.99	- - - -	0.64 0.60 0.64 2.99

Combined scenarios: Primary exposure of professional users

Summary table: combined systemic exposure from professional uses			
Exposure scenario	**Tier/PPE**	**Active substance**	**Estimated total uptake (µg/kg bw/d)**
Scenario 9+12	1 /No PPE	Permethrin Tebuconazole Propiconazole IPBC	292.32 272.67 290.47 1341.16
	2a / Gloves	Permethrin Tebuconazole Propiconazole IPBC	139.28 129.19 137.44 623.80
	2b / Gloves + impermeable coveralls	Permethrin Tebuconazole Propiconazole IPBC	18.61 16.06 16.76 58.14
	2c / Gloves + impermeable coveralls + filtering half masks (FFP11)	Permethrin Tebuconazole Propiconazole IPBC	13.07 11.91 12.61 53.99
Scenario 10+11+12	1 /No PPE	Permethrin Tebuconazole Propiconazole IPBC	473.11 443.53 473.10 2217.46
	2a / Gloves	Permethrin Tebuconazole Propiconazole IPBC	14.22 13.32 14.21 66.42
	2b / Gloves + impermeable coveralls	Permethrin Tebuconazole Propiconazole IPBC	6.65 6.22 6.63 30.92

Scenario 4: Secondary exposure: Professional – sanding treated wood posts

Description of Scenario 4 – Professional – sanding treated wood posts

Professional – sanding treated wood (chronic exposure)

Exposure of professional towards dust during sanding of treated wood was estimated using the example calculation provided in the TNsG on Human Exposure (2002) Part 3, Page 50.

Concentration of active substance in the wood dust = Total deposit of product into respiratory tract / task x % of active substance in the biocidal product

Active substance concentration on hand = Total deposit of product on hands/ task x % of active substance in the biocidal product

$Exposure_{inhalation}$ = Concentration of active substance in the wood dust x Inhalatory uptake / Body weight

$Exposure_{dermal}$ = Active substance concentration on hand x Dermal uptake / Body weight

Total systemic exposure = $Exposure_{dermal}$ + $Exposure_{inhalation}$

	Parameters	Value
Tier 1	Size of the treated wood Volume wooden post[1]: 4 cm x 4 cm x 250 cm = 4000 cm^3 Surface area wooden post: 4032 cm^2, if the surface area of the 2 ends of the post is included Volume of treated wood in the post: 393 cm3 (superficial treatment, only penetration in the 1 mm outermost layer: volume of the post – volume of the untreated inner core of the post = 4x4x250 -3.8x3.8x249.8 = 393 cm3).	393 cm^3
	Biocidal product concentration in the outer 1 mm layer Product specific information: application rate AXIL 3000 P /worst case = 300 mL/m^2 (density of the dilution ~1) The default values of the surface of treated wood is 4032 cm^2 The biocidal product concentration on a 4032 cm^2 layer is 30 mg/cm^2 x 4032 cm^2 = 120960 mg per 4032 cm^2 We have the default values of the size of treated wood: 4032 cm^2 which corresponds to 393 cm^3 (superficial treatment), thus the concentration biocidal product per volume unit is 120960 /393 cm^3 = 307.7862595 mg/cm^3.	307.79 mg bp/cm^3
	% of active substance in the biocidal product (worst case dilution of 35%) Permethrin Tebuconazole Propiconazole IPBC	 0.35% 0.2625% 0.2625% 0.2625%
	$Exposure_{inhalation}$	
	Inhalation rate[2]	1.25 m^3/h
	Body weight adult[2]	60 kg
	Exposure for wood dust during sanding for 60 min[1]	5 mg/m^3
	Duration of the work	360 minutes (6 hours)

	Density of wood[3]	0.4 g/cm^3
	Volume of wood dust	37.5.10^{-3}/0.4= 0.09375 cm^3
	Total deposit of biocidal product into respiratory track Inhaled wood dust amount : inhalation rate x duration of the work (hours) x exposure for wood dust during sanding for 6 hours = 1.25 x 6 x 5= 37.5 mg Volume of wood dust : Inhaled wood dust amount (g) / density of wood = 37.5x10^{-3}/0.4=0.09375 cm^3 Total deposit of biocidal product into respiratory track : Volume of wood dust x Biocidal product concentration in the outer 1 mm layer = 0.09375 x 307.79 = 29 mg	29 mg bp
	Inhalatory uptake	100%
	Exposure$_{dermal}$	
	Hand inner surface area (half of both hands area[2])	410 cm^2
	% of hand contaminated during sanding[4]	20%
	Biocidal product concentration on wood surface	30 mg bp /cm^2
	Transfer coefficient (rough sawn wood, dried fluid)[2]	2%
	Dermal uptake : Permethrin Tebuconazole Propiconazole IPBC	 12% 15% 16% 75%
	Total deposit of biocidal product on hands/ task Biocidal product concentration on wood surface x Hand inner surface area x % of hand contaminated during sanding x Transfer coefficient (%) : 30 mg/cm^2 x 410 cm^2 x 20/100 x 2/100 = 49 mg	49 mg bp

[1] TNsG on Human Exposure (2002) Part 3, Page 50

[2] Biocides Human Health Exposure Methodology, Oct 2015

[3] MOTA, 2013 from TM III 2008

[4] TNsG 2002, User Guidance version 1, p52

Calculations for Scenario 4 : Professional – sanding treated wood posts

Please for details calculations refer to annex 3.2.

Estimated exposure from sanding treated wood posts for professional (chronic exposure)						
Exposure scenario	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake (µg/kg bw/d)**	**Estimated dermal uptake (µg/kg bw/d)**	**Estimated oral uptake (µg/kg bw/d)**	**Estimated total uptake (µg/kg bw/d)**
Scenario 4 : Professional – sanding treated wood posts (chronic exposure)	Tier 1 No PPE	Permethrin Tebuconazole Propiconazole IPBC	1.683 1.262 1.262 1.262	0.344 0.323 0.344 1.614	- - - -	2.027 1.585 1.606 2.876

* Updated following higher application rate for curative treatment (MAC DEC 2019).

(IV) Non-professional exposure

The product is not intended to be used by non-professional and sould not be available for non-professional. Therefore the assessment of non-professional exposure is not relevant.

(V) Exposure of the general public

Scenario 5: Secondary exposure: Adult – Processing treated dried wood

Description of Scenario 5 – Processing treated dried wood – General public

Adult non-professional – sanding treated wood (acute exposure)

Exposure of professional towards dust during sanding of treated wood was estimated using the example calculation provided in the TNsG on Human Exposure (2002) Part 3, Page 50.

Concentration of active substance in the wood dust = Total deposit of product into respiratory tract / task x % of active substance in the biocidal product

Active substance concentration on hand = Total deposit of product on hands/ task x % of active substance in the biocidal product

$Exposure_{inhalation}$ = Concentration of active substance in the wood dust x Inhalatory uptake / Body weight

$Exposure_{dermal}$ = Active substance concentration on hand x Dermal uptake / Body weight

Total systemic exposure = $Exposure_{dermal}$ + $Exposure_{inhalation}$

	Parameters	Value
Tier 1	Size of the treated wood Volume wooden post[1]: 4 cm x 4 cm x 250 cm = 4000 cm^3 Surface area wooden post: 4032 cm^2, if the surface area of the 2 ends of the post is included Volume of treated wood in the post: 393 cm^3 (superficial treatment, only penetration in the 1 mm outermost layer: volume of the post – volume of the untreated inner core of the post = 4x4x250 -3.8x3.8x249.8 = 393 cm^3).	393 cm^3
	Biocidal product concentration in the outer 1 mm layer Product specific information: application rate AXIL 3000 P /worst case = 300 mL/m^2 (density of the dilution ~1) The default values of the surface of treated wood is 4032 cm^2 The biocidal product concentration on a 4032 cm^2 layer is 30 mg/cm^2 x 4032 cm^2 = 120960 mg per 4032 cm^2 We have the default values of the size of treated wood: 4032 cm^2 which corresponds to 393 cm^3 (superficial treatment), thus the concentration biocidal product per volume unit is 120960 /393 cm^3 = 307.7862595 mg/cm^3.	307.79 mg bp/cm^3
	% of active substance in the biocidal product (worst case dilution of 35%) Permethrin Tebuconazole Propiconazole IPBC	 0.35% 0.2625% 0.2625% 0.2625%
	$Exposure_{inhalation}$	
	Inhalation rate[2]	1.25 m^3/h
	Body weight adult[2]	60 kg
	Exposure for wood dust during sanding for 60 min[1]	5 mg/m^3
	Duration of the work	60 minutes (1 hour)

	Density of wood[3]	0.4 g/cm^3
	Volume of wood dust	6.25.10^{-3}/0.4= 0.015625 cm^3
	Total deposit of biocidal product into respiratory track Inhaled wood dust amount : inhalation rate x duration of the work (hours) x exposure for wood dust during sanding for 6 hours = 1.25 x 1 x 5= 6.25 mg Volume of wood dust : Inhaled wood dust amount (g) / density of wood = 6.25x10^{-3}/0.4=0.015625 cm^3 Total deposit of biocidal product into respiratory track : Volume of wood dust x Biocidal product concentration in the outer 1 mm layer = 0.015625 x 307.79 = 5 mg	5 mg bp
	Inhalatory uptake	100%
	Exposure$_{dermal}$	
	Hand inner surface area (half of both hands area[2])	410 cm^2
	% of hand contaminated during sanding[4]	20%
	Biocidal product concentration on wood surface	30 mg bp /cm^2
	Transfer coefficient (rough sawn wood, dried fluid)[2]	2%
	Dermal uptake : Permethrin Tebuconazole Propiconazole IPBC	 12% 15% 16% 75%
	Total deposit of biocidal product on hands/ task Biocidal product concentration on wood surface x Hand inner surface area x % of hand contaminated during sanding x Transfer coefficient (%) : 30 mg/cm^2 x 410 cm^2 x 20/100 x 2/100 = 49 mg	49 mg bp

[1] TNsG on Human Exposure (2002) Part 3, Page 50

[2] Biocides Human Health Exposure Methodology, Oct 2015

[3] MOTA, 2013 from TM III 2008

[4] TNsG 2002, User Guidance version 1, p52

Calculations for Scenario 5 : Processing treated dried wood – General public

Please for details calculations refer to annex 3.2.

Estimated exposure from Processing treated dried wood – General public						
Exposure scenario	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake (µg/kg bw/d)**	**Estimated dermal uptake (µg/kg bw/d)**	**Estimated oral uptake (µg/kg bw/d)**	**Estimated total uptake (µg/kg bw/d)**
Scenario 5 : Processing treated dried wood – General public (adult - acute exposure)	Tier 1 No PPE	Permethrin Tebuconazole Propiconazole IPBC	0.281 0.210 0.210 0.210	0.344 0.323 0.344 1.614	- - - -	0.625 0.533 0.555 1.825

* Updated following higher application rate for curative treatment (MAC DEC 2019).

Scenario 6 - Toddler chewing wood off-cut

Description of Scenario 6 – Toddler chewing wood off-cut		
Toddler, general public – Toddler chewing wood off-cut (acute exposure) The relevant exposure route is oral. This is an incidental event and the exposure duration is therefore best described as acute. This scenario is considered to represent the worst case for secondary oral exposure Exposure of toddler chewing wood off-cut was estimated using the example calculation provided in the TNsG on Human Exposure (2002) Part 3, Page 50. Maximum absorption of active substance = Application rate AXIL 3000P x % of active substance in the biocidal product Extraction from wood = Maximum absorption of active substance x Surface area of the wood chip Systemic exposure = Extraction From wood x Extraction of active substance when chewing x Oral uptake / Body weight		
	Parameters	Value
Tier 1	Size of the wood chip[1] Volume: 4 cm x 4 cm x 1 cm= 16 cm^3 Surface area: 32 cm^2 (worst case = treated at 2 sides of the chips)	16 cm^3 32 cm^2
	% of active substance in the biocidal product (worst case dilution of 35%) Permethrin Tebuconazole Propiconazole IPBC	 0.35% 0.2625% 0.2625% 0.2625%
	Application rate AXIL 3000 P / worst case = 300 ml/m^2	30 mg/ cm^2
	Extraction of active substance when chewing[1]	10%
	Oral uptake	100%
	Body weight toddler[2]	10 kg

[1] TNsG 2002, User Guidance version 1, p56

[2] Biocides Human Health Exposure Methodology, Oct 2015

Calculations for Scenario 6 : Toddler chewing wood off-cut

Please for details calculations refer to annex 3.2.

Estimated exposure from Toddler chewing wood off-cut						
Exposure scenario	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake (µg/kg bw/d)**	**Estimated dermal uptake (µg/kg bw/d)**	**Estimated oral uptake (µg/kg bw/d)**	**Estimated total uptake (µg/kg bw/d)**
Scenario 6 : Toddler chewing wood off-cut (toddler - acute exposure)	Tier 1 No PPE	Permethrin Tebuconazole Propiconazole IPBC	- - - -	- - - -	33.6 25.2 25.2 25.2	33.6 25.2 25.2 25.2

* Updated following higher application rate for curative treatment (MAC DEC 2019).

Scenario 7 – Toddler– playing on and mouthing weathered structure outdoors

Description of Scenario 7 – Toddler– playing on and mouthing weathered structure outdoors

Toddler, general public – Toddler– playing on and mouthing weathered structure outdoors (chronic exposure)

The relevant exposure routes are dermal and oral. Duration can be up to chronic, assuming that playing in the environment may happen daily. This scenario is considered to represent the worst case for secondary chronic exposure.

Exposure of toddler playing on and mouthing weathered structure outdoors the example calculation provided in the TNsG on Human Exposure (2002) Part 3, Page 50.

Active concentration on hand = Application rate AXIL 3000 P x % of active substance in the biocidal product x Hand surface area x % of hand contaminated x Transfer coefficient

$Exposure_{dermal}$ = Active substance concentration on hand x Dermal uptake / Body weight

$Exposure_{oral}$ = Active substance concentration on hand x Oral uptake / Body weight

Total systemic exposure = $Exposure_{dermal}$ + $Exposure_{oral}$

	Parameters	Value
Tier 1	Application rate AXIL 3000 P / worst case = 300 ml/m^2	30 mg/ cm^2
	% of active substance in the biocidal product (worst case dilution of 35%) Permethrin Tebuconazole Propiconazole IPBC	 0.35% 0.2625% 0.2625% 0.2625%
	Hand surface area[2]	230.4 cm^2
	% of hand contaminated[1]	20%
	Transfer coefficient (rough sawn wood, dried fluid)[2]	2%
	Dermal uptake : Permethrin Tebuconazole Propiconazole IPBC	 12% 15% 16% 75%
	Oral uptake	100%
	Body weight[2]	10 kg

[1] TNsG 2002, User Guidance version 1, p53

[2] Biocides Human Health Exposure Methodology, Oct 2015

Calculations for Scenario 7 : Toddler– playing on and mouthing weathered structure outdoors

Please for details calculations refer to annex 3.2.

Estimated exposure from toddler playing on and mouthing weathered structure outdoors						
Exposure scenario	**Tier/ PPE**	**Active substance**	**Estimated inhalation uptake (µg/kg bw/d)**	**Estimated dermal uptake (µg/kg bw/d)**	**Estimated oral uptake (µg/kg bw/d)**	**Estimated total uptake (µg/kg bw/d)**
Scenario 7 : Toddler playing on and mouthing weathered structure outdoors (toddler - chronic exposure)	Tier 1 No PPE	Permethrin Tebuconazole Propiconazole IPBC	- - - -	1.16 1.09 1.16 5.44	9.68 7.26 7.26 7.26	10.84 8.35 8.42 12.70

* Updated following higher application rate for curative treatment (MAC DEC 2019).

Scenario 8 – Inhalation of volatized residues indoors (IPBC only)

Description of Scenario 8– Inhalation of volatized residues indoors (IPBC only)

For Permethrin, propiconazole and tebuconazole : exposure to volatilized residues indoor can be considered negligible based on HEEG opinion 13 (see above).

However, for IPBC, based on HHEG opinion 13, exposure to volatilized residues indoor can not be considered negligible and have been calculated.

A model for inhalation of volatilized residues from treated wood indoors is worked out in the TNsG 2002, User Guidance version 1 p52. The model assumes a moderately ventilated room and residence time of 18 h/day. As a worst-case an inhalation exposure is taken as 1% of the saturated vapour pressure of the active substance.

Saturated vapour concentration = $\frac{\text{vapour pressure x molecular weight}}{\text{Gas constant x temperature in degrees Kelvin}}$

Systemic dose = 1% SVC x inhalation rate x duration / Body Weight

The body weight and inhalation rate have been updated according Biocide Human Health Exposure Methodology, October 2015.

	Parameters	Value
Tier 1 No PPE	Vapour pressure[1]	IPBC: 4.5×10^{-3} Pa (20°C)
	Molecular weight[1]	IPBC: 281.1 g/mol
	Gas constant	8.314 J/mol/K
	Temperature (degrees Kelvin)	298 K
	Saturated vapour concentration (SVC)	IPBC 4.5×10^{-3} x 281.1 / (8.314x298) = 5×10^{-3} mg/m^3
	Body weight[2]	Adult: 60 kg Child: 23.9 kg Toddler: 10 kg Infant : 8 kg
	Inhalation rate[2]	Adult: 1.25 m^3 air/h Child: 1.32 m^3 air/h Toddler: 1.26 m^3 air/h Infant : 0.84 m^3 air/h
	Duration	18 hours

[1] Assessment Report on IPBC (RMS DK, February 2008)

[2] Biocides Human Health Exposure Methodology, Oct 2015

Calculations for Scenario 8 – Inhalation of volatized residues indoors

Estimated exposure from general public inhalation volatized residues indoors						
Exposure scenario	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake (µg/kg bw/d)**	**Estimated dermal uptake (µg/kg bw/d)**	**Estimated oral uptake (µg/kg bw/d)**	**Estimated total uptake (µg/kg bw/d)**
Scenario 8 : general public inhalation volatized residues indoors (chronic exposure)	Tier 1 No PPE	IPBC only adult child toddler infant	 1.915 5.076 11.579 9.650	 - - - -	 - - - -	 1.915 5.076 11.579 9.650

Combined scenarios

Summary table: combined systemic exposure from general public uses						
Scenarios combined	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake (µg/kg bw/d)**	**Estimated dermal uptake (µg/kg bw/d)**	**Estimated oral uptake (µg/kg bw/d)**	**Estimated total uptake (µg/kg bw/d)**
Scenario 7+8 (toddler)	1 /No PPE	IPBC	11.579	5.44	7.26	24.28

* Updated following higher application rate for curative treatment (MAC DEC 2019).

(VI) Monitoring data

Not applicable

(VII) Dietary exposure

No exposure is foreseen as regards to the intended use of the product. However the following RMM was found on the label and is highly advised in order to avoid any misuses of the product:

"Do not apply the product on wood which may come into contact with food, feedstuff or livestock".

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

Occupational exposure during production and formulation of biocidal product is not covered by the BPR. It is expected that production and formulation are performed in conformity with European and national worker protection legislation.

(IX) Summary of exposure assessment

Scenarios and values to be used in risk assessment				
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Active substance**	**Estimated total uptake (µg / kg bw)**
1. Automated spraying - Deluge	Professionals – Primary exposure	1 /No PPE	Permethrin Tebuconazole Propiconazole IPBC	527.656 2967.870 2967.870 2967.870
	Professionals – Primary exposure	2a / Gloves	Permethrin Tebuconazole Propiconazole IPBC	39.150 220.026 220.026 220.026
	Professionals – Primary exposure	2b / Gloves + impermeable coveralls	Permethrin Tebuconazole Propiconazole IPBC	6.683 37.398 37.398 37.398
	Professionals – Primary exposure	2c / Gloves + impermeable coveralls + filtering half masks (FFP11)	Permethrin Tebuconazole Propiconazole IPBC	6.653 37.375 37.375 37.375
1 bis. Automated spraying – Deluge – limitation to maximum 10% dilution rate	Professionals – Primary exposure	1 /No PPE	Permethrin Tebuconazole Propiconazole IPBC	274.821 1545.766 1545.766 1545.766
	Professionals – Primary exposure	2a / Gloves	Permethrin Tebuconazole Propiconazole IPBC	20.391 114.597 114.597 114.597
	Professionals – Primary exposure	2b / Gloves + impermeable coveralls	Permethrin Tebuconazole Propiconazole IPBC	3.481 19.478 19.478 19.478
	Professionals – Primary exposure	2c / Gloves + impermeable coveralls + filtering half masks (FFP11)	Permethrin Tebuconazole Propiconazole IPBC	3.465 19.466 19.466 19.466
2. Automated dipping	Professionals – Primary exposure	1 /No PPE	Permethrin Tebuconazole Propiconazole IPBC	1492.096 8393.040 8393.040 8393.040

	Professionals – Primary exposure	2a / Gloves	Permethrin Tebuconazole Propiconazole IPBC	123.520 694.800 694.800 694.800
	Professionals – Primary exposure	2b / Gloves + impermeable coveralls	Permethrin Tebuconazole Propiconazole IPBC	19.309 108.612 108.612 108.612
2bis. Fully automated dipping	Professionals – Primary exposure	1 /No PPE	Permethrin Tebuconazole Propiconazole IPBC	373.024 2098.260 2098.260 2098.260
	Professionals – Primary exposure	2a / Gloves	Permethrin Tebuconazole Propiconazole IPBC	30.880 173.700 173.700 173.700
	Professionals – Primary exposure	2b / Gloves + impermeable coveralls	Permethrin Tebuconazole Propiconazole IPBC	4.827 27.153 27.153 27.153
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	[redacted]	[redacted]	[redacted]	[redacted]
	[redacted]	[redacted]	[redacted]	[redacted]
	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	[redacted]	[redacted]	[redacted]	[redacted]
	[redacted]	[redacted]	[redacted]	[redacted]

	[redacted]	[redacted]	[redacted]	[redacted]
4. Professional – sanding treated wood posts*	Professionals – Secondary exposure	1 /No PPE	Permethrin Tebuconazole Propiconazole IPBC	2.027 1.585 1.606 2.876
5. Non-professional - processing Treated dried wood*	General public (adults) – secondary acute exposure	1 /No PPE	Permethrin Tebuconazole Propiconazole IPBC	0.625 0.533 0.555 1.825
6. Chewing wood off-cut*	General public (toddlers) – secondary acute exposure	1 /No PPE	Permethrin Tebuconazole Propiconazole IPBC	33.6 25.2 25.2 25.2
7. Playing and mouthing playground structure*	General public (toddlers) – secondary chronic exposure	1 /No PPE	Permethrin Tebuconazole Propiconazole IPBC	10.84 8.35 8.42 12.70
8. Inhalation volatized residues indoors	General public – secondary chronic exposure	1 /No PPE	IPBC	adult 1.915 child 5.076 toddler 11.579 infant 9.650
Combined exposure Scenarios 7+8*	General public (toddler) – secondary chronic exposure	1 /No PPE	IPBC	24.28

* Updated following higher application rate for curative treatment (MAC DEC 2019).

9. Application of product by spraying	Professionals – Primary exposure	1 /No PPE	Permethrin Tebuconazole Propiconazole IPBC	284.59 265.42 282.74 1304.92
	Professionals – Primary exposure	2a / Gloves	Permethrin Tebuconazole Propiconazole IPBC	136.08 126.19 137.23 608.77
	Professionals – Primary exposure	2b / Gloves + impermeable coveralls	Permethrin Tebuconazole Propiconazole IPBC	17.97 15.46 16.13 55.15
	Professionals – Primary exposure	2c / Gloves + impermeable coveralls + filtering half masks (FFP11)	Permethrin Tebuconazole Propiconazole IPBC	12.43 11.31 11.97 51.00
10. Application of product by borehole impregnation	Professionals – Primary exposure	1 /No PPE	Permethrin Tebuconazole Propiconazole IPBC	448.06 420.04 448.04 2100.04
	Professionals – Primary exposure	2a / Gloves	Permethrin Tebuconazole Propiconazole IPBC	4.54 4.24 4.52 21.04
	Professionals – Primary exposure	2b / Gloves + impermeable coveralls	Permethrin Tebuconazole Propiconazole IPBC	4.54 4.24 4.52 21.04
	Professionals – Primary exposure	2c / Gloves + impermeable coveralls + filtering half masks (FFP11)	Permethrin Tebuconazole Propiconazole IPBC	4.49 4.21 4.49 21.01
11. Application of product by brushing	Professionals – Primary exposure	1 /No PPE	Permethrin Tebuconazole Propiconazole IPBC	17.32 16.24 17.32 81.17
	Professionals – Primary exposure	2a / Gloves	Permethrin Tebuconazole Propiconazole IPBC	6.48 6.07 6.48 30.35

	Professionals – Primary exposure	2b / Gloves + impermeable coveralls	Permethrin Tebuconazole Propiconazole IPBC	1.47 1.38 1.47 6.88
12. Post-application, Cleaning of the spray equipment	Professionals – Primary exposure	1 /No PPE	Permethrin Tebuconazole Propiconazole IPBC	7.73 7.25 7.73 36.25
	Professionals – Primary exposure	2a / Gloves	Permethrin Tebuconazole Propiconazole IPBC	3.21 3.01 3.21 15.03
	Professionals – Primary exposure	2b / Gloves + impermeable coveralls	Permethrin Tebuconazole Propiconazole IPBC	0.64 0.60 0.64 2.99
	Professionals – Primary exposure	2c / Gloves + impermeable coveralls + filtering half masks (FFP11)	Permethrin Tebuconazole Propiconazole IPBC	0.64 0.60 0.64 2.99
Combined exposure Scenarios 9+12	Professionals – Primary exposure	2b / Gloves + impermeable coveralls	Permethrin Tebuconazole Propiconazole IPBC	18.61 16.06 16.76 58.14
Combined exposure Scenarios 10+11+12	Professionals – Primary exposure	2b / Gloves + impermeable coveralls	Permethrin Tebuconazole Propiconazole IPBC	6.65 6.22 6.63 30.92

2.2.6.3 Risk characterisation for human health

The following AEL values were derived during assessment of the active substance for the purpose of inclusion into Annex I of 98/8/EC for use as a wood preservative. Please refer to the Assesment Report of **Permethrin** (RMS IE, April 2014) for more information. ADI and ARfD values were not derived.

Reference values to be used in Risk Characterisation for Permethrin

Reference	Study	NOAEL (LOAEL)	AF[1]	Correction for oral absorption	Value

$AEL_{short-term}$	2-year rat toxicity study	50 mg/kg bw/d	100 (inter-& intra-specific differences)	No (100%)	0.5 mg/kg bw/d
$AEL_{medium-term}$	1-year, oral, dog	5 mg/kg bw/d	100 (inter-& intra-specific differences)	No (100%)	0.05 mg/kg bw/d
$AEL_{long-term}$	1-year, oral, dog	5 mg/kg bw/d	100 (inter-& intra-specific differences)	No (100%)	0.05 mg/kg bw/d

The following AOEL value was derived during assessment of the active substance for the purpose of inclusion into Annex I of 98/8/EC for use as a wood preservative. Please refer to the Assessment Report of **Tebuconazole** (RMS DK, November 2007) for more information. ADI and ARfD values were not derived.

Reference values to be used in Risk Characterisation for Tebuconazole

Reference	Study	NOAEL (LOAEL)	AF[1]	Correction for oral absorption	Value
$AOEL_{short/long-term}$	1-year, oral, dog	3 mg/kg bw/d	100 (inter-& intra-specific differences)	No (100%)	0.03 mg/kg bw/d

The following AOEL values were derived during assessment of the active substances for the purpose of inclusion into Annex I of 98/8/EC for use as a wood preservative. Please refer to the Assessment Report of **Propiconazole** (RMS FI, November 2007) for more information. ADI and ARfD values were not derived.

However, this values were reviewed during the assessment of the active substances for use as PT9 (in 2013) and PT7 (in 2015).

Please refer to the Assessment Report of **Propiconazole** (PT 7 - RMS FI, January 2015) for more information.

Reference values to be used in Risk Characterisation for Propiconazole

Reference	Study	NOAEL (LOAEL)	AF	Correction for oral absorption	Value
$AOEL_{short-term}$	Developmental study, rat	30 mg/kg bw/d	100 (inter-& intra-specific differences)	No (100%)	0.3 mg/kg bw/d

***$AOEL_{LongTerme}$ delete after MAC**

Reference values to be used in Risk Characterisation for Propiconazole

Reference	Study	NOAEL (LOAEL)	AF	Correction for oral absorption	Value
$AEL_{short-term}$	Developmental study, rat	30 mg/kg bw/d	100 (inter-& intra-specific differences)	No (100%)	0.3 mg/kg bw/d
$AEL_{medium-term}$	2-generation study, rat	8 mg/kg bw/d	100 (inter-& intra-specific differences)	No (100%)	0.08 mg/kg bw/d
$AEL_{long-term}$	2 years study, rat	4 mg/kg bw/d	100 (inter-& intra-specific differences)	No (100%)	0.040 mg/kg bw/d
ADI	2 years study, rat	4 mg/kg bw/d	100 (inter-& intra-specific differences)	No (100%)	0.040 mg/kg bw/d
ARfD	Developmental study, rat	30 mg/kg bw/d	100 (inter-& intra-specific differences)	No (100%)	0.3 mg/kg bw/d

The following AOEL values were derived during assessment of the active substances for the purpose of inclusion into Annex I of 98/8/EC for use as a wood preservative. Please refer to the Assessment Report of **IPBC** (RMS DK, February 2008) for more information. ADI and ARfD values were not derived.

Reference values to be used in Risk Characterisation for IPBC

Reference	Study	NOAEL (LOAEL)	AF	Correction for oral absorption	Value
$AOEL_{short-term}$	90-day, oral rat	35 mg/kg bw/d	100 (inter-& intra-specific differences)	No (100%)	0.35 mg/kg bw/d
$AOEL_{long-term}$	2-year, oral, rat	20 mg/kg bw/d	100 (inter-& intra-specific differences)	No (100%)	0.2 mg/kg bw/d

(I) Risk for industrial users

Systemic effects

Task/ Scenario	Tier	Active substance	Systemic NOAEL mg/kg bw/d	AEL µg/kg bw/d	Estimated uptake µg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Primary							

Scenario 1	1 /No PPE	Permethrin Tebuconazole Propiconazole IPBC	5 3 8 20	50 30 80 200	527.656 2967.870 2967.870 2967.870	1055.31 9892.90 3709.84 1483.93	No No No No
	2a / Gloves	Permethrin Tebuconazole Propiconazole IPBC	5 3 8 20	50 30 80 200	39.150 220.026 220.026 220.026	78.30 733.42 275.03 110.01	Yes No No No
	2b / Gloves + impermeable coveralls	Permethrin Tebuconazole Propiconazole IPBC	5 3 8 20	50 30 80 200	6.683 37.398 37.398 37.398	13.37 124.66 46.75 37.40	Yes No Yes Yes
	2c / Gloves + impermeable coveralls + filtering half masks (FFP11)	Permethrin Tebuconazole Propiconazole IPBC	5 3 8 20	50 30 80 200	6.653 37.375 37.375 37.375	13.31 124.58 46.72 18.69	Yes No Yes Yes
Scenario 1 bis	1 /No PPE	Permethrin Tebuconazole Propiconazole IPBC	5 3 8 20	50 30 80 200	274.821 1545.766 1545.766 1545.766	549.64 5152.55 1932.21 772.88	No No No No
	2a / Gloves	Permethrin Tebuconazole Propiconazole IPBC	5 3 8 20	50 30 80 200	20.391 114.597 114.597 114.597	40.78 389.99 143.25 57.30	Yes No No Yes
	2b / Gloves + impermeable coveralls	Permethrin Tebuconazole Propiconazole IPBC	5 3 8 20	50 30 80 200	3.481 19.478 19.478 19.478	6.96 64.93 24.35 9.74	Yes Yes Yes Yes
	2c / Gloves + impermeable coveralls + filtering half masks (FFP11)	Permethrin Tebuconazole Propiconazole IPBC	5 3 8 20	50 30 80 200	3.465 19.466 19.466 19.466	6.93 64.89 24.33 9.73	Yes Yes Yes Yes
Scenario 2	1 /No PPE	Permethrin Tebuconazole Propiconazole IPBC	5 3 8 20	50 30 80 200	1492.096 8393.040 8393.040 8393.040	2984.19 27976.80 10491.30 4196.52	No No No No
	2a / Gloves	Permethrin Tebuconazole Propiconazole IPBC	5 3 8 20	50 30 80 200	123.520 694.800 694.800 694.800	247.04 2316 868.50 347.40	No No No No
	2b / Gloves + impermeable coveralls	Permethrin Tebuconazole Propiconazole IPBC	5 3 8 20	50 30 80 200	19.309 108.612 108.612 108.612	38.62 362.04 135.76 54.31	Yes No No Yes

Scenario 2 bis	1 /No PPE	Permethrin Tebuconazole Propiconazole IPBC	5 3 8 20	50 30 80 200	373.024 2098.260 2098.260 2098.260	746.05 6994.20 2622.82 1049.13	No No No No
	2a / Gloves	Permethrin Tebuconazole Propiconazole IPBC	5 3 8 20	50 30 80 200	30.880 173.700 173.700 173.700	61.76 579 217.12 86.85	Yes No No Yes
	2b / Gloves + impermeable coveralls	Permethrin Tebuconazole Propiconazole IPBC	5 3 8 20	50 30 80 200	4.827 27.153 27.153 27.153	9.65 90.51 33.94 13.58	Yes Yes Yes Yes
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

			[redacted]	[redacted]			
	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Local effects

Mixing and loading of undiluted product.

As the undiluted product is corrosive to eyes and sensitive, a qualitative local risk assessment according to the guidance on the BPR: Volume III HH part B is performed.

Hazard			Exposure							Risk	
Hazard category	Effects in terms of C&L	Additional relevant hazard information	PT	Who is exposed	Tasks, uses, processes	Potential exposures route	Frequency and duration of potential exposure	Potential degree of exposure	Relevant RMM & PPE	Conclusion on risk	Uncertainties attaced to conclusion may increase (↑) or decrease (↓) risk or both (↑↓)
Skin sens 1 EYE DAM1	H317 H318	Skin Sens 1 (medium) EYE DAM 1 (High)	8	PROF/ INDUSTRIAL USERS	Mixing and Loading the concentrated product	Dermal, Inhalation	Frequency depending on the uses : 1 to several tasks/day	Low (operated in closed drums)	with gloves, without RPE	Acceptable	↓ PPE ↓ Professional user ↓ No direct contact expected ↓ P sentences on the label

The P-sentences on the label are sufficient in order to protect the user. No additional RMM are needed.

Diluted product: No local risk is foreseen since the diluted product will not be classified as corrosive or sensitive anymore (dilution rate 19.2) according to the rules laid down in Regulation (EC) No 1272/2008 (CLP).

- EYE DAM 1 : 0.68% of component which have triggered the classification EYE DAM 1 of AXIL 3000P is inferior to the GCL of 3%
- SKIN SENS 1: 0.192% of component which have triggered the classification SKIN SENS 1 of AXIL 3000P is inferior to the GCL of 1%

Conclusion

Normal use of AXIL 3000 P by industrial professionals has a sufficiently large safety margin for the **scenario 2bis (fully automated dipping)** [redacted] when using proper **PPE** (chemical resistant gloves, impermeable coverall).

There is no safe use identified when the product is intended to be used on hardwood by automated spraying (scenario 1)

However by limiting the uses with a **maximum dilution rate of 10%** (**scenario 1bis**), a safe used is identified when proper **PPE** are used (chemical resistant gloves, impermeable coverall) for application by **automated spraying**.

Industrial secondary exposure is foreseen mainly during the cleaning/maintenance of the system. Any sort of maintenance/repair work on the system (hoses, valves etc.) may potentially lead to exposure. Cleaning may also potentially lead to exposure. However it is assumed that this type of tasks will be done by others professionals compared to application tasks (primary exposure). The exposure is considered lower than the exposure resulting of the application of the product. As no model are available in order to estimate the exposure, if PPE are required for the application task, it is advice to use the same PPE for the potentially secondary exposure.

Remark: during bilateral discussion for approval of this product, some discussion take place on the choice of Belgium of 10% for dermal absorption for permethrin. It has to be noted that using default 75% of dermal absorption for permethrin does not change the conclusion for this product.

(II) Risk for professional users

Systemic effects

Task/ Scenario	Tier	Active substance	Systemic NOAEL mg/kg bw/d	AEL µg/kg bw/d	Estimated uptake µg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Primary							
Scenario 9	1 /No PPE	Permethrin	5	50	284.59	569.18	No
		Tebuconazole	3	30	265.42	884.72	No
		Propiconazole	4	40	282.74	706.85	No
		IPBC	20	200	1304.92	652.46	No
	2a / Gloves	Permethrin	5	50	136.08	272.15	No
		Tebuconazole	3	30	126.19	420.62	No
		Propiconazole	4	40	137.23	335.57	No
		IPBC	20	200	608.77	304.38	No
	2b / Gloves + impermeable coveralls	Permethrin	5	50	17.97	35.94	Yes
		Tebuconazole	3	30	15.46	51.55	Yes
		Propiconazole	4	40	16.13	40.31	Yes
		IPBC	20	200	55.15	27.58	Yes
	2c / Gloves + impermeable coveralls + filtering half	Permethrin	5	50	12.43	24.86	Yes
		Tebuconazole	3	30	11.31	37.69	Yes
		Propiconazole	4	40	11.97	29.92	Yes
		IPBC	20	200	51.00	25.50	Yes

	masks (FFP11)						
Scenario 10	1 /No PPE	Permethrin Tebuconazole Propiconazole IPBC	5 3 4 20	50 30 40 200	448.06 420.04 448.04 2100.04	896.11 140.14 1120.1 1050.02	No No No No
	2a / Gloves	Permethrin Tebuconazole Propiconazole IPBC	5 3 4 20	50 30 40 200	4.54 4.24 4.52 21.04	9.07 14.14 11.30 10.52	Yes Yes Yes Yes
	2b / Gloves + impermeable coveralls	Permethrin Tebuconazole Propiconazole IPBC	5 3 4 20	50 30 40 200	4.54 4.24 4.52 21.04	9.07 14.14 11.30 10.52	Yes Yes Yes Yes
	2c / Gloves + impermeable coveralls + filtering half masks (FFP11)	Permethrin Tebuconazole Propiconazole IPBC	5 3 4 20	50 30 40 200	4.49 4.21 4.49 21.01	8.88 14.03 11.23 10.50	Yes Yes Yes Yes
Scenario 11	1 /No PPE	Permethrin Tebuconazole Propiconazole IPBC	5 3 4 20	50 30 40 200	17.32 16.24 17.32 81.17	34.64 54.12 43.30 40.59	Yes Yes Yes Yes
	2a / Gloves	Permethrin Tebuconazole Propiconazole IPBC	5 3 4 20	50 30 40 200	6.48 6.07 6.48 30.35	12.96 20.24 16.19 15.17	Yes Yes Yes Yes
	2b / Gloves + impermeable coveralls	Permethrin Tebuconazole Propiconazole IPBC	5 3 4 20	50 30 40 200	1.47 1.38 1.47 6.88	2.94 4.60 3.68 3.44	Yes Yes Yes Yes
Scenario 12	1 /No PPE	Permethrin Tebuconazole Propiconazole IPBC	5 3 4 20	50 30 40 200	7.73 7.25 7.73 36.25	15.46 24.16 19.33 18.12	Yes Yes Yes Yes
	2a / Gloves	Permethrin Tebuconazole Propiconazole IPBC	5 3 4 20	50 30 40 200	3.21 3.01 3.21 15.03	6.41 10.02 8.02 7.51	Yes Yes Yes Yes
	2b / Gloves + impermeable coveralls	Permethrin Tebuconazole Propiconazole IPBC	5 3 4 20	50 30 40 200	0.64 0.60 0.64 2.99	1.28 1.99 1.59 1.49	Yes Yes Yes Yes
	2c / Gloves + impermeable coveralls + filtering half	Permethrin Tebuconazole Propiconazole	5 3 4	50 30 40	0.64 0.60 0.64	1.28 1.99 1.59	Yes Yes Yes

	masks (FFP11)	IPBC	20	200	2.99	1.49	Yes
Secondary							
Scenario 4*	1 /No PPE	Permethrin	5	50	2.027	4.06	Yes
		Tebuconazole	3	30	1.585	5.28	Yes
		Propiconazole	4	40	1.606	4.02	Yes
		IPBC	20	200	2.876	1.44	Yes

* Updated following higher application rate for curative treatment (MAC DEC 2019).

Combined scenarios

Task/ Scenario	Tier	Active substance	Systemic NOAEL mg/kg bw/d	AEL mg/kg µw/d	Estimated uptake µg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Primary							
Scenario 9+12	2b / Gloves + impermeable coveralls	Permethrin	5	50	18.61	37.22	Yes
		Tebuconazole	3	30	16.06	53.54	Yes
		Propiconazole	4	40	16.76	41.90	Yes
		IPBC	20	200	58.14	29.07	Yes
Scenario 10+11+12	2b / Gloves + impermeable coveralls	Permethrin	5	50	6.65	13.29	Yes
		Tebuconazole	3	30	6.22	20.73	Yes
		Propiconazole	4	40	6.63	16.58	Yes
		IPBC	20	200	30.92	15.45	Yes

Local effects

No local effects are expected due to the dilution of the product.

Conclusion

Normal use of AXIL 3000 P by professionals has a sufficiently large safety margin for the scenarios 9 (spraying), 10 (injection), 12 (cleaning of the equipment), 11 (brushing) when using proper PPE (chemical resistant gloves, impermeable coverall).

Normal use of AXIL 3000 P by professionals has a sufficiently large safety margin for the combined exposure of scenarios 9+12 (spraying+cleaning of equipment) and 10+11+12 (Injection+Brushing+cleaning equipment) when using proper PPE (chemical resistant gloves, impermeable coverall).

Due to the exposure to combined active substances in the product, for the scenarios 9+12, use of an additional PPE (respiratory protective equipment with a protection factor of 4) as a risk is identified for the liver when respiratory protection is not worn.

No risk is foreseen for the secondary exposure of professional sanding treated wood posts (chronic exposure).

(III) Risk for non-professional users

No exposure is foreseen. Risk is not applicable

(IV) Risk for the general public

Systemic effects

Task/ Scenario	Tier	Active substance	Systemic NOAEL mg/kg bw/d	AEL µg/kg µw/d	Estimated uptake µg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Secondary – acute phase							
Scenario 5 (adult)*	1 /No PPE	Permethrin	50	500	0.625	0.12	Yes
		Tebuconazole	3	30	0.533	1.78	Yes
		Propiconazole	30	300	0.555	0.18	Yes
		IPBC	35	350	1.825	0.52	Yes
Scenario 6 (toddler)*	1 /No PPE	Permethrin	50	500	33.6	6.72	Yes
		Tebuconazole	3	30	25.2	84	Yes
		Propiconazole	30	300	25.2	8.4	Yes
		IPBC	35	350	25.2	7.2	Yes
Secondary – chronic phase							
Scenario 7 (toddler)*	1 /No PPE	Permethrin	5	50	10.84	21.68	Yes
		Tebuconazole	3	30	8.35	27.82	Yes
		Propiconazole	4	40	8.42	21.05	Yes
		IPBC	20	200	12.70	6.35	Yes
Scenario 8 (general public)	1 /No PPE	IPBC	20	200			
		- Adult			1.915	0.96	Yes
		- Child			5.076	2.54	Yes
		- Toddler			11.579	5.79	Yes
		- Infant			9.650	4.82	Yes

Combined scenarios

Task/ Scenario	Tier	Active substance	Systemic NOAEL mg/kg bw/d	AEL mg/kg µw/d	Estimated uptake µg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Secondary – chronic phase							
Scenario 7+8 (toddler)*	1 /No PPE	IPBC	20	200	24.28	12.14	Yes

* Updated following higher application rate for curative treatment (MAC DEC 2019).

Local effects

No local effects are expected.

Conclusion

Normal use of AXIL 3000 P has a sufficiently large safety margin for the secondary exposed general public, for acute and chronic phase exposure, for the separate scenarios 5, 6, 7, and 8 as well as for the combined scenarios.

(V) Risk for consumers via residues in food

No exposure is foreseen as regards to the intended use of the product. However the following RMM is highly advised on the label in order to avoid any misuses of the product:

"Do not apply the product on wood which may come into contact with food, feedstuff or livestock".

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

The combined toxicological effects of the 4 active substances have not been investigated with regard to repeated exposure, as we believe that the active substances do not exhibit systemic toxicity by the same mode of action. It is not expected that combined exposure to the 4 active substances will result in an additional risk above the estimated risks based on the individual substances.

UPDATED Dec 2019 – NA-MAC

The applicant apply for a major change in the authorization of the product AXIL 3000 P, additional uses have been requested: AXIL 3000 P is a wood preservative for professional use which is intended for curative treatment of wood against wood-destroying insects. Its field of use is to protect construction wood in conditions of use classes 1 and 2. The biocidal product is a concentrate water-based to be diluted 35% w/w with water. The curative treatment is performed by double spraying and by Injection + Brushing processes.

Professional combined exposure (chronic exposure scenario)

*The **Tier 1** concerns the acceptability of each substance. Please refer to point (I) Risk for industrial users.*
For each active substance separately, the risk are acceptable when PPE are worn (gloves and impermeable coveralls) for scenarios 9 (spraying), 10 (injection), 12 (cleaning of the equipment), 11 (brushing); including combined scenario.

*The **Tier 2** concerns the mixture risk assessment by an additivity approach :*

Permethrin	Tebuconazole	Propiconazole	IPBC	HI	Risk
HQ (Exposure/AEL)				(Σ HQ a.s)	
Combined exposure from **Spaying** (gloves + impermeable coveralls)					
0.36	0.52	0.40	0.27	**1.55**	Tier 3B
Combined exposure from **Injection** (gloves + impermeable coveralls)					
0.09	0.14	0.11	0.10	0.45	Acceptable
Combined exposure from **Brushing** (gloves + impermeable coveralls)					
0.03	0.05	0.04	0.03	0.15	Acceptable
Combined exposure from **Cleaning of the equipment** (gloves + impermeable coveralls)					
0.01	0.02	0.02	0.01	0.06	Acceptable
Combined exposure from **Spraying + cleaning of the equipment** (gloves + impermeable coveralls)					
0.37	0.53	0.42	0.29	**1.62**	Tier 3B
Combined exposure from **Brushing + injection + cleaning of the equipment** (gloves + impermeable coveralls)					
0.13	0.21	0.17	0.15	0.66	Acceptable

- ➔ HI < 1, for combined exposure from **Brushing + injection + cleaning of the equipment** (gloves + impermeable coveralls) and therefore the risk is acceptable.
- ➔ HI ≥ 1, a **Tier 3B** approach is considered since the 4 active substances have target organs in common.

The liver is a target organ common to permethrin, propiconazole, tebuconazole and IPBC.
The kidney is a target organ common to permethrin, propiconazole and IPBC.
Blood is a target organ common to propiconazole and tebuconazole.
The adrenal is a target organ common to propiconazole and tebuconazole.

Specific target organ long term AELS can be derived for each active substance based on the available data in the CARs.

	Permethrin	**Tebuconazole**	**Propiconazole**	**IPBC**
General long term AEL	0.05	0.03	0.04	0.2
Specific AEL: liver	0.05	0.06	0.08	0.2
Specific AEL: kidney	0.05	-	0.5	0.35
Specific AEL: Hemato		0.3	0.761	
Specific AEL: adrenals		0.03	0.04	

Please for details calculations refer to annex 3.2.

TIER 3B - Liver:

Permethrin	Tebuconazole	Propiconazole	IPBC	HI (∑ HQ a.s)	Risk
HQ (Exposure/AEL)					
Combined exposure from **Spaying** (gloves + impermeable coveralls)					
0.36	0.26	0.20	0.27	**1.09**	**Not acceptable**
Combined exposure from **Spaying** (gloves + impermeable coveralls + **RPE**)					
0.25	0.19	0.15	0.25	0.84	Acceptable
Combined exposure from **Spraying + cleaning of the equipment** (gloves + impermeable coveralls + **RPE**)					
0.26	0.20	0.16	0.27	0.89	Acceptable

TIER 3B - Kidney:

Permethrin	Tebuconazole	Propiconazole	IPBC	HI (∑ HQ a.s)	Risk
HQ (Exposure/AEL)					
Combined exposure from **Spaying** (gloves + impermeable coveralls + **RPE**)					
0.25	n.r.	0.02	0.15	0.42	Acceptable
Combined exposure from **Spraying + cleaning of the equipment** (gloves + impermeable coveralls + **RPE**)					
0.26	n.r.	0.03	0.15	0.44	Acceptable

TIER 3B – Blood:

Permethrin	Tebuconazole	Propiconazole	IPBC	HI (∑ HQ a.s)	Risk
HQ (Exposure/AEL)					

Combined exposure from **Spaying** (gloves + impermeable coveralls + **RPE**)					
n.r.	0.04	0.01	n.r.	0.05	Acceptable
Combined exposure from **Spraying + cleaning of the equipment** (gloves + impermeable coveralls + **RPE**)					
n.r.	0.04	0.02	n.r.	0.06	Acceptable

TIER 3B – Adrenal:

Permethrin	Tebuconazole	Propiconazole	IPBC	HI (∑ HQ a.s)	Risk
HQ (Exposure/AEL)					
Combined exposure from **M&L + Automated spraying** (gloves + impermeable coveralls)					
n.r.	0.38	0.30	n.r.	0.68	Acceptable
Combined exposure from **Spraying + cleaning of the equipment** (gloves + impermeable coveralls + **RPE**)					
n.r.	0.40	0.31	n.r.	0.71	Acceptable

The following application gives unacceptable results for professional users for the target organ - liver:

- Spraying with gloves and coveralls

However, the risk is acceptable when an additional PPE is worn (RPE with protection factor of 4).

Toddler combined exposure (chronic exposure scenario)

*The **Tier 1** concerns the acceptability of each substance. Please refer to point (IV) Risk for the general public.*
For each active substance separately, the risk are acceptable for general public chronic exposure.

*The **Tier 2** concerns the mixture risk assessment by an additivity approach :*

Permethrin	Tebuconazole	Propiconazole	IPBC	HI (∑ HQ a.s)	Risk
HQ (Exposure/AEL)					
Toddler (genral public) – Playing and mouthing playground structure Remark for IPBC it is considered combined exposure including expsore to vapour					
0.06	0.84	0.08	0.07	**1.06**	Tier 3B

➔ HI ≥ 1, a **Tier 3B** approach is considered since the 4 active substances have target organs in common.

The liver is a target organ common to permethrin, propiconazole, tebuconazole and IPBC.
The kidney is a target organ common to permethrin, propiconazole and IPBC.
Blood is a target organ common to propiconazole and tebuconazole.
The adrenal is a target organ common to propiconazole and tebuconazole.

Specific target organ long term AELS can be derived for each active substance based on the available data in the CARs.

	Permethrin	**Tebuconazole**	**Propiconazole**	**IPBC**
General ACUTE term AEL	0.5	0.03	0.3	0.35

Specific AEL: liver - ACUTE	0.5	0.06	0.3	0.350
Specific AEL: kidney - ACUTE	0.5	-	0.5	0.35
Specific AEL: Hemato - ACUTE		0.3	0.761	
Specific AEL: adrenals - ACUTE		0.03	0.04	

Please for details calculations refer to annex 3.2.

TIER 3B - Liver:

Permethrin	Tebuconazole	Propiconazole	IPBC	HI (∑ HQ a.s)	Risk
HQ (Exposure/AEL)					
Toddler (genral public) – Playing and mouthing playground structure Remark for IPBC it is considered combined exposure including expsore to vapour					
0.07	0.42	0.08	0.07	0.64	Acceptable

TIER 3B - Kidney:

Permethrin	Tebuconazole	Propiconazole	IPBC	HI (∑ HQ a.s)	Risk
HQ (Exposure/AEL)					
Toddler (genral public) – Playing and mouthing playground structure Remark for IPBC it is considered combined exposure including expsore to vapour					
0.07	n.r.	0.05	0.07	0.19	Acceptable

TIER 3B – Blood:

Permethrin	Tebuconazole	Propiconazole	IPBC	HI (∑ HQ a.s)	Risk
HQ (Exposure/AEL)					
Toddler (genral public) – Playing and mouthing playground structure Remark for IPBC it is considered combined exposure including expsore to vapour					
n.r.	0.08	0.03	n.r.	0.11	Acceptable

TIER 3B – Adrenal:

Permethrin	Tebuconazole	Propiconazole	IPBC	HI (∑ HQ a.s)	Risk
HQ (Exposure/AEL)					
Toddler (genral public) – Playing and mouthing playground structure Remark for IPBC it is considered combined exposure including expsore to vapour					
n.r.	0.84	0.08	n.r.	0.92	Acceptable

The risk is acceptable.

2.2.7 Risk assessment for animal health

The product is not used on animals. Indirect exposure to the product may occur for pets and domestic animal particularly in private area. However, due to the lack of appropriate guidance,

exposure is assumed to be similar to these of toddlers and children and no specific measure is needed (except for cats due to the presence of permethrin into the biocidal product).

Cats are known to be more sensible to pyrethroids than others animals due to a slower metabolisation of these substances. Intoxication are very common and may be lethal. In order to protect cats, the following Risk Mitigation Measure must be added on the label:
"Contain permethrin (pyrethroids), may be lethal to cats. Cats must avoid contact with treated object/area".

2.2.8 Risk assessment for the environment

AXIL 3000 P is wood preservative for industrial use which has 3 functions: insecticide, anti-termite and fungicide. Its field of use is Use Classes 1 to 3 to protect wood construction.

The biocidal product is a water-based concentrate that will be diluted in water. The dilution rates used in this risk assessment is 19.2% or 10% for fully automated dipping, depending on the wood category, 10% for automated [redacted] A top coat is required to be applied after treatment with the product for use classes 3.1 and 3.2.

AXIL 3000 P is also intended for curative treatment of wood against wood-destroying insects. Its field of use is to protect construction wood in conditions of use classes 1 and 2. The biocidal product is a concentrate water-based to be diluted 35% w/w with water. The curative treatment is performed by double spraying and by Injection + Brushing processes.

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

-Use class 2 (UC 2): situation in which the wood-based product is under cover and fully protected from the weather but where occasional but not persistent wetting may occur.

-Use class 3 (UC 3): situation in which the wood-based product is not covered and not in contact with the ground. It is either continually exposed to the weather or is protected from the weather but subject to frequent wetting.

The product contains the active substances Permethrin at 1 % w/w, Propiconazole at 0.75 % w/w, Tebuconazole at 0.75% w/w and IPBC at 0.75 % w/w. AXIL 3000 P is applied diluted with the following application rates:

- automated spraying (100g/m2) (industrial process),
- short dipping (100g/m2) (industrial process),
[redacted]. double spraying (300g/m2),
- injection + Brushing (300g/m2).

The environmental risk assessment focusses on the use class 3 as relevant emissions to environmental compartments.

In addition to the active substances Permethrin, IPBC, Tebuconazole and Propiconazole the product contains [redacted] other substances which are not considered as substance of concern for the environment. The information provided in the CAR of Permethrin, IPBC, Tebuconazole and Propiconazole are considered enough to perform an assessment of the biocidal product AXIL 3000 P and therefore no new data/information on the 4 active substances is required.

2.2.8.1 Effects assessment on the environment

No new data relevant for the environmental evaluation, nor on the product, nor on the active substance, have been submitted.

All the data refer to the chapter 'Fate and distribution in the environment' and 'Effects on environmental organisms' are from Doc IIA as well as from Doc IIB for the active substances Permethrin, Tebuconazole, Propiconazole and IPBC. A summary is presented below for each of the active substance.

Environmental fate and behavior of the active substance

- **Permethrin**

Aquatic compartment including STP and sediment

Permethrin was observed to be hydrolytically stable between pH 3.0/4.0 to 7.6/7 at 25/50°C respectively. Only at pH 9.0/9.6 was permethrin observed to hydrolyse, with DT50 values for cis- and trans-permethrin estimated at 35 days and 42 days, respectively (at pH 9.6 and 25°C). Permethrin is not readily biodegradable according to OECD 301B (CO2 evolution method)/US EPA OPPTS 835.3110 and OECD 301 F (oxygen consumption). Permethrin is strongly adsorbed to soil (Mean Kf oc 73,442 L/kg (n= 10)).

Permethrin (46:54 and 53:47 cis:trans) was observed to degrade in aerobic water/sediments systems, with whole-system DT50 values of cis- and trans-permethrin calculated at 63.7 days and 27.3 days, respectively at 25°C (equivalent to corresponding values at 12 °C of 180.2 days and 77.2 days).

The degradation scheme proposed for the behaviour of permethrin in aerobic watersediment systems involves as a first step transformation along parallel pathways to 3-phenoxybenzyl alcohol (PB alcohol) and 3-(2,2-dichlorovinyl)-2,2-dimethyl-(1-cyclopropane)carboxylate (DCVA), followed by transformation of 3-phenoxybenzyl alcohol to 3-phenoxybenzoic acid (PBA), with carbon dioxide and bound residues as terminal products.

Maximum observed levels of DCVA, PBA and PB alcohol in the water compartment were 62.6 %AR, 28.8%AR and 38.2 %AR respectively. DCVA and PBA were also major metabolites in the sediment compartment (21.7 % and 16.4 % respectively).

Permethrin was observed to degrade more slowly under anaerobic conditions, with whole-system DT50 values of cis- and trans-permethrin calculated at 179.4 days and 114.5 days, respectively (equivalent to corresponding values at 12 °C of 507.6 days and 323.9 days). Cis- and trans-permethrin appeared to be rather immobile in the sediment, remaining in the upper portion (0-5 cm). DT50 values determined for the cis- and trans-permethrin isomers in the sediment phase ranged from 118 to 256 days and 18 to 62 days, respectively.

Direct photolysis of permethrin (49:51 cis:trans) indicated slow degradation of the test material resulting in a DT50 value of 118 days with 12 hr sunlight per day under outdoor conditions at latitude of 50°N and the fall season.

Atmosphere

Volatilization of permethrin is considered to be negligible based on the vapour pressure (2.155 x 10-6 Pa at 20°C, 25:75 cis:trans) and Henry constant (4.6 x 10-3 - > 4.5 x 10-2 Pa m3 mol-1). Permethrin volatilisation loss from a soil surface over 24 hours to the atmosphere was calculated to be 0.73% assuming a temperature of 25 °C. Permethrin is rapidly degraded and would not be transported over large distances in the atmosphere in gaseous phase.

Terrestrial compartment

Degradation of permethrin was investigated under aerobic conditions in several soils. The range of reliable SFO DT50s ranged from 77 d to ~141 d at 12°C. The corresponding geomean DT50 was 106d. The *cis* isomer degraded more slowly than the *trans* isomer based on the *cis:trans* ratio at the time of application changing from 40:60 to 50:50 by day 30 and 78:22 by day 365. It can be expected that a DT50 value of 106 days is conservative enough to represent the degradation in soil at 12°C of permethrin samples containing a cis:trans ratio of 25:75.

The route of degradation of permethrin in soil appears to be dominated by a two-step process. Permethrin breaks down to form DCVA (max 11.3 %AR, SFO DT50 12°C 33.1-~175 d) and PBA (max 15.0 % AR, 1.7-2.5 d at 12°C), and ultimately converts to CO2.

Permethrin was observed to be relatively stable when exposed to photolysing conditions in soil. A DT50 of 200 d was estimated. No transformation product greater than 10 %AR was observed.

Permethrin is strongly adsorbed to soil (Mean Kfoc 73,441 L/kg, Koc 26,930 n = 9). Therefore, leaching is not expected to occur. The two major soil metabolites (DCVA & PBA) are expected to be more mobile. The mean Kfoc for DCVA was 93.2 L/kg (n = 5). For PBA the Kfoc was 141.2 L/kg.

- **Tebuconazole**

Tebuconazole fate and distribution in the environment

Tebuconazole is stable to hydrolysis. Direct photodegradation of Tebuconazole in water is low and the substance may be considered photolytically stable in both water and soil. However, indirect photolysis of Tebuconazole may occur in water. The solubility of Tebuconazole in water is 29 mg/L at 20°C.

Tebuconazole is not readily biodegradable and biodegradation half-life in surface water is estimated to be about 198 days. However, Tebuconazole will be adsorbed to the sediment and therefore a dissipation half-life in surface water is estimated to be 43 days in a water/sediment study. Tebuconazole is not metabolized rapidly in soil in laboratory experiments: the half-life for primary degradation is greater than one year. In field studies the dissipation half-life is 77 days.

Tebuconazole has a low mobility potential (Koc = 992 mL/g). The BCF bioaccumulation factor for fish varies from 31 to 93. However, the higher value includes the metabolites as well. For the risk assessment, a BCF of 78 is used since this value seems to be the highest reliable value found.

1,2,4-Triazole is the primary metabolite from the degradation of Tebuconazole. However it appears to breakdown more rapidly in soil than Tebuconazole.

The risk quotients are more favorable for the metabolites than for Tebuconazole for both the aquatic and terrestrial environment and therefore the metabolite will not be considered further in the risk assessment.

Air will not be an environmental compartment of concern for Tebuconazole used in wood preservatives because of the very low vapour pressure of this compound (1.7 10-6 Pa at 20°C) and these wood preservatives are not applied by spraying. It should however be noted that the calculated DT50 of Tebuconazole in air is more than 2 days and it is therefore considered persistent in air.

- **Propiconazole**

Propiconazole fate and distribution in the environment

Propiconazole is moderately soluble in water having water solubility of around 100 mg/L at pH 7 at 20°C. Propiconazole is very slightly volatile having vapour pressure around 5.6 10-5 Pa at 25°C. Hydrolysis and direct photolysis do not play a major role in the degradation of Propiconazole in surface waters. Propiconazole is not readily biodegradable. If Propiconazole enters a water body, a large quantity will be instantaneously removed from the aqueous phase by rapid adsorption to suspended sediments. The subsequent degradation in the aquatic system will be mainly of biological nature. Dissipation half-life of 6.4 days in water and degradation half-life of 636 days in water/sediment system are used in the PEC calculations. There was no metabolite accounting > 10% of the active substance found in the water/sediment key study.

In the laboratory studies the half-life of Propiconazole in soil ranged from 29 to 72 days with a median of 45 days at 20 to 25 °C. Mineralization of Propiconazole was < 5% of the applied radioactivity in all studies and the amount of non-extractable increased even up to around 50% at 120 days but never exceeded 70% of the applied radioactivity.

The maximum dissipation half-life of 129 days in soil derived from field studies is used as the worst case in the PECsoil calculations for Propiconazole when risk after 30 days (TIME 1) is considered. The geometric mean dissipation half-life of 177 days in soil (from field studies) is used in the PEC_{soil} calculations for Propiconazole when risk after several years (TIME 2) is considered.

In the laboratory studies there were two degradation products of Propiconazole accounting more than 10% of the active substance in soil (1,2,4-triazole and CGA 118 245). Degradation half-life of 1,2,4- triazole was around 9.3 days in soil and degradation half-life of CGA 118 245 was around 1 day in soil.

Propiconazole adsorbs very rapidly to soils with most of the short-term (24 hrs) adsorption taking place within an hour or less. With an arithmetic mean of Koc (adsorption) = 944 mL/g (Koc = 1000 mL/g in EUSES calculation) Propiconazole is regarded as slightly mobile in soil. The two degradation products of Propiconazole accounting for more than 10% in the soil degradation studies are considered mobile in soil. Arithmetic mean values for 1,2,4-triazole and CGA 118 245 are Koc (adsorption) = 69 mL/g and Koc (adsorption) = 129 mL/g, respectively.

Log Kow of Propiconazole is 3.7 implying a slight bioaccumulation potential. Propiconazole is slightly bioaccumulative to fish with a BCF of 180. Based on the estimation of BCF for terrestrial bioconcentration, Propiconazole is not bioaccumulative to terrestrial organisms.

The estimated half-life of Propiconazole in the troposphere is between 10.2 and 42 hours assuming the OH concentration (5*105) given in the TGD (Part II, 2003, equation 28) and a 24-hour day.

- **IPBC**

IPBC fate and distribution in the environment

IPBC is stable to hydrolysis. Direct photodegradation of IPBC in water is low and the substance may be considered photolytically stable in water. The water solubility of IPBC is 168 mg/L at 20°C.

IPBC is not readily biodegradable but is primary biodegradable according to Zahn-Wellens test. The biodegradation half-life in surface water is estimated to about 1.4 hour at 20-22°C. IPBC

is metabolised rapidly in soil in laboratory experiments, the half-life is estimated to be 2.1 hour at 20-22°C. In degradation of IPBC, the primary degradate was propargyl-butyl-carbamate (PBC).

PBC was found in hydrolysis, aerobic soil, and anaerobic aquatic metabolism studies. In hydrolysis, PBC was the only degradation product identified.

In soil, PBC was degraded to CO2, bound soil residues and an unidentified metabolite. 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. QSAR estimation indicates a toxicity of this metabolite is comparable to that found for IPBC. Therefore in this case it is not considered necessary to ask for experimental ecotoxicological data for this metabolite.

Iodine will be evaluated by Sweden as an active substance for disinfectant and an effect and risk assessment will therefore not be performed here.

IPBC has a medium to high mobility potential (Koc = 126 mL/g by HPLC method).

The bioaccumulation potential is not significant based on a log Pow value of 2.8.

Air will not be an environmental compartment of concern for IPBC used in wood preservatives because of the low vapour pressure of this compound (2.36 10-3 Pa at 25°C). It should also be noted that the calculated DT50 of IPBC in air is only about 15 hours and is therefore not considered persistent in air.

Effect assessment of the active substance

All the data refer to the chapter Effects assessment are from Doc IIA as well as from Doc IIB for the active substances Permethrin, Tebuconazole, Propiconazole and IPBC.

There has not been submitted any new data regarding the active substances. The PNEC values for IPBC have been taken from the Assessment Report for PT 8 and also including updates in the Assessment Report for PT13. For Permethrin the PNEC values have been taken from the Assessment Report for PT8. For Propiconazole the PNEC values have been taken from the Assessment Report for Propiconazole in PT 7 (January 2015), because new data has been included compared to the Assessment Report for Propiconazole in PT 8 (December 2007). For Tebuconazole the PNEC values have been taken from the Assessment Report for PT8 (Novembre 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	**$PNEC_{water}$ ($mg.l^{-1}$)**	**$PNEC_{sediment}$ ($mg.kg^{-1}wwt$)**	**$PNEC_{soil}$ ($mg.kg^{-1}wwt$)**	**$PNEC_{STP}$ ($mg.l^{-1}$)**
Tebuconazole	1.0E-03	5.5E-01	1.0E-01	3.2E-01
Propiconazole	6.8E-03	5.4E-02	1.0E-01	1.0E+02

IPBC	5.0E-04	Covered by surface water	4.3E-03	4.4E-01
Permethrin	4.7E-07	2.17E-04	8.76E-02	4.95E-03
1,2,4-triazole	n.r	n.r	1.0E-02	n.r
PBC	4.13E-02	Covered by surface water	1.49E-01	The one for IPBC is used as a worst case
DCVA	1.5E-02	1.2E-02	4.6	n.r
PBA	1.0E-02	9.0E-03	1.44	n.r

n.r.: not relevant for the concerned compartment

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

No other constituent apart from the active substances has an influence on the environmental classification and labelling of the product.

Harmonised environmental classification of the active substances

The environmental classification of the active substances is the following:

Harmonised env. Classification for the active substances			
Active substance	**Env. Classification**	**M-Factor**	**Concentration of a.s. in the product (%)**
Tebuconazole	H400, H410	M=1 M(chronic)=10	0.75
Propiconazole	H400, H410	M=1	0.75
IPBC	H400, H410	M=10 M(chronic)=1	0.75
Permethrin	H400, H410	M=100 M(chronic)=10000	1

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:*** GHS09 Warning H410

(II) Further Ecotoxicological studies

No new data is available compared to CAR (see 2.2.8) and no further ecotoxicological studies are required.

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

No new data is available compared to CAR (see 2.2.8).

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

The product is not in the form of bait or granules, so none such data is required.

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

The product is not in the form of bait or granules, so none such data is required.

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

Not relevant.

(VII)Foreseeable routes of entry into the environment on the basis of the use envisaged

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 vacuum pressure /double vacuum an assessment of cumulative leaching from treated wood in-service over a 20 years period should be applied. Hence, the assessment times are 30 days (TIME 1) for short term consideration and 15 or 20 years (service life) for the longer time period (TIME 2). If a risk is identified for TIME 1, 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.

Curative treatment

According to the ESD for PT 8: Revised Emission Scenario Document for Wood preservatives (OECD series No. 2, 2013), for wood in conditions of UC 1 and UC 2 the potential emissions from treated wood to the outer environment are considered negligible.

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

No new data was submitted or is required. Information on the active substances suffices for the environmental risk assessment of the product. Moreover, the product does not contain any other substances relevant for the environment apart from the active substance.

[redacted]

[redacted]		
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

[redacted]

(IX) Testing for distribution and dissipation in soil (ADS)

No new data was submitted or is required.

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

No new data was submitted or is required.

(XI) Testing for distribution and dissipation in air (ADS)

No new data was submitted or is required.

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

No new data was submitted or is required.

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

No new data was submitted or is required.

2.2.8.2 Exposure assessment

The exposure assessment focusses on the use class 3 as relevant exposures to environmental compartments.

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

- Application and storage of treated wood prior to shipment;
- Treated wood in service.

Several relevant emission scenarios have been identified based on intended uses.

In the case of application and storage of treated wood prior to shipment, the emission scenarios used for the product AXIL 3000 P cover:

- Industrial preventive processes - Automated spraying process (Flow-coating)
- Industrial preventive processes - Short Dipping

[redacted]

The storage scenario employed in this assessment assumes that the storage area is uncovered and unpaved. In reality **freshly treated timber must be stored on impermeable hard standing to prevent direct losses to soil or water and any losses must be collected for reuse or disposal.**

In the case of treated wood in service, the following emission scenarios have been run for use class 3 : House, Noise barrier and Bridge over pond.

For two of the emission scenarios of treated wood in service, calculations of emissions in soil have been done with substance **removal processes in soil taken into account**; according to OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 2, Part 3.

For all the four AXIL 3000 P active substances: Permethrin, Tebuconazole, Propiconazole and IPBC, the environmental risk assessment has been calculated from semi-field leaching tests done on AXIL 3000 P.

[redacted]

(I) General information

Assessed PT	PT8
Assessed scenarios	**Scenario 1:** (ESD PT8, Sep. 2013, §4.1.1) Automated spraying • Product application • Storage of treated wood prior to shipping **Scenario 2:** (ESD PT8, Sep. 2013, §4.1.2) Short dipping • Product application • Storage of treated wood prior to shipping **Scenario 3:** (ESD PT8, Sep. 2013, §4.3.3) In-service leaching from treated wood – Automated spraying/short dipping • House • 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	Scenario 1-3: 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	Scenario n°: 1 - 3 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 is performed for the UC 1 and UC 2.

(II) Emission estimation

The emission estimation focusses on the use in class 3 as relevant emissions to environmental compartments.

AXIL 3000 P is a concentrate water-based wood preservative containing 1% Permethrin, 0.75% Tebuconazole, 0.75% Propiconazole and 0.75% IPBC. For treatment, 100g of diluted product are applied per square meter of wood. The worst case application rate used in the scenarios is: 100g/m^2 (100ml/m^2) and the dilution rate used in this risk assessment is 19.2%.

Input parameters for calculating the local emission and concentration		
Input	**Value**	**Unit**
Scenarios 1 - 3		
Application rate of biocidal product	0.1	[l.m^{-2}]
Quantity of a substance applied per m^2 of wood (Q_{ai})		
Tebuconazole	1.44E-04	[kg.m^{-2}]
Propiconazole	1.44E-04	[kg.m^{-2}]
IPBC	1.44E-04	[kg.m^{-2}]
Permethrin	1.92E-04	[kg.m^{-2}]

First order rate constant for removal from soil (*k*) ($k=Ln2/DT_{50}$)		
Tebuconazole	0.009	[d^{-1}]
Propiconazole	0.00845	[d^{-1}]
IPBC	3.54	[d^{-1}]
Permethrin	0.00654	[d^{-1}]
Cumulative quantity of substance leached out of 1 m^2 of treated wood over the initial assessment period TIME 1 (30 days)		
Tebuconazole	1.02E-01	[$mg.m^{-2}$]
Propiconazole	9.41E-02	[$mg.m^{-2}$]
IPBC	1.26E-01	[$mg.m^{-2}$]
Permethrin	1.32E-03	[$mg.m^{-2}$]
Cumulative quantity of substance leached out of 1 m^2 of treated wood over a longer assessment period TIME 2 (15 years)		
Tebuconazole	4.40E+01	[$mg.m^{-2}$]
Propiconazole	4.28E+01	[$mg.m^{-2}$]
IPBC	2.45E+01	[$mg.m^{-2}$]
Permethrin	4.10E-01	[$mg.m^{-2}$]
Average daily flux during the storage period ($FLUX_{storage}$) for automated spraying and short dipping processes (see annex 3.7)		
Tebuconazole	2.26E-08	[$kg.m^{-2}.d^{-1}$]
Propiconazole	2.10E-08	[$kg.m^{-2}.d^{-1}$]
IPBC	8.29E-09	[$kg.m^{-2}.d^{-1}$]
Permethrin	4.02E-10	[$kg.m^{-2}.d^{-1}$]
Fraction released to facility drain ($F_{facilitydrain}$)		
Tebuconazole	0.003	[-]
Propiconazole	0.03	[-]
IPBC	0.03	[-]
Permethrin	0.0001	[-]
Fraction released to air (F_{air})		
Tebuconazole	0.001	[-]
Propiconazole	0.001	[-]
IPBC	0.001	[-]
Permethrin	0.001	[-]

Scenario 1: *Industrial processes – automated spraying*

This type of superficial application process is typically used in sawmills and carpentry / joinery shops.

The wood, whether in debarked logs or fully or partly machined timber are moved through one or more longitudinal or transversal boxes on a continuously moving conveyor system.

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

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

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

The treatment apparatus is typically established in a contained or bunded area fabricated from materials resistant to the wood preservative product. Provision is made for the collection, recycling and reuse of wood preservative collected from the conveyor or drip dry area.

The release of wood preservatives from the treating installation or where the treated timber is stored into a surface water drain or drain connected to a Sewage Treatment Plant (STP) is not permitted and so any installation where this occurs is in contravention of environmental protection legislation and the licence to operate the treatment process.

Even though release of the collected waste water to a sewage treatment plant (STP) is nowadays not permitted anymore in EU member state countries, the corresponding emission pathway (facility drain to STP to surface water) is nevertheless a worst case assessment of which can be of relevance outside the EU.

Product application

Emissions can occur to the air directly due to spray drift and evaporation from the spray box and from the treated (wet) wood after it exits from the spray box and dries on the belt or in the sorting tray, and as it is bundled for stacking at the sorting and stacking areas. Sorting is the process whereby workers sort the treated wood according to its size and appearance into different stacks where the wood is bundled for placement in the yard. Ventilation in most cases is via fans only.

Mill/carpentry floors are cemented, so run-off is generally collected and recycled via drip pads. However, unintentional spills, floor cleaning, equipment cleaning and washing waters, drag-out on tires may reach the facility drain. The facility drain is assumed to drain into the public sewage treatment plant (STP).

To estimate emissions into the air and the facility drain following industrial treatment of UC 3 woods by automated spraying, the revised ESD for PT8 describes one scenario: Application phase in automated spraying.

The $AREA_{wood\text{-}treated}$ of 20000 $m^2.d^{-1}$ (large plant) represents a worst case situation and is therefore used in this risk assessment.

The input parameters for calculating the local emission following an application by automated spraying process are presented in the following table.

Input parameters for calculating the local emission				
Input	**Nomenclature**	**Value**	**Unit**	**Remarks**

Scenario: Application phase in automated spraying process				
Wood area treated per day (large plant)	$AREA_{wood\text{-}treated}$	20000	[$m^2.d^{-1}$]	D
Application rate: quantity of a.i. applied per 1 m^2 of wood area	Q_{ai}	**See above**	[$kg.m^{-2}$]	S
Fraction released to facility drain	$F_{facilitydrain}$	**See above**	[--]	D
Fraction released to air	F_{air}	**See above**	[--]	D
Fraction of spray drift deposition	F_{drift}	0.001	[--]	D

D=default, S=based on information of applicant

- **Calculations**

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

$$E_{local,air} = Q_{ai} \,.\, AREA_{wood\text{-}treated} \,.\, (F_{air} + F_{drift})$$

$$E_{local,facilitydrain} = Q_{ai} \,.\, AREA_{wood\text{-}treated} \,.\, F_{facilitydrain}$$

Resulting local emissions		
Active substance	**Local emission ($Elocal_{air}$) [$kg.d^{-1}$]**	**Local emission ($Elocal_{facilitydrain}$) [$kg.d^{-1}$]**
Tebuconazole	5.76E-03	8.64E-03
Propiconazole	5.76E-03	8.64E-02
IPBC	5.76E-03	8.64E-02
Permethrin	7.68E-03	3.84E-04

Storage phase

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

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

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

Input parameters for calculating the local emissions and concentrations				
Input	**Nomenclature**	**Value**	**Unit**	**Remarks**
Scenario: Storage phase in automated spraying process				
Effective surface area of treated wood, considered to	$AREA_{wood\text{-}expo}$	11	[$m^2.m^{-2}$]	D

be exposed to rain, per 1m^2 storage area (i.e. soil)				
Surface area of the storage place (large plant)	$AREA_{storage}$	790	[m^2]	D
Duration of the initial assessment period	*TIME1*	30	[d]	D
Duration of a longer assessment period	*TIME2*	7300	[d]	D
Duration of storage of treated wood prior to shipment	$TIME_{storage}$	3	[d]	D
Average daily flux i.e. the average quantity of an active ingredient that is daily leached out of 1 m^2 of treated wood during 3 days storage period [kg.m^{-2}.d^{-1}]	$FLUX_{storage,spray}$	**See above**	[kg.m^{-2}.d^{-1}]	S
Volume of treated wood stacked per m^2 of storage area (i.e. soil)	$VOLUME_{wood-stacked}$	2	[m^3.m^{-2}]	D
Bulk density of wet soil	RHO_{soil}	1700	[kg.m^{-3}]	D
Soil depth	$DEPTH_{soil}$	0.5	[m]	D
Volume of (wet) soil	V_{soil}	395	[m^3]	D
Fraction of rainwater running off the storage site	F_{runoff}	0.5	[-]	D

D=default, S=based on information of applicant

- **Calculations**

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

$$Q_{leach,storage,time1} = FLUX_{storage,spray} \,.\, AREA_{wood-expo} \,.\, AREA_{storage} \,.\, TIME\ 1$$

$$Q_{leach,storage,time2} = FLUX_{storage,spray} \,.\, AREA_{wood-expo} \,.\, AREA_{storage} \,.\, TIME\ 2$$

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

$$E_{local,surfacewater,time1} = Q_{leach,storage\ time1} \,.\, F_{runoff} \,/\, TIME\ 1$$

$$E_{local,surfacewater,time2} = Q_{leach,storage\ time2} \,.\, F_{runoff} \,/\, TIME\ 2$$

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

$$C_{local,surfacewater,time\ 1} = E_{local,surfacewater,time1} \,/\, FLOW_{surfacewater}$$

$$C_{local,surfacewater,time\ 2} = E_{local,surfacewater,time2} / FLOW_{surfacewater}$$

$$C_{local,soil,time\ 1} = Q_{leach,storage,time1} \cdot (1 - F_{runoff}) / V_{soil} \cdot RHO_{soil}$$

$$C_{local,soil,time\ 2} = Q_{leach,storage,time2} \cdot (1 - F_{runoff}) / V_{soil} \cdot RHO_{soil}$$

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

Resulting cumulative quantity of substance leached		
Active substance	**cumulative quantity of substance leached over 30 days TIME 1 [kg]**	**cumulative quantity of substance leached after 20 years TIME 2 [kg]**
Tebuconazole	5.90E-03	1.44E+00
Propiconazole	5.48E-03	1.33E+00
IPBC	2.16E-03	5.26E-01
Permethrin	1.05E-04	2.55E-02

Resulting local emissions to surface water compartment		
Active substance	**Local emission due to leaching after 30 days TIME 1 [kg.d^{-1}]**	**Local emission due to leaching after 20 years TIME 2 [kg.d^{-1}]**
Tebuconazole	9.84E-05	9.84E-05
Propiconazole	9.13E-05	9.13E-05
IPBC	3.61E-05	3.61E-05
Permethrin	1.75E-06	1.75E-06

Resulting local concentrations to surface water compartment		
Active substance	**Local concentration into surface water after 30 days TIME 1[mg.l^{-1}]**	**Local concentration into surface water after 20 years TIME 2 [mg.l^{-1}]**
Tebuconazole	3.80E-06	3.80E-06
Propiconazole	3.52E-06	3.52E-06
IPBC	1.39E-06	1.39E-06
Permethrin	6.74E-08	6.74E-08

Resulting local concentrations to soil compartment		
Active substance	**Local concentration in soil after 30 days TIME 1[kg.kg$_{wwt}^{-1}$]**	**Local concentration in soil after 20 years TIME 2 [kg.kg$_{wwt}^{-1}$]**
Tebuconazole	4.40E-09	1.07E-06
Propiconazole	4.08E-09	9.93E-07
IPBC	1.61E-09	3.92E-07

Permethrin	7.80E-11	1.90E-08

Scenario 2: *Industrial processes – short dipping*

Dipping and immersion are superficial application processes and are typically used in sawmills and carpentry / joinery shops. They are batch processes and are usually automatic in operation. In either case they involve the submerging of a pack or single piece (only in small scale operations) of wood into a dipping tank filled with ready for use wood preservative solution. Packs of wood are typically loaded on automatic equipment (e.g. a hydraulic mast) and lowered into the dipping tank.

The immersion period lasts min. 30 seconds to 3 minutes for AXIL 3000 P. After the required immersion period the packs or pieces of wood, which are slightly raised at one end to aid liquid run off, are hoisted out of the liquid and usually held above the open tank for excess liquid to fall back into the dipping tank and be re-used. When the excess liquid has been drained, the pieces or packs of wood are moved to a post treatment conditioning location which is usually bunded and the timber is allowed to dry before being moved off-site or used on site. Any further drips are contained and recycled.

Some installations may have local exhaust ventilation. The release of wood preservatives from the treating installation or where the treated timber is stored into a surface water drain or drain connected to a STP is not permitted and so any installation where this occurs is in contravention of environmental protection legislation and the licence to operate the treatment process.

Even though release of the collected waste water to a sewage treatment plant (STP) is nowadays not permitted anymore in EU member state countries, the corresponding emission pathway (facility drain to STP to surface water) is nevertheless a worst case assessment of which can be of relevance outside the EU.

After the treatment, wood must be stored in a covered and paved area to reduce the leaching during use.

Product application

The dipping baths are usually open and can lead to emissions to air by evaporation and codistillation with water or solvent. A distinction is made between wood preservative products dissolved in water and those using organic solvents as the carriers for the active substance. Only those using organic solvents can evaporate into the air.

Mill/carpentry floors are cemented, so run-off is generally collected and recycled. However, unintentional spills, floor cleaning, equipment cleaning and washing waters may reach the facility drain.

To estimate emissions into the air and the facility drain following industrial treatment of UC 3 woods by short dipping, the revised ESD for PT8 describes one scenario: Application phase in short dipping.

The input parameters for calculating the local emission following an application by short dipping process are presented in the following table.

Input parameters for calculating the local emission				
Input	**Nomenclature**	**Value**	**Unit**	**Remarks**
Scenario: Application phase in short dipping process				

Volume of wood treated per day	$VOLUME_{wood-treated}$	100	[$m^3.d^{-1}$]	D
Application rate: quantity of a.i. applied per 1 m^3 of wood	Q_{ai}	**See values in table above * 40**	[$kg.m^{-3}$]	S
Fraction released to facility drain	$F_{facilitydrain}$	**See above**	[--]	D
Fraction released to air	F_{air}	**See above**	[--]	D

D=default, S=based on information of applicant

- **Calculations**

The local emissions to air and facility drain during the day of application are calculated according to the equations 4.14 and 4.15 from the revised ESD PT8 as following:

$$E_{local,air} = Q_{ai} \,.\, VOLUME_{wood\text{-}product} \,.\, F_{air}$$

$$E_{local,facilitydrain} = Q_{ai} \,.\, VOLUME_{wood\text{-}product} \,.\, F_{facilitydrain}$$

The results are presented in the following table.

Resulting local emissions		
Active substance	**Local emission ($Elocal_{air}$) [$kg.d^{-1}$]**	**Local emission ($Elocal_{facilitydrain}$) [$kg.d^{-1}$]**
Tebuconazole	5.76E-04	1.73E-03
Propiconazole	5.76E-04	1.73E-02
IPBC	5.76E-04	1.73E-02
Permethrin	7.68E-04	7.68E-05

Storage phase

Concerning storage, a distinction is made between joineries and other facilities. Joineries in which the preservation treatment is applied on wooden articles that have been made to shape, (fence panels, composites, windows, doors and door frames, floors, architrave and decorative features) do not have an open storage area. These treated commodities/articles are immediately further processed (e.g. painted) and are not stored after wood preservation treatment.

During storage at other facilities than joineries, soil can be exposed – if the storage place is not covered - due to leaching from treated wood via rainfall. In addition, surface water can be exposed via rain run-off from the storage place.

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

Input parameters for calculating the local emissions and concentrations				
Input	**Nomenclature**	**Value**	**Unit**	**Remarks**
Scenario: Storage phase in short dipping process				

Effective surface area of treated wood, considered to be exposed to rain, per 1m^2 storage area (i.e. soil)	$AREA_{wood\text{-}expo}$	11	[$m^2.m^{-2}$]	D
Surface area of the storage place	$AREA_{storage}$	700	[m^2]	D
Duration of the initial assessment period	*TIME1*	30	[d]	D
Duration of a longer assessment period	*TIME2*	7300	[d]	D
Duration of storage of treated wood prior to shipment	$TIME_{storage}$	14	[d]	D
Average daily flux i.e. the average quantity of an active ingredient that is daily leached out of 1 m^2 of treated wood during 14 days storage period	$FLUX_{storage,dipp}$	**See above**	[$kg.m^{-2}.d^{-1}$]	S
Bulk density of wet soil	RHO_{soil}	1700	[$kg.m^{-3}$]	D
Soil depth	$DEPTH_{soil}$	0.5	[m]	D
Volume of (wet) soil	V_{soil}	350	[m^3]	D
Fraction of rainwater running off the storage site	F_{runoff}	0.5	[-]	D

D=default, S=based on information of applicant

- **Calculations**

The cumulative quantities of substance leached over 30 days and 7300 days ($Q_{leach,storage,time}$) are calculated according to the equations 4.17 and 4.18 from the revised ESD PT8 as following:

$$Q_{leach,storage,time1} = FLUX_{storage,dip} \,.\, AREA_{wood\text{-}expo} \,.\, AREA_{storage} \,.\, TIME\ 1$$

$$Q_{leach,storage,time2} = FLUX_{storage,dip} \,.\, AREA_{wood\text{-}expo} \,.\, AREA_{storage} \,.\, TIME\ 2$$

The local emissions to surface water during the storage phase are calculated according to the equations 4.21 and 4.22 from the revised ESD PT8 as following:

$$E_{local,surfacewater,time1} = Q_{leach,storage\ time1} \,.\, F_{runoff} \,/\, TIME\ 1$$

$$E_{local,surfacewater,time2} = Q_{leach,storage\ time2} \,.\, F_{runoff} \,/\, TIME\ 2$$

The local concentrations into the soil and the surface water are calculated according to the equations 4.19/4.20/4.23/4.24 from the revised ESD PT8 as following:

$$C_{local,surfacewater,time\ 1} = E_{local,surfacewater,time1} \,/\, FLOW_{surfacewater}$$

$$C_{local,surfacewater,time\ 2} = E_{local,surfacewater,time2} \,/\, FLOW_{surfacewater}$$

$$C_{local,soil,time\ 1} = Q_{leach,storage,time1} \cdot (1 - F_{runoff}) / V_{soil} \cdot RHO_{soil}$$

$$C_{local,soil,time\ 2} = Q_{leach,storage,time2} \cdot (1 - F_{runoff}) / V_{soil} \cdot RHO_{soil}$$

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

Resulting cumulative quantity of substance leached		
Active substance	**cumulative quantity of substance leached over 30 days TIME 1 [kg]**	**cumulative quantity of substance leached after 20 years TIME 2 [kg]**
Tebuconazole	5.23E-03	1.27E+00
Propiconazole	4.86E-03	1.18E+00
IPBC	1.92E-03	4.66E-01
Permethrin	9.29E-05	2.26E-02

Resulting local emissions to surface water compartment		
Active substance	**Local emission due to leaching after 30 days TIME 1 [kg.d^{-1}]**	**Local emission due to leaching after 20 years TIME 2 [kg.d^{-1}]**
Tebuconazole	8.72E-05	8.72E-05
Propiconazole	8.09E-05	8.09E-05
IPBC	3.19E-05	3.19E-05
Permethrin	1.55E-06	1.55E-06

Resulting local concentrations to water compartment		
Active substance	**Local concentration into surface water after 30 days TIME 1[mg.l^{-1}]**	**Local concentration into surface water after 20 years TIME 2 [mg.l^{-1}]**
Tebuconazole	3.36E-06	3.36E-06
Propiconazole	3.12E-06	3.12E-06
IPBC	1.23E-06	1.23E-06
Permethrin	5.97E-08	5.97E-08

Resulting local concentrations to soil compartment		
Active substance	**Local concentration in soil after 30 days TIME 1[kg.kg$_{wwt}^{-1}$]**	**Local concentration in soil after 20 years TIME 2 [kg.kg$_{wwt}^{-1}$]**
Tebuconazole	4.40E-09	1.07E-06
Propiconazole	4.08E-09	9.93E-07
IPBC	1.61E-09	3.92E-07
Permethrin	7.80E-11	1.90E-08

Scenario 3: *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.

The removal processes is not taken into account in the "bridge over pond" scenario because the first order rate constant for removal from water corresponds to 0 for the 4 active substances.

House scenario

In the house, the primary receiving compartment is considered to be the soil following leaching due to rainfall. The default values for the size of the receiving soil are: 50 cm distance from the house and a soil depth of 50 cm. This correspond to a soil volume of 13 m^3.

In this scenario the emissions over 30 days and 15 years are based on emissions due to leaching and emissions during the application are not taken into account.

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	*TIME2*	5475	[d]	D
Cumulative quantity of substance leached out of 1 m^2 of treated wood over the initial assessment period	$Q^*_{leach,time1}$	**See above**	[$kg.m^{-2}$]	S
Cumulative quantity of substance leached out of 1 m^2 of treated wood over a longer assessment period	$Q^*_{leach,time2}$	**See above**	[$kg.m^{-2}$]	S
(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

- **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:

$$E_{soil,leach,time1} = AREA_{house} \cdot Q^*_{leach,\ time1} / TIME\ 1$$

$$E_{soil,leach,time2} = AREA_{house} \cdot Q^*_{leach,\ time2} / TIME\ 2$$

The local concentrations into the soil are calculated according to the equations 3.11 and 3.12 from the revised ESD PT8 as following:

$$\boldsymbol{C}local_{soil,TIME1} = [E_{soil,leach,TIME1}/(V_{soil} \cdot RHO_{soil} \cdot k)] - [E_{soil,leach,TIME1}/(V_{soil} \cdot RHO_{soil} \cdot k)] \cdot (e^{-TIME1 \cdot k})$$

$$\boldsymbol{C}local_{soil,TIME2} = [E_{soil,leach,TIME2}/(V_{soil} \cdot RHO_{soil} \cdot k)] - [E_{soil,leach,TIME2}/(V_{soil} \cdot RHO_{soil} \cdot k)] \cdot (e^{-TIME2 \cdot k})$$

The results are presented in the following tables (considering removal processes).

Resulting local emissions to soil compartment		
Active substance	**Local emission in soil due to leaching after 30 days TIME 1 [mg.d^{-1}]**	**Local emission in soil due to leaching after 15 years TIME 2 [mg.d^{-1}]**
Tebuconazole	4.25E-01	1.00E+00
Propiconazole	3.92E-01	9.77E-01
IPBC	5.25E-01	5.59E-01
Permethrin	5.50E-03	9.36E-03

Resulting local concentrations to soil compartment		
Active substance	**Local concentration in soil after 30 days TIME 1[mg.kg$_{wwt}^{-1}$]**	**Local concentration in soil after 15 years TIME 2 [mg.kg$_{wwt}^{-1}$]**
Tebuconazole	5.06E-04	5.05E-03
Propiconazole	4.70E-04	5.25E-03
IPBC	6.71E-06	7.15E-06
Permethrin	6.78E-06	6.48E-05

Bridge over pond scenario

AXIL 3000 P is not intended to be used for treating commodities such as bridges over water bodies but in order to describe the emission pathway into open water bodies the scenario bridge over pond has been calculated.

The bridge over pond scenario describes a wooden bridge which is located over a pond. It is assumed that the emissions of active substance following leaching due to rainfall and up

directly in the adjacent static surface water. The default value for the size of the receiving water body is set to 1000 m^3.

In this scenario the emissions over 30 days and 15 years are based on emissions due to leaching and emissions during the application are not taken into account.

The removal processes is not taken into account in the bridge over pond scenario because the first order rate constant for removal from water corresponds to 0 for the 4 active substances.

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	*TIME2*	5475	[d]	D
Cumulative quantity of substance leached out of 1 m^2 of treated wood over the initial assessment period	$Q^*_{leach,time1}$	**See above**	[$kg.m^{-2}$]	S
Cumulative quantity of substance leached out of 1 m^2 of treated wood over a longer assessment period	$Q^*_{leach,time2}$	**See above**	[$kg.m^{-2}$]	S
Water volume under bridge	V_{water}	1000	[m^3]	D

D=default, S=based on information of applicant

- **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:

$$Q_{leach,time1} = AREA_{bridge} \,.\, Q^*_{leach,\ time1}$$

$$Q_{leach,time2} = AREA_{bridge} \,.\, Q^*_{leach,\ time2}$$

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:

$$\boldsymbol{C}local_{water,leach,TIME1} = Q_{leach,time1\ .\ 0.001} \,/\, V_{water}$$

$$\boldsymbol{C}local_{water,leach,TIME2} = Q_{leach,time2\ .\ 0.001} \,/\, V_{water}$$

$$\boldsymbol{C}local_{water,total,TIME1} = \boldsymbol{C}local_{water,leach,TIME1}$$

$$\boldsymbol{C}local_{water,total,TIME2} = \boldsymbol{C}local_{water,leach,TIME2}$$

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

Resulting cumulative quantity of substance leached to water compartment		
Active substance	**cumulative quantity of substance leached over 30 days TIME 1 [mg]**	**cumulative quantity of substance leached after 15 years TIME 2 [mg]**
Tebuconazole	1.02E+00	4.40E+02
Propiconazole	9.41E-01	4.28E+02
IPBC	1.26E+00	2.45E+02
Permethrin	1.32E-02	4.10E+00

Resulting local concentrations to water compartment		
Active substance	**Local concentration into surface water after 30 days TIME 1[mg.l^{-1}]**	**Local concentration into surface water after 15 years TIME 2 [mg.l^{-1}]**
Tebuconazole	1.02E-03	4.40E-01
Propiconazole	9.41E-04	4.28E-01
IPBC	1.26E-03	2.45E-01
Permethrin	1.32E-05	4.10E-03

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.

In this scenario the emissions over 30 days and 15 years are based on emissions due to leaching and emissions during the application are not taken into account because pre-treated wood is used for the construction of noise barriers.

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	*TIME2*	5475	[d]	D
Cumulative quantity of substance leached out of 1 m^2 of treated wood over the initial assessment period	$Q^*_{leach,time1}$	**See above**	[kg.m^{-2}]	S

Cumulative quantity of substance leached out of 1 m² of treated wood over a longer assessment period	$Q^*_{leach,time2}$	**See above**	[kg.m^{-2}]	S
(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

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:

$$E_{STP,time\ 1} = AREA_{noise\text{-}barrier} \times F_{STP} \times Q^*_{leach,\ time1} / Time\ 1$$

$$E_{STP,time\ 2} = AREA_{noise\text{-}barrier} \times F_{STP} \times Q^*_{leach,\ time2} / Time\ 2$$

The local emissions into the soil are calculated according to the equations 3.5 and 3.6 from the revised ESD PT08 as following:

$$E_{soil,leach,time\ 1} = AREA_{noise\text{-}barrier} \times F_{STP} \times Q^*_{leach,\ time1} / Time\ 1$$

$$E_{soil,leach,time\ 2} = AREA_{noise\text{-}barrier} \times F_{STP} \times Q^*_{leach,\ time2} / Time\ 2$$

The local concentrations into the soil are calculated according to the equations 3.11 and 3.12 from the revised ESD PT8 as following:

$$\mathbf{C}local_{soil,TIME1} = [E_{soil,leach,TIME1}/(V_{soil} \cdot RHO_{soil} \cdot k)] - [E_{soil,leach,TIME1}/(V_{soil} \cdot RHO_{soil} \cdot k)] \cdot (e^{-TIME1 \cdot k})$$

$$\mathbf{C}local_{soil,TIME2} = [E_{soil,leach,TIME2}/(V_{soil} \cdot RHO_{soil} \cdot k)] - [E_{soil,leach,TIME2}/(V_{soil} \cdot RHO_{soil} \cdot k)] \cdot (e^{-TIME2 \cdot k})$$

The results are presented in the following tables (considering removal processes only for soil compartment).

Resulting local emissions to STP compartment		
Active substance	**Local emission into STP due to leaching after 30 days TIME 1 [mg.d^{-1}]**	**Local emission into STP due to leaching after 15 years TIME 2 [mg.d^{-1}]**
Tebuconazole	7.14E+00	1.69E+01
Propiconazole	6.59E+00	1.64E+01
IPBC	8.82E+00	9.40E+00

Permethrin	9.24E-02	1.57E-01

Resulting local emissions to soil compartment		
Active substance	**Local emission into soil due to leaching after 30 days TIME 1 [mg.d^{-1}]**	**Local emission into soil due to leaching after 15 years TIME 2 [mg.d^{-1}]**
Tebuconazole	3.06E+00	1.69E+01
Propiconazole	2.82E+00	7.04E+00
IPBC	3.78E+00	4.03E+00
Permethrin	3.96E-02	6.74E-02

Resulting local concentrations to soil compartment		
Active substance	**Local concentration into soil after 30 days TIME 1[mg.kg$_{wwt}^{-1}$]**	**Local concentration into soil after 15 years TIME 2 [mg.kg$_{wwt}^{-1}$]**
Tebuconazole	1.89E-04	1.89E-03
Propiconazole	1.76E-04	1.96E-03
IPBC	2.51E-06	2.68E-06
Permethrin	2.54E-06	2.42E-05

(III) Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway							
Scenario		**Air**	**STP**	**Soil**	**Ground-water**	**Surface water**	**Biota**
Industrial processes: Automated sraying and Short dipping	Application phase	(Yes)	**Yes**	No	No	**Yes**	(Yes)
	Storage phase	(Yes)	No	**Yes**	(Yes)	**Yes**	(Yes)
Service life	House	(Yes)	No	**Yes**	**Yes**	No	(Yes)
	Bridge over pond	(Yes)	No	No	No	**Yes**	(Yes)
	Noise barrier	(Yes)	Yes	**Yes**	(Yes)	No	(Yes)

The compartments marked with "Yes" are those of concern for which predicted emissions and local concentrations have been determined for the active substances as well as the relevant metabolites (for the groundwater).

The compartments marked with "(Yes)" are those that might in principle be relevant, but not in the case of the present active substances and their relevant metabolites because of their substance-specific properties.

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**	**Permethrin**
Molecular weight	g/mol	307.8	342.2	281.1	391.29
Melting point	°C	105		66.15	34
Boiling point	°C		250		305
Vapour pressure (at 20 °C)	Pa	1.7E-06	5.6E-05	4.5E-03	3.04E-06
Water solubility (at 20 °C)	mg/l	2.9E+01	1.00E+02	5.3E-03	5.30E-03
Log Octanol/water partition coefficient	Log 10	3.49	3.72	2.81	4.67
Organic carbon/water partition coefficient (Koc)	l/kg	992	944	126	26930
Henry's Law Constant (at 20 °C)	$Pa/m^3/mol$	1.00E-05	9.2E-05	6.45E-03	4.5E-02
Biodegradability		Not biodegradable	Not biodegradable	Not biodegradable	Not biodegradable

Input parameters (only set values) for calculating the fate and distribution in the environment for the relevant metabolites					
Input	**Unit**	**1.2.4-Triazole**	**PBC**	**DCVA**	**PBA**
Molecular weight	g/mol	69.1	155.2	209.07	214.22
Vapour pressure (at 20 °C)	Pa	2.2E-01	1.88E+01	2.6E-01	4.21E-04
Water solubility (at 20 °C)	mg/l	7.0E+05	2.86E+05	127.6	16.91
Organic carbon/water partition coefficient (Koc)	l/kg	89	198.1	188.53	37.55
Fraction transformed (soil)	-	0.09 (Tebuconazole) 0.43 (Propiconazole)	1 (IPBC)	0.113 (Permethrin)	0.15 (Permethrin)

(IV) Calculated PEC values

The Predicted Environmental Concentration (PEC) calculations follow the available guidance documents (Revised Emission Scenario Document for Wood Preservatives (OECD, 2013); Guidance on the BPR: Volume IV Environment, Part B Risk Assessment (active substances) (2015)).

The PECs for Tebuconazole, Propiconazole, IPBC and Permethrin in the environmental compartments derived in the following sections are calculated on the basis of the emission scenarios available for Product Type 8, taking into account degradation processes and/or dilution (where applicable). The PEC values presented in the following tables are rounded values from EXCEL spread sheets from ECHA. The calculations for the different PECs within EXCEL are always carried out with unrounded values.

In the Assessment Reports for IPBC the reported PNEC for the sediment was derived using the equilibrium method. So the risk of the sediment compartment is the same as that assessed for surface water. Therefore, the risk of the sediment will not be considered further and the calculation of $PEC_{sediment}$ values is not considered necessary.

Metabolites of IPBC, Propiconazole, Tebuconazole and Permethrin are considered to be transient or less persistent than their respective parent, and are less toxic. In the CARs, the risk quotients are more favorable for the metabolites than for the active substances for both the aquatic and terrestrial environment and the metabolites are not considered further in the risks assessment. The only exception concern the metabolite 1.2.4-Triazole which has a slightly higher PNECsoil than the PNECsoil of its parents (Propiconazole and tebuconazole).

Therefore, emissions and PEC values were calculated for parents only and the PECsoil values were also calculated for the parents and the metabolites as a Tier 2. In addition, the soil compartment is the one presenting the highest risks, in this way this Tier 2 (with metabolites) represents a worst case.

Furthermore, the WG-II-2018 proposed the following conclusion: ”WG agreed that at AS approval if at first tier major metabolites are found much less toxic than AS, there is no need for their full quantitative risk assessment (with the exception of groundwater assessment)”.

In this idea and taking into account the great difference in toxicity between active substances and their metabolites and also the properties of the concerned metabolites the environmental risk assessment for metabolites is considered to be covered by the risk assessment for parents for the AXIL 3000 P.

Tebuconazole		**$PEC_{Surface\ water}$ (mg/l)**	**PEC_{STP} (mg/l)**	**$PEC_{Sediment}$ (mg/kg_{wwt})**	**PEC_{soil} (mg/kg_{wwt})**
Industrial processes					
Application phase	Automated spraying (large plant)	3.84E-04	3.85E-03	8.59E-03	/
	Short dipping	7.70E-05	7.71E-04	1.72E-03	/
Storage phase	Automated spraying (Time 1)	3.80E-06	/	8.49E-05	4.40E-03
	Automated spraying (Time 2)	3.80E-06	/	8.49E-05	1.07E+00
	Short dipping (Time 1)	3.36E-06	/	7.51E-05	4.40E-03

	Short dipping (Time 2)	3.36E-06	/	7.51E-05	1.07E+00
In-service					
Service life	House (Time 1)	/	/	/	5.06E-04
	House (Time 2)	/	/	/	5.05E-03
	Noise barrier (Time 1)	3.18E-07	3.18E-06	7.10E-06	1.89E-04
	Noise barrier (Time 2)	7.52E-07	7.53E-06	1.63E-05	1.89E-03
	Bridge over pond (Time 1)	1.02E-03	/	2.28E-02	/
	Bridge over pond (Time 2)	4.40E-01	/	9.83E+00	/

Propiconazole		**$PEC_{Surface\ water}$ (mg/l)**	**PEC_{STP} (mg/l)**	**$PEC_{Sediment}$ (mg/kg_{wwt})**	**PEC_{soil} (mg/kg_{wwt})**
Industrial processes					
Application phase	Automated spraying (large plant)	3.86E-03	3.87E-02	8.23E-02	/
	Short dipping	7.73E-04	7.74E-03	1.65E-02	/
Storage phase	Automated spraying (Time 1)	3.52E-06	/	7.50E-05	4,08E-03
	Automated spraying (Time 2)	3,52E-06	/	7,50E-05	9,93E-01
	Short dipping (Time 1)	3,12E-06	/	6,65E-05	4,08E-03
	Short dipping (Time 2)	3,12E-06	/	6,65E-05	9,93E-01
In-service					
Service life	House (Time 1)	/	/	/	4.70E-04
	House (Time 2)	/	/	/	5.25E-03
	Noise barrier (Time 1)	2.94E-07	2.95E-06	6.27E-06	1.76E-04
	Noise barrier (Time 2)	7.33E-07	7.34E-06	1.56E-05	1.96E-03
	Bridge over pond (Time 1)	9.41E-04	/	2.00E-02	/
	Bridge over pond (Time 2)	4.28E-01	/	9.12E+00	/

IPBC		**$PEC_{Surface\ water}$ (mg/l)**	**PEC_{STP} (mg/l)**	**PEC_{soil} (mg/kg_{wwt})**
Industrial processes				
Application phase	Automated spraying (large plant)	4.25E-03	4.25E-02	/
	Short dipping	8.51E-04	8.51E-03	/
	Automated spraying	1.39E-06	/	1.61E-03

Storage phase	(Time 1)			
	Automated spraying (Time 2)	1.39E-06	/	3.92E-01
	Short dipping (Time 1)	1.23E-06	/	1.61E-03
	Short dipping (Time 2)	1.23E-06	/	3.92E-01
In-service				
Service life	House (Time 1)	/	/	6.71E-06
	House (Time 2)	/	/	7.15E-06
	Noise barrier (Time 1)	4.34E-07	4.34E-06	2.51E-06
	Noise barrier (Time 2)	4.62E-07	4.62E-06	2.68E-06
	Bridge over pond (Time 1)	1.26E-03	/	/
	Bridge over pond (Time 2)	2.45E-01	/	/

Permethrin		**$PEC_{Surface\ water}$ (mg/l)**	**PEC_{STP} (mg/l)**	**$PEC_{Sediment}$ (mg/kg_{wwt})**	**PEC_{soil} (mg/kg_{wwt})**
Industrial processes					
Application phase	Automated spraying (large plant)	5.09E-06	5.30E-05	2.99E-03	/
	Short dipping	1.02E-06	1.06E-05	5.97E-04	/
Storage phase	Automated spraying (Time 1)	6.74E-08	/	3.95E-05	7.80E-05
	Automated spraying (Time 2)	6.74E-08	/	3.95E-05	1.90E-02
	Short dipping (Time 1)	5.97E-08	/	3.50E-05	7.80E-05
	Short dipping (Time 2)	5.97E-08	/	3.50E-05	1.90E-02
In-service					
Service life	House (Time 1)	/	/	/	6.78E-06
	House (Time 2)	/	/	/	6.48E-05
	Noise barrier (Time 1)	1.23E-09	1.28E-08	7.18E-07	2.54E-06
	Noise barrier (Time 2)	2.08E-09	2.17E-08	1.22E-06	2.42E-05
	Bridge over pond (Time 1)	1.32E-05	/	7.74E-03	/
	Bridge over pond (Time 2)	4.10E-03	/	2.40E+00	/

Relevant degradation products and their assessment for the soil compartment

For the **Permethrin**, aquatic metabolites including 3-(2,2-dichlorovinyl)-2,2-dimethyl-(1 cyclopropane)carboxylate (DCVA) and 3-phenoxybenzoic acid (PBA) are far less toxic to soil

organisms than the parent active ingredient and are not considered to be ecotoxicologically relevant. In addition, the rates of degradation of permethrin in these two metabolites are rather low and are therefore not taken into account for this tier 2. In this case the PECsoil values for Permethrin is considered as a worst case for the mixture toxicity.

Degradation of **IPBC** yields the primary degradate propargyl butyl carbamate (PBC) as well as iodine. PEC values have been calculated for PBC only for the soil compartment which is the compartment with the higher risk. Therefore, emissions of PBC (degradation product of IPBC) are also 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.

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 AXIL 3000P.

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.

The cumulative quantities of substance leached out of 1 m2 of treated wood for each metabolite were calculate taking into account the degradation rate and the molar mass of the metabolite and the molar mass of the parent.

We present only the PECs results for the house and noise-barrier in-service scenarii because we consider these scenarii as worst cases for the soil compartment knowing that there are RMM for the storage phase after the application phase.

PEC_{soil} (mg/kg ww)	**Scenario: In-service**			
	House		**Noise barrier**	
	Time 1	**Time 2**	**Time 1**	**Time 2**
PBC (from IPBC)	1.58E-04	1.91E-04	5.93E-05	7.17E-05
1.2.4-Triazole (from propiconazole)	4.25E-05	6.39E-04	1.59E-05	2.39E-04

1.2.4-Triazole (from tebuconazole)	1.07E-05	1.52E-04	3.99E-06	5.69E-05

(V) Primary and secondary poisoning

a) Primary poisoning

The product is a wood preservative (Product Type 8). The product is a water-based concentrate and is applied in liquid form by automated spraying and short dipping (industrial processes). A direct uptake of the product is unlikely.

b) 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.

The reported Log Pow values for **Permethrin** of 4.6, indicating it is a fat-soluble molecule with a potential to bioconcentrate. However, experimentally derived BCF values for fish and chironomid ranged from 290 to 620 l/kg. Permethrin is not considered to fulfil the Bioaccumulative or very bioaccumulative criteria. Therefore, an assessment of secondary poisoning doesn't need to be performed.

2.2.8.3 Risk characterisation

The risk characterisation focusses on the use in class 3 as relevant risks to environmental compartments.

The environmental risk characterization for biocidal active substances in the context of Article 5 and Annex VI of Directive 98/8 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. As stated in section 2.2.8.2, air is not regarded as compartment of concern for this product with the proposed use patterns; also, there are no concerns of secondary poisoning or for the groundwater compartment because of the active substances-specific properties.

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.

Tebuconazole		PEC/PNEC$_{Surface\ water}$	PEC/PNEC$_{STP}$	PEC/PNEC$_{Sediment}$	PEC/PNEC$_{soil}$
Industrial processes					
Application phase	Automated spraying (large plant)	3.84E-01	1.20E-02	1.56E-02	/
	Short dipping	7.70E-02	2.41E-03	3.13E-03	/
Storage phase	Automated spraying (Time 1)	3.80E-03	/	1.54E-04	4.40E-02
	Automated spraying (Time 2)	3.80E-03	/	1.54E-04	**1.07E+01**
	Short dipping (Time 1)	3.36E-03	/	1.37E-04	4.40E-02
	Short dipping (Time 2)	3.36E-03	/	1.37E-04	**1.07E+01**
In-service					
Service life	House (Time 1)	/	/	/	5.06E-03
	House (Time 2)	/	/	/	5.05E-02
	Noise barrier (Time 1)	3.18E-04	9.94E-06	1.29E-05	1.89E-03
	Noise barrier (Time 2)	7.52E-04	2.35E-05	2.96E-05	1.89E-02
	Bridge over pond (Time 1)	**1.02E+00**	/	4.15E-02	/
	Bridge over pond (Time 2)	**4.40E+02**	/	**1.79E+01**	/

Propiconazole		PEC/PNEC$_{Surface\ water}$	PEC/PNEC$_{STP}$	PEC/PNEC$_{Sediment}$	PEC/PNEC$_{soil}$
Industrial processes					
Application phase	Automated spraying (large plant)	5.68E-01	3.87E-04	**1.52E+00**	/
	Short dipping	1.14E-01	7.74E-05	3.06E-01	/
Storage phase	Automated spraying (Time 1)	5.18E-04	/	1.39E-03	4.08E-02
	Automated spraying (Time 2)	5.18E-04	/	1.39E-03	**9.93E+00**
	Short dipping (Time 1)	4.59E-04	/	1.23E-03	4.08E-02
	Short dipping (Time 2)	4.59E-04	/	1.23E-03	**9.93E+00**
In-service					

Service life	House (Time 1)	/	/	/	4.70E-03
	House (Time 2)	/	/	/	5.25E-02
	Noise barrier (Time 1)	4.32E-05	2.95E-08	1.16E-04	1.76E-03
	Noise barrier (Time 2)	1.08E-04	7.34E-08	2.89E-04	1.96E-02
	Bridge over pond (Time 1)	1.38E-01	/	3.70E-01	/
	Bridge over pond (Time 2)	**6.29E+01**	/	**1.69E+02**	/

IPBC		PEC/PNEC$_{Surface\ water}$	PEC/PNEC$_{STP}$	PEC/PNEC$_{soil}$
Industrial processes				
Application phase	Automated spraying (large plant)	**8.50E+00**	9.66E-02	/
	Short dipping	**1.70E+00**	1.93E-02	/
Storage phase	Automated spraying (Time 1)	2.78E-03	/	3.74E-01
	Automated spraying (Time 2)	2.78E-03	/	**9.12E+01**
	Short dipping (Time 1)	2.46E-03	/	3.74E-01
	Short dipping (Time 2)	2.46E-03	/	**9.12E+01**
In-service				
Service life	House (Time 1)	/	/	1.56E-03
	House (Time 2)	/	/	1.66E-03
	Noise barrier (Time 1)	8.68E-04	9.86E-06	5.84E-04
	Noise barrier (Time 2)	9.24E-04	1.05E-05	6.23E-04
	Bridge over pond (Time 1)	**2.52E+00**	/	/
	Bridge over pond (Time 2)	**4.90E+02**	/	/

Permethrin		PEC/PNEC$_{Surface\ water}$	PEC/PNEC$_{STP}$	PEC/PNEC$_{Sediment}$	PEC/PNEC$_{soil}$
Industrial processes					
Application phase	Automated spraying (large plant)	**1.08E+01**	1.07E-02	**1.38E+01**	/
	Short dipping	**2.17E+00**	2.14E-03	**2.75E+00**	/
Storage phase	Automated spraying (Time 1)	1.43E-01	/	1.82E-01	8.90E-04
	Automated spraying	1.43E-01	/	1.82E-01	2.17E-01

	(Time 2)				
	Short dipping (Time 1)	1.27E-01	/	1.61E-01	8.90E-04
	Short dipping (Time 2)	1.27E-01	/	1.61E-01	2.17E-01
In-service					
Service life	House (Time 1)	/	/	/	7.74E-05
	House (Time 2)	/	/	/	7.40E-04
	Noise barrier (Time 1)	2.62E-03	2.59E-06	3.31E-03	2.90E-05
	Noise barrier (Time 2)	4.43E-03	4.38E-06	5.62E-03	2.76E-04
	Bridge over pond (Time 1)	**2.81E+01**	/	**3.57E+01**	/
	Bridge over pond (Time 2)	**8.72E+03**	/	**1.11E+04**	/

Relevant degradation products for the soil compartment :

PEC/PNEC$_{soil}$	**Scenario: In-service**			
	House		**Noise barrier**	
	Time 1	**Time 2**	**Time 1**	**Time 2**
PBC (from IPBC)	1.06E-03	1.28E-03	3.98E-04	4.81E-04
1.2.4-Triazole (from propiconazole)	4.25E-03	6.39E-02	1.59E-03	2.39E-02
1.2.4-Triazole (from tebuconazole)	1.07E-03	1.52E-02	3.99E-04	5.69E-03
Summation of 1.2.4-Triazole (from propiconazole and tebuconazole)	5.32E-03	7.91E-02	1.99E-03	2.96E-02

(I) Atmosphere

The product AXIL 3000 P is a water-based product and the active substances Permethrin, 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.

(II) 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 AXIL 3000 P represent acceptable risks for STP.

(III) Aquatic compartment

For the aquatic compartment (surface-water and sediment), risks were identified during the application phase (Automated spraying or short dipping) and during the service life for the bridge over pond scenario. Those risks are primarily due to the high toxicity of Permethrin to aquatic and sediment organisms but Propiconazole, Tebuconazole and IPBC are also problematic substances.

So we can conclude that the use of AXIL 3000 P represent acceptable risks for water compartment if appropriate risk mitigation measures are considered.

- To avoid unacceptable risk for the aquatic and sediment organisms, the biocidal product may only be applied to wood, which will not be used above or close to surface waters.

- Application should be conducted within a contained area on impermeable hard standing with bunding and any losses from the application of the product should be collected for reuse or disposal.

(IV) Terrestrial compartment

For the soil, the industrial storage scenario provided elevated PEC/PNEC ratios for TIME 2. According to the revised ESD for PT 8 it can be assumed, that most storage places are sealed and run-off from storage places will be collected and disposed of safely – this is not taken into account in the calculations.

So we can conclude that the use of AXIL 3000 P represent acceptable risks for soil compartment if appropriate risk mitigation measures are considered.

- To avoid losses to the soil the 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.

- Application should be conducted within a contained area on impermeable hard standing with bunding and any losses from the application of the product should be collected for reuse or disposal.

- A non-biocidal top coat must be applied on treated wood used outdoor, above ground (use class 3.1) to avoid leaching of active substances.

(V) Groundwater

According to Annex VI of the BPR (point 68) a groundwater assessment has to be conducted for all active substances and all relevant metabolites. The estimations of releases of active substances and metabolites for the groundwater compartment, were calculated with the FOCUS PEARL v.4.4.4 software for the following substances:

- [redacted]

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.

[redacted]		
[redacted]		
[redacted]	[redacted]	[redacted]
[redacted]		
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
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Conclusion:

The calculated $PEC_{groudwater}$ have been compared to the drinking water standard for pesticides (set at 0.1 µg/l) for each relevant substance. For all 9 EU scenarios, PECgroundwater are all below 0.1 µg/l.

Based on these results, it can be concluded that the use of the product will not pose a significant risk of groundwater contamination.

(VI) Primary and secondary poisoning

There are no concerns of primary of secondary poisoning.

(VII) Mixture toxicity

As the biocidal product consists of more than one active substance, the environmental risk should be based on the combined risk. It is found that the model of concentration addition can be recommended as the best reference model when evaluating combined risk of chemical mixtures.

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.

AXIL 3000 P		PEC/PNEC$_{Surface\ water}$	PEC/PNEC$_{STP}$	PEC/PNEC$_{Sediment}$	PEC/PNEC$_{soil}$
Industrial processes					
Application phase	Automated spraying (large plant)	**2.03E+01**	1.20E-01	**2.38E+01**	/
	Short dipping	**4.06E+00**	2.40E-02	**4.76E+00**	/
Storage phase	Automated spraying (Time 1)	1.51E-01	/	1.86E-01	4.60E-01
	Automated spraying (Time 2)	1.51E-01	/	1.86E-01	**1.12E+02**
	Short dipping (Time 1)	1.33E-01	/	1.65E-01	4.60E-01
	Short dipping (Time 2)	1.33E-01	/	1.65E-01	**1.12E+02**
In-service					
Service life	House (Time 1)	/	/	/	1.14E-02
	House (Time 2)	/	/	/	1.05E-01
	Noise barrier (Time 1)	3.85E-03	2.24E-05	4.31E-03	4.26E-03
	Noise barrier (Time 2)	6.21E-03	3.85E-05	6.86E-03	3.94E-02
	Bridge over pond (Time 1)	**3.18E+01**	/	**3.86E+01**	/
	Bridge over pond (Time 2)	**9.72E+03**	/	**1.17E+04**	/

Tier 2 :

TIER 2: AXIL 3000 P	**Scenario: In-service**			
	House		**Noise barrier**	
	Time 1	**Time 2**	**Time 1**	**Time 2**
	1.37E-02	1.57E-01	5.14E-03	5.87E-02

Conclusion:

All Σ (PEC/PNEC) ratios are lower than 1 for the evaluated scenarios except for the "bridge over pond: service life" scenario, the "Application phase" and the "Industrial storage TIME 2" scenarios (for automated spraying and short dipping).

The conclusions for this section are identical to those developed above for each active substance.

The uses of AXIL 3000 P by industrial processes - automated spraying and short dipping - and the uses of treated wood in UC3 do not represent unacceptable risks to the environment if appropriate risk mitigation measures are considered.

(VIII) Aggregated exposure (combined for relevant emission sources)

Not relevant.

Overall conclusion on the risk assessment for the environment of the product
The risk characterisation of the biocidal product AXIL 3000 P indicates that : • Preventive treatments by the industrial processes - automated spraying and short dipping - and the uses of treated wood in UC 1, UC 2 and UC3 do not represent unacceptable risks to the environment if appropriate risk mitigation measures are considered. • Curative treatments by spraying, brushing and injection in conditions of UC 1 and 2 do not represent unacceptable risks to the environment if appropriate risk mitigation measures are considered. [redacted]

2.2.9 Measures to protect man, animals and the environment

Measures to protect cats known for being sensible to pyrethroids: "Contain permethrin (pyrethroids), may be lethal to cats. Cats must avoid contact with treated object/area".

Measures to protect man:

- "Do not apply the product on wood which may come into contact with food, feedstuff or livestock" as no dietary exposure have been assessed based on the intended uses of AXIL 3000P.

In addition, pyrethroids like permethrin are known to cause paresthesia (burning and prickling of the skin without irritation) in susceptible persons. This local effect is normally not severe and disappears when direct exposure is terminated. However, an advice is required to warn susceptible persons:

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

The biocidal product may only be applied to wood, which will not be used above or close to surface waters.

The 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.

Application should be conducted within a contained area on impermeable hard standing with bunding and any losses from the application of the product should be collected for reuse or disposal.

A non-biocidal topcoat must be applied on treated wood used outdoor, above ground (use class 3.1) to avoid leaching of active substances.

For more details, please see relevant sections of the risk assessment.

2.2.10 Assessment of a combination of biocidal products

Not relevant.

2.2.11 Comparative assessment

Active substances in the biocidal product and criteria for substitution and exclusion

The biocidal product AXIL 3000 P contains four active substances: propiconazole, IPBC, tebuconazole and permethrin.

IPBC and propiconazole are not PBT candidates.

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

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). However, tebuconazole is not considered as meeting the exclusion criteria according to Article 5(1). Therefore tebuconazole can be considered to meet the criteria in Article 10(1)d, notably it meets two of the criteria for being PBT in accordance with Annex XIII to regulation (EC) No 1907/2006.

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). The Belgian CA has therefore used the approach in the EU guidance on the comparative assessment of the biocidal product. In line with this Note for Guidance, the Belgian CA began the comparative assessment with the screening phase to identify whether the diversity of the active substances - mode of action combination in authorised biocidal products is adequate.

Screening phase of comparative assessment

2.2.11.1 Intended use of the biocidal product and properties of active substances

Article 23(3) and the Note for Guidance focus the comparative assessment on the uses specified in the application of the biocidal product, as the requirement for a comparative assessment is product specific.

Table 2.9.2.1.-1 Intended uses of the biocidal product

Product Type	8 Wood preservatives
Where relevant, an exact description of the authorised use	Preventive
Target organism (including, where relevant) development stage)	Xylophages insects (including termites) White and brown rot fungi
Field(s) of use	Outdoor use – use class1 to 3
Application method(s)	Surface application: fully automated dipping or automated spraying
Category(ies) of users	Professional (Industrial)

Permethrin is responsible for the insecticidal activity only. The other 3 active substances are responsible only for fungicidal activity. The comparative assessment is focused on only fungicidal activity.

IPBC is a carbamate fungicide. The target sites of carbamates in fungi are cell membrane permeability and fatty acids.

Tebuconazole and Propiconazole are azole fungicides intended for use against wood rotting fungi (basidiomycota). The actives act by interfering with the basic metabolism of the fungal cell wall and contents.

Of the three fungicidal active substances in the biocidal product tebuconazole is highly effective against the wood rotting fungi *Coniophora puteana* and *Gloeophyllum trabeum,* but is less effective against the wood rotting fungus *Poria placenta*.

Propiconazole is effective against the wood rotting fungus *P. placenta*, but is less effective against the wood rotting fungi *C. puteana* or *G. trabeum*.

IPBC has some activity against brown wood-rotting fungi but its efficacy largely lies with its activity against blue-stain (wood staining) fungi. IPBC is usually not used stand-alone but in combination with propiconazole to achieve efficacy against wood decay. Propiconazole is effective against wood decay.

In combination products, especially well-balanced efficacy against a broad range of wood rotting fungi can be achieved with minimising the amounts of each active.

The big advantage of tebuconazole/propiconazole with respect to the single actives, is that the mixture offers advantages in efficiency as much less triazole is necessary for the long term protection of wood against decay fungi. The very high efficacy of tebuconazole towards the brown rot fungi *C. puteana*. and *G. trabeum* is well compensating the moderate effectiveness of propiconazole towards these fungi, and in case of the fungi *P.placenta* and *C. versicolor*.

the 1:1 mixture of tebuconazole and propiconazole is showing even high effectiveness compared to the individual effectiveness of each single triazole.

2.2.11.2 Chemical diversity of the active substances – mode of action combination in authorised biocidal products

According to the information available to the Belgian CA, there are about 2583 biocidal products authorised under Product Type 8 (Wood Preservatives) of the Biocidal Products Directive and Biocidal Products Regulations (including Mutual Recognitions and same product authorisations). More than 40 active substances (insecticides and fungicides) are approved for PT8 applications. Most of these products with fungicidal activity are based on propiconazole, tebuconazole, and IPBC or a mixture of these active substances.

The Fungicide Resistance Action Committee (FRAC), an international scientific committee with an overview of the global position, has provided the following information on the potential for resistance; this has been derived from experience with plant protection products rather than wood preservative products.

Table 2.9.2.2-1 Mode of action and risk of resistance formation for PT8 fungicidal substances in authorised biocidal products

Active substance	Tebuconazole	Propiconazole	IPBC
Mode of action	G: sterol biosynthesis in membranes G1: C14-demethylase in sterol biosynthesis	G: sterol biosynthesis in membranes G1: C14-demethylase in sterol biosynthesis	F: lipid synthesis and membrane integrity F4: cell membrane permeability, fatty acids (proposed)
FRAC code	3	3	28
Risk of resistance formation	Medium (resistance management required)	Medium (resistance management required)	Low to medium (resistance management required)

Occurrence of resistance

IPBC

According to the Annex I CAR for IPBC and the Fungicide Resistance Action Committee (FRAC) Code List (http://www.frac.info/publication/publication.htm) the risk of resistance formation against carbamate fungicides is regarded to be low to medium.

Tebuconazole and Propiconazole

Tebuconazole and Propiconazole are DeMethylation Inhibitor (DMI) fungicides within Sterol Biosynthesis Inhibitor (SBI) Class I. According to the FRAC Code List, DMI fungicides show no cross resistance to other SBI classes. There are big differences in the activity spectra of DMI fungicides. Resistance to DMI fungicides 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. It is considered generally wise

to accept that cross resistance is present between DMI fungicides active against the same fungus, and the risk of resistance formation against DMI fungicides is regarded to be medium

According to the Annex I CARs for tebuconazole and propiconazole, for wood preservation with tebuconazole-and propiconazole-containing products, cases of resistances are not reported or known up to the time being.

2.2.11.3 Effects of removal or substitution of tebuconazole in biocidal product

On the basis of the information provided it can be assumed that removal of tebuconazole from the biocidal product would leave a gap in the activity of the biocidal product against certain target pests where the remaining fungicidal active substances in the biocidal product have only weak activity.(see also 2.9.2.1 – properties of active substances)

Regarding substitution by other PT 8 fungicidal active substances in biocidal products, two of these active substances are already included in the biocidal product, and on the basis of the information on their activity profiles are not considered viable substitutes for tebuconazole. Regarding substitution by the remaining PT8 fungicidal active substance, dichlofluanid, according to the Annex I CAR for dichlofluanid this fungicide is targeted against wood-staining fungi (blue-staining fungi). However, it would not be expected to be able to substitute for tebuconazole regarding activity against wood rotting fungi such as *C. puteana* or *G. trabeum.*

Conclusion on comparative assessment

According to section 4 of the Note for Guidance, if the outcome of the comparative assessment is not sufficiently conclusive to conclude that the criteria of Article 23(3) of BPR are met, the product could be authorised for a period not exceeding 5 years in accordance with Article 23(6).

Taking into account:

- assuming that substitution of tebuconazole by one of the remaining available fungicidal active substances would reduce the activity of the biocidal product to control certain target organisms and
- the available information on the risk of resistance formation for the PT8 remaining fungicides

the Belgian CA considers that if tebuconazole were substituted in the biocidal product the chemical diversity would be inadequate for the given PT/use/target organism combination, and there would be an increased potential for fungicide resistance where activity gaps are left. Therefore, the Belgian CA concludes that there is not an adequate chemical diversity and in line with Article 23(3)(b) and the Note for Guidance, and since tebuconazole does not meet the exclusion criteria as outlined in Article 5(1), consider it valid to conduct no further investigation at this point. As such, the comparative assessment for Axil 3000 P can be finalised at the screening stage and the application taken forward to product authorisation in accordance with Article 23(6) of BPR.

3 ANNEXES

3.1 LIST OF STUDIES FOR THE BIOCIDAL PRODUCT

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3.2 OUTPUT TABLES FROM EXPOSURE ASSESSMENT TOOLS

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3.3 NEW INFORMATION ON THE ACTIVE SUBSTANCE

No new data were submitted.

3.4 RESIDUE BEHAVIOUR

Not relevant.

3.5 SUMMARIES OF THE EFFICACY STUDIES (B.5.10.1-XX)

Please refer to the table ***2.2.5.5.1 summary of experimental data.***

3.6 CONFIDENTIAL ANNEX

Please see separate document.

3.7 OTHER

Environmental Risk Assessment – Annex

Leaching calculations