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

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FAMILY FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)

PUBLIC

AQUA LIGNEX I

Product type PT8

IPBC and Permethrin

as included in the Union list of approved active substances

Case Number in R4BP: BC-TW024078-06

Evaluating Competent Authority: Austria

03/02/2023 (Final)

Table of Contents

1 CONCLUSION

Austria was the Competent Authority responsible for evaluation of the biocidal product family AQUA LIGNEX I. The dossier submission date 29/04/2016 is to be taken into account for relevance of (new) guidance.

The ready-to-use products included in the BPF AQUA LIGNEX I are liquid, water-based formulations which contain 0.8%(w/w) of the active substance IPBC (3-Iodo-2-propynyl butyl carbamate) and 0.1%(w/w) of the active substance permethrin.

The products contain the following substances <0.1% w/w:
- Octamethylcyclotetrasiloxane (D4) (CAS Nr.: 556-67-2)
- Decamethylcyclopentasiloxane (D5) (CAS Nr.: 541-02-6)
- Dodecamethylcyclohexasiloxane (D6) (CAS Nr.: 540-97-6)

According to "CA-June21-Doc.4.3 Final - Categorization biocidal product containing PBT-vPvB substance", "*The authorisation holder should try to substitute the substance identified as PBT or vPvB and contained in a biocidal product regardless whether the concentration is above or below 0.1% w/w. This effort shall be proven at the authorisation process*."
The applicant has shown effort to try to substitute the respective substances in the BPF. D4, D5 and D6 are "impurities" of cyclosiloxanes nature derived from the production process (applicant's statement). The applicant has identified other defoamers to replace the currently used mixtures and to lower the content of the respective substances. The replacement will take place after authorisation of the BPF via application for a change.

The assessment considered:

- The conclusions and recommendations of the Assessment Report for the approval of the active substance IPBC as well as permethrin including the "elements to be taken into account by Member States when authorising products"
- The specific provisions from Inclusion Directive for the active substance IPBC (COMMISSION DIRECTIVE 2008/79/EC in combination with COMMISSION IMPLEMENTING DECISION (EU) 2019/1969)
- The specific provisions from Inclusion Regulation for the active substance permethrin (COMMISSION IMPLEMENTING REGULATION (EU) No 1090/2014)

Approval of the active substance:
The active substance IPBC is included in the Union list of approved active substances and the specific provisions laid down there are fulfilled:

- In view of the assumptions made during the risk assessment, products authorised for industrial and/or professional use, must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial and/or professional users can be reduced to an acceptable level by other means.
- In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation measures must be taken to protect those compartments. In particular, labels and/or safety data sheets of products authorised for industrial use shall indicate that freshly treated timber must be stored after treatment under

shelter or on impermeable hardstanding to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal.'

The active substance permethrin is included in the Union list of approved active substances and the specific provisions laid down there are fulfilled:

- For industrial or professional users, safe operational procedures and appropriate organizational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products shall be used with appropriate personal protective equipment.
- Appropriate risk mitigation measures shall be taken to protect the soil and aquatic compartments. In particular: labels and, where provided, safety data sheets of products authorised shall indicate that industrial application shall be conducted within a contained area or on impermeable hard standing with bunding, that freshly treated timber shall be stored after treatment under shelter or on impermeable hardstanding, or both, to prevent direct losses to soil or water, and that any losses from the application of the product shall be collected for reuse or disposal.
- Products shall not be authorised for wood that will be exposed to frequent weathering unless data is submitted to demonstrate that the product will meet the requirements of Article 19 and Annex VI of Regulation (EU) No 528/2012, if necessary by the application of appropriate risk mitigation measures.

The fields of use are as follows:
Use # 1 – Wood boring beetles, wood discolouring fungi – brushing - non professional user, indoor/outdoor
Use # 2 – Wood boring beetles, wood discolouring fungi – brushing - professional user - indoor/outdoor
Use # 3 – Wood boring beetles, wood discolouring fungi – industrial superficial applications (brushing, automated spraying, manual dipping, flow coating/deluge treatment) - industrial user – indoor

Identity and analytical methods were described in sufficient detail to meet the information requirements as laid down in annex III of regulation (EU) no. 528/2012. The physical-chemical properties and respective characteristics of the biocidal product have been evaluated and are deemed acceptable for the appropriate use, storage and transport of the biocidal product.

Based on the authorised use including the general directions of use and any possibly defined risk mitigation measures and provided that there will be no misuse, the following can be concluded:

- Data on the biocidal product family have demonstrated sufficient efficacy against the target organisms. No unacceptable resistance is expected when applying resistance management strategies.
- For human health the risk characterisation for the biocidal product family indicated acceptable risks for the authorised uses with the required risk mitigation measures. The assessment of the biocidal product family was conducted according to the common principles set out in Annex VI of Regulation (EC) No 528/2012 and considered the maximum risks to human health. Concerning the ED assessment,

pending the ED evaluation of the active substances at their renewal stage, no indications were identified.

- Also for the environment, the risk characterisation resulted in acceptable risks for all authorised uses in all exposed environmental compartments. The assessment of secondary poisoning has shown that no adverse effects for birds and mammals are to be expected.

The biocidal product family contains permethrin which is meeting the P and T criterion according to CG 54 and therefore is a candidate for substitution. A comparative assessment is included under 2.2.12.

The biocidal product family has no indications for endocrine-disrupting properties.

It can be concluded that the conditions of Article 19 1)-4) and 6) of regulation (EU) no. 528/2012 are fulfilled and that the products in the family may be authorised.

The biocidal product will be authorised for a period not exceeding **5 years** in accordance with Article 23(6) of Regulation (EU) No 528/2012.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product family

Identifier[1]	**Country (if relevant)**
AQUA LIGNEX I	Austria

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	J.F. Amonn Srl/GmbH
	Address	Via Altmann 12 Altmannstraße; I-39100; Bolzano/Bozen; Italy
Authorisation number	AT-0016052-BPF	
Date of the authorisation	Please see authorisation letter.	
Expiry date of the authorisation	Please see authorisation letter.	

2.1.1.3 Manufacturer of the products of the family

Name of manufacturer	Amonn Coatings G.m.b.H
Address of manufacturer	An der Landesbahn 7 2100 Korneuburg, Austria
Location of manufacturing sites	An der Landesbahn 7 2100 Korneuburg, Austria

2.1.1.4 Manufacturers of the active substances

Active substance	Permethrin
Name of manufacturer	LANXESS Deutschland GmbH
Address of manufacturer	Kennedyplatz 1, 50569 Cologne, Germany
Location of manufacturing sites	Bilag Industries Pvt Ltd 306/3, II Phase, GIDC, Vapi-396195, India

Active substance	IPBC
Name of manufacturer	Troy Chemical Company B.V.
Address of manufacturer	Uiverlaan 12e, 3140 AC Maassluis, The Netherlands
Location of manufacturing sites	TROY Corporation Inc. 8 Vreeland Road, 07932 Florham Park, New Jersey, United States

[1] Identifying product name from R4BP

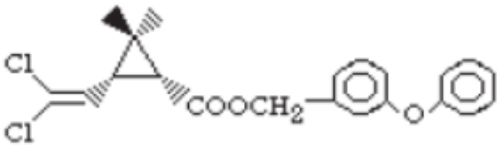
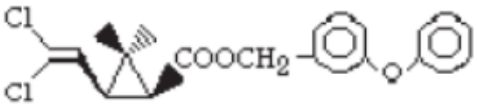
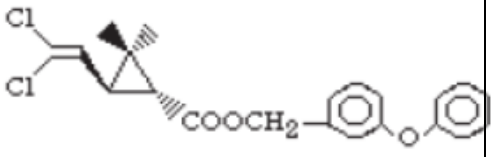
2.1.2 Product composition and formulation

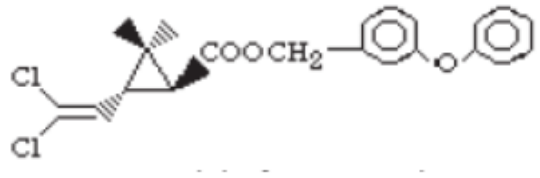
NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

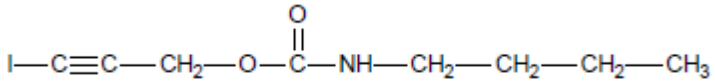
Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	Permethrin
IUPAC or EC name	3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate
EC number	258-067-9
CAS number	52645-53-1
Index number in Annex VI of CLP	n.a.
Minimum purity / content	930 g/kg Cis:trans ratio: 25:75.
Structural formula	1Rcis isomer –  1Scis isomer –  1Rtrans isomer – 

	1Strans isomer – 

Main constituent(s)	
ISO name	IPBC, 3-Iodo-2-propynyl butyl carbamate
IUPAC or EC name	3-iodoprop-2-yn-1-yl N-butylcarbamate
EC number	259-627-5
CAS number	55406-53-6
Index number in Annex VI of CLP	n.a.
Minimum purity / content	980 g/kg
Structural formula	

2.1.2.2 Candidate(s) for substitution

Based on the minutes of the 40th BPC meeting and the respective CG Dokument (CG-54-2022-13 AP 16.2[2]) Permethrin is meeting the T and P criterion and therefore fullfills substitution criteria according to Article 10(1)(d) of the BPR. A comparative assessment in included under 2.2.12.

2 Minutes of 40th BPC meeting (January 2022) (0e1c8d2b-ba6f-8199-b5d9-709bd4221fbe (europa.eu)) and CG-54-2022-13 AP 16.2 AS meeting exc subst crit 31102022

2.1.2.4 Qualitative and quantitative information on the composition of the biocidal product family

FIRST INFORMATION LEVEL

Composition of biocidal product family "AQUA LIGNEX I"

Common name	IUPAC name	Function	CAS number	EC number	Content (% w/w)	
					Min	Max
IPBC	3-Iodo-2-propynyl butyl carbamate	active substance	55406-53-6	259-627-5	0.8*	0.8*
Permethrin	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	active substance	52645-53-1	258-067-9	0.1**	0.1**
For full composition please refer to the Confidential Annex						

* corresponding to 0.784%(w/w) pure active substance based on a purity of 98%
** corresponding to 0.093%(w/w) pure active substance based on a purity of 93%

SECOND INFORMATION LEVEL

Common name	IUPAC name	Function	CAS number	EC number	Content (% w/w)	
					Min	Max
IPBC	3-Iodo-2-propynyl butyl carbamate	active substance	55406-53-6	259-627-5	0.8	0.8
Permethrin	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	active substance	52645-53-1	258-067-9	0.1	0.1
For full composition please refer to the Confidential Annex						

THIRD INFORMATION LEVEL: individual products

Composition of individual products

For full composition of the individual products including non-active substances, please refer to the confidential annex.

Tradenames		AQUA LIGNEX I 00-Farblos	AQUA LIGNEX I 01-Eiche	AQUA LIGNEX I 02-Lärche
Common name	IUPAC name	Content [%(w/w)]	Content [%(w/w)]	Content [%(w/w)]
IPBC	3-iodoprop-2-yn-1-yl N-butylcarbamate	0.8	0.8	0.8
Permethrin	(3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane-1-carboxylate	0.1	0.1	0.1

Tradenames		AQUA LIGNEX I 03-Kastanie	AQUA LIGNEX I 04-Nuss	AQUA LIGNEX I 07-Ebenholz
Common name	**IUPAC name**	**Content [%(w/w)]**	**Content [%(w/w)]**	**Content [%(w/w)]**
IPBC	3-iodoprop-2-yn-1-yl N-butylcarbamate	0.8	0.8	0.8
Permethrin	(3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane-1-carboxylate	0.1	0.1	0.1

Tradenames		AQUA LIGNEX I 09-Palisander	AQUA LIGNEX I 10-Nuss Hell	AQUA LIGNEX I 11-Mahagoni
Common name	**IUPAC name**	**Content [%(w/w)]**	**Content [%(w/w)]**	**Content [%(w/w)]**
IPBC	3-iodoprop-2-yn-1-yl N-butylcarbamate	0.8	0.8	0.8
Permethrin	(3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane-1-carboxylate	0.1	0.1	0.1

Tradenames		AQUA LIGNEX I 13-Kiefer	AQUA LIGNEX I 27-Teak	AQUA LIGNEX I 35-Wenge
Common name	**IUPAC name**	**Content [%(w/w)]**	**Content [%(w/w)]**	**Content [%(w/w)]**
IPBC	3-iodoprop-2-yn-1-yl N-butylcarbamate	0.8	0.8	0.8
Permethrin	(3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane-1-carboxylate	0.1	0.1	0.1

Tradenames		AQUA LIGNEX I 42-Grün	AQUA LIGNEX I 48-Eiche Mittel	AQUA LIGNEX I Kastanie LM Euroholz
Common name	**IUPAC name**	**Content [%(w/w)]**	**Content [%(w/w)]**	**Content [%(w/w)]**
IPBC	3-iodoprop-2-yn-1-yl N-butylcarbamate	0.8	0.8	0.8
Permethrin	(3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane-1-carboxylate	0.1	0.1	0.1

Tradenames		**AQUA LIGNEX I Noce Biondo T28 LM Nuova Elmas**	**AQUA LIGNEX I Mogano T15 LM Nuova Elmas**	**AQUA LIGNEX I Eiche Dunkel LM Euroholz**
Common name	**IUPAC name**	**Content [%(w/w)]**	**Content [%(w/w)]**	**Content [%(w/w)]**
IPBC	3-iodoprop-2-yn-1-yl N-butylcarbamate	0.8	0.8	0.8
Permethrin	(3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane-1-carboxylate	0.1	0.1	0.1

Tradenames		**AQUA LIGNEX I Nuss Hell 3 LM**	**AQUA LIGNEX I Nuss Mittel**	**AQUA LIGNEX I Lärche LM Silvestri**
Common name	**IUPAC name**	**Content [%(w/w)]**	**Content [%(w/w)]**	**Content [%(w/w)]**
IPBC	3-iodoprop-2-yn-1-yl N-butylcarbamate	0.8	0.8	0.8
Permethrin	(3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane-1-carboxylate	0.1	0.1	0.1

Tradenames		**AQUA LIGNEX I Kastanie LM Silvestri**	**AQUA LIGNEX I Altfichte LM Silvestri**	**AQUA LIGNEX I Kastanie 2LM**
Common name	**IUPAC name**	**Content [%(w/w)]**	**Content [%(w/w)]**	**Content [%(w/w)]**
IPBC	3-iodoprop-2-yn-1-yl N-butylcarbamate	0.8	0.8	0.8
Permethrin	(3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane-1-carboxylate	0.1	0.1	0.1

Tradenames		AQUA LIGNEX I Larice AC Ceal Prati	AQUA LIGNEX I Noce Chiaro AC Ceal Prati	AQUA LIGNEX I Quercia AC Ceal Prati
Common name	**IUPAC name**	**Content [%(w/w)]**	**Content [%(w/w)]**	**Content [%(w/w)]**
IPBC	3-iodoprop-2-yn-1-yl N-butylcarbamate	0.8	0.8	0.8
Permethrin	(3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane-1-carboxylate	0.1	0.1	0.1

Tradenames		AQUA LIGNEX I 10B Hellgelb	AQUA LIGNEX I Kiefer 1LM R	AQUA LIGNEX I Nuss Hell 4LM R
Common name	**IUPAC name**	**Content [%(w/w)]**	**Content [%(w/w)]**	**Content [%(w/w)]**
IPBC	3-iodoprop-2-yn-1-yl N-butylcarbamate	0.8	0.8	0.8
Permethrin	(3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane-1-carboxylate	0.1	0.1	0.1

Tradenames		AQUA LIGNEX I Nuss Dunkel 3LM R	AQUA LIGNEX I Kastanie 1LM R	AQUA LIGNEX I Noce Speciale Silvestri
Common name	**IUPAC name**	**Content [%(w/w)]**	**Content [%(w/w)]**	**Content [%(w/w)]**
IPBC	3-iodoprop-2-yn-1-yl N-butylcarbamate	0.8	0.8	0.8
Permethrin	(3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane-1-carboxylate	0.1	0.1	0.1

Tradenames		AQUA LIGNEX I Mogano AC Massa	AQUA LIGNEX I Teak LM Zennaro	AQUA LIGNEX I Verde AC Alce
Common name	**IUPAC name**	**Content [%(w/w)]**	**Content [%(w/w)]**	**Content [%(w/w)]**
IPBC	3-iodoprop-2-yn-1-yl N-butylcarbamate	0.8	0.8	0.8
Permethrin	(3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane-1-carboxylate	0.1	0.1	0.1

Tradenames		AQUA LIGNEX I Eiche LM Zennaro	AQUA LIGNEX I Lärche LM Zennaro	AQUA LIGNEX I Kastanie LM Zennaro
Common name	**IUPAC name**	**Content [%(w/w)]**	**Content [%(w/w)]**	**Content [%(w/w)]**
IPBC	3-iodoprop-2-yn-1-yl N-butylcarbamate	0.8	0.8	0.8
Permethrin	(3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane-1-carboxylate	0.1	0.1	0.1

Tradenames		AQUA LIGNEX I Nuss LM Zennaro	AQUA LIGNEX I Kiefer LM Illen	AQUA LIGNEX I Nuss Hell LM Lariano
Common name	**IUPAC name**	**Content [%(w/w)]**	**Content [%(w/w)]**	**Content [%(w/w)]**
IPBC	3-iodoprop-2-yn-1-yl N-butylcarbamate	0.8	0.8	0.8
Permethrin	(3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane-1-carboxylate	0.1	0.1	0.1

Tradenames		AQUA LIGNEX I Nr. 06 Altholz	AQUA LIGNEX I Nr. 20 Fichte	AQUA LIGNEX I Nr. 34-Eiche Dunkel.
Common name	**IUPAC name**	**Content [%(w/w)]**	**Content [%(w/w)]**	**Content [%(w/w)]**
IPBC	3-iodoprop-2-yn-1-yl N-butylcarbamate	0.8	0.8	0.8
Permethrin	(3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane-1-carboxylate	0.1	0.1	0.1

Tradenames		AQUA LIGNEX I Farblos LM Silvestri
Common name	**IUPAC name**	**Content [%(w/w)]**
IPBC	3-iodoprop-2-yn-1-yl N-butylcarbamate	0.8
Permethrin	(3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane-1-carboxylate	0.1

2.1.2.5 Information on technical equivalence

Is the source of IPBC the same as the one evaluated in connection with the approval for listing of the active substance on the Union list of approved active substances under Regulation (EU) No 528/2012?

Yes ☒

No ☐

Is the source of permethrin the same as the one evaluated in connection with the approval for listing of the active substance on the Union list of approved active substances under Regulation (EU) No 528/2012?

Yes ☒

No ☐

2.1.2.6 Information on the substance(s) of concern

In the single products of the product family no substances of concern, neither for human health nor for the environment, were identified according to Article 3 1(f) of Reg. (EU) No. 528/2012.

2.1.2.7 Type of formulation

AL (any other liquid)

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	Aquatic Acute 1 Aquatic Chronic 1
Hazard statement	H400 Very toxic to aquatic life. H410 Very toxic to aquatic life with long lasting effects.
Labelling	
pictograms	
	GHS09
Signal words	Warning
Hazard statements	H410 Very toxic to aquatic life with long lasting effects.
Precautionary statements	P101 If medical advice is needed, have product container or label at hand. P102 Keep out of reach of children. P103 Read carefully and follow all instructions. P273 Avoid release to the environment. P391 Collect spillage. P501 Dispose of contents/container in accordance with local regulations.
Additional information	EUH208 Contains reaction mass of CMIT/MIT (5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1), BIT (1,2-benzisothiazolin-3-one), MIT (2-methyl-2H-isothiazol-3-one), IPBC (3-iodo-2-propynylbutylcarbamate) and permethrin. May produce an allergic reaction.
Note	n.a.

2.1.4 Authorised uses

2.1.4.1 Use description use #1

Use # 1 – Wood boring beetles, wood discolouring fungi – brushing – non-professional user, indoor/outdoor

Product Type	8
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Common name: wood boring beetles (shown on *H. bajulus*) Scientific name: wood boring beetles Development stage: larvae Common name: wood discolouring fungi (bluestain) Scientific name: not applicable Development stage: no data
Field of use	Application (i.e. brushing): indoor, outdoor Preventive preservation of wood used indoors and outdoors, above ground and not in direct contact to water (e.g. garage doors, wooden sidings of outer walls, etc.). Please mind the restrictions. The product is formally validated in use class 1 and against all target organisms in situations of use classes 2 and 3.
Application method(s)	Application: brushing
Application rate(s) and frequency	Application rate: 200 g b.p./m^2 Frequency: One single treatment with ca. 200 g b.p./m^2 includes the application of 2 (minimum) to 3 layers of the biocidal product depending on the adsorption of the wooden substrate.
Category(ies) of users	Non-professional
Pack sizes and packaging material	Lacquer lined tin can (0.75 L, 1 L, 2.5 L, 4 L, 5 L, 6 L), closure: lever lid, lacquer lined tin

2.1.4.2 Use-specific instructions for use

2.1.4.3 Use-specific risk mitigation measures

For indoor application of the product the treated area is restricted to a maximum of 2 m^2.

N-127: Do not apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock/pets.

N-246: During product application (to timbers) and whilst surfaces are drying, do not contaminate the environment. All losses of the product have to be contained by covering the ground (e.g. by tarpaulin) and disposed of in a safe way.

N-241 modified: Application of this product is not allowed into, above or adjacent to surface water. Release into the aquatic compartment must be prevented.

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

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

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

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2.1.4.7 Use description use #2

Use # 2 – Wood boring beetles, wood discolouring fungi – brushing - professional user - indoor/outdoor

Product Type	8
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Common name: wood boring beetles (shown on *H. bajulus*) Scientific name: wood boring beetles Development stage: larvae Common name: wood discolouring fungi (bluestain) Scientific name: not applicable Development stage: no data
Field of use	Application (i.e. brushing): indoor, outdoor Preventive preservation of wood and wood products for use indoors and outdoors, for wood above ground and not in direct contact to water (e.g. garage doors, wooden sidings of outer walls, etc.) For use class 1 (wood installed indoors not exposed to weather or wetting) the application of the product is restricted to static, small-scale wooden structures. The product is formally validated in use class 1 and against all target organisms in situations of use classes 2 and 3.
Application method(s)	Application: brushing
Application rate(s) and frequency	Application rate: 200 g b.p./m^2 Frequency: One single treatment with ca. 200 g b.p./m^2 includes the application of 2 (minimum) to 3 layers of the biocidal product depending on the adsorption of the wooden substrate.
Category(ies) of users	Professional
Pack sizes and packaging material	Lacquer lined tin can (0.75 L, 1 L, 2.5 L, 4 L, 5 L, 6 L, 20 L, 25 L), closure: lever lid, lacquer lined tin HDPE drum with lid and HDPE clamping ring (100 L)

2.1.4.8 Use-specific instructions for use

2.1.4.9 Use-specific risk mitigation measures

N-78: Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information). N-127: Do not apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock/pets. N-246: During product application (to timbers) and whilst surfaces are drying, do not contaminate the environment. All losses of the product have to be contained by covering the ground (e.g. by tarpaulin) and disposed of in a safe way. N-241, modified: Application of this product is not allowed into, above or adjacent to surface water. Release into the aquatic compartment must be prevented.

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

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

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

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2.1.4.13 Use description use #3

Use # 3 – Wood boring beetles, wood discolouring fungi – industrial superficial applications (brushing, automated spraying, manual dipping, flow coating/deluge treatment) - industrial user – indoor

Product Type	8
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Common name: wood boring beetles (shown on *H. bajulus*) Scientific name: wood boring beetles Development stage: larvae Common name: wood discolouring fungi (bluestain) Scientific name: not applicable Development stage: no data
Field(s) of use	Application: indoor Preventive preservation of wood and wood products for use indoors and outdoors, for wood above ground and not in direct contact to water (e.g. garage doors, wooden sidings of outer walls, etc.) For use class 1 (wood installed indoors not exposed to weather or wetting) the application of the product is restricted to static, small-scale wooden structures. The product is formally validated in use class 1 and against all target organisms in situations of use classes 2 and 3.
Application method(s)	Industrial superficial applications: Brushing, automated spraying, dipping or flow coating/deluge treatment in industrial settings. Dipping is restricted to manual dipping.
Application rate(s) and frequency	Application rate: 200 g b.p./m^2 Frequency: One single treatment with ca. 200 g b.p./m^2
Category of users	Industrial
Pack sizes and packaging material	Lacquer lined tin can (20 L, 25 L), closure: lever lid, lacquer lined tin HDPE drum with lid and HDPE clamping ring (100 L) IBC (HDPE) with HDPE screw closure (1000 L)

2.1.4.14 Use-specific instructions for use

2.1.4.15 Use-specific risk mitigation measures

N-78: Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).
N-13: All industrial application processes must be carried out within a contained area situated on impermeable hard standing with bunding to prevent run-off and a recovery system in place (e.g. sump).
N-370: Freshly treated timber must be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water, and that any losses of the product, including any contaminated water/soil must be collected for reuse or disposal in accordance with local/national/international requirements.

For automated spraying, manual dipping, flow coating/deluge treatment the following RMM applies:
N-10: Wear a protective coverall [type 6, EN 13034 or type 3, EN 14605 or type 4, EN 14605]*.

* Applicant to specify the coverall type within the product information (SDS, etc…)

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

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

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

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2.1.5 General directions for use

2.1.5.1 Instructions for use

N-359: Comply with the instructions for use
Strip any old, badly adhering layers of paint. The wood to be treated must be dry and free from dust and grease. Do not apply at temperatures below +10°C (air, surface and product). Stir well before applying.
Apply in total approximately 200 g b.p./m^2.
Waiting time between recoating is 4-6 hours.
N-29, modified: Ensure adequate ventilation during and after the application, until treated surfaces have dried.

N-247: Can be harmful to protected species such as bats, hornets or birds. The presence of protected species in the area to be treated must be assessed prior to use of the product. Appropriate protective measures must be taken if necessary.

2.1.5.2 Risk mitigation measures

N-15: Do not use on wood which may come in direct contact with food, feed and livestock.

N-315, modified: Keep children and pets (especially cats) away from treated surfaces until dried.

N-335, modified: Due to the particular sensitivity of cats to permethrin, the product shall only be applied on wood which is applied in areas where contact of cats to treated wood can be excluded.

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

N-360: If medical advice is needed, have product container or label at hand.

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

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

IF ON SKIN: Take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation or rash occur: Get medical advice.

IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.

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

Do not allow product to reach sewage system or water courses.
In case of seepage into water or sewage system inform responsible authorities.
Collect the liquid with absorbent material (sand, diatomaceous earth, sawdust).

2.1.5.4 Instructions for safe disposal of the product and its packaging

Product residues, contaminated materials (including absorbent material) and empty containers must be collected and disposed of in accordance with the national waste disposal legislation and any regional and/or local authority requirements.

Do not discharge the biocidal product nor diluted solution of the biocidal product into

the sewage system or the environment (in particular surface water).

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

N-316: Keep out of reach of children and non-target animals/pets. Shelf life: 3 years Store in a dry, well-ventilated area. Store only in the original container protected from frost. Store below 30°C. Protect from heat and direct sunlight. Keep container tightly sealed. Close partially used packaging well.

2.1.6 Other information

Obligatory label elements:

This biocidal product contains permethrin which is dangerous to bees.

The biocidal product is solely effective against wood boring beetles and wood discolouring fungi (bluestain). It is not effective against wood rotting fungi.

Further information:
Occupational exposure limit:
The Union OEL values of CAS 34590-94-8 and CAS 112-34-5 must be indicated in the SDS (section 8.1 and 3):
The occupational exposure limit value of 2-[(1-methoxypropan-2-yl)oxy]propan-1-ol (CAS 34590-94-8) is 50 ppm (308 mg/m^3)[3].
The occupational exposure limit values of 2-(2-butoxyethoxy)ethanol (CAS 112-34-5) are 10 ppm (67.5 mg/m^3, long-term exposure limit) and 15 ppm (101.2 mg/m^3, short-term exposure limit)[4]

Substances identified as PBT or vPvB:
The BPF contains the substances octamethylcyclotetrasiloxane (D4), decamethylcyclopentasiloxane (D5) and dodecamethylcyclotetrasiloxane (D6) in concentrations <0.1 % w/w. According to CA-June21-Doc.4.3_final, *"the authorisation holder should try to substitute the substance identified as PBT or vPvB and contained in a biocidal product regardless whether the concentration above or below 0.1% w/w. This effort shall be proven at the authorisation process."*

[3] https://echa.europa.eu/substance-information/-/substanceinfo/100.047.353
[4] https://echa.europa.eu/substance-information/-/substanceinfo/100.003.601

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)
Lacquer lined tin can	0.75 L	Lacquer lined tin (Lacquer: one epoxyphenol resin layer, second layer of polyester resin paint)	Lever lid, lacquer lined tin	Non-professional, Professionals	Yes
Lacquer lined tin can	1 L	Lacquer lined tin (Lacquer: one epoxyphenol resin layer, second layer of polyester resin paint)	Lever lid, lacquer lined tin	Non-professional, Professionals	Yes
Lacquer lined tin can	2.5 L	Lacquer lined tin (Lacquer: one epoxyphenol resin layer, second layer of polyester resin paint)	Lever lid, lacquer lined tin	Non-professional, Professionals	Yes
Lacquer lined tin can	4 L	Lacquer lined tin (Lacquer: one epoxyphenol resin layer, second layer of polyester resin paint)	Lever lid, lacquer lined tin	Non-professional, Professionals	Yes
Lacquer	5 L	Lacquer	Lever	Non-	Yes

lined tin can		lined tin (Lacquer: one epoxyphenol resin layer, second layer of polyester resin paint)	lid, lacquer lined tin	professional, Professionals	
Lacquer lined tin can	6 L	Lacquer lined tin (Lacquer: one epoxyphenol resin layer, second layer of polyester resin paint)	Lever lid + clamping ring, lacquer lined tin	Non-professional, Professionals	Yes
Lacquer lined tin can	20 L	Lacquer lined tin (Lacquer: one epoxyphenol resin layer, second layer of polyester resin paint)	Lever lid + clamping ring, lacquer lined tin	Professionals, Industry	Yes
Lacquer lined tin can	25 L	Lacquer lined tin (Lacquer: one epoxyphenol resin layer, second layer of polyester resin paint)	Lever lid + clamping ring, lacquer lined tin	Professionals, Industry	Yes
Drum with lid (Open top drum)	100 L	HDPE	Lid + clamping ring, HDPE	Professionals, Industry	Yes
IBC	1000 L	HDPE	Screw closure, HDPE	Industry	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

Letters of access are available for Annex II-data.
Please confer to chapter 3.1 for information on Annex III-data submitted on the biocidal product.

2.1.8.2 Access to documentation

A letter of access to the active substance data was granted to the authorisation holder from Lanxess Deutschland GmbH for permethrin, and from Troy Chemical Company B.V. for IPBC.

2.2 Assessment of the biocidal product (family)

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

Please refer to the DRAs in the respective IUCLID files, section 13.

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 analysis	100% undiluted product (Aqua Lignex I 27-Teak, Batch number 315687)	liquid	Anonymous 2016a
Colour at 20°C and 101.3 kPa	Organoleptic analysis	100% undiluted product (Aqua Lignex I 27-Teak, Batch number 315687)	brown opaque	Anonymous 2016a
Odour at 20°C and 101.3 kPa	Organoleptic analysis	100% undiluted product (Aqua	characteristic odour	Anonymous 2016a

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		Lignex I 27-Teak, Batch number 315687)		
Acidity / alkalinity	CIPAC MT 191 CIPAC MT 75.3 OECD 122	100% undiluted product (Aqua Lignex I 27-Teak, Batch number 315687)	The pH of test item at 20°C is 8.1.	Anonymous 2016a
Relative density / bulk density	Guideline A.3 in Council Regulation (EC) No 440/2008 part A CIPAC method MT 3.2 OECD Test No 109	100% undiluted product (Aqua Lignex I 03-Kastanie, batch number 335007)	The test item density is 1.0285 g/mL at 20°C, the relative density (D_{20}^{20}) is 1.0303 and the relative density (D_4^{20}) is 1.0285.	Anonymous 2021a
Storage stability test – **accelerated storage**	CIPAC MT 46.3 (12 weeks at 35 °C)	100% undiluted product (Aqua Lignex I 03-Kastanie, batch number 31.03.15)	Physical state, colour: T0: liquid brown T12: Liquid brown; IPBC concentration: T0: 0.81% T12: 0.79%; Permethrin: T0:0.099% T12:0.097% pH undiluted: T0: 7.4 T12: 7.2; pH at 1% in water: T0: 7.4 T12: 7.1 Packaging: Commercial lacquer lined tin can.	Anonymous 2016b
Storage stability test – **long term storage at ambient**	GIFAP N° 17	100% undiluted product	T0: Physical state and colour: Liquid, brown. Stability of packaging	Anonymous 2018a

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
temperature (the choice of the worst case package is explained in next page in "Conclusion on the physical, chemical properties")			and packaging formulation interactions: no significant interactions were observed. IPBC content: 0.81% Permethrin content: 0.099% pH value: 7.4 (undiluted); 7.4 (1% dilution) T36: Physical state, colour: liquid Brown IPBC: 0.78% Permethrin: 0.102% No significant interactions were observed; <0,01% weight loss of the package; pH undiluted: 7.5 pH at 1% in water: 7.7 Packaging: Commercial lacquer lined tin can.	
Storage stability test – **low temperature stability test for liquids**			Study waived. The test product is not intended to be used at low temperature condition. It is clearly indicated in the product label. In the storage condition is reported: "store in a cool place but protected from frost". For this reason, the study was waived.	
Effects on content of the active substance and technical characteristics of the biocidal product - **light**			Study waived Considering the packaging type, the product is not expected to be exposed to light before application. Moreover, the test was	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			not performed because the active substances contained in the products do not absorb wavelengths greater than 290 nm, which indicates that the molecules are not susceptible to breakdown by light.	
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**		100% undiluted product (Aqua Lignex I 03-Kastanie, batch number 31.03.15)	The effects of temperature was investigated as part of the accelerated stability study (35°C for 12 weeks). The samples for the long term study are stored in a cabinet in an indoor-room (without windows) at the stated temperature and a controlled humidity of 40–60% r.h.	Anonymous 2016b Anonymous 2018a
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	UN Manual of Tests and Criteria: Part III, 37.4: test methods for corrosion to metals	100% undiluted product (Aqua Lignex I 27-Teak, Batch number 315687)	A corrosive study to metals was performed: The mass loss on each metal specimen (aluminium and carbon steel) after 7 days at 55°C proved to be not significant and less than 13.5%. Therefore the test was considered negative for each specimen type.	Anonymous 2016d
Wettability			Study waived The data are required for solid preparations which are to be dispersed in water. The product is a ready to use liquid formulation.	
Suspensibility, spontaneity and dispersion stability			Study waived According to ECHA guidelines, the study is expected to be performed in case of	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			wettable powders, water dispersible granules, or water dispersible powders. The test was not performed because the products do not have these characteristics	
Wet sieve analysis and dry sieve test			Study waived According to ECHA guidelines, the study is expected to be performed in case of wettable powders, water dispersible granules, or water dispersible powders. The test was not performed because the products do not have these characteristics.	
Emulsifiability, re-emulsifiability and emulsion stability			Study waived According to ECHA guidelines, the study is expected to be performed in the case of an emulsion product. The test was not performed because the products do not have this characteristic	
Disintegration time			Study waived According to ECHA guidelines, the disintegration time is applicable to all products that are tablets and depend on disintegration of the tablet in a solvent (water) for optimal efficacy. The product has not these characteristics.	
Particle size distribution, content of dust/fines,			Study waived According to the ECHA guidelines, this study is	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
attrition, friability			expected to be performed for powder/granular biocidal products and biocidal products that are applied in a manner that generates exposure to aerosols. The test was not performed because the products do not have these characteristics.	
Persistent foaming			Study waived According to ECHA guidelines, persistent foaming is determined to measure the amount of foam likely to be present in a spray tank or other application equipment following dilution of the preparation. The test was not performed because the product is a ready to use formulation, applied by brushing.	
Flowability/ Pourability/ Dustability			Study waived According to the ECHA guidelines, the tests are expected to be performed in case of granular formulations applied through application equipment that would subject the granules to pressure and/or heat, or in case of suspensions or dustable powders. The tests were not performed because the products are liquids and do not have these characteristics.	
Burning rate —			Study waived	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
smoke generators			According to the ECHA guidelines, evidence is required that the preparation may be satisfactorily applied as a smoke and that the burning rate and burning completeness support the proposed use. The test was not performed because the products under exam is not a smoke generator.	
Burning completeness — smoke generators			Study waived According to the ECHA guidelines, evidence is required that the preparation may be satisfactorily applied as a smoke and that the burning rate and burning completeness support the proposed use. The test was not performed because the products under exam is not a smoke generator.	
Composition of smoke — smoke generators			Study waived According to the ECHA guidelines, evidence is required that the preparation may be satisfactorily applied as a smoke and that the burning rate and burning completeness support the proposed use. The test was not performed because the products under exam is not a smoke generator.	
Spraying pattern — aerosols			Study waived The test was not performed because the product is not applied as spray and does not generate aerosols.	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Only by industrial application it can be used as a spray but in a controlled system.	
Physical compatibility			Study waived The product is not intended to be used with other products.	
Chemical compatibility			Study waived The product is not intended to be used with other products.	
Degree of dissolution and dilution stability			Study waived The test was not performed because is required for water soluble formulations of tablets. Our products are liquid formulations.	
Surface tension	-Method A.5– Surface Tension of Council Regulation (EC) No. 440/2008, -Published in O.J. L 142, 2008; OECD 115 – Surface Tension of Aqueous Solutions; -Guidance on the Biocidal Products Regulation, Volume I: Identity/physico-chemical properties/analytical methodology – Part A:	100% undiluted product	According to test method A.5, the surface tension is 31.3 mN/m, at 20°C	Anonymous 2017a

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	Information Requirements Part A: Information Requirements - Version 1.1 November 2014.			
Viscosity	CIPAC L/MT 192	100% undiluted product (Aqua Lignex I 27-Teak, Batch number 315687)	The rotational viscosity at 20°C is 4.05 cP. The rotational viscosity at 40°C is 3.34 cP.	Anonymous 2016a

Conclusion on the physical, chemical and technical properties of the product
The product family consists of liquid formulations. The products proved to be stable in a long term storage stability study at ambient temperature for 36 months. For the long term storage test, 0.75 liter tin cans were used. Reasons: it was assumed that with tin cans the container material is most critical. In small containers the surface-to-volume ratio plus the ratio of potentially leaky lid area to volume is most unfavourable.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives			Study waived According to CLP Reg. "An explosive substance or mixture is a solid or liquid substance or mixture of substances which is in itself capable by chemical reaction of producing gas at such a temperature and pressure and at such a speed as to cause damage to the surroundings". The substances in the products do not contain functional groups listed in table A6.1 of annex VI of the UN-MTC, hence explosive properties can be excluded. Therefore, the study does not need to be conducted.	
Flammable gases			Study waived The study does not need to be conducted because the substance is a liquid	
Flammable aerosols			Study waived The study does not need to be conducted because the substance is a liquid	
Oxidising gases			Study waived The study does not need to be conducted because the substance is a liquid	
Gases under pressure			Study waived The study does not need to be conducted because the substance is a liquid	
Flammable liquids	Method A.9[5]-Flash	100% undiluted	According to the test method A.9, the sample labelled as AQUA	Anonymous 2016c

[5] An experimental study as for method A.9 of Regulation n. 440/2008 was performed in order to establish the flash point of the product. As described in Regulation n. 440/2008, the performance of method A.9 by equilibrium method has to be performed according to ISO 1516, ISO 3680, ISO 1523, ISO 3679. The ISO 3679 method has also been followed to conduct the study, as specified in the study report provided by the sponsor. The method is listed in the table 2.6.3 annex I of

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	point of Council regulation (EC) No. 440/2008 Method ISO 3679:2015	product (Aqua Lignex I 27-Teak, Batch number 315687)	LIGNEX I does not ignite and turns off the test flame at 45°C.	
Flammable solids			Study waived The study does not need to be conducted because the substance is a liquid	
Self-reactive substances and mixtures			Study waived The substances in the products do not contain functional groups listed in table A6.1 and A6.3 of annex VI of the UN-MTC, hence seld-reactive properties can be excluded. Therefore, the study does not need to be conducted.	
Pyrophoric liquids			Study waived According to section 2.9 of Annex I to the CLP Regulation the test was not performed. In fact the experience in manufacture and handling shows that is known to be stable at room temperature for prolonged periods of time.	
Pyrophoric solids			Study waived The study does not need to be conducted because the substance is a liquid	
Self-heating substances and mixtures			Study waived The phenomenon of self-heating applies only to solids. The surface of liquids is not large enough for reaction with air and the test method is not applicable to liquids. Therefore liquids are not classified as self-heating.	

CLP Regulation (which lists methods for determining the flash point of flammable liquids). For this reason, the provided study is considered suitable to the requirements of flammable liquids endpoint.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Substances and mixtures which in contact with water emit flammable gases			Study waived The product is an aqueous solution. The study is scientifically unjustified	
Oxidising liquids			The screening on co-formulants of AQUA LIGNEX I has been performed taking into account the following guidance documents: • Guidance on the BPR: Volume I Parts A+B+C Version 2.0 May 2018 • Guidance on the Application of the CLP Criteria Version 5.0 – July 2017 • Technical Notes for Guidance, February 2008 where present, oxygen, fluorine and chlorine are chemically bonded only to carbon or hydrogen, so no oxidising properties are expected. For substances where oxygen is bonded to Si or Ca, data on oxidising properties from the available REACH dossier have been examined; no oxidising properties are expected. Moreover, none of the chemical groups suggesting an alert for oxidising properties is present in the substances. Based on the screening, the mixture AQUA LIGNEX I is not considered to have oxidising properties, therefore a study is not deemed necessary.	
Oxidising solids			Study waived. The study does not need to be conducted because the substance is a liquid.	
Organic peroxides			Study waived In the formulation there are no co-formulants that are peroxides. The study is scientifically unjustified.	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Corrosive to metals	UN Manual of Tests and Criteria: Part III, 37.4: test methods for corrosion to metals	100% undiluted product (Aqua Lignex I 27-Teak, Batch number 315687)	A corrosive study to metals was performed: The mass loss on each metal specimen (aluminium and carbon steel) after 7 days at 55°C proved to be not significant and less than 13.5%. Therefore the test was considered negative for each specimen type.	Anonymous 2016d
Auto-ignition temperatures of products (liquids and gases)	EU method A.15 Method A.9	100% undiluted product (Aqua Lignex I 27-Teak, Batch number 315687)	According to the test method A.15, the auto-ignition temperature of the sample labelled as AQUA LIGNEX I does not ignite itself up to 600°C.	Anonymous 2016c
Relative self-ignition temperature for solids			Study waived The study does not need to be conducted because the substance is a liquid	
Dust explosion hazard			Study waived The product under exam isn't a dust and isn't able to produce dust. For this reason the test was not performed.	

Conclusion on the physical hazards and respective characteristics of the product
Based on the assessment of the representative product, the BPF is not classified for physical hazards.

2.2.4 Methods for detection and identification

Analytical methods for the analysis of the product as such including the active substance, impurities and residues								
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**	**Precision**		**Reference**
					Mean	Mean	RSD	
IPBC	HPLC-DAD	16.40-45.60 µg/mL / 6 measurements	R^2: 0.9995	No interferences from matrix were detected	100.2%	0.806 %	0.27 %	Anonymous 2016e
Permethrin	HPLC-DAD	15.59-43.09 µg/mL / 6 measurements	R^2: 0.9995	No interferences from matrix were detected	99.9%	0.0978%	0.77 %	Anonymous 2016e

Analytical methods for monitoring
Please refer to the CARs of the active substances

Analytical methods for soil
Please refer to the CARs of the active substances.
Emission of the a.s. in soil is considered negligible according to the "Effects and Exposure Assessment and Risk Characterisation for the Biocidal Product" document presented. Therefore no analytical method to detect the a.s. in soil was presented.

Analytical methods for air
Please refer to the CARs of the active substances.
Emission of the a.s. in air is considered negligible according to the "Effects and Exposure Assessment and Risk Characterisation for the Biocidal Product" document presented. Therefore no analytical method to detect the a.s. in air was presented.

Analytical methods for water
Please refer to the CARs of the active substances.
The ecotoxicological results show a low aquatic toxicity of AQUA LIGNEX I (Aquatic Chronic 3); this means that the release on the aquatic compartment during service life do not pose unacceptable risks. Therefore no analytical method to detect the a.s. in water was presented.

Analytical methods for animal and human body fluids and tissues
Analytical methods for the determination of IPBC residues in animal and human body fluids and tissues were not submitted for the biocidal product, since this point is covered by the data set of the active substance. For IPBC an analytical method in animal and human body

fluids is described in the IPBC assessment reports PT 6 (September 2013) and PT13 (January 2015).

Analytical methods for monitoring of active substances and residues in food and feeding stuff

Neither the active substances nor the treated articles come into contact with food producing animals, food of plant or animal origin, or feeding stuffs. Therefore, the study was not deemed necessary

Conclusion on the methods for detection and identification of the product
Analytical methods for the determination of IPBC and permethrin are available (Anonymous 2016e). Specificity, linearity, accuracy and precision were checked and found acceptable. Methods for the detection of IPBC and permethrin in soil, air, water, animal and human body fluids and tissues were deemed acceptable at EU level and can be found in the respective CARs. No other data is required. The products are not intended to be used on surface in contact with food/feed of plant and animal origin; therefore, analytical method for the determination of the active substances in food/feed of plant and animal origin is not required.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

The PT 8 product family is used for the preventive treatment of the wood subject to attack by wood boring beetles (shown on *H. bajulus*) and blue stain. The products are intended for indoor and outdoor application by non-professional, professional and industrial users to protect wood in UC 1-3 (UC 2 and 3 restricted to blue stain fungi). The product is formally validated in Use class 1 and against all target organisms in situations of use classes 2 and 3.

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

Organisms to be controlled: larvae of *Hylotrupes bajulus L*. (house longhorn beetle) representative for wood boring beetles (according to EN 599-1), wood discolouring fungi (blue stain fungi): *Aureobasidium pullulans spp., Sydowia polyspora*

Objects to be protected: The product is a water-based, protective wood preservative, resistant to weathering, for the preventive protection of wood against blue stain and insect attack (UC 1-3). The field of use covers wood and wood products indoors and outdoors, for wood above ground and not in direct contact to water (e.g. garage doors, wooden sidings of outer walls, etc.) Use class 1 for non-professional users (wood installed indoors not exposed to weather or wetting) is restricted to supporting wooden structures that are static, small-scale components.

2.2.5.3 Effects on target organisms, including unacceptable suffering

Permethrin is a contact insecticide which causes convulsions, paralysis and ultimately death in target organisms. Its effects are characterised by progressive fine whole body tremor, exaggerated start response, uncoordinated muscle twitching and hyperexcitability. Permethrin also induces hepatic microsomal enzymes (Ireland, 2014).
IPBC acts as a fungicidal active substance by reducing the numbers of viable fungi.

2.2.5.4 Mode of action, including time delay

Permethrin is a type I axonic poison which exerts its effects by means of hyperexcitation of both the peripheral and central nervous systems of target insects (Ireland, 2014).
IPBC has a carbamate structure and its target sites in fungi are cell membrane permeability and fatty acids.

2.2.5.5 Efficacy data

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Insecticide	Indoor, outdoor	Aqua Lignex I 03 – Kastanie (HSL 298) on Scotch pine, sap wood.	*Hylotrupes bajulus L* Recently hatched larvae	EN 46 (CEN 1988-11-01) Version e 46-1 EN 73 (CEN 1988-11-01)	Preventive treatment: Brushing, 3 applications wet in wet Concentration tested: 100% (m/m) Preservative retention: 197.5 g/m^2 Conditioning period after impregnation: 28 days	The product proved to be effective against the tested target organism , according to EN 599-1 criteria.	*Anonymous 2016f* *(see note 1)*
Insecticide	Indoor, outdoor	Aqua Lignex I 03 – Kastanie (HSL 298) on Scotch pine, sap wood.	*Hylotrupes bajulus L* Recently hatched larvae	EN 46 (CEN 1997-01-22) Version e 46-1 EN 84 (CEN 1988-11-01)	Preventive treatment: Brushing, 3 applications wet in wet Concentration tested: 100% (m/m) Preservative retention: 180-200 g/m^2 Conditioning period after impregnation: 28 days	The product proved to be effective against the tested target organism , according to EN 599-1 criteria.	*Anonymous 2016g* *(see note 1)*
Fungicide	Indoor, outdoor	Aqua Lignex I 03 – Kastanie (HSL 298) on Scotch pine, sap wood.	*Aureobasidium pullulans spp. Sydowia polyspora*	DIN EN 152_1	Preventive treatment: Brushing, 3 applications wet in wet Concentration tested: 100% (m/m) Preservative retention: 197 g/m^2 Conditioning period after impregnation: 28 days. Replicates : Each 6 blocks for test product, virulence control,	Visual evaluation acc. to EN 152 : Test product : 0 Untreated control : 3	*Anonymous 2016h* *(see note 2)*

					reference control ; 9 untreated controls.		
Fungicide	Indoor, outdoor	Aqua Lignex I 03 – Kastanie (HSL 298) on Scotch pine, sap wood.	*Aureobasidium pullulans spp.* *Sydowia polyspora*	DIN EN 152_1 After 6 months of field testing	Preventive treatment: Brushing, 3 applications wet in wet Concentration tested: 100% (m/m) Preservative retention: 199 g/m^2 Conditioning period after impregnation: 6 months. Replicates : Each 6 blocks for test product, virulence control, reference control ; 9 untreated controls.	Visual evaluation acc. to EN 152 : Test product : 0 Untreated control : 3	*Anonymous 2016i* *(see note 2)*

Remarks from the testing laboratory:

Note 1:

For validity, 70% of larvae in controls must be alive. (EN 46-1 section 8.4.2) If freshly hatched larvae of *Hylotrupes bajulus* still live at the end of the test, they must have tunnelled (gnawed) into the wood. Reason: The tiny baby larvae do not have enough nutrient reserves to survive four weeks without feeding. So, of course the number of larvae that gnawed consists of dead ones which gnawed plus all living ones.

Note 2:

Untreated controls MPA described as „well stained" are not just „strongly stained", but extremely stained on the surface. It is quite easy to achieve such surface staining with untreated C1.1 and C1.2 blocks (EN 152; 7.5.2). It is considerably harder to achieve sufficient interior staining. Our admittedly imprecise formulation was therefore primarily focused on declaring that also interior staining was well above requirements. So the text should be: "All untreated controls were strongly blue-stained on the surface (rating 3) and sufficiently stained in the interior".

EN 152 section 5.2.8 requires that additional test blocks must be treated with 80 g/m² resp. 100 mL /m² of reference product (0,49% dichlofluanid) for evidence of sufficient virulence. This virulence control showed a surface blue stain ≥1 (median). Therefore the test is valid (acc. to EN 152 section 9).

Conclusion on the efficacy of the product

The test product proved to be effective in the experimental conditions, at the application rate of ca. 200 g/m^2. The product is effective for preventive treatment against insects (*Hylotrupes bajulus* as representative beetle species, according to EN 599-1) and blue stain fungi, as proved by the experimental studies listed above.

The product proved to be effective against the tested target organism (recent hatched larvae of Hylotrupes bajulus L.), according to EN 46-1 (2009) after evaporation ageing

procedure according to EN73 (2014).
The product proved to be effective against the tested target organism (Hylotrupes bajulus L. larvae), according to EN 46-1 (2009) after leaching procedure according to EN 84 (1997).
The claim against wood boring beetles is sufficiently supported by the provided valid tests against the target beetle *Hylotrupes bajulus*. This is in-line with the Guidance in force at the time of dossier submission, the Transitional Guidance on Efficacy assessment for PT 8 (2015), where it is stated for Use Class 1 ("Test species"): *Data should demonstrate activity against one or more of the following species: Hylotrupes bajulus, Anobium punctatum, Lyctus brunneus, and where appropriate, termites. For general claims against "wood boring beetles": The majority of efficacy tests for authorisation are likely to be for treatments against H. bajulus. Therefore data against this beetle species should be available and will be considered adequate to cover this claim.*
Considering the Guidance in force, the eCA accepts the general claim against wood boring beetles.
The product proved to be effective against blue stain fungi (*Aureobasidium pullulans, Sydowia polyspora*) according to EN 152(2011) after 4 weeks artificial weathering.
The product proved to be effective against blue stain fungi (*Aureobasidium pullulans, Sydowia polyspora*) according to EN 152-1(2011) after 6 months of field testing.
The product is formally validated in Use class 1 and against all target organisms in situations of use classes 2 and 3.

Justification for the claim against blue stain (wood discolouring fungi):
According the Guidance on the BPR: Volume II Parts B+C, Version 3.0 April 2018 (ECHA 2018) products which only claim protection against bluestain can be authorised for uses where the exemption of the requirement for efficacy against wood destroying fungi can be justified (section 5.5.8.2.2.3).
Therefore the applicant provided an expert statement including a literature study which confirms the different behavior of chromogenic fungi compared to wood destroying fungi (concerning required humidity/time). Whereas bluestain fungi can occur in sapwood after only a short exposure to moisture (inadequate/improper storage, insufficient protection during installation/construction process etc.), wood destroying fungi (rot) need a longer-lasting moisture load (fungal infestation begins from 2 weeks onwards) for maturation. Besides to the differences in growth conditions of bluestain and rot fungi, it is also necessary to consider the intended use of the product. The product is specifically requested to prevent the depreciation of wood, which is in the main part caused by wood discolouring fungi, it is not intended to protect against wood-destroying fungi as this is not the focus of the market demand. Chromogenic fungi in themselves are not a problem for the static resistance of wooden structures (contrary to rot fungi) but limit their commercial value for aesthetic reasons. Furthermore, they offer a fertile ground for the growth of wood-destroying fungi and limit the adhesion of subsequently applied protective cycles. For this reason, the growth of bluestain must always be prevented, even during storage, transport and assembly of the wood. EN 599-1 refers in its functional description to wood preservation for the durability of wood but does not refer to aesthetic, value-reducing problems caused by bluestain with regard to the classification of products into Use classes.
In summary, the product is proved to be effective against bluestain fungi and the eCA accepts the justification due to the difference in the life cycles of bluestain and rot fungi, the sufficient short-term humidifaction for the formation of bluestain and due to the intended use of the product and the focus of the market demand.

Justification concerning the application "brushing" in comparison to the other claimed superficial methods of application:
Brushing, dipping, spraying and flow coating/aspersion treatment are all methods of superficial non-pressure treatment. According the Guidance on the BPR: Volume II Parts B+C, Version 3.0 April 2018 (chapter 5.5.8.1.5)(ECHA 2018), details on penetrability/retention are not required for superficial treatments. For these reasons, data on retention were not provided. Brushing, spraying and flow coating are generally done on cut or machined surfaces of previously treated wood. Penetration of preservative into wood is superficial, resulting mostly from capillary action. Dipping consists of immersing wood in a preservative solution for several seconds to several minutes. It allows better penetration. The brushing application can be considered the representative method of application for all surface treatments in terms of the quantity applied. Moreover, compared to dipping/flow coating, a lower level of penetration of the product in the wood can be achieved via brushing or spraying. Kollmann and Cote (1968) already stated that dipping (complete immersion) provides greater uniformity of coverage than brushing and provides more effectiveness compared to brushing and spraying. Also the "Wood preservation & wood products treatment pest control study guide" (2005) reported about the better penetration of preservatives into wood by dipping application in contrast to brushing. For this reason, it can be considered a "worst case" application method. According to Guidance on the BPR: Volume II Parts B+C, Version 3.0 April 2018, "Efficacy tests must be performed on the product with the lowest concentration of the active substance, under the worst case circumstances". This principle is usually applied to the BPF authorisations, but it is reasonable to apply it even when different conditions of product application are present, in order to avoid unnecessary use of test organisms. For all these reasons, the test performed via brushing can be used to cover also the other application methods.

2.2.5.6 Occurrence of resistance and resistance management

For Permethrin, there are no reported cases of development of resistance involving the use in wood preservation products (Ireland, 2014).
For industrial wood preservation using IPBC this is not an issue. Resistance is usually associated with continued application and resistance is formed between applications such that subsequent applications are less efficacious. Industrial wood preservatives are usually applied only once and there is no evidence to suggest resistance. Also, for other kinds of wood preservation with IPBC-containing products, cases of resistances are not reported or known up to the time being (Denmark, 2008).

2.2.5.7 Known limitations

For an optimal efficacy, the wood to be treated must be dry and free from dust and grease. The product should not be applied at temperatures below 10°C.

2.2.5.8 Evaluation of the label claims

The efficacy tests presented fully support the label claim. See below the claim matrix (according to ECHA 2018, Guidance on the BPR: Volume II Parts B+C Version 3 April 2018):

Categories	Matrix Wording	code for product
intended Use 1		
User Category	Non professional	A.10
Wood Category	softwood and hardwood	B.10, B.20
Wood product	Solid wood; panel; plywood panels	C.10, C.20, C.21
Application aim and field of use	Preventive treatment/blue stain in service (preventive effectiveness against wood destroying insects and blue stain)	D.30
Method of applications and rate	Application: brush Application rate: 200 g/m²	F.10
Target organisms	*Hylotrupes bajulus* (larvae), *Aureobasidium pullulans* (blue stain fungi), *Sydowia polyspora* (blue stain fungi)	G.31, G21.2

Categories	Matrix Wording	code for product
intended Use 2		
User Category	Professional	A.30
Wood Category	softwood and hardwood	B.10, B.20
Wood product	Solid wood; panel; plywood panels	C.10, C.20, C.21
Application aim and field of use	Preventive treatment/blue stain in service (preventive effectiveness against wood destroying insects and blue stain)	D.30
Method of applications and rate	Application: brush Application rate: 200 g/m²	F.10

Target organisms	Hylotrupes bajulus (larvae), Aureobasidium pullulans (blue stain fungi), Sydowia polyspora (blue stain fungi)	G.31, G21.2

Categories	Matrix Wording	code for product
intended Use 3		
User Category	Industrial	A.20
Wood Category	softwood and hardwood	B.10, B.20
Wood product	Solid wood; panel; plywood panels	C.10, C.20, C.21
Application aim and field of use	Preventive treatment/blue stain in service (preventive effectiveness against wood destroying insects and blue stain)	D.30
Method of applications and rate	Application: brushing, spray treatment, dipping, automated spraying, flow coating; Application rate: 200 g/m²	F.10, F.11, F.12, F14
Target organisms	Hylotrupes bajulus (larvae), Aureobasidium pullulans (blue stain fungi), Sydowia polyspora (blue stain fungi)	G.31, G21.2

Find in attachment in IUCLID section 6.1 the relative tables file.

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

The products are not intended to be used in combination with other biocidal products.

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

The assessment of human health effects is based on the Competent Authority Report (CAR) and assessment report (AR) of permethrin (Ireland, 2014) and IPBC (Denmark, 2008). For the human health effect assessment of AQUA LIGNEX I products data on a tested mixture for some endpoints were submitted by the applicant. The effects of the product on human health for other endpoints can be derived from information on the individual co-formulants and the active substance in the mixture.

Skin corrosion and irritation

Summary table of in vitro studies on skin corrosion/irritation					
Method, Guideline, GLP status, Reliability	**Test substance, Doses**	**Relevant information about the study**	**Results**	**Remarks** *(e.g. major deviations)*	**Reference**
OECD Guideline 431 (In Vitro Skin Corrosion: Human Skin Model Test, EpiDerm™), GLP: yes, Klimisch 2	The test item AQUA LIGNEX I 27-Teak was topically applied on two tissues replicates for 3 min and 60 minutes at RT.	Three-dimensional Reconstructed Human Epithelium (RHE) tissues, consisting of normal human keratinocytes cultured for 17-days on an inert 0.6 cm^2, polycarbonate filter at the air-liquid interface, were used.	NOT CORROSIVE to skin.	Test report did not include a demonstration of proficiency and an acceptance range based on historical data.	Anonymous 2016j
OECD Guideline 439 (In Vitro Skin Irritation: Reconstructed Human Epidermis Test Method), GLP: yes, Klimisch 2	The test item AQUA LIGNEX I 27-Teak was topically applied on two tissues replicates for 60 minutes at 37°C ± 1°C. Post-treatment incubation	Three-dimensional Reconstructed Human Epithelium (RHE) tissues, consisting of normal human keratinocytes cultured for 17-days on an inert 0.63 cm^2 polycarbonate filter at the air-liquid interface, were used.	NOT IRRITANT to skin.	Test report did not include a demonstration of proficiency and an acceptance range based on historical data.	Anonymous 2016k

	for 42 hours at 37°C ± 1°C.				

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	The biocidal product family does not cause skin irritation.
Justification for the value/conclusion	Experimental data
Classification of the product according to CLP and DSD	Not classified for skin corrosion or skin irritation. Pyrethroids (including permethrin) may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice.

Eye irritation

Summary table of in vitro studies on serious eye damage and eye irritation					
Method, Guideline, GLP status, Reliability	**Test substance, Doses**	**Relevant information about the study**	**Results**	**Remarks** *(e.g. major deviations)*	**Reference**
OECD Guideline 437 (Bovine Corneal Opacity and Permeability Test Method for Identifying Ocular corrosive and Severe Irritants), GLP: yes, Klimisch 2	750 µL of the test substance AQUA LIGNEX I 27-Teak or the control substance was introduced into the anterior chamber. 10 minutes incubation at 32 ± 1°C	3 corneas for the test item 3 corneas as negative controls treated with physiological saline 0.9% NaCl 3 corneas as positive control treated with ethanol 100%	No prediction can be made regarding the classification of the test substance according to the evaluation criteria.	Test report did not include a demonstration of proficiency and an acceptance range based on historical data.	Anonymous 2016l
OECD Guideline 492 (Reconstructed human Cornea-like	50 µL of the test substance AQUA LIGNEX I 27-Teak were	50 µL of the test substance, 50 µL of methyl acetate used as positive control and 50 µL of	NOT IRRITANT to eyes.	Test report did not include a demonstration of proficiency and an	Anonymous 2017b

Epithelium (RhCE) test method for identifying chemicals not requiring classification and labelling for eye irritation or serious eye damage), GLP: yes, Klimisch 2	applied on triplicate tissues for 30 minutes at 37°C ± 1°C.	ultrapure water used as negative control. Two tissue replicates have been used for MTT assay and one tissue replicate has been used for the histological analysis.		acceptance range based on historical data.	

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	The biocidal product family does not cause eye irritation.
Justification for the value/conclusion	Experimental data
Classification of the product according to CLP and DSD	Not classified.

Respiratory tract irritation

Conclusion used in Risk Assessment – Respiratory tract irritation	
Value/conclusion	The biocidal product family does not cause respiratory tract irritation.
Justification for the value/conclusion	Application of criteria on mixture classification based on ingredients as set out in the CLP Regulation 1272/2008. Co-formulants or active substances are either not classified themselves for this endpoint or are present in the product at a concentration below the generic and specific concentration limit.
Classification of the product according to CLP and DSD	Not classified.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	The biocidal product family is not sensitizing to skin.
Justification for the value/conclusion	Application of criteria on mixture classification based on ingredients as set out in the CLP Regulation 1272/2008. Co-formulants or active substances are either not classified themselves for this endpoint or are present in the product at a concentration below the cut off value. The active substances 3-iodo-2-propynyl-butyl-carbamate (IPBC) and permethrin and co-formulants CMIT/MIT (5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) and BIT (1,2-benzisothiazolin-3-one) are at concentrations in all products of the BPF triggering labelling with EUH208 according to CLP Regulation 1272/2008 Annex II.
Classification of the product according to CLP and DSD	Not classified. EUH208 Contains reaction mass of CMIT/MIT (5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1), BIT (1,2-benzisothiazolin-3-one), MIT (2-methyl-2H-isothiazol-3-one), IPBC (3-iodo-2-propynylbutylcarbamate) and permethrin. May produce an allergic reaction.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitization	
Value/conclusion	The biocidal product family does not cause respiratory sensitization.
Justification for the value/conclusion	Application of criteria on mixture classification based on ingredients as set out in the CLP Regulation 1272/2008. Co-formulants or active substances are either not classified themselves for this endpoint or are present in the product at a concentration below the cut off value.
Classification of the product according to CLP and DSD	Not classified.

Acute toxicity

Acute toxicity by oral route

Summary table of animal studies on acute oral toxicity						
Method Guideline GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance Dose levels Type of administration** *(gavage, in diet, other)*	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**Value LD50**	**Remarks** *(e.g. major deviations)*	**Reference**
OECD Guideline 420 (Acute Oral Toxicity-Fixed Dose Method), GLP: yes, Klimisch 1	Rat; Sprague-Dawley; Female; No. of animal per sex per dose: 5	Oral gavage; Test item: AQUA LIGNEX I 27-Teak; Vehicle: Physiological saline; Dose: 2000 mg/kg bw	No clinical signs have been observed during the observation period. Necropsy of the other rats did not show any abnormalities.	LD_{50} > 2000 mg/kg bw	None	Anonymous 2016m

Value used in the Risk Assessment – Acute oral toxicity	
Value	LD_{50} > 2000 mg/kg bw
Justification for the selected value	Experimental evidence
Classification of the product according to CLP and DSD	Not classified.

Acute toxicity by inhalation

Value used in Risk Assessment – Acute inhalation toxicity	
Value	The biocidal product family is not acutely toxic via inhalation.
Justification for the value/conclusion	Classification of the mixture was conducted by calculation according to the CLP Regulation 1272/2008 Annex I: 3.1.3.6. Information from submitted MSDS were used for classification by calculation resulting in an ATEmix of 95.38 mg/L which is above 20 mg/L, therefore no classification for acute inhalation toxicity is required. For more information on the classification calculations refer to the Confidential Annex.
Classification of the product according to CLP and DSD	Not classified

Acute toxicity by dermal route

Value used in Risk Assessment – Acute dermal toxicity	
Value	The biocidal product family is not acutely toxic via the dermal route.
Justification for the value/conclusion	Application of criteria on mixture classification based on ingredients as set out in the CLP Regulation 1272/2008. Co-formulants or active substances are either not classified themselves for this endpoint or are present in the product at a concentration below the cut off value.
Classification of the product according to CLP and DSD	Not classified

Information on dermal absorption

There are no dermal absorption studies available with the specific formulation of AQUA LIGNEX I BPF. In the Assessment Report for permethrin in PT8 (Ireland, 2014) it is stated that product specific studies should be submitted for product authorisation. Therefore, an absorption value of 50% for water-based formulations should be applied as a default for permethrin according to Guidance on dermal absorption (EFSA, 2017). The representative product in the Assessment Report for IPBC (Denmark, 2008) was solvent-based and therefore does not readily meet the criteria for read across regarding dermal absorption. According to to Guidance on dermal absorption (EFSA, 2017) an absorption value of 50% for water-based formulations should therefore be applied as a default for IPBC.

Value(s) used in the Risk Assessment – Dermal absorption		
Substance	Permethrin	IPBC
Value(s)	50%	50%
Justification for the selected value(s)	Default value for water-based formulation according to according to Guidance on dermal absorption (EFSA, 2017).	Default value for water-based formulation according to according to Guidance on dermal absorption (EFSA, 2017).

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

Please see section 2.1.2.5 and the confidential appendix for further information on substances of concern.

Available toxicological data relating to a mixture

Products of the AQUA LIGNEX I family are not intended for concomitant use with other products.

Other

Not applicable.

2.2.6.2 Exposure assessment

A tiered approach is followed for exposure estimation. In tier 1 the maximum theoretically possible exposure is calculated (conservative assumptions, realistic worst case), considering validated toxicological parameters (e.g. dermal absorption). If this exposure assessment produces an unacceptable outcome in risk assessment, a tier 2 assessment is performed (i.e. refinement of the exposure studies/models, considering specific data like for example time budgets, transfer factors and the effects of exposure reduction measures, e.g. personal protective equipment). In case the predicted exposure from tier 2 still represents a risk, a third tier would be necessary considering surveys or studies with the actual product or with a surrogate.

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

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

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
1	Flow coating / automated spraying	Primary Exposure, chronic: Industrial application via flow coating/automated spraying (closed system)	Industrial user
2	Automated dipping treatment	Primary Exposure, chronic: Industrial application via automated dipping treatment	Industrial user
3a	Manual dipping treatment	Primary Exposure, chronic: Industrial/Professional application via manual dipping treatment	Industrial/professional user
3b	Manual Dipping (post-application)	Primary exposure, acute and chronic: Dermal exposure during the post-application phase.	Industrial/professional user
4a	Brush treatment	Primary Exposure, chronic: Industrial/professional application via brushing (dermal, inhalation)	Industrial/professional user
4b	Washing out of a brush	Primary Exposure, acute and chronic: After the application, the wood preservative is washed out of the brush, acute (non-professionals) or chronic (professionals)	Industrial/professional/non-professional user
5	Sanding/sawing of treated wood	Secondary Exposure, acute and chronic: Sanding / processing of treated wood, acute (non-professionals) or chronic (professionals)	Professional/ non-professional user
6	Brush treatment	Primary Exposure, acute: Non-professional application via brushing (dermal, inhalation)	Non-professionals
7	Mouthing of treated wood chips	Secondary Exposure, acute: A toddler picks up and chews a wood off-cut which has been treated with wood preservative	General public
8	Playing on treated wood structures	Secondary Exposure, chronic: Toddler is playing outdoors on a playground structure made of treated wood	General public
9	Inhalation of volatilised residues indoors	Secondary Exposure, chronic: Inhalation of volatilised residues indoors released in the living area of a domestic house.	General public

Industrial exposure

Scenario [1]

Description of Scenario [1] flow coating/automated spraying (closed system)		
Flow coating is an industrial process, in which timber is passed through an enclosed tunnel wherein the wood preservative is applied. Due to this setup the operator's exposure is expected to be low, and mainly occurs when handling freshly treated wood. As there is no model available for automated flow coating, the professional Dipping Model 1 (HEAdhoc Recommendation no.6 version 4, scenario 28 and BHHEM page 199), is considered as a good approximation for assessing exposure from the deluge processes. Dipping Model 1 covers exposure of industrial users and includes dipping wooden articles, mixing/loading, handling wet articles and loading/unloading. Deluge process are operated on a batch basis, assuming as a worst case one batch per day, with a duration of 60 minutes per event. Therefore the model is reflective of conditions where operatives may contact treatment fluids and wet objects. The indicative value for hand exposure is an 'inside glove' value. Nevertheless, according to HEEG Opinion 9, it is assumed that operators wear coated coveralls when handling wet wood preservatives. Similar to flow coating, automated spraying (closed system) is assumed to be a fully enclosed process, whereby operator exposure occurs mainly by handling treated wet wood. Therefore automated spraying in a closed system is highly expected to be covered by Dipping Model 1. Mixing and Loading: M&L is already included in Dipping Model 1. Additionally, loading of biocidal products (PT 8) in industrial settings is expected to be fully-automated transfer/pumping. Exposure during fully-automated transfer/pumping is expected to be associated with negligible or only accidental exposure (see HEEG Opinion no. 1, page. 8).		
	Parameters	**Value**
Tier 1	Concentration of substance in product	0.8% (IPBC) 0.1% (Permethrin)
	Indicative hand exposure (inside gloves)[1]	25.7 mg/min.
	Indicative body exposure[1]	178 mg/min.
	Inhalation exposure[1]	<1 mg/m^3
	Inhalation absorption[2]	100%
	Inhalation rate[3]	1.25 m^3/h
	Body weight[3]	60 kg
	Event exposure duration[1]	60 min/day
	Dermal absorption rate of substances	50% (IPBC) 50% (Permethrin)
Tier 2	Coated coveralls[4]	90 % protection (10% penetration)

[1] ECHA, 2020, HEAdhoc recommendation no 6 v.4, scenario 28
[2] ECHA 2017b, page 194

[3] ECHA 2017a, HEAdhoc recommendation no 14, Appendix A
[4] EC 2010a, HEEG opinion 9, page 3

Calculations for Scenario [1]

$$Inhalative\ exposure\ \left[\frac{mg}{kg\ bw\ day}\right] = indicative\ value\ \left[\frac{mg}{m^3}\right] \times \frac{inhalative\ absorption\ [\%]}{100} \times concentration\ of\ a.s.in\ biocidal\ product \times inhalation\ rate\ \left[\frac{m^3}{min}\right] \times duration\ [min/day] \times \frac{1}{body\ weight\ [kg]}$$

$$Potential\ hands\ exposure\ \left[\frac{mg}{kg\ bw\ day}\right] = Indicative\ exposure\ value\ \left[\frac{mg}{min}\right] \times \frac{concentration\ of\ a.s.in\ biocidal\ product[\%]}{100} \times \frac{dermal\ abs.[\%]}{100} \times duration\ [min/day]\ \times \frac{1}{body\ weight\ [kg]}$$

$$Potential\ body\ exposure\ \left[\frac{mg}{kg\ bw\ day}\right] = Indicative\ exposure\ value\ \left[\frac{mg}{min}\right] \times \frac{concentration\ of\ a.s.in\ biocidal\ product[\%]}{100} \times \frac{dermal\ abs.[\%]}{100} \times duration\ [min/day]\ \times \frac{Clothing\ penetration\ [\%]}{100} \times \frac{1}{body\ weight\ [kg]}$$

Summary table: Industrial use flow coating/automated spraying [mg/kg bw/day]						
Scenario	**Tier/PPE**	**Estimated uptake**				
			inhalation	**dermal**	**oral**	**total**
Scenario [1] adult	Tier 1/ PPE (gloves)	**IPBC**	0.0002	0.8148	n.a.[1]	**0.8150**
		Permethrin	0.0000	0.1019		**0.1019**
	Tier 2/ PPE (gloves and coated coveralls)	**IPBC**	0.0002	0.1740	n.a.[1]	**0.1742**
		Permethrin	0.0000	0.0218		**0.0218**

[1]n.a. not assessed

Calculations for Scenario [1]

Please see Annex 3.2 for detailed calculations.

Further information and considerations on scenario [1]

Please see detailed description of scenario.

Description of Scenario [2] Automated dipping

Primary dermal and inhalation exposure occurs when products of the biocidal product family AQUA LIGNEX I are applied in an industrial scale via automated dipping process.

Exposure during automated dipping mainly occurs at the beginning and the end of a cycle when treated wood is touched by an industrial user during loading and de-loading from the dipping tank.

This scenario is based on the scenario available in HEAdhoc recommendation no. 6, version 4 scenario no. 19 for the assessment of industrials using a PT 8 ("Handling Model 1", water-based products), which represents the closest possible equivalent exposure model.

Inhalation exposure values for the active substances are considered negligible. But the product contains 2 potential SoCs (dipropylene glycol methylether and 2-(2-butoxyethoxy)ethanol), which have an vapour pressure of 40 Pa and 2,7 Pa respective and therefore are considered volatile. In line with HEAdhoc recommendation no. 6, version 4 scenario no. 19 ("*For volatile compounds the assessment of vapour in addition is necessary.*") an inhalation exposure assessment is performed. Indicative values are used from "Handling Model 1".

According to HEEG Opinion no. 9 it is assumed that operators wear coated coveralls when handling wet wood preservatives. The indicative value for hand exposure is an 'inside glove' value. As for exposure by hands, as a worst-case, no gloves replacement in every cycle has been considered.

Tier 2a: A protection factor of 90% was used as a reasonable and conservative default value to convert the potential to actual body exposure when wearing coated coveralls, according to HEEG Opinion 9.

Tier 2b: A protection factor of 95% was used when wearing impermeable coveralls (HEEG Opinion 9). Additionally indicative hand values for new gloves were used, meaning gloves have to be replaced after each cycle.

Mixing and Loading: Loading of biocidal products (PT 8) in industrial settings is expected to be fully-automated transfer/pumping. Exposure during fully-automated transfer/pumping is expected to be associated with negligible or only accidental exposure (see HEEG Opinion no. 1, page. 8).

	Parameters	**Value**
Tier 1	Concentration of substance in product	0.8% (IPBC) 0.1% (Permethrin) 1.8% (Dipropylene glycol methylether) 2.31% (2-(2-butoxyethoxy)ethanol)
	Body weight[1]	60 kg
	Exposure duration[2, 4]	4 cycles/day 60 min/cycle

	Indicative hand exposure[2] (Inside used gloves; water-based product)	1080 mg b.p./cycle
	Indicative body exposure[2] (water-based product)	8570 mg b.p./cycle
	Indicative inhalative exposure[5]	1.9 mg/m³
	Dermal absorption rate of substances	50% (IPBC) 50% (Permethrin)
	Inhalation rate[1]	1.25 m³/h = 0.021 m³/min
	Inhalative absorption[6]	100%
Tier 2a	Coated coverall[3]	90% protection (10% penetration)
Tier 2b	Impermeable coverall[3]	95% protection (5% penetration)
	Indicative hand exposure[2] (Inside new gloves; water-based product)	540 mg b.p./cycle

[1] ECHA 2017a, HEAdhoc recommendation no 14, Appendix A
[2] ECHA 2020, HEAdhoc recommendation no 6, scenario 19
[3] EC 2010a, HEEG opinion 9, page 3
[4] EC 2009, HEEG opinion 8, page 2
[5] ECHA 2020, HEAdhoc recommendation no 6, scenario 21
[6] ECHA 2017b, page 194

Calculations for Scenario [2]

$$Potential\ hands/body\ exposure\ \left[\frac{mg}{kg\ bw\ day}\right] = Indicative\ exposure\ value\ \left[\frac{mg}{cycle}\right] \times \frac{dermal\ abs.\ [\%]}{100} \times \frac{conc.\ substance\ in\ product\ [\%]}{100} \times \frac{coverall\ penetration\ [\%]}{100} \times cycles\ [1/day] \times \frac{1}{body\ weight\ [kg]}$$

$$Inhalative\ exposure\ \left[\frac{mg}{kg\ bw\ day}\right] = indicative\ value\ \left[\frac{mg}{m^3}\right] \times \frac{conc.\ substance\ in\ product\ [\%]}{100} \times inhalation\ rate\ \left[\frac{m^3}{min}\right] \times cycle\ time\ per\ day\ [min/day] \times \frac{1}{body\ weight\ [kg]}$$

Summary table: systemic exposure for industrial automated dipping [mg/kg bw/day]						
Scenario	**Tier/PPE**	**Estimated uptake**				
			inhalation	**dermal**	**oral**	**total**
Scenario [2] adult	Tier 1 / PPE (gloves)	**IPBC**	n.a.[1]	2.5733	n.a.[1]	**2.5733**
		Permethrin		0.3217		**0.3217**
		Dipropylene glycol methylether	0.0029	n.a.[1]		**0.0029**
		2-(2-butoxyethoxy)ethanol	0.0037			**0.0037**
Scenario [2] adult	Tier 2a / PPE (used gloves and coated coverall)	**IPBC**	n.a.[1]	0.5165		**0.5165**
		Permethrin		0.0646		**0.0646**
	Tier 2b / PPE (new gloves and impermeable coverall)	**IPBC**		0.2583		**0.2583**
		Permethrin		0.0323		**0.0323**

[1]n.a. not assessed

Calculations for Scenario [2]

Please see Annex 3.2 for detailed calculations.

Further information and considerations on scenario [2]

Please see detailed description of scenario.

Combined scenarios - industrials

It is assumed that an industrial worker encounters inhalative exposure at home.

Summary table: combined systemic exposure from industrial uses					
Scenarios combined	**Estimated uptake [mg/kg bw/day]**				
		inhalation	**dermal**	**oral**	**total**
Scenarios [1+9], Tier 2/2	**IPBC**	0.0004	0.1740	n.a.[1]	**0.1744**
	Permethrin	0.0000	0.0218		**0.0218**

[1]n.a. not assessed

Professional exposure

In section professional exposure (some) applications for industrial users are included as these are covered by professional exposure estimation.

Scenario [3a] – Primary exposure during application by manual dipping

Description of Scenario [3a] Manual dipping		
Primary dermal and inhalation exposure occurs when members of the biocidal product family AQUA LIGNEX I is applied by professionals/industrials in a manual dipping process. Exposure during manual dipping mainly occurs at following working tasks according to HEEG opinion 8: *"In manual dipping operations, the operator lifts and places – by hand – the wooden article into the dipping tank. The operator then pushes, using a post, the wooden article under the wood preservative in the dipping tank and/or uses a broom to brush the wood preservative onto the wooden article (the article is still in the dipping tank as the preservative is brushed on the wood). The operator then lifts by his/her gloved hand the wooden article from the dipping tank and stacks the article to dry."* Dipping Model 1 (HEAdhoc recommendation no. 6, version 4 scenario no. 22) is used for the assessment of professionals. The model covers professional users carrying out a range of dipping activities, including mixing/loading, handling wet articles, machine minding and loading/unloading, involving a variety of articles. It is assumed that operators spend 30 minutes dipping per day according to HEEG opinion 8. The indicative value for hand exposure is an 'inside glove' value. Tier 2: As it is assumed that operators wear coated coveralls when handling wet wood preservatives a protection factor of 90% was used as a reasonable and conservative default value to convert the potential to actual body exposure when wearing coated coveralls (HEEG Opinion 9).		
	Parameters	**Value**
Tier 1	Concentration of substance in product	0.8% (IPBC) 0.1% (Permethrin)
	Body weight[1]	60 kg
	Inhalation rate[1]	1.25 m^3/h
	Inhalative absorption[3]	100%
	Exposure duration (Application)[2]	30 min/day
	Indicative hand exposure[2] (inside gloves)	25.7 mg b.p./min
	Indicative body exposure[2]	178 mg b.p./min
	Indicative inhalation exposure[2] For calculation 1 mg/m^3 was used)	<1 mg/m^3
	Dermal absorption rate of substances	50% (IPBC) 50% (Permethrin)

Tier 2	Coated coverall[4]	90% protection (10% penetration)

[1] ECHA 2017a, HEAdhoc recommendation no 14, Appendix A
[2] ECHA 2020, HEAdhoc recommendation no 6, scenario 22
[3] ECHA 2017b, page 194
[4] EC 2010a, HEEG opinion 9, page 3

Calculations for Scenario [3a]

$$Inhalative\ exposure\ \left[\frac{mg}{kg\ bw\ day}\right] = indicative\ value\ \left[\frac{mg}{m^3}\right] \times \frac{inhalative\ absorption\ [\%]}{100} \times concentration\ of\ a.s.\ in\ biocidal\ product \times inhalation\ rate\ \left[\frac{m^3}{min}\right] \times duration\ [min/day] \times \frac{1}{body\ weight\ [kg]}$$

$$Potential\ hands\ exposure\ \left[\frac{mg}{kg\ bw\ day}\right] = Indicative\ exposure\ value\ \left[\frac{mg}{min}\right] \times \frac{concentration\ of\ a.s.\ in\ biocidal\ product[\%]}{100} \times \frac{dermal\ abs.\ [\%]}{100} \times duration\ [min/day]\ \times \frac{1}{body\ weight\ [kg]}$$

$$Potential\ body\ exposure\ \left[\frac{mg}{kg\ bw\ day}\right] = Indicative\ exposure\ value\ \left[\frac{mg}{min}\right] \times \frac{concentration\ of\ a.s.\ in\ biocidal\ product[\%]}{100} \times \frac{dermal\ abs.\ [\%]}{100} \times duration\ [min/day]\ \times \frac{Clothing\ penetration\ [\%]}{100} \times \frac{1}{body\ weight\ [kg]}$$

Summary table: systemic exposure for professional manual dipping [mg/kg bw/day]						
Scenario	**Tier/PPE**	**Estimated uptake**				
			inhalation	**dermal**	**oral**	**total**
Scenario [3a] adult	Tier 1 / PPE (gloves)	**IPBC**	0.0001	0.4074	n.a.[1]	**0.4075**
		Permethrin	0.0000	0.0509	n.a.[1]	**0.0509**
Scenario [3a] adult	Tier 2 / PPE (gloves and coated coverall)	**IPBC**	See above (Tier 1)	0.0870	n.a.[1]	**0.0871**
		Permethrin	See above (Tier 1)	0.0109	n.a.[1]	**0.0109**

[1]n.a. not assessed

Calculations for Scenario [3a]

Please see Annex 3.2 for detailed calculations.

Further information and considerations on scenario [3a]

Please see detailed description of scenario.

Scenario [3b] – Primary exposure in post application phase of manual dipping (manual draining and reloading)

Description of Scenario [3b] Manual draining and reloading after manual dipping
Primary dermal exposure occurs after manual dipping process via manual draining and reloading (post application phase). This scenario is based on the scenario and recommendations provided in HEAdhoc recommendation no. 6, version 4 scenario no. 22, page 20-22 (Mixing and loading Model 4). Therein it is stated that *a realistic scenario should include the mixing and loading, application and the post-application phase.* Therefore manual draining and reloading (10 loadings/month: HEAdhoc no. 6, page 22; post-application phase) have to be added to exposure at application stage, which is estimated in scenario manual dipping. According to the model, dermal exposure (hands) is foreseen, while inhalation exposure to aerosols is not considered to be relevant. Mixing and loading is already considered in application scenarios. For acute exposure: as a worst case 2 loadings per day are assumed (1 time emptying the tank and 1 time refilling). For chronic exposure: Assuming a maximum of 23 working days/month a value of 0.44 loadings/day (10/23) was used for post application phase. Taking into account the product density of 1028.5 mg/mL a value of 514.25 mg/loading is

used (1028.5 mg/mL * 0.5 mL/loading).

The indicative value for hand exposure (0.5 mL b.p./loading) is provided without protective gloves. In order to be in line with dipping scenarios a protection factor of 90% was used to convert the potential to actual hand exposure when using appropriate gloves (according to HEEG Opinion 9).

	Parameters	**Value**
Tier 1	Concentration of substance in product	0.8% (IPBC) 0.1% (Permethrin)
	Body weight[1]	60 kg
	Indicative exposure[2] (without gloves)	0.5 mL b.p/loading referring to 514.25 mg/loading
	Product density	1.0285 g/ml
	Number of loadings per day[2] (chronic)	0.44 loadings/day
	Number of loadings per day[2] (acute)	2 loadings/day
	Dermal absorption rate of substances	50% (IPBC) 50% (Permethrin)
	Protective gloves[3]	90% protection (10% penetration)

[1] ECHA 2017a, HEAdhoc recommendation no 14, Appendix A

[2] ECHA 2020, HEAdhoc recommendation no 6, scenario 22

[3] EC 2010a, HEEG opinion 9, page 4

Calculations for Scenario [3b]

$$Potential\ hands\ exposure\ \left[\frac{mg}{kg\ bw\ day}\right] = Indicative\ exposure\ value\ \left[\frac{mg}{loading}\right] \times \frac{dermal\ abs.\ [\%]}{100} \times \frac{gloves\ penetration\ [\%]}{100} \times concentration\ of\ a.s.\ in\ biocidal\ product \times loadings\ per\ day\ [m^2] \times \frac{1}{body\ weight\ [kg]}$$

Summary table: systemic exposure for professional manual dipping post-application phase [mg/kg bw/day]						
Scenario	**Tier/PPE**	**Estimated uptake**				
			inhalation	**dermal**	**oral**	**total**
Scenario [3b] Adult - chronic	Tier 1 / PPE (gloves)	**IPBC**	n.a.[1]	0.0015	n.a.[1]	**0.0015**
		Permethrin	n.a.[1]	0.0002	n.a.[1]	**0.0002**
Scenario [3b] Adult - acute	Tier 1 / PPE (gloves)	**IPBC**	n.a.[1]	0.0069	n.a.[1]	**0.0069**
		Permethrin	n.a.[1]	0.0009	n.a.[1]	**0.0009**

[1]n.a. not assessed

Calculations for Scenario [3b]

Please see Annex 3.2 for detailed calculations.

Further information and considerations on scenario [3b]

Please see detailed description of scenario.

Scenario [4a] Primary exposure during application by brushing

Description of Scenario [4a] Brush application by professionals/industrial use
Products of AQUA LIGNEX I biocidal product family may be applied by professionals via brushing/rolling. The activities of the professional/industrial users include stirring the ready-to-use product and applying it to wood using a brush indoors or outdoors. The model "Professional brush treatment" to be found in HEAdhoc recommendation no. 6, scenario no. 23 PT 8 is used for the dermal and inhalation exposure estimation. Potential exposure via dermal and inhalation route has been calculated assuming an exposure duration of 240 minutes/day, equating to an application area of 31.6 m^2, the indicative values normalized to 1 % active substance are reported as: • Potential dermal exposure hands: 0.5417 mg/m^2 of treated surface • Potential dermal exposure body: 0.2382 mg/m^2 of treated surface • Potential inhalation exposure (non-volatile compounds): 0.0016 mg/m^2 of treated surface For Tier 1, no PPEs (coverall, gloves, RPE) have been considered.

Tier 2: It is highly assumed a professional worker wears at least gloves. Therefore a protection factor of 90% was used as a reasonable and conservative default value to convert the potential to actual hand exposure when using appropriate gloves, according to HEEG Opinion 9.

This estimation covers industrial as well as professional use.

	Parameters	**Value**
Tier 1	Concentration of substance in product	0.8% (IPBC) 0.1% (Permethrin)
	Inhalation rate[2]	1.25 m³/h
	Body weight of adult[2]	60 kg
	Dermal absorption rate of substances	50% (IPBC) 50% (Permethrin)
	Inhalative absorption[3]	100%
	Exposure duration[1]	240 min
	Application area per day[1]	31.6 m²
	Indicative value hands[1]	0.5417 mg/m²
	Indicative value body[1]	0.2382 mg/m²
	Indicative value inhalation (non-volatile compounds)[1]	0.0016 mg/m² treated surface
Tier 2	Protective gloves[4]	90% protection (10% penetration)

[1] ECHA 2020, HEAdhoc recommendation no 6, scenario 23
[2] ECHA 2017a, HEAdhoc recommendation no 14, Appendix A
[3] ECHA 2017b, page 194
[4] EC 2010b, HEEG opinion 9, page 4

Calculations for Scenario [4a]

$$Inhalative\ exposure\ \left[\frac{mg}{kg\ bw\ day}\right] = indicative\ value\ \left[\frac{mg}{m^3}\right] \times \frac{inhalative\ absorption\ [\%]}{100} \times concentration\ of\ a.s.\ in\ biocidal\ product \times inhalation\ rate\ \left[\frac{mg}{m^2}\right] \times \frac{1}{body\ weight\ [kg]}$$

$$Potential\ \frac{hands}{body}\ exposure\ \left[\frac{mg}{kg\ bw\ day}\right] = Indicative\ exposure\ value\ \left[\frac{mg}{m^2}\right] \times \frac{dermal\ abs.\ [\%]}{100} \times \frac{gloves\ penetration\ [\%]}{100} \times concentration\ of\ a.s.\ in\ biocidal\ product \times application\ area\ per\ day\ [m^2] \times \frac{1}{body\ weight\ [kg]}$$

Remark: as indicative values are normalized to 1 % active substance the values for "concentration of substance in product" have to be used unitless ("0.8" for IBPC and "0.1" for permethrin").

Summary table: Professionals brushing [mg/kg bw/day]						
Scenario	**Tier/PPE**	**Estimated uptake**				
			inhalation	**dermal**	**oral**	**total**
Scenario [4a] adult	Tier 1 /no PPE	**IPBC**	0.0007	0.1643	n.a.[1]	**0.1650**
		Permethrin	0.0001	0.0205	n.a.[1]	**0.0206**
	Tier 2 / PPE (protective gloves)	**IPBC**	See above (Tier 1)	0.0616	n.a.[1]	**0.0623**
		Permethrin	See above (Tier 1)	0.0077	n.a.[1]	**0.0078**

[1]n.a. not assessed

Calculations for Scenario [4a]

Please see Annex 3.2 for detailed calculations.

Further information and considerations on scenario [4a]

Please see detailed description of scenario.

Scenario [4b] – Washing out of a brush (primary exposure, post-application phase)

Description of Scenario [4b] Washing out of a brush
Users of the biocidal products of AQUA LIGNEX I are expected to wash out the brush after usage. This post-application task may lead to some degree of exposure of hands. It is expected this task lasts for no more than 15 minutes. According to HEEG Opinion 11 a water-based formulation – like AQUA LIGNEX I biocidal product family - might be removed by washing the brush under a water stream, a process that would result in negligible dermal exposure. Thus, as discussed at WGIII2017, inclusion of a brush washing scenario may not be warranted for water-based products. However, the product is classified for Aquatic Acute 1 and Aquatic Chronic 1 and therefore release of wastewater into the aquatic compartment must be prevented (cf. section 2.1.5.4). Nevertheless, in order to assess the contribution of an eventual brush-washing phase to general exposure, the General Exposure Calculator for Washing out Of Brushes of the annex to HEEG Opinion 11 is used. To assess primary exposure, the model described in the HEEG Opinion 11 has been used. The working procedure is described as follows: *"Cleaning the brush used for applying paint may be done by repeated dipping and swilling it in a vessel containing an appropriate solvent. A large brush might have a size of 10 x 10 x 2 cm, corresponding to a volume of 200 mL. It is assumed that after painting one eighth (1/8) of the brush volume is paint. Cleaning is assumed to be done in three steps, each time using fresh solvent. The volume at each step should be large enough to allow a sufficient dilution of the residues in the brush. For a brush having a volume of 200 mL the*

volume of the cleaning solvent would be at least 400 ml per step. Each washing step is assumed to result in an approximately 10-fold dilution of the residues in the brush (i.e. 10% of the paint originally on the brush remains after one washing). After each step the brush is assumed to be squeezed by the hand to get rid of as much solvent as possible. It is assumed that with this step 50% of the solution in the washed brush is released and may potentially contaminate the hand. However, it is further assumed that the squeezing is not done by the bare hand but rather by wrapping it first with a cleaning rag, which absorbs 90% of the released liquid. It is assumed the brush is washed and squeezed for a maximum of 3 times. It is emphasised, the described exposure scenario for washing out a brush reflects a worst-case situation which assumes all contamination remains on the hands at the end of the activity and is available for dermal absorption."

Inhalation exposure is considered negligible by the model. No PPEs (coverall, gloves) have been considered.

This estimation covers industrial as well as (non-)professional use.

	Parameters	**Value**
Tier 1	Concentration of substance in product	0.8% (IPBC) 0.1% (Permethrin)
	Product density	1.0285 g/ml
	Body weight[1]	60 kg
	Volume of brush[2]	200 mL (=cm^3)
	Volume of paint remaining on brush after painting (1/8 of 200 mL)[2]	25 mL (=cm^3)
	Cloth absorption of a.s. squeezed out of brush[2]	90%
	Dermal absorption rate of substances	50% (IPBC) 50% (Permethrin)

[1] ECHA 2017a, HEAdhoc recommendation no 14, Appendix A

[2] EC 2010b, HEEG Opinion 11

Calculations for Scenario [4b]

Please see HEEG 11 "General Exposure Calculator For Washing Out Of Brushes" for detailed calculations. All output tables are provided in Annex 3.2.

Further information and considerations on scenario [4b]

Please see detailed description of scenario.

Summary table: Professional/industrial brushing [mg/kg bw/day]						
Scenario	**Tier/PPE**	**Estimated uptake**				
			inhalation	**dermal**	**oral**	**total**
Scenario [4b] adult	Tier 1 /no PPE	**IPBC**	n.a.[1]	0.0090	n.a.[1]	**0.0090**
		Permethrin	n.a.[1]	0.0011	n.a.[1]	**0.0011**

[1]n.a. not assessed

Scenario [5]

Description of Scenario Sawing/Sanding of treated wood
Secondary exposure occurs during sanding or sawing of treated wood. The application rate is given with 200 g biocidal product per square meter. The realistic worst case is based on the assumption that a wooden post (4 cm x 4 cm x 2.5 m, surface area of 4032 cm^2) is sanded by an adult worker without protective equipment. Further it was assumed that all biocidal product is present in the outer 1cm of the post and the wood dust concentration not exceeding the applicable occupational exposure limits for dust at the workplace (5 mg/m^3). The amount of active substance on surface is calculated as follows: IPBC: 200 g/m^2 x 0.8% = 1.6 g/m^2 → 0.16 mg/cm^2 Permethrin: 200 g/m^2 x 0.1% = 0.2 g/m^2 → 0.02 mg/cm^2 The sanding generates a certain dust concentration in air. Exposure occurs via inhalation for max. 6 hours per day (reflecting professionals, long term exposure). This covers as a worst case also short term exposure and thus non-professional use. For dermal exposure, contact with hands is assessed. It is based on the surface area exposed, the percentage of this area that is affected by contamination. Tier 2: Transfer coefficient (dislodgeable residues) of painted wood (MDF) was taken into account.

Description of Scenario [5]		
	Parameters	**Value**
Tier 1	Application rate of product	200 g/m^2 (20.0 mg/cm^2)
	Concentration of substance in product	0.8% (IPBC) 0.1% (Permethrin)
	Amount of active substance on surface	0.16 mg/cm^2 (IPBC) 0.02 mg/cm^2 (Permethrin)
	Volume of post[1]	4000 cm^3 (0.04 x 0.04 x 2.5 m)

	Surface of post[1]	4032 cm^2 (4 x 0.04 m x 2.5 m + 2 x 0.04 m x 0.04 m)
	Volume of outer 1cm layer of post	3008 cm^3 (0.04 m x 0.04 m x 2.5 m – 0.02 x 0.02 m x 2.48 m)
	Exposure duration[2]	6h per day
	Inhalation rate[3]	1.25 m³/h
	Dust concentration in air[1]	5 mg/m³
	Wood density[4]	400 mg/cm³
	Inhalative absorption[5]	100%
	Body weight of adult[3]	60 kg
	Hand surface area (palms)[3]	410 cm²
	Contaminated hand surface area[6]	40%
	Dermal absorption rate of substances	50% (IPBC) 50% (Permethrin)
	Frequency of sanding/sawing[1]	1 per day
Tier 2	Transfer coefficient (dislodgeable residues) of painted wood[7]	3%

[1] EC 2002a, page 50f; This guidance document was used as this scenario was not described in ECHA, 2015a
[2] EC 2002c, Part 3, p. 37
[3] ECHA 2017a, HEAdhoc recommendation no 14, Appendix A
[4] Technical Agreement for Biocides, 2021, page 21
[5] ECHA, 2017b, page 194
[6] ECHA, 2015b, HEAdhoc recommendation No 5
[7] ECHA, 2015a, page 171, Table

Calculations for Scenario [5]

$$Inhalative\ systemic\ exposure\ \left[\frac{mg}{kg\ bw\ day}\right] = Amount\ of\ active\ substance\ on\ surface\ [mg/cm^2] * sanded\ surface\ of\ post\ [cm^2] * \frac{1}{Volume\ of\ outer\ layer\ [cm^3]} * Exposure\ time\ [h] * Inhalation\ rate\ \left[\frac{m^3}{h}\right] * Dust\ concentration\ in\ air\ \left[\frac{mg}{m^3}\right] * \frac{1}{Wood\ density\ \left[\frac{mg}{cm^3}\right]} * \frac{inhalative\ absorption[\%]}{100} * \frac{1}{60\ [kg]}$$

$$Dermal\ systemic\ exposure\ \left[\frac{mg}{kg\ bw\ day}\right] = Amount\ of\ active\ substance\ on\ surface\ [mg/cm^2] * \frac{transfer\ coefficient\ [\%]}{100}\ [\%] * Hand\ surface\ area\ [cm^2] * \frac{Contaminated\ hand\ surface\ area\ [\%]}{100} * \frac{dermal\ absorption\ [\%]}{100} * frequency\ of\ use\ [\frac{1}{day}]\ * \frac{1}{60\ [kg]}$$

Summary table: Professionals/non-professionals sanding or sawing of treated wood [mg/kg bw/day]						
Scenario	**Tier/PPE**	**Estimated uptake**				
			inhalation	**dermal**	**oral**	**total**
Scenario [5] adult	Tier 1 /no PPE	**IPBC**	0.0003	0.2187	n.a.[1]	**0.2190**
		Permethrin	0.0000	0.0273		**0.0274**
	Tier 2 /no PPE	**IPBC**	See above (Tier 1)	0.0044	n.a.[1]	**0.0069**
		Permethrin		0.0005		**0.0008**

[1]n.a. not assessed

Calculations for Scenario [5]

Please see Annex 3.2 for detailed calculations.

Further information and considerations on scenario [5]

Please see detailed description of scenario.

Combined scenario – professionals

Pre-application, application and post-application working tasks of dipping processes are likely to occur on the day of application, therefore combined scenario has been assessed. Additionally it is assumed that the professional worker encounters inhalative exposure at home.

Summary table: combined systemic exposure from professional/industrial manual dipping application					
Scenarios combined	**Estimated uptake [mg/kg bw/day]**				
		inhalation	**dermal**	**oral**	**total**
Scenarios [3a + 3b chronic + 9], Tier 2/1/2	**IPBC**	0.0003	0.0885	n.a.[1]	**0.0888**
	Permethrin	0.0000	0.0111	n.a.[1]	**0.0111**

[1]n.a. not assessed

Cleaning of brushes is likely to occur on the day of application, therefore combined scenario has been assessed. Additionally it is assumed that the professional worker encounters inhalative exposure at home.

Summary table: combined systemic exposure from professional/industrial brushing					
Scenarios combined	**Estimated uptake [mg/kg bw/day]**				
		inhalation	**dermal**	**oral**	**total**
Scenarios [4a + 4b + 9], Tier 2/1/2	**IPBC**	0.0009	0.0706	n.a.[1]	**0.0715**
	Permethrin	0.0001	0.0088		**0.0089**

[1]n.a. not assessed

Non-professional exposure

Scenario [6]

Description of Scenario [6] Brush application by non-professionals
Products of AQUA LIGNEX I biocidal product family may be applied by non-professionals in-situ via brushing/rolling. The activities of the non-professional users are stirring the RTU product and applying it to wood using a brush outdoors. Brushing indoors: "Consumer product painting model 1" (ECHA, 2015b, p. 216) covers application indoors of "*rough wooden joists and the underside of floor boards, overhead indoors*" and therefore represents the worst case as it also includes exposure arising from decanting the product from the tin. In this model dermal as well as inhalation exposure are covered. Although "Consumer product painting model 1" is considered as the best approximation for exposure and covers dermal and inhalation exposure estimation. Brushing outdoors: Consumer product painting model 3 (ECHA, 2015b p. 216) covers application of *"brushing sheds and fences, outdoor (directly from can)"* and therefore is used for exposure estimation for non-professionals brushing outdoors. Duration: • Outdoor/Indoor: The exposure duration for non-professionals is 155 min/day painting once or twice a year, acc. to TNsG 2002b, Part 2, page 78. • Indoor (Tier 2): Based on the publication of Garrod et al. (Ann. Occup. Hyg. 44: 421-426, 2000) the median work rate of a non-professional user is 7.6 min/m^2. For 2 m^2 an application duration of 15.2 min may be assumed, which was rounded up to 20 min. Although 7.6 min/m^2 was determined for outdoor treatment it is also considered applicable for indoor application, especially when rounded up. This scenario is best described as acute.

For non-professional use no PPEs are foreseen.		
	Parameters	**Value**
Tier 1	Concentration of substance in product	0.8% (IPBC) 0.1% (Permethrin)
	Inhalation rate[3]	1.25 m³/h
	Body weight of adult[3]	60 kg
	Dermal absorption rate of substances	50% (IPBC) 50% (Permethrin)
	Inhalative absorption[4]	100%
	Exposure duration outdoor[1]	155 min
	Indoor indicative exposure value of hands/forearms (no gloves)[2]	150 mg/min
	Indoor indicative exposure value rest of body[2] (legs, feet, face)	35.7 mg/min
	Indoor indicative inhalative exposure value[2]	3.1 mg/m³
	Outdoor indicative exposure value of hands (no gloves)[2]	5.91 mg/min
	Outdoor indicative exposure value body[2]	16.9 mg/min
	Outdoor indicative inhalative exposure value[2]	1.63 mg/m³
Tier 2	Exposure duration indoor	20 min

[1] EC 2002b, Part 2, page 78
[2] ECHA, 2015a, page 216
[3] ECHA 2017a, HEAdhoc recommendation no 14, Appendix A
[4] ECHA, 2017b, page 194

Calculations for Scenario [6]

$$Inhalative\ exposure\ \left[\frac{mg}{kg\ bw\ day}\right] = indicative\ value\ \left[\frac{mg}{m^3}\right] \times \frac{inhalative\ absorption\ [\%]}{100} \times \frac{conc.\ substance\ in\ product\ [\%]}{100} \times inhalation\ rate\ \left[\frac{m^3}{min}\right] \times duration\ [min] \times \frac{1}{body\ weight\ [kg]}$$

$$Potential\ hands/body\ exposure\ \left[\frac{mg}{kg\ bw\ day}\right] = Indicative\ exposure\ value\ \left[\frac{mg}{min}\right] \times \frac{dermal\ abs.\ [\%]}{100} \times \frac{conc.\ substance\ in\ product\ [\%]}{100} \times duration\ [min]\ \times \frac{1}{body\ weight\ [kg]}$$

Summary table: Non-professionals brushing indoors [mg/kg bw/incident]						
Scenario	**Tier/PPE**	**Estimated uptake**				
			inhalation	**dermal**	**oral**	**total**
Scenario [6] adult	Tier 1 /no PPE	**IPBC**	0.0013	1.9189	n.a.[1]	**1.9202**
		Permethrin	0.0002	0.2398	n.a.[1]	**0.2400**
	Tier 2 /no PPE	**IPBC**	0.0002	0.2476	n.a.[1]	**0.2478**
		Permethrin	0.0000	0.0310	n.a.[1]	**0.0310**

[1]n.a. not assessed

Summary table: Non-professionals brushing outdoors [mg/kg bw/incident]						
Scenario	**Tier/PPE**	**Estimated uptake**				
			inhalation	**dermal**	**oral**	**total**
Scenario [6] adult	Tier 1 /no PPE	**IPBC**	0.0007	0.2357	n.a.[1]	**0.2364**
		Permethrin	0.0001	0.0295	n.a.[1]	**0.0296**

[1]n.a. not assessed

Calculations for Scenario [6]

Please see Annex 3.2 for detailed calculations.

Further information and considerations on scenario [6]

Consumer painting model 1 was judged to be the most appropriate model for the applied use (UC 1-3, non-professional, brushing/rolling, indoor) instead of HEAdhoc recommendation # 10 ("The most appropriate model to be used for the scenario of non-professional application of paints by brushing and rolling") due to following considerations:

Although HEAdhoc #10 is also applicable for indoor use, the model does not cover overhead application what has to be assumed for this product and use. In HEAdhoc #10 it is additionally stated, that outdoor simulation was simulated and data generation have been derived from „a mix" of level and upwards orientation. On the other side, Consumer Product Painting Model 1 was conducted indoors, exclusively in overhead direction.

In our point of view overhead working represents a realistic very worst case considering following practical example: Woodworkers frequently sell and assemble the wooden structure of a roof in the rough, and the end customer takes care of the protective treatment himself, resulting in almost exceptionally overhead brushing/rolling.

Thus, we are of the opinion that Consumer Product Painting Model 1 becomes the most adequate model for non-professional indoor application via brushing and rolling, representing the "very worst case while painting." (HEAdhoc recommendation #10, page 4).

Calculation with model provided in HEAdhoc recommendation # 10 would result in following estimated uptake:

Summary table: Non-professionals brushing [mg/kg bw/incident] HEAdhoc recommendation # 10						
Scenario	**Tier/PPE**	**Estimated uptake**				
			inhalation	**dermal**	**oral**	**total**
Scenario [6] adult	Tier 1 /no PPE	**IPBC**	0.0007	0.0613	n.a.[1]	**0.0620**
		Permethrin	0.0001	0.0077	n.a.[1]	**0.0078**

Combined scenario – non-professionals

In following combined scenario it assumed, that a non-professional user is brushing outdoors/indoors, cleaning the brush afterwards, is sawing/sanding treated wood and additionally encounters inhalative exposure via volatilized residues.

Summary table: combined systemic exposure					
Scenarios combined	**Estimated uptake [mg/kg bw/day]**				
		inhalation	**dermal**	**oral**	**total**
Scenarios [6 outdoors + 4b + 5 + 9], Tier 1/1/2/2	**IPBC**	0.0012	0.2491	n.a.[1]	**0.2503**
	Permethrin	0.0001	0.0311		**0.0312**

[1]n.a. not assessed

Summary table: combined systemic exposure					
Scenarios combined	**Estimated uptake [mg/kg bw/day]**				
		inhalation	**dermal**	**oral**	**total**
Scenarios [6 indoors + 4b + 5 + 9], Tier 2/1/2/2	**IPBC**	0.0010	0.2610	n.a.[1]	**0.2620**
	Permethrin	0.0002	0.0326		**0.0328**

Exposure of the general public

Scenario [7]

Description of Scenario [7] Mouthing of treated wood chips - toddler		
Mouthing of treated wood chips (secondary exposure): A toddler picks up and chews a wood cut-off. The relevant exposure route is oral. This is an incidental event and exposure duration is therefore best described as acute. It is assumed that only a small fraction of the total preservative become released by chewing. A reasonable assumption is that 10% may become released. A piece of the size of 4x4x1 cm (corresponding to 16 cm^3 and 48 cm^2) is chewed. Tier 1: As a worst case it is assumed that all surface of wood piece (48 cm^2) is covered evenly with wood preservative. Thereby, substances are extracted by chewing. Oral absorption is 100%. Remarks: This scenario is considered highly conservative. First, it is expected to be unlikely that parents allow their toddlers to stay near a working place where treated wood is processed. Furthermore, it is assumed that whole surface of wood piece is evenly covered with biocidal product. Additionally chewing the raw surface of the wood off-cut is considered unpleasant. It is therefore unlikely that the toddler would chew a wood off-cut for a significant time.		
	Parameters	**Value**
Tier 1	Application rate product	200 g/m^2
	Concentration of substance in product	0.8% (IPBC) 0.1% (Permethrin)
	Amount of active substance on surface	0.16 mg/cm^2 (IPBC) 0.02 mg/cm^2 (Permethrin)
	Size of wood chip (4x4x1 cm)[1]	16 cm^3
	Surface of wood chip[1] (4x4x2+4x1x4 cm)	48 cm^2
	Extraction of substance by chewing[1]	10%
	Body weight toddler[2]	10 kg
	Frequency[1]	1/day
	Oral absorption rates	100 % IPBC 100 % Permethrin

[1] EC 2002a, page 50ff; This guidance document was partly used as this scenario was not described in ECHA, 2015a.
[2] ECHA 2017a, HEAdhoc recommendation no 14, Appendix A

Calculations for Scenario [7]

Amount of active substance on surface:

IPBC: 200g/m² x 0.8% = 1.6 g/m² → 0.16 mg/cm²
Permethrin: 200g/m² x 0.1% = 0.2 g/m² → 0.02 mg/cm²

$$Oral\ systemic\ exposure, tier\ 1\ \left[\frac{mg}{kg\ bw\ day}\right] = amount\ of\ active\ substance\ on\ surface\ \left[\frac{mg}{cm^2}\right] * wood\ chip\ surface\ area\ [cm^2] * * \frac{Extraction\ [\%]}{100} * \frac{Oral\ absorption\ [\%]}{100} * Frequency\ \left[\frac{1}{day}\right] * \frac{1}{body\ weight\ [kg]}$$

Summary table: systemic exposure for general public from toddler mouthing of treated wood chips [mg/kg bw/day]						
Scenario	**Tier/PPE**	**Estimated uptake**				
			inhalation	**dermal**	**oral**	**total**
Scenario [7] toddler	Tier 1 /no PPE	**IPBC**	n.a.[1]	n.a.[1]	0.0768	**0.0768**
		Permethrin			0.0096	**0.0096**

[1]n.a. not assessed

Calculations for Scenario [7]

Please see Annex 3.2 for detailed calculations.

Further information and considerations on scenario [7]

Please see detailed description of scenario.

Scenario [8]

Description of Scenario [8] Toddler playing on treated wood structures		
Toddler playing on treated wood structures (secondary exposure): Toddler is playing outdoors on a playground structure made of treated wood. The scenario for the toddler covers the scenario for the child. For exposure assessment 200 g/m^2 were used for calculations as worst case. Additionally it is assumed, that all active substance is on surface. In general, both cases - dermal and oral exposure - are expected to occur in parallel. As a worst case it is assumed that all of the contamination of the toddler's hand is ingested during mouthing behavior for the active substances. This reflects the worst case absorption values. Tier 1: The realistic worst case is based on the assumption that a toddler is playing outdoors on a playground structure made of treated wood. The surface concentration is assumed to be 100%. The hand surface area is given with 230.4/2=115.2 cm² (both hand palms without backs) of which 40% are contaminated (1 event per day). Tier 2: Transfer coefficient (dislodgeable residues) of painted wood (MDF) was taken into account.		
	Parameters	**Value**
Tier 1	Application rate product	200 g/m^2
	Concentration of substance in product	0.8% (IPBC) 0.1% (Permethrin)
	Amount of active substance on surface	0.16 mg/cm^2 (IPBC) 0.02 mg/cm^2 (Permethrin)
	Hand surface area[1]	115.2 cm²
	Contaminated hand surface area[2]	40%
	Body weight toddler[1]	10 kg
	Playing events[3]	1 / day
	Oral absorption rates	100% IPBC 100% Permethrin
Tier 2	Transfer factor (dislodgeable residues)[4]	3%

[1] ECHA 2017a, HEAdhoc recommendation no 14, Appendix A
[2] ECHA 2015b, HEAdhoc recommendation No 5
[3] EC 2002a, page 50ff; This guidance document was partly used as this scenario was not described in ECHA, 2015a.
[4] ECHA 2015a, page 171, Table

Calculations for Scenario [8]

Amount of active substance on surface:

IPBC: 200g/m² x 0.8% = 1.6 g/m² → 0.16 mg/cm²
Permethrin: 200g/m² x 0.1% = 0.2 g/m² → 0.02 mg/cm²

$$\frac{Dermal}{Oral}\ systemic\ exposure, tier\ 1\ \left[\frac{mg}{kg\ bw\ day}\right] = amount\ of\ active\ substance\ on\ surface\ \left[\frac{mg}{cm^2}\right] * hand\ surface\ area\ [cm^2] * \frac{Contamination\ hand\ surface\ area\ [\%]}{100} * \frac{Oral\ absorption\ [\%]}{100} * Frequency\ \left[\frac{1}{day}\right] * \frac{1}{body\ weight\ [kg]}$$

Summary table: systemic exposure for general public from playing on treated wood structures [mg/kg bw/day]						
Scenario	**Tier/PPE**	**Estimated uptake**				
			inhalation	**dermal**	**oral**	**total**
Scenario [8] toddler	Tier 1 /no PPE	**IPBC**	n.a.[1]	**-**[3]	0.7273[2]	**0.7273**
		Permethrin			0.0922[2]	**0.0922**
	Tier 2 /no PPE	**IPBC**	n.a.[1]	**-**[3]	0.0221[2]	**0.0221**
		Permethrin			0.0028[2]	**0.0028**

[1]n.a. not assessed
[2]worst case for combined dermal and oral route
[3]Please see description of scenario [8]

Calculations for Scenario [8]

Please see Annex 3.2 for detailed calculations.

Further information and considerations on scenario [8]

Please see detailed description of scenario.

Scenario [9]

Description of Scenario [9] Inhalation of volatilised residues		
Inhalation of volatilised residues: toddler inhaling volatilised residues from treated timber indoors. As worst case 24 h/day of inhalation exposure is assumed. This scenario also covers children and adults. According to the HEEG Opinion 13 (EC 2011) endorsed at TM IV 2011 and amended after TM III 2013 long-term exposure to volatilised residues can be neglected if the following Tier 1 screening tool which is based on the toddler (inhalation rate of 8 m³/24h and bw of 10 kg) representing the worst case, is ≤ 1: $$0.328 \bullet \frac{MW(g/mol) \bullet VP(Pa)}{AEL_{long-term}} \leq 1$$ As this is true for Permethrin (0.0055) long-term exposure to volatilised residues is negligible for adults, infants and children for this a.s. Calculated value for IPBC (2.07) showed that this a.s. has to be included in further considerations with regard to long-term inhalation exposure to volatilised residues. For tier 1 assessment it is assumed a toddler is exposed to the saturated vapour concentration (SVC) of the active substance for 24 hours a day. This represents a very conservative estimation as it is not possible for the air to hold more than the saturated vapour concentration of a substance at a given temperature. No ventilation rate assumed. Tier 2 exposure calculations were performed using ConsExpo-Tool based on default input values obtained from respective ConsExpo factsheets as well as information on the composition and intended uses of the product family. The used release area of 4 m² is a worst case estimation of treated wood following the intended uses. For details on the exposure calculations please refer to Appendix 3.2.		
	Parameters	**Value**
Tier 1	Concentration of active substance/SoC in product	0.8% (IPBC) 0.1% (Permethrin)
	Inhalative absorption[1]	100%
	long-term inhalation rate[2] (toddler)	8.0 m³/24h
	Long-term inhalation rate[2] (adult)	16.0 m³/24h
	Bodyweight (toddler)[2]	10 kg
	Bodyweight (adult)[2]	60 kg
	Exposure duration	24 hours
	Gas constant	8.31451 J/molK

	Vapour pressure	2.36-4.5 × 10^{-3} Pa (IPBC at 25°C)[3] 2.155 x 10^{-6} Pa (Permethrin at 20°C)[4]
	Molecular weight	281.1 g/mol (IPBC)[3] 391.29 g/mol (Permethrin)[4]
Tier 2	ConsExpo	
	Model [6]	Exposure to vapour -evaporation
	Room size [7] (*"A default value for an unspecified living area is given as a volume of 20 m3 , comparable with a small bedroom"*)	20 m^3
	Ventilation rate [7] *("bedroom, mechanical ventilation; renovated in 1987; closed windows")*	0.6/h
	Molecular weight matrix[8] *("waterborne paint - The compound of interest is not the main solvent")*	45 g/mol
	Exposure duration[6]	Set to 1 day
	Emission duration[6]	Set to 1 day
	Mass transfer[6]	Langmuir
	Release area	4 m^2
	Product amount	4 m^2 x application rate 200 g/m^2=800 g
	Absorption fraction[9] *("Absorption fraction: the fraction of the inhaled substance that enters the blood through the lung wall. If no information is available, the value should be set to 1, as the worst case.")*	1

[1] ECHA, 2017b, page 193
[2] ECHA 2017a, HEAdhoc recommendation no 14, Appendix A
[3] Denmark, 2008, page 23-24
[4] Ireland, 2014, page 52-53
[6] ConsExpo model documentation https://www.rivm.nl/bibliotheek/rapporten/2017-0197.pdf#page=36
[7] ConsExpo General Fact sheets, https://www.rivm.nl/bibliotheek/rapporten/090013003.pdf
[8] ConsExpo Paint Product Fact Sheets, https://www.rivm.nl/bibliotheek/rapporten/320104008.pdf
[9] ConsExpo model documentation https://www.rivm.nl/bibliotheek/rapporten/2017-0197.pdf#page=48

Calculations for estimating inhalative exposure for Scenario [9]

Tier 1: SVC

$$Inhalative\ systemic\ exposure\ Tier\ 1\ (SVC)\ \left[\frac{mg}{kg\ bw\ day}\right] = \frac{\left(vapour\ pressure\ [Pa] * molecular\ weight\ \left[\frac{g}{mol}\right]\right)}{\left(gas\ constant\ \left[\frac{j}{Kmol}\right] * temperature\ [K]\right)} * 1000 * Alveolar\ ventilation\ rate\ \left[\frac{m^3}{d}\right] * \frac{inhalative\ absorption[\%]}{100} * \frac{1}{body\ weight\ [kg]}$$

Tier 2: ConsExpo: Please see relevant output sheets in annex 3.2.

Summary table: systemic exposure for general public from volatilised residues given in [mg/kg bw/day]						
Scenario	**Tier/PPE**	**Estimated uptake**				
			inhalation	**dermal**	**oral**	**total**
Scenario [9] toddler	Tier 1 /no PPE	**IPBC**	0.4084	n.a.[1]	n.a.[1]	**0.4084**
Scenario [9] adult	Tier 1 /no PPE	**IPBC**	0.1361			**0.1361**
Scenario [9] toddler	Tier 2 /no PPE ConsExpo	**IPBC**	5.2×10^{-4}			**0.0005**
Scenario [9] adult	Tier 2 /no PPE ConsExpo	**IPBC**	1.7×10^{-4}			**0.0002**

[1]n.a. not assessed

***Calculations for scenario* [7, 8, 9]**

Please see Annex 3.2 for detailed calculations.

Further information and considerations on scenario [7, 8, 9]

All relevant information is provided in descriptions of scenarios.

Combined scenarios for general public

In following combined scenario it is assumed, that a toddler is playing on treated wood structures, is mouthing a treated wood chip and additionally encounters inhalative exposure via volatilised residues.

Summary table: combined systemic exposure for general public					
Scenarios combined	**Estimated uptake [mg/kg bw/day]**				
		inhalation	**dermal**	**oral**	**total**
Scenarios [7 + 8 + 9], Tier 1/2/2	**IPBC**	0.0005	-[1]	0.0989	**0.0994**
	Permethrin	negligible	-[1]	0.0124	**0.0124**

[1]cf. to explanation in scenario "toddler playing on treated wood structures"

Monitoring data

No surveys or studies with the biocidal products of the AQUA LIGNEX I family or with a surrogate are available for monitoring.

Dietary exposure

Direct contact of biocidal product family to human and animal food or feed can be excluded due to the authorised use. A dietary risk assessment due to direct contact to foodstuff is therefore not necessary.

Information of non-biocidal use of the active substance

According to ECHA 2017b, section 4.4, combined exposures stemming from different uses (i.e. combination of biocidal and non-biocidal uses) is not assessed at present due to lack of guidance. Therefore, information of non-biocidal use was not examined at this stage. If relevant, it will be provided at a later stage (e.g. renewal phase).

Estimating Livestock Exposure to Active Substances used in Biocidal Products

Impregnated wood must not come in contact with food or feedstuffs. The RMM's 'N-15: Do not use on wood which may come in direct contact with food, feed and livestock.' and 'N-127: Do not apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock/pets.' should be applied.

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

The biocidal product family is not authorised for treatment of wood intended for packaging or storage of food or feeding stuffs. Transfer into food therefore can be excluded if product is used within authorised uses.
Furthermore following use instruction is stated: Do not use on wood that may come in direct contact with food and feeding stuff.

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

Occupational exposure during production and formulation of the biocidal product is not assessed under the requirements of the BPR. It is assumed that the production is performed in conformity with national and European occupational safety and health regulations.
In addition, production or formulation of biocidal products are already covered by REACH legislation, where the registrants (manufacturers/importers) of substances are obliged to consider human hazard and exposure and to provide RMMs/exposure scenarios for ensuring safe use (e.g. via SDS in the supply chain). Moreover, it is assumed that industrial production sites are subject to permit for installation. Therefore, it is not considered relevant to perform an additional exposure assessment under the biocide regime.

Concerning production process the applicant provided following information:

AQUA LIGNEX I is produced in closed mixing vessel constructed of stainless steel suitable for the production of water based products, equipped with a variable-speed mixer.
During formulation the correct amounts of water and resin are put in the clean vessel. The mixer is started and then the correct amounts of the active substances, solvents and additives are added in the order specified in the recipe while stirring continuously. The batch is stirred until homogeneous. The colourless basic product is pumped into mobile, open vessels in which the pigment preparations are added under stirring.
When the target values are met the product is filled.
The product is pumped to the filling line and filled into the tin cans. The tin cans up to 6 L volume are packed in cardboard boxes and the palletized. The other package sizes are palletized.
Personal Protective equipment like protective goggles, impervious rubber gloves, dust masks and safety boots are provided and worn by the persons producing and filling the product.

Aggregated exposure

The methodology how to assess aggregated exposure has not been developed yet. This chapter might be subject to revision at product authorisation renewal stage.

Summary of exposure assessment

Scenario number	Exposed group	Tier/PPE	IPBC	Permethrin
[1]	*Industrials*	Tier 1/no PPE	**0.8150**	**0.1019**
		Tier 2/ PPE (coated coveralls)	**0.1742**	**0.0218**
[2]	*Industrials*	Tier 1 / PPE (gloves)	**2.5733**	**0.3217**
		Tier 2a / PPE (used gloves and coated coverall)	**0.5165**	**0.0646**
		Tier 2b / PPE (new gloves and impermeable coverall)	**0.2583**	**0.0323**

[1 + 9]	*Industrials*	Tier 2/2	**0.1744**	**0.0218**
[3a]	*Industrials/Professionals*	Tier 1 / PPE (gloves)	**0.4075**	**0.0509**
		Tier 2 / PPE (gloves and coated coverall)	**0.0871**	**0.0109**
[3b]	*Industrials/Professionals*	Tier 1 / PPE (gloves) chronic	**0.0015**	**0.0002**
		Tier 1 / PPE (gloves) acute	**0.0069**	**0.0009**
[4a]	*Industrials/Professionals*	Tier 1 /no PPE	**0.1650**	**0.0206**
		Tier 2 / PPE (protective gloves)	**0.0623**	**0.0078**
[4b]	*Industrials/Professionals/Non-professionals*	Tier 1 /no PPE	**0.0090**	**0.0011**
[5]	*Professionals/Non-professionals*	Tier 1 /no PPE	**0.2190**	**0.0274**
		Tier 2 /no PPE	**0.0069**	**0.0008**
[3a + 3b acute + 9]	*Professionals*	Tier 2/1/2	**0.0942**	**0.0118**
[4a + 4b + 9]	*Professionals*	Tier 2/1/2	**0.0715**	**0.0089**
[6]	*Non-professionals*	Tier 1 /no PPE - indoor	**1.9202**	**0.2400**
		Tier 2 /no PPE - indoor	**0.2478**	**0.0310**
		Tier 1 /no PPE - outdoor	**0.2364**	**0.0296**
[6 outdoors + 4b + 5 + 9]	*Non-professionals*	Tier 1/1/1/2	**0.2503**	**0.0312**
[6 indoors + 4b + 5 + 9]	*Non-professionals*	Tier 2/1/2/2	**0.2620**	**0.0328**
[7]	*General public*	Tier 1 /no PPE	**0.0768**	**0.0096**
[8]	*General public*	Tier 1 /no PPE	**0.7273**	**0.0922**
		Tier 2 /no PPE	**0.0221**	**0.0028**
[9]	*General public*	Tier 1 /no PPE - toddler	**0.4084**	*negligible*
		Tier 1 /no PPE - adult	**0.1361**	
		Tier 2 /no PPE - toddler	**0.0005**	
		Tier 2 /no PPE - adult	**0.0002**	
[7 + 8 + 9]	*General public*	Tier 1/2/2	**0.0994**	**0.0124**

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation (from AR of permethrin, Ireland 2014 and IPBC, Denmark 2008)

Reference	Study	NOAEL (LOAEL)	AF[1]	Correction for oral absorption	Value
$AEL_{short-term}$	IPBC: 90 day gavage rat Permethrin: Rat 2 year oral study (acute effect)	IPBC: ~35 mg/kg bw/day Permethrin: 59.46 mg/kg bw/day	IPBC: 100 Permethrin: 100	IPBC: No[2] Permethrin: No[2]	IPBC: 0.35 mg/kg bw/day Permethrin 0.5 mg/kg bw/day
$AEL_{medium-term}$	IPBC: N.A. Permethrin: 12-month dog study	IPBC: N.A. Permethrin: 5 mg/kg bw/day	IPBC: N.A. Permethrin: 100	IPBC : N.A. Permethrin: No[2]	IPBC: N.A. Permethrin 0.05 mg/kg bw/day
$AEL_{long-term}$	IPBC: 104 weeks chronic toxicity/ carcinogenicity rat study Permethrin: 12-month dog study	IPBC: 20 mg/kg bw/day Permethrin 5 mg/kg bw/day	IPBC: 100 Permethrin: 100	IPBC: No[2] Permethrin: No[2]	IPBC: 0.2 mg/kg bw/day Permethrin 0.05 mg/kg bw/day

[1] Inter/Intra species variation.

[2] Please refer to the respective CARs

Maximum residue limits or equivalent

MRLs are not relevant for this biocidal product family as the products will not come into contact with food or animal feeding stuffs when used in compliance with the authorised use. For permethrin MRLs for certain food items can be found in Regulation (EU) 2017/623.

Local effects

According to the Guidance on BPR: Volume III Parts B+C (ECHA, 2017b) risk characterisation (RC) for local effects is only required when the biocidal product is classified for local effects. If none of the active substances or co-formulants are classified for local effects or are present at concentrations that do not trigger classification, no RC for local effects is necessary.

Since AQUA LIGNEX I is not classified as irritating/corrosive or as sensitising a risk assessment for these local effects is not required.

The biocidal product family contains the pyrethroid permethrin. Pyrethroids are known to cause paresthesia, which are normally transient and do not persist. Therefore, an appropriate labelling on the packaging is added to inform susceptible persons. Moreover, non-professional users are not expected to use the product on a regular basis and therefore are less frequently exposed to the biocidal product. In the case of industrial and professional users the use of PPEs (e.g. chemical resistant gloves) reduce dermal exposure to the biocidal product.

Additionally, the content of several ingredients is above the concentration limit triggering elucidation and therefore the biocidal product family is labeled with 'EUH208 Contains reaction mass of CMIT/MIT (5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1), BIT (1,2-benzisothiazolin-3-one), MIT (2-methyl-2H-isothiazol-3-one), IPBC (3-iodo-2-propynylbutylcarbamate) and permethrin. "May produce an allergic reaction." As discussed in the previous paragraph, non-professional users are less frequently exposed to the biocidal product and in case of industrial/professional users the dermal exposure to the biocidal product is reduced by the use of PPEs. In addition the applicant has proposed good ventilation during product application and included "N-29, modified: Ensure adequate ventilation during and after the application, until treated surfaces have dried." in the Instructions for use (cf. chapter 2.1.5).

Risk for industrial users

Systemic effects

Task/ Scenario	Active substance	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/ no)
Scenario [1] Flow coating/ spray treatment	IPBC	1 / gloves	20	0.2[1]	0.8150	407.50	No
		2 / gloves and coated coverall	20	0.2[1]	0.1742	87.10	Yes
	Permethrin	1 / gloves	5	0.05[1]	0.1019	203.80	No
		2 / gloves and coated coverall	5	0.05[1]	0.0218	43.60	Yes
Scenario [2] automated dipping	IPBC	1 / gloves	20	0.2[1]	2.5733	1286.65	No
		2a / used gloves and coated	20	0.2[1]	0.5165	258.25	No

Task/ Scenario	Active substance	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/ no)
		coverall					
		2b / new gloves and impermeable coverall	20	0.2[1]	0.2583	129.15	No
	Permethrin	1 / gloves	5	0.05[1]	0.3217	643.40	No
		2a / used gloves and coated coverall	5	0.05[1]	0.0646	129.20	No
		2b / new gloves and impermeable coverall	5	0.05[1]	0.0323	64.60	Yes

[1] $AEL_{long\ term}$

Combined scenarios

Scenarios combined	Active substance	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/ no)
Scenarios [1 + 9 adult]	IPBC	2/2	20	0.2[1]	0.1744	87.20	Yes
	Permethrin	2/2	5	0.05[1]	0.0218	43.60	Yes

[1] $AEL_{long\ term}$

Conclusion

Exposure of industrial users to biocidal products generally takes place via the inhalation and/or dermal route. The quantitative risk characterisation for industrial users takes into account the $AEL_{long\text{-}term}$ of IPBC (0.2 mg/kg bw/d) and permethrin (0.05 mg/kg bw/d) as reference value.

A risk for industrial users referring to the active substances IPBC and permethrin resulting from the use of the biocidal product is unlikely if the risk characterisation for each scenario results in an estimated uptake of the active substances of less than 100% of the $AEL_{long\text{-}term}$ (ECHA, 2017b).

Acceptable risk for scenario [1] "Flow coating/spray treatment" were obtained in tier 2 when PPEs are prescribed. Protective gloves and coated coverall should be used to obtain safe use. Scenario [1] is also representative for automated spraying application.
Also for the combined scenarios [1 + 9 adult] including volatilised indoor residues to the chemical body burden of workers gave acceptable risks for combined exposure to the active substances.
Insect preventive wood protection in UC 1 is only necessary if the wooden component cannot be controlled after installation, e.g. by cladding. An example is wood under roof, not exposed to weathering and no humidification. In residential areas application of wood preservation should be kept to the minimum necessary. Therefore, the field of use is modified as follows: "For use class 1 (wood installed indoors not exposed to weather or wetting) the application of the product is restricted to static, small-scale wooden structures."

The application method automated dipping (scenario [2]) did not result in acceptable risk levels in tier 1. Even the use of an impermeable coverall and replacing old gloves with new gloves after each cycle in tier 2b results in a %AEL of 129.15% for IPBC and therefore does not reduce the risk to an acceptable level.
The model used for the scenario is very conservative with high indicative exposure values for hand and body for water-based products, but represents the closest possible equivalent exposure model. The dermal route is the major exposure route for the active substances in this scenario. Initially, a default dermal absorption value of 75% was proposed by the applicant. This value was updated in the authorisation process to the default value of 50% for water-based formulations according to the current EFSA guideline (EFSA, 2017). The dermal absorption of 50% is still a conservative value, but without further information regarding dermal absorption or surveys or studies with actual products, no additional refinements are possible. Therefore, the application of the biocidal product via automated dipping is not authorised.

The risk assessment for all other scenarios concerning industrial users (manual dipping and brushing) is covered by the risk assessment of the same scenarios for professional users as presented in the following section (see below).

Quantitative assessment of inhalative exposure towards 2-[(1-methoxypropan-2-yl)oxy]propan-1-ol and 2-(2-butoxyethoxy)ethanol
Inhalative exposure of industrial users to 2-[(1-methoxypropan-2-yl)oxy]propan-1-ol and 2-(2-butoxyethoxy)ethanol was calculated for scenario [2] "automated dipping" to evaluate occupational exposure to these volatile compounds for which Union OELs are available. The OELs were converted to mg/kg bw/d by using the following equation: IOELV*human respiration volume under light activity for workers (wRV) (10 m^3/person) / body weight (60 kg). Respiratory volume is taken from ECHA (2012).

Task/ Scenario	Substance	Inhalative exposure [mg/kg bw/d]	Occupational exposure limit (OEL)	% OEL
Scenario [2] Automated dipping	2-[(1-methoxypropan-2-yl)oxy]propan-1-ol	0.0029	308 mg/m^3 or 51.33 mg/kg bw/d	0.0057
	2-(2-butoxyethoxy)ethanol	0.0037	67.5 mg/m^3 or 11.25 mg/kg bw/d	0.0329

Considering the results in the table above inhalative exposure to 2-[(1-methoxypropan-2-yl)oxy]propan-1-ol and 2-(2-butoxyethoxy)ethanol is considered negligible as 2-(2-butoxyethoxy)ethanol and 2-[(1-methoxypropan-2-yl)oxy]propan-1-ol are three to four orders of magnitude lower than their respective EU-OELs.
Please refer to chapter 3.6.4.1 in the confidential annex for further discussion regarding potential SoCs.

Risk for professional users

Systemic effects

Task/ Scenario	Active substance	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes /no)
Scenario [3a] Manual dipping	IPBC	1 / gloves	20	0.2[1]	0.4075	203.75	No
		2 / gloves and coated coverall	20	0.2[1]	0.0871	43.55	Yes
	Permethrin	1 / gloves	5	0.05[1]	0.0509	101.80	No
		2 / gloves and coated coverall	5	0.05[1]	0.0109	21.80	Yes
Scenario [3b] Draining and reloading after dipping - chronic	IPBC	1 / gloves	20	0.2[1]	0.0015	0.75	Yes
	Permethrin	1 / gloves	5	0.05[1]	0.0002	0.40	Yes
Scenario [3b] Draining and reloading after dipping - acute	IPBC	1 / gloves	20	0.2[1]	0.0069	3.45	Yes
	Permethrin	1 / gloves	5	0.05[1]	0.0009	1.80	Yes
Scenario [4a] Brushing	IPBC	1 / no PPE	20	0.2[1]	0.1650	82.50	Yes
		2 / gloves	20	0.2[1]	0.0623	31.15	Yes
	Permethrin	1 / no PPE	5	0.05[1]	0.0206	41.20	Yes
		2 / gloves	5	0.05[1]	0.0078	15.60	Yes
Scenario [4b] Washing brusher	IPBC	1 / no PPE	20	0.2[1]	0.0090	4.50	Yes
	Permethrin	1 / no PPE	5	0.05[1]	0.0011	2.20	Yes
Scenario [5] Sanding/ sawing of treated wood	IPBC	1 / no PPE	20	0.2[1]	0.2190	109.50	No
		1 / no PPE	20	0.2[1]	0.0069	3.45	Yes

Task/ Scenario	Active substance	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes /no)
	Permethrin	1 / no PPE	5	0.05[1]	0.0274	54.80	Yes
		1 / no PPE	5	0.05[1]	0.0008	1.60	Yes

[1] $AEL_{long\ term}$

Combined scenarios

Scenarios combined	Active substance	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes /no)
Scenarios [3a + 3b chronic + 9 adult]	IPBC	2/1/2	20	0.2[1]	0.0888	44.40	Yes
	Permethrin	2/1/2	5	0.05[1]	0.0111	22.20	Yes
Scenarios [4a + 4b + 9 adult]	IPBC	2/1/2	20	0.2[1]	0.0715	35.75	Yes
	Permethrin	2/1/2	5	0.05[1]	0.0089	17.80	Yes

[1] $AEL_{long\ term}$

Conclusion

Acceptable risk levels for scenario [3a] "Manual dipping" were obtained in tier 2 when PPEs (gloves and coated coverall) are prescribed. Post application exposure via manual draining and reloading after manual dipping processes were assessed in scenario [3b chronic], resulting in an acceptable risk when protective gloves are used. Furthermore, an acute scenario regarding draining and reloading after manual dipping was assessed [3b acute] if this task is performed twice in one workday. An acceptable risk was obtained when protective gloves are used.
It is likely, that dipping processes and post-application tasks occur on the day of application. Therefore the combined scenario including application (scenario [3a]), post-application (scenario [3b] chronic) and possible inhalation of volatized indoor residues at home (scenario [9 adult]) has been assessed, which resulted in acceptable risk levels.
Acceptable risk levels for application via brushing are obtained when PPE are prescribed as demonstrated by scenario [4a]. Therefore, as an RMM protective gloves are necessary. Dermal exposure during cleaning (i.e. washing out) of a brush is usually negligible, as the biocidal products of the BPF are water-based and the brush might be cleaned by washing it under a water stream. However, the product is classified for Aquatic Acute 1 and Aquatic Chronic 1 and therefore release of wastewater into the aquatic compartment must be prevented. (cf. section 2.1.5.4). Therefore, scenario [4b] "Washing brush" was assessed and combined with scenarios [4a] "brushing" and for IPBC also with scenario [9 adult] "Inhalation of volatized residue". Acceptable risk levels were obtained for scenario [4b] as well as for the combined scenario [4a+4b+9].

Insect preventive wood protection in UC 1 is only necessary if the wooden component cannot be controlled after installation, e.g. by cladding. An example is wood under roof, not exposed to weathering and no humidification. In residential areas application of wood

preservation should be kept to the minimum necessary. Therefore, the field of use is modified as follows: "For use class 1 (wood installed indoors not exposed to weather or wetting) the application of the product is restricted to static, small-scale wooden structures."

Secondary exposure to professional workers (scenario [5] "sanding/sawing of treated wood") is assessed. The calculation of the risk through secondary exposure to treated wood shows an acceptable risk for workers during sanding of treated wood without PPE in tier 2 assessment, where a transfer coefficient (dislogable residues) of 2% was taken into consideration. This scenario also covers the worst case for short-term exposure during sanding/sawing of treated wood by non-professional user, as no PPEs were necessary to obtain acceptable risk levels.

Risk for non-professional users

Systemic effects

Task/ Scenario	Active substance	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes /no)
Scenarios [6] brushing indoor	IPBC	1 / no PPE	35	0.35[1]	1.9202	548.63	No
		2 / no PPE, area 2m²	35	0.35[1]	0.2478	70.80	Yes
	Permethrin	1 / no PPE	59.46	0.5[1]	0.2400	48.00	Yes
		2 / no PPE, area 2m²	59.46	0.5[1]	0.0310	6.20	Yes
Scenarios [6] brushing outdoor	IPBC	1 / no PPE	35	0.35[1]	0.2364	67.54	Yes
	Permethrin	1 / no PPE	59.46	0.5[1]	0.0296	5.92	Yes

[1] $AEL_{short\ term}$

Combined scenarios

Scenarios combined	Active substance	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes /no)
Scenarios [6 outdoors + 4b + 5 + 9 adult]	IPBC	1/1/2/2	35	0.35[1]	0.2503	71.51	Yes
	Permethrin	1/1/2/2	59.46	0.5[1]	0.0312	6.24	Yes

[1] $AEL_{short\ term}$

Conclusion

Non-professional users are not expected to be regularly exposed to the biocidal product and thus the $AEl_{short\ term}$ values are used in the risk characterisation calculations for all scenarios for this type of user. For non-professional use no PPEs are foreseen. The biocidal product family is used for the preventive treatment of wood via brushing in Use Classes (UC) 1-3. Therefore, scenario [6] "Brushing Indoor" was calculated, resulting in an exceedance of the quotient between estimated uptake and $AEL_{short\ term}$ of IPBC suggesting an unacceptable probable risk. After restriction of the treated area to 2 m^2 risks were acceptable. Therefore the following risk mitigation measure is set, "For indoor application of the product the treated area is restricted to maximal 2 m^2." This restriction would also support the notion that in residential areas application of wood preservation should be kept to the minimum necessary.

However, if another exposure model according to HEAdhoc Recommendation No. 10 was used, lower exposure estimates (~400%) were achieved that would result in acceptable risks. The HEAdhoc Recommendation No. 10 makes no distinction between indoor and outdoor application. However, this model was not optimized for indoor applications as the corresponding conditions of an outdoor application (including wind) were simulated when performing the measurements (cf. chapter 2.2.6.2). Thus, for this product family the TNsG Consumer Painting Model 1 estimates were used for risk charaterisation ratio calculations.

The exposure model used for scenario [6] "Brushing outdoor" covers the outdoor application of the biocidal product by brushing. For this scenario an acceptable risk at tier 1 was calculated.

Furthermore, scenario [6] "Brushing outdoor" was combined with scenarios [4b], [5] and [9] depicting a combined scenario where a non-professional user applies the biocidal product via brushing, washes out the brush afterward, is sawing/sanding treated wood and is additionally exposed to possible inhalation of volatized indoor residues at home. The combination of these scenarios did not lead to an unacceptable risk for non-professional users.

Risk for the general public

Systemic effects

Task/ Scenario	Active substance	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes /no)
Scenarios [7] Toddler chewing wood	IPBC	1 / no PPE	35	0.35[1]	0.0768	21.94	Yes
	Permethrin	1 / no PPE	59.46	0.5[1]	0.0096	1.92	Yes
Scenario [8] Toddler playing on treated wood structure	IPBC	1 / no PPE	20	0.2[2]	0.7273	363.65	No
		1 / no PPE	20	0.2[2]	0.0221	11.05	Yes
	Permethrin	1 / no PPE	5	0.05[2]	0.0922	184.40	No
		1 / no PPE	5	0.05[2]	0.0028	5.60	Yes
Scenario [9] Inhalation of volatised residue, toddler	IPBC	1 / no PPE	20	0.2[2]	0.4084	204.20	No
		1 / no PPE	20	0.2[2]	0.0005	0.25	Yes
Scenario [9] Inhalation of volatised residue, adult[3]	IPBC	1 / no PPE	20	0.2[2]	0.1361	68.05	Yes
		1 / no PPE	20	0.2[2]	0.0002	0.10	Yes

[1] $AEL_{short\ term}$

[2] $AEL_{long\ term}$

[3] calculated for combined exposure scenarios (industrial, professional and non-professional)

Combined scenarios

Scenarios combined		Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes /no)
Scenarios [7 + 8 + 9 toddler]	IPBC	1/2/2	35	0.35[1]	0.0994	28.40	Yes
	Permethrin	1/2/2	59.46	0.5[1]	0.0124	2.48	Yes

[1] $AEL_{short\ term}$

Conclusion
For mouthing exposure it was assumed that a toddler picks up and chews a wood off-cut (scenario [7]). The scenario is considered highly conservative considering the low likelihood of unattended toddlers close to working places and unpleasant taste of treated wood off-cuts. For scenario [7] an acceptable risk at tier 1 was calculated.

For exposure via dermal contact and subsequent oral exposure via mouthing it was assumed that a toddler plays on a playground structure made of treated wood (scenario [8]). As a worst case it is assumed that all of the contamination of the infant's hand is ingested during mouthing behaviour for a.s. For tier 2 a transfer coefficient for dislogable residues of 2% was considered. For this secondary exposure scenario risks are acceptable at tier 2.

Chronic inhalation exposure can occur from treated wood installed indoors. According to the result obtained by using the equation proposed by HEEG opinion 13 for the a.s. permethrin long-time exposure to volatised residues can be neglected.
As a worst case, secondary exposure of a toddler by inhalation of volatilised residues indoors were calculated for IPBC (scenario [9] "Inhalation of volatised residue, toddler"). Acceptable risk levels were obtained at tier 2.

For risks of combined exposure of scenario 8, 7 and 9 the short term AEL for IPBC and permethrin was used because the combination of the exposure scenarios is likely to occur on an intermittent/acute exposure basis.

In all general public exposure scenarios no exceedance of the corresponding reference values of permethrin was observed, resulting in acceptable risks.

The exposure assessment for the general public is based on the assumption that only contact to dried residues occur. Therefore, the RMM 'Keep children and pets (especially cats) away from treated surfaces until dried.' is required.

Risk for consumers via residues in food

The products of the AQUA LIGNEX I family must not be used for treatment of wood that may come in contact with food or feed. A risk for consumers via residues in food is thus excluded. The RMM 'Do not use on wood which may come in direct contact with food, feed and livestock.' is required.

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

The Guidance on Human health risk assessment (ECHA, 2017b) describes a tiered approach for the risk assessment for products containing multiple active substances. In Tier 1 the risk assessment is performed for each individual active substance separately, as described in the above sections.

Tier 2 is a screening approach based on dose-addition (and thus does not take possible synergistic effects into account). There is no specific information showing synergistic effects between permethrin and IPBC. The hazard index (HI) is calculated by addition of the individual hazard quotient (HQ, the ratio of exposure-to-reference value) for each active substance.

HI = ∑ HQa.s.

If HI ≤ 1 the risk related to use of the mixture will be considered acceptable;

If HI > 1 the risk related to use of the mixture will be considered unacceptable and refinement of the cumulative risk assessment is performed in Tier 3.

Scenarios	**IPBC**	**Permethrin**	**Conclusion**
Scenario [1] Flow coating / spray treatment			
With PPE (coated coverall)			
%AEL	87.10	43.60	Acceptable
HQ	0.8710	0.4360	Not acceptable
	HI = 1.307		
Scenario [1 + 9]			
With PPE (coated coverall)			
%AEL	87.20	43.60	Acceptable
HQ	0.8720	0.4360	Not acceptable
	HI = 1.308		
Scenario [3a] Manual dipping			
With PPE (gloves and coated coverall)			
%AEL	43.55	21.80	Acceptable
HQ	0.4355	0.2180	Acceptable
	HI = 0.654		
Scenario [3b] Draining and reloading after dipping - chronic			
With PPE (gloves)			
%AEL	0.75	0.40	Acceptable
HQ	0.0075	0.0040	Acceptable
	HI = 0.012		
Scenario [4a] Brushing			
With PPE (gloves)			
%AEL	31.15	15.60	Acceptable
HQ	0.3115	0.0320	Acceptable
	HI = 0.468		
Scenario [4b] Washing brusher			
Without PPE			
%AEL	4.50	3.20	Acceptable
HQ	0.0450	0.0320	Acceptable
	HI = 0.077		
Scenario [3a + 3b chronic + 9]			
Combined scenarios with/without PPEs			
%AEL	44.40	22.20	Acceptable
HQ	0.4440	0.2220	Acceptable
	HI = 0.666		
Scenario [4a + 4b + 9]			
Combined scenarios with/without PPEs			

%AEL	35.75	18.80	Acceptable
HQ	0.3575	0.1880	Acceptable
	HI = 0.546		
Scenario [5] Sanding and sawing of treated wood			
Without PPE			
%AEL	3.45	1.60	Acceptable
HQ	0.0345	0.0160	Acceptable
	HI = 0.051		
Scenario [6 outdoors] brushing			
Without PPE			
%AEL	67.54	5.92	Acceptable
HQ	0.6754	0.0592	Acceptable
	HI = 0.735		
Scenario [6 indoors] brushing			
Without PPE, treated area 2m^2			
%AEL	70.80	6.20	Acceptable
HQ	0.7080	0.0620	Acceptable
	HI = 0.770		
Scenario [6 indoors + 4b + 5 + 9]			
Without PPE			
%AEL	74.86	6.56	Acceptable
HQ	0.7486	0.0656	Acceptable
	HI = 0.814		
Scenario [6 outdoors + 4b + 5 + 9]			
Without PPE			
%AEL	71.51	6.34	Acceptable
HQ	0.7151	0.0634	Acceptable
	HI = 0.779		
Scenario [7] Toddler chewing wood			
Without PPE			
%AEL	21.94	1.92	Acceptable
HQ	0.2194	0.0192	Acceptable
	HI = 0.239		
Scenario [8] Toddler playing on treated wood structure			
Without PPE			
%AEL	11.05	5.60	Acceptable
HQ	0.1105	0.0560	Acceptable
	HI = 0.167		
Scenario [7 + 8 + 9 toddler]			
Without PPE			
%AEL	28.40	2.48	Acceptable
HQ	0.2840	0.0248	Acceptable
	HI = 0.309		

The calculations in the table above show an acceptable risk for mixture toxicity for all scenarios but scenario [1] and the combined scenario [1 + 9]. In the scenarios an

exceedance of the hazard index occurred thus the risk is considered unacceptable and further Tier 3 refinement is necessary.

Tier 3 is the combined exposure assessment by grouping the substances with common target organ/mode of action (3A), combined exposure assessment with specific AEL by target organ/mode of action (3B) and combined exposure assessment by considering mechanism of action, if known (3C) (cf. ECHA, 2017b).

A compilation of target organ(s)/mode of action(s) for each substance is listed in the table below including the effects relevant for the point of departure (PoD). The two active substances are then grouped related to their common target organ(s)/mode of action(s) (Tier 3A). For each group of target organ, HQ are summarized for each substance and subsequent HI are calculated.

Comparison of target organs and point of departures for active substances and SoCs used for risk characterisation

Substance	Point of Departure (PoD)/study type/species	PoD (organs and organ systems for systemic toxicity)	Additional target organs observed in other studies
IPBC	NOAEL 20 mg/kg bw/d 104 weeks chronic toxicity/ carcinogenicity rat study	NOAEL was based on gastrointestinal effects with inflammation and epithelial hyperplasia in the forestomach and histopathology in the salivary glands.	Liver (increased absolute and relative weights, hepatocyte enlargement), kidney (increased absolute and relative weights), lungs (increased incidence in foamy macrophages aggregates), thyroid (mice, weight increase and histopathological lesions), decrease of cholinesterase activity (inhalation), larynx
Permethrin	NOAEL 5 mg/kg bw/d 12-month dog study	The NOAEL has been established on the basis of increased liver weight in males and females and histopathological changes in the adrenals in both sexes.	Kidney (increase in relative organ weight (dog only, one study also with bilirubin decrease), central nervous system (neurotoxicity (rat, mice), such as tremors, staggered gait and effects on hind limb, alteration of motor activity and acetylcholine receptors, effects on the hematopoietic system

For permethrin reference values were based on liver effects. For IPBC, reference values were derived based on gastrointestinal effects with histopathology in the stomach, forestomach and salivary glands also leading to reduced body weight (gain).

The liver is a target organ common to permethrin an IPBC. Another target organ common to permethrin an IPBC is the kidney.
Several carbamate compounds are known for inhibiting acetyl cholinesterase. This effect was also observed for the carbamate IPBC but less pronounced.
In a neurotoxicity inhalation study in mice (Ireland, 2014, Doc IIIA- A6.9) there was evidence that repeated inhalation exposure to permethrin has a negative impact on motor

activity and acetylcholine receptors (reduction of acetylcholine receptors in females at medium and high dose). Acetyl cholinesterase activities remained at the control level.
Considering that permethrin does not inhibit acetyl cholinesterase and the less distinct effect of IPBC on acetyl cholinesterase activity, it is considered that effects are covered by mixture assessment of liver and kidney.

Derivation of organ specific AELs

Permethrin:
For permethrin reference values were based on liver effects, therefore no adjustment can be made for this substance.
In the case of kidney effects AEL and PoD are at the most sensitive point and there is no deviation from the NOAEL of 5 mg/kg bw/d to derive an organ specific AEL.

IPBC:
Liver-specific AEL for IPBC
Liver weights (absolute and/or relative) were increased in many studies and were sometimes accompanied by hepatocellular changes (Denmark, 2007, Doc IIIA- A6.4.1/01; Doc IIIA- A6.4.1/02; Doc IIIA- A6.4.1/03; Doc IIIA- A6.7/01)

In a reliable and GLP compliant 28-day gavage study in Wistar rats (n=5/sex/dose) statistically significant increase in the absolute and relative mean liver weight in males at 30 mg/kg bw/day without changes in body weight occurred. Relative and absolute liver weights were increased by 13% and 27%, respectively. Significant increases for both sexes were reached at the next higher dose level at 100 mg/kg bw/d, for male the change was not reversible after a recovery period. Also at this dose level in males, but not females at 100 mg/kg bw/day slight centrilobular cytoplasmatic change was noted. Total bilirubin was decreased in females at 30 mg/kg bw/day and above. The NOAEL was 10 mg/kg bw/d and was justified by RMS DK also based on the observed liver effects (Denmark, 2007, Doc IIIA- A6.3.1/01), however when considering relative liver weight alone 30 mg/kg bw/d would not qualify for a LOAEL.

The 90-day gavage study in SD rats (Denmark, 2007, Doc IIIA- A6.4.1/01, Klimisch 1, GLP) a NOAEL of 35 mg/kg bw/d was found. The toxicological relevant increase in relative mean liver weight in both sexes at 80 mg/kg bw/d is considered adverse because it is > 15 %, which is the threshold according to the TAB entry on the "Interpretation of liver effects" (ECHA, 2021a). The following statistically significant changes were observed at 80 mg/kg bw/day: decreased bilirubin in males and females, decreased creatinine and triglycerides in females, increased albumin in males and females, increased cholesterol and total protein in females. At 35 mg/kg bw/day, decreased bilirubin in males and females and decreased creatinine in females were observed. Aspartate aminotransferase (ALT), alanine aminotransferase (AST), γ-glutamyl transpeptidase (GGT) were not changed. Therefore a liver-specific NOAEL of 35 mg/kg bw/d (LOAEL = 80 mg/kg bw/d) can be derived from this study (Denmark, 2007, Doc IIIA- A6.4.1/01).

The 13 weeks gavage study in SD rats (Denmark, 20087 Doc IIIA- A6.4.1/02, Klimisch 1, GLP) showed at a dose of 50 mg/kg bw/d an increase in relative mean liver weight of 14.8 % in female rats. According to the TAB entry on the "Interpretation of liver effects" and its annex a non-adverse/adaptive effect on the liver is identified at doses that induce mean relative (to body weight) liver weight changes ≤ 15% (as compared to concurrent controls), in the absence of histopathological liver damage and relevant clinical chemistry changes (e.g. toxicologically significantly increased alanine aminotransferase, aspartate aminotransferase, alkaline phosphatase, bilirubin, etc.). In the case of this study, the increase in relative mean liver weight is almost 15 % and histopathological lesions

(cytomegaly) were found in the highest dosing group (125 mg/kg bw/d, all animals 20/20). At the dose of 125 mg/kg bw/d, relative mean liver weight increased to > 31 % compared to the control in both sexes. In satellite animals treated with 125 mg/kg bw/d hepatocyte enlargement was not observed after the 28-day recovering period and was thus considered reversible. Furthermore, relevant clinical chemistry parameters showed no differences between any of the study groups. There was no increase protein, albumin protein, albumin, ALT, AST and GGT activity or bilirubin levels (cholesterol not measured). Combining all of this, the increase in relative mean liver weight at a dose of 50 mg/kg bw/d is likely an adaptive response and considered non-adverse.
Therefore, a liver-specific NOAEL of 50 mg/kg bw/d (LOAEL = 125 mg/kg bw/d) was derived from this study. (Denmark, 2007, Doc IIIA- A6.4.1/02)

The 104 weeks chronic toxicity/ carcinogenicity rat study (Denmark, 2007, Doc IIIA-A6.7/01, GLP, Klimisch 1) was used to derive the $AEL_{long\text{-}term}$ for IPBC. 15 rats per group were sacrificed at interim kill after 52 weeks. Increases of adjusted absolute mean liver weights were observed at 40 mg/kg bw/d and at 80 mg/kg bw/d at interim kill. Considering that no liver histopathology was noted in the treated interim kill animals and no increase in adjusted absolute mean liver weight was noted at terminal kill (after 104 weeks). Changes in clinical chemistry parameters occurred at several sampling points but were not fully consistent of pronounced liver dysfunction.
At terminal kill at 80 mg/kg bw/d there was a dose related increased incidence in dark red foci in liver in all males.
The statistically significant increase in the adjusted absolute liver weights at interim sacrifice was considered as being of toxicologically relevance in high-dose males and females (relative >15% weight changes) but also in mid-dose females at 40 mg/kg bw/d (increase +19%) by RMS DK. If compared to the mean female body weights at the interim 52-week sacrifice the relative liver weight increase is +32%. Therefore, a liver-specific NOAEL of 40 mg/kg bw/d is uncertain and conservatively a NOAEL of 20 mg/kg bw/d would also account for the interim observed liver effects in this study.
On the other hand at study termination liver organ weights were not different compared to control for both sexes (Denmark, 2007, Doc IIIA- A6.7/01).

In the 3 months rabbit study (Denmark, 2007, Doc IIIA- A6.4.1/03, GLP, Klimisch 1) a toxicological relevant increase in relative mean liver weight > 15 % was observed at a dose of 75 mg/kg bw/d. At this dose no increase in liver relevant enzyme activity (ALT, AST, GGT) was observed. However, histopathology showed finely granular brown pigmentation in the liver and hepatocyte hypertrophy. A liver-specific NOAEL of 13 mg/kg bw/d (LOAEL = 75 mg/kg bw/d) was derived from this study. In the developmental toxicity study in rabbit (NZW, Klimisch 1, GLP) by gavage at 40 mg/kg bw/day, pale, mottled and/or granular liver was observed in 4/18 dams that were prematurely sacrificed due to local irritating effects of the GI. At terminal sacrifice there were no statistically significant differences in mean absolute and relative liver weights only when premature decedents are excluded from analysis (Denmark, 2007, Doc IIIA-A6.8.1/02). In the range finding study rated Klimisch 2 this lesion was already observed starting at 25 mg/kg bw/d with an incidence of 2/5, also observed at 75 and 100 mg/kg bw/d but not 10 mg/kg bw/d or control (Denmark, 2007, Doc IIIA-A6.8.1/01).

Liver effects were also observed in mice, though at higher dose levels. In an eight week dietary dose range finding study at 250 (only males), 500, and 1000 mg/kg bw/day, centrilobular hepatocyte enlargement was noted, accompanied with fine granular pigmentation. At 500 and 1000 mg/kg bw/day pigmentation occurred also in Kupffer cells. No changes were observed at 50 mg/kg bw/day or in controls (Denmark, 2007, Doc IIIA-A6.3.1/05). In a chronic dietary toxicity/carcinogenicity study an increased incidence in

males for hepatocellular adenomas (considered not relevant to humans) at 150 mg/kg bw/d was found (Denmark, 2007 Doc IIIA- A6.7/04/05/06/07/08/09)

In conclusion, several repeated dose toxicity studies with high reliability reported adaptive/adverse effects on the liver. Different rat strains and species were investigated. Concerning liver as a target organ mice seemed to be less susceptible than rats or rabbits. Nevertheless, hepatocyte hypertrophy and finely granular pigmentation occurred in rabbits and in mice, for the latter at much higher dose levels.
The lowest "liver NOAEL" was determined in a 90-day rabbit study with 13 mg/kg bw/d (LOAEL 75 mg/kg bw/day) based on organ weight and histopathological changes. In the developmental toxicity study, gross lesions were described as pale, mottled and/or granular (no histopathology was performed) observed already at lower dose levels of 25 and 40 mg/kg bw/d. For rats histopathological liver findings consistent of hypertrophy were observed at higher dose levels (100 and 125 mg/kg bw/d) and relative liver weight changes (around and greater of 15 %, often observed initially in one sex) started at 40 mg/kg bw/d and 50 mg/kg bw/day. Most, but not all studies showed that the liver weights increases were reversible or level off upon long/chronic study duration. Clinical chemistry parameters did not support pronounced liver toxicity.
Specifically for the liver histopathological finding, a greater sensitivity of the rabbit cannot be fully ruled out, but difference could also occur from the administration regime (dietary versus gavage) or study set-up. The 90-day study in rats could provide a suitable starting point with a NOAEL of 35 mg/kg bw/d. However, there is still considerable uncertainty if the "true" NOAEL for liver effects is really higher than 20 mg/kg bw/d.

Kidney-specific AEL for IPBC
In two studies of the CAR of IPBC kidney effects were observed (Denmark, 2007).
In the 90-day study in SD rats (Bien, 2002) absolute and relative mean kidney weight was statistically significant increased in female rats at a dose of 80 mg/kg bw/d by 9% compared to control. No treatment-related findings concerning urinalysis were reported. A NOAEL of 35 mg/kg bw/d was derived from this study (Denmark, 2007, Doc IIIA-A6.4.1/01).
In the second study, a 28 day rat study (Wistar) relative kidney weights were statistically increased (around 12% compared to control) at a dose of 30 and 100 mg/kg bw/d also only in females. After the recovery period of 14 days, no changes in absolute or relative kidneys weights were observed in the high dose group (100 mg/kg bw/d). Nevertheless, effects occurred without body weight changes at 30 mg/kg bw/d and are considered as toxicological relevant (Denmark, 2007, Doc IIIA- A6.3.1/01, RAC 2012).
The differences in onset of effects could be due to the different rat strains or study set-up. Therefore a higher kidney specific AEL (with a higher point of departure than 20 mg/kg bw/d) seems not fully justified and there are considerable uncertainties to set the point of departure of 35 mg/kg bw/d from the 90-day study.
However, based on the mixture assessment in other PARs (Denmark 2018 and 2021, Germany 2022a and 2022b) the NOAEL of 35 mg/kg bw/d was used for the kidney specific AEL.

Target organ/ Mode of Action	**IPBC** NOAEL (AEL)	**Permethrin** NOAEL (AEL)
Liver (chronic)	35 mg/kg bw/d (0.35 mg/kg bw/d)	5 mg/kg bw/d (0.05 mg/kg bw/d)
Kidney (chronic)	35 mg/kg bw/d (0.35 mg/kg bw/d)	5 mg/kg bw/d (0.05 mg/kg bw/d)

The derived $AEL_{long\text{-}term}$ are based on different target organs for the individual active substances, however there are overlaps of effects (liver and kidney) which makes it reasonable to combine the risk values for all active substances.

Target organ/ Mode of Action	IPBC	Permethrin	HI	Conclusion
Scenario [1]				
Combined exposure (mg/kg bw/d)	0.1742	0.0218	-	-
HQ Liver (chronic)	0.4977	0.4360	0.934	Acceptable
HQ Kidney (chronic)	0.4977	0.4360	0.934	Acceptable
Scenarios [1 + 9]				
Combined exposure (mg/kg bw/d)	0.1744	0.0218	-	-
HQ Liver (chronic)	0.4983	0.4360	0.934	Acceptable
HQ Kidney (chronic)	0.4983	0.4360	0.934	Acceptable

Conclusion
The refined assessment for the combined exposure to several active substances using liver- and kidney-specific AELs resulted in acceptable risks for scenario [1] "Flow coating/automated dipping" and the combined scenario [1 + 9] including volatilised indoor residues.

2.2.7 Risk assessment for animal health

Risk assessment for pets, domestic animals and livestock is covered by human health risk assessment. As the risk of secondary exposure of general public was considered acceptable, no adverse effects are expected also for animals, when applied according to the label instructions. Additionally, the following risk mitigation measures are assigned: "Do not use on wood which may come in direct contact with food, feed and livestock."
However, cats are more sensitive to pyrethroids like permethrin. Therefore, the access of cats to freshly treated objects has to be avoided and the RMM "Keep children and pets (especially cats) away from treated surfaces until dried." and the instruction for use "Due to the particular sensitivity of cats to permethrin, the product shall only be applied on wood which is applied in areas where contact of cats to treated wood can be excluded." have been added.

2.2.8 Risk assessment for the environment

2.2.8.1 Effects assessment on the environment

The biocidal product family AQUA LIGNEX I contains the two active substances permethrin and IPBC. The risk assessment of the biocidal product is performed based on the information given in the active substances CARs.

The active substance permethrin was evaluated and approved according to Regulation (EU) No 528/2012 for PT 8 and PT 18. A final Assessment Report (AR) for PT 8 (Ireland, 2014) agreed by the EU Member States and the European Commission is available.
The following PNEC values, including the newly derived and agreed one for permethrin (Addendum to permethrin CAR, Ireland (2017)), were used in the environmental risk assessment:

Used PNECs in the environmental risk assessment				
Compartment	**Permethrin**	**DCVA**	**PBA**	**Unit**
STP	4.95E-03	-	-	mg/L
Freshwater	4.70E-07	0.015	>0.010	mg/L
Sediment	2.17E-04	0.012	0.009	mg/kg_{wwt}
Soil	0.175	4.6	1.44	mg/kg_{wwt}
$PNEC_{oral\ bird}$	≥16.7	-	-	mg a.s/kg food
$PNEC_{oral\ small\ mammal}$	120	-	-	mg a.s/kg food

The active substance IPBC was evaluated and approved according to Regulation (EU) No 528/2012 for PT 6, PT 8, and PT 13. A final AR for PT 8 agreed by the EU Member States and the European Commission is available.
The following PNEC values are used in the risk assessment for IPBC (Denmark, 2008):

Used PNECs in the environmental risk assessment			
Compartment	**IPBC**	**PBC**	**Unit**
STP	0.44	Covered by IPBC	mg/L
Freshwater	0.0005	0.0413	mg/L
Sediment	Covered by surface water	Covered by surface water	mg/kg_{wwt}
Soil	0.005	0.149	mg/kg_{wwt}

The PNEC for the sediment is calculated using the equilibrium partitioning method (EPM). However, the risk to the sediment is the same as that described for surface water. Therefore, the risk of the sediment will not be considered further.

As reported in the Assessment Report of IPBC, PBC was identified as a relevant metabolite of IPBC in water, sediment and soil, because it was found in degradation studies at above the limit value of 10%. Due to a relatively short half-life of PBC (T½ of 31.2, 31.4 and 9.5 days at 12°C in water, sediment and soil, respectively), PBC can be regarded as a transient metabolite. In addition, the ecotoxicity of PBC is a factor of 300 – 1000 lower for fish, invertebrates and algae compared to IPBC.

The metabolite PBC was not assessed in the STP since IPBC is considered as worst case in this compartment.

IPBC quickly degrades to PBC, iodide and iodate within the environmental compartments. As reported in the Assessment Report on Iodine (Sweden, 2013), iodine and iodine compounds are ubiquitously distributed and there is a natural cycle of iodine species in the environment. Environmental background values as presented in the table below are likely to be encountered for soil, water and air.

Compartment	Background level (as iodine)
Soil	Typically 0.5 - 20 mg/kg dw but with extremes up to 98 mg/kg Global mean value of 5 mg/kg
Groundwater	Mean concentration: 1 µg/l Range: < 1-70 µg/l with extremes up to 400 µg/l
Freshwater (river and lake)	0.5 - 20 µg/l
Marine water	45 - 60 µg/L
Rainwater	0.1-15 µg/l
Freshwater sediment	Typically: 6 mg/kg
Marine sediment	Typically: 3-400 mg/kg
Air	Atmosphere: 10-20 ng/m^3 Atmospheric concentration: over land 2-14 ng/m^3; over ocean 17-52 ng/m^3 Marine air contains: 100 µg/l (may refer to local inhalable air)

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

The classification of the biocidal product family AQUA LIGNEX I is based on the harmonised classification or the latest scientific knowledge, respectively, of the active substances permethrin and IPBC. IPBC is classified under Regulation (EG) Nr. 1272/2008 (CLP) as Aquatic Acute 1 (M=10) and Aquatic Chronic 1 (M=1) (ATP06). Permethrin is classified as Aquatic Acute 1 (M=1000) and Aquatic Chronic 1 (M=1000) (CLP00). Classification according to the CAR of permethrin (Ireland, 2014) is aquatic acute 1 (M=100) and aquatic chronic 1 (M=10000). Therefore, the biocidal product has to be classified as Aquatic Acute 1, H400: Very toxic to aquatic life and Aquatic Chronic 1, H410: Very toxic to aquatic life with long lasting effects. It has to be labelled with the pictogram GHS09, the signal word warning, the hazard statement H400 Very toxic to aquatic life (may be omitted), H410 Very toxic to aquatic life with long lasting effects and the precautionary statements P273, P391 and P501.

Further Ecotoxicological studies

Summary table - Further ecotoxicological studies

Summary table of further ecotoxicological studies							
Method, Guideline, GLP status, Reliability	Species/ Inocu-lum	End point	Exposure		Results	Remarks	Refe-rence
			Design	Duration	EC_{50}		
Short-term toxicity to fish OECD Guideline 203 (Fish, Acute Toxicity Test), GLP, reliability 3	BRACHYDANIO RERIO	LC50	The assay of acute toxicity has been performed by means of static assay in which the solution (5 g/L) has not been changed for the whole test period.	96h	116.463 mg/L	N.A	S-2016-00295AM (IUCLID section 9.2.1.1)
Short-term toxicity to aquatic invertebrates, OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test), GLP, reliability 3	Daphnia magna	EC50	After a range finding test, the organisms have been exposed to 5 different dilutions of the test item for a total period of 48 hours.	48h	18.723 mg/L	N.A	S-2016-00296AM (IUCLID section 9.2.1.2)
Toxicity to aquatic algae and cyanobacteria, OECD Guideline 201 (Freshwater Alga and Cyanobacteria, Growth Inhibition Test), GLP, reliability 3		EC50	After the results of the range finding test, an EC50 test has been performed. The algae have been exposed to 5 different dilutions of the test item for 72 hours.	72h	21.907 mg/L	N.A	S-2016-00297AM(IUCLID section 9.2.1.3)

[1] Please include the reference to IUCLID.

Conclusion used in Risk Assessment – Further ecotoxicological studies	
Value/conclusion	The studies provided by the applicant are scored as Klimisch 3 – not reliable due to the lack of a reliable analytical detection method for the tested mixture for concentration control and stability. Therefore, the achieved LC50 values will not be taken into account for classification and labelling of the product. The biocidal product family AQUA LIGNEX I is classified based on the harmonised classification of the active substances permethrin and IPBC which results in a classification with Aquatic Acute 1 and Aquatic Chronic 1.
Justification for the value/conclusion	Analytical detection method is not sufficient and not convincing for an expert judgement

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

There is no risk of primary poisoning of non-target animals since AQUA LIGNEX I is directly applied on the wood to be treated and no emission on the environment are considered.

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

No data is available

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

No data is available

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

No data is available

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

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

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

Summary table on further studies on fate and behaviour in the environment						
Method, Guideline, GLP status, Reliability	Compartment	Temp [°C]	Initial TS concentration, C_0[mg/l]	% of biodegradation (28 days)	Re-marks	Re-ference
Aerobic biodegradability, OECD 310:2006, GLP, reliability 3	*Aqueous medium*	*25±2° C*	20	11	*On the basis of the results obtained, interpreted in accordance to OECD 310:2006, the test item "AQUA LIGNEX I " should be considered NOT biodegradable in aerobic condition*	*S-2016-00298AM (IUCLID 10.2)*

Conclusion used in Risk Assessment – Further studies on fate and behaviour in the environment	
Value/conclusion	The provided study on aerobic biodegradability does not meet the validity criteria according to OECD 310:2014/OECD 310:2006 since no exact TIC values of the blanks are specified. Nevertheless, this does not change the classification of the biocidal product family as not biodegradable. The biodegradability of AQUA LIGNEX I is therefore determined considering the degradation behaviour of the active substances permethrin and IPBC. The active substances are defined as not readily biodegradable according to OECD 301B (Ireland, 2014; Denmark, 2008).
Justification for the value/conclusion	Validity criteria are not fulfilled.

Leaching behaviour (ADS)

A semi-field leaching study according to the guideline NT BUILD 509 (Anonymous 2017c) has been carried out to support the application of the AQUA LIGNEX I biocidal product family by various superficial treatments to wood that will be available for use up to use class 3.
For the test, a pigmented product of the product family, AQUA LIGNEX I 03-Kastanie, has been used. In the formulation of the AQUA LIGNEX I biocidal product family, the quantities of biocide are rigorously maintained, as well as the ones of all additives. Only the amount of water varies for the coloured formulations, to compensate for the presence of pigments concentrates. It is not to be expected, that the pigments alter the leaching behaviour of IPBC and permethrin (Applicant's statement, NAP-C-1571773-24-00/F), therefore the product is considered an adequate representative of the product family.
The full composition of the product family and the composition of the tested formulation are provided in the confidential annex.
The study was conducted using AQUA LIGNEX I 03-Kastanie applied by brushing. Brushing treatment is accepted as a representative for different superficial treatment processes. For the study pine sapwood was treated with 195.3 g product/m² (mean value), resulting in a mean final active ingredient inventory of 1560 mg IPBC/m^2 and 195 mg/m^2 permethrin. This product application amount is slightly below the application amount proposed for the AQUA LIGNEX I biocidal product family, but is considered acceptable.
In total three treated test set-ups are established and one untreated test set-up. The test panels have been exposed to weathering outdoors above ground in a vertical position for 2 years. Run-off leachates are continuously collected and analysed for IPBC and permethrin. Sampling took place at eight time points comprising 1275 mm of rainfall.

Leaching rates used for risk assessment
Mean cumulative leaching data for both active substances are presented within the below table. All derived leaching rates for IPBC include the concentrations of PBC found.

Test duration [days]	Cumulated precipitation [mm]	Cumulated loss of a.s.			
		IPBC		Permethrin	
		[mg/m²]	[%]	[mg/m²]	[%]
21	52	1,60	0,10	0,0013	0,0007
62	120	3,12	0,20	0,0015	0,0008
112	241	3,77	0,24	0,0023	0,0012
267	484	17,94	1,15	0,0023	0,0012
366	640	18,85	1,21	0,0028	0,0015
484	803	19,00	1,22	0,0028	0,0015
608	994	20,40	1,31	0,0028	0,0015
731	1275	20,92	1,34	0,0030	0,0015

* including PBC

The parameters $Q^*_{leach,time}$ have been calculated according to the procedure described in the ESD for PT8 (OECD 2013), Appendix 2 to the following equations:

1. Fitting of the experimental FLUX (Δt) = f(t) curves

$$log_{10}FLUX(t) = a + b.log_{10}(t) + c.log_{10}(t)^2 \qquad A2\_1$$

The polynomial regression of second order determines the following parameters of the fit function for IPBC and Permethrin which are summarized in the below table:

Summary of polynominal fit parameter		
Parameter	**IPBC**	**Permethrin**
A	-7,4873	-11,033
B	0,1038	1,0022
C	0,1023	-0,4579

Once the parameter a, b and c are determined the experimental FLUX(t)=f(t) curve, can be re-calculated. Based on the FLUX(t)s the leached cumulative amounts Q* are calculated.

2. Calculation of $Q^*_{leach,time}$ [kg/m²]

$$Q^*_{leach,time} = \sum_{t=1day}^{nday} FLUX(t) = (FLUX)_{1day} + (FLUX)_{2day} + (FLUX)_{3day} + \ldots.(FLUX)_{nday} \qquad A2\_3$$

$$\boldsymbol{n = integer}\ number\ of\ days,\ i.e.,\ 1,2,3,4\ldots\ldots$$

The extrapolated leached amount Q* of IPBC is 2.65 mg/m² after 30 days and 45.28 mg/m² after 365 days. The extrapolated leached amount Q* is 754.65 mg/m² after 5 years and 9727.18 mg/m² after 15 years.
The extrapolated leached amount Q* of permethrin is $9.89x10^{-4}$ mg/m² after 30 days and $5.40x10^{-3}$ mg/m² after 365 days. The extrapolated leached amount Q* is 1.09x10-2 mg/m² after 5 years and $1.10x10^{-2}$ mg/m² after 15 years.

Testing for distribution and dissipation in soil (ADS)

No study was submitted since these information are available through the letter of access of the active substances

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

No study was submitted since these information are available through the letter of access of the active substances

Testing for distribution and dissipation in air (ADS)

No study was submitted since these information are available through the letter of access of the active substances

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

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

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

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

2.2.8.2 Exposure assessment

General information

Assessed PT	PT 8
Assessed scenarios	Scenario 1: Indoor application and indoor use of treated wood Scenario 2a: In-situ treatment: brushing – house - professional Scenario 2b: In-situ treatment: brushing – house – non-professional Scenario 2c: In-situ treatment: brushing – bridge over pond - professional Scenario 2d: In-situ treatment: brushing – bridge over pond - non-professional Scenario 3: Dipping/immersion application - (industrial) Scenario 4: Automated spray and flow coating application - (industrial) Scenario 5: Service life of treated timber - house - non-professional Scenario 6: Service life of treated timber - noise barrier Scenario 7: Service life of treated timber - bridge over pond - non-professional
Und ESD(s) used	ESD for PT 8: Revised Emission Scenario Document for Wood Preservatives (OECD 2013) ECHA 2021b: Technical Agreements for Biocides Environment (ENV), Release date: 9 November 2021
Approach	Average consumption
Distribution in the environment	Calculated in EUSES 2.2.0
Groundwater simulation	The concentration of the active substance in groundwater is estimated via the pore water concentration, with EUSES 2.2.0. In Scenario 5, for PBC, iodide and iodate, simulation for leaching to groundwater has been refined with the model FOCUS PEARL 4.4.4.
Confidential Annexes	NO
Life cycle steps assessed	Production: No* Formulation No* Use: Yes Service life: Yes
Remarks	-

*Environmental exposure during production and formulation of the biocidal product is not assessed under the requirements of the BPR. These life cycle steps are already covered by REACH legislation, where the registrants (manufacturers/importers) of substances are obliged to consider environmental hazard and exposure and to provide RMMs/exposure scenarios for ensuring safe use (e.g. via SDS in the supply chain). Moreover, it is assumed that industrial production sites are subject to permit for installation. Therefore, it is not considered relevant to perform an additional exposure assessment under the biocide regime.

The biocidal product family „AQUA LIGNEX I" belongs to product type 8 and contains next to IPBC the active substance permethrin. The product is a ready-to-use protective water-based wood preservative to be used by non-professionals, professionals and industrial users in order to control wood boring beetles and wood discoloring fungi in use class 1-3.
The present environmental exposure assessment is performed only for the active ingredients and their metabolites.
PEC values of the major metabolites of permethrin (DCVA and PBA) and IPBC (PBC, iodide and iodate) are calculated based on 100% formation from their parent compounds.

Emission estimation

Assessed Scenarios

Emissions to the environment can occur during timber treatment and service life of the treated timber. Generally, no emission from wood is expected in situations where wood or wood-based products are under cover, protected from the weather and are not exposed to wetting (even where high environmental humidity leads to occasional but not persistent wetting). In situations where wood or wood-based products are not covered and in contact with the ground, either continually exposed to the weather or subject to frequent wetting (use class 3), emissions to soil and water are possible and subject to the following scenarios. Estimation of the active substance concentration in air is recommended only for industrial preventive treatments (OECD 2013). For this reason, and due to the fast degradation and low vapour pressure of the active ingredients, emissions to air are considered negligible.

Scenario 1: Indoor application and indoor use of treated wood

According the OECD ESD for wood preservatives, for indoor treatments like brushing no scenario is proposed in this document because the emissions to the environment, during these treatments and from treated wood after the treatments, are considered to be negligible.

Scenario 2: Outdoor brushing application (in-situ treatment)

In accordance with the Emission Scenario Document for PT 8 local concentration at the end of the day of application are calculated by applying the following scenarios:

- House for in situ application
  The "House" scenario has been assessed as worst-case scenario for the soil compartment for the use under UC 3 conditions. Therefore, the fence scenario is not assessed separately.
- Bridge over pond scenario for in situ application
  As a counterpart, the "bridge over pond" scenario is considered the worst-case scenario for the aquatic compartment in UC 3.

Both scenarios are calculated for professional use (house: scenario 2a, bridge over pond: scenario 2c) and non-professional use (house: scenario 2b, bridge over pond: scenario 2d)) using the respective default values.

Scenario 3: Dipping/immersion application (industrial process)

The exposure assessment for the dipping application process (automatic or manual in operation) covers both, application and storage of the treated wood. Concerning the treatment process the primary receiving environmental compartments are local air and the facility drain.

During the storage of treated wood, directly exposed compartments are soil and surface water via run-off from the storage side.

Scenario 4: Automated spraying and flow coating (industrial process)

The exposure scenario automated spraying also includes flow coating treatments and covers both, application and storage of the treated wood. Concerning the treatment process the primary receiving environmental compartments are local air and the facility drain.

During the storage of treated wood, directly exposed compartments are soil and surface water via run-off from the storage side.

Service life (Scenarios 5, 6 and 7)
For the exposure assessment for treated wood in service, three scenarios are assessed for the use in UC 3.

- Scenario 5: House scenario
  For the house scenario the primary receiving environmental compartment is considered to be soil via rain run-off. The house scenario is considered as worst-case scenario for the soil compartment under UC 3 conditions. Therefore, the fence scenario is not assessed separately.
  Brushing application conditions are used to represent a worst case situation. Here, the product may be applied in-situ and therefore the application phase should be included. However, because emission during application is prevented due to risk mitigation measures, application is not included in the calculations for wood in service. Emissions from in-situ application by brushing are covered in scenario 2.
- Scenario 6: Noise barrier
  Concerning the noise barrier scenario, it is assumed that the leachate resulting from the rainfall either ends up directly in the adjacent soil in a proportion of 30% or is collected in the gutter and sewer (70%), and finally enters a municipal sewage treatment plant (STP). The noise barrier scenario is considered as the most critical wood in service scenario for the STP under UC 3 conditions.
  Since treatment by brushing is not applicable to the noise barrier scenario, automatic spraying is assessed as representative for industrial treatments. Emissions from application are not covered by this scenario.
- Scenario 7: Bridge over pond
  As a third scenario and worst-case for the water compartment under UC 3 conditions, the bridge over pond scenario is assessed. For this scenario it is assumed that the leachate of the bridge resulting from rainfall ends up directly in the adjacent water body.
  Brush application conditions are used to represent a worst case situation. Here, the product may be applied in-situ and therefore the application phase should be included. However, since application of this product is not allowed into, above or adjacent to surface water, application is not included in the calculations for wood in service. Emissions from in-situ application by brushing are covered in scenario 2.

Assessed Service Life
During the Arona Leaching Workshop in June 2005 (EC 2005), it was agreed that a long-term assessment of in-service uses of wood should be carried out. For automated spraying and dipping treatments an assessment of cumulative leaching from treated wood in-service over a 15 year period was proposed, for in-situ brushing 5 years. Hence, the assessment times are 30 days (TIME 1) for short term consideration and 5 or 15 years for the longer time period (TIME 2). At the follow-up leaching workshop in Varese (held 12th of June 2013), the Environment Working Group has agreed to implement a further TIME 2 value of 365 days (ECHA 2014), if a risk for the initial assessment period of 30 days is identified. Hence, the environmental behaviour of the active substances from the AQUA LIGNEX I biocidal product family is assessed for the use as a wood preservative for TIME 1 (30 days), TIME 2 (365 days) and for a long-term exposure TIME 3 (5 or 15 years) corresponding to the service life time.

Calculations for Scenario 2, 3, 4, 5, 6 and 7

Treatment of wood is concluded via various treatment processes by non-professionals, professionals and industrial users. The worst-case use rate of the AQUA LIGNEX I biocidal product family is 200 g/m^2, corresponds to a maximum rate of 0.2 g permethrin/m^2 and 1.6 g IPBC/m^2.

A summary of leaching behaviour of the active substances in the biocidal product from treated wood is presented in chapter EFFECTS ASSESSMENT ON THE ENVIRONMENT subchapter Leaching behaviour.

Local emission are performed using EUSES 2.2.0. All Input parameters used for the calculation are described in annex 3.2 of this document. A short summary of the values which have been indicated as "Set values" in the emission scenarios or default values to be selected from a list are summarised here:

Input parameters for calculating the local emission					
		Permethrin	**IPBC**	**Unit**	**Remarks**
General table					
Application rate of the product		0.2	0.2	[L/m^2]	S
Fraction of substance in the product		1.00E-03	8.00E-03	[-]	S
Density of the product		1028.5	1028.5	[kg/m^3]	S
Application rate of the active substance		0.2	1.6	[g/m^2]	S
Quantity of active substance applied per m³of wood [(a)]		8E-03	64E-03	[kg/m^3]	S
Initial assessment period		30	30	[d]	D
Intermediate assessment period		365	365	[d]	D
Longer assessment period (storage place)		7.30E+03	7.30E+03	[d]	D
Cumulative quantity of substance leached out of 1m²:	initial assessment period	9.89E-04	2.06	[mg/m²]	S
	intermediate assessment period	5.40E-03	45.28	[mg/m²]	S
	service life (5 years)	1.09E-02	754.65	[mg/m²]	S
	service life (15 years)	1.1E-02	1600[(c)]	[mg/m²]	S
Flow rate of surface water (creek/river)		2.59E+04	2.59E+04	[m³/d]	D
Scenario 2a+2c: Outdoor brushing application, by professionals					
Fraction of product lost to soil/water during application		0.03	0.03	[-]	D
Scenario 2b+2c: Outdoor brushing application, non-professional					
Fraction of product lost to soil/water during application		0.05	0.05	[-]	D
Scenario 3: Dipping application, incl. storage of treated wood					
Average daily flux during 14 days storage period [(b)]		4.10E-12	2.90E-08	[kg/m²/d]	S
Fraction released to facility drain		1E-04	0.03	[-]	D
Fraction released to air		1E-03	1E-03	[-]	D
Scenario 4: Automated spraying (flow coating) application, incl. storage of treated wood Large plant, as worst-case					
Surface area of the storage place		790	790	[m2]	D
Average daily flux during 3 days storage period[(b)]		4.10E-12	2.90E-08	[kg.m-2.d-1]	D
Scenario 5: Treated wood in service – House					

Input parameters for calculating the local emission				
	Permethrin	**IPBC**	**Unit**	**Remarks**
Cover in situ treatment	No	No	[-]	S
Service life	1.83E+03	1.83E+03	[d]	S
Service life (15 years)	5475	5475	[d]	S
Scenario 6: Treated wood in service – Noise barrier				
Service life (15 years)	5475	5475	[d]	S
Scenario 7: Treated wood in service – Bridge over pond				
Cover in situ treatment	No	No		S
Service life	1,83E+03	1,83E+03	[d]	S
Service life (15 years)	5475	5475	[d]	S

(a) Conversion from g as/m^3 wood to g as/m^2 wood is based on the assumption to 1 m^3 wood corresponds to 40 m^2 wood

(b) No average daily flux i.e. the average quantity of a substance that is daily leached out of 1 m² of treated wood of treated wood during 14 day storage period is available. The average flux is estimated using the leaching test result. It is calculated the mean of a.s. leachate/day in a 731 day test.

(c)The leached amount Q* for IPBC is extrapolated to 9727.18 mg/m² after 15 years. However, if the application rate 200 g b.p./m2 and the IPBC content of 0.8 %(w/w) in the product is used to derive the IPBC content per m² we calculate a maximum content of 1600 mg IPBC /m².

Calculations are performed using EUSES 2.2.0. EUSES output files are included in Appendix 3.2 of this document. A brief summary of the resulting local emissions is presented here:

Scenario 2a*:* Outdoor brushing application, by professionals, house scenario

Resulting local emission to relevant environmental compartments			
Compartment	**PERMETHRIN**	**IPBC**	**Remarks**
Soil	7.71E-04 kg/d	6.17E-03 kg/d	-

Scenario 2b: Outdoor brushing application, non-professional, house scenario

Resulting local emission to relevant environmental compartments			
Compartment	**PERMETHRIN**	**IPBC**	**Remarks**
Soil	1.29E-03 kg/d	0.010285 kg/d	-

Scenario 2c*:* Outdoor brushing application, by professionals, bridge over pond

Resulting local emission to relevant environmental compartments			
Compartment	**PERMETHRIN**	**IPBC**	**Remarks**
Surface water	6.17E-05 kg/d	4.94E-04 kg/d	-

Scenario 2d: Outdoor brushing application, non-professional, bridge over pond

Resulting local emission to relevant environmental compartments			
Compartment	**PERMETHRIN**	**IPBC**	**Remarks**
Surface water	1.03E-04 kg/d	8.23E-04 kg/d	-

Scenario 3: Dipping application, incl. storage of treated wood

Resulting local emission to relevant environmental compartments			
Compartment	**PERMETHRIN**	**IPBC**	**Remarks**
Wastewater	8.00E-05 kg/d	0.192 kg/d	-
Soil	1.58E-08 kg/d	1.12E-04 kg/d	Local emission over the initial assessment period
	1.58E-08 kg/d	1.12E-04 kg/d	Local emission over the longer assessment period
Surface water	1.58E-08 kg/d	1.12E-04 kg/d	Local emission over the initial assessment period
	1.58E-08 kg/d	1.12E-04 kg/d	Local emission over the longer assessment period

Scenario 4: Automated spraying (flow coating) application, incl. storage of treated wood Large plant, as worst-case

Resulting local emission to relevant environmental compartments			
Compartment	**PERMETHRIN**	**IPBC**	**Remarks**
Wastewater	0.016 kg/d	0.987 kg/d	-
Soil	1.78E-08 kg/d	1.26E-04 kg/d	Local emission over the initial assessment period
	1.78E-08 kg/d	1.26E-04 kg/d	Local emission over the longer assessment period
Surface water	1.78E-08 kg/d	1.26E-04 kg/d	Local emission over the initial assessment period
	1.78E-08 kg/d	1.26E-04 kg/d	Local emission over the longer assessment period

Scenario 5: Treated wood in service – House

Resulting local emission to relevant environmental compartments			
Compartment	**PERMETHRIN**	**IPBC**	**Remarks**
Soil	4.12E-09 kg/d	8.58E-06 kg/d	Leaching over the initial assessment period (30 days)
	1.85E-09 kg/d	1.55E-05 kg/d	Leaching over the intermediate assessment period (365 days)

Resulting local emission to relevant environmental compartments			
Compartment	**PERMETHRIN**	**IPBC**	**Remarks**
	7.47E-10 kg/d	5.17E-05 kg/d	Leaching over the service life (1825 days)
	2.51E-10 kg/d	3.65E-05 kg/d	Leaching over the service life (5475 days)

Scenario 6: Treated wood in service – Noise barrier

Resulting local emission to relevant environmental compartments			
Compartment	**PERMETHRIN**	**IPBC**	**Remarks**
Soil	2.97E-08 kg/d	6.18E-05 kg/d	Leaching over the initial assessment period (30 days)
	1.33E-08 kg/d	1.12E-04 kg/d	Leaching over the intermediate assessment period (365 days)
	1.81E-09 kg/d	2.63E-04 kg/d	Leaching over the service life (5475 days)
STP	6.92E-08 kg/d	1.44E-04 kg/d	Leaching over the initial assessment period (30 days)
	3.11E-08 kg/d	2.61E-04 kg/d	Leaching over the intermediate assessment period (365 days)
	4.22E-09 kg/d	3.73E-03 kg/d	Leaching over the service life (5475 days)

Scenario 7: Treated wood in service – Bridge over pond

Resulting local emission to relevant environmental compartments			
Compartment	**PERMETHRIN**	**IPBC**	**Remarks**
Surface water	3.30E-10 kg/d	6.87E-07 kg/d	Leaching over the initial assessment period (30 days)
	1.48E-10 kg/d	1.24E-06 kg/d	Leaching over the intermediate assessment period (365 days)
	5.97E-11 kg/d	4.14E-06 kg/d	Leaching over the service life (1825 days)
	2.01E-11 kg/d	2.92E-06 kg/d	Leaching over the service life (5475 days)

Fate and distribution in exposed environmental compartments

AQUA LIGNEX I is formulated as a liquid containing 0.8% of IPBC and 0.1% of permethrin as active substances. Different scopes of application for non-professionals, professionals and industrial users have been applied for, including outdoor application and use. Therefore, different environmental compartments may be directly or indirectly be exposed to the product and thus to the active substances through application, storage and/or during service life of the treated wood. The following table presents all foreseeable routes of entry to the environment for the envisaged usage.

Identification of relevant receiving compartments based on the exposure pathway					
Scenario	**STP**	**Freshwater[1]**	**Soil**	**Air**	**Biota**
Brushing application indoor	-	-	-	-	-
Brushing application outdoor – house - non-professional /professional	-	-	++	(Q)	+
Brushing application outdoor – bridge over pond - non-professional /professional	-	++	-	-	+
Dipping/immersion application	++	++, +	++, +[2]	(Q)	+
Automated spray and flow coating application	++	++, +	++, +[2]	(Q)	+
Service life (House)	-	-	++	(Q)	+
Service life (Noise barrier)	++	+	+[2]	(Q)	+
Service life and in situ treatment (Bridge over pond)	-	++	-	-	+

++ Compartment directly exposed, + Compartment indirectly exposed, - Compartment not exposed, (Q) Qualitative assessment, depending on application or substance-specific properties
1 Including sediment, 2 Including groundwater via STP surplus sludge application

Input parameters* (only set values) for calculating the fate and distribution in the environment for Permethrin			
Input	Value	Unit	Remarks
Molecular weight	391.29	g/mol	-
Melting point	33	°C	-
Vapour pressure (at 20°C)	2.155×10^{-6}	Pa	-
Water solubility (at 20°C)	0.18	mg/L	-
Log Octanol/water partition coefficient	4.67	Log 10	-
Organic carbon/water partition coefficient (Koc)	26930	L/kg	-
Henry's Law Constant	4.6×10^{-3}	Pa/m3/mol	-
Biodegradability	Not readily biodegradable	-	-
DT50 for degradation in soil	106	d (at 12ºC)	-
DT50 for biodegradation in water/sediment	46.7	d (at 12ºC)	-
BCF (fish)	570	L/kg	-
BCF (earthworm)	15108	L/kg	-

* Values are deduced from the Permethrin PT8 AR (Ireland 2014)

Input parameters* (only set values) for calculating the fate and distribution in the environment for IPBC			
Input	Value	Unit	Remarks
Molecular weight	281.1	g/mol	-
Melting point	65.8	°C	-
Vapour pressure (at 25°C)	4.5 x 10-3	Pa	-
Water solubility (at 20°C)	168	mg/L	-
Log Octanol/water partition coefficient	2.81	Log10	-
Organic carbon/water partition coefficient (Koc)	134.5	L/kg	-
Henry's Law Constant (at 25°C)	6.45 x 10-3	Pa/m3/mol	-
Biodegradability	Inherent biodegradability	-	IPBC is primary biodegradable according to a Zahn-Wellens test. IPBC degrades rapidly (within 2 hours) to PBC.
DT_{50} for degradation in soil	4.7h (= 0.1958 d)	d (at 12ºC)	-
DT_{50} for biodegradation in water/sediment	3.3h (= 0.1375 d)	d (at 12ºC)	-

* Values are deduced from the IPBC PT8 AR (Denmark 2008)

The elimination of IPBC and permethrin in the environment after release to the sewer system is simulated using SimpleTreat module of EUSES 2.2.0. EUSES. Output reports concerning the release pathway via sewage treatment plant (STP) are reported in annex 3.2 of this report. The distribution in the STP is summarised in the following table:

Calculated fate and distribution in the STP			
Compartment	**Percentage [%]**		**Remarks**
	IPBC	**Permethrin**	
Air	9.53E-03	1.4E-03	-
Water	98.28	26.19	-
Settler	1.195	52.55	-
Sludge	0.517	21.26	-
Degraded in STP	0	0	-

Calculated PEC values

According the OECD ESD for wood preservatives, for indoor treatments like brushing no scenario is proposed in this document because the emissions to the environment, during these treatments and from treated wood after the treatments, are considered to be negligible.

Predicted environmental concentrations (PECs) form outdoor use of the biocidal product are calculated according to the Exposure Scenario Document (ESD) for wood preservatives (version 2013). The software EUSES 2.2.0 has been used to calculate distribution of the active substances permethrin and IPBC in several compartments. Removal of the active substances from exposed environmental compartments has been considered for tier II.
EUSES output files are included in Appendix 3.2 of this document. A summary of the calculated PEC values is presented the tables below.

In addition to the parent compounds, the potential exposure to the environment from metabolites of permethrin and IPBC have been assessed.

The following metabolites are identified in all compartments:

- Permethrin: 3-(2,2-dichorovinyl)-2,2-dimethyl-(1-cyclopropane) carboxylate (DCVA) and 3-phenoxybenzoic acid (PBA)
- IPBC: propargyl butyl carbamate (PBC), iodine and iodate

In general, concentrations of metabolites in the environmental compartments are calculated based on the PECs of the parent by multiplying with the differences in molar weight. This approach considers 100% transformation of the parent into the metabolites.

Conversion factors used:

- DCVA (from permethrin): 0.534
- PBA (from permethrin): 0.547
- PBC (from IPBC): 0.552
- Iodine (from IPBC): 0.451
- Iodate (from IPBC): 0.622

Metabolites were not considered in the case of release into the sewage system, as none of the active substances is readily biodegradable and information on the occurrence of metabolites during wastewater treatment is lacking (e.g. no wastewater treatment plant simulation studies are available). It is therefore assumed that metabolites are formed after their release into the aquatic or terrestrial environment.

Summary table on calculated PEC values					
Permethrin					
	$PEC_{surface\ water}$	**$PEC_{sediment}$**	**PEC_{STP}**	**PEC_{soil}**	**$PEC_{pore\ water}$**
	[mg/l]	[mg/kg_{wwt}]	[mg/l]	[mg/kg_{wwt}]	[µg/l]
Outdoor brushing application, house					
Scenario 2a: professional	-	-	-	3.50E-02	7.30E-02
Scenario 2b: non-professional	-	-	-	5.80E-02	1.22E-01
Outdoor brushing application, bridge over pond					
Scenario 2c: professional	6.17E-05	3.6E-2	-	-	-
Scenario 2d: non-professional	1.03E-04	6.0E-2	-	-	-
Dipping application, incl. storage of treated wood					
Scenario 3: storage place (initial period)	6.09E-10	3.57E-07	-	7.96E-07	1.67E-06
Scenario 3: storage place (longer period) - Tier I	6.09E-10	3.57E-07	-	1.94E-04	4.07E-04
Scenario 3: storage place (longer period) - Tier II*	-	-	-	4.06E-06	8.53E-06
Scenario 3: application (release via STP)	8.28E-07	5.9E-04	1.05E-05	1.09E-04	1.51E-04
Automated spraying (flow coating) application, incl. storage of treated wood Large plant, as worst-case					
Scenario 4: storage place (initial period)	6.87E-10	4.03E-07	-	7.96E-07	1.67E-06
Scenario 4: storage place (longer period) – Tier I	6.87E-10	4.03E-07	-	1.94E-04	4.07E-04
Scenario 4: storage place (longer period) – Tier II*	-	-	-	4.06E-06	8.53E-06
Scenario 4: application (release via STP)	1.66E-10	1.18E-07	2.1E-09	1.16E-03	2.44E-03
Treated wood in service – house - non-professional, as worst-case					
Scenario 5: leaching over 30 days – Tier I	-	-	-	5.59E-06	1.18E-05
Scenario 5: leaching over 365 days – Tier I	-	-	-	3.05E-05	6.43E-05
Scenario 5: leaching over 5 years – Tier I	-	-	-	6.17E-05	1.3E-04
Scenario 5: leaching over 15 years – Tier I	-	-	-	6.22E-05	1.31E-04
Scenario 5: leaching over 30 days - Tier II*	-	-	-	5.08E-06	1.07E-05
Scenario 5: leaching over 365 days - Tier II*	-	-	-	1.16E-05	2.44E-05
Scenario 5: leaching over 5 years – Tier II*	-	-	-	5.17E-06	1.09E-05
Scenario 15: leaching over 5 years – Tier II*	-	-	-	1.74E-06	3.66E-06

Summary table on calculated PEC values					
Permethrin					
	$PEC_{surface\ water}$	**$PEC_{sediment}$**	**PEC_{STP}**	**PEC_{soil}**	**$PEC_{pore\ water}$**
	[mg/l]	[mg/kg_{wwt}]	[mg/l]	[mg/kg_{wwt}]	[µg/l]
Treated wood in service – Noise barrier					
Scenario 6: release via STP	5.31E-11	3.11E-08	5.52E-10	5.62E-09	7.65E-09
Scenario 6: leaching to soil over 30 days - Tier I	-	-	-	2.09E-06	4.41E-06
Scenario 6: leaching to soil over 365 days - Tier I	-	-	-	1.14E-05	2.41E-05
Scenario 6: leaching to soil over 15 years – Tier I	-	-	-	2.33E-05	4.9E-05
Scenario 6: leaching to soil over 30 days - Tier II*	-	-	-	1.9E-06	4E-06
Scenario 6: leaching to soil over 365 days - TierII*	-	-	-	4.35E-06	9.15E-06
Scenario 6: leaching to soil over 15 years - Tier II*				6.51E-07	1.37E-06
Treated wood in service – bridge over pond - non-professional, as worst-case					
Scenario 7: leaching over 30 days - Tier I	9.89E-09	5.8E-06	-	-	-
Scenario 7: leaching over 365 days - Tier I	5.40E-08	3.17E-05	-	-	-
Scenario 7: leaching over 5 years - Tier I	1.09E-07	6.39E-05	-	-	-
Scenario 7: leaching over 15 years - Tier I	1.1E-07	6.45E-05	-	-	-
Scenario 7: leaching over 30 days - Tier II*	4.29E-09	2.51E-06	-	-	-
Scenario 7: leaching over 365 days - Tier II*	8.14E-09	4.77E-06	-	-	-
Scenario 7: leaching over 5 years - Tier II*	3.88E-09	2.27E-06	-	-	-
Scenario 7: leaching over 15 years - Tier II*	1.34E-09	7.84E-07	-	-	-

*In Tier II removal is considered.

Summary table on calculated PEC values (Permethrin metabolite)				
DCVA				
	$PEC_{surface\ water}$	**$PEC_{sediment}$**	**PEC_{soil}**	**$PEC_{pore\ water}$**
	[mg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/l]
Outdoor brushing application, house				
Scenario 2a: professional	-	-	1.87E-02	3.90E-02
Scenario 2b: non-professional	-	-	3.10E-02	6.51E-02
Outdoor brushing application, bridge over pond				
Scenario 2c: professional	3.29E-05	1.92E-02	-	-
Scenario 2d: non-professional	5.50E-05	3.20E-02	-	-
Dipping application, incl. storage of treated wood				
Scenario 3: storage place (initial period)	3.25E-10	1.91E-07	4.25E-07	8.92E-07
Scenario 3: storage place (longer period)	3.25E-10	1.91E-07	1.04E-04	2.17E-04
Scenario 3: application (release via STP)	4.42E-07	3.15E-04	5.82E-05	8.06E-05
Automated spraying (flow coating) application, incl. storage of treated wood Large plant, as worst-case				
Scenario 4: storage place (initial period)	3.67E-10	2.15E-07	4.25E-07	8.92E-07
Scenario 4: storage place (longer period)	3.67E-10	2.15E-07	1.04E-04	2.17E-04
Scenario 4 application release via STP	8.86E-11	8.86E-11	6.19E-04	1.30E-03
Treated wood in service – house - non-professional, as worst-case				
Scenario 5: leaching over 30 days	-	-	2.99E-06	6.30E-06
Scenario 5: leaching over 365 days	-	-	1.63E-05	3.43E-05
Scenario 5: leaching over 5 years	-	-	3.29E-05	6.94E-05
Scenario 5: leaching over 15 years	-	-	3.32E-05	7.00E-05
Treated wood in service – Noise barrier				
Scenario 6: release via STP	2.84E-11	1.66E-08	3.00E-09	4.09E-09
Scenario 6: leaching to soil over 30 days	-	-	1.12E-06	2.35E-06
Scenario 6: leaching to soil over 365 days	-	-	6.09E-06	1.29E-05
Scenario 6: leaching to soil over 15 years	-	-	1.24E-05	2.62E-05
Treated wood in service – bridge over pond - non-professional, as worst-case				
Scenario 7: leaching over 30 days	5.28E-09	3.10E-06	-	-
Scenario 7: leaching over 365 days	2.88E-08	1.69E-05	-	-
Scenario 7: leaching over 5 years	5.82E-08	3.41E-05	-	-
Scenario 7: leaching over 15 years	5.87E-08	3.44E-05	-	-

Summary table on calculated PEC values (Permethrin metabolite)				
PBA				
	$PEC_{surface\ water}$	**$PEC_{sediment}$**	**PEC_{soil}**	**$PEC_{pore\ water}$**
	[mg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/l]
Outdoor brushing application, house				
Scenario 2a: professional	-	-	1.91E-02	3.99E-02
Scenario 2b: non-professional	-	-	3.17E-02	6.67E-02
Outdoor brushing application, bridge over pond				
Scenario 2c: professional	3.37E-05	1.97E-02	-	-
Scenario 2d: non-professional	5.63E-05	3.28E-02	-	-
Dipping application, incl. storage of treated wood				
Scenario 3: storage place (initial period)	3.33E-10	1.95E-07	4.35E-07	9.13E-07
Scenario 3: storage place (longer period)	3.33E-10	1.95E-07	1.06E-04	2.23E-04
Scenario 3: application (release via STP)	4.53E-07	3.23E-04	5.96E-05	8.26E-05
Automated spraying (flow coating) application, incl. storage of treated wood Large plant, as worst-case				
Scenario 4: storage place (initial period)	3.76E-10	2.20E-07	4.35E-07	9.13E-07
Scenario 4: storage place (longer period)	3.76E-10	2.20E-07	1.06E-04	2.23E-04
Scenario 4: application release via STP	9.08E-11	6.45E-08	6.35E-04	1.33E-03
Treated wood in service – house - non-professional, as worst-case				
Scenario 5: leaching over 30 days	-	-	3.06E-06	6.45E-06
Scenario 5: leaching over 365 days	-	-	1.67E-05	3.52E-05
Scenario 5: leaching over 5 years	-	-	3.37E-05	7.11E-05
Scenario 5: leaching over 15 years	-	-	3.40E-05	7.17E-05
Treated wood in service – Noise barrier				
Scenario 6: release via STP	2.90E-11	1.70E-08	3.07E-09	4.18E-09
Scenario 6: leaching to soil over 30 days	-	-	1.14E-06	2.41E-06
Scenario 6: leaching to soil over 365 days	-	-	6.24E-06	1.32E-05
Scenario 6: leaching to soil over 15 years	-	-	1.27E-05	2.68E-05
Treated wood in service – bridge over pond - non-professional, as worst-case				
Scenario 7: leaching over 30 days	5.41E-09	3.17E-06	-	-
Scenario 7: leaching over 365 days	2.95E-08	1.73E-05	-	-
Scenario 7: leaching over 5 years	5.96E-08	3.50E-05	-	-
Scenario 7: leaching over 15 years	6.02E-08	3.53E-05	-	-

Summary table on calculated PEC values					
IPBC					
	$PEC_{surface\ water}$	**$PEC_{sediment}$**	**PEC_{STP}**	**PEC_{soil}**	**$PEC_{pore\ water}$**
	[mg/l]	[mg/kg_{wwt}]	[mg/l]	[mg/kg_{wwt}]	[µg/l]
Outdoor brushing application, house					
Scenario 2a: professional	-	-	-	2.79E-01	112
Scenario 2b: non-professional	-	-	-	4.65E-01	187
Outdoor brushing application, bridge over pond					
Scenario 2c: professional	4.94E-04	1.83E-03	-	-	-
Scenario 2d: non-professional	8.23E-04	3.05E-03	-	-	-
Dipping application, incl. storage of treated wood					
Scenario 3: storage place (initial period)	4.31E-06	1.60E-05	-	5.63E-03	2.26
Scenario 3: storage place (longer period) - Tier I	4.31E-06	1.60E-05	-	1.37	550
Scenario 3: storage place (longer period) - Tier II*	-	-	-	5.30E-05	2.13E-02
Scenario 3: application (release via STP)	7.75E-03	3.50E-2	9.43E-2	5.58E-05	3.74E-03
Automated spraying (flow coating) application, incl. storage of treated wood Large plant, as worst-case					
Scenario 4: storage place (initial period)	4.86E-06	1.80E-05	-	5.63E-03	2.26
Scenario 4: storage place (longer period) – Tier I	4.86E-06	1.80E-05	-	1.37	550
Scenario 4: storage place (longer period) – Tier II*	-	-	-	5.30E-05	2.13E-02
Scenario 4: application (release via STP)	3.99 E-2	1.80E-1	4.85E-1	2.87E-04	1.92E-02
Treated wood in service – house - non-professional, as worst-case					
Scenario 5: leaching over 30 days – Tier I	-	-	-	1.17E-02	4.67
Scenario 5: leaching over 365 days – Tier I	-	-	-	2.56E-01	103
Scenario 5: leaching over 5 years – Tier I	-	-	-	4.27	1710
Scenario 5: leaching over 15 years – Tier I	-	-	-	9.05	3630
Scenario 5: leaching over 30 days - Tier II*	-	-	-	1.10E-04	4.40E-02
Scenario 5: leaching over 365 days - Tier II*	-	-	-	1.98E-04	7.96E-02
Scenario 5: leaching over 5 years – Tier II*	-	-	-	6.61E-04	2.65E-01
Scenario 5: leaching over 15 years – Tier II*	-	-	-	4.67E-04	0.187

Summary table on calculated PEC values					
IPBC					
	$PEC_{surface\ water}$	**$PEC_{sediment}$**	**PEC_{STP}**	**PEC_{soil}**	**$PEC_{pore\ water}$**
	[mg/l]	[mg/kg_{wwt}]	[mg/l]	[mg/kg_{wwt}]	[µg/l]
Treated wood in service – Noise barrier					
Scenario 6: release via STP	1.83E-04	6.797E-04	1.83E-03	1.09E-06	7.26E-05
Scenario 6: leaching to soil over 30 days - Tier I	-	-	-	4.36E-03	1.75
Scenario 6: leaching to soil over 365 days - Tier I	-	-	-	9.59E-02	38.5
Scenario 6: leaching to soil over 15 years – Tier I	-	-	-	3.39	1360
Scenario 6: leaching to soil over 30 days - Tier II*	-	-	-	4.11E-05	1.60E-2
Scenario 6: leaching to soil over 365 days – Tier II*	-	-	-	7.42E-05	2.90E-2
Scenario 6: leaching to soil over 15 years – Tier II*	-	-	-	1.75E-04	7.00E-2
Treated wood in service – bridge over pond - non-professional, as worst-case					
Scenario 7: leaching over 30 days - Tier I	2.06E-05	5.8E-06	-	-	-
Scenario 7: leaching over 365 days - Tier I	4.53E-04	1.68E-03	-	-	-
Scenario 7: leaching over 5 years - Tier I	7.55E-03	2.80E-02	-	-	-
Scenario 7: leaching over 15 years - Tier I	1.60E-02	5.90E-2	-	-	-
Scenario 7: leaching over 30 days - Tier II*	1.35E-07	5.02E-07	-	-	-
Scenario 7: leaching over 365 days - Tier II*	2.46E-07	9.12E-07	-	-	-
Scenario 7: leaching over 5 years - Tier II*	8.20E-07	3.04E-06	-	-	-
Scenario 7: leaching over 15 years - Tier II*	5.80E-07	2.15E-06	-	-	-

*In Tier II removal is considered.

Summary table on calculated PEC values (IPBC metabolite)				
PBC				
	$PEC_{surfacewater}$	**$PEC_{sediment}$**	**PEC_{soil}**	**$PEC_{porewater}$**
	[mg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/l]
Outdoor brushing application, house				
Scenario 2a: professional	-	-	1.54E-01	61.8
Scenario 2b: non-professional	-	-	2.57E-1	103.2
Outdoor brushing application, bridge over pond				
Scenario 2c: professional	2.73E-04	1.01E-03	-	-
Scenario 2d: non-professional	4.54E-04	1.68E-03	-	-
Dipping application, incl. storage of treated wood				
Scenario 3: storage place (initial period)	2.38E-06	8.83E-06	3.11E-03	1.25
Scenario 3: storage place (longer period)	2.38E-06	8.83E-06	7.56E-01	304
Scenario 3: application (release via STP)	4.28E-03	1.93E-02	3.08E-05	2.06E-03
Automated spraying (flow coating) application, incl. storage of treated wood Large plant, as worst-case				
Scenario 4: storage place (initial period)	2.68E-06	9.94E-06	3.11E-03	1.25
Scenario 4: storage place (longer period)	2.68E-06	9.94E-06	7.56E-01	304
Scenario 4: application release via STP	2.20E-2	9.90E-2	1.58E-4	1.00E-2
Treated wood in service – house - non-professional, as worst-case				
Scenario 5: leaching over 30 days	-	-	6.46E-3	2.57784
Scenario 5: leaching over 365 days	-	-	1.41E-1	56.9
Scenario 5: leaching over 5 years	-	-	2.36	944
Scenario 5: leaching over 5 years – Tier II*	-	-	1.67E-2	-
Scenario 5: leaching over 15 years	-	-	5.00	2003
Scenario 5: leaching over 15 years –TierII*	-	-	1.67E-2	-
Treated wood in service – Noise barrier				
Scenario 6: release via STP	1.01E-04	3.75E-04	6.02E-07	4.01E-05
Scenario 6: leaching to soil over 30 days	-	-	2.41E-03	9.67E-01
Scenario 6: leaching to soil over 365 days	-	-	5.29E-02	21.2
Scenario 6: leaching to soil over 15 years	-	-	1.18	750
Scenario 6: leaching to soil over 15 years Tier II*	-	-	8.46E-03	-
Treated wood in service – bridge over pond - non-professional, as worst-case				
Scenario 7: leaching over 30 days	1.14E-05	4.22E-05	-	-
Scenario 7: leaching over 365 days	2.50E-04	9.27E-04	-	-
Scenario 7: leaching over 5 years	4.17E-03	1.55E-02	-	-
Scenario 7: leaching over 15 years	8.35E-03	3.25E-02	-	-

*Tier II: time dependent concentration in soil according to the equation no. (3.7) and of the ESD for PT8 (OECD 2013)

Summary table on calculated PEC values (IPBC metabolite)				
Iodide				
	$PEC_{surfacewater}$	**$PEC_{sediment}$**	**PEC_{soil}**	**$PEC_{porewater}$**
	[mg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/l]
Outdoor brushing application, house				
Scenario 2a: professional	-	-	1.26E-01	50.5
Scenario 2b: non-professional	-	-	2.10E-01	84.3
Outdoor brushing application, bridge over pond				
Scenario 2c: professional	2.23E-04	8.25E-04	-	-
Scenario 2d: non-professional	3.71E-04	1.38E-03	-	-
Dipping application, incl. storage of treated wood				
Scenario 3: storage place (initial period)	1.94E-06	7.22E-06	2.54E-03	1.02
Scenario 3: storage place (longer period)	1.94E-06	7.22E-06	6.18E-01	248
Scenario 3: application (release via STP)	3.50E-03	1.58E-02	2.52E-05	1.69E-03
Automated spraying (flow coating) application, incl. storage of treated wood Large plant, as worst-case				
Scenario 4: storage place (initial period)	2.19E-06	8.12E-06	2.54E-03	1.02
Scenario 4: storage place (longer period)	2.19E-06	8.12E-06	6.18E-01	248
Scenario 4: application release via STP	1.80E-2	8.10E-2	1.29E-04	8.67E-03
Treated wood in service – house - non-professional, as worst-case				
Scenario 5: leaching over 30 days	-	-	5.28E-03	2.11
Scenario 5: leaching over 365 days	-	-	1.15E-1	46.5
Scenario 5: leaching over 5 years	-	-	1.93	771
Scenario 5: leaching over 15 years	-	-	4.08	1637
Treated wood in service – Noise barrier				
Scenario 6: release via STP	8.25E-05	3.07E-04	4.92E-07	3.27E-05
Scenario 6: leaching to soil over 30 days	-	-	1.97E-03	7.90E-01
Scenario 6: leaching to soil over 365 days	-	-	4.32E-02	17.4
Scenario 6: leaching to soil over 15 years	-	-	1.52	613
Treated wood in service – bridge over pond - non-professional, as worst-case				
Scenario 7: leaching over 30 days	9.29E-06	3.45E-05	-	-
Scenario 7: leaching over 365 days	2.04E-04	7.58E-04	-	-
Scenario 7: leaching over 5 years	3.41E-03	1.26E-02	-	-
Scenario 7: leaching over 15 years	4.39E-03	1.63E-02	-	-

Summary table on calculated PEC values (IPBC metabolite)				
Iodate				
	$PEC_{surface\ water}$	**$PEC_{sediment}$**	**PEC_{soil}**	**$PEC_{pore\ water}$**
	[mg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/l]
Outdoor brushing application, house				
Scenario 2a: professional	-	-	1.74E-01	69.7
Scenario 2b: non-professional	-	-	2.89E-01	116
Outdoor brushing application, bridge over pond				
Scenario 2c: professional	3.07E-04	1.14E-03	-	-
Scenario 2d: non-professional	5.12E-04	1.90E-03	-	-
Dipping application, incl. storage of treated wood				
Scenario 3: storage place (initial period)	2.68E-06	9.95E-06	3.50E-03	1.41
Scenario 3: storage place (longer period)	2.68E-06	9.95E-06	8.52E-01	342
Scenario 3: application (release via STP)	4.82E-03	2.17E-02	3.47E-05	2.33E-03
Automated spraying (flow coating) application, incl. storage of treated wood Large plant, as worst-case				
Scenario 4: storage place (initial period)	3.02E-06	1.12E-05	3.50E-03	1.41
Scenario 4: storage place (longer period)	3.02E-06	1.12E-05	8.52E-01	342
Scenario 4: application release via STP	2.50E-2	1.12E-1	1.79E-04	1.20E-02
Treated wood in service – house - non-professional, as worst-case				
Scenario 5: leaching over 30 days	-	-	7.28E-03	2.90
Scenario 5: leaching over 365 days	-	-	1.59E-1	64.1
Scenario 5: leaching over 5 years	-	-	2.66	1063.62
Scenario 5: leaching over 15 years	-	-	5.63	2257
Treated wood in service – Noise barrier				
Scenario 6: release via STP	1.14E-04	4.23E-04	6.78E-07	4.52E-05
Scenario 6: leaching to soil over 30 days	-	-	2.71E-03	1.09
Scenario 6: leaching to soil over 365 days	-	-	5.96E-02	23.9
Scenario 6: leaching to soil over 15 years	-	-	2.11	846
Treated wood in service – bridge over pond - non-professional, as worst-case				
Scenario 7: leaching over 30 days	1.28E-05	4.75E-05	-	-
Scenario 7: leaching over 365 days	2.82E-04	1.04E-03	-	-
Scenario 7: leaching over 5 years	4.70E-03	1.74E-02	-	-
Scenario 7: leaching over 15 years	9.96E-04	3.67E-02	-	-

PEC for groundwater

For application sites and industrial treatment plants (storage sites) exposure and risk for the terrestrial compartment cannot be excluded. Hence, risk reductions are necessary and no groundwater assessment is carried out as emission to the groundwater is limited by the risk mitigation measures.

For the risk assessments of treated wood in service and indirect exposure via sewage sludge application as an indication for potential groundwater levels the concentration in pore water of agricultural soil is taken. The concentration of the active substance in pore water is estimated with EUSES 2.2.0. The results are listed in the tables below.

Summary of Clocal$_{soil\ pore\ water}$ for Permethrin and its metabolites			
SCENARIO	**Clocal $_{soil\ pore\ water}$ (µg/L)***		
	Permethrin	**DCVA**	**PBA**
Scenario 3 application release via STP	1.51E-04	8.06E-05	8.26E-05
Scenario 4 application release via STP	2.44E-03	1.30E-03	1.33E-03
Scenario 5 leaching - house over 5 years	1.09E-05	6.94E-05	7.11E-05
Scenario 5 leaching - house over 15 years	3.66E-06	7.00E-05	7.17E-05
Scenario 6 application release via STP	7.65E-09	4.09E-09	4.18E-09

*concentrations in the soil pore water of agricultural soil (arable soil; 180 days).

The Assessment Report for IPBC states that environmental fate and behaviour of IPBC and PBC indicate that the active substance and its metabolite are not expected to migrate to groundwater since they rapidly degrade in soil (DT_{50} values (12°C) =0.196 days (IPBC) and 9.5 days (PBC)). Thus, the concentration simulation models of potential concentrations in groundwater are not considered relevant for the proposed used pattern (Denmark, 2008).

These assumptions are supported by pore water concentrations in soil of IPBC and its metabolites as an indication for concentrations in groundwater (see tables below).

Summary of Clocal$_{soil\ pore\ water}$ for IPBC and its metabolites				
SCENARIO	**Clocal $_{soil\ pore\ water}$ (µg/L)***			
	IPBC	**PBC**	**Iodide**	**Iodate**
Scenario 3 application release via STP	3.74E-03	2.06E-03	1.69E-03	2.33E-03
Scenario 4 application release via STP	1.92E-02	1.00 E-02	8.67E-03	1.20E-02
Scenario 5 leaching - house over 5 years	2.65E-01	944	771	1063.62
Scenario 5 leaching - house over 15 years	0.187	2003	1637	2257
Scenario 6 application release via STP	7.26E-05	4.01E-05	3.27E-05	4.52E-05

*concentrations in the soil pore water of agricultural soil (arable soil; 180 days).

Porewater concentrations > 0.1 µg/L for IPBC and PBC were calculated in the house scenarios for service life. For iodide and iodate porewater concentrations above the natural background concentration were calculated in these scenarios.

As stated in the above, IPBC is not expected to reach groundwater. However, this does not refer to PBC, iodide and iodate. For this reason, a refinement of these values has been conducted following the approach as stated in the Supplement to Appendix 4 of ESD for PT8 (OECD 2013). As stated at p.176, point 580, when considering the use of treated wood in service, a groundwater assessment is only necessary for the house scenario, which can be considered to be the worst-case for soil exposure, thus covering all other scenarios. For these reason, the refinement has been conducted for Scenario 5 (House) only.
Metabolites concentration in groundwater, as resulted from the refinement by FOCUS PEARL 4.4.4, is summarised in the table below.

Summary of Clocal groundwater for IPBC metabolites			
SCENARIO	**Clocal groundwater (µg/L)**		
	PBC	**Iodide**	**Iodate**
Scenario 5: leaching over 5 years (worst-case)	< 0.000001	< 0.000001	< 0.000001

The input and output values are embedded in Annex 3.2.

Emission to air:
Volatilisation of permethrin is considered to be negligible based on the vapour pressure and Henry constant.
IPBC volatilisation is also expected to be negligible because of its low vapour pressure. In addition the calculated DT_{50} of IPBC in air is about 15 hours and IPBC is therefore not considered persistent in air.

Primary and secondary poisoning

Primary poisoning
In addition to 'secondary poisoning', in some cases primary poisoning (e.g. for rodenticides or insecticides), may take place and needs to be assessed. The product is a wood preservative (PT 8). It is ready to use and is directly applied in liquid form on the wood to be treated. Hence, a direct uptake of the product is unlikely. In addition for primary poisoning no guidance is given in the ESD for PT 8 (OECD 2013). PEC values from primary poisoning have therefore not been calculated.
For information on considerations referring to the risks posed to animals from the biocidal product, please also refer to the risk assessment for animal health.

Secondary poisoning
According to the ECHA Guidance on BPR: Vol IV Environment Parts B+C Version 2.0 (ECHA 2017c), section 3.8.2, a potential for bioaccumulation is indicated by different substance characteristics such as e.g. a log K_{ow} value ≥3, a high BCF-value or if the substance is "*known to have a potential to accumulate in living organism*". IPBC has a low log K_{ow} value below the trigger value of 3 (i.e. 2.8) and thus, bioaccumulation is not indicated.

Permethrin has log K_{OW}-values above this trigger value (i.e. 4.27) and thus, a potential for bioaccumulation is indicated. Therefore, for permethrin it needs to be assessed whether the intended uses result in a risk concerning secondary poisoning. Further information on the assessment of secondary poisoning is provided below.

Secondary poisoning via contaminated FISH
The $PEC_{oral,predator}$ is calculated for the aquatic food chain according to the equation no. 107 of the ECHA Guidance on BPR: Vol IV Environment Parts B+C.
The highest $PEC_{surface\ water}$ is used as input parameter in the calculations.
BMF is the biomagnification factor from fish to predator. The biomagnification factor (BMF) should ideally be based on measured data. However, the availability of such data is at present very limited and therefore default values should be used. The ECHA Guidance on BPR gives the following default values for BMF, based on experimental BCF values, or if experimental BCF values are not available, on log K_{ow}:

Log Kow	**BCF**	**BMF**
<4.5	<2000	1
4.5-5	2000-5000	2
5-8	>5000	10
8-9	2000-5000	3
>9	<2000	1

A measured average BCF_{fish} of 500-570 L/kg has been described in the permethrin assessment report. The worst case of 570 L/kg used in the calculations. Based on this BCF value, then a BMF of 1 is applied.

Calculation of the predicted environmental concentration for permethrin in fish (ECHA Guidance on BPR: Vol IV Environment Parts B+C Version 2.0, equation 107)			
Parameter	**Definition**	**Value**	**Unit**
Predicted environmental concentration in surface water	PEC_{water}	1.03E-04	mg/L
Bioconcentration factor for fish on wet weight basis	BCF_{fish}*	570	$L/kg_{wet\ fish}$
Biomagnification factor in fish	BMF	1	-
Predicted Environmental Concentration in fish	$PEC_{oral,\ predator} = PEC_{water} \cdot BCF_{fish} \cdot BMF$	**5.86E-02**	**$mg/kg_{wet\ fish}$**

* Value is deduced from the Permethrin PT8 AR (Ireland 2014)

Secondary poisoning via contaminated EARTHWORMS
The $PEC_{oral,predator}$ is calculated for the terrestrial food chain according to the equation no. 103c of the ECHA Guidance on BPR: Vol IV Environment Parts B+C.

The highest PEC_{soil} and pore water concentration are used as input parameter in the calculations. A PEC value without degradation is taken into account as a worst case:

Calculation of the predicted environmental concentration for permethrin in earthworms			
Parameter	**Definition**	**Value**	**Unit**
Local concentration in soil ($PEC_{agric,\ 180\ days}$)	$PECloca l_{soil}$	5.80E-02	mg/kg_{wwt}
Bioconcentration factor for earthworm on wet weight basis	BCF*	15108	$L/kg_{wet\ earthworm}$
Fraction of gut loading in worm	F_{gut}	0.1	kg/kg
Conversion factor for soil concentration wet-dry weight soil	$CONV_{soil}$	1.13	kg_{wwt}/kg_{dwt}
Predicted Environmental Concentration in pore water	$PECloca l_{soil,porewater}$	1.22E-04	mg/L
Predicted Environmental Concentration in earthworms	$C_{earthworm} = \frac{BCF_{earthworm} \cdot C_{porewater} + C_{soil} \cdot F_{gut} \cdot CONV_{soil}}{1 + F_{gut} \cdot CONV_{soil}}$	**1.66**	**$mg/kg_{wet\ earthworm}$**

* Value is deduced from the Permethrin PT8 AR (Ireland 2014)

2.2.8.3 Risk characterisation

For risk characterisation, only scenarios relevant for the respective compartment and compound are addressed and respective PEC/PNEC values are calculated and reflected in this section.

Atmosphere

Conclusion: In conclusion emission to air of both active substances (permethrin and IPBC) is considered negligible due to their low vapour pressure (permethrin: 2.155 x 10^{-6} Pa at 20°C, IPBC: 2.36 x 10^{-3} Pa at 20°C).

Sewage treatment plant (STP)

Permethrin:

- $PNEC_{STP}$ = 0.00495 mg a.s./L

Calculated $PEC/PNEC_{STP}$ values – Permethrin	
	$PEC/PNEC_{STP}$ (Permethrin)
Scenario 3 application (release via STP)	2.12E-03
Scenario 4 application (release via STP)	4.24E-07
Scenario 6 application (release via STP)	1.12E-07

IPBC:

- $PNEC_{STP}$ = 0.44 mg a.s./L

Calculated $PEC/PNEC_{STP}$ values – IPBC & its metabolites PBC, Iodate and Iodide	
	$PEC/PNEC_{STP}$ (IPBC)
Scenario 3 application (release via STP)	0.21
Scenario 4 application (release via STP)	**1.1**
Scenario 6 application (release via STP)	4.16E-03

No unacceptable risk was identified for permethrin in the sewage system. PEC/PNEC ratios for the two metabolites DCVA and PBA were not calculated since permethrin is not readily biodegradable in the sewer and information on the appearance of metabolites during sewage treatment is lacking. Metabolites are only relevant in the water, sediment and soil compartment.
An unacceptable risk was identified for IPBC in scenario 4. According to the emission scenario document for PT 8, 4.1.1.1 release of wood preservatives into a surface water drain or drain connected to a STP is nowadays not permitted in the EU member countries and therefore, exposure to the STP is not expected. Moreover, the calculated scenario 4 is a worst-case scenario. A risk for the environment is not expected when the biocidal product is used within the framework of the European legislation.

The metabolite PBC was not assessed for the STP since IPBC is considered as worst case for PBC in this compartment. Nevertheless, predicted environmental concentration for the major metabolites PBC has been calculated for STP. As the PEC is lower than those predicted for IPBC and also the ecotoxicity of this metabolite is lower (factor of 300–1000 lower for fish, invertebrates and algae) it is considered that any risk will be covered by the risk assessment carried out for the parent active ingredient. As a result, no PEC/PNEC ratios have been calculated specifically for the metabolite.
For iodate and iodide, no PNEC and/or background levels are available. Therefore, and because IPBC is calculated as worst case, no PEC/PNEC values were calculated for these metabolites.

Conclusion: no unacceptable risk was identified for the sewage treatment plant.

Aquatic compartment

Permethrin:

- $PNEC_{surface\ water}$ = 0.00047 µg a.s/L

DCVA:

- $PNEC_{surface\ water}$ = 0.015 mg/L

PBA:

- $PNEC_{surface\ water}$ ≥0.010 mg/L

Calculated $PEC/PNEC_{surface\ water}$ values – Permethrin & its metabolites DCVA and PBA

	$PEC/PNEC_{surface\text{-}water}$ (Permethrin)	**$PEC/PNEC_{surface\text{-}water}$ (DCVA)**	**$PEC/PNEC_{surface\text{-}water}$ (PBA)**
Outdoor brushing application, bridge over pond			
Scenario 2c: professional	**131.3**	2.19E-03	3.37E-03
Scenario 2d: non-professional	**219.1**	3.66E-03	5.63E-03
Dipping application, incl. storage of treated *wood*			
Scenario 3: storage place (initial period)	1.29E-03	2.16E-08	3.33E-08
Scenario 3: storage place (longer period) - tier I	1.29E-03	2.16E-08	3.33E-08
Scenario 3: application (release via STP)	**1.76**	2.94E-05	4.53E-05
Automated spraying (flow coating) application, incl. storage of treated wood Large plant, as worst-case			
Scenario 4: storage place (initial period)	1.46E-03	2.45E-08	3.76E-08

Calculated PEC/PNEC$_{surface\ water}$ values – Permethrin & its metabolites DCVA and PBA			
Scenario 4: storage place (longer period) – tier I	1.46E-03	2.45E-08	3.76E-08
Scenario 4: application (release via STP)	3.53E-06	5.91E-09	9.08E-09
Treated wood in service – Noise barrier			
Scenario 6: release via STP	1.09E-04	1.89E-09	2.90E-09
Treated wood in service – bridge over pond - non-professional, as worst-case			
Scenario 7: leaching over 30 days - tier I	0.021	3.52E-07	5.41E-07
Scenario 7: leaching over 365 days - tier I	0.115	1.92E-06	2.95E-06
Scenario 7: leaching over 5 years - tier I	0.232	3.88E-06	5.96E-06
Scenario 7: leaching over 15 years - tier I	0.234	3.91E-06	6.02E-06
Scenario 7: leaching over 30 days - tier II	9.13E-03	-	-
Scenario 7: leaching over 365 days - tier II	1.73E-02	-	-
Scenario 7: leaching over 5 years - tier II	8.26E-03	-	-
Scenario 7: leaching over 15 years - tier II	2.85E-03	-	-

Several risks for the aquatic compartment were identified for permethrin. Application of the product in the bridge over pond scenario (scenarios 2c and 2d) for professional and non-professional users resulted in PEC/PNEC ratio >>1.

Therefore, the following risk mitigation measures have to be applied:

N-246: *During product application (to timbers) and whilst surfaces are drying, do not contaminate the environment. All losses of the product have to be contained by covering the ground (e.g. by tarpaulin) and disposed of in a safe way.*

N-241 modified: *Application of this product is not allowed into, above or adjacent to surface water. Release into the aquatic compartment must be prevented.*

An unacceptable risk was also identified for scenario 3 application, for release to surface water via STP. According to the emission scenario document for PT 8, 4.1.2 release of wood preservatives into surface water drain or drain connected to a STP is nowadays not permitted in the EU and therefore, exposure to surface water via STP is not expected. Moreover, the calculated scenario is a worst-case scenario. A risk for the environment is not expected when the biocidal product is used within the framework of the European legislation.

In addition, as reported in the Assessment Report on IPBC PT 8, *in any case risk reduction measurement at the storage sites (*scenario 3 and 4*) like covering the soil has to be done*. Also, the BPC opinion on the application for approval of the active substance permethrin in

product type 8 concluded that *appropriate risk mitigation measures shall be taken to protect the soil and aquatic compartments.*

Therefore, respective risk mitigation measures will be applied:

N-13: *All industrial application processes must be carried out within a contained area situated on impermeable hard standing with bunding to prevent run-off and a recovery system in place (e.g. sump).*

N-370: *Freshly treated timber must be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water, and that any losses of the product, including any contaminated water/soil must be collected for reuse or disposal in accordance with local/national/international requirements.*

No unacceptable risk was calculated for the metabolites DCVA and PBA.

Permethrin:
- $PNEC_{sediment}$ = 0.001 mg/kg dwt (2.17×10^{-4} wwt)

DCVA:
- $PNEC_{sediment}$ = 0.055 mg/kg dwt (0.012 mg/kg wwt)

PBA:
- $PNEC_{sediment}$ = 0.042 mg/kg dwt (0.009 mg/kg wwt)

Calculated $PEC/PNEC_{sediment}$ values – Permethrin & its metabolites DCVA and PBA			
	$PEC/PNEC_{sediment}$ (Permethrin)	**$PEC/PNEC_{sediment}$ (DCVA)**	**$PEC/PNEC_{sediment}$ (PBA)**
Outdoor brushing application, bridge over pond			
Scenario 2c: professional	**165.9**	**1.6**	**2.2**
Scenario 2d: non-professional	**276.5**	**2.7**	**3.6**
Dipping application, incl. storage of treated wood			
Scenario 3: storage place (initial period)	1.65E-03	1.59E-08	2.17E-05
Scenario 3: storage place (longer period) - tier I	1.65E-03	1.59E-08	2.17E-05
Scenario 3: storage place (longer period) - tier II	-	-	-
Scenario 3: application (release via STP)	**2.72**	0.026	3.59E-02
Automated spraying (flow coating) application, incl. storage of treated wood, Large plant, as worst-case			
Scenario 4: storage place (initial period)	1.86E-03	1.79E-05	2.44E-05
Scenario 4: storage place (longer period) – tier I	1.86E-03	1.79E-05	2.44E-05

Calculated PEC/PNEC$_{sediment}$ values – Permethrin & its metabolites DCVA and PBA			
Scenario 4: storage place (longer period) – tier II*	-	-	-
Scenario 4: application (release via STP)	5.44E-04	7.38E-09	7.17E-06
Treated wood in service – Noise barrier			
Scenario 6: release via STP	1.43E-04	1.38E-06	1.89E-06
Treated wood in service – bridge over pond - non-professional, as worst-case			
Scenario 7: leaching over 30 days - tier I	0.0058	2.58E-04	3.52E-04
Scenario 7: leaching over 365 days - tier I	0.0317	1.41E-03	1.92E-03
Scenario 7: leaching over 5 years - tier I	0.0639	2.84E-03	3.88E-03
Scenario 7: leaching over 15 years - tier I	0.0645	6.25E-04	8.40E-04
Scenario 7: leaching over 30 days - tier II	1.16E-02	-	-
Scenario 7: leaching over 365 days - tier II	2.19E-02	-	-
Scenario 7: leaching over 5 years - tier II	1.05E-02	-	-
Scenario 7: leaching over 15 years - tier II	7.84E-04	-	-

Since for permethrin and its metabolites unacceptable risks were also calculated for the sediment in scenario 2c, 2d and 3, the same RMMs (N-246, N-241 modified, N-13 and N-370) apply as for surface water.

No unacceptable risk was found for the metabolites DCVA and PBA for storage and service life. Risks during application are covered by the applied risk mitigation measure.

IPBC:

- $PNEC_{surface\ water}$ = 0.0005 mg/L

PBC:

- $PNEC_{surface\ water}$ = 0.0413 mg/L

Iodate and iodide:

- Background level in freshwater: 0.5-20 µg/L (20 µg/L value used for risk characterisation)
- Background level in sediment: Typically: 6 mg/kg

Calculated PEC/PNEC$_{surface\ water}$ values – IPBC & its metabolites PBC, Iodate and Iodide				
	PEC/PNEC	**PEC/PNEC**	**PEC/PNEC**	**PEC/PNEC**

Calculated PEC/PNEC$_{surface\ water}$ values – IPBC & its metabolites PBC, Iodate and Iodide				
	surface water (IPBC)	**surface water (PBC)**	**surface water (Iodide)**	**surface water (Iodate)**
Outdoor brushing application, house				
Scenario 2a: professional	0.988	6.35E-03	0.011	0.015
Scenario 2b: non-professional	**1.64**	1.05E-02	0.019	0.026
Dipping application, incl. storage of treated wood				
Scenario 3: storage place (initial period)	8.62E-03	5.53E-05	9.70E-05	1.34E-04
Scenario 3: storage place (longer period) - tier I	8.62E-03	5.53E-05	9.70E-05	1.34E-04
Scenario 3: storage place (longer period) - tier II*	-	-	-	-
Scenario 3: application (release via STP)	**15.5**	9.95E-2	0.175	0.241
Automated spraying (flow coating) application, incl. storage of treated wood Large plant, as worst-case				
Scenario 4: storage place (initial period)	9.72E-03	6.23E-5	1.09E-04	1.51E-04
Scenario 4: storage place (longer period) – tier I	9.72E-03	6.23E-5	1.09E-04	1.51E-04
Scenario 4: storage place (longer period) – tier II*	-	-	-	-
Scenario 4: application (release via STP)	**79.7**	0.512	0.895	**1.24**
Treated wood in service – Noise barrier				
Scenario 6: release via STP	0.366	2.45E-03	3.13E-03	5.70E-03
Treated wood in service – bridge over pond - non-professional, as worst-case				
Scenario 7: leaching over 30 days - tier I	0.041	2.76E-04	4.65E-04	6.40E-04
Scenario 7: leaching over	0.906	6.05E-03	1.02E-02	1.41E-02

Calculated PEC/PNEC$_{surface\ water}$ values – IPBC & its metabolites PBC, Iodate and Iodide				
365 days - tier I				
Scenario 7: leaching over 5 years - tier I	**15.1**	1.01E-01	1.71E-01	0.235
Scenario 7: leaching over 15 years - tier I	**32**	0.202	0.219	0.049
Scenario 7: leaching over 30 days - tier II	2.70E-04	-	-	-
Scenario 7: leaching over 365 days - tier II	4.92E-04	-	-	-
Scenario 7: leaching over 5 years - tier II	1.64E-03	-	-	-
Scenario 7: leaching over 15 years - tier II	1.16E-03	-	-	-

For IPBC and partly its metabolites unacceptable risks were identified in scenarios 2d, 3 and additionally in scenario 4 (application, release to surface water via STP) and 7 (wood in service – bridge over pond – leaching over 365 days). These are covered by the applied risk mitigation measures (N-246, N-241 modified, N-13 and N-370) and European legislation framework.
Unacceptable risks in scenario 7 were eliminated when removal was assumed (tier II).

The calculation of the PEC/PNEC for the sediment for IPBC and its metabolites is not relevant as there is no data on sediment dwelling organisms for IPBC or PBC. Therefore, the risk assessment for sediment based on the EPM will give the same results as that for surface water. Iodate and iodide are also covered by assessment of surface water (Sweden, 2013) and (Denmark, 2008).

Conclusion: Some of the PEC/PNEC values for IPBC, permethrin and their relevant metabolites show unacceptable risks for the aquatic environment. Nevertheless, it is possible to lower the risks to an acceptable level by introducing risk mitigation measures.

Terrestrial compartment

Permethrin:

- $PNEC_{soil}$ = 0.198 mg/kg dwt (0.175 mg/kg wwt)
  (ref. Addendum to the CAR of Permethrin, 2017)

DCVA:

- $PNEC_{soil}$ = 4.6 mg/kg wwt

PBA:

- $PNEC_{soil}$ = 1.44 mg/kg wwt

Calculated PEC/ $PNEC_{soil}$ values – Permethrin & its metabolites DCVA and PBA			
	$PEC/PNEC_{soil}$ (Permethrin)	**$PEC/PNEC_{soil}$ (DCVA)**	**$PEC/PNEC_{soil}$ (PBA)**
Outdoor brushing application, house			
Scenario 2a: professional	0.2	4.07E-03	1.33E-02
Scenario 2b: non-professional	0.33	6.74E-03	2.20E-04
Dipping application, incl. storage of treated wood			
Scenario 3: storage place (initial period)	4.55E-06	9.24E-08	3.11E-07
Scenario 3: storage place (longer period) - tier I	1.11E-03	2.26E-05	7.36E-05
Scenario 3: storage place (longer period) - tier II	2.32E-05	-	-
Scenario 3: application (release via STP)	6.23E-04	1.27E-05	4.14E-05
Automated spraying (flow coating) application, incl. storage of treated wood Large plant, as worst-case			
Scenario 4: storage place (initial period)	4.55E-06	9.24E-08	3.02E-07
Scenario 4: storage place (longer period) – tier I	1.11E-03	2.26E-05	7.36E-05
Scenario 4: storage place (longer period) – tier II	2.32E-05	-	-
Scenario 4: application (release via STP)	6.63E-03	1.35E-04	4.41E-04
Treated wood in service – house - non-professional, as worst-case			
Scenario 5: leaching over 30 days – tier I	3.19E-05	6.50E-07	2.13E-06
Scenario 5: leaching over 365 days – tier I	1.74E-04	3.54E-06	1.16E-05
Scenario 5: leaching over 5 years – tier I	3.53E-04	7.15E-06	2.34E-05
Scenario 5: leaching over	3.14E-04	7.21E-06	2.36E-05

Calculated PEC/ $PNEC_{soil}$ values – Permethrin & its metabolites DCVA and PBA			
15 years – tier I			
Scenario 5: leaching over 30 days - tier II	2.90E-05	-	-
Scenario 5: leaching over 365 days - tier II	6.63E-05	-	-
Scenario 5: leaching over 5 years – tier II	2.95E-05	-	-
Scenario 5: leaching over 15 years – tier II	8.78E-06	-	-
Treated wood in service – Noise barrier			
Scenario 6: release via STP	3.21E-08	6.52E-10	2.13E-09
Scenario 6: leaching to soil over 30 days - tier I	1.19E-05	2.43E-07	7.92E-07
Scenario 6: leaching to soil over 365 days - tier I	6.51E-05	1.32E-06	4.33E-06
Scenario 6: leaching to soil over 15 years – tier I	1.33E-04	2.69E-06	8.82E-06
Scenario 6: leaching to soil over 30 days - tier II	1.08E-05	-	-
Scenario 6: leaching to soil over 365 days – tier II	2.49E-05	-	-
Scenario 6: leaching to soil over 15 years – tier II	3.72E-06	-	-

No unacceptable risk was identified for permethrin and its metabolites for the soil compartment.

IPBC:

- $PNEC_{soil}$ = 0.005 mg/kg wwt

PBC:

- $PNEC_{soil}$ = 0.149 mg/kg wwt

Iodide/iodate:

- Background level in soil: Typically, 0.5 - 20 mg/kg dwt but with extremes up to 98 mg/kg. Global mean value of 5 mg/kg dwt (20 mg/kg value used for risk assessment).

Calculated PEC/$PNEC_{soil}$ values – IPBC & its metabolites PBC, Iodate and Iodide				
	PEC/$PNEC_{soil}$ (IPBC)	**PEC/$PNEC_{soil}$ (PBC)**	**PEC/$PNEC_{soil}$ (Iodide)**	**PEC/$PNEC_{soil}$ (Iodate)**
Outdoor brushing application, house				
Scenario 2a:	**55.8**	**1.03**	6.30E-03	8.70E-03

Calculated PEC/PNEC$_{soil}$ values – IPBC & its metabolites PBC, Iodate and Iodide				
professional				
Scenario 2b: non-professional	**93.0**	**1.72**	1.05E-02	1.45E-02
Dipping application, incl. storage of treated wood				
Scenario 3: storage place (initial period)	**1.13**	0.021	1.27E-04	1.75E-04
Scenario 3: storage place (longer period) - tier I	**274**	**5.07**	3.40E-02	0.043
Scenario 3: storage place (longer period) - tier II	0.011	-	-	-
Scenario 3: application (release via STP)	0.011	2.07E-04	1.26E-06	1.74E-06
Automated spraying (flow coating) application, incl. storage of treated wood Large plant, as worst-case				
Scenario 4: storage place (initial period)	0.13	0.021	1.27E-04	1.75E-04
Scenario 4: storage place (longer period) – tier I	**274**	**5.07**	3.09E-02	0.043
Scenario 4: storage place (longer period) – tier II	0.011	-	-	-
Scenario 4: application (release via STP)	0.057	1.06E-03	6.45E-06	8.90E-06
Treated wood in service – house - non-professional, as worst-case				
Scenario 5: leaching over 30 days – tier I	**2.34**	4.33E-02	2.46E-04	3.60E-04
Scenario 5: leaching over 365 days – tier I	**51.2**	0.946	5.75E-03	7.96E-03
Scenario 5: leaching over 5 years – tier I	**854**	**15.8**	0.092	0.133
Scenario 5: leaching over 15 years – tier I	**181**	**33.6**	0.204	0.282
Scenario 5:	0.022	-	-	-

Calculated PEC/PNEC$_{soil}$ values – IPBC & its metabolites PBC, Iodate and Iodide				
leaching over 30 days - tier II				
Scenario 5: leaching over 365 days - tier II	0.039	-	-	-
Scenario 5: leaching over 5 years – tier II	0.132	0.112	-	-
Scenario 5: leaching over 15 years – tier II	9.34E-02	0.112	-	-
Treated wood in service – Noise barrier				
Scenario 6: release via STP	2.18E-04	4.04E-06	2.64E-08	3.39E-08
Scenario 6: leaching to soil over 30 days - tier I	0.872	0.016	9.85E-05	1.35E-04
Scenario 6: leaching to soil over 365 days - tier I	**19.2**	0.355	2.16E-03	2.98E-03
Scenario 6: leaching to soil over 15 years – tier I	**678**	**7.92**	0.076	0.106
Scenario 6: leaching to soil over 30 days - tier II	8.20E-03	-	-	-
Scenario 6: leaching to soil over 365 days – tier II	0.015	-	-	-
Scenario 6: leaching to soil over 15 years – tier II	0.035	0.057	-	-

Several scenarios resulted in unacceptable risks for the soil compartment for IPBC and its metabolite PBC.
To reduce the risk to acceptable levels for application by non-professionals/professionals (scenario 2a/2b) the following risk mitigation measure will be applied:

N-246: *During product application (to timbers) and whilst surfaces are drying, do not contaminate the environment. All losses of the product have to be contained by covering the ground (e.g. by tarpaulin) and disposed of in a safe way*.

N-241 modified: *Application of this product is not allowed into, above or adjacent to*

surface water. Release into the aquatic compartment must be prevented.

As reported in the Assessment Report on IPBC PT 8, *in any case risk reduction measurement at the storage sites (*scenario 3 and 4*) like covering the soil has to be done*. Also, the BPC opinion on the application for approval of the active substance permethrin in product type 8 concluded that *appropriate risk mitigation measures shall be taken to protect the soil and aquatic compartments.*

Therefore, respective risk mitigation measures will be applied:

N-13: *All industrial application processes must be carried out within a contained area situated on impermeable hard standing with bunding to prevent run-off and a recovery system in place (e.g. sump).*

N-370: *Freshly treated timber must be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water, and that any losses of the product, including any contaminated water/soil must be collected for reuse or disposal in accordance with local/national/international requirements.*

Unacceptable risks in scenario 5 and 6 are eliminated when removal is considered (tier II).

Conclusion: Some of the PEC/PNEC values for permethrin, IPBC and their relevant metabolites show unacceptable risks for the terrestrial environment. Nevertheless, it is possible to lower the risks to an acceptable level by introducing risk mitigation measures.

Groundwater

No specific limit values are established for the active substances and their metabolites (DCVA, PBA, PBC) under Directive 98/83/EC (Drinking Water Directive) and therefore, the general limit of 0.1 µg/L for organic pesticides applies. For iodide and iodate, a value of 70 µg/L was used for the risk assessment (Sweden, 2013).
Only emissions via sludge application and emission via treated wood in service – house scenario (worst-case) is considered relevant for groundwater assessment (for argumentation cf. 2.2.8.2 exposure assessment – groundwater).

Summary of PEC/PNEC$_{GW}$ for Permethrin and its metabolites			
SCENARIO	**PEC/PNEC$_{GW}$**		
	Permethrin	**DCVA**	**PBA**
Scenario 3 application (release via STP)	1.51E-03	8.06E-04	8.26E-04
Scenario 4 application (release via STP)	2.44E-02	1.30E-02	1.33E-02
Scenario 5 leaching - house over 5 years	1.09E-04	6.94E-04	7.11E-04
Scenario 5 leaching - house over 15 years	3.66E-05	7.00E-04	7.17E-04
Scenario 6 application (release via STP)	7.65E-08	4.09E-08	4.18E-08

Summary of PEC/PNEC$_{GW}$ for IPBC and its metabolites			
SCENARIO	**PEC/PNEC$_{GW}$**		
	PBC	**Iodide**	**Iodate**
Scenario 3 application (release via STP)	2.06E-02	2.41E-02	3.33E-02
Scenario 4 application (release via STP)	1.00 E-01	1.24E-01	1.71E-01
Scenario 5 leaching - house over 5 years	**9440**	**11.0**	**15.2**
Scenario 5 leaching - house over 15 years	**20032**	**23.4**	**32.2**
Scenario 6 application (release via STP)	4.01E-04	4.67E-04	6.46E-04

Summary of PEC/PNEC$_{GW}$ for IPBC metabolites			
SCENARIO	**PEC/PNEC$_{GW}$**		
	PBC	**Iodide**	**Iodate**
Scenario 5: leaching over 5 years (worst-case)	1.00E-05	1.43E-08	1.43E-08

Conclusion:
Unacceptable risks were calculated for the metabolites of IPBC for treated wood in service – leaching over 5 and 15 years, respectively. Therefore, a refinement of these values was conducted using FOCUS PEARL 4.4.4. The refinement resulted in acceptable risks for the groundwater compartment for all metabolites.

Therefore, no unacceptable risk for groundwater is expected during the use of the BPF AQUA LIGNEX I.

Primary and secondary poisoning

Primary poisoning

There is no risk of primary poisoning of non-target animals since AQUA LIGNEX I is directly applied on wood and no emission on the environment were considered.

Secondary poisoning

Permethrin:

For the risk characterisation the following PNEC-values were used:

- $PNEC_{birds}$ = 16.7 mg a.s./kg food
- $PNEC_{small\ mammals}$ = 120 mg a.s./kg food

Summary table on secondary poisoning for permethrin				
Scenario	**Concentration**	**$PEC_{oral\ predator}$**	**$PEC/PNEC_{birds}$**	**$PEC/PNEC_{mammals}$**
Scenario 7 – aquatic food chain	[mg/kg_{wwt}]	5.86E-02	3.51E-03	4.88E-04
Scenario 2b – terrestrial food chain	[mg/kg_{wwt}]	1.66E+00	9.95E-02	1.38E-02

Conclusion: The PEC/PNEC ratios for secondary poisoning for mammals and birds via ingestion of contaminated fish or earthworms are far <1 and therefore no unacceptable risk is expected.

Mixture toxicity

Following the Guidance Volume IV Environment (Part B+C) (ECHA, 2017c) a mixture toxicity assessment is required. The required data and the necessity of a mixture toxicity assessment are described in the following screening steps. The decision of concerned environmental compartments are chosen based on the decision logic of the case study "Wood preservative" described in the Guidance Volume IV Environment (Part B+C-Appendix 12), (ECHA, 2017c).

Screening step

Screening Step 1: Identification of the concerned environmental compartments

According to the intended use of the product, the applied RMMs and the exposures a mixture toxicity assessment for the following scenarios is necessary:

- STP-[6] Noise barrier
- Surface water-[6] Noise barrier
- Surface water-[7] Bridge over pond
- Sediment-[6] Noise barrier
- Sediment-[7] Bridge over pond
- Soil-[5]-House scenario
- Soil-[6]-Noise barrier

Screening Step 2: Identification of relevant substances

As relevant substances, only the active substances IPBC and permethrin were identified.

Screening Step 3: Screen on synergistic interactions

There are no evidence for synergistic effects for the product or its constituents based on the ecotoxicological studies presented.

Tiered approach

The environmental risk assessment for the product is based on the active substances permethrin and IPBC and a mixture assessment is needed.

Tier 1. PEC/PNEC summation

STP [6] Application (release via STP) – Noise barrier			
	$PEC/PNEC_{STP}$ [mg/kg_{wwt}]		PEC/PNEC summation
a.s	Permethrin	IPBC	
	1.12E-07	4.16E-03	4.16E-03

Tier 1		
RQ product	Acceptable risk for the environment? (Y/N)	Remarks
<1	Yes	No

Surface water/Sediment [6] Treated wood in service - Noise barrier			
	$PEC/PNEC_{sw/sed}$[mg/kg_{wwt}]		PEC/PNEC summation
a.s	Permethrin	IPBC	
Freshwater	1.09E-04	0.366	0.366
Sediment	1.43E-04	0.366	0.366

Tier 1		
RQ product	Acceptable risk for the environment? (Y/N)	Remarks
<1	Yes	No

Surface water/Sediment [7] Treated wood in Service - Bridge over Pond (Tier II)				
		$PEC/PNEC_{sw/sed}$[mg/kg_{wwt}]		PEC/PNEC summation
a.s		Permethrin	IPBC	
Freshwater	Time 1	9.13E-03	2.70E-04	9.40E-03
	Time 2	1.73E-02	4.92E-04	1.73E-02
	Time 3 (5y)	8.26E-03	1.64E-03	9.90E-03
	Time 3 (15y)	2.85E-03	7.04E-03	9.89E-03
Sediment	Time 1	1.16E-02	2.70E-04	1.19E-02
	Time 2	2.19E-02	4.92E-04	2.24E-02
	Time 3 (5y)	1.05E-02	1.64E-03	1.21E-02
	Time 3 (15y)	7.84E-04	7.04E-03	7.82E-03

Tier 1		
RQ product	Acceptable risk for the environment? (Y/N)	Remarks
<1	Yes	No

Soil [5] Treated wood in service - House (Tier II)			
	PEC/PNEC$_{soil}$ [mg/kg$_{wwt}$]		PEC/PNEC summation
a.s	Permethrin	IPBC	
Time 1	2.90E-05	0.022	0.022
Time 2	6.63E-05	0.039	0.039
Time 3 (5y)	2.95E-05	0.132	0.132
Time 3 (15y)	8.78E-06	0.568	0.568

Tier 1		
RQ product	Acceptable risk for the environment? (Y/N)	Remarks
<1	Yes	No

Soil [6] Treated wood in service - Noise barrier (Tier II)			
	PEC/PNEC$_{soil}$ [mg/kg$_{wwt}$]		PEC/PNEC summation
a.s	Permethrin	IPBC	
Time 1	1.08E-05	8.20E-03	8.20E-03
Time 2	2.49E-05	0.015	0.015
Time 3 (15y)	3.72E-06	0.212	0.212

Tier 1		
RQ product	Acceptable risk for the environment? (Y/N)	Remarks
<1	Yes	No

Conclusion: Acceptable cumulative risks for all compartments were identified.

Tier 2: modified Toxic Unit Summation (TUS)

Not applied

Tier 3: Standard Toxic Unit Summation (TUS)

Not applied

Tier 4: Experimental testing

Not applied

Aggregated exposure (combined for relevant emmission sources)

Aggregated exposure was assessed according to the scheme given below. The active substance(s) are of concern in other regulatory areas like e.g. cosmetics or paints and coatings (IPBC) or plant protection products (permethrin). Annual tonnages for biocidal use are not available for both substances.
The active substances are used in different user categories and they are also approved for different PTs (PT 8 and PT 18 for permethrin and PT 6, PT 8 and PT 13 for IPBC) according to the biocidal products regulation.
Although it might be possible, that use of these substances takes place at the same time, it is not likely, that they would overlap in the same space. Therefore, no aggregated exposure is calculated.

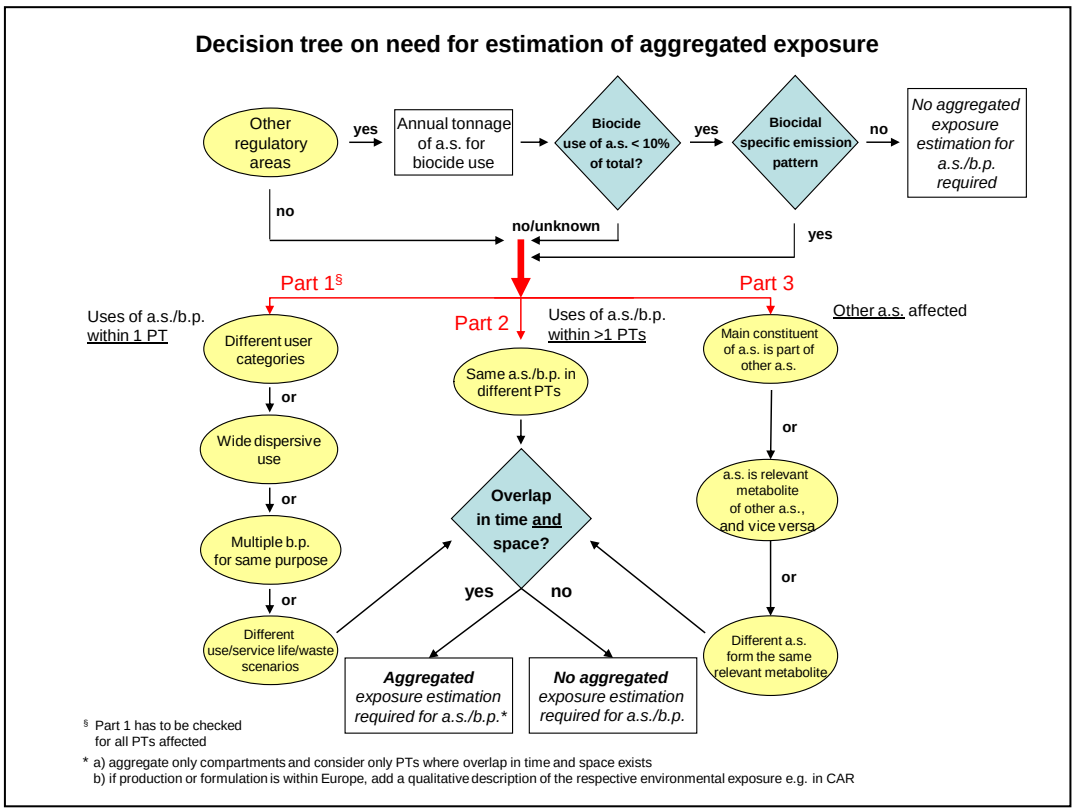


Figure 1: Decision tree on the need for estimation of aggregated exposure

Overall conclusion on the risk assessment for the environment of the product
Risk ratios were calculated for both active substances for the authorised uses and respective directly or indirectly exposed compartments. STP: No unacceptable risks were identified for the STP.

Aquatic compartment:

Unacceptable risks were calculated for surface water and sediment for scenarios [2c] and [2d] – application-bridge over pond scenario for both, permethrin and IPBC and the metabolites DCVA and PBA (only relevant in sediment).

Unacceptable risks were also calculated for Scenario [3] (for IPBC and permethrin) and [4] (only for IPBC and iodate), application release via STP also for both, surface water and sediment.

In order to reduce the calculated risks by application for the aquatic compartment, the following risk mitigation measures are introduced:

N-246: During product application (to timbers) and whilst surfaces are drying, do not contaminate the environment. All losses of the product have to be contained by covering the ground (e.g. by tarpaulin) and disposed of in a safe way.

N-241 modified: Application of this product is not allowed into, above or adjacent to surface water. Release into the aquatic compartment must be prevented.

N-13: All industrial application processes must be carried out within a contained area situated on impermeable hard standing with bunding to prevent run-off and a recovery system in place (e.g. sump)

N-370: Freshly treated timber must be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water, and that any losses of the product, including any contaminated water/soil must be collected for reuse or disposal in accordance with local/national/international requirements.

Terrestrial compartment:

For soil, unacceptable risks were identified for IPBC and its metabolite PBC, only. Respective scenarios are [2a], [2b], [3] and [4]. Further exceedances (Scenarios [5] and [6]) could be removed by considering removal (tier II).

In order to reduce the calculated risk for the terrestrial compartment, the same risk mitigation measures are introduced as for the aquatic compartment except N-241 modified (N-246, N-13 and N-370):

Groundwater:

No risks were identified for groundwater.

Finally, it can be concluded, that no unacceptable risk for the environment is posed by the authorised uses of the biocidal product family AQUA LIGNEX I, if the proposed RMMs are applied.

2.2.9 Measures to protect man, animals and the environment

Recommended methods and precautions concerning storage of active substance/biocidal product; shelf life of biocidal product:
Please cf. to chapter 2.1.4 and 2.1.5.

Recommended methods and precautions concerning fire; in case of fire nature of reaction products, combustion gases etc:
Fire extinguishing Media:CO_2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

First aid instructions, antidotes:
Please cf. to chapter 2.1.4 and 2.1.5.

Emergency measures to protect environment in case of accident:
Please cf. to chapter 2.1.4 and 2.1.5.

Control measures of repellents or poison included in the biocidal product, to prevent action against non-target organisms:
There is no risk of primary poisoning of non-target animals since the AQUA LIGNEX I is directly applied on the wood to be treated. No secondary poisoning is expected during application and service life of wood treated with AQUA LIGNEX I.

2.2.10 Assessment of a combination of biocidal products

AQUA LIGNEX I is not intended to be authorised for the use in combination with other biocidal products.

2.2.11 Assessment on endocrine disrupting properties of co-formulants

The ED assessment for the biocidal product family AQUA LIGNEX I was performed according to CA-March21_Doc.4.3 Proposal to bridge the endocrine disruptor assessment of biocidal non-active substances with REACH screening and assessment. The detailed procedure and outcome of the ED assessment is given in the confidential Annex restricted to authorities (chapter 3.6.5).

There are no significant indications of ED properties, hence the biocidal product family is not an endocrine disruptor.

2.2.12 Comparative assessment

Background

The biocidal product family „AQUA LIGNEX I" contains the active substance permethrin, which meets the criteria for substitution pursuant to Article 10(1) of the Biocides Regulation (EU) No 528/2012 (BPR) and thus it becomes a candidate for substitution (CFS). Permethrin is considered to be persistent (P) and toxic (T) but not bioaccumulative (B)[6]. Therefore, it meets two of the three criteria for being PBT in accordance with Annex XIII to Regulation (EC) No 1907/2006.
Consequently, in line with Article 23(1) of the Biocides Regulation the Austrian Competent Authority has performed a comparative assessment for the biocidal product family „AQUA LIGNEX I", based on the *„Technical Guidance Note on comparative assessment of biocidal products*" (CA-May15-Doc.4.3.a).
For this comparative assessment the Austrian Competent Authority used the list of biocidal products authorized in Austria for PT 8 (in the version of 12.05.2022), accessible on https://www.biozide.at/, which is maintained by the Environment Agency Austria („Umweltbundesamt") on behalf of the Austrian Federal Ministry for Climate Action, Environment, Energy, Mobility, Innovation and Technology („BMK"). This was done due to the lack of a tool in the current version of R4BP3 to search SPCs, pursuant to the *„Technical Guidance Note on comparative assessment of biocidal products*"(CA-May15-Doc.4.3.a).

Intended uses for the relevant biocidal product (family) in the application

The biocidal product family „AQUA LIGNEX I" belongs to product type 8 and contains next to IPBC the active substance permethrin. The product is a ready-to-use protective water-based wood preservative to be used by non-professionals, professionals and industrial users in order to control wood boring beetles (*Hylotrupes bajulus)* and wood discolouring fungi (blue stain fungi) in use class 1-3.

Product Type	8
Where relevant, an exact description of the authorised use	---
Target organism(s), development stage	Common name: wood boring beetles Scientific name: *Hylotrupes bajulus* Development stage: larvae Common name: wood discolouring fungi (bluestain) Scientific name: not applicable Development stage: no data
Field of use	Application: Non-professional (brushing): indoor, outdoor Preservation of wood for preventive use in use class 1-3.

6 Minutes of 40th BPC meeting (January 2022) (0e1c8d2b-ba6f-8199-b5d9-709bd4221fbe (europa.eu)) and CG-54-2022-13 AP 16.2 AS meeting exc subst crit 31102022

	Use class 1 (wood installed indoors not exposed to weather or wetting) is restricted to static, small-scale wooden structures. Glazed finish on wood and wood products indoors and outdoors, for wood above ground and not in direct contact to water (e.g. garage doors, wooden sidings of outer walls, etc.) Professional (brushing): indoor, outdoor Preservation of wood for preventive use in use class 1-3. Use class 1 (wood installed indoors not exposed to weather or wetting) is restricted to static, small-scale wooden structures. Glazed finish on wood and wood products indoors and outdoors, for wood above ground and not in direct contact to water (e.g. garage doors, wooden sidings of outer walls, etc.) Industrial: indoor (in industrial settings) Preservation of wood for preventive use in use class 1-3. Use class 1 (wood installed indoors not exposed to weather or wetting) is restricted to static, small-scale wooden structures. Glazed finish on wood and wood products indoors and outdoors, for wood above ground and not in direct contact to water (e.g. garage doors, wooden sidings of outer walls, etc.)
Category(ies) of users	Non-professionals, professionals, industrial
Application method(s)	Non-professionals: brushing Professionals: brushing Industrials: Brushing, automated spraying, dipping or flow coating/deluge treatment in industrial settings.

As stated in CA-May15-Doc.4.3.a – Final, elements 1 to 5 in the table above should be considered as the critical ones. But the AT CA mentions, that in (33) of Note for Guidance it is stated that, if an *„eCA considers that an application method makes that the BP is used in practice for very different purposes or under very different circumstances […], some application methods could be considered as separate uses to be covered under the comparative assessment."* Furthermore, according to (57) *„at least three different and independent active substances/mode of action combinations should remain available through authorized BPs for a given use […] in order to consider that the chemical diversity is adequate."*
Therefore the application method might be taken into consideration as the exposure differs depending on the application methods.

Mapping of existing alternatives to the relevant biocidal product in Austria:

Identified eligible alternative biocidal products:
According to the information available to the AT CA, there are over 700 trade names of biocidal products authorized in Austria under product type 8 (wood preservatives), based on a significantly lower number of biocidal product/s (families).

Currently in Austria there are 21 biocidal product (families) against *Hylotrupes bajulus* L. authorised. But only 3 of these are authorized for the control of wood discolouring fungi too. These are listed in the following table:

Remark: In order to avoid any double usage of biocidal products to control the mentioned target organisms these are assessed as one.

Product name	**Active substance**	**Target organism(s)**	**Application method(s)**	**Categories of users**
TEKNOL AQUA 1415-01	Propiconazol Permethrin IPBC	Wood rotting fungi, wood discolouring fungi, *Reticulitermes* spp., *Hylotrupes bajulus* L., *Anobium punctatum* De Geer, *Lyctus brunneus*	Professionals: Brushing, manual dipping Industrials: manual and automated dipping	Professionals, industrials
TWP 092i	IPBC Propiconazol Cypermethrin	Wood destroying fungi (brown rot fungi): *Gloeophyllum trabeum* *Coniophora puteana* *Poria Placenta* Blue stain fungi: *Aureobasidium pullulans* *Sclerophoma pithyophilla* Wood boring insects: *Hylotrupes bajulus* L. Termites: *Reticulitermes termites*	Brushing and rolling	Non-professionals, professionals
Induline SW-900 IT	Cypermethrin IPBC Propiconazol	*Sclerophoma pithyophila, Aureobasidium pullulans* spp. *Coniophora puteana*, *Gloeophyllum trabeum*, *Poria placenta* *Coriolus versicolor* *Hylotrupes bajulus* L. *Anobium punctatum* De Geer *Reticulitermes* spp.	Professionals, trained professionals: Brushing Industrials: Fully automated dipping, flow coating, spraying in closed facilities (spray tunnel)	Professionals, industrials
Koranol Holzbau Grund	IPBC Permethrin Propiconazol	*Ascomycetes* – Wood discolouring fungi - hyphae *Basidiomycetes* – Wood rotting fungi - hyphae *Hylotrupes bajulus* – House longhorn beetle - larvae - Termites (genus *Reticulitermes*)	Professionals: Manual dipping brushing, borehole injection with and without pressure Industrials: Fully automated dipping, manual dipping, Flow coating (deluging)	Professionals, industrials

			Preventive and curative uses.	

Taking a closer look on the already authorised biocidal products against the target organisms it crystallises, that all of them contain – amongst others - the active substance propiconazol, which fulfills the exclusion criteria for being reprotoxic 1B. All of them contain IBPC and two each cypermethrin and permethrin respectively with both having the same mode of action. Three are authorised for professional and industrial usage and just one is authorised for non-professional use (and professional as well). Thus it becomes the only alternative for brushing for non-professional use.

Identified eligible non-chemical alternatives
Eligible non-chemical alternatives are non-chemical means of control and prevention methods. These should already exist on the EU market and for which the eCA, on the basis of the available information, considers that there is robust evidence that the alternative does not give rise to concern in terms of safety for humans, animals or the environment and has demonstrated sufficient effectiveness under field conditions.
According to the AT CA, there are no such non-chemical alternatives that have sufficient efficiency and at the same time no significant economic or practical disadvantages to be applied on a large scale.

Screening phase

Description of the assessment of the adequate chemical diversity in authorized biocidal products to minimize the occurrence of resistance and conclusion.

Chemical diversity
Article 23(3)(b) BPR refers to the adequate chemical diversity of the available active substances within a given product type/use/target organism combination as one of the two sine qua non conditions to be met in order to allow a restriction or prohibition of a biocidal product subject to comparative assessment. During the screening phase, it shall be checked whether the diversity of the active substance, product type and mode of action combination in authorised biocidal products is adequate to minimise the occurrence of resistance in the target organisms. The screening phase shall allow through a simple assessment to judge whether it is required or not to perform a comprehensive comparative assessment. As proposed as general rule in ”CA-May15-Doc.4.3.a” at least three different and independent active substance/mode of action - combinations should be available through authorized biocidal products for a given use to provide adequate chemical diversity as stipulated by Article 23(3)(b) BPR.

Mode of action:
Permethrin belongs to the group of pyrethroids, which are sodium channel modulators. Their mode of action is to keep sodium channels open, causing hyperexcitation and, in some cases, nerve block.
Sodium channels are involved in the propagation of action potentials along nerve axons.

Consideration on whether the CFS(s) meet(s) at least one of the exclusion criteria listed in Article 5(1) but can benefit from derogation in accordance with Article 5(2) of the BPR
The active substance permethrin is neither carcinogenic, mutagenic or reprotoxic, nor is it a PBT or vPvB substance and therefore it does not meet any of the exclusion criteria in Article 5(1) of Regulation (EU) No 528/2012. But as mentioned before, it meets two of the

three criteria for being PBT in accordance with Annex XIII to Regulation (EC) No 1907/2006 and thus it becomes a candidate substitution pursuant to Article 10(1) of the BPR.

Conclusion of the screening phase:
Stop comparative assessment. Taking into account the available information summarised here, the Austrian Competent Authority concludes that the chemical diversity of active substances in authorized biocidal products to minimize the occurrence of resistance cannot be assured. Additionally the current biocidal product becomes the only alternative for some uses without an active substance that fulfills exclusion criteria.
In line with Article 23(3)(a) and (b) of the BPR, the Note for Guidance (CA-May15-Doc.4.3.a – Final) and since permethrin does not meet the exclusion criteria as outlined in Article 5(1) of the BPR, it is valid to conduct no further investigation at this point; comparative assessment is stopped and finalized at this stage.
The biocidal product family "AQUA LIGNEX" will be authorised for a period not exceeding 5 years in accordance with Article 23(6) of Regulation (EU) No 528/2012.

3 ANNEXES

3.1 List of studies for the biocidal product (family)

Section No. in IUCLID	Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
3.1 3.2 3.9	Anonymous	2016a	**Chemical and physical caracterization on test item "Aqua Lignex I"**	Eurofins Biolab srl	S-2016-00291 AM	yes	yes	J.F. Amonn S.P.A./AG Divisione Color Via Altmann, 12 I-39100 Bolzano
3.3	Anonymous	2021a	**Aqua Lignex I 03-Kastanie//Castagno: Determination of the Relative Density**	ChemService S.r.l. Controlli e Ricerche	CH – 0513/2021	yes	yes	J.F. Amonn S.r.l./GmbH Via Altmann 12, I-39100 Bolzano, Italy
3.4.1.1	Anonymous	2016b	**Accelerated stability test (35°C) of wood preservation formulation Aqua Lignex I 03-Kastanie (HSL 298)**	MPA Eberswalde	31/15/2618/07	no	yes	Amonn Coatings GmbH An der Landesbahn 7 A-2100 Korneuburg
3.8	Anonymous	2017a	**Surface Tension on the Sample AQUA LIGNEX I**	Innovhub – Stazioni Sperimentali per l'Industria	1602486	yes	yes	J.F. Amonn S.P.A./AG Divisione Color Via Altmann,

								12 I-39100 Bolzano
4.2 4.17	Anonymous	2016c	**Flash point and Auto-Ignition Temperature on the Sample Aqua Lignex I**	Innovhub – Stazioni Sperimentali per l'Industria	201600612	yes	yes	J.F. Amonn S.P.A./AG Divisione Color Via Altmann, 12 I-39100 Bolzano
3.4.2.3 4.16	Anonymous	2016d	**Corrosion properties of test item „Aqua Lignex I"**	Eurofins Biolab srl	S-2016-00696 AM	yes	yes	J.F. Amonn S.P.A./AG Divisione Color Via Altmann, 12 I-39100 Bolzano
3.4.1.2	Anonymous	2018a	**Long term stability test of wood preservation formulation – Aqua Lignex I 03-Kastanie (HSL 298)**	MPA Eberswalde	31/15/2618/03D	no	yes	Amonn Coatings GmbH An der Landesbahn 7 A-2100 Korneuburg
5	Anonymous	2016e	**Long term stability test of wood preservation formulation – Aqua Lignex I 03-Kastanie (HSL 298)**	MPA Eberswalde	31/15/2618/03B	no	yes	Amonn Coatings GmbH An der Landesbahn 7 A-2100 Korneuburg
6.7	Anonymus	2016f	Determination of the preventive action against recently hatched larvae of	MPA Eberswalde	32/15/9871/03A	no	yes	Amonn Coatings GmbH An der

			Hylotrupes bajulus (L.) according to EN 46-1 (2009) after evaporative ageing procedure according to EN 73 (2014)					Landesbahn 7 A-2100 Korneuburg
6.7	Anonymus	2016g	Determination of the preventive action against recently hatched larvae of *Hylotrupes bajulus* (L.) according to EN 46-1 (2009) after leaching procedure according to EN 84 (1997)	MPA Eberswalde	32/15/9871/04A	no	yes	Amonn Coatings GmbH An der Landesbahn 7 A-2100 Korneuburg
6.7	Anonymus	2016h	Laboratory method for determining the protective effectiveness of a preservative treatment against blue stain according to EN 152 (2011) after 4 weeks artificial weathering.	MPA Eberswalde	32/15/9871/02A	no	yes	Amonn Coatings GmbH An der Landesbahn 7 A-2100 Korneuburg
6.7	Anonymus	2016i	Laboratory method for determining the protective effectiveness of a preservative treatment against blue stain according to EN 152 (2011) after 6 months of field testing.	MPA Eberswalde	32/15/9871/01A	no	yes	Amonn Coatings GmbH An der Landesbahn 7 A-2100 Korneuburg
8.1.1	Anonymous	2016j	IN VITRO SKIN CORROSION – RECONSTRUCTED HUMAN EPIDERMIS (RHE) TEST METHOD ACCORDING TO OECD	Eurofins Biolab S.r.l	S-2016-00293 AM	Yes	Yes	J.F. AMON SPA/AG, Divisione Color

			N. 431 ON: "AQUA LIGNEX I"					
8.1.1	Anonymous	2016k	IN VITRO SKIN IRRITATION – RECONSTRUCTED HUMAN EPIDERMIS (RHE) TEST METHOD ACCORDING TO OECD N. 439 ON: "AQUA LIGNEX I"	Eurofins Biolab S.r.l	S-2016-00294 AM	Yes	Yes	J.F. AMON SPA/AG, Divisione Color
8.1.2	Anonymous	2016l	SCREENING FOR THE EYE IRRITANCY POTENTIAL USING THE BOVINE CORNEAL OPACITY AND PERMEABILITY ASSAY WITH AQUA LIGNEX I	BSL BIOSERVICE	162770	Yes	Yes	J.F. AMON SPA/AG, Divisione Color
8.1.2	Anonymous	2017b	In vitro ocular irritation on "Aqua Lignex I": reconstructed epiocular tissue model test method	Eurofins Biolab Srl	S-2016-03306 AM	Yes	Yes	J.F Amonn SPA
8.5.1	Anonymous	2016m	ACUTE ORAL TOXICITY - FIXED DOSE METHOD - ON "AQUA LIGNEX I"	Eurofins Biolab Srl	S-2016-01213	Yes	Yes	J.F. AMON SPA/AG, Divisione Color
9.2.1.1	Anonymous	2016n	Short-term toxicity to fish OECD Guideline 203 (Fish, Acute Toxicity Test)	Eurofins Biolab Srl	S-2016-00295AM	Yes	Yes	J.F. AMON SPA/AG, Divisione Color
9.2.1.2	Anonymous	2016o	Short-term toxicity to aquatic invertebrates, OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test)	Eurofins Biolab Srl	S-2016-00296AM	Yes	Yes	J.F. AMON SPA/AG, Divisione Color
9.2.1.3	Anonymous	2016p	Toxicity to aquatic	Eurofins Biolab Srl	S-2016-00297AM	Yes	Yes	J.F. AMON

			algae and cyanobacteria, OECD Guideline 201 (Freshwater Alga and Cyanobacteria, Growth Inhibition Test)					SPA/AG, Divisione Color
10.2	Anonymous	2016q	Aerobic biodegradability, OECD 310:2006	Eurofins Biolab Srl	S-2016-00298AM	Yes	Yes	J.F. AMON SPA/AG, Divisione Color
10.3	Anonymous	2017c	NT Build 509 " Leaching of active ingredients from preservative-treated timber-Semi-field testing"	MPA Eberswalde - Materialprüfanstalt Brandenburg GmbH	No. 31/15/2468/03/C	Yes	Yes	J.F. AMON SPA/AG, Divisione Color

3.2 Output tables from exposure assessment tools

HUMAN EXPOSURE:

Tabelle final AL
HExpo_update_com

ENVIRONMENTAL EXPOSURE

EUSES output files permethrin

Outdoor brushing application, house

STUDY		
STUDY IDENTIFICATION		
Study name	AQUA LIGNEX I-scenario2	S
Study description	PERMETHRIN	S
Author		D
Institute		D
Address		D
Zip code		D
City		D
Country		D
Telephone		D
Telefax		D
Email		D
Calculations checksum	810BEE0E	S

Outdoor brushing application, bridge over pond

STUDY		
STUDY IDENTIFICATION		
Study name	AQUA LIGNEX I-scenario2	S
Study description	PERMETHRIN	S
Author		D
Institute		D
Address		D
Zip code		D
City		D
Country		D
Telephone		D
Telefax		D
Email		D
Calculations checksum	0BEB8BFD	S

Dipping application, incl. storage of treated wood

STUDY
STUDY IDENTIFICATION

Study name	AQUA LIGNEX I	S
Study description	PERMETHRIN-scenario 3	S
Author		D
Institute		D
Address		D
Zip code		D
City		D
Country		D
Telephone		D
Telefax		D
Email		D
Calculations checksum	3A30A330	S

Automated spraying (flow coating) application, incl. storage of treated wood
Large plant, as worst-case

STUDY
STUDY IDENTIFICATION

Study name	AQUA LIGNEX I-scenario 4	S
Study description	PERMETHRIN-scenario 4	S
Author		D
Institute		D
Address		D
Zip code		D
City		D
Country		D
Telephone		D
Telefax		D
Email		D
Calculations checksum	0D2FE1D3	S

Treated wood in service – house - non-professional, as worst-case

STUDY
STUDY IDENTIFICATION

Study name	AQUA LIGNEX I-scenario 5	S
Study description	PERMETHRIN-scenario 5	S
Author		D
Institute		D
Address		D
Zip code		D
City		D
Country		D
Telephone		D
Telefax		D
Email		D
Calculations checksum	0E7B69D5	S

Treated wood in service – Noise barrier

STUDY		
STUDY IDENTIFICATION		
Study name	AQUA LIGNEX I-scenario 6	S
Study description	PERMETHRIN-scenario 6	S
Author		D
Institute		D
Address		D
Zip code		D
City		D
Country		D
Telephone		D
Telefax		D
Email		D
Calculations checksum	5C4906BE	S

Treated wood in service – bridge over pond - non-professional, as worst-case

STUDY		
STUDY IDENTIFICATION		
Study name	AQUA LIGNEX I-scenario 7	S
Study description	PERMETHRIN-scenario 7	S
Author		D
Institute		D
Address		D
Zip code		D
City		D
Country		D
Telephone		D
Telefax		D
Email		D
Calculations checksum	76E9211C	S

EUSES output files IPBC

Outdoor brushing application, house

STUDY
STUDY IDENTIFICATION

Study name	AQUA LIGNEX-IPBC 2	S
Study description	SCENARIO 2	S
Author		D
Institute		D
Address		D
Zip code		D
City		D
Country		D
Telephone		D
Telefax		D
Email		D
Calculations checksum	95F473DE	S

Outdoor brushing application, bridge over pond

STUDY
STUDY IDENTIFICATION

Study name	AQUA LIGNEX-IPBC 2	S
Study description	SCENARIO 2	S
Author		D
Institute		D
Address		D
Zip code		D
City		D
Country		D
Telephone		D
Telefax		D
Email		D
Calculations checksum	65BDBC2C	S

Dipping application, incl. storage of treated wood

STUDY			
STUDY IDENTIFICATION			
Study name	AQUA LIGNEX-IPBC 3		S
Study description	SCENARIO 3		S
Author			D
Institute			D
Address			D
Zip code			D
City			D
Country			D
Telephone			D
Telefax			D
Email			D
Calculations checksum	7E4B2255		S
DEFAULTS			
DEFAULT IDENTIFICATION			
General name	Standard Euses 2.2		D
Description	According to Vol. IV Part B+C and R16		D
CHARACTERISTICS OF COMPARTMENTS			
GENERAL			
Density of solid phase	2.5	[kg.l-1]	D
Density of water phase	1	[kg.l-1]	D
Density of air phase	1.3E-03	[kg.l-1]	D
Environmental temperature	12	[oC]	D
Standard temperature for Vp and Sol	25	[oC]	D
Temperature correction method	Temperature correction for local distribution		D
Constant of Junge equation	0.01	[Pa.m]	D
Surface area of aerosol particles	0.01	[m2.m-3]	D
Gas constant	8.314472	[Pa.m3.mol-1.K-1]	D
SUSPENDED MATTER			
Volume fraction solids in suspended matter	0.1	[m3.m-3]	D
Volume fraction water in suspended matter	0.9	[m3.m-3]	D
Weight fraction of organic carbon in suspended matter	0.1	[kg.kg-1]	D
Bulk density of suspended matter	1.15E+03	[kgwwt.m-3]	O
Conversion factor wet-dry suspended matter	4.6	[kgwwt.kgdwt-1]	O
SEDIMENT			
Volume fraction solids in sediment	0.2	[m3.m-3]	D
Volume fraction water in sediment	0.8	[m3.m-3]	D
Weight fraction of organic carbon in sediment	0.05	[kg.kg-1]	D
SOIL			
Volume fraction solids in soil	0.6	[m3.m-3]	D
Volume fraction water in soil	0.2	[m3.m-3]	D
Volume fraction air in soil	0.2	[m3.m-3]	D
Weight fraction of organic carbon in soil	0.02	[kg.kg-1]	D
Weight fraction of organic matter in soil	0.034	[kg.kg-1]	O
Bulk density of soil	1.70026E+03	[kgwwt.m-3]	O
Conversion factor wet-dry soil	1.133507	[kgwwt.kgdwt-1]	O
STP SLUDGE			
Fraction of organic carbon in raw sewage sludge	0.3	[kg.kg-1]	D
Fraction of organic carbon in settled sewage sludge	0.3	[kg.kg-1]	D
Fraction of organic carbon in activated sewage sludge	0.37	[kg.kg-1]	D
Fraction of organic carbon in effluent sewage sludge	0.37	[kg.kg-1]	D

Automated spraying (flow coating) application, incl. storage of treated wood Large plant, as worst-case

STUDY
STUDY IDENTIFICATION

Study name	AQUA LIGNEX-IPBC 4	S
Study description	SCENARIO 4	S
Author		D
Institute		D
Address		D
Zip code		D
City		D
Country		D
Telephone		D
Telefax		D
Email		D
Calculations checksum	0038CB0F	S

Treated wood in service – house - non-professional, as worst-case

STUDY
STUDY IDENTIFICATION

Study name	AQUA LIGNEX-IPBC 5 amat	S
Study description	SCENARIO 5 amat	S
Author		D
Institute		D
Address		D
Zip code		D
City		D
Country		D
Telephone		D
Telefax		D
Email		D
Calculations checksum	994B145A	S

Treated wood in service – Noise barrier

STUDY
STUDY IDENTIFICATION

Study name	AQUA LIGNEX-IPBC 6	S
Study description	SCENARIO 6	S
Author		D
Institute		D
Address		D
Zip code		D
City		D
Country		D
Telephone		D
Telefax		D
Email		D
Calculations checksum	4FF0405A	S

Treated wood in service – bridge over pond - non-professional, as worst-case

STUDY		
STUDY IDENTIFICATION		
Study name	AQUA LIGNEX-IPBC 7	S
Study description	SCENARIO 7	S
Author		D
Institute		D
Address		D
Zip code		D
City		D
Country		D
Telephone		D
Telefax		D
Email		D
Calculations checksum	516CC740	S

FOCUS PEARL files

FOCUS PEARL input files

Treated wood in service – house - non-professional, as worst-case


Input for FOCUS PEARL.xlsx


PBC_input_focus pearl.txt

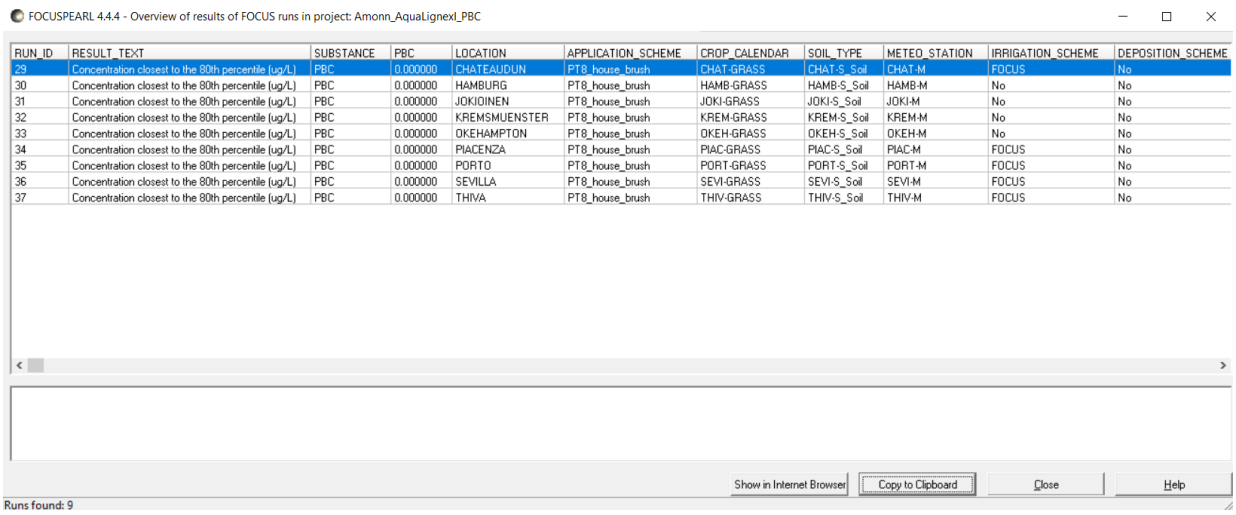

Iodide_input_focus pearl.txt


Iodate_input_focus pearl.txt

FOCUS PEARL output files

Treated wood in service – house - non-professional, as worst-case


PBC_output_focus pearl.txt



RUN_ID	RESULT_TEXT	SUBSTANCE	PBC	LOCATION	APPLICATION_SCHEME	CROP_CALENDAR	SOIL_TYPE	METEO_STATION	IRRIGATION_SCHEME	DEPOSITION_SCHEME
29	Concentration closest to the 80th percentile (ug/L)	PBC	0.000000	CHATEAUDUN	PT8_house_brush	CHAT-GRASS	CHAT-S_Soil	CHAT-M	FOCUS	No
30	Concentration closest to the 80th percentile (ug/L)	PBC	0.000000	HAMBURG	PT8_house_brush	HAMB-GRASS	HAMB-S_Soil	HAMB-M	No	No
31	Concentration closest to the 80th percentile (ug/L)	PBC	0.000000	JOKIOINEN	PT8_house_brush	JOKI-GRASS	JOKI-S_Soil	JOKI-M	No	No
32	Concentration closest to the 80th percentile (ug/L)	PBC	0.000000	KREMSMUENSTER	PT8_house_brush	KREM-GRASS	KREM-S_Soil	KREM-M	No	No
33	Concentration closest to the 80th percentile (ug/L)	PBC	0.000000	OKEHAMPTON	PT8_house_brush	OKEH-GRASS	OKEH-S_Soil	OKEH-M	No	No
34	Concentration closest to the 80th percentile (ug/L)	PBC	0.000000	PIACENZA	PT8_house_brush	PIAC-GRASS	PIAC-S_Soil	PIAC-M	FOCUS	No
35	Concentration closest to the 80th percentile (ug/L)	PBC	0.000000	PORTO	PT8_house_brush	PORT-GRASS	PORT-S_Soil	PORT-M	FOCUS	No
36	Concentration closest to the 80th percentile (ug/L)	PBC	0.000000	SEVILLA	PT8_house_brush	SEVI-GRASS	SEVI-S_Soil	SEVI-M	FOCUS	No
37	Concentration closest to the 80th percentile (ug/L)	PBC	0.000000	THIVA	PT8_house_brush	THIV-GRASS	THIV-S_Soil	THIV-M	FOCUS	No

Iodide_output_focus pearl.txt

FOCUSPEARL 4.4.4 - Overview of results of FOCUS runs in project: Amonn_AquaLignexI_iodide

RUN_ID	RESULT_TEXT	SUBSTANCE	IOD1	LOCATION	APPLICATION_SCHEME	CROP_CALENDAR	SOIL_TYPE	METEO_STATION	IRRIGATION_SCHEME	DEPOSITION_SCHEME	REPORT_TYPE
38	Concentration closest to the 80th percentile (ug/L)	IOD1	0.000000	CHATEAUDUN	PT8_house_brush_iodide	CHAT-GRASS	CHAT-S_Soil	CHAT-M	FOCUS	No	Leaching
39	Concentration closest to the 80th percentile (ug/L)	IOD1	0.000000	HAMBURG	PT8_house_brush_iodide	HAMB-GRASS	HAMB-S_Soil	HAMB-M	No	No	Leaching
40	Concentration closest to the 80th percentile (ug/L)	IOD1	0.000000	JOKIOINEN	PT8_house_brush_iodide	JOKI-GRASS	JOKI-S_Soil	JOKI-M	No	No	Leaching
41	Concentration closest to the 80th percentile (ug/L)	IOD1	0.000000	KREMSMUENSTER	PT8_house_brush_iodide	KREM-GRASS	KREM-S_Soil	KREM-M	No	No	Leaching
42	Concentration closest to the 80th percentile (ug/L)	IOD1	0.000000	OKEHAMPTON	PT8_house_brush_iodide	OKEH-GRASS	OKEH-S_Soil	OKEH-M	No	No	Leaching
43	Concentration closest to the 80th percentile (ug/L)	IOD1	0.000000	PIACENZA	PT8_house_brush_iodide	PIAC-GRASS	PIAC-S_Soil	PIAC-M	FOCUS	No	Leaching
44	Concentration closest to the 80th percentile (ug/L)	IOD1	0.000000	PORTO	PT8_house_brush_iodide	PORT-GRASS	PORT-S_Soil	PORT-M	FOCUS	No	Leaching
45	Concentration closest to the 80th percentile (ug/L)	IOD1	0.000000	SEVILLA	PT8_house_brush_iodide	SEVI-GRASS	SEVI-S_Soil	SEVI-M	FOCUS	No	Leaching
46	Concentration closest to the 80th percentile (ug/L)	IOD1	0.000000	THIVA	PT8_house_brush_iodide	THIV-GRASS	THIV-S_Soil	THIV-M	FOCUS	No	Leaching

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Runs found: 9

Iodate_output_focus pearl.txt

FOCUSPEARL 4.4.4 - Overview of results of FOCUS runs in project: Amonn_AquaLignexI_iodate

RUN_ID	RESULT_TEXT	SUBSTANCE	IOD2	LOCATION	APPLICATION_SCHEME	CROP_CALENDAR	SOIL_TYPE	METEO_STATION	IRRIGATION_SCHEME	DEPOSITION_SCHEME	REPORT_TYPE
2	Concentration closest to the 80th percentile (ug/L)	IOD2	0.000000	CHATEAUDUN	PT8_house_brush_iodate	CHAT-GRASS	CHAT-S_Soil	CHAT-M	FOCUS	No	Leaching
3	Concentration closest to the 80th percentile (ug/L)	IOD2	0.000000	HAMBURG	PT8_house_brush_iodate	HAMB-GRASS	HAMB-S_Soil	HAMB-M	No	No	Leaching
4	Concentration closest to the 80th percentile (ug/L)	IOD2	0.000000	JOKIOINEN	PT8_house_brush_iodate	JOKI-GRASS	JOKI-S_Soil	JOKI-M	No	No	Leaching
5	Concentration closest to the 80th percentile (ug/L)	IOD2	0.000000	KREMSMUENSTER	PT8_house_brush_iodate	KREM-GRASS	KREM-S_Soil	KREM-M	No	No	Leaching
6	Concentration closest to the 80th percentile (ug/L)	IOD2	0.000000	OKEHAMPTON	PT8_house_brush_iodate	OKEH-GRASS	OKEH-S_Soil	OKEH-M	No	No	Leaching
7	Concentration closest to the 80th percentile (ug/L)	IOD2	0.000000	PIACENZA	PT8_house_brush_iodate	PIAC-GRASS	PIAC-S_Soil	PIAC-M	FOCUS	No	Leaching
8	Concentration closest to the 80th percentile (ug/L)	IOD2	0.000000	PORTO	PT8_house_brush_iodate	PORT-GRASS	PORT-S_Soil	PORT-M	FOCUS	No	Leaching
9	Concentration closest to the 80th percentile (ug/L)	IOD2	0.000000	SEVILLA	PT8_house_brush_iodate	SEVI-GRASS	SEVI-S_Soil	SEVI-M	FOCUS	No	Leaching
10	Concentration closest to the 80th percentile (ug/L)	IOD2	0.000000	THIVA	PT8_house_brush_iodate	THIV-GRASS	THIV-S_Soil	THIV-M	FOCUS	No	Leaching

3.3 New information on the active substance

Not available.

3.4 Residue behaviour

Not available.

3.5 Summaries of the efficacy studies (B.5.10.1-xx)[7]

Please refer to the 6.7 IUCLID section.

3.6 Confidential annex

Please refer to separate document.

3.7 Other Information

3.7.1 Reference list (excluding list of studies, cf. to chapter 3.1)

Anonymous (1999). Estrogenic and antiestrogenic activity of octamethylcyclotetrasiloxane (D4) in Sprague-Dawley and Fischer 344 immature female rats using an uterotrophic assay. May 26, 1999

CA-March-Doc.4.3 (2021). Proposal to bridge the endocrine disruptor assessment of biocidal non-active substances with REACH screening and assessment. March, 2021

CA-June22-Doc.4.8 (2022). CA Identification as a substance of concern of a non-active substance meeting the criteria for being endocrine disruptor. June, 2022

Coordination group 2021: Harmonized appr._SoC and workplace exp. limits_vf. Final version – agreed CG-45

Denmark 2007, COMPETENT AUTORITY REPORT IPBC Product type 8, Doc II + III, August 2007

Denmark 2008, Assessment Report IPBC, Product type 8, 22 February 2008; Available at: https://echa.europa.eu/documents/10162/9d72fc6a-6a37-045e-7609-975327cca21d

Denmark 2018, PRODUCT ASSESSMENT REPORT, TWP 097i, PT 8, January 2018

Denmark 2021, PRODUCT ASSESSMENT REPORT, TEKNOL AQUA 1411-01, PT 8, February 2021

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

EC 2002a: Human Exposure to Biocidal Products (TNsG June 2002), *User guidance version 1*

EC 2002b: Human Exposure to Biocidal Products (TNsG June 2002), *Guidance on Exposure Estimation, part 2*

EC 2002c: Human Exposure to Biocidal Products (TNsG June 2002), *Guidance on Exposure Estimation, part 3*

EC 2005, Report of the Leaching Workshop (open session), June 2005; https://echa.europa.eu/documents/10162/16908203/pt8_leaching_workshop_2005_en.pdf

EC 2008: HEEG Opinion 1 *HEEG Opinion on the use of available data and models for the assessment of the exposure of operators during the loading of products into vessels or systems in industrial scale*

EC 2009: HEEG Opinion 8 *HEEG opinion Defaults and appropriate models to assess human exposure for dipping processes (PT 8)*

EC 2010a: HEEG Opinion 9 *Default protection factors for protective clothing and gloves*

EC 2010b: HEEG Opinion 11 *HEEG opinion on Exposure model Primary exposure scenario – washing out of a brush which has been used to apply a paint*

EC 2011 HEEG: Opinion 13 *HEEG opinion on Assessment of Inhalation Exposure of Volatilised Biocide Active Substance*

ECHA 2012: Guidance on information requirements and chemical safety assessment. Chapter R.8: Characterisation of dose (concentrations)-response for human health, V 2.1, November 2012

ECHA 2014, Follow-up of the 2nd EU Leaching Workshop on wood preservatives, September 2014

ECHA 2015a: *Biocides Human Health Exposure Methodology*, Version 1, October 2015

ECHA 2015b: HEAdhoc Recommendation no. 5 *Non-professional use of antifouling paints: exposure assessment for a toddler*

ECHA 2017a HEAdhoc Recommendation no. 14 *Default human factor values for use in exposure assessments for biocidal products*

ECHA 2017b: Guidance on the Biocidal Products Regulation, Volume III Human Health - Assessment & Evaluation (Parts B+C) Version 4.0

ECHA 2017c, Guidance on the Biocidal Products Regulation. Volume IV Environment - Assessment and Evaluation (Parts B + C), Version 2.0, ECHA October 2017

ECHA 2018, Guidance on the Biocidal products regulation. Volume II Efficacy – Assessment and Evaluation (Parts B+C). Version 3.0, April 2018.

ECHA 2020: HEAdhoc Recommendation no. 6 *Methods and models to assess exposure to biocidal products in different product types, version 4*

ECHA 2021a: *Technical Agreements for Biocides - Human Health (TOX)*, August 2021

ECHA 2021b, Technical Agreements for Biocides Environment (ENV), Release date: 9 November 2021

ECHA 2021c: Guide on the classification and labelling of titanium dioxide, 1. Edition

EFSA 2017: Guidance on dermal absorption, European Food Safety Authority. EFSA Journal 2017;15(6):4873

Franzen A, Greene T, Van Landingham C, Gentry R. Toxicology of octamethylcyclotetrasiloxane (D4). Toxicol Lett. 2017 Oct 20; 279 Suppl 1:2-22. doi: 10.1016/j.toxlet.2017.06.007

Germany 2022a, PRODUCT ASSESSMENT REPORT, Aqua Primer PIP, PT 8, July 2022

Germany 2022b, PRODUCT ASSESSMENT REPORT, Primer TIP, PT 8, August 2022

Ireland 2014, Assessment Report Permethrin, Product type 8, April 2014; Available at: https://echa.europa.eu/documents/10162/49872cf9-4c65-ce75-2230-d7d8befef7ab

Ireland 2017, Addendum to Assessment Report for Permethrin, Product type 8 and 18, March 2017; Available at: https://echa.europa.eu/documents/10162/73628fe1-d739-97db-2aa8-d165e6898008

Jean PA, Sloterb ED, Plotzke KP (2017). Effects of chronic exposure to octamethylcyclotetrasiloxane and decamethylcyclopentasiloxane in the aging female Fischer 344 rat, Toxicology Letters 279, 54–74

Kollmann, F.F.P., Coté Jr., W.A. (1968) *Principles of Wood Science and technology*. Springer Verlag.

MAK-Commission 2002: The MAK-Collection for Occupational Health and Safety (2002). Weinheim, Germany: Wiley-VCH Verlag GmbH & Co. KGaA.

OECD 2013, OECD Series on Emission Scenario Documents Number 2. Revised Emission Scenario Document for Wood Preservatives, Paris, France.

RAC 2012, Opinion proposing harmonised classification and labelling at EU level of 3-iodo-2-propynyl butylcarbamate (IPBC), 28 November 2012; Available at: https://echa.europa.eu/documents/10162/90b1f273-b977-465f-297a-f30168ca947c

Siddiqui, WH, Stump DG, Plotzke KP, Holson JF, and Meeks RG (2007) A two-generation reprod uctive toxicity study of octamethylcyclotetrasiloxane (D4) in rats exposed by wholebody vapor inhalation. Reproductive Toxicology 23: 202-215

Sweden 2013, Assessment Report Iodine, Product type 1, 3, 4, 22, December 2013; Available at: https://echa.europa.eu/documents/10162/58304937-b2c6-6bb8-4f76-e86037bff558

Voss, G. (1987) *Insecticide/acaricide resistance: industry's efforts and plans to cope.* International Congress of plant Protection, 1987, Abstract 88.

WOOD PRESERVATION & WOOD PRODUCTS TREATMENT PEST CONTROL STUDY GUIDE (2004-2005 Version), Volume X, edited by Cichowlaz, S.D., Nevada State Dept. of Agriculture

LEGAL NORMS

Regulation (EC) No 1272/2008: Commission Regulation (EU) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006; Available at: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02008R1272-20170101

Regulation (EU) 2017/623: Commission Regulation (EU) 2017/623 of 30 March 2017 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acequinocyl, amitraz, coumaphos, diflufenican, flumequine, metribuzin, permethrin, pyraclostrobin and streptomycin in or on certain products; Available at: ELI https://eur-lex.europa.eu/eli/reg/2017/623/oj